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Assessing the Impact of Collared versus Collarless Stems on Implant Migration, Patient Activity and Patient Function Following Total Hip Arthroplasty: A Randomized Clinical Trial

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Abstract

Total hip arthroplasty (THA) is a common procedure used to treat end-stage hip osteoarthritis (OA). Various designs of implants are currently used to successfully perform these procedures. However, the role of these design variations on early implant migration and patient recovery is still being studied. In this study patients were prospectively randomized to receive either a collared or collarless femoral stem. Differences were compared between groups assessing implant migration, patient activity and patient functional differences. Compared to the collarless femoral stem, it is believed that a collared femoral stem provides improved axial stability early in the post-operative timeline. This study provides strong evidence towards the improved stability of collared femoral stems within the first two weeks post-operatively. This study also compares the implant groups and expresses an increase in activity level early in recovery for patients receiving collared femoral stems.

Keywords

Total Hip Arthroplasty, Orthopaedic Surgery, Direct Anterior Approach, Radiostereometric Analysis, Activity, Function

Co-Authorship Statement

Maxwell Perelgut – Patient recruitment, patient follow-up, data collection, data analysis and manuscript preparation.

Dr. Teeter – Study design, data interpretation, and manuscript editing.

Dr. Lanting – Study design, data interpretation and manuscript editing.

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Table of Contents

Abstract i

Co-Authorship Statement ii

Acknowledgments iii

Table of Contents v

List of Tables viii

List of Figures ix

List of Appendices xi

List of Abbreviations xii

Chapter 1 1

1 Introduction 1

1.1 Osteoarthritis 1

1.2 Hip Anatomy 1

1.3 Total Hip Arthroplasty 5

1.4 Surgical Approaches for THA 6

1.4.1 Direct Anterior 6

1.4.2 Direct Lateral 8

1.4.3 Direct Posterior 9

1.5 Implant Design 10

1.6 Radiostereometric Analysis 14

1.7 Wearables 18

1.7.1 Function 18

1.7.2 Activity 19

1.8 Patient Reported Outcome Measures 19

1.9 Thesis Objectives and Hypothesis 20

1.10 References 21

Chapter 2 30

2 Determining the Early Impact Implant Design has on Implant Migration Following Total Hip Arthroplasty...30

2.1 Introduction 30

2.2 Methods 31

2.2.1 Inclusion and Exclusion Criteria 32

2.2.2 Surgical Intervention 32

2.2.3 Analysis Follow-Up..32

2.2.4 Patient Reported Outcome Measure Follow-Up 33

2.2.5 Statistical Analysis 34

2.3 Results 35

2.3.1 Demographics...35

2.3.2 Radiostereometric Analysis – 24 Hour Baseline....................................37

2.3.3 Radiostereometric Analysis – 2 Week Baseline......................................39

2.3.4 Case Studies..41

2.4 Discussion...43

2.5 References 47

Chapter 3 52

3 Understanding the Impact Femoral Implant Design has on Patient Activity and Function 52

3.1 Introduction 52

3.1.1 Total Hip Arthroplasty 52

3.2 Methods 54

3.2.1 Inclusion and Exclusion Criteria 54

3.2.2 Surgical Intervention 54

3.2.3 Activity Follow-Up 54

3.2.4 TUG Follow-Up 55

3.2.5 Patient Reported Outcome Measure Follow-Up 56

3.2.6 Statistical Analysis 57

3.3 Results 57

3.3.1 Demographics 57

3.3.2 Activity – Pre-Operation to Three months 58

3.3.3 Function – Pre-Operation to Three months 59

3.4 Discussion 60

3.5 References 64

Chapter 4 68

4 Conclusion 68

4.1 Overview of Objectives 68

4.2 Summary of Results 68

4.3 Future Directions 69

4.4 Conclusions 69

Appendices 70

List of Tables

Table 1: Patient demographics for the two implant groups, presented as mean ± standard deviations (where applicable) 35

Table 2: Clinical outcome scores, presented as mean ± standard deviation, minimum and maximum values 36

Table 3: Patient demographics and implant used for the three patient cases, presented as patient specific metrics 41

Table 4: Patient demographics for the two implant groups, presented as mean ± standard deviations (where applicable) 57

Table 5: Clinical outcome scores, presented as mean ± standard deviation, minimum and maximum values 58

List of Figures

Figure 1: Bony anatomy of the hip joint (AP view) 2

Figure 2: Acetabular articular cartilage (Sagittal view) 3

Figure 3: Anterior hip ligaments 3

Figure 4: Anterior hip muscles 4

Figure 5: Posterior hip muscles 4

Figure 6: Direct anterior approach (Lateral view) 7

Figure 7: Traction table setup used for DA THA 8

Figure 8: Direct lateral approach (Posterior view) 9

Figure 9: Direct posterior approach (Posterior view) 10

Figure 10: Uncemented and cemented femoral components 11

Figure 11: Collared and collarless femoral implants 12

Figure 12: Femoral component illustrating proper immediate collar-calcar contact 13

Figure 13: Collared implant illustrating excess varus rotation 13

Figure 14: Three-dimensional object location reconstruction using stereo x-rays 14

Figure 15: Uniplanar RSA calibration cage 15

Figure 16: X-ray illustrating tantalum bead placement in the femur around the implant (the red arrows are pointing to the beads) 16

Figure 17: Model based RSA software illustrating the projection of the implant onto stereo radiographs 17

Figure 18: Participant flow through the study 34

Figure 19: Line graphs showing the average migration in all planes across three months (12 weeks) using a baseline within 24 hours post-operatively 38

Figure 20: Line graphs showing the average migration in all planes across three months (12 weeks) using a baseline two weeks post-operatively 40

Figure 21: Line graphs showing migration patterns of selected cases for collared and collarless implants over three months (12 weeks)..42

Figure 22: Participant flow through the study 56

Figure 23: Line graph showing the average steps taken per day for patients that received a collared and a collarless femoral stem over three months (12 weeks) 59

Figure 24: Line graph showing the average total time taken to complete the TUG test for patients that received a collared and a collarless femoral stem over three months (12 weeks) 60

List of Appendices

Appendix A: Ethics Approval 70

Appendix B: Letter of Information and Consent 71

Appendix C: Screening and Consent Document 78

Appendix D: Demographics Questionnaire 80

Appendix E: Short Form 12 (SF-12) 82

Appendix F: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). 83

Appendix G: University of California, Los Angeles (UCLA) Activity Score 84

Appendix H: Harris Hip Score (HHS) 85

Appendix I: Charlson Commorbidity Index 86

Appendix J: Curriculum Vitae 87

List of Abbreviations

BMI	Body Mass Index
DA	Direct Anterior
DL	Direct Lateral
DP	Direct Posterior
HHS	Harris Hip Score
OA	Osteoarthritis
PROM(s)	Patient Reported Outcome Measure(s)
RA	Rheumatoid Arthritis
ROM	Range of Motion
RSA	Radiostereometric Analysis
SD	Standard Deviation
SF-12	Short Form 12 questionnaire
THA	Total Hip Arthroplasty
TUG	Timed-Up-and-Go
UCLA	University of California, Los Angeles (e.g. UCLA activity score)
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index questionnaire
6MWT	6-Minute Walk Test

Chapter 1

1 Introduction

1.1 Osteoarthritis

Osteoarthritis (OA) is the most common form of arthritis in the world, mainly impacting the weight bearing joints of the lower body [1]. OA is a degenerative joint disease causing the gradual degradation of the joint cartilage over time. This leads to painful, stiff and deformed joints resulting in an altered quality of life for the individual. As age and obesity are major risk factors for OA, the economic impact of this disease continues to rise [2].

OA is the single most common cause of disability in older adults [3]. Worldwide, adults over the age of 60 have a 10-15% chance of having some degree of OA, with women accounting for 55% of those affected [4,5]. The disease affects 10% of all Canadians aged 15 or older [6,7]. In 2016-2017, 55,981 hip replacements were performed in Canada, which is a 5-year increase of 17.8% [5]. The most common causes for requiring a hip replacement were degenerative arthritis (81.2%) and acute hip fracture (15.1%) [5]. The burden of OA costs the Canadian government over $1 billion annually [5].

1.2 Hip Anatomy

The hip is one of the largest weight bearing joints of the body and can experience forces up to five times an individual's body weight [8]. The hip is a ball-and-socket joint. The ball component of this joint is comprised of the femoral head and the socket is formed of the acetabulum, which is part of the pelvis (Figure 1). The rounded head of the femur and the concave acetabulum are covered in hyaline cartilage. This synovial joint is relatively stable and has a large range of motion allowing for rotation (internal and external), flexion, extension, abduction and adduction.

The acetabulum in contained within portions of the ilium, ischium and pubis (Figure 1). It is cup shaped and positioned laterally within the pelvis bone allowing for femoral head articulation. The acetabulum is rimmed with a fibrocartilaginous labrum which is an extension of the bony structure of the pelvis, deepening the socket (Figure 2). This labrum functions to improve joint stability, seals synovial fluid in the joint capsule, acts as a pressure distributor and as a shock absorber [9].

Further increasing the stability of the hip joint are the ligaments and muscles surrounding the joint capsule. The iliofemoral, pubofemoral and ischiofemoral ligaments surround the joint (Figure 3), along with the quadricep and gluteal muscles (Figure 4 and Figure 5). These soft tissues work together to provide rotation, flexion, extension, abduction and adduction of the hip joint.

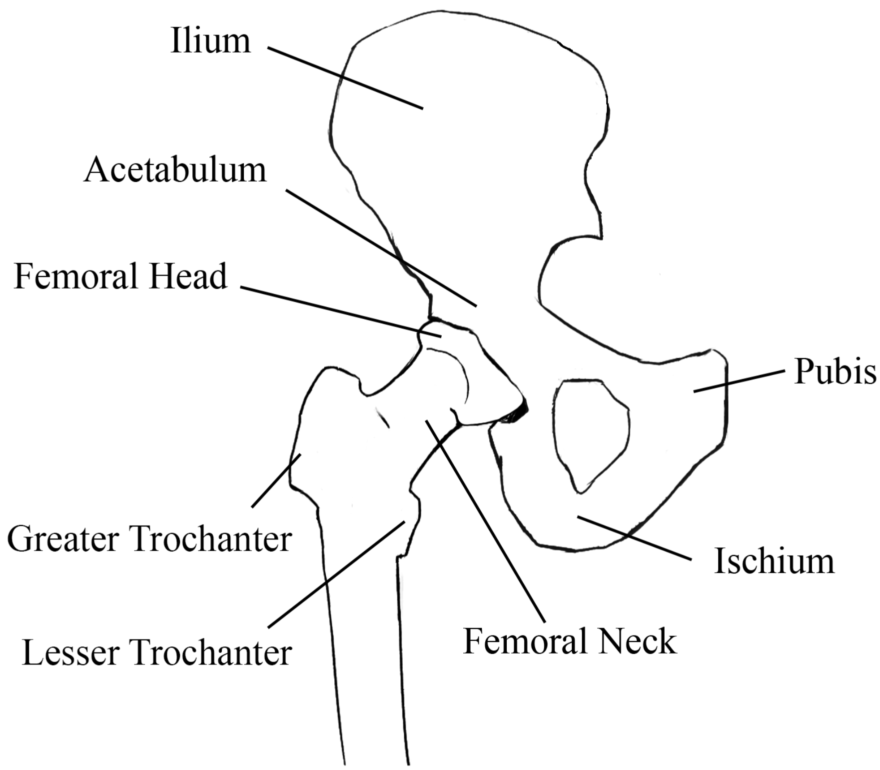

Figure 1: Bony anatomy of the hip joint (AP view)

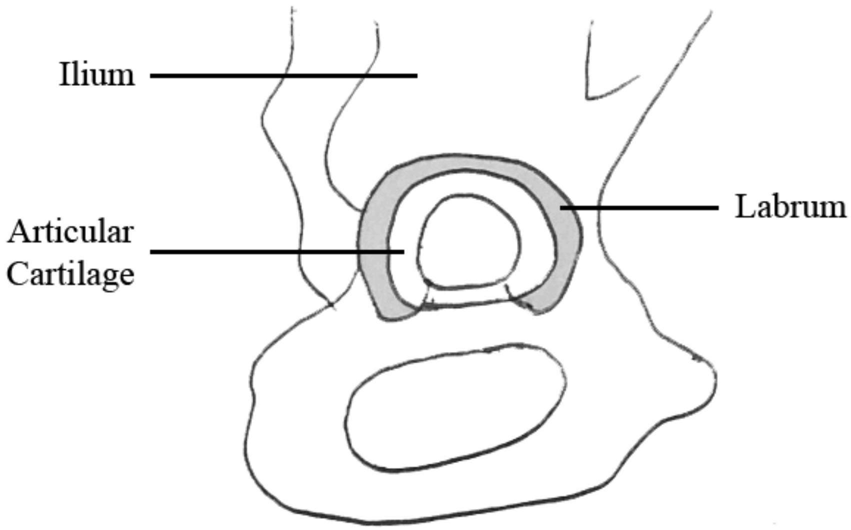

Figure 2: Acetabular articular cartilage (Sagittal view)

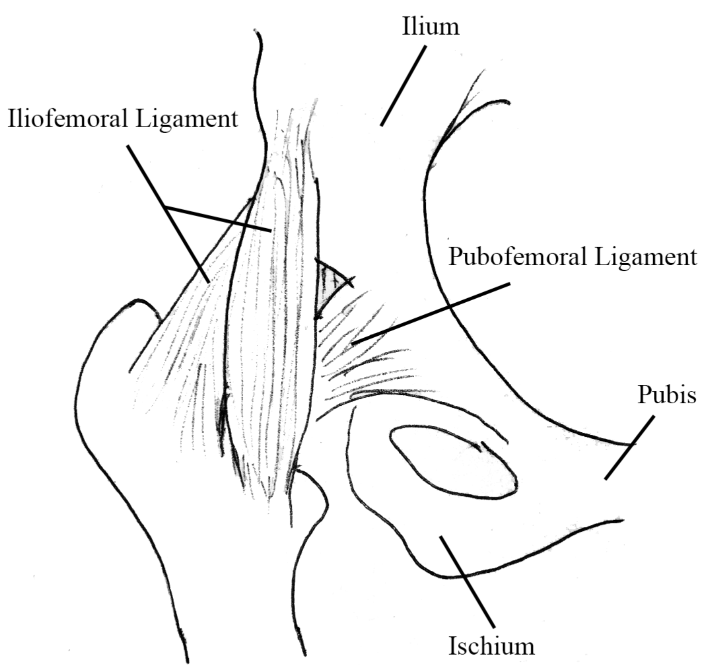

Figure 3: Anterior hip ligaments

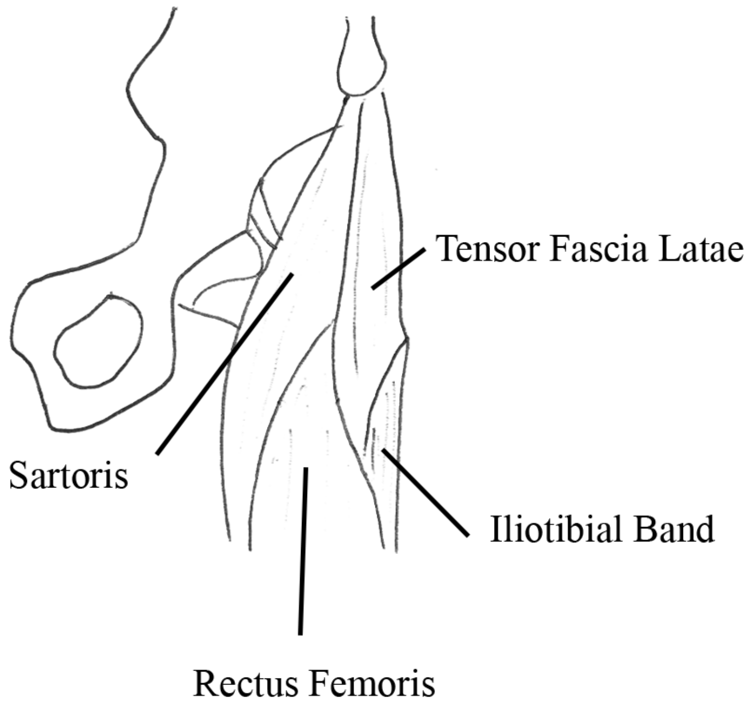

Figure 4: Anterior hip muscles

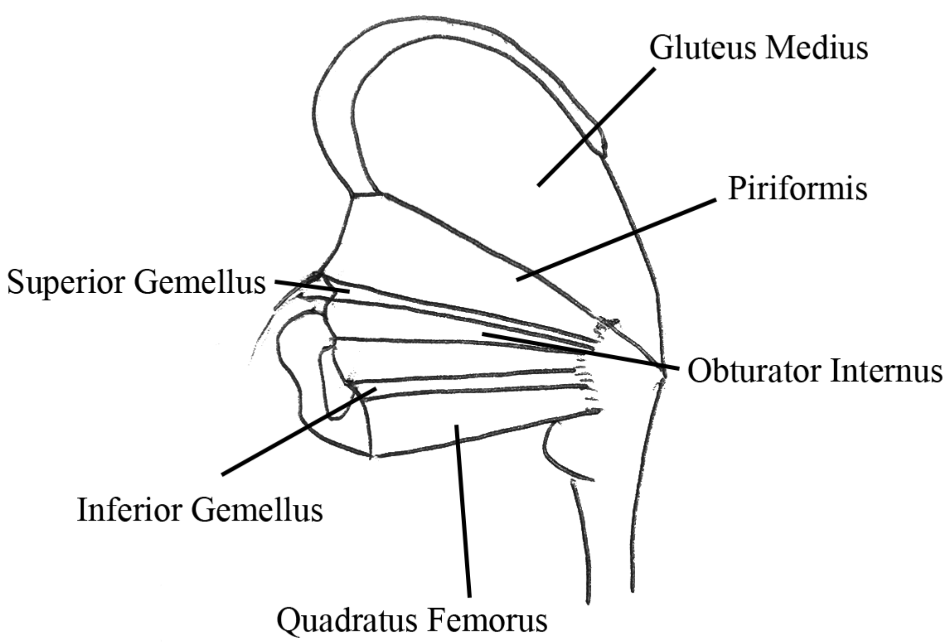

Figure 5: Posterior hip muscles

1.3 Total Hip Arthroplasty

Total hip arthroplasty (THA) is the procedure used to treat patients who have exhausted non-surgical intervention to mitigate the debilitating pain and limited range of motion (ROM) they are experiencing. The first repeatably successful THA procedure was developed in the 1960's by Sir John Charnley [10]. This procedure can be used to treat many hip related diseases including OA, rheumatoid arthritis, and bone fractures.

THA is the accepted procedure for patients with OA of the hip [11]. This procedure is very successful, with more than 90% of patients experiencing pain relief [12]. The most significant decrease in pain and function is experienced within the first three months post-operatively [12].

The longevity of a joint replacement is important as the population is aging and expecting implants to last longer. Implants that ultimately fail require revision. According to the Canadian Joint Replacement Registry Annual Report, in 2016-2017 there were 4,664 hip revisions performed representing 8.6% of all THA procedures conducted that year [13]. As THA procedures are performed on patients of all ages, it is important to understand the risks associated with undergoing the procedure earlier in life. Bayliss et al. found that the 10-year survival rate for THA procedures was 95.6% among all age groups [14]. When categorizing patients older and younger than 70 years, this study found that there was a 5% risk of revision in their lifetime for older patients and a 35% risk of revision in their lifetime for younger patients [14]. There are many reasons for THA revisions including pre-operative patient demographic, clinical factors and surgical factors.

Patients demand shorter recovery times and increased activity earlier post-operatively, adding pressure to implement rapid recovery care pathways. The combination of patient input and cost savings using these pathways are pushing for new ways to conduct THA procedures to solve these challenges. Rapid recovery care and outpatient procedures appear to be this solution. In order to facilitate this, focus needs to be put on surgical changes leading to a decrease in post-operative pain, ultimately resulting in shorter recovery times and more patient activity. These procedural changes could drastically reduce inpatient care for most primary THA patients. The increasing adaptation of the direct anterior (DA) surgical approach compared to other THA surgical approaches has demonstrated earlier function, less pain and shorter recovery times [15]. Another key aspect of these procedures is the implementation of new surgical instrumentation that orthopaedic partners are providing. The combination of new equipment and surgical approaches which further improve patient recovery are working towards providing a solution to the rapid recovery pressures.

1.4 Surgical Approaches for THA

During the THA procedure, the damaged femoral and acetabular surfaces are removed and replaced with a metal stem placed into the centre of the femur and a metal socket placed in the acetabulum of the pelvis. A metal or ceramic head is placed on the femoral stem, replacing the arthritic femoral head. A liner is placed within the cup allowing for a smooth articulating interface for the femoral head [16].

A key component of preoperative planning for the THA procedure is selecting the surgical approach to be used. This decision can be influenced by surgeon preference, previous incisions, obesity, risk for dislocation, implant selection, or level of deformity. The surgical approach used should provide appropriate access to the joint capsule while minimizing the risk to neurovascular structures and limit soft tissue damage.

1.4.1 Direct Anterior

The DA surgical approach was first described by Hueter in 1881 [17]. This approach is geared towards rapid recovery care [18–20]. It requires the patient to be placed in a supine or lateral decubitus position allowing for an anterior approach to be used (Figure 6). Although the procedure can be performed on a normal operating table without imaging, many surgeons prefer a specialized table with fluoroscopy allowing them to gain better visibility of the joint (Figure 7). These specialized tables allow individual control of each limb, providing traction, rotation and angulation [21].

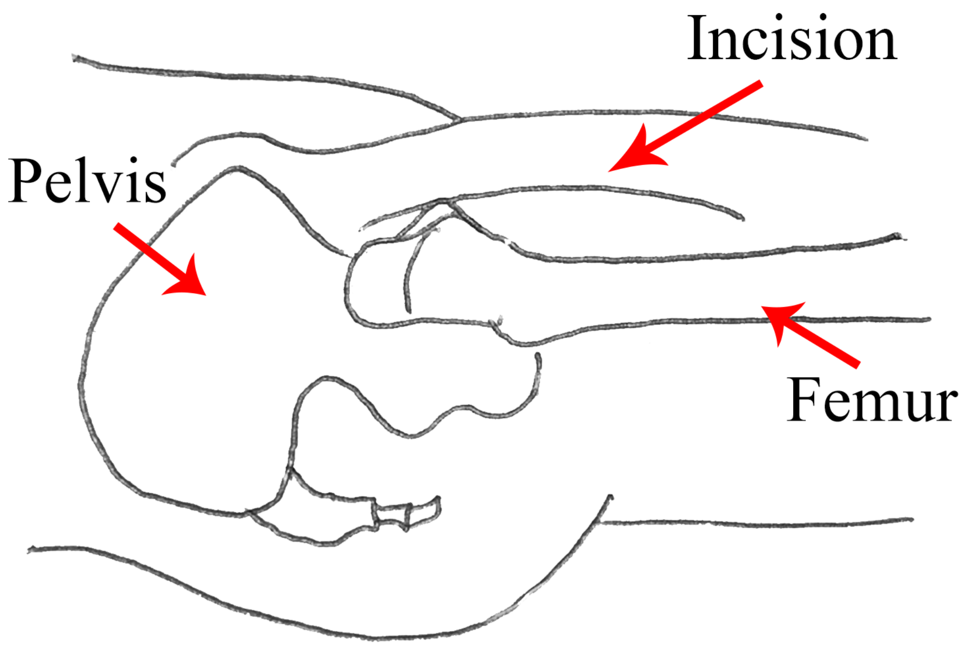

Figure 6: Direct anterior approach (Lateral view)

There are many advantages to the DA approach. This procedure is considered a muscle sparing and inter-nervous approach [21]. It provides an early recovery with greater patient activity and decreased surgical pain. Patients that receive this procedure also experience a low hip joint dislocation rate [22]. The great benefits of this procedure do come at a cost. This is a challenging procedure that surgeons experience a steep learning curve to master [23]. It can be more difficult to achieve proper femoral exposure and femoral preparation in the DA approach resulting in an increased risk of malalignment, under sizing the implant or ultimately aseptic loosening [24,25]. It is believed that using a collared femoral stem can help mitigate the risk of aseptic loosening and fracture by providing improved immediate stability of the implant along with providing the surgeon with the confidence that they can more precisely control leg length during THA procedures when the collar abuts the calcar of the femur [26,27].

Figure 7: Traction table setup used for DA THA

1.4.2 Direct Lateral

The modern direct lateral (DL) surgical approach was described by Hardinge in 1982 and is the most common procedure in Canada with more than 60% of orthopaedic surgeons using this approach [28,29]. The DL approach provides excellent exposure of both the proximal femur and the acetabulum. This procedure requires the patient to be in a lateral or supine (distinct minority) position on the table and is able to be conducted using a normal operating table with a patient positioning device to hold the pelvis in place during the procedure (Figure 8).

The greater proximal femur exposure during the DL approach allows for easier component positioning. The avoidance of major nerves during this operation reduces the risk of excess damage as well. Similar to the DA approach, the DL approach is known for low dislocation rates [30]. This procedure does have disadvantages to it as well. The joint capsule exposure comes at the cost of an increase in damage to the muscles used during abduction. If the procedure is conducted unilaterally, it may result in asymmetry between legs and can result in abnormal gait that may be experienced long after recovery [31].

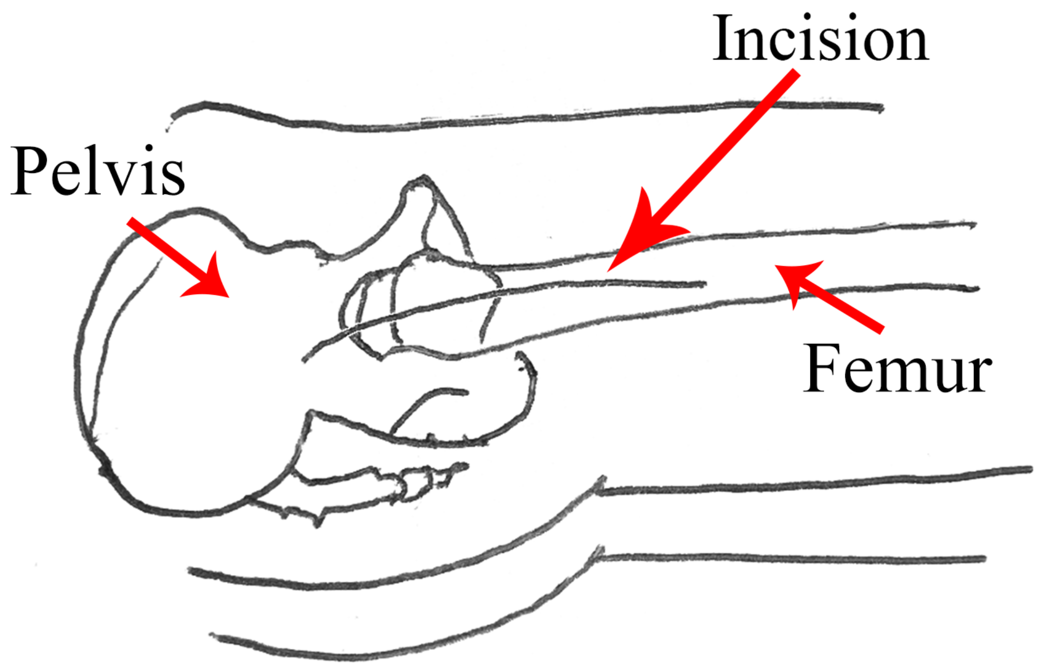

Figure 8: Direct lateral approach (Posterior view)

1.4.3 Direct Posterior

In the 1950s Moore made the direct posterior (DP) approach popular [32]. The DP approach provides excellent acetabular and femoral exposure. This procedure requires the patient to be positioned laterally on a normal operating table while using a patient positioning device to stabilize the pelvis during the procedure (Figure 9). Worldwide this procedure is most commonly used, while in Canada it is used about one-third of the time [29,33].

The main advantage of the DP approach is not splitting the gluteus medius that leads to the post-operative limp after the DL approach. Another advantage is the reduced risk of nerve damage that the DA approach brings with it. These advantages come at the cost of an increase in dislocation risk.

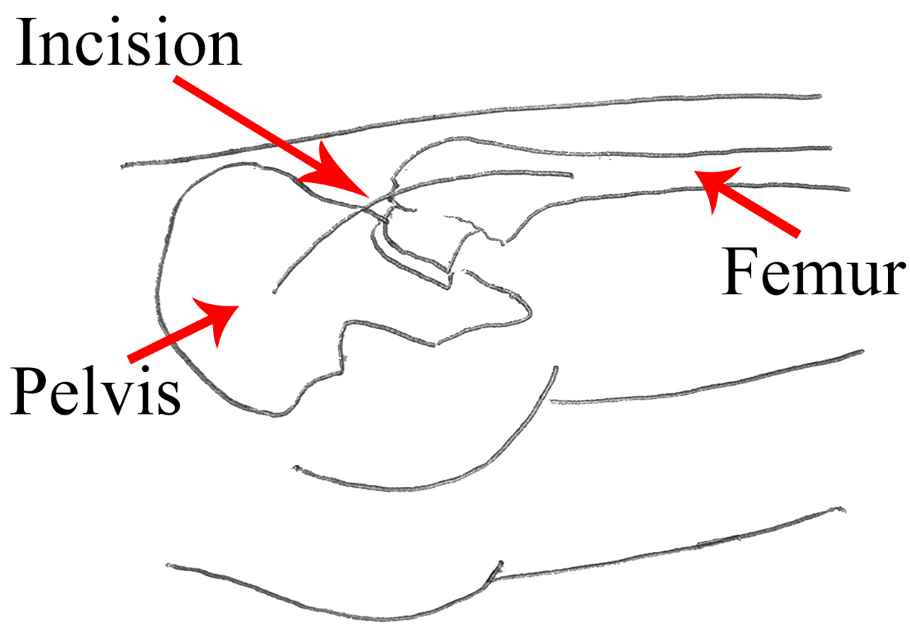

Figure 9: Direct posterior approach (Posterior view)

1.5 Implant Design

There are four main components of hip implants: the cup, the head, the stem and the liner. The cup is fixed to the acetabulum, the stem is inserted into the femur and the head is attached to the end of the stem allowing for smooth contact between the cup and the stem. There are two ways of fixing the stem into the femur: cemented and uncemented. The best fixation method for primary THA procedures continues to be debated and the longevity of the THA depends on the mechanical integrity of the implant-bone bond [34]. If this bond happens to be damaged, there may be relative motion resulting in a failed THA. Cemented implants have two interfaces, implant-cement and cement-bone, and is believed to provide immediate fixation of the implant (Figure 10). Although this provides a benefit in the short term, some view it as a concern in young and more active patients as dynamic loading of the hip joint may cause micro cracks in the cement resulting in relative motion of the implant and gradual debonding from the cement [35]. Uncemented implants are press-fit into the bone, relying on biological fixation to ensure long-term survival of the implant (Figure 10) [36]. Although both cemented and uncemented femoral fixation are used worldwide, North America mainly uses uncemented femoral fixation as the primary method for THA procedures [37].

Beyond fixation methods, the specific design of the implant may have an impact on the replacement longevity. Hip implants have undergone many design revisions while striving for the best solution and long-term survivorship. For an uncemented stem to obtain adequate biological fixation, motion between the implant and bone should be minimized. A solution to this problem has been attempted by adding a collar to the press-fit hydroxyapatite coated stems, preventing implant subsidence by providing better immediate stability (Figure 11) [27].

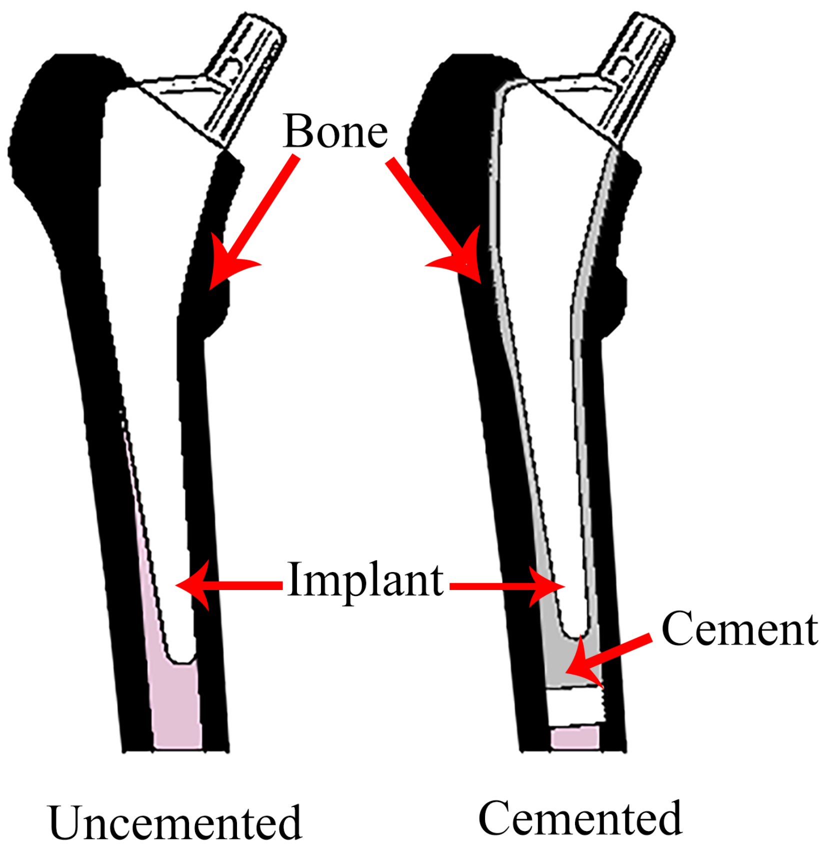

Figure 10: Uncemented and cemented femoral components

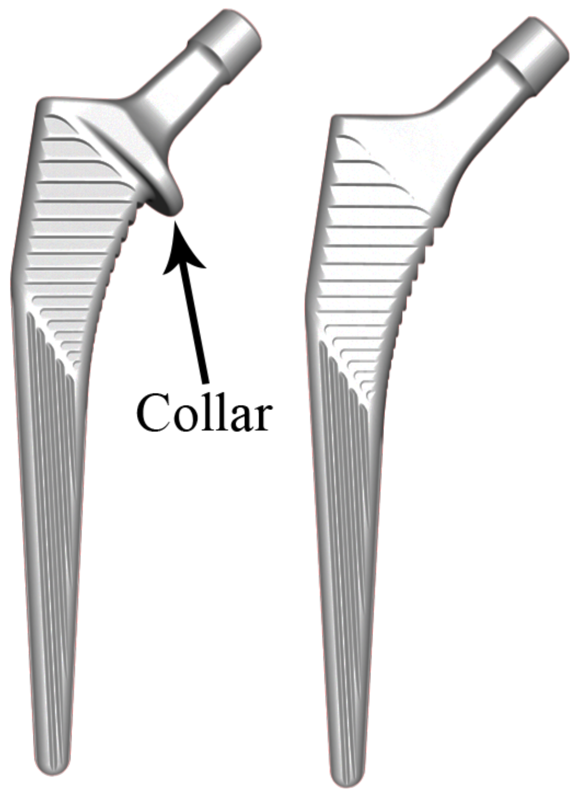

Figure 11: Collared and collarless femoral implants

Recent literature has identified greater amounts of subsidence for collarless stems leading to loosening, instability and periprosthetic fracture [38–42]. The increasing pressure for rapid recovery care is pushing patients, and their implants, to provide better stability earlier on. The femoral stem collar improves the immediate stability, provides greater resistance to subsidence and reduces the risk of early micromotion ultimately allowing better implant biological fixation [27,38]. The goal is to maintain the stem's initial intraoperative position, decrease the amount of subsidence, and achieve accurate patient leg length. This is accomplished by inserting the implant such that the collar rests on the calcar (Figure 12).

Improper collar-calcar contact exposes the limitations that a collared femoral stem has compared to a collarless femoral stem. Uneven stress distributions between the collar and calcar can lead to implant subsidence and rotation of the collared implant (Figure 13)

[43,44]. The stress shielding a collar provides if improperly inserted can lead to implant loosening and failure through repetitive loading [45].

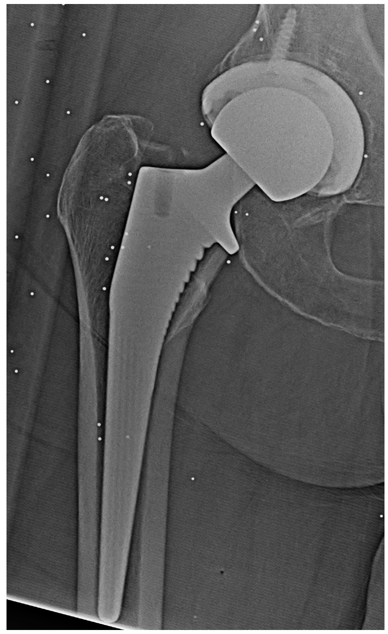

Figure 12: Femoral component illustrating proper immediate collar-calcar contact

Figure 13: Collared implant illustrating excess varus rotation

1.6 Radiostereometric Analysis

Implant fixation is important when assessing the success of a THA procedure [46,47]. To analyze implant stability throughout recovery, surgeons measure the relative implant positioning between patient follow-up visits. Using biological and component landmarks, the relative motion of the implant to the bone is measurable. A limitation of using biological landmarks and clinical x-rays is the lack of leg positioning uniformity between visits leading to less accurate measurements. It is reported that a migration of at least 2 mm is necessary before any migration can be determined [48].

In order to ensure measurement accuracy between visits, a stereo x-ray technique called radiostereometric analysis (RSA) is used. This stereo x-ray technique used to image a single object on two films provides the necessary information required to extract the three-dimensional location of the object in space. Knowing where both the x-ray sources and detectors are positioned relative to each other and tracing a line between the projected image to the sources, provides the location of the object in space being the intersection of the lines (Figure 14).

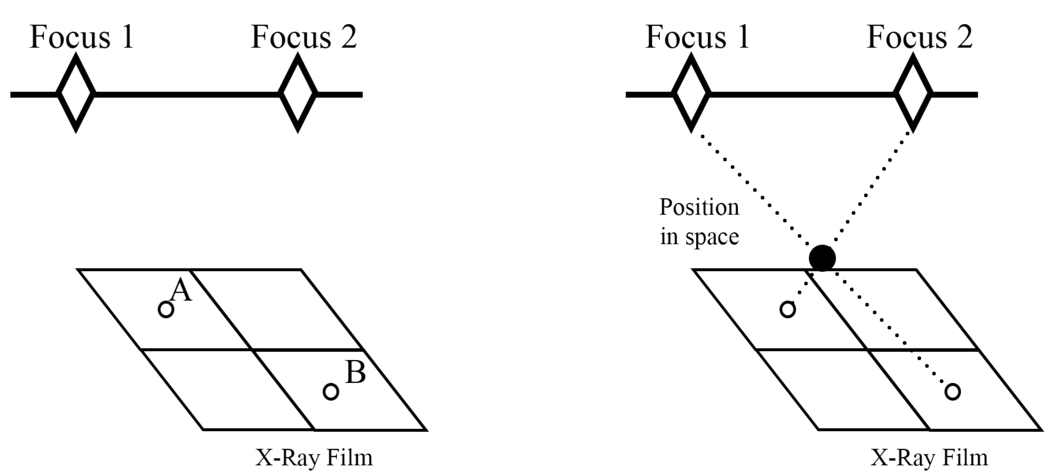

Figure 14: Three-dimensional object location reconstruction using stereo x-rays

Modern RSA techniques, explained by Selvik, use the same theory to measure component locations in space [49]. Rather than using a set apparatus with known distances between sources and films, it now uses a cage with control and fiducial beads to calculate the relative location of the sources and detectors (Figure 15). This is an extremely accurate measurement technique used to help surgeons monitor implant migrations throughout recovery. Modern RSA can be as precise as hundreds of microns for translation and half a degree for rotation [50]. It is based on the assumption that the components and environment are made up of rigid bodies. A rigid body is a solid body with zero deformity, or deformity so small that it can be considered negligible. When using markers, this rigid body can be understood as the distance between any two markers on the rigid body remaining constant over time. If any of these distances between markers change over time, it is assumed that the body has become deformed.

Figure 15: Uniplanar RSA calibration cage

In RSA the translation and rotations are measured between rigid bodies. When analyzing the motion of the implant relative to the bone, a rigid body is assigned to the implant and another is assigned to the bone. As biological landmarks are difficult to consistently and accurately identify in all radiographs, markers are injected into the cortical bone surrounding the implant. These markers are radiolucent tantalum beads that remain fixed and stationary in the bone.

In order to create a rigid body for the bone, a minimum of three non-colinear beads are required [51]. As an inherent limitation of x-rays, some beads may not be visible due to the variation in limb internal/external rotation that would block the beads with the implant components. In order to compensate for unmeasurable beads, between five and nine beads are inserted into the bone to form the rigid body. The accuracy of the RSA measurements is not only dependent on the number of beads and their stability, but also their spread. It is important to have a large distance between the beads as well as a good distribution of these beads in all three axes [50]. The more colinear the beads are inserted, the lower the measurement accuracy will be (Figure 16) [52].

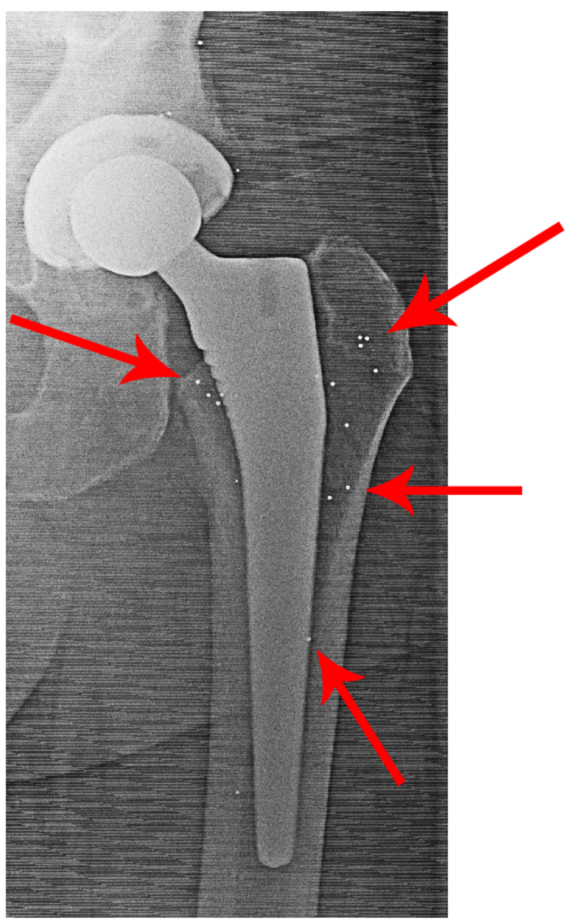

Figure 16: X-ray illustrating tantalum bead placement in the femur around the implant (the red arrows are pointing to the beads)

Creating the rigid body for the component can be done in two ways. Using a marker-based method, beads are embedded in the implant prior to fixation. This comes with the limitation of beads being undetectable as a result of imaging angles. This disadvantage can be resolved using a model-based method. A three-dimensional model of the implant is created, and using specific model-based RSA software, the digital implant model can be fit to the radiographs and represent the rigid body of the component (Figure 17) [53].

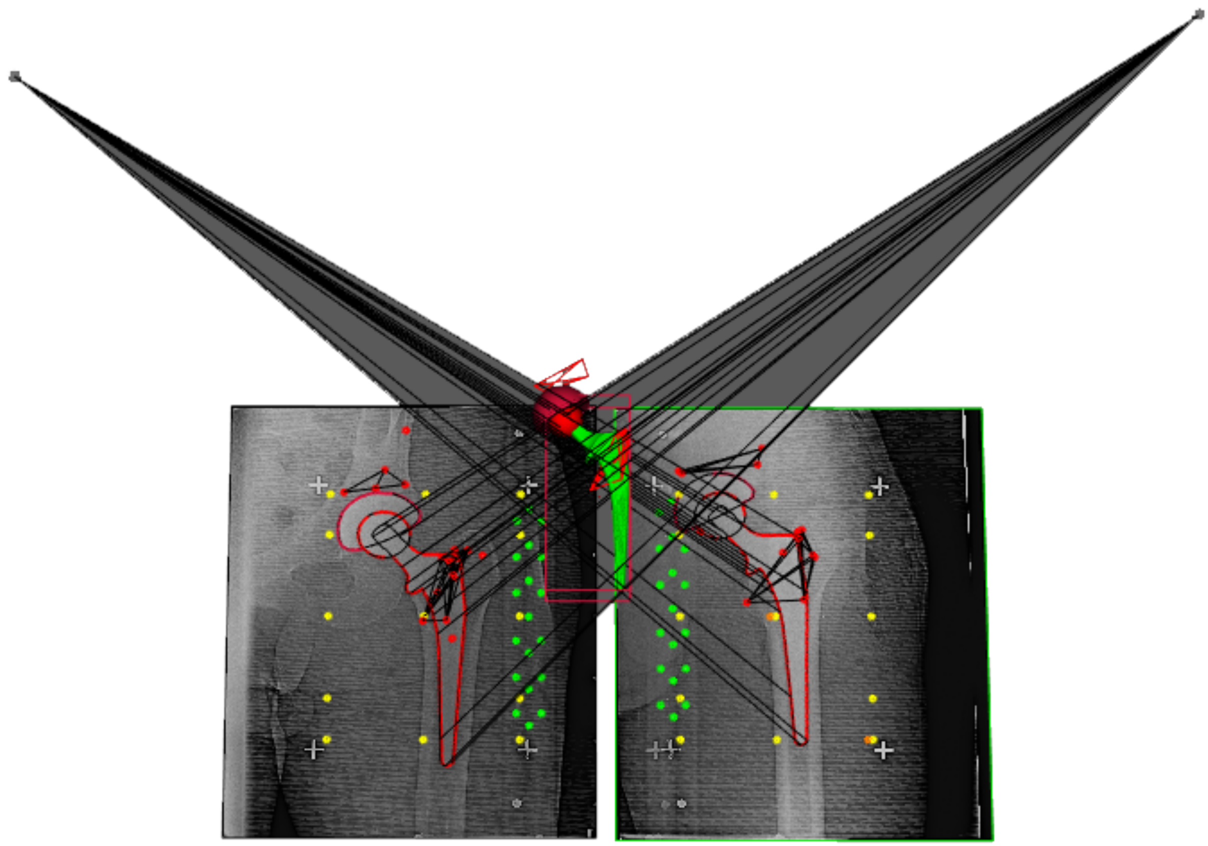

Figure 17: Model based RSA software illustrating the projection of the implant onto stereo radiographs

Taking into account the rigid body of the bone, comprised of markers, and the rigid body of the component, from the digital implant model, the relative location of the component to the bone can be recorded. A standardized component coordinate system aligned with the longitudinal axis of the stem as well as the geometric centre of the y-position is used to repeatably measure implant positioning. Obtaining multiple RSA images throughout the recovery process allows for implant migration tracking. RSA provides us with the ability to measure implant migration early post-operatively, long before anything would manifest clinically which provides us with the ability to predict implant success. Studies have shown that early implant subsidence is an indicator for late aseptic loosening [54,55].

1.7 Wearables

The main goal of THA is to eliminate OA pain and improve patients' quality of life [56,57]. There are different ways to measure patient activity, including subjective patient diaries, self-reported scores and objective testing. Objective testing can provide more accurate insight as patients tend to over- or under-estimate their activity when self-reporting [58,59]. Function can be measured using a series of standardized tests and activity can be measured using wearable trackers. Wearable trackers are light and easy to use devices that measure an individual's activity and functional levels. These technologies have been successfully used to monitor physical activity levels in THA patients [60].

1.7.1 Function

Functional tests are used to assess THA patients clinically. These tests are used to represent daily mobility while in clinic. Common functional tests include the timed-up-and-go (TUG) test and the 6-minute walk test (6MWT) [61]. The TUG test originated as a risk assessment for falls, categorizing patients based on their time to complete the entire test. Patients are asked to start in a seated position, stand up and walk to a marker three metres away, turn around at the marker and walk back to the chair to sit. This test uses a threshold of 14 seconds to complete the entire test to classify if patients are at a high risk for falls or not, where lower times indicate greater functional ability [62]. The 6MWT is used to assess an individual's aerobic and endurance capacity. The total distance walked in six minutes is used to compare patient performance. Markers are placed 30 metres apart and patients are asked to walk to and from the markers for the entire six-minute period. It has been studied that a minimum difference of 2.27 seconds for the TUG test and 45 metres travelled for the 6MWT is required to determine a real change in patient performance during different tests [63,64].

The TUG test is an assessment of function as it compares all aspects of mobility including standing, sitting, walking and turning in a short distance over a short period of time in a controlled environment [65]. As the TUG test only takes into account the temporal component, it can be further analyzed using inertial sensors [66]. Patients may impart different strategies to complete the test and result in the same amount of time passed, ultimately expressing no difference in function. Using inertial sensors provides insight into the gait analysis of this functional test highlighting the strategies patients use. A patient with a limp that completes the TUG test in the same amount of time as a healthy patient will express no difference temporally. When adding in the analysis of their gait, the variation between individuals is measured. Test times are good at predicting function, but it does not give the full information of the patient's recovery [67].

1.7.2 Activity

Wearable activity trackers are readily available tools used to measure patient activity. These trackers use accelerometers to measure an individual's daily step counts, intensity of their activity, and calories burned throughout the day [68]. Studies have analyzed the relationship between patient activity to step counts, as well as patient activity to functional recovery [69,70]. A variety of wrist-worn wearable trackers are validated and reliably used to measure an individual's activity [71]. The availability of these trackers makes it an obvious metric to analyze for patients undergoing a THA procedure. As full recovery from THA procedures has been shown to last as long as four years, tracking the recovery and comparing activity to pre-operative results can show insight into an individual's activity changes [72].

1.8 Patient Reported Outcome Measures

Patient reported outcome measures (PROMs) use a series of questionnaires to quantify patient qualities such as pain and function. It allows the patient to provide direct feedback on their care. PROMs are generic and disease specific tools used frequently in clinics to assess patients' pre- and post-operative health. The Short Form 12 (SF-12), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Harris Hip

Score (HHS) and the University of California, Los Angeles (UCLA) activity score questionnaires are commonly used in orthopaedic clinics to measure general mental and physical wellbeing, lower limb function with respect to OA, patient activity and THA specific functional outcomes respectively. The SF-12 is a measure of a patients mental and physical wellbeing. The WOMAC is widely used to evaluate the condition of patients with hip OA and uses a set of five items to measure pain, two for stiffness, and 17 for functional limitation. The HHS is specifically designed for assessing patients undergoing hip surgery and consists of 10 items assessing pain, function, absence of deformity, and range of motion. The UCLA activity score is a general PROM with a 10-item scale ranging all activity levels.

PROMs provide a simple insight into an individual's THA procedure, but this insight comes with limitations [73]. A limiting factor of PROMs is their vulnerability to bias and ceiling or floor effects [74–76]. A patient's individual expectations can influence the outcomes of these questionnaires due to the drastic improvements patients experience from this procedure [77].

1.9 Thesis Objectives and Hypothesis

Given the increasing demand for rapid recovery care pathways, there is an increase in enhanced recovery care pathway surgeries and a decrease in time away from patient activities. To facilitate rapid recovery care pathways, orthopaedic industry partners are adapting their designs to potentially help reduce the recovery time. The objectives of this thesis are to: 1) determine the impact implant design has on femoral stem fixation, and 2) understand the role implant design has on patient activity and function early on following a THA procedure. We hypothesize that the collared femoral stem will result in less implant migration and a quicker recovery than patients who receive the collarless femoral stem.

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Chapter 2

2 Determining the Early Impact Implant Design has on Implant Migration Following Total Hip Arthroplasty

2.1 Introduction

Arthritis, most commonly osteoarthritis (OA) and rheumatoid arthritis (RA), is a disease that affects the joints of the body. OA is a degenerative disease that affects the load bearing joints, whereas RA is an autoimmune disease that can impact any joint. Patients who suffer from end-stage hip OA elect to undergo a total hip arthroplasty (THA). This common orthopaedic procedure has been reported as one of the most successful and reliable procedures today with an 86% success rate at 15 years [1]. Not only is it an extremely successful procedure, but it is among the most common elective surgeries performed in Canada with over 50,000 conducted annually and this number is expected to rise [2]. Diagnosis of hip OA is determined through radiography, patient history and physical assessment. Although the majority of patients are between 60-80 years of age, there is no specific age when an individual would require a THA [3].

Different surgical approaches can be used for primary THA procedures with each one having its own inherent advantages and disadvantages. The direct anterior (DA) approach has recently gained traction due to its muscle sparing nature. As there is a push for rapid recovery care pathways, the reduction in recovery time as a result of inter-nervous and inter-muscular approach is beneficial [4–6]. The DA approach comes with the benefit of faster recovery, reduced pain post-operatively, reduced length of hospital stay and a quicker return to daily activities [7–10]. A downside of the DA approach is the steep learning curve associated with this procedure that may impact the complication and failure rate. The limited field-of-view may also add to this concern by making it more difficult to insert standard femoral stems [11]. Rivera et al found that the DA approach can lead to a three-times higher likelihood of using an undersized stem when compared to other surgical approaches [11]. The difficulty in femoral preparation and the potential complications could lead to this under sizing and ultimately increased migration [11].

It is important to understand the impact the DA approach has on implant migration as early migration can be an indicator of an early risk of revision in the future [12]. Subsidence of THA components is a natural occurrence throughout recovery as a result of the net forces during normal ambulation [13]. There are many implant designs available to surgeons including cemented and cementless femoral stems [14]. Implant design has evolved to help mitigate the problems rising from migration. It is important to analyze new implant designs as these novel implants may not be better than their predecessors [15]. Some studies have shown that there is reduced implant migration with axial loading when there is proper collar seating [16,17]. It is important to investigate the implant migration clinically to determine the success of the new design.

Clinical x-rays require a minimum subsidence of 2 mm before any migration can be determined [18]. In order to measure the migration between implants more accurately, radiostereometric analysis (RSA) is used, ultimately leading to the prediction of loosening [19,20]. RSA allows accurate measurements of three-dimensional objects and compares relative motion between them [21]. RSA has been shown to be the most accurate method of measuring in-vivo implant migration [22]. Subsidence of 2.7 mm or more in the first two years for cementless femoral stems have shown to be associated with an increase in the risk of revision due to aseptic loosening [23]. This risk makes it important to measure the early migration of each implant design.

The purpose of this study was to measure the early implant migrations of collared and collarless femoral stems for patients undergoing the DA surgical approach. We hypothesized that patients receiving the collared femoral stem will experience less implant migration than those who receive the collarless femoral stem.

2.2 Methods

After obtaining research ethics board approval, patients were enrolled pre-operatively between January 2018 and February 2019. Patients with unilateral hip OA who were undergoing a primary THA procedure were eligible to participate in this prospective randomized clinical trial. This study was powered for RSA, allowing for early migration measurements of the orthopaedic implants. A recent RSA study measuring migration of the collarless Corail stem found a mean subsidence of 0.58 mm at two years with a standard deviation of 0.91 mm [24]. Using a paired t-test to compare subsidence between the collared and collarless groups, with alpha = 0.05, power = 0.8, n = 18 (allowing for a 20% drop out), and assuming an SD of 0.91 mm, we will detect differences between groups of 0.63 mm or greater [25]. Assuming we will observe the same mean subsidence as Campbell et al, a difference of 0.63 mm would be a subsidence of 1.21 mm which is above the threshold indicating a high risk of early loosening requiring revision [24,25].

2.2.1 Inclusion and Exclusion Criteria

Patients included in this study were undergoing a primary THA procedure diagnosed with unilateral hip OA. Exclusion criteria included a BMI greater than 40, symptomatic contralateral OA, bilateral or revision THA procedures, cognitive defects or neuromuscular disorders that would prevent a walking test, the inability to understand English and if the patient lived more than 100 km from our research centre in London, Ontario.

2.2.2 Surgical Intervention

Patients were referred to the University Hospital, London Health Sciences Centre. Those who were undergoing the DA surgical approach were randomly selected pre-operatively to either receive a collared or a collarless Depuy Corail femoral stem (Figure 18). A block randomization with concealed envelopes was used to assign participants to either implant.

2.2.3 Analysis Follow-Up

To enable RSA analysis, a minimum of six 1 mm diameter tantalum beads were inserted into the proximal cortical bone of the femur intraoperatively. A baseline RSA exam was conducted within the first 24 hours post-operatively, before the patient was discharged from the hospital. Each patient received an RSA exam at follow-up visits to the hospital (two-, four-, six-weeks and three months). All RSA exams were conducted with the patient in a supine position over a uniplanar calibration cage (RSA Biomedical, Umea, Sweden) to ensure no weightbearing forces are imparted on the hip joint. The radiographs were analyzed using commercial model-based RSA software (RSAcore, Leiden, The Netherlands). Positive translation directions are defined as proximal translation, y-axis, medial translation, x-axis, and anterior translation, z-axis. Positive rotation directions are defined as internal rotation, about the y-axis, valgus rotation, about the z-axis, and anterior tilt, about the x-axis. Cumulative implant migrations were determined using the 24 hour as well as the two week RSA exams to illustrate the changes starting within 24 hours post-operatively as well as from two weeks onwards. Individual patient cases were identified that illustrated different implant migration patterns compared to the average among implants within their group.

2.2.4 Patient Reported Outcome Measure Follow-Up

Demographics such as height, weight and age were collected pre-operatively **(**Table 1**)**. The Short Form 12 (SF-12) along with the University of California, Los Angeles (UCLA) activity score, the Western Ontario and McMaster Universities Arthritis Index (WOMAC) and the Harris Hip Score (HHS) were also collected from each patient pre-operatively and at three months post-operatively.

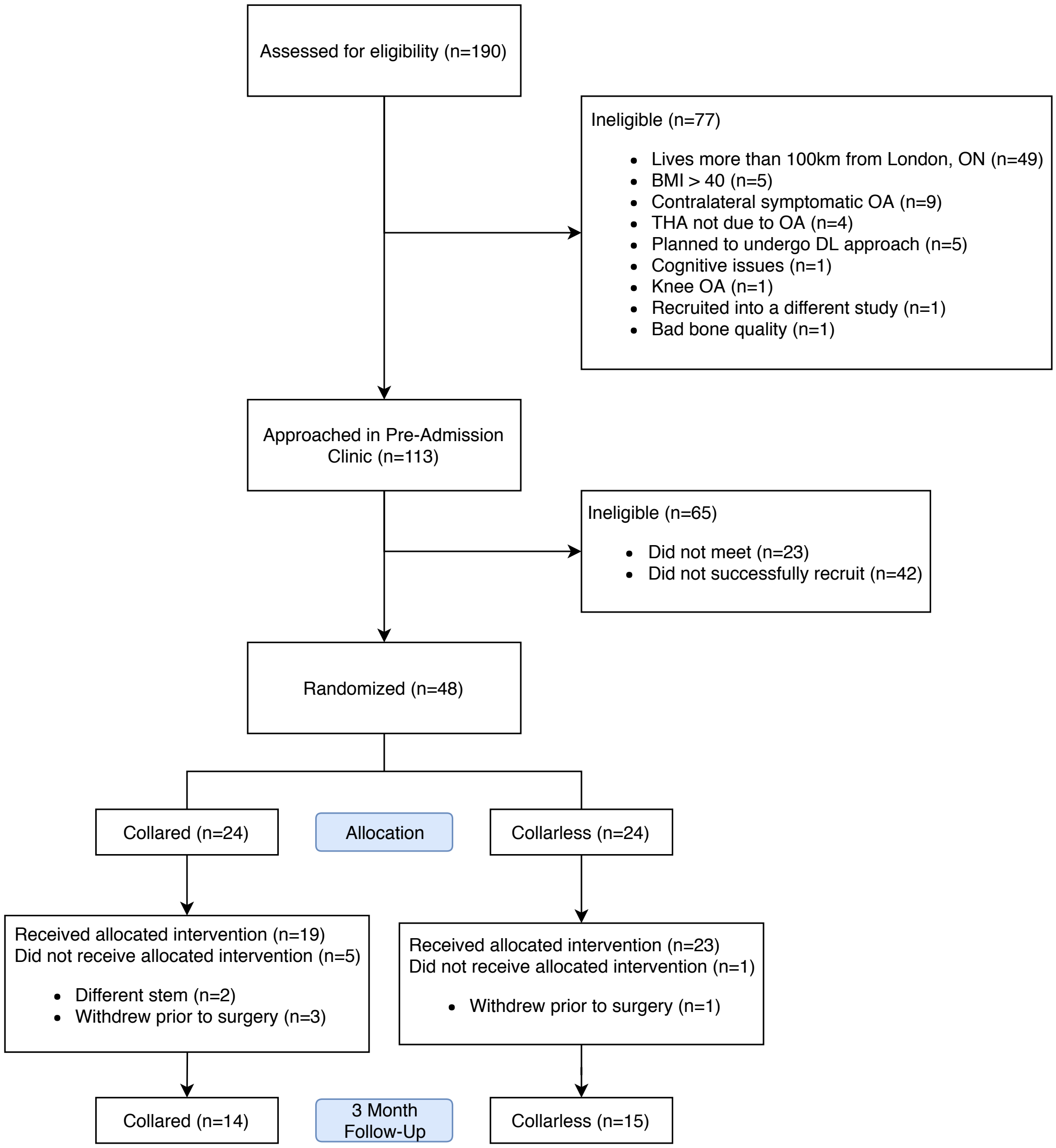

Figure 18: Participant flow through the study

2.2.5 Statistical Analysis

Demographics, patient reported outcome measures (PROMs) and RSA migrations were reported with descriptive statistics including means, standard deviations and ranges. Data was tested to be normal or not to determine which statistical tests were appropriate. Demographics between groups were compared using unpaired t-tests, while the ratios of male:female and right:left hip were compared using a Fisher's exact test. To compare the migration of the collared implant to the collarless implant a 2-way ANOVA was used.

The outcome scores were compared between groups using Mann-Whitney tests. All statistical tests were conducted using GraphPad Prism version 8.

2.3 Results

2.3.1 Demographics

There were no significant differences in patient demographics (Table 1), SF-12, WOMAC, HHS or UCLA outcome measures (Table 2) between the implant groups.

Table 1: Patient demographics for the two implant groups, presented as mean ± standard deviations (where applicable)

Characteristic	Collared	Collarless	p value
Age at surgery (years)	64.6 ± 8.7	65.0 ± 8.1	0.872
Patient sex	12 Male, 7 Female	12 Male, 11 Female	0.542
Surgical side	12 Left, 7 Right	9 Left, 14 Right	0.214
Height (m)	1.75 ± 0.08	1.73 ± 0.11	0.393
Weight (kg)	88.69 ± 18.44	91.31 ± 20.83	0.672
BMI (kg/m^2)	28.80 ± 5.1	30.35 ± 4.89	0.321

Table 2: Clinical outcome scores, presented as mean ± standard deviation, minimum and maximum values

Outcome Measure	Collared	Collarless	p value
SF-12 MCS			
Pre-Operation	55.15 ± 9.17 (36.52 to 66.40)	57.28 ± 5.96 (45.84 to 65.73)	0.431
3 Months	58.17 ± 3.35 (52.96 to 62.97)	58.16 ± 4.35 (51.16 to 61.97)	0.370
SF-12 PCS			
Pre-Operation	36.64 ± 10.88 (23.79 to 57.29)	30.65 ± 8.81 (20.44 to 46.86)	0.091
3 Months	49.80 ± 5.29 (39.27 to 55.50)	43.08 ± 10.64 (28.49 to 55.26)	0.142
WOMAC Total			
Pre-Operation	52.67 ± 13.24 (28.09 to 86.16)	47.31 ± 18.95 (15.94 to 77.27)	0.356
3 Months	88.64 ± 6.28 (80.78 to 100.0)	77.79 ± 18.00 (51.11 to 100.0)	0.077
HHS Total			
Pre-Operation	62.44 ± 7.81 (45.00 to 75.00)	55.88 ± 10.33 (39.00 to 73.00)	0.188
3 Months	98.33 ± 2.88 (93.00 to 100.0)	96.80 ± 4.43 (91.00 to 100.0)	0.220
UCLA			
Pre-Operation	5.53 ± 1.65 (3 to 8)	5.22 ± 1.78 (2 to 6)	0.566
3 Months	6.86 ± 1.41 (4 to 9)	6.47 ± 1.51 (4 to 8)	0.478
Comorbidity Index			
Pre-Operation	0.16 ± 0.50 (0 to 2)	0.39 ± 0.66 (0 to 2)	0.167

2.3.2 Radiostereometric Analysis – 24 Hour Baseline

The average migrations and rotations for collared and collarless femoral stems using an RSA examination baseline within 24 hours post-operatively are shown in Figure 19. The collarless group demonstrated significantly greater subsidence (negative proximal migration) at two weeks than the collared group (mean difference = 2.90 mm, $p = 0.005$). The collarless group also demonstrated significantly greater anterior tilt at two weeks than the collared group (mean difference = 0.55°, $p = 0.002$). There was no significant difference at two weeks between groups for medial-lateral translation (mean difference = 0.34 mm, $p = 0.190$), posterior-anterior translation (mean difference = 0.35 mm, $p=0.069$), valgus rotation (mean difference = 0.58°, $p = 0.181$) or internal rotation (mean difference = 1.08°, $p = 0.281$).

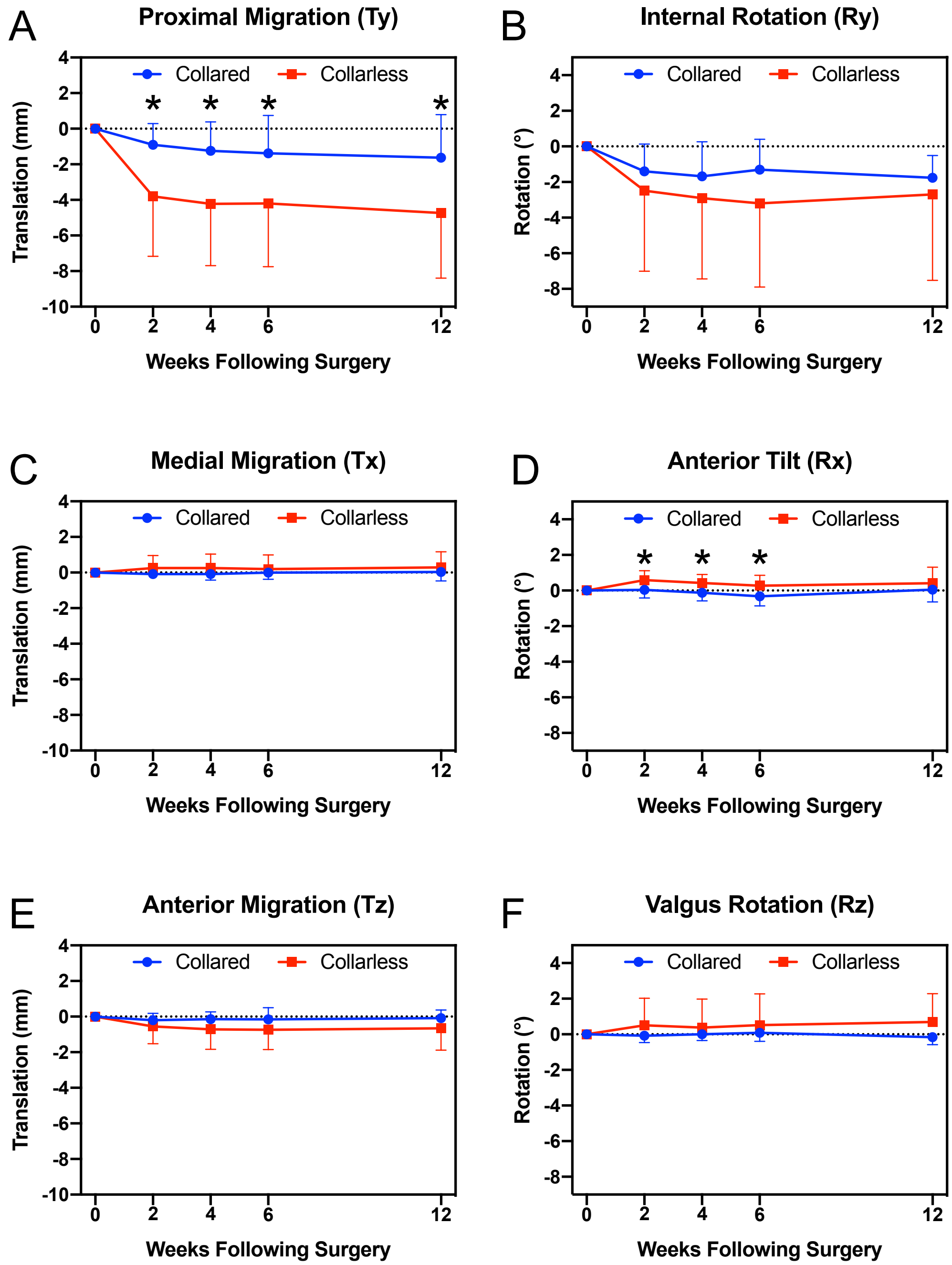

Figure 19: Line graphs showing the average migration in all planes across three months (12 weeks) using a baseline within 24 hours post-operatively. A) Subsidence in the coronal plane; B) internal rotation about the coronal plane; C) lateral-medial translation in the axial plane; D) anterior tilt about the axial plane; E) posterior-anterior translation in the sagittal plane; F) valgus rotation about the sagittal plane. Significant differences are represented using an '*' ($p<0.05$)

2.3.3 Radiostereometric Analysis – 2 Week Baseline

The average migrations and rotations for collared and collarless femoral stems using an RSA examination baseline at two weeks post-operatively are shown in Figure 20. There was no significant difference between groups at three months for subsidence (mean difference = 0.21 mm, $p = 0.831$), medial-lateral translation (mean difference = 0.16 mm, $p = 0.183$), posterior-anterior translation (mean difference = 0.19 mm, $p = 0.137$), internal rotation (mean difference = 0.11°, $p = 0.458$), anterior tilt (mean difference = 0.17°, $p = 0.722$) or valgus rotation (mean difference = 0.12°, $p = 0.583$).

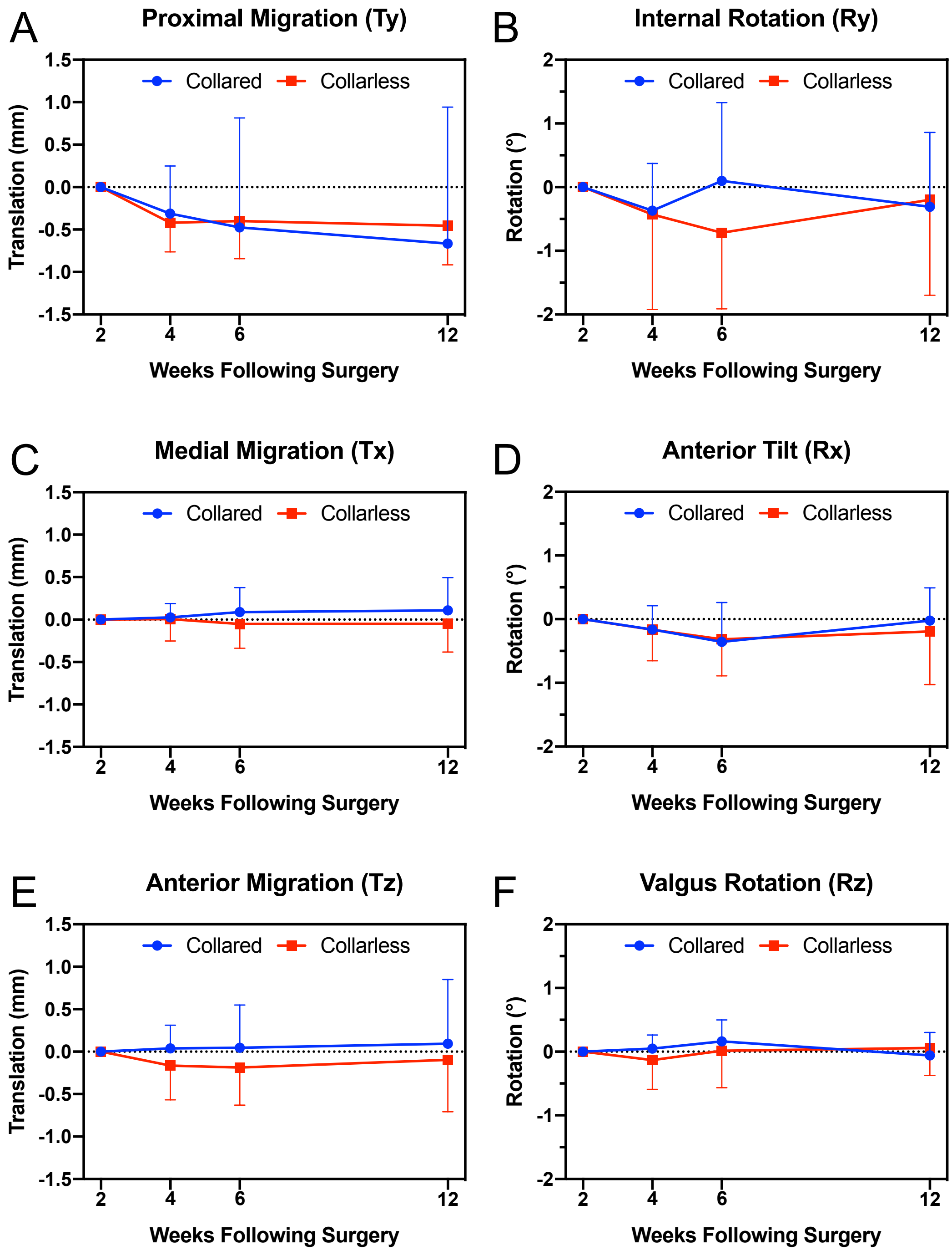

Figure 20: Line graphs showing the average migration in all planes across three months (12 weeks) using a baseline two weeks post-operatively. A) Subsidence in the coronal plane; B) internal rotation about the coronal plane; C) lateral-medial translation in the axial plane; D) anterior tilt about the axial plane; E) posterior-anterior translation in the sagittal plane; F) valgus rotation about the sagittal plane

2.3.4 Case Studies

Patients with substantial femoral stem migrations are described in Table 3 and shown in Figure 21.

Table 3: Patient demographics and implant used for the three patient cases, presented as patient specific metrics

Characteristic	A (Collared)	B (Collarless)	C (Collarless)
Age (years)	62	85	69
Sex (M/F)	M	F	F
Surgical side	L	L	R
Height (m)	1.89	1.58	1.68
Weight (kg)	98.4	54.9	72
BMI (kg/m^2)	27.6	22.0	25.7
Implant	Size 16 High-Offset	Size 12 Standard	Size 9 Standard

Patient A received a collared stem and demonstrated a consistent rate of subsidence up to 7.52 mm at six weeks, which then slowed with an increase to 8.61 mm at 12 weeks. This patient experienced external rotation of their implant of 4.64° at two weeks, which then slowed approaching four weeks with an increase to 4.96°, and at six weeks their implant rotated internally ending up at 1.81° of external rotation. This patient's implant followed the same valgus rotational trend that other patients with collared stems did.

Patient B received a collarless stem and demonstrated a large amount subsidence in the first two weeks of 11.12 mm which gradually increased to 11.46 mm at 12 weeks. This patient, similar to the average patients that received collarless stems, experienced external rotation. Their implant initially externally rotated 1.94° in the first two weeks, then rotating internally approaching 12 weeks, resulting in 0.71° of external rotation. Similarly, this patient's implant initially experienced a valgus rotation of 2.14° at two weeks, slowly approaching 2.29° of valgus rotation at 12 weeks.

Patient C received a collarless stem and also demonstrated a large amount of subsidence in the first two weeks of 11.49 mm which gradually increased to 13.01 mm at 12 weeks. This patient, unlike the average patients receiving collarless implants, experienced internal rotation. Their implant initially rotated 0.50° in the first two weeks, and continued to internally rotate, reaching 3.66° at 12 weeks. This patient's implant experienced excess valgus rotation in the first two weeks of 4.48° which slowed approaching 12 weeks resulting in 4.80° of valgus rotation.

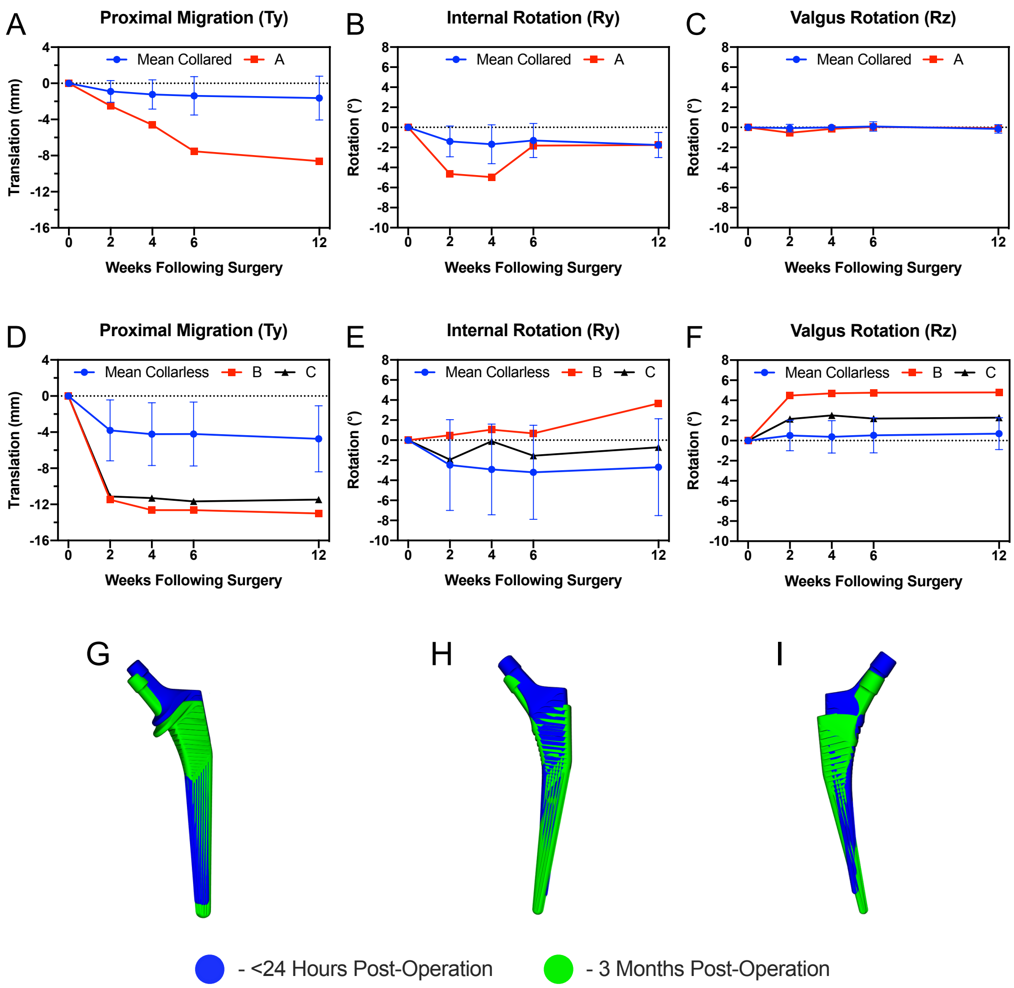

Figure 21: Line graphs showing migration patterns of selected cases for collared and collarless implants over three months (12 weeks). A) subsidence, B) internal rotation and C) valgus rotation for patient A compared to the collared mean; D) subsidence, E) internal rotation and F) valgus rotation for patients B and C compared to the collarless mean; G) visualization of patient A's implant migration over three months; H) visualization of patient implant B's migration over three months; I) visualization of patient C's implant migration over three months

2.4 Discussion

The aim of this study was to measure the early migration patterns for collared and collarless femoral stems in patients undergoing the DA approach. It has been shown that RSA is the preferred tool for measuring implant fixation [19]. Studies have evaluated early migration using clinical x-rays assessing migrations starting on the day of discharge, but these are unable to assess migrations to the precision required to determine relevant variations. Studies have evaluated early migration using RSA, but these have used baseline images taken after multiple weightbearing days, omitting the crucial migration information occurring immediately post-operatively [24,26]. This study is the first to measure the Corail stem migration using a baseline RSA exam within 24 hours post-operatively and assessing implant migration throughout the early recovery period.

The Corail femoral stem was first introduced in 1986, and with refinements over the years, has been proven to last with 96.17% survival for collarless stems and 97.66% survival for collared stems at 10 years [27]. Although femoral stems have a good survival rate, studies have found that early migration is an indicator for an increased risk of revision in the future [12,23–25,28–33]. Initial subsidence ultimately plateaus once mechanical stability is reached. The majority of osseointegration occurs within the first three months but has been reported to take up to three years in some cases [34,35]. This is the reason why it is most important to ensure stability early on in the first three months to guarantee good long-term fixation.

Campbell et al [24] assessed 30 patients that received the cementless Corail collarless femoral stem and obtained RSA radiographs throughout recovery at six months, one- and two-years using a baseline of three- or four-days post-operation. They observed a mean subsidence of 0.73 mm at six months with minimal subsidence thereafter. Strom et al [26] assessed 29 patients that received the cementless CLS collarless femoral stem, which has a tapered neck geometry similar to the Corail stem. They obtained RSA radiographs throughout recovery at one day, one week and three months using a baseline x-ray immediately post-operation. They saw a mean subsidence of 0.69 mm (unrestricted weightbearing) and 0.47 mm (partial weightbearing) at three months with minimal migration thereafter. We obtained follow-up radiographs throughout recovery at two-, four-, six-weeks and three months using a baseline within 24 hours post-operation. The majority of the subsidence in our study occurred within the first two weeks. We observed larger subsidence in the first two weeks for both collared and collarless implants that other studies saw in their early timeframes. By taking many follow-up images within three months, we are able to determine when during early recovery the stems become stabilized, whereas other studies focussed on the migrations experienced over longer periods of time.

Using a baseline RSA exam within 24 hours post-operation with early follow-ups, we were able to observe the migration patterns early in recovery. It was not possible to obtain RSA radiographs intraoperatively as the calibrated equipment required is not accessible in the operating room. There is a greater force required to induce subsidence in a collared femoral stem compared to a collarless one [17]. If the collared femoral stem is inserted with the collar resting properly on the calcar during the procedure, then the forces leading to subsidence will be supported by the collar, maintaining the implant's initial position [17,36]. Our data supports the literature and demonstrates that within the first two weeks post-operation the collarless femoral stem subsided significantly more than the collared femoral stem. A striking feature of our study is the amount of femoral stem subsidence observed within the first two weeks that plateaus thereafter. During the first two weeks, collarless femoral stems subsided a mean of 3.80 ± 3.37 mm while collared femoral stems subsided a mean of 0.90 ± 1.20 mm. Between two weeks and three months, the stems only subside an additional 0.46 ± 0.46 mm for collarless stems and 0.67 ± 1.61 mm for collared stems (Figure 20). This lends support to the idea that once the collar rests on the calcar, it results in improved stability and fixation allowing better biological fixation.

Our data demonstrates that collared femoral stems rotated externally 1.40° and collarless femoral stems rotated externally 2.48° within the first two weeks. This rotation stabilized after the second week and only rotated an additional 0.36° for the collared implant and an additional 0.22° for the collarless implant. Other studies have observed internal and external rotations that were similar to what we observed from two weeks to three months during their baseline to initial follow-up images. This leads us to believe that we are observing migrations in the first two weeks that other studies missed due to their late baseline images [24,26]. Similar to other studies, we saw small amounts of implant valgus rotation, anterior tilt, lateral-medial translation and posterior-anterior translation which is consistent with reports in the literature from other cementless stems.

In both implant groups there were instances where the implant greatly exceeded the mean magnitude of migration (Figure 21). One of the collared femoral stems was not inserted completely during the procedure resulting in a lack of collar-calcar contact. This patient experienced constant implant subsidence to six weeks that no other patients receiving collared implants experienced. They experienced the same valgus rotation as the other collared implants but experienced more external rotation during the six weeks that the collar was not resting on the calcar. This incomplete insertion resulted in it acting more like a collarless stem while subsiding into its ultimate position. Two of the patients that received collarless implants experienced large amounts of subsidence and valgus rotation as well as varying amounts of internal-external rotation in the first two weeks that was not seen in the other patients receiving collarless implants. This could lend support to the idea that without a collar, implants that are not properly inserted into the femur will migrate large amounts until mechanical stability is reached. The large amount of implant subsidence in these three cases show the magnitude of implant migration when a stem does not achieve optimal primary fixation intra-operatively. This can potentially lead to leg length discrepancies noticeable to patients.

The primary limitation of this study is the assessment of a single device. A secondary limitation of this study is the lack of evaluation ensuring that all collared implants had the collar resting on the calcar intraoperatively. A third limitation is the time-period between the operation and our baseline RSA imaging. Patients did bear weight before the baseline exam, <24 hours after the procedure, and as a result we may not have captured all of the implant migration. This RSA study is ideal for predicting long term implant stability as there is a detailed understanding of the early variations between designs. When patients are called back for five-, ten- and even twenty-year post-operative imaging, we will be able to determine the impact that these early migrations had on their long-term stability.

In conclusion, both the collared and collarless femoral stems illustrate good early fixation in the first three months with the majority of the stem migration occurring in the first two weeks post operatively. When comparing between the implants following a DA THA procedure it was observed that collared stems experience significantly less subsidence than their collarless counterpart in the first two weeks. It was also observed that, although small, there was significantly less anterior-tilt for collared stems compared to collarless stems as well. No significant differences were observed between groups for any migrations that occurred between two weeks and three months.

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Chapter 3

3 Understanding the Impact Femoral Implant Design has on Patient Activity and Function

3.1 Introduction

3.1.1 Total Hip Arthroplasty

Osteoarthritis (OA) is a degenerative disease that impacts over 37% of the Canadian population and affects the load bearing joints of the body [1]. Individuals who suffer from end-stage hip OA may elect to undergo total hip arthroplasty (THA). THA is a procedure known to both reduce pain and improve patient function [2]. This surgical procedure is among the most common elective surgeries performed in Canada, with over 50,000 annually conducted and this number is expected to continue rising [3]. There is increasing pressure for THA procedures to provide improved rapid recovery care, pushing for better implant stability earlier on [4].

There are many different surgical approaches that can be used to perform a THA. The three main approaches are the direct anterior (DA), direct lateral (DL) and direct posterior (DP) with each one having its own advantages and disadvantages. The muscle sparing nature of the DA approach leads to a reduction in recovery time as well as less pain post-operatively that the others do not [2]. Studies have shown that early activity post-operatively can result in a positive impact in the recovery process after the arthroplasty procedure [5–7].

An adequate understanding of patient functionality is an integral component of providing the best possible care and possibly support enhanced recovery pathways. It is important to interpret the impact that varying implant designs have on recovery. Orthopaedic implant manufacturers have developed femoral stems to provide stability of the femoral component [8]. Femoral stem micromotion may result in a failure of the implant to properly in-grow [9]. This may ultimately lead to pain that can in turn impact a patient's activity and function. Manufacturers have modified their implants to improve implant stability such as the addition of a medially placed collar on the femoral stem. It is important to clinically test the impact that these new designs have on patient recovery. If this design improves patient early recovery then it can be beneficial to the rapid recovery care pathways sought after by current health care providers.

Physical assessments and patient reported outcome measures (PROMs) are standards of practice used by clinicians to assess an individual's function pre- and post-operatively. A limiting factor of PROMs is their vulnerability to bias and ceiling effects [10]. Although unintentional, when patients are asked to report unbiased measures, there is a risk that unrealistic personal expectations may impact the outcomes. Standard pre- and post-operative assessments include clinicians asking patients to briefly walk up and down a hall. This test provides the necessary information to determine what specific functional impairments they are experiencing. It is difficult to assess all aspects of the patient's stride during this test. Instrumenting a functional test to assess this would provide an objective unbiased metric necessary to analyze a patient's progress. The timed-up-and-go (TUG) test is a frequently used measure of an individual's mobility. Originating as a risk assessment for falls, the TUG test has been validated for clinical use to assess patients in rehabilitation programs [11]. Historically, clinicians have been focused on the total time to complete the test. Instrumenting this test using wearable inertial sensors proximal and distal to each knee would provide unbiased objective metrics to quantify individual patient functionality. This test can be repeated throughout recovery to assess an individual's recovery process. Another benefit of instrumenting this test is the ability to gain insight into the different functional components the patient is required to accomplish. The TUG test has shown good test-retest reliability [12]. Another method to objectively assess patient activity throughout recovery is using off-the-shelf activity trackers. These fitness trackers are validated to accurately monitor an individual's steps [13]. Measuring the change in a patient's average steps per day during the early recovery period can also give more insight into the daily recovery a patient is experiencing.

The purpose of this study was to measure the impact collared and collarless femoral stems have on activity and function of patients during the early recover period following THA via the DA surgical approach. We hypothesize that patients receiving collared implants will have more activity and function earlier in recovery compared to those patients receiving the collarless implant.

3.2 Methods

Research ethics board approval was obtained prior to patients being enrolled in this study. Recruitment occurred between January 2018 and February 2019. Patients undergoing a primary unilateral THA procedure for hip OA were eligible to participate in this prospective randomized clinical trial.

3.2.1 Inclusion and Exclusion Criteria

Patients included in this study were diagnosed with unilateral hip OA and set to undergo a primary THA procedure. The following are the exclusion criteria used to determine patient eligibility: A BMI greater than 40, symptomatic contralateral OA, bilateral or revision THA procedures, cognitive or neuromuscular disorders, the inability to understand English and if the patient lived more than 100km from our research centre in London, Ontario.

3.2.2 Surgical Intervention

Patients were referred to the University Hospital, London Health Sciences Centre. Those who were undergoing the DA surgical approach were randomly selected pre-operatively to either receive a collared or a collarless Depuy Corail femoral stem (Figure 22). A block randomization with concealed envelopes was used to assign participants to either receive a collared or a collarless implant.

3.2.3 Activity Follow-Up

Each patient was given a Fitbit™ (San Francisco, CA) activity tracker at their pre-admission appointment prior to surgery to allow the average steps per day taken throughout recovery to be recorded. Patients were asked to wear the activity tracker every day for a minimum of a full week prior to each visit to the hospital (day of surgery, two-, four-, six-weeks, and three months). The average steps taken per day over seven days prior to each follow-up visit was used to calculate an average number of daily steps taken for each visit.

3.2.4 TUG Follow-Up

Patients completed an instrumented TUG test at each visit (pre-operatively, two-, four-, six-weeks, and three months). This test required patients to wear inertial sensors, one distal and one proximal to each knee to measure flexion, velocity and acceleration of each lower limb segment [14]. Patients were asked to start in a seated position, stand up and walk to a marker three metres away, turn around at the marker, walk back to the chair and sit down. Chairs of the same height were used for all tests and patients were asked to complete the test three times and the average was recorded.

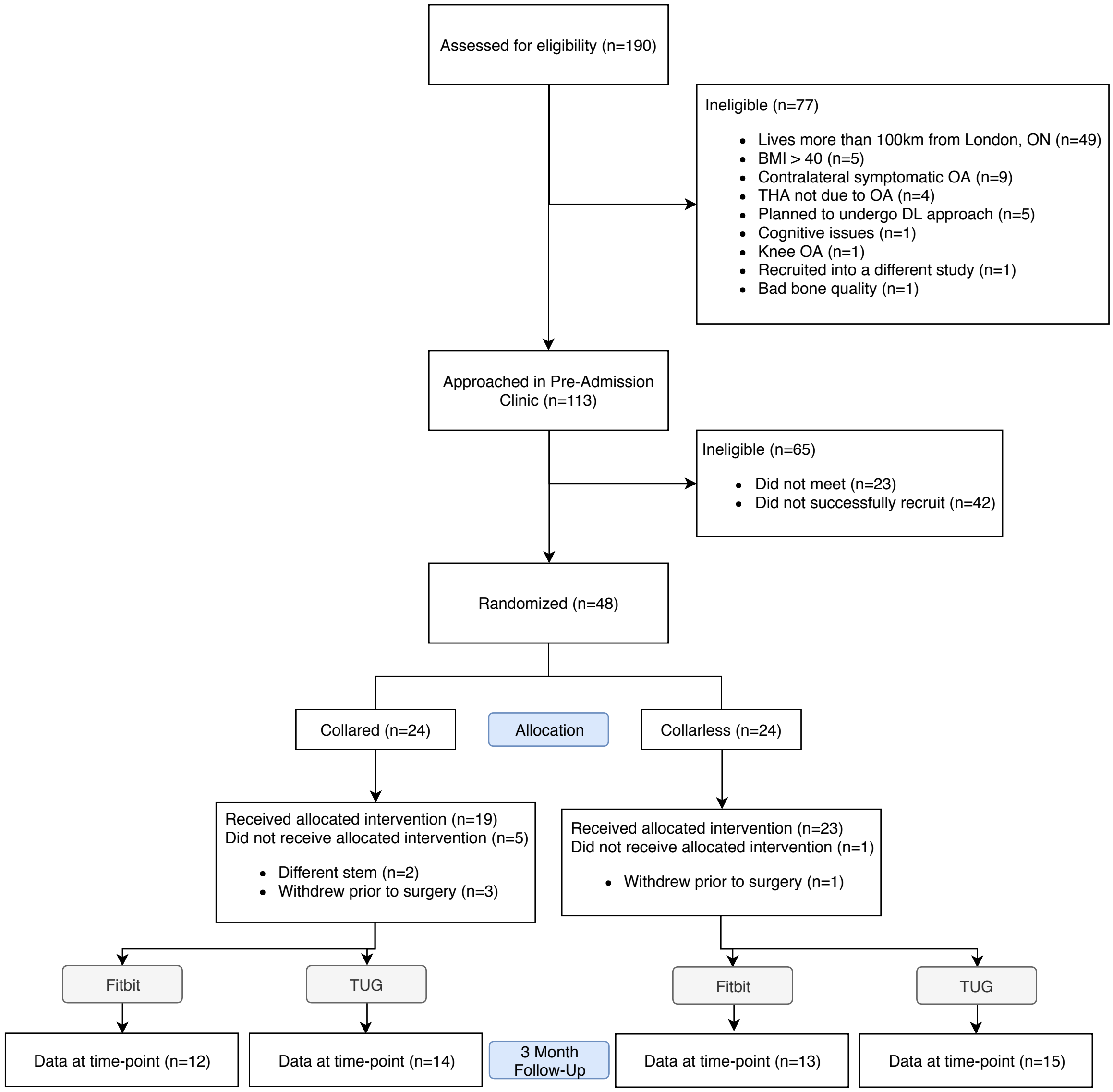

Figure 22: Participant flow through the study

3.2.5 Patient Reported Outcome Measure Follow-Up

Demographics were collected pre-operatively for both groups (Error! Reference source not found.). The Short Form 12 (SF-12), University of California, Los Angeles (UCLA) activity score, the Western Ontario and McMaster Universities Arthritis Index (WOMAC), and the Harris Hip Score (HHS) were collected for each patient pre-operatively and at three months post-operatively. The UCLA activity score was collected at an additional three visits at two-, four- and six-weeks post-operatively.

3.2.6 Statistical Analysis

Demographics, patient reported outcome measures (PROMs), TUG metrics and Fitbit™ metrics were reported with descriptive statistics including means, standard deviations and ranges. Data was tested to be normal or not to determine which statistical tests were appropriate. Demographics between groups were compared using unpaired t-tests, while the ratios of male:female and right:left hip was compared using a Fisher's exact test. To compare the average steps per day as well as TUG metrics throughout recovery, a 2-way ANOVA was used. The outcome scores will be compared between groups using a Mann-Whitney test. All statistical tests were conducted using GraphPad Prism.

3.3 Results

3.3.1 Demographics

There were no differences in patient demographics (Table 4), SF-12, WOMAC, HHS or UCLA outcome measures (Table 5) between the implant groups.

Table 4: Patient demographics for the two implant groups, presented as mean ± standard deviations (where applicable)

Characteristic	Collared	Collarless	p value
Age at surgery (years)	64.6 ± 8.7	65.0 ± 8.1	0.872
Patient sex	12 Male, 7 Female	12 Male, 11 Female	0.542
Surgical side	12 Left, 7 Right	9 Left, 14 Right	0.214
Height (m)	1.75 ± 0.08	1.73 ± 0.11	0.393
Weight (kg)	88.69 ± 18.44	91.31 ± 20.83	0.672
BMI (kg/m^2)	28.80 ± 5.1	30.35 ± 4.89	0.321

Table 5: Clinical outcome scores, presented as mean ± standard deviation, minimum and maximum values

Outcome Measure	Collared	Collarless	p value
SF-12 MCS			
Pre-Operation	55.15 ± 9.17 (36.52 to 66.40)	57.28 ± 5.96 (45.84 to 65.73)	0.431
3 Months	58.17 ± 3.35 (52.96 to 62.97)	58.16 ± 4.35 (51.16 to 61.97)	0.370
SF-12 PCS			
Pre-Operation	36.64 ± 10.88 (23.79 to 57.29)	30.65 ± 8.81 (20.44 to 46.86)	0.091
3 Months	49.80 ± 5.29 (39.27 to 55.50)	43.08 ± 10.64 (28.49 to 55.26)	0.142
WOMAC Total			
Pre-Operation	52.67 ± 13.24 (28.09 to 86.16)	47.31 ± 18.95 (15.94 to 77.27)	0.356
3 Months	88.64 ± 6.28 (80.78 to 100.0)	77.79 ± 18.00 (51.11 to 100.0)	0.077
HHS Total			
Pre-Operation	62.44 ± 7.81 (45.00 to 75.00)	55.88 ± 10.33 (39.00 to 73.00)	0.188
3 Months	98.33 ± 2.88 (93.00 to 100.0)	96.80 ± 4.43 (91.00 to 100.0)	0.220
UCLA			
Pre-Operation	5.53 ± 1.65 (3 to 8)	5.22 ± 1.78 (2 to 6)	0.566
2 Weeks	3.80 ± 1.57 (2 to 8)	3.32 ± 0.95 (2 to 6)	0.455
4 Weeks	4.93 ± 1.54 (3 to 8)	4.40 ± 1.19 (3 to 6)	0.267
6 Weeks	5.67 ± 1.54 (3 to 8)	4.85 ± 1.60 (3 to 8)	0.139
3 Months	6.86 ± 1.41 (4 to 9)	6.47 ± 1.51 (4 to 8)	0.478
Comorbidity Index			
Pre-Operation	0.16 ± 0.50 (0 to 2)	0.39 ± 0.66 (0 to 2)	0.167

3.3.2 Activity – Pre-Operation to Three months

The average steps taken per day for patients that received a collared and a collarless stem is shown in Figure 23. The collared group took significantly more steps than the collarless group at six weeks (mean difference = 2468 steps, p = 0.032) and three months (mean difference = 3010 steps, p = 0.036). The collared group was also taking significantly more steps at three months than they were pre-operatively (mean difference = 3311 steps, p = 0.001). The collarless group was taking significantly less steps at six weeks than they were pre-operatively (mean difference = 1830 steps, p = 0.021). There was no significant difference between groups pre-operatively (mean difference = 334 steps, p > 0.999), at two weeks (mean difference = 557 steps, p > 0.999) or at four weeks (mean difference = 1035 steps, p > 0.999).

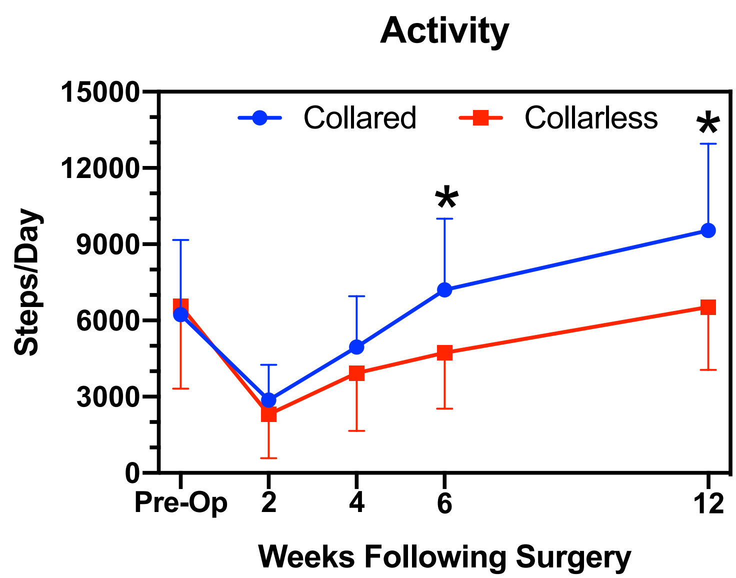

Figure 23: Line graph showing the average steps taken per day for patients that received a collared and a collarless femoral stem over three months (12 weeks)

3.3.3 Function – Pre-Operation to Three months

The total time taken to complete the TUG test for patients that received a collared and a collarless stem is shown in Figure 24. The collared group took significantly less time to complete the TUG test at three months than they did pre-operatively (mean difference = 3.26 s, p = 0.042). The collarless group also took significantly less time to complete the TUG test at three months than they did pre-operatively (mean difference = 3.66 s, p = 0.002). There were no significant differences between groups pre-operatively (mean difference = 0.35 s, p > 0.999), at two weeks (mean difference = 0.55 s, p > 0.999), at four weeks (mean difference = 0.04 s, $p > 0.999$), at six weeks (mean difference = 0.44 s, $p > 0.999$) or at three months (mean difference = 0.05 s, $p > 0.999$).

Pre-operative measurements between groups showed no significant differences for their operative limb flexion angles ($p = 0.970$), velocities ($p = 0.864$) or accelerations ($p = 0.471$) as well as for their non-operative limb flexion angles ($p = 0.481$), velocities ($p = 0.381$) or acceleration ($p = 0.888$). At three months there were also no significant differences measured between groups for their operated limb measurements of flexion angles ($p = 0.611$), velocities ($p = 0.438$) or accelerations ($p = 0.491$) as well as for their non-operated limb measurements of flexion angles ($p = 0.552$), velocities ($p = 0.619$) or acceleration ($p = 0.623$).

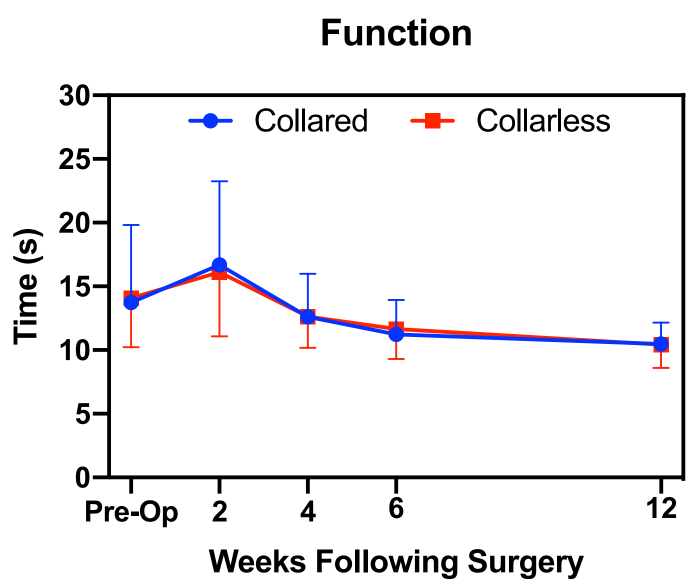

Figure 24: Line graph showing the average total time taken to complete the TUG test for patients that received a collared and a collarless femoral stem over three months (12 weeks)

3.4 Discussion

To our knowledge, this prospective study is the first to assess the impact having a collared or collarless stem design has on patient activity and function during the early recovery period after a primary THA. Our study describes the recovery process for patients receiving both collared and collarless cementless femoral stems. By three months post-operation, patients experienced improved activity and function compared to their pre-operative baselines in both groups. We reported no significant differences between groups prior to surgery. We also saw no differences between groups at any time-points for PROMs. According to multiple studies, questionnaires suffer from ceiling and bias effects limiting the amount we can tell from these patients [10,15,16]. This study partially supports our hypothesis expressing the increased level of activity in patients receiving collared implants compared to patients receiving collarless implants, but the same level of function.

Current literature has indicated that there is a minimal adjustment to a patient's lifestyle after their procedure to incorporate more activity. de Groot et al [17] reported on 80 patients undergoing a total joint arthroplasty and measured only a 0.7% increase in physical activity at six months post-operation compared to their pre-operative levels. A recent literature review concluded that activity levels can be accurately measured using pedometers [18]. Fujita et al [19] reported that patients set to undergo a primary THA procedure take an average of 4632 ± 2246 steps per day pre-operatively and by six months they are taking 5657 ± 2106 steps per day. They reported a significant increase in average steps taken after six months of recovery. A limitation of their study is the lack of information obtained within that first six-month time-frame. Our study measured a significant increase in the number of steps taken per day as early as three months compared to pre-operative step counts for patients receiving collared implants. The average steps taken per day for patients in our study that received the collarless stem agrees with the literature as they were still not taking significantly more steps three months post-operation than they were pre-operation. However, we also observed that patients receiving collared implants were already taking the same number of steps at six weeks (7202 ± 2800) and more steps at three months (9542 ± 3411) than the healthy controls (7228 ± 3132) reported by Fujita et al [19]. Studies have shown that there is still a risk of thigh pain after successful THAs [20]. According to Demey et al [8] the forces required to cause a collared implant to subside are much greater than those needed to cause a collarless implant to subside. This pain can be caused by a variety of factors, one of which is bone-prosthesis micromotion that may lead to a reduction in activity early in recovery as a result of this pain. In the previous chapter of this thesis, we reported that micromotion leading to subsidence is more apparent in collarless implants. This may result in leg length discrepancy and may be an explanation as to why we observed patients receiving collared implants taking significantly more steps per day at six weeks and three months compared to patients receiving collarless implants when there was no significant difference seen between these groups pre-operatively.

Unlike with activity, there were no functional significant differences observed between patients receiving collared and collarless implants (p=0.861) throughout recovery. We assessed function by having patients complete a TUG test while we measured the total time taken to complete the test along with various metrics assessing flexion, acceleration and velocity of each limb. Yuksel et al [12] validated the use of this test and found it to be sensitive in detecting changes in patients recovering from joint replacement surgeries. They determined the smallest detectable change for this test to be 2.27 seconds [12]. As walking is related to an active and independent lifestyle, this assessment after total joint arthroplasties provides crucial information about the healing process [21,22]. Studies have reported the TUG test to be a simple, reliable and valid test used to assess various populations as well as leg strength [11,23,24]. Poitras et al [25] conducted a study that used the TUG test to assess the functional recovery of total hip arthroplasty patients. They found patients to take 10.8 ± 4.6 s pre-operatively, 12.4 ± 4.3 s at two weeks and 9.4 ± 3.0 s at six weeks. The difference in time to complete the test between the three time-points in their study was less than 2.27 s, implying that there were no clinically relevant changes between follow-ups. Our study expressed the same trend, although showing a clinically relevant increase in time to complete the TUG test at two weeks and an eventual decrease in time approaching six weeks. Both groups in our study experienced improvements in TUG test time exceeding 3 seconds from pre-operation to three months, representing a clinically meaningful improvement in function. It has been reported that patients who take longer than 14 seconds to complete the TUG test are at a high risk of falls [26]. Patients in both groups in our study are classified under the high risk of falls category at two weeks, and already at four weeks they are in the low risk category. This risk continued to decrease approaching three months. We observed no difference in flexion, acceleration or velocity of each limb at any time point which suggests that both groups are walking functionally similar throughout their recovery.

The primary limitation of this study is the small number of patients in each group. Another limitation is our assessment of only one surgical approach. Observing these stems in patients undergoing different surgical approaches will shed more light on the impact this has on patient activity and function throughout recovery. Lastly, a limitation of this study is the use of wearable activity trackers while patients are using gait aids. We did however find that there was no significant difference between groups at any time point for how many were using gait aids.

In conclusion, the collared femoral stem allows patients to become more active earlier in their recovery process compared to the collarless femoral stem. The average steps taken per day for patients receiving collared implants was 2468 more than patients receiving collarless implants at six weeks and 3010 more at three months post-operatively. However, there was no measurable difference in the time to complete the TUG test between groups at the three-month time-point, although both groups had clinically meaningful improvements in function at three months compared to pre-operatively. Surgeons can take this information into account when planning DA THA procedures as it allows patients to be more active earlier. We can conclude that the collared femoral stem assists in providing patients with a rapid recovery.

3.5 References

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Chapter 4

4 Conclusion

4.1 Overview of Objectives

Our study assessed the impact implant design has on femoral stem migration and patient recovery. The increasing demand for rapid recovery care puts increasing pressure on outpatient procedures such as the direct anterior (DA) approach to be used. In order to provide this care, orthopaedic industry partners need to adapt to ensure patients are receiving the best possible treatment to benefit their recovery. The specific objectives of this study were to better understand the impact a collar on the femoral stem has on implant migration, patient activity, and patient function throughout the early recovery period.

4.2 Summary of Results

In chapter two of this thesis, the early implant migration patterns for collared and collarless femoral stems were assessed. Translations and rotations were measured for each implant at two-, four-, six-weeks and three months post-operatively using a baseline radiostereometric analysis (RSA) exam within 24 hours after their procedure. It was concluded that collared femoral stems have more stability earlier in recovery compared to collarless femoral stems as seen by the significantly less subsidence and anterior-tilt experienced within the first two weeks. There were no significant differences in stem migrations between groups from two weeks onwards. The early baseline RSA exam in this study is something to be considered when designing RSA studies assessing implant migration. Studies often have two- or six-week baseline exams missing the early migrations. Both stems are currently used for THA procedures. The results of this study will better inform surgeons on which implant should be used to ensure a more stable fixation earlier in recovery.

In chapter three of this thesis, the impact femoral stem design has on patient activity and function was analyzed. This study demonstrated that patients receiving the collared femoral stem were more active earlier on in recovery. This study found patients in the collared group taking significantly more steps per day on average compared to those in the collarless group as early as six weeks post-operatively. Although this study found a difference in patient activity, patients had similar function throughout their early recovery between groups. There was a clinically meaningful improvement in function at three months post-operation in comparison to pre-operation within patients that received collared and collarless implants. The results of this study will provide surgeons with a better understanding of which implant provides the best early recovery to improve the rapid recovery care process.

4.3 Future Directions

For this master's thesis, implant migration, patient activity and patient function for individuals undergoing the DA approach was assessed. These patients either received a collared or a collarless implant and were evaluated over the first three months post-operatively. While this thesis provides important insight into the variation in recovery patterns between the two implant groups, it does not touch on the impact these different stem designs have on patients receiving the direct lateral or direct posterior surgical approaches. Future research in this area should include an analysis on the impact stem design has on implant migration, patient activity and patient function after undergoing different surgical approaches. Future work should also be conducted assessing these patients longer into their recovery. This will provide information on the impact these stem designs and surgical approaches have on long term recovery.

4.4 Conclusions

This thesis set out to establish the relationship between implant design and implant migration, and implant design and recovery progression for patients undergoing the DA surgical approach for a total hip arthroplasty (THA). This thesis provides strong evidence towards the connection between using a collared stem and reducing implant migration. This thesis also provides evidence for patients improving early recovery after THA procedures when receiving collared femoral stems. By incorporating these findings into pre-surgical planning, patient recovery timelines may be reduced by utilizing the collared femoral stem.

Appendices

Appendix A: Ethics Approval

LAWSON FINAL APPROVAL NOTICE

LAWSON APPROVAL NUMBER: R-17-461

PROJECT TITLE: The Collared Femoral Component: Supporting the Transition to Enhanced Recovery Pathways?

PRINCIPAL INVESTIGATOR: Dr. Brent Lanting

LAWSON APPROVAL DATE: Thursday, 7 December 2017

Health Sciences REB#: 109401

ReDA ID: 4053

Please be advised the above project was reviewed by Lawson Administration and the project:

Was Approved

Please provide your Lawson Approval Number (R#) to the appropriate contact(s) in supporting departments (eg. Lab Services, Diagnostic Imaging, etc.) to inform them that your study is starting. The Lawson Approval Number must be provided each time services are requested.

Dr. David Hill
V.P. Research
Lawson Health Research Institute

All future correspondence concerning this study should include the Lawson Approval Number and should be directed to Sherry Paiva, Research Approval Officer, Lawson Health Research Institute, 750 Baseline Road, East, Suite 300.

cc: Administration

Appendix B: Letter of Information and Consent

London Health Sciences Centre

Comparing direct anterior and lateral surgical approaches for collared and collarless implants and correlating joint motion to hip implant performance.

Principle Investigator
Dr. Brent Lanting [redacted]

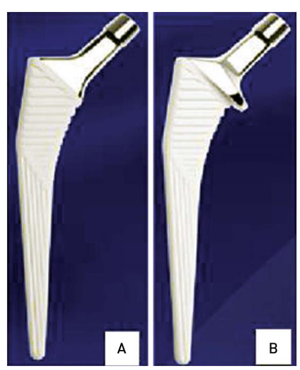
Co-Investigators
Dr. Edward Vasarhelyi [redacted]
Dr. Jacquelyn Marsh
Dr. Matthew Teeter

Study Coordinators
Maxwell Perelgut
Bryn Zomar
Harley Williams
Jordan Broberg
[redacted]

You are being invited to voluntarily participate in a research study designed for patients undergoing total hip replacement (THR) surgery at London Health Sciences Centre. This letter of information describes the research study and your role as a participant. Please read this letter of information carefully. Do not hesitate to ask anything about the information provided. Your surgeon or the study coordinator will describe the study and answer your questions. You may take as much time as you need to decide whether to participate and can discuss participation with your friends, family, family doctor, etc.

PURPOSE

There are two main designs of implants used in THR, collared and collarless (see image below).The collared implant has a lip at the top edge has been shown to provide improved resistance to twisting (stability), but it's unknown if this increase in stability improves early function for patients. Greater stability immediately after surgery would provide surgeons with greater confidence that their patients can embark on rapid recovery pathways (earlier discharge from hospital, quicker rehabilitation, quicker return to activities), but not all surgeons are supportive of collared implants due to a lack of literature demonstrating the benefits.



A. Collarless hip implant
B. Collared hip implant

____
Participant's Initials

London Health Sciences Centre

The purpose of this study is to compare movement of the hip implant between the collared and collarless implant designs up to 2 years after surgery. This study will also compare implant movement between two common surgical approaches used by the surgeons at University Hospital, the direct anterior (incision from the front) and the direct lateral (incision from the side).

PROCEDURE

This is a randomized study with 50 participants in each group for a total of 100 participants. Eligible patients receiving THR surgery will be enrolled if they meet the inclusion criteria, and will then be randomized to undergo a THR with either a collared or collarless implant. Both types of implant are used by the surgeons' in their normal standard practice. You will be randomly assigned, like the flip of a coin, to one of the two groups. You will not be told which group you have been randomized to until you reach the final study visit. The surgical approach used during your surgery is determined based on your surgeon's preference and is not affected by your participation in this study.
During your surgery you will have tantalum beads inserted into the top of your thigh bone and around the socket of your pelvis (at your hip joint). These beads are the size of the head of a pin and will have no impact on how your hip will function after the surgery. The tantalum beads will be used as markers to assess for any microscopic movement of the implant and will remain in place indefinitely. To measure this movement, we will ask you to have a special kind of x-ray called radiostereometric analysis (RSA) taken after surgery on the day you are discharged from the hospital and at every follow-up visit. A member of the study team will escort you to Robarts Research Institute (attached to University Hospital) where the x-rays will be taken, and a wheelchair will be provided for you if needed. The x-ray will take less than 15 minutes to complete. These x-rays will be taken in addition to the standard x-rays taken as part of the standard of care at the hospital.

You will be asked to complete questionnaires that will assess your functional ability, quality of life and costs at specific visits after surgery. These questionnaires will take approximately 20 minutes to complete.

You will also be asked to perform the Timed Up and Go (TUG) at each visit. Any gait aids (such as a cane, crutches or walker) that are normally used will be permitted during the TUG. The TUG involves getting up from a chair, walking 3 metres to a point marked on the floor, turning around and returning to sitting in the chair. During the TUG we will have you wear sensors that will measure speed, step length, stride length, etc. As part of this study you will also be given a FitBit (a type of pedometer, worn in a bracelet, that can track your activity) to wear for 7 days prior to your surgery and each visit to the clinic. You will be asked to set up an account with FitBit at your first visit (research staff will assist you with this) and at each follow-up visit you will be asked to log into your account to download the data.

For this study, in addition to the standard visits to the hospital after surgery (at 2 weeks, 6 weeks, 3 months, 1 year and 2 years), we will ask you to also come in at 4 weeks and 6 months specifically for the research study. Standard x-rays will still be taken at 6 weeks, 1 year and 2 years as part of your normal clinic appointments. Questionnaires and study specific testing will occur at each visit outlined in the flow chart below.

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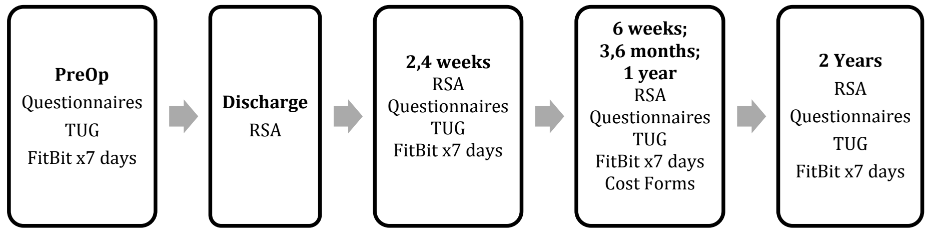

INCLUSION AND EXCLUSION CRITERIA

You will be eligible to participate in this study if you:

1. Have osteoarthritis in one of your hips;
2. Will have a total hip replacement.

You will not be eligible to participate in this study if you:

1. Have osteoarthritis in your other hip;
2. Will have a revision hip replacement;
3. Will have both hips replaced in the same surgery;
4. Have a neuromuscular disorder that would prevent you from performing the TUG;
5. Have a body mass index greater than 40;
6. Live more than 100 km from London, Ontario;
7. Are unable to understand English, as questionnaires are only provided in English.

RISKS

Both implant designs and surgical approaches used in the study are part of the surgeons' standard practice. Standard anesthetic and surgical risks that apply in standard practice will apply to you. You can opt out of any questionnaires that make you uncomfortable. You could fall or injure yourself while performing the walk tests; however, the risks are no greater than those encountered with typical postoperative rehab protocols.

There is always a slight chance of cancer from excessive exposure to radiation. Special care is taken during x-ray examinations to use the lowest radiation dose possible while producing the best images for evaluation.

The scientific unit of measurement for radiation dose is the millisevert (mSv). People are exposed to radiation from natural sources all the time. The average person receives an effective dose of about 3-5 mSV per year from naturally occurring radioactive materials and cosmic radiation from outer space. The 8 RSA examinations in this study will expose you to 1.2 mSv of ionizing radiation, or 40% of the yearly background radiation we are all exposed to yearly.

London Health Sciences Centre

The tantalum bead insertion is an additional procedure that is not used in routine surgery. The beads are secured in the bone and there is little to no significant risk related to their insertion.

BENEFITS

There are no known benefits to you for taking part in this study; however, possible benefits may include greater stability in the collared implant group. The findings from this study will contribute to our improvement in the treatment of future patients undergoing THR. This study will help identify if one type of implant provides greater stability and reduces the risk of future revision surgery.

NEW INFORMATION

During the study, you will be informed of any significant new finding (either good or bad), such as changes in the risks or benefits resulting from participation in the study or new alternatives to participation that might change your decision to continue participating in this study. If new information is provided to you, written consent to continue participating in this study will be requested.

RESEARCH RELATED INJURY

If you become ill or injured as a direct result of participating in this trial, necessary medical treatment will be available at no additional cost to you. Your signature on the consent only indicates that you have read to your satisfaction the information regarding your participation in the study and agree to participate in the trial. In no way does this waive your legal rights nor release the Principal Investigator, the research team, or involved institutions from their legal and professional responsibilities.

CONFIDENTIALITY

Any personal health information collected or other information related to you will be de-identified with a unique number to ensure that persons outside of the study will not be able to identify you. In any publication, presentation or report, your name will not be used and any information that discloses your identity will not be released or published unless required by law. Despite these protections being in place, there is always a risk of unintentional release of information. The study personnel will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will be accidentally released is small.

When you create your FitBit account, you will be asked to provide an email address and some personal information (such as birthdate, height, weight, etc.), however, only your email address is required to set up your account. Research staff will not have access to your account. There is a remote chance that your account could be "hacked" by someone who is not supposed to have your information, but this risk is small.

RSA image data will be processed at the Robarts Research Institute, a secure research facility. This data will be stored on a password-protected computer, and will be made anonymous by coding it with a numeric identifier.

London Health Sciences Centre

Study data will be kept for 15 years. Representatives of the University of Western Ontario Health Sciences Research Ethics Board may require access to your study-related records or follow-up with you to monitor the conduct of this research. Representatives of Lawson Quality Assurance (QA) Education Program may look at study data for QA purposes.

VOLUNTARY PARTICIPATION

Participation in this study is completely voluntary. You may refuse to answer any questions you do not want to answer and remain in the study. You are free to withdraw at any time without affecting the quality of the care you receive at this institution, and by signing this form you do not waive your legal rights. When you withdraw your permission, no new health information will be gathered after that date. Information that has already been gathered may still be used. If you would like to withdraw from this study, you will need to provide written or verbal confirmation to the study coordinator: Maxwell Perelgut at [redacted]

ALTERNATIVES TO STUDY PARTICIPATION

If you choose not to participate, you will continue to be followed by your surgeon as per standard of care for all orthopaedic joint replacement patients.

COST/COMPENSATION

Parking passes will be provided for visits that are outside standard of care (4-weeks and 6-months after surgery). You will also be allowed to keep the FitBit at the end of the study.

CONFLICT OF INTEREST

Drs. Brent Lanting and Edward Vasarhelyi are both paid consultants for DePuy, which is the company that manufactures the Corail implant and provides funding for this research study. If this study were to find very positive outcomes of this implant, it is very unlikely that these consultants will receive any benefit. DePuy is not involved in study conduct, but will receive a report of study results once the study is complete.

London Health Sciences Centre

CONTACT FOR QUESTIONS

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Office of Human Research Ethics at [redacted] or [redacted]

For more information concerning this study and research-related risks or injuries, you may contact the Principal Investigator, Dr. Brent Lanting, at [redacted], or the study coordinator Maxwell Perelgut, at [redacted]

You will be provided with a copy of this consent document once it has been signed.

Sincerely,

Dr. Brent Lanting, MD, FRCSC
Dr. Edward Vasarhelyi, MD, FRCSC
Dr. Jacquelyn Marsh, PhD
Dr. Matthew Teeter, PhD
Bryn Zomar, MSc, PhD(c)
Maxwell Perelgut, Master's Student
Harley Williams, Master's Student
Jordan Broberg, Master's Student

London Health Sciences Centre

<u>**Letter of Consent**</u>

Comparing direct anterior and lateral surgical approaches for collared and collarless implants and correlating joint motion to hip implant performance.

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction. I will receive a copy of the Letter of Information and this signed consent form.

Print participant's full name Date

Participant's signature

Name of person obtaining consent Date

Signature of person obtaining consent

____
Participant's Initials

Appendix C: Screening and Consent Document

Collared/Collarless Screening and Consent Document

Patient Name: ____________________ Patient PIN: ___________________________

Date Screened: ___________________ Estimated Surgery Date: _________________

Mailed: ☐ Yes ☐ No _______________ Preadmission Date: _____________________

Surgeon: ☐ Lanting ☐ Vasarhelyi

Inclusion Criteria:	1. Osteoarthritis of the hip?	☐ Yes ☐ No
	2. Booked for primary unilateral total hip arthroplasty?	☐ Yes ☐ No
	2. Access to a computer or a smartphone?	☐ Yes ☐ No
Exclusion Criteria:	1. Symptomatic osteoarthritis in the contralateral hip?	☐ Yes ☐ No
	2. Bilateral total hip arthroplasty?	☐ Yes ☐ No
	3. Revision arthroplasty?	☐ Yes ☐ No
	4. Cognitive defects/neuromuscular disorders?	☐ Yes ☐ No
	5. Inability to understand English?	☐ Yes ☐ No
	6. Live more than 100km from London, Ontario	☐ Yes ☐ No
	7. BMI greater than 40?	☐ Yes ☐ No

Status: ☐ Eligible

☐ Ineligible

☐ Meets inclusion criteria, but declined

☐ Other: ____

Consent Discussion:

Was the study explained to the patient in detail? ☐ Yes ☐ No

Did the patient have any questions? ☐ Yes ☐ No

Were all questions answered to the patient's satisfaction? ☐ Yes ☐ No

Was the patient given time to read the consent form? ☐ Yes ☐ No

Did the patient need more time to think about the study? ☐ Yes ☐ No

Was the consent form signed? ☐ Yes ☐ No

Was a copy of the consent given to the patient? ☐ Yes ☐ No

Questions asked by patient:

____
____
____
____
____
____

Surgeon Reviewed Eligibility (sign and date): ____

Date Randomized: ____

Notes:

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Signature: ________________________________ Date: _________________________

Appendix D: Demographics Questionnaire

Collared vs Collarless RCT — Study ID: ____________

Date: _______________

Demographics

1. **Age:** ____________________
2. **Operative Hip:** ❑ Left ❑ Right
3. **Do you have symptoms in your other hip?** ❑ Yes ❑ No
4. **Dominant Side:** ❑ Left ❑ Right
5. **Gender:** ❑ Male ❑ Female
6. **Height:** ___________ **Weight:** ___________
7. **Do you currently smoke cigarettes?**

   ❑ I have never smoked
   ❑ No, I quit more than 12 months ago
   ❑ No, I quit in the last 12 months
   ❑ Yes: **How often do you smoke?** ❑ Every day ❑ Some days

8. **How much schooling have you completed?**

   ❑ Less than high school
   ❑ Some college
   ❑ Postgraduate school or degree
   ❑ Graduated from high school
   ❑ Graduated from college

9. **Which statements describe your current employment situation?**

   ❑ Currently working
   □ Full Time
   □ Part Time
   ❑ Disability/WSIB
   ❑ Unemployed
   ❑ Homemaker
   ❑ Student
   ❑ Retired (not due to ill health)
   ❑ Retired (due to ill health)
   ❑ Other ________________________

10. ❑ **Check this box if you are off work for reasons unrelated to your hip problem.**

    Please describe the reason: ______________________________________

11. **What is your current marital situation?**

    ❑ Married
    ❑ Living with significant other
    ❑ Divorced/Separated
    ❑ Widowed
    ❑ Single (never married)

Version: 12-Jan-2018

Collared vs Collarless RCT

Study ID: ___________

Date: _______________

12. Please indicate your living status (pre-hip replacement).

- ❑ Living alone
- ❑ Living with spouse/partner
- ❑ Living with family (includes extended)
- ❑ Living with non-family, unpaid (includes friends)
- ❑ Living with paid attendant
- ❑ Living in residential care facility
- ❑ Living in hospital/long-term care/nursing home
- ❑ Other _____________________________

13. Are there stairs where you live that you are required to use?

❑ No ❑ Yes

14. Have you had a previous joint replacement?

❑ No ❑ Yes: ❑ Other Hip
❑ Right Knee
❑ Left Knee

Appendix E: Short Form 12 (SF-12)

Collared vs Collarless RCT

Study ID: ___________

Date: _______________

SF-12

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:	Excellent (1)	Very Good (2)	Good (3)	Fair (4)	Poor (5)

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much:

	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.	1	2	3
3. Climbing several flights of stairs.	1	2	3

During the past 4 weeks have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	YES	NO
4. Accomplished less than you would like.	1	2
5. Were limited in the kind of work or other activities.	1	2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	YES	NO
6. Accomplished less than you would like.	1	2
7. Didn't do work or other activities as carefully as usual.	1	2

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at All (1)	A little bit (2)	Moderately (3)	Quite a bit (4)	Extremely (5)

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks?

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	1	2	3	4	5	6
10. Did you have a lot of energy?	1	2	3	4	5	6
11. Have you felt downhearted and blue?	1	2	3	4	5	6

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc)?

All of the time (1)	Most of the time (2)	Some of the time (3)	A little of the time (4)	None of the time (5)

Version: 25-May-2017

Appendix F: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Collared vs Collarless RCT

Study ID: ___________

Date: _______________

WOMAC

A. Think about the ***pain*** you felt in your hip/knee during the last 48 hours.

Question: How much pain do you have?	None	Mild	Moderate	Severe	Extreme
1. Walking on a flat surface	0	1	2	3	4
2. Going up or down stairs	0	1	2	3	4
3. At night while in bed, pain disturbs your sleep	0	1	2	3	4
4. Sitting or lying	0	1	2	3	4
5. Standing upright	0	1	2	3	4

B. Think about the ***stiffness*** (not pain) you felt in your hip/knee during the last 48 hours. Stiffness is a sensation of ***decreased*** ease in moving your joint.

	None	Mild	Moderate	Severe	Extreme
6. How ***severe*** is your ***stiffness after first awakening*** in the morning?	0	1	2	3	4
7. How ***severe*** is your stiffness after sitting, lying, or resting ***later in the day***?	0	1	2	3	4

C. Think about the ***difficulty*** you had in doing the following daily physical activities dues to your hip/knee during the last 48 hours. By this we mean your ***ability to move around and look after yourself***.

Question: What degree of difficulty do you have?	None	Mild	Moderate	Severe	Extreme
8. Descending stairs	0	1	2	3	4
9. Ascending stairs	0	1	2	3	4
10. Rising from sitting	0	1	2	3	4
11. Standing	0	1	2	3	4
12. Bending to the floor	0	1	2	3	4
13. Walking on a flat surface	0	1	2	3	4
14. Getting in and out of a car, or on or off a bus	0	1	2	3	4
15. Going shopping	0	1	2	3	4
16. Putting on your socks or stockings	0	1	2	3	4
17. Rising from bed	0	1	2	3	4
18. Taking off your socks or stockings	0	1	2	3	4
19. Lying in bed	0	1	2	3	4
20. Getting in or out of the bath	0	1	2	3	4
21. Sitting	0	1	2	3	4
22. Getting on or off the toilet	0	1	2	3	4
23. Performing heavy domestic duties	0	1	2	3	4
24. Performing light domestic duties	0	1	2	3	4

Version: 25-May-2017

Appendix G: University of California, Los Angeles (UCLA) Activity Score

Collared vs Collarless RCT

Study ID: ___________

Date: _______________

UCLA Activity Score

Check one box that best describes current activity level.

◯ 1: Wholly Inactive, dependent on others, and can not leave residence

◯ 2: Mostly Inactive or restricted to minimum activities of daily living

◯ 3: Sometimes participates in mild activities, such as walking, limited housework and limited shopping

◯ 4: Regularly Participates in mild activities

◯ 5: Sometimes participates in moderate activities such as swimming or could do unlimited housework or shopping

◯ 6: Regularly participates in moderate activities

◯ 7: Regularly participates in active events such as bicycling

◯ 8: Regularly participates in active events, such as golf or bowling

◯ 9: Sometimes participates in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labor or backpacking

◯ 10: Regularly participates in impact sports

Version: 25-May-2017

Appendix H: Harris Hip Score (HHS)

Collared vs Collarless RCT

Study ID: ___________

Date: _______________

Harris Hip Score

PAIN	
None/ignores	44
Slight, occasional, no compromise in activity	40
Mild, No effect on ordinary activity, pain after unusual activity, uses aspirin	30
Moderate, tolerable, makes concessions, occasional codeine	20
Marked, serious limitations	10
Totally disabled	0

FUNCTION – GAIT (LIMP)	
None	11
Slight	8
Moderate	5
Severe	0

FUNCTION – GAIT (SUPPORT)	
None	11
Cane, long walks	7
Cane, full time	5
Crutch	4
2 canes	2
Unable to walk/2 crutches	0

FUNCTION – GAIT (DISTANCE WALKED)	
Unlimited	11
6 blocks (1hour)	8
2-3 blocks (½ hour)	5
Indoors only/Less than 1 block	2
Bed and chair	0

FUNCTION – FUNCTIONAL ACTIVITIES (STAIRS)	
Normally	4
Normally with banister	2
Any method	1
Not able	0

FUNCTION – FUNCTIONAL ACTIVITIES (SOCKS/TIE SHOES)	
With ease	4
With difficulty	2
Unable	0

FUNCTION – FUNCTIONAL ACTIVITIES (SITTING)	
Any chair, 1 hour	5
High chair, ½ hour	3
Unable	0

FUNCTION – FUNCTIONAL ACTIVITIES (TRANSPORT)	
Enter public transport/Car	1
Not able to use public transport	0

ABSENCE OF DEFORMITY	
None	4
Fixed ADD>10° OR Fixed IRE>10° OR Leg length discrepancy >3cm OR PFC >30°	0

RANGE OF MOTION	
Flexion 90°	1
Abduction 30°	1
Adduction 20°	1
External Rotation 20°	1
Internal Rotation 15°	1

Version: 29-May-2017

Appendix I: Charlson Commorbidity Index

Collared vs Collarless RCT

Study ID: ___________

Date: _______________

Charlson Comorbidity Index

Assigned weighting for diseases	Conditions	Client's weighting
1	❑ Myocardial infarct	
	❑ Congestive cardiac insufficiency	
	❑ Peripheral vascular disease	
	❑ Dementia	
	❑ Cerebrovascular disease	
	❑ Chronic pulmonary disease	
	❑ Conjunctive/connective tissue disease	
	❑ Slight diabetes, without complications	
	❑ Ulcers	
	❑ Chronic diseases of the liver or cirrhosis	
	❑ None	
	SUBTOTAL:	__________
2	❑ Hemiplegia	
	❑ Moderate or severe kidney disease	
	❑ Diabetes with complications	
	❑ Tumors	
	❑ Leukaemia	
	❑ Lymphoma	
	❑ None	
	SUBTOTAL:	__________
3	❑ Moderate or severe liver disease	
	❑ None	
	SUBTOTAL:	__________
4	❑ Malignant tumor, metastasis	
	❑ AIDS	
	❑ None	
	SUBTOTAL:	__________
	TOTAL WEIGHTING:	__________

Version: 25-May-2017

Appendix J: Curriculum Vitae

Maxwell Edward Perelgut, BMSc

MESc Candidate, Biomedical Engineering Science, Western University

EDUCATION

Master of Engineering Science, *Biomedical Engineering* 2017–Present
University of Western Ontario, London, Ontario
Specialization: Musculoskeletal Health Research
Thesis: Assessing the Impact of Collared versus Collarless Stems on Implant Migration, Patient Activity and Patient Function Following Total Hip Arthroplasty: A Randomized Clinical Trial.

Bachelor of Medical Science, *Hon. Spec. Medical Biophysics* 2013–2017
University of Western Ontario, London, Ontario
Concentration: Medical Science
Thesis: An accurate anatomical model of the human cochlea internal structures using medical images.

RESEARCH EXPERIENCE

Research Assistant - Biomedical Engineering 2017–Present
Western University, London, Canada - Under the supervision of Dr. Matthew Teeter
- Conducting a randomized clinical trial comparing total hip arthroplasty surgical approaches and implant designs and correlating joint motion to hip implant performance.

Undergraduate Honors Thesis - Medical Biophysics 2016–2017
Western University, London, Canada - Under the supervision of Dr. Hanif Ladak
- Created an anatomical model of the human cochlea's internal structures using medical images to aid in cochlear implant surgery.

Undergraduate Research Project - Medical Biophysics 2015–2016
Western University, London, Canada - Under the supervision of Dr. Abbas Samani
- Measured thoracic tumor motion during external beam radiation therapy (EBRT) using chest motion data to improve radiation therapy.

Research Coordinator 2014
Benchmarksix, Toronto, Canada - Under the supervision of Dr. Mohan Srivastava
- Conducted a comprehensive data analysis of global temperature anomalies to determine the accuracy of current global warming models.

PUBLICATIONS

1. Heaaven, S., **Perelgut, M.E.**, Vasarhelyi, E.M., Howard, J.L., Teeter, M.G., Lanting, B.L. "Fully Hydroxyapatite-Coated Collared Femoral Stems in Direct Anterior vs. Direct Lateral Hip Arthroplasty.". *Submitted to Hip International*, 2019.

CONFERENCE ABSTRACTS AND PRESENTATIONS

Presentations

1. **Perelgut, M.E.**, Vasarhelyi, E.M., Lanting, B.L., Teeter, M.G. "Determining the Impact Hip Femoral Stem Design has on Subsidence and Patient Activity for Patients Undergoing Primary Uni-

lateral Total Hip Arthroplasty". *Podium Presentation at the International Combined Orthopaedic Research Societies - Top Canadian Research*, 2019.

2. Teeter, M.G., **Perelgut, M.E.**, Yuan, X., Vasarhelyi, E.M., Lanting, B.L. "Total Hip Arthroplasty Surgical Approach and Implant Design: Effects on Patient Function, Patient Activity, and Implant Migration". *Podium Presentation at the International RSA Meeting*, 2019.

Posters

1. **Perelgut, M.E.**, Vasarhelyi, E.M., Lanting, B.L., Teeter, M.G. "Total Hip Arthroplasty Surgical Approach and Implant Design: Effects on Patient Function, Patient Activity, and Implant Migration". *Poster Presentation at the Imaging Network of Ontario Symposium*, 2019.
2. **Perelgut, M.E.**, Vasarhelyi, E.M., Lanting, B.L., Teeter, M.G. "How are Patient Function, Activity, and Implant Migration Impacted by Total Hip Arthroplasty Surgical Approach and Implant Design?". *Poster Presentation at the London Health Research Day*, 2019.
3. Heaven, S., **Perelgut, M.E.**, Howard, J.L., Vasarhelyi, E.M., Teeter, M.G., Lanting, B.L. "Fully Hydroxyapatite-coated Collared Femoral Stems in Direct Anterior vs. Direct Lateral Hip Arthroplasty a 5 year retrospective review". *Submitted to the Canadian Orthopaedic Association Annual Scientific Meeting*, 2019.
4. **Perelgut, M.E.**, Bloomfield, R.A., Vasarhelyi, E.M., Lanting, B.L., Teeter, M.G. "Determining the Effectiveness of Using Wearable Sensors to Measure the Functional Status of Total Hip Arthroplasty Patients". *Poster Presentation at the Canadian Bone and Joint Conference*, 2018.
5. **Perelgut, M.E.**, Vasarhelyi, E.M., Lanting, B.L., Teeter, M.G. "New Metrics to Determine the Functional Status of Total Hip Arthroplasty Patients". *Poster Presentation at the Department of Surgery Research Day*, 2018.
6. **Perelgut, M.E.**, Bloomfield, R.A., Vasarhelyi, E.M., Lanting, B.L., Teeter, M.G. "Total Hip Arthroplasty Surgical Approach and Implant Design: Effects on Patient Function and Implant Migration". *Poster Presentation at the Robarts Research Retreat*, 2018.

TEACHING ASSISTANTSHIPS

Programming Fundamentals for Engineers, *ES 1036* — Fall 2018
Western University, London, Canada.

Programming Fundamentals for Engineers, *ES 1036* — Winter 2018
Western University, London, Canada.
- Received 7 nominations for GSTA Award of Excellence.

WORKSHOPS ATTENDED

The following are workshops presented by the Ivey International Centre for Health Innovation in collaboration with the Collaborative Program in Musculoskeletal Health Research.

- Future of Healthcare, *Dr. Khayat* — November 2018
- Introduction to Decision Analytics, *Dr. Cirpriano* — October 2018
- Capacity planning in healthcare: Historical approaches and future directions, *Dr. Myer* — March 2018
- Small & Medium Enterprises- Builing the Case for Commercialization & Venture Capital Investment, *Dr. Khayat* — September 2017

AWARDS

Western Graduate Research Scholarship, 2018–2019	$4,500
Canadian Musculoskeletal Health Research Stipend 2018–2019	$600
Western Graduate Research Scholarship, 2017–2018	$4,500
Canadian Musculoskeletal Health Research Stipend 2017–2018	$600
Deans Honour List, University of Western Ontario, 2016–2017	
Scholarship of Excellence, 2013	$2,000