7-21-2016 12:00 AM

Inpatient versus Outpatient Total Hip Arthroplasty

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Graduate Program in Kinesiology
A thesis submitted in partial fulfillment of the requirements for the degree in Master of Science

Abstract

We conducted a randomized controlled trial to evaluate patients undergoing a total hip arthroplasty (THA) who were discharged from the hospital either on the day of surgery (outpatient) or were admitted overnight following surgery (inpatient). Our primary outcome was the rate of serious adverse events during the first three months postoperatively. Secondary outcome measures included cost, patient satisfaction, functional outcomes, quality of life and pain. We found no statistically significant difference between the two groups in serious adverse events. We found that outpatient THA was less expensive from the perspectives of the hospital and ministry of health; but the difference in cost was balanced by a relatively equivalent increase in indirect expenditures paid by society. No other statistically significant differences were found between groups. Based on the results from this preliminary analysis of a larger ongoing study, outpatient THA is safe and can contribute to significant cost savings.

Keywords

Total hip arthroplasty, THA, outpatient, inpatient, direct anterior, cost, patient satisfaction

Co-Authorship Statement

This study was designed in collaboration with Dr. Dianne Bryant and Dr. Brent Lanting. I was responsible for writing the application for ethics approval and for registering the trial with clinicaltrials.gov. I worked with Dr. Bryant and the staff at Empower Health Research Inc. to create the study database including logic and edit checks. It was my responsibility to screen patients, recruit eligible patients and conduct followup visits for participating patients. For this thesis, I wrote the original draft of the manuscript. Dr. Bryant, Dr. Jackie Marsh and Dr. Lanting provided me with suggestions and comments to improve the final thesis submission.

Acknowledgments

I would like to thank my co-supervisors, Dr. Dianne Bryant and Dr. Brent Lanting, for all of their help and support throughout my graduate studies at Western University. I sincerely want to thank them for this amazing opportunity over the last two years. There are a number of other people I would like to thank for their assistance and support:

- All the staff in the outpatient orthopaedic clinic for always being available to help and for their good company in clinic.
- Sandra Wimperis for her continual assistance and accommodation throughout my studies.
- My fellow graduate students for their support. Special thanks to Bryn for her help with data collection.
- The staff at the pre-admission clinic for their assistance with our study.
- Dr. Jackie Marsh, Dr. Lyndsay Somerville and all of the staff in the Kirkley Center for their expertise, support and company.
- The orthopaedic surgery residents and fellows for their expertise and assistance with our study.
- My friends and family for their continual support throughout my two years in graduate school.

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List of Abbreviations

THA	Total Hip Arthroplasty
LOS	Length of Stay
OA	Osteoarthritis
MoH	Ministry of Health
LFCN	Lateral Femoral Cutaneous Nerve
AIIS	Anterior Inferior Iliac Spine
ASIS	Anterior Superior Iliac Spine
TFL	Tensor Fascia Latae

Chapter 1

1 Introduction

Total hip arthroplasty (THA) is an established and proven procedure used to treat patients with advanced arthritis of the hip. Considered one of the most successful surgeries in orthopaedics, studies have demonstrated a greater than 90% implant survival rate at 15-20 years post-surgery[1,2]. For this reason and the increasing aging population, the demand for THAs is growing rapidly. However, healthcare budgets are finite[3], and thus we must find a more cost effective manner to offer this treatment while maintaining patient safety.

A significant portion of the cost associated with THA is attributed to overnight admission[4,5]; so much so that a number of surgical centers have started performing THAs on an outpatient basis[3,5-15]. To improve the chances of successful outpatient THA, clinicians have implemented changes to analgesia, the timing of physiotherapy, and applied advanced surgical techniques[5,16]. Changes to surgical techniques includes reducing muscle damage and careful hemostasis[16,17], which leads to minimal soft tissue damage. This in turn should reduce pain, enable early mobilization and faster return to normal gait following surgery[16,17].

Another common theme within the literature is that appropriate patient selection is essential to ensure safe and successful outpatient THA[5,18]. Patients with pre-existing comorbidities that put them at greater risk of adverse events during the immediate postoperative period should not be included[18]. However, healthy patients with willing caregivers have a greater chance of successful discharge on the same day of surgery following a hip replacement[16,18].

The primary concern with performing outpatient THAs is patient safety. An evaluation of the serious adverse events that require re-admission to hospital or additional surgical intervention during the first few postoperative days; possibly extending to the first three months postoperative, can determine the safety of an outpatient THA pathway. With the

constraint on healthcare resources, developing a successful outpatient THA pathway opens up the potential for substantial cost savings from the perspective of the Ministry of Health, the institution, and society.

Chapter 2

2 Literature Review

This review focuses on four main areas of the literature: anatomy of the hip, osteoarthritis (OA), total hip arthroplasty (THA), and outpatient THA. The first section pertaining to anatomy focuses on the muscles, ligaments and nerves most frequently affected by surgical procedures. The second section will discuss OA, including symptoms, causes, diagnoses, treatments and the economic burden in Canada. The third section will discuss total hip arthroplasty; a surgical treatment for late-stage hip OA. Specifically, we will outline the history, the advantages and disadvantages of the direct anterior (DA) approach, the cost of THA and the potential cost savings associated with decreasing the length of stay (LOS) in the hospital following the procedure. Finally, we will review the literature pertaining to same day discharge (outpatient) following THA and summarize the complication rates, clinical outcomes, economic analyses, and variability within the literature.

2.1 Anatomy of the Hip

The hip is a ball-and-socket synovial joint that is formed by the head of the femur and the acetabulum of the pelvis. The hip is a multiaxial joint that is capable of multiple movements and a large range of motion, including flexion, extension, abduction, adduction, lateral and medial rotation, and circumduction[19].

The acetabulum consists of three bony components: the ilium, ischium and pubic bones[19]. It is a cup-shaped fossa on the lateral aspect of the pelvis. A fibrocartilage labrum is attached to the edges of the acetabulum, which provides a deeper fossa and a more secure articulation between the acetabulum and the head of the femur. This deepening of the fossa improves the stability of the joint by holding the femoral head more securely and preventing easy dislocation of the hip[19].

The transverse acetabular ligament bridges the acetabular notch and joins the ends of the acetabular labrum, forming a complete ring[19]. Beneath this ligament is the acetabular foramen. The transverse acetabular ligament helps deepen and constrict the acetabulum to prevent inferior movement of the femoral head[19].

Both the acetabulum and the femoral head are coated with hyaline cartilage, which provides a smooth surface for movement of the joint. The exception is over a central depression of the femoral head called the fovea[19]. This depression serves as an attachment point for the only intracapsular ligament of the head of the femur (ligamentum teres). The artery of the ligament of head of femur runs with the ligamentum teres through the acetabular foramen to supply the femoral head[19,20].

Surrounding the hip joint is a strong joint capsule. The capsule is attached proximally at the labrum and the edge of the acetabular notch, and distally at the intertrochanteric line and the neck of the femur[19].

Reinforcing the capsular ligament are three extracapsular ligaments: iliofemoral ligament, pubofemoral ligament, ischiofemoral ligament[20,21]. Anteriorly, the strong Y-shaped iliofemoral ligament runs across the front of the hip joint, joining the anterior inferior iliac spine (AIIS) and acetabulum proximally to the intertrochanteric line of the femur distally. The iliofemoral ligament is the strongest ligament in the body and contributes to maintaining posture and limiting joint hyperextension[20].

The pubofemoral ligament reinforces the inferior and anterior surfaces of the joint. It prevents excessive abduction and extension of the joint[19].

The thinnest of the three ligaments is the ischiofemoral ligament, which is situated on the posterior surface of the joint capsule[21]. It originates at the ischium of the pelvis and inserts on the greater trochanter of the femur. The ischiofemoral ligament restricts hyperextension of the femur at the hip joint[21].

Innervation to the hip joint comes from several nerves that pass nearby. The femoral nerve (L2 to L4) innervates the anterior portion of the hip joint[22]. The nerve to the quadratus femoris (L4 to S1) innervates the posterior side of the hip joint. Finally, small branches of the sciatic nerve (L4 to S3), obturator nerve (L2 to L4) and superior gluteal nerve (L4 to S1) provide innervation to the hip joint[22].

The medial and lateral circumflex femoral arteries, and the artery to the ligamentum teres provide vascular supply to the hip joint[23]. The medial circumflex femoral artery provides the majority of the arterial supply. Damage to this artery can result in avascular necrosis of the femoral head[19].

There are a number of muscles that help move and support the joint. These include muscles on the anterior thigh, medial thigh, posterior thigh and gluteal region[19].

The anterior compartment of the thigh is composed of the sartorius and quadriceps femoris[19]. The sartorius originates at the ASIS and crosses obliquely to insert on the medial aspect of the tibia in a three-pronged tendinous structure called the pes anserinus[20]. The function of the sartorius is to abduct, medially rotate and flex the thigh[19]. The femoris is comprised of four muscles, with the rectus femoris being the only muscle that crosses the hip joint. The direct head of the rectus femoris originates at the anterior inferior iliac spine (AIIS) and the indirect head originates at the hip capsule. These two heads of the muscle insert at the base of the patella[19,20]. The rectus femoris crosses both the hip and knee joint, thus it helps with both hip flexion and knee extension. The femoral nerve innervates both the sartorius and rectus femoris[19].

The muscles of the medial compartment of the thigh are pectineus, adductor longus, adductor brevis, adductor magnus, gracilis and obturator externus[19]. These muscles originate from the pubic rami and runs along the posterior shaft of the femur. With the exception of obturator externus (lateral rotator), these muscles are the adductors of the thigh[19]. The obturator nerve is the primary nerve that innervates the medial compartment of the thigh[19].

Two other muscles of the hip are related to the anteromedial thigh: The tensor fascia latae (TFL) and the iliopsoas[19]. The TFL originates on the crest of the iliac wing as well as at the ASIS, and inserts on the iliotibila tract that attaches to the lateral condyle of the tibia[20,24]. It acts to abduct, medially rotate and flex the thigh, while also helping to stabilize the trunk on the thigh. The superior gluteal nerve (L4-L5) innervates the TFL[19,24].

The iliopsoas is formed from the union of the iliacus and psoas muscles[19]. This muscle originates on the iliac fossa and lower spine in the posterior abdominal wall and enters the anteromedial thigh beneath the inguinal ligament to insert onto the lesser trochanter of the femur. The iliopsoas is the main flexor of the thigh at the hip joint and helps stabilize the hip. The anterior rami of lumbar nerves (L1 to L3) innervates the iliopsoas[19].

The lateral femoral cutaneous nerve (LFCN) innervates the skin on the lateral aspect of the thigh[20,25,26]. This nerve is part of the lumbar plexus that arises from the dorsal aspect of the second and third lumbar nerves. The LFCN emerges from the middle of the psoas muscle and crosses the iliacus obliquely towards the ASIS[25,26]. It then passes underneath the inguinal ligament and over the sartorius muscle, where it divides into an anterior and posterior branch[25,26]. The anterior branch is distributed to the anterior and lateral parts of the thigh. The posterior branch supplies the posterior aspect of the thigh, from the greater trochanter to the middle of the thigh[25,26].

The gluteal region consists of three large gluteal muscles and the deeper group of smaller muscles. The large muscles include the gluteus maximum, gluteus medius and gluteus minimus[19]. These muscles work to extend and abduct the thigh at the hip joint. The deeper group is comprised of five muscles: piriformis, gemellus superior, obturator internus, gemellus inferior, and quadratus femoris[19]. The deep muscles originate on the lateral pelvis and insert on the greater trochanter of the femur. Their action is to externally rotate the thigh at the hip joint and abduct the thigh when the limb is flexed. Branches of the sacral plexus of nerves innervate the muscles of the gluteal region. The superior (L4 to S1) and inferior (L5 to S2) gluteal nerves innervate the gluteal muscles[19].

Three other branches of the sacral plexus innervate the deeper muscles: the nerve to piriformis (S1, S2), nerve to obturator internus (L5 to S2), and nerve to quadratus femoris (L4 to S1)[19].

The superior and inferior gemelli combine with the obturator internus to form the conjoint tendon[27]. The tendons of these muscles join before inserting into the medial aspect of the greater trochanter.

The posterior thigh is compromised of three hamstring muscles that originate from the ischial tuberosity of the pelvis and insert onto the proximal tibia or fibula[19]. This group consists of the semitendinosus, semimembranosus and biceps femoris. These muscles are two-joint muscles, which act to extend the hip and flex the leg. The sciatic nerve (L5 to S2) innervates the posterior thigh muscles[19].

2.2 Osteoarthritis

Osteoarthritis (OA) is a degenerative joint disease that leads to the breakdown of articular cartilage and the underlying bone[28-30]. This disease can result in pain, stiffness and loss of function[28-30]. OA is commonly seen in weight-bearing joints, such as the knee and hip[28-31]. As OA progresses, there is usually visible asymmetric joint space narrowing on radiographic imaging, as well as sclerosis, bone cysts and the breaking down of bone and development of abnormal bony growths called osteophytes[30]. OA is the most prevalent type of arthritis, affecting more than 10% (approximately 4.6 million) of Canadians[28,29,31]. By 2036, this number is expected to grow to an estimated 7.5 million Canadians[28,29,32].

2.2.1 Symptoms of OA

The symptoms of OA vary depending on the severity of the disease and which joint is affected. However, common symptoms include pain, stiffness and limited range of motion[28]. These symptoms can severely affect quality of life[28]. In weight-bearing joints, OA commonly results in impaired mobility. These symptoms can cause patients to live a

sedentary life, which can then lead to secondary complications such as obesity and heart disease. This inactivity can also cause muscle weakness and impaired balance[31].

2.2.2 Causes of OA

OA is commonly subdivided into either primary OA or secondary OA[33]. Primary OA refers to a disease that is idiopathic in nature with multiple risk factors, such as obesity, age, sex and genetics. Secondary OA is considered a systemic or localized disease, caused by risk factors such as previous joint injury, Paget's disease, or developmental deformities[33]. It is not always possible to attribute a specific classification to an individual with OA since recent literature suggests that certain cases of OA previously considered primary are caused by minor developmental deformities[34,35].

In obese patients, excess weight puts additional stress on weight-bearing joints, which can be a predisposing factor for OA[28,36]. Furthermore, being overweight or obese can affect your metabolism, also a suggested contributing factor for OA[28,36]. Individuals of any age can develop OA, but the prevalence of OA increases with age[28,32]. Fifty-eight percent of the individuals with OA are greater than 65 years of age[32]. Sex may be a contributing risk factor to OA, as two out of three Canadians affected by arthritis are women[32]. Previous joint injuries can damage the tissue of the joint[28]. These injuries can contribute to muscular deconditioning, leading to increased joint loads and development and progression of OA[37]. Finally, genetics can contribute to the development of OA, as those with a family history of OA have an increased risk of developing the disease[33].

2.2.3 Treatment for OA

OA is a progressive disease that tends to get worse over time[28]. Currently, there is no cure for OA[28,38]. However, there are treatments available to manage symptoms. These therapies have two main objectives: to relieve pain and to preserve function[28,33,38]. It is recommended that patients with early-stage OA treat their disease with nonoperative treatments, such as exercise, maintaining a healthy lifestyle and using pain and anti-

inflammatory medications[28,33,38]. Patients with more severe OA generally require operative treatment, such as joint replacement[28].

2.2.4 Economic Burden of OA in Canada

In addition to the physical burden, OA poses a large economic burden on the Canadian economy. Health-care costs and lost productivity associated with OA is estimated to be close to $30 billion each year[29]. Projections expect the economic burden to double to $67 billion by 2031. Although OA is considered a condition that afflicts older adults, 12% of workers in Canada currently have OA, and within a generation, it's estimated that this number will grow to almost 30% of workers.

Costs associated with OA are generally divided into direct costs (i.e. costs of visits to health professionals, of procedures, and of investigative tests) and indirect costs (i.e. time lost for paid work by patient or caregiver)[39]. In 2004, Maetzel et al.[39] calculated that the average total 6 month cost per patient with OA in Canada is $2856, with $1976 (69.2%) associated with direct costs and $880 (30.8%) associated with indirect costs.

The rise in the aging population in Canada, coupled by the rising rates of obesity will have significant consequences on the future of the Canadian health care system[29]. If administered effectively, total joint replacements (TJR) can lead to significant cumulative savings in both direct and indirect health care costs[29]. Patients undergoing a TJR can expect a significant reduction in pain and improvement in quality of life, allowing many to return to their regular daily activities. Studies have estimated that TJRs can result in $1.5 billion cumulative savings over the next 10 years, and $14.3 billion saved over 30 years[29].

In 2009, Hawker et al.[40] conducted a population-based economic analysis to assess the changes in direct health care costs, as well as pain and disability in patients who underwent a primary TJR compared to matched controls who did not receive a TJR. This study found that patients that underwent a TJR experienced reductions in pain and disability (WOMAC post-pre $p < 0.0001$), as well as arthritis-attributable health care

costs ($p < 0.0001$)[40]. The matched controls illustrated worsening of their general health and their health care costs remained stable or increased ($p = 0.80$)[40].

2.2.5 OA of the Hip

Hip OA is typically associated with hip pain that develops gradually and worsens with weight-bearing activities[33]. During a physical exam, patients with hip OA generally indicate pain in the groin area or buttocks and sometimes on the inside of the knee or thigh[33]. The American College of Rheumatology has recommended that to diagnosis OA of the hip, patients must present with hip pain and at least two of the following: erythrocyte sedimentation rate of <20 mm/hr, radiographic femoral or acetabular osteophyte formation, and radiographic joint-space narrowing[33,41]. Radiographic evidence of hip OA is present in about 5% of the population over the age of 65 years[33]. Late-stage OA of the hip is often characterized by both structural damage and patient reported pain, stiffness and loss of function[30]. Total hip arthroplasty (THA) is recommended for patients that demonstrate radiographic evidence of joint damage in conjunction with persistent pain or disability[42].

2.3 Total Hip Arthroplasty

In the 1960's, Sir John Charnley pioneered modern THA[43-45], which revolutionized the treatment of advanced arthritis of the hip, by improving range of motion, stability and quality of life[44,45]. Common diagnoses that are treated by THA include: osteoarthritis, rheumatoid arthritis, acute hip fractures, developmental dysplasia, osteonecrosis, and post-traumatic arthritis[46].

THA is considered one of the most successful orthopaedic surgeries[42,45]. The demand for THA is growing rapidly due to the proven success and increase in the aging population. In Canada, there has been a 5-year increase of 19.1% (49,503 in 2013-2014 versus 41,473 in 2009-2010), and a 1-year increase of 5%[46].

In 2013-2014, age-standardized hospitalization rates for patients undergoing THA, aged 20 and older was 139 per 100,000[46]. There was a marked difference between males and females, as males had an age-standardized rate of 127, while the females rate was 148[46].

Even with the proven success of THA, there is always an inherent risk with any surgical procedures. Since 2009-2010, 1.6% primary hip replacements were revised within the first year, 2.0% were revised within two years and 2.4% were revised within 3 years[46]. Although the risk for revision is low, the risk increases over time. The Canadian Joint Replacement Registry in 2015 reported that the most common reason for revisions were aseptic loosening (23.9%), infections (17.9%), instability (12.6%), bearing wear (8.9%), periprosthetic fracture (6.5%) and others (14.7%)[46].

2.3.1 Cost of THA

Although proven to be an effective treatment in reducing pain and functional limitations, there are concerns over the large share of health care resources and high costs associated with THA[47]. Several researchers have attempted to evaluate methods to reduce costs without compromising patient safety and functional outcomes[48].

For example, in 2004, Antoniuou et al.[49] investigated three different public teaching hospitals with 940 Canadian patients undergoing a THA and found that the average total cost per procedure was $6766 ± $119; which included both direct and overhead costs. The mean total cost for THA was significantly cheaper in Canada compared to the United States ($6766 versus $13,339; $p < 0.0001$). A large contributor to the increase in cost in American centers is the cost of the implant, which is approximately $8017 in the United States and $1695 in Canada[49].

Martineua and colleagues[50] found that total costs associated with THA are greater in low-volume (< 300 THA/year) compared to high-volume (> or = 300 THA/year) Canadian hospitals. They reported figures in US dollars and concluded that high volume versus low volume overhead costs were $1380 ± 35 versus $2432 ± 49, direct costs were $3023 ± 93 versus $4952 ± 91, and total costs were $4403 ± 117 versus $7385 ± 38, respectively[50].

Most of the disparity was the cost of the implant, as high volume centers tend to have controlled unit costs per implant. This study concluded that for optimal cost containment, THAs should be predominately performed in high-volume centers[50]. Further predictors for increase in cost associated with THA are cerebrovascular disease (39.4% increase in cost; $p < 0.002$), female sex (7% increase in cost; $p < 0.01$) and existing complications (12.5% increase in cost; $p < 0.04$)[50].

2.3.2 Length of Stay

A significant portion of the cost of THA comprises the LOS in hospital[4]. Similar to the risk factors associated with increase in cost, predictors for increase in LOS comprise of low-volume center (9.9% increase in LOS; $p < 0.008$), cerebrovascular disease (45.8% increase in LOS; $p < 0.0007$), female sex (9.5% increase in LOS; $p < 0.002$) and complications (24.8% increase in LOS; $p < 0.0002$)[50]. Although the cost of a THA is less in Canada compared to the United States, Antoniuou et al.[49] found that between 1999 and 2001 Canadian patients spent more time in the hospital compared to American patients (7.2 versus 4.2 days; $p < 0.0001$).

In Canada, the median LOS in 2013-2014 was four days for both male and female hip replacement recipients[46]. Although there has been a recent push towards decreasing the LOS following hip replacements, the median LOS for both sexes has not changed over the last year[46]; which is perhaps attributable to raised concerns that reducing LOS will lead to suboptimal outcomes for other postoperative measures, such as increases in readmission and revision rates[48,51]. However, Vorhies and colleagues[48] retrospectively assessed 1802 THA patients and concluded that there was no association between decreasing LOS and increasing hospital readmissions. This finding was in agreement with several other publications[3,52,53].

To further contain the cost of THA, some have suggested that changes to clinical pathways, like accelerated perioperative care and rehabilitation interventions, may be cost-effective from the perspective of the patient, society and the Ministry of Health[54,55].

Specifically, in 2009, Larsen and colleagues[55] found that the cost of their accelerated program (education preoperatively and intensive mobilization postoperatively) was approximately US $4000 less than their standard of care group (surgical information on day of admission and gradual mobilization according to patient's tolerance), with an additional gain of 0.05 QALY. Similarly, Brunenberg and colleagues[54] reported that costs were lower (US $1261 per patient) and functional improvement was greater ($p < 0.001$) when patients were fast-tracked by receiving a preassessment screening and preoperative arrangements for home care compared to the standard of care whereby patients were not screened and arrangement for care was addressed postoperative.

At our institution, the current length of stay for patients post THA is 2-3 days. This relatively short LOS is potentiated by effective blood conservation leading to lower transfusion rates, periarticular injections to help manage pain, improved patient education, and early, aggressive physiotherapy on the day of surgery.

2.3.3 Direct Anterior Approach

Originated by Dr. Judet in 1947, the DA hip replacement became a novel approach to facilitate exposure to the hip joint during an arthroplasty[56,57]. Originally, this approach required the removal of the anterior TFL from the iliac crest and the release of the piriformis[56-58]. However, the DA approach has been refined by Dr. Matta in 1996 to allow exposure of both the head of the femur and the acetabulum through a single incision intermuscular approach, that in about half of patients does not require a release of any muscles or tendons[58,59]. This approach allows for consistent component positioning and leg length resoration[58].

2.3.3.1 Surgical Technique

The following DA surgical technique for THA is used at the University Hospital, London Health Sciences Centre. This approach is performed using a modified Heuter approach[60].

All DA surgeries are performed using a general anesthetic. The procedure begins by positioning the patient supine on a specialized operative traction table (Hana fracture

table; Mizuho OSI, Union City, California)[59]. The incision is made 2-4 cm lateral to the ASIS (Figure 1). This incision is carried for 8-12 cm at 20 degrees from the sagittal plane toward the lateral aspect of the ipsilateral knee[59]. Next, the LFCN is transposed medially and protected and a plane is developed between the TFL and the sartorius. A hip retractor is used to displace the rectus femoris medially and the gluteus medius laterally to expose the anterior hip capsule[59].

Once gentle traction is applied to the operative limb, a Muller retractor is used to perform a capsulotomy to expose the femoral neck. A saw is used to make a femoral neck osteotomy, and then a corkscrew removes the femoral head[58,59].

Traction is released and the acetabulum is reamed to bleeding bone and appropriate depth and diameter. The acetabular component is inserted with the use of an offset inserter handle to minimize soft tissue trauma. Intraoperative fluoroscopy confirms and optimizes the component position[59]. Once the final acetabular component is inserted, the operative limb is carefully extended, adducted and externally rotated to facilitate accessibility to the femur[58]. A bone hook elevates the proximal femur anteriorly. If the femur cannot be sufficiently elevated, the conjoint tendon +/- piriformis is released to optimize exposure[59].

A double offset femoral broach handle permits easier access to the proximal femur during preparation. After trialing using fluoroscopy to assess leg lengths and offset as well as ensure appropriate stem size and alignment, the stem is then implanted into the femoral canal and the final head is impacted onto the stem[59]. Once the final implants are in place, the hip is reduced and fluoroscopy is used to ensure appropriate the implant positioning and the leg lengths. The wound is sutured closed and sterile dressing is applied[59].

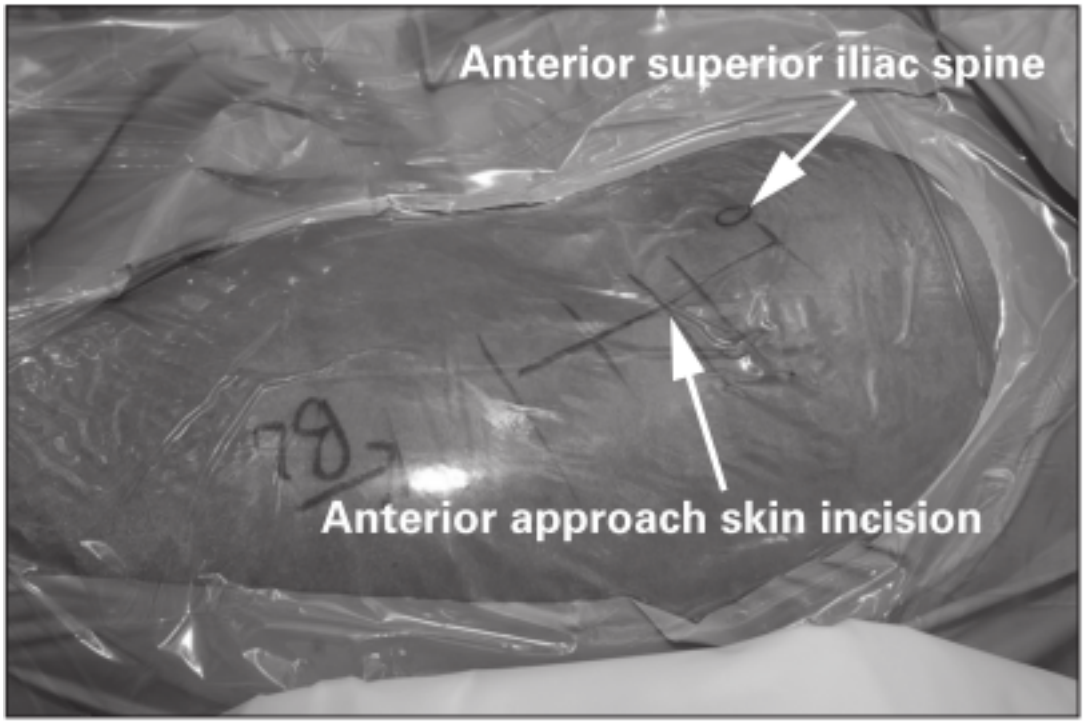

Figure 1: Location of skin incision for the direct anterior total hip arthroplasty surgical approach

Reproduced with permission from: Petis et al. Surgical approach in primary total hip arthroplasty: anatomy, technique and clinical outcomes, Canadian Journal of Surgery, Vol. 58(2), pp. 128-139, 2015[59].

2.3.3.2 Advantages and Disadvantages of the DA Approach

From a clinical perspective, the DA approach provides several advantages to the traditional posterolateral or lateral approaches. The posterolateral approach is associated with a high dislocation rate and requires the division of the posterior capsule and external rotators[58,61]. The lateral approach has demonstrated a lower dislocation rate, but requires the detachment of the gluteus medius and minimus and is associated with abductor dysfunction post-operatively[58,62]. The DA approach is an internervous approach to the hip that avoids the dissection of muscles or tendons from bone, leaves the posterior capsule intact, restores gait kinematics earlier, and results in a low dislocation rate[25,26,58,59,63,64].

Postoperative dislocation rates following a THA occur in between 0.4% and 12% of patients[58,64,65]. However, Matta et al.[58] performed 494 THA done through the DA approach and noted an overall dislocation rate of 0.61%, which is in accordance with a dislocation rate of 0.96% reported by Siguier and colleague[64].

Conversely, the DA approach is associated with an increase in complications associated with the lateral femoral cutaneous nerve (LFCN), which can cause reduced sensation to the anterolateral thigh[66]. Bhargava and colleagues[25] noted that LFCN impairment occurred in 12/81 patients (14.8%) undergoing a DA THA, however permanent impairment occurred in only 2/81 (<3%) and the majority of these cases resolved by one year post-surgery. Goulding et al.[26] reported a significantly higher incidence of LFCN impairment in patients undergoing a DA THA (37/55, 67%). However, it did not lead to functional limitations compared to asymptomatic patients[26]. In addition, we have found that patients with an elevated body mass index (BMI) (>40 kg/m^2) are at a greater risk of wound complications associated with the anterior approach and are advised to undergo other approaches, such as lateral or posterior[59].

Finally, most surgeons using the DA approach prefer to use a specialized operating table (Figure 2) and intraoperative fluoroscopy[66] to improve component positioning and ensure leg lengths are more accurate[58,67]. While the specialized orthopaedic table allows for rotational control of the femur and facilitates femoral exposure with minimal muscle trauma, the additional intraoperative fluoroscopy helps lower the dislocation rate by optimizing both the acetabular and femoral component positioning[58,59]. Other surgical approaches do not use specialized tables or intraoperative fluoroscopy. These factors can be costly and hinder the technique's generalizability across hospitals[25,63,66].

From a cost savings perspective, several studies have suggested that the DA approach reduces LOS and promotes earlier functional recovery following surgery[59,66,68,69]. At our institution, Petis et al.[66] conducted an economic analysis of differing surgical approaches and found that the mean hospital LOS was significantly shorter with the DA approach (33.9 hours; 95% CI; 29.6-38.2) vs. lateral (64.2 hours; 95% CI, 56.7-71.7; $p < 0.001$)

and DA vs. posterior approach (65.8 hours; 95% CI, 56.7-74.8; $p < 0.001$). This reduced LOS resulted in a significantly reduced cost compared to other surgical approaches. The overall costs (in 2013 Canadian dollars), including intraoperative costs and hospital stay, were significantly less for the DA approach ($7300.22; 95% confidence interval [CI], 7064.49-7535.95) vs. lateral ($7853.10; 95% CI, 7577.29-8128.91; $p = .031$) or posterior approach ($8287.46; 95% CI, 7906.42-8668.51; $p < 0.001$)[66].

Interestingly, when costs are compartmentalized, intraoperative cost of operating room time (2013 Canadian dollars) was significantly more expensive for the DA approach (1729.90; 95% CI, 1668.14-1791.66) vs. lateral (1435.24; 95% CI, 1336.83-1533.65; $p < 0.001$) or posterior approach (1629.92; 95% CI, 1532.29-1727.55; $p < 0.001$)[66]. Similarly, total cost of procedure was significantly more expensive for the DA approach ($5799.79; 95% CI, 5718.52-5881.06) vs. lateral ($5274.39; 95% CI, 5158.55-5390.24; $p < 0.001$) vs. posterior approach ($5274.39; 95% CI, 5158.55-5390.24; $p < 0.001$)[66].

Even with the additional operative costs, including the specialized table that has a 5-year longevity[66] ($120 000 in 2013 Canadian dollars) and intraoperative fluoroscopy, the DA approach leads to a reduced overall cost. Patients undergoing a DA hip replacement can be discharged earlier from the hospital due to reduced postoperative pain, earlier functional recovery and quicker restoration of normalized gait[66,69]. From the perspective of the hospital, the significant reduction in LOS translates into significant cost savings[66].

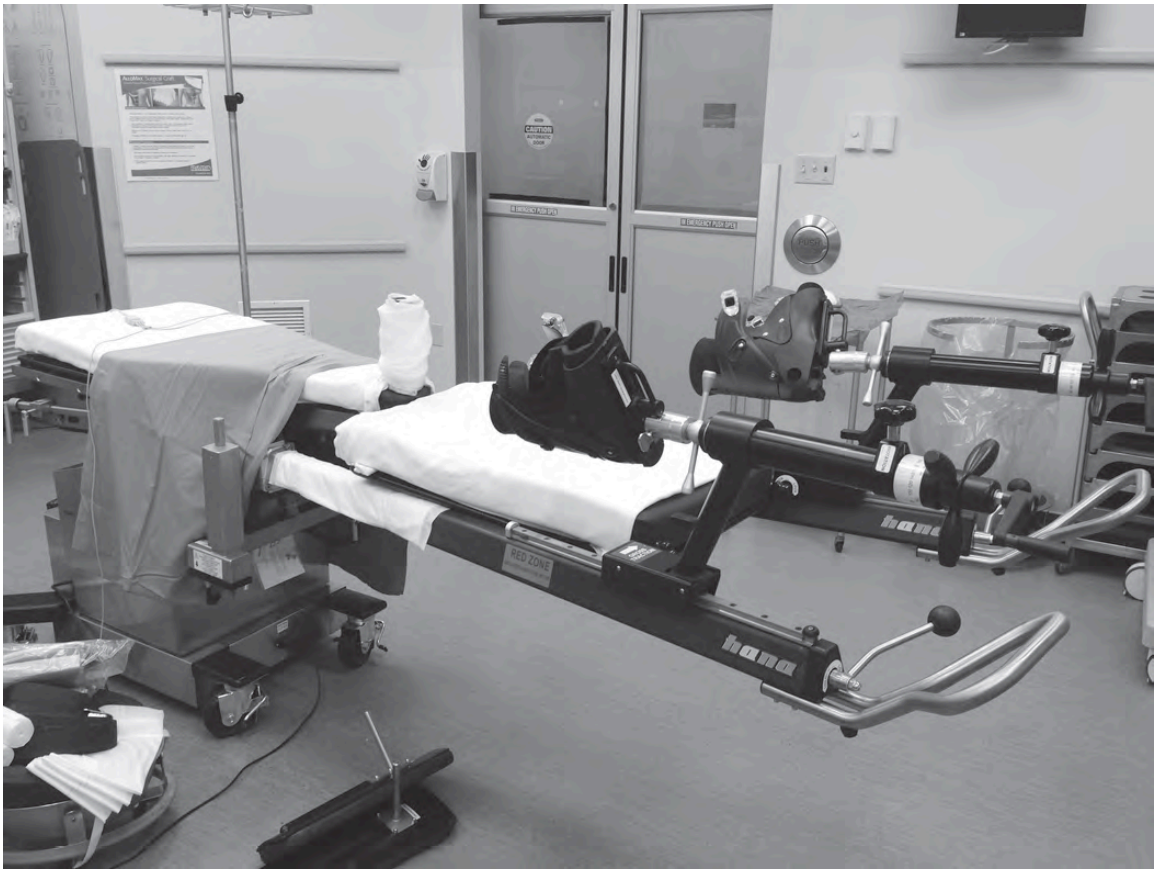

Figure 2: Specialized operative traction table (Hana fracture table, Mizuho OSI) used during a direct anterior total hip arthroplasty

Reproduced with permission from: Petis et al. Surgical approach in primary total hip arthroplasty: anatomy, technique and clinical outcomes, Canadian Journal of Surgery, Vol. 58(2), pp. 128-139, 2015[59].

2.4 Outpatient versus Inpatient THA

We conducted a systematic review of the literature to determine the safety and feasibility of outpatient joint replacement surgery (Figure 3)[16]. The majority of studies included within our systematic review reported complication, revision and readmission rates[16]. In the literature, there is a clear distinction between acute complications either intraoperative or immediately postoperative and the long-term complications that occur outside the

hospital. In general, the case series investigating the safety and feasibility of outpatient joint replacements reported low complication rates ranging from 0/160 (0%)[70] to 38/150 (25.3%)[14] during the acute phase, and 0/100 (0%)[8] to 8/86 (9.4)[71] for long-term complications. Lovald et al.[72] outlined that the majority of adverse events suffered by patients undergoing outpatient joint replacement surgery are accidental falls, urinary retention, infection, deep vein thrombosis, joint pain, joint stiffness and wound complications.

More importantly, the comparison studies did not show a higher complication rate for outpatient procedures compared to inpatient procedures. As readmission rates are increasingly used as a performance indicator, there is concern that outpatient surgery may increase readmission rates. However, Lovald et al.[72] illustrated that in a Medicare sample from 1997-2009, readmissions were similar between outpatient TKA ($n = 454$) and standard 3-4 day stay TKA ($n = 71,341$) at 90 days ($p = 0.13$), 1 year ($p = 0.10$) and 2 years ($p = 0.75$) post surgery. Similarly, in both comparison studies investigating outpatient THAs[3,10], no difference was found in complication rates between the inpatient and outpatient groups.

Study	Year	Type of Study	Control Group	Experimental Group	Mean Duration of Follow-up	Outcomes	Conclusion
THA studies							
Non-comparative observational studies							
Berger[6]	2003	Consecutive case series	NA	Outpatient THA (n = 100)	1 yr	Readmissions, radiographic findings, complications, component placement	2-incision technique is safe and facilitates a rapid patient recovery
Berger et al.[8]	2004	Consecutive case series	NA	Outpatient THA (n = 100)	3 mo	Readmissions, complications, HHS, SF-12 score, radiographic findings, return to activities (driving, work, walking independently, walking one-half mile)	Rapid rehabilitation protocol is safe and fulfills the potential benefits of a rapid recovery
Berger et al.[14]	2009	Consecutive case series	NA	Outpatient THA (n = 150)	3 mo	HHS, satisfaction, complications, readmissions	Outpatient THA can be safely performed in select patients
Berry et al.[9]	2003	Consecutive case series	NA	Outpatient THA (n = 200)	1 yr	Complications, revisions, readmissions	Outpatient THA can be safely performed in select patients
Chen and Berger[12]	2013	Consecutive case series	NA	Outpatient THA (n = 86)	3 mo	Readmissions, complications	Outpatient THA can be safely performed in select patients
Dorr et al.[13]	2010	Consecutive case series	NA	Outpatient THA (n = 53)	6 mo	Complications, readmissions, satisfaction, pain scores, functional data, HHS	Outpatient THA can be safely performed in select patients
Mears et al.[15]	2009	Consecutive case series (therapeutic)	NA	Outpatient THA (295)	3 mo	Readmissions, complications	Outpatient THA can be safely performed in select patients
Comparative studies							
Aynardi et al.[3]	2014	Therapeutic study (case-control)	Inpatient THA (n = 78)	Outpatient THA (n = 119)	1 yr	Length of stay, final cost (USD), complications, readmissions	Outpatient THA can be safely performed in select patients

Bertin[10]	2005	Prospective economic analysis (cohort study)	Inpatient THA (n = 10)	Outpatient THA (n = 10)	1 yr	Cost, complications	Outpatient THA is financially advantageous
TKA and UKA studies							
Non-comparative observational studies							
Berger et al.[73]	2006	Consecutive case series	NA	Outpatient TKA (n = 50)	3 mo	Complications, readmission, range of motion	Outpatient TKA can be safely performed in select patients
Berger et al.[71]	2009	Consecutive case series	NA	Outpatient TKA (n = 86) and outpatient UKA (n = 25)	3 mo	Readmissions, complications	Outpatient TKA and UKA are feasible in large percentage of patients
Cross and Berger[74]	2014	Retrospective case series	NA	Outpatient UKA (n = 105)	3 mo	Complications, readmissions	Large cohort of unselected patients had successful outpatient UKA
Dervin et al.[75]	2012	Consecutive case series	NA	Outpatient UKA (n = 24)	6 mo	Adverse events, pain scores, medication diaries, range of motion, WOMAC, KOOS	Continuous femoral nerve block can be used in select patients to assist outpatient UKA
Gondusky et al.[70]	2014	Consecutive case series	NA	Outpatient UKA (n = 160)	1 yr	Complications, extension, flexion, KSCRS functional score, KSCRS knee score, KSCRS total score	Outpatient UKA can be safely performed in select patients
Lovald et al.[76]	2014	Retrospective case series	NA	Outpatient or short-stay TKA (n = 5,401)	1 yr	Mortality, readmission, revision, complications, accidental falls, pain and stiffness	Outpatient TKA can be safely performed in select patients
Comparative studies							
Kolisek et al.[77]	2009	Prognostic study (cohort study)	Inpatient TKA (n = 64)	Outpatient TKA (n = 64)	2 yr	Length of stay, readmission, adverse events, Knee Society knee score, Knee Society function score, range of motion, satisfaction	Outpatient TKA can be safely performed in select patients
Lovald et al.[72]	2014	Retrospective cohort	3 to 4-day TKA (n = 71,341)	Outpatient TKA (n = 454)	2 yr	Cost, mortality, readmission, revision, postoperative complications	Outpatient TKA can be safely performed in select patients

*NA = not applicable

Figure 3: Articles Included in Systematic Review

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2.4.1 Optimal Patient Selection

For successful outpatient THA surgery, a number of studies conclude that careful patient selection is necessary (e.g., restrictions on age, BMI and severity of comorbidities). Six studies[10,15,71,72,74,76] included in our systematic review recruited an unselected population, where all patients undergoing a joint replacement were included. These were largely feasibility studies[10,15,71,74] or studies retrospectively examining the Medicare database[72,76]. The purpose of these studies was not to suggest that outpatient joint replacements are appropriate for all patients, but rather to identify factors associated with a longer hospital stay. Both Mears et al.[15] and Bozic et al.[78] identified four factors: 1) female sex ($p < 0.001$), 2) increasing age ($p < 0.001$), 3) increasing blood loss ($p < 0.001$) and 4) an ASA classification of 3 or 4 ($p < 0.01$). Supplementary literature investigating fast-track pathways following THA have identified additional risk factors that are associated with prolonged hospital stay: existing comorbidities, preoperative use of walking aids, obesity, longer incision length, and longer operative time[4,48,52,53,79].

2.4.2 Clinical Outcomes

Three case series reported on clinical outcomes following outpatient hip replacements[8,14,80]. Dewelius et al.[80] discharged 90 patients within twenty-four hours of surgery and reported that Harris Hip scores improved from 52 points preoperatively to 90 points at one year postoperatively, which is similar to improvements reported following inpatient care[81,82]. Two similar studies by Berger and colleagues[8,14] reported similar improvements for patients undergoing outpatient THA. Specifically, in their first case series, Berger et al.[8] recruited 100 consecutive patients, with 97 patients meeting the criteria for same day discharge. Mean Harris Hip scores improved from 56 points (range,

32-77) preoperatively to 91 points (range, 61-100) at 3 weeks ($p < 0.001$), 94 points (range, 79-100) at 6 weeks ($p < 0.001$), and 96 points (range, 74-100 points) at 3 months postoperatively ($p < 0.001$)[8]. In a second case series, Berger et al.[14] discharged 150 patients on the same day of surgery following a hip replacement and reported that mean Harris Hip scores improved from 51 points preoperatively (range, 32-74) to 91 points (range, 56-100) at 6 weeks ($p < 0.01$) and 95 points (range 62-100) at 3 months postoperatively ($p < 0.01$).

Two studies evaluated satisfaction post outpatient THA[13,14]. Berger et al.[14] assessed satisfaction at 2-weeks postoperatively by asking the question, "would you be discharged home the same day following the same clinical pathway again?"[14]. Of the 150 patients included, 144 patients were satisfied, while 5 patients were dissatisfied due to postoperative nausea, and one patient was dissatisfied due to postoperative pain[14]. Dorr et al.[13] administered a 6-item questionnaire at the patient's 6-week follow up visit of 53 patients. Of the 52 patients that completed the questionnaire, 96% would have same day surgery again, 19% reported that postoperative pain was a problem, 87% claimed that outpatient THA gave them more confidence and accelerated their recovery, and 94% of patients would recommend same day surgery to others.

In contrast to previously reported publications[77,83], Lovald et al.[72] found that in certain instances there were less favourable outcomes for the shorter stay groups following TKA. The authors attributed this finding to sites that implemented outpatient protocols before their clinical teams were ready; recommending that institutions should gradually reduce the length of stay until the clinical staff is comfortable performing joint replacements in an outpatient setting[71,72].

2.4.3 Economic Benefits

One of the benefits of the movement towards outpatient joint replacements is the potential for considerable cost savings. Two economic analyses concluded that there is a marked decrease in costs associated with outpatient THA compared to inpatient THA[3,10].

Aynardi et al.[3] illustrated that the overall cost in the outpatient setting was significantly lower than inpatient, $24,529 versus $31,327 ($p = 0.0001$). Bertin[10] found that the total average charge for the outpatient group, including preoperative, intraoperative and postoperative charges, was approximately $2500 less than for the inpatients.

2.4.4 Limitations of the Current Literature

We found that surgical techniques vary across outpatient THA literature[16]. For studies that specifically defined their surgical technique, there was one study that used direct anterior Smith-Peterson[3], four studies that used two-incision[6,8,9,14], one study that used posterolateral[10], one study that used antereolateral Watson-Jones[12], and one study that used posterior MIS[13]. Differences in operation time, blood loss, and type of anaesthesia exist depending on the technique used. These differences could account for differing perioperative care and cause expertise bias. Further, according to the Cochrane Risk of Bias Assessment Tool for Non-Randomized Studies of Interventions (ACROBAT-NRSI)[84], the quality of the studies included in our systematic review was poor (Figures 4 and 5).

Study	Evidence of Selection Bias/Prognostic Imbalance	Bias Due to Confounding Factors?	Was Assessment of Outcomes Precisely Measured or Unbiased?	Was Follow-up of Participants Sufficiently Complete?	Bias Due to Selection of Reported Results or Due to Missing Data?	Comparability of Cohorts on Important Confounding Factors
Aynardi et al.[3]	High risk	High risk	Moderate risk	Low risk	Low risk	High risk
Bertin[10]	Moderate risk	High risk	Moderate risk	Low risk	Low risk	Low risk
Kolisek et al.[77]	High risk	High risk	Low risk	Low risk	Moderate risk	Moderate risk
Lovald et al.[72]	Low risk	Moderate risk	Low risk	Low risk	Low risk	Moderate risk

Figure 4: Risk-of-Bias Assessment of Comparative Studies in Systematic Review

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Study	Evidence of Selection Bias/Prognostic Imbalance	Study Design	Bias Due to Confounding Factors?	Was Assessment of Outcomes Precisely Measured or Unbiased?	Was Follow-up of Participants Sufficiently Complete?	Was There Blinding of the Outcome Assessor and Study Participants?
Berger[6]	Weak	Weak	Moderate	Moderate	Strong	Weak
Berger et al.[8]	Weak	Weak	Moderate	Strong	Strong	Weak
Berger et al.[73]	Weak	Weak	Moderate	Strong	Strong	Weak
Berger et al.[14]	Weak	Weak	Weak	Moderate	Strong	Weak
Berger et al.[71]	Moderate	Weak	Moderate	Strong	Strong	Weak
Berry et al.[9]	Weak	Weak	Weak	Strong	Strong	Weak
Chen and Berger[12]	Weak	Weak	Weak	Moderate	Strong	Weak
Cross and Berger[74]	Moderate	Weak	Moderate	Strong	Strong	Weak
Dervin et al.[75]	Weak	Weak	Weak	Strong	Strong	Weak
Dorr et al.[13]	Weak	Weak	Weak	Strong	Moderate	Weak
Gondusky et al.[70]	Weak	Weak	Weak	Strong	Strong	Weak
Lovald et al.[76]	Strong	Weak	Moderate	Strong	Strong	Weak
Mears et al.[15]	Strong	Weak	Strong	Weak	Strong	Weak

Figure 5: Quality Assessment of Non-Comparative Observational Studies in the Systematic Review

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Finally, our systematic review found evidence of gender inequality in the current outpatient joint replacement literature[16]. The majority of studies in the systematic review had more males than females in the outpatient cohorts. However, as of 2013-2014 in Canada, patients undergoing arthroplasties were more frequently female than male for both hips (58.4%) and knees (60.2%)[46]. The under-representation of females in outpatient studies could be related to gender differences in patient characteristics, ability to manipulate gait aids, societal roles in terms of caregiving, or a potential underlying gender bias by the surgeon toward males in their preliminary outpatient trials.

2.5 Summary

The disease burden of hip OA continues to increase rapidly. For late-stage hip OA, THA is a proven and effective treatment to relieve pain, restore function and improve quality of life. However, it is imperative to develop pathways to ensure the health care system operates efficiently. The literature demonstrates that one of the most costly aspects of hip replacements is the length of hospital stay following the procedure. There are a limited number of published studies that have evaluated a fast-track pathway and demonstrated that a reduction in LOS leads to significant cost savings. A less invasive surgical approach and selection of the optimal patient may allow for safe outpatient THA.

Two studies have compared outpatient THA to an inpatient cohort[3,10]. Both of these studies were prospective cohort studies that included a cost analysis. In both instances, outpatient THA was safely performed on appropriately selected patients at a substantial cost savings. However, the sample sizes were small and neither study randomized their patient populations.

Reducing the cost of healthcare improves access to services for both patients and healthcare centers. In addition to the potential cost savings, in certain physician-owned centers in the United States there is an increased payment gained by the physician when joint replacements are performed on an outpatient basis. Thus, these centers are motivated to perform THA as an outpatient procedure. Therefore, it is timely to perform a

randomized trial with high methodological rigor to determine whether outpatient THA is safe and financially advantageous.

Chapter 3

3 Objectives

Our primary research objective was to compare the rate of serious adverse events during the first three months postoperative following a total hip arthroplasty (THA) using either the inpatient or outpatient model of care. We defined serious adverse events based on U.S. Food and Drug Administration (FDA) criteria as any event when the patient outcome is death, life-threatening, hospitalization (initial or prolonged), and disability or permanent damage[85].

Our secondary objectives were to compare inpatient and outpatient THA using the following outcomes: cost; patient satisfaction; functional outcomes; quality of life; pain; and the extent of assistance provided by the caregiver.

We tested the hypothesis that the rate of serious adverse events in patients following an outpatient care pathway would not be different to the rate in patients following an inpatient care pathway during the first three months post-THA. We also hypothesized that there would be a significant cost savings associated with outpatient care but no other differences between the two care pathways for patient satisfaction, functional outcomes, quality of life, pain or caregiver assistance.

Chapter 4

4 Materials and Methods

4.1 Study Design

This was a single-centre randomized controlled trial (RCT) that took place in London, Ontario. The study involved patients undergoing a primary total hip arthroplasty through the direct anterior (DA) surgical approach. Study participants were randomly allocated to be discharge on the day of surgery (outpatient) or admitted to the hospital overnight following surgery (inpatient). Patients consented to study participation at their initial consultation, which took place up to six months prior to surgery. Baseline assessments were performed at the patients' pre-admission clinic visit, which took place within one month prior to surgery. Follow-up assessments occurred according to the standard postoperative visit schedule at our centre for this surgery. This study was approved by the University of Western Ontario Health Sciences Research Ethics Board and took place at the London Health Sciences Centre (LHSC), University Hospital between June 2015 and June 2016.

4.2 Eligibility Criteria

Patients were eligible for this study if they were undergoing a primary unilateral total hip arthroplasty using the DA approach. Patients were ineligible for participation if they lived further than a 60 minute drive from the institution, had an ASA score greater than 3, significant pain management issues, a history of anesthesia related complications, obesity that significantly impacted their ability to mobilize, pannus that limits adequate wound exposure for healing, anaphylaxis to penicillin, significant psycho / social issues that prevented the patient from managing safely at home, or cognitive issues that precluded the ability to understand instructions or to give informed consent. Patients were also ineligible if they lacked an appropriate social network to provide them with assistance during the immediate postoperative period. There were no formal age restrictions, but it

was up to the participating surgeon's discretion whether the patient was deemed medically fit for same day discharge.

4.3 Treatments

Patients undergoing a primary DA THA were discharged either on day 0 (outpatient) or were admitted to the hospital overnight (inpatient). For the participating surgeon, both treatments were standard of care. Perioperative care protocols and the frequency of follow-up visits were identical between groups. All patients were required to meet the hospital standard discharge criteria before being sent home following surgery. To meet the discharge criteria, a patient must be capable of using the required gait aid, have appropriate pain control, an absence of nausea and vomiting, be free of excess bleeding, be alert and oriented, meet the appropriate targets from physiotherapy for discharge, have possession of take-home medications, and be in the company of a caregiver.

4.4 Methods to Reduce Bias

4.4.1 Randomization

Patients were approached about study participation at their initial consultation after the investigating surgeon deemed the patient eligible for outpatient care. Once consented, the patient was randomized to one of two groups (outpatient or inpatient), using a computer generated 1:1 randomization scheme, in permuted blocks of two or four, with stratification by previous joint replacement (either contralateral THA, ipsilateral TKA or contralateral TKA).

4.4.2 Blinding

We blinded patients to the fact that they were part of a randomized trial. To maintain the blind, we asked all participating health care staff (surgeons, nurses, physiotherapists, residents, fellows etc.) to withhold from the patient that their discharge pathway was randomly assigned for the purpose of this study. It is our opinion that knowledge of randomization would threaten the feasibility and validity of this study. Although patients

were blinded to the randomization, they were told an approximate discharge date prior to surgery to ensure they received the necessary pre-operative education and had made the appropriate plans with caregivers. Because patients were assessed on the day of discharge, the research assistant was not blind to group allocation. However, since the outcomes measures were patient-reported and the research assistant used standardized instructions while interacting with patients, we were not concerned with observer bias.

4.4.3 Modified Zelen Design

The ethical justification for a Zelen study design[86] is that both study groups received standard of care and thus, patients were not put at increased risk through randomization. The original single non-consent design described by Zelen[86] does not complete the consent process for patients who are randomized to a standard of care intervention.

In this study, there were two modifications to the Zelen design. The first was to ask patients to consent to participation in a study where every aspect of the study is fully described with the exception of the randomization or the between-groups objectives. The second modification was to conduct a debriefing session with the patient upon completion of the study protocol. At three months post-surgery, patients were fully informed about their random allocation to inpatient or outpatient surgery and why this study design was felt appropriate. Afterwards, we asked patients for their consent to use their data in the between-group comparisons.

We felt that the Zelen design was necessary to reduce bias introduced by the patient or caregiver's preference for one discharge pathway over the other. From the costing perspective, a patient sent home the same day, who is aware that others remain in-hospital may be more likely to return to hospital through the emergency department, even though it is extremely rare for urgent complications to occur within the first two weeks following THA. This is a costly decision from the institution's perspective. In contrast, we know anecdotally that patients who stay overnight in hospital postoperative who fit our eligibility criteria could have managed at home and might have been more comfortable had they been discharged as an outpatient.

Furthermore, this study design is imperative to ensure validity in patient-reported outcomes like satisfaction, functional ability and quality of life. If patients randomized to inpatient THA knew that other patients were discharged the same day, they could feel dissatisfied simply because they feel that going home would have been the preferred option. Alternatively, patients allocated to the inpatient group may feel more satisfied if they felt they had better care, greater access to the surgeon or better pain control while in-hospital. On the other hand, if patients in the outpatient group knew that other patients remained as inpatients, they may feel more satisfied knowing that they were able to go home and recover with greater privacy in the comforts of their own home in the company of their family/friends while other patients remained in a ward room.

4.4.4 Intention to Treat

Patients were not randomized until the surgeon deemed the patient eligible for participation. At the patient's pre-admission appointment, both the nursing staff and physiotherapist met with the patient to further assess their eligibility.

If a patient randomized to the outpatient protocol requested to stay longer in the hospital or did not meet the discharge criteria for outpatient care such as severe comorbidities or inadequate caregiver assistance, then the patient followed the inpatient protocol. Moreover, if a patient randomized to the inpatient protocol was adamant on being discharged from the hospital on the same day of surgery, then the patient followed the outpatient protocol. As per the intention to treat principle, we analyzed all patients according to the group to which they were randomly allocated regardless of whether their discharge pathway was adhered to following surgery.

4.4.5 Standardization of Intervention

Both treatment groups were considered standard-of-care for the participating surgeon. In both groups, each patient received the same postoperative mobility and care instructions from a physiotherapist and education from a nurse but the timing of these interventions was focused during the preoperative appointment for those randomized to outpatient care

and postoperative for those randomized to inpatient care. During the physiotherapy consult, all patients underwent a mobility assessment, and were instructed on crutch walking and exercises required for successful recovery post-surgery.

4.5 Outcome Measures

Once patients consented to participate in the study, the study coordinator registered the patients into the secure web-based data management system (EmPower Health Research, Inc, www.empowerhealthresearch.ca). Patients had the option of either logging into the online system to directly access their questionnaires or to receive hard copies of the questionnaires at each appointment. We measured all patients preoperatively at the preadmission appointment (within one month prior to surgery), on the day of discharge from hospital, and at two weeks, six weeks and three months post-operative.

4.5.1 Primary Outcome Measure

The primary outcome was any serious adverse event within the first three months postoperative. We adopted the Food and Drug Administration's (FDA) definition of serious adverse, which includes re-admission to hospital, additional surgical intervention, disability or permanent damages, life threatening adverse event, or death[85]. Events of interest include deep infection, deep vein thrombosis, dislocation, periprosthetic fracture, pulmonary embolism, myocardial infarction, urinary retention, and death.

4.5.2 Secondary Outcome Measures

Secondary outcome measures included cost, patient satisfaction, expectations, patient-reported disease-specific health-related quality of life (HRQOL), functional outcomes, general health and extent of caregiver assistance.

4.5.2.1 Hospital Cost

We recorded all surgical procedure related costs, as well as total length of stay in the hospital. This queried details of the patient's care pathway following surgery, including

the time spent in PACU, day surgery (for outpatient group) and the orthopaedic inpatient unit (for inpatient group).

4.5.2.1.1 Patient Costs

We asked patients to keep a daily diary to record any costs they incurred related to their hip for the first two weeks following discharge from the hospital. This included any medication use, assistance from others, the amount of time from paid employment their caregivers required to provide care, any additional costs associated with the hip replacement, and daily pain scores.

4.5.2.1.2 Healthcare Resource Use

Patients recorded any healthcare use regarding their hip replacement at each of their follow up visits post-surgery. The cost form consisted of 14 patient-reported domains: emergency room visits and hospitalization, family doctor visits, specialist visits and outpatient clinics, health care professional visits, tests, procedures and surgeries, prescription medications, over-the-counter medications, employment status and time-off work from paid employment, caregiver employment status and time-off from paid employment, change in employment status, homemaking and volunteer activities, assistance from others, assistance living, and any other miscellaneous costs.

4.5.2.1.3 Sources of Cost Data

We obtained the unit cost for all hospital related resources from LHSC's case costing department. The cost of the physician, specialist, clinic, laboratory tests and medical procedures were collected from the Ontario Ministry of Health Schedule of Benefits and we obtained the cost of drugs from the Ontario Drug Benefit Formulary. For patients less than 65 years of age, patients self-reported any prescription drug costs.

We standardized the operating room costs for each surgery. This includes implants and additional surgical equipment. We included the costs specific to a direct anterior including the specialized table, lead aprons and intra-operative fluoroscopy. The

fluoroscopy was monetized on a per-minute basis and included both the direct and indirect costs of the technician and use of the machine.

We used the average Canadian wage reported by Statistics Canada to account for time off of paid employment for both patients and their caregiver. The current value of minimum wage in Ontario accounted for lost time for patients or caregivers who were retired, or those who lost time from volunteer or home making activities.

4.5.2.2 Patient Satisfaction

Published opinions regarding the measurement of patient satisfaction suggest that greater validity comes with questions that inquire about satisfaction with a specific component of the experience rather than the experience in general[87-89]. However, there are no reliable or validated questionnaires regarding satisfaction following THA. Therefore, we constructed a questionnaire consisting of 20 questions pertaining to satisfaction with pain control, safety, quality of care and privacy. Each question was either rated on a 100-mm visual analogue scale (VAS) or on a five-seven point ordinal scale (completely satisfied to completely unsatisfied). Patients were only asked to fill out this questionnaire at their two week follow-up visit, as the questions were geared towards assessing the patient's satisfaction with their care pre-operatively, and immediately post-operatively.

Additionally, patients were asked to report their satisfaction with the entire experience at each of their postoperative visits. Specifically, we asked five questions querying satisfaction with pain while sitting and lying down, hip function when getting out of bed, performing light household duties and leisure activities. Each question included five ordinal response options (very satisfied, satisfied, neutral, dissatisfied, very dissatisfied).

4.5.2.3 Expectations

Expectations were assessed pre- and post-operatively. Before surgery, patients were asked the degree of pain relief and functional ability expected following the surgery (a lot, somewhat, a little, no expectation). Post-operatively, patients were asked whether

they felt their preoperative expectations with respect to pain control and function were too high, met, or too low.

4.5.2.4 Euro-QoL

To measure utility, we used the European Quality of Life Scale (Euro-QoL). The Euro-QoL comprises of two sections, the EQ-5D index and the EQ-5D visual analogue scale (VAS). The EQ-5D index is a self-administered five-item generic measure of HRQOL that includes domains of mobility, self-care, usual activities, pain and discomfort and anxiety and depression. Each item is scored using a five-point response scale and can be converted to a utility value from 0 (worst) to 1.0 (best) using a scoring formula. The EQ-5D VAS is a 0 (worst) to 100 (best) scale that assesses patient-perceived health status. The results from the EQ-5D can be used for economic evaluation to measure utility and calculate each patient's quality-adjusted life year (QALY). In patients undergoing hip replacements, the Euro-QoL has been shown to be valid and reliable[90].

4.5.2.5 Western Ontario McMaster Osteoarthritis Index

The WOMAC is a 24-item self-administered questionnaire that measures symptoms and physical disability for people with osteoarthritis that consists of three sections; pain, stiffness and daily activities. Each question is rated on a five-point ordinal scale, ranging from zero (none) to four (extreme). There are five questions regarding pain, two related to stiffness, and 17 related to physical function. The maximum score for the pain, stiffness, and physical function domains are 20 points, eight and 68 where a higher score indicates better outcome. A global score can be computed by summing the scores for the three subscales[91].

This outcome measure has been tested and found to be valid, reliable and sensitive for detecting important health changes post-surgery[91]. The WOMAC demonstrates convergent construct validity with numerous impairment and disability measures (ex. Harris Hip Score and Short Form-36)[91]. Regarding responsiveness, there was a large effect size calculated for all three subscales (1.7-2.58, 1.0-2.17 and 1.8-2.9,

respectively)[91]. Online data collection is similar to traditional paper methods and each method can be used interchangeably without a significant effect on criterion validity[92].

4.5.2.6 Harris Hip Score

The Harris hip score (HHS) is a valid and reliable measure administered by the surgeon to study the clinical outcomes of hip replacements. There are ten items that cover the domains of pain, function, absence of deformity and range of motion. It is a disease-specific test that gives a maximum total score of 100, with the higher scores indicating better results. Previous reports have indicated that a total score below 70 points represents a poor result[93].

Reports have illustrated that the HHS has high convergent validity with both the WOMAC and 36-Item Short-Form Health Survey. The HHS has excellent test re-test reliability (ICC=0.94) and inter-observer reliability (ICC=0.74-1.00)[94].

4.5.2.7 Short Form-12

The Short Form 12 (SF-12) is a patient-reported measure that is used to measure health-related quality of life. It consists of a 12-question health survey monitoring outcomes following surgery. Each question is rated on a three-to-five point ordinal scale with separate scores for physical and mental function. Higher scores indicate better health and function.

Reliability of the SF-12 is good for both the physical (ICC=0.84) and mental (ICC=0.80) sections. For patients undergoing THA, the minimal detectable change is 12.18 for the physical section, and 14.14 for the mental section[95]. Similar to WOMAC, electric versions of SF-12 are comparable to paper versions when administered to joint arthroplasty patients[92].

4.5.2.8 Visual Analog Scale

The Visual Analog Scale is a self-administered pain assessment. Patients indicate their pain on a ten-centimetre continuous scale that ranges from zero to ten, where zero

represents no pain, and ten represents the worst pain imaginable. At discharge from the hospital, patients mark their average pain since their surgery. At every other visit, patients mark their average pain over the past week.

Test-retest reliability for this scale has been shown to be excellent (r = 0.94,)[96]. In terms of construct validity, the VAS is highly correlated to verbal descriptive scales and numeric rating scales, with correlations ranging from 0.71-078 and 0.62-0.91, respectively[96].

4.5.2.9 Pain Catastrophizing Scale

The Pain Catastrophizing Scale (PCS) is a 13-item patient-reported instrument used to assess patient's level of catastrophic thinking. Each question is rated on a five-point ordinal scale, spanning from zero (not at all) to four (all the time). The PCS is comprised of three subscales that assess rumination, magnification and helplessness. Either the score can be computed for each subscale separately, or a total score encompassing the whole PCS. Patients were asked to complete this questionnaire at their pre-admission visit. It has shown adequate to excellent internal consistency for the total PCS (0.87), rumination (0.87), magnification (0.66), and helplessness (0.78)[97].

4.5.2.10 Self-Efficacy for Managing Chronic Disease

The Self-Efficacy for Managing Chronic Disease questionnaire is a patient-reported questionnaire assessing how confident patients are in doing certain activities. This is a six-item instrument, each comprising of a ten-point ordinal scale, ranging from one (not at all confident) to ten (totally confident). Higher numbers indicate greater self-efficacy. The score for the scale is the mean of the six items. The self-efficacy questionnaire was administered at the patient's pre-admission visit. Internal consistency reliability is excellent (0.91)[98].

4.5.2.11 Caregiver Assistance Scale

Caregiver assistance was measured using the Caregiver Assistance Scale (CAS)[99]. The CAS is comprised of 17 questions assessing the degree of assistance provided by the caregiver for a variety of tasks throughout the recovery period. The scale ranges from zero (no assistance provided) to six (a lot of assistance provided). We also collected demographic information for each caregiver to evaluate whether the caregiver's responses are influenced by their sex, gender role or their relationship with the patient.

4.5.2.12 Patient Characteristics and Surgical Details

We collected demographic data, including date of birth, gender, BMI, smoking status, comorbidities, and working status to evaluate the between-group similarities. We also recorded anaesthesia time, surgical time, and blood loss for each procedure. Furthermore, we asked patients to record any calls made by them or their caregiver to the surgeon's office, on-call resident or orthopaedic outpatient clinic. Finally, we asked patients to report when they discontinued the use gait aids.

4.6 Sample Size

Based on the investigating surgeon's current practice loads, we estimated that 140 patients would be eligible during the study period. As the risk of serious adverse event following THA is low, it is not feasible to recruit a sufficient sample size to detect a difference in event rates during the study period. Therefore, we did not conduct a formal sample size calculation; rather we conducted this study using a convenience sample of 140 patients.

4.7 Data Analysis

We used SPSS version 23.0 to perform the analysis. We used descriptive statistics to present the demographic characteristics of the patients in each treatment group using means and standard deviations for continuous variables (age, BMI) and proportions for nominal variables (sex, operative hip, previous THA, dominant side).

For the primary outcome of early serious adverse events, we first determined the absolute risk of adverse events in each group. We then calculated the relative risk (RR) with 95% confidence intervals around the estimate.

We used an ANCOVA test for all outcome measures with a baseline measurement (EQ-5D, WOMAC, SF-12, HHS, Pain NRS) to determine whether there was a statistically significant difference between groups. The independent variable was the group (inpatient or outpatient), the dependent variable was the outcome measure score and the covariates were baseline measurements.

Graphically, we presented a plot of each outcome measure over time with each group as a separate line and included 95% confidence intervals. Time zero represented baseline measurements.

We presented the mean and standard deviation for all continuous data (Satisfaction, EQ-5D, WOMAC, SF-12, HHS, Pain NRS, Pain Catastrophizing, Self-Efficacy and CAS) for each group at each time point and then calculated mean between-group differences with 95% confidence intervals around the estimate. All tests were two-sided with $p \leq 0.05$ indicating statistical significance.

We tested the assumptions for ANCOVA, which are normality, homogeneity of variance, random independent samples, and the relationship between the dependent variable and covariate is linear. To test for normality, we plotted a histogram of each outcome and assessed the results for skewness and kurtosis. If the assumption of normality was not met, we performed a Mann-Whitney U non-parametric test to establish the robustness of our results.

4.7.1 Cost Effectiveness Analysis

We conducted a cost-effectiveness analysis from three perspectives: 1) public health care payer (Ontario Ministry of Health), 2) the hospital, and 3) society. The health care payer perspective included any direct health costs covered by our publicly funded system. This

includes hospital, procedure related, surgeon, clinician and other health-care provider time, test procedures or surgeries, and medications for patients on disability or aged 65 years and older. In addition to these costs, the societal perspective includes any out-of-pocket costs to the patient (such as physical therapy, medication, or assistive devices not covered by the provincial insurance plan), as well as any indirect costs such as time involved with appointments, time off of employment for patients or caregivers, as well as time off from homemaking or caregiving activities as a result of the intervention.

We calculated the incremental cost-effectiveness ratio (ICER), with early postoperative complications as the effectiveness measure. The ICER represents the ratio of incremental cost (mean difference in cost between the two groups) to incremental effects (mean difference in serious adverse event rate between the two groups). This ratio provides an estimate of the additional cost per complication avoided.

We conducted a sensitivity analysis to examine the degree of uncertainty in our cost analysis. Specifically, we assigned patient's average daily income as both the patient reported household income per 8-hour workday and as minimum wage ($11.25 per hour, $90 per 8 hour work day). Furthermore, we assigned minimum wage to caregiver time off of work. Finally, we assigned $0 to days off of homemaking activities instead of minimum wage.

4.7.2 Missing Data

For missing end point data we used the last outcome carried forward, and for missing midpoint data we used the mean of the group for that time point.

Chapter 5

5 Results

5.1 Patient Flow

Figure 6 outlines the flow of participants through each stage of the study. From June 2015 to May 2016, 172 patients were screened for eligibility, 67 were ineligible, eight declined to participate and two eligible patients were enrolled in another study and therefore excluded.

At the time of analysis, 43 patients had fully completed the study protocol to three-months post-operative. One patient in the inpatient group withdrew from the study following surgery because of an unwillingness to complete the study's forms. A second patient in the inpatient group was withdrawn from the study after suffering a periprosthetic intraoperative fracture that led to an extended hospital stay.

Four patients received the intervention assigned to the other group (contamination). Specifically, two patients in the inpatient group requested same day discharge and two patients in the outpatient group required additional monitoring and the physiotherapists recommended they be admitted overnight. These patients are analyzed according to the intention-to-treat principle.

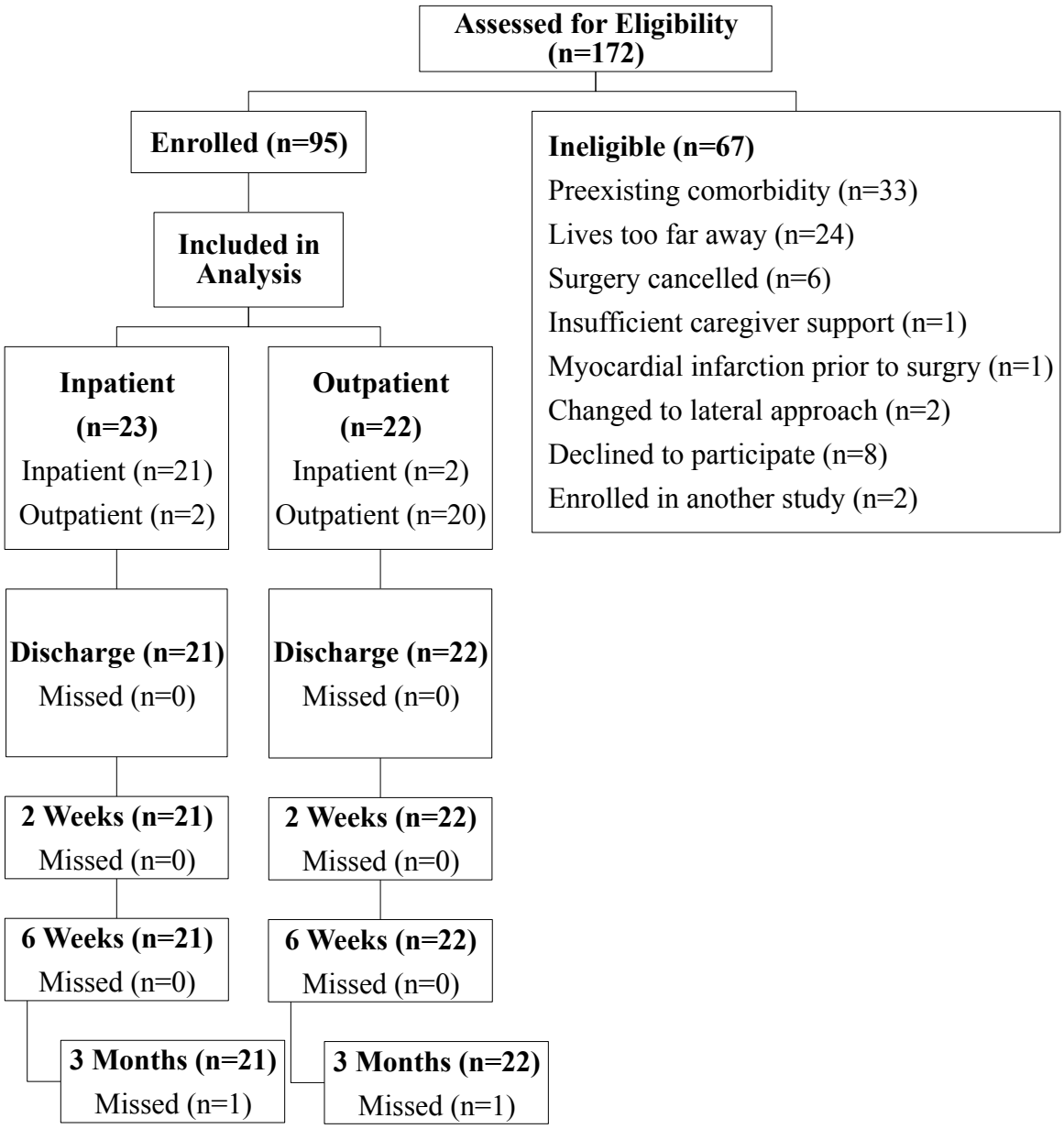

Figure 6: Participant flow through the study

*The first 43 patients to complete follow-up were included in this analysis, including the four crossover patients

5.2 Demographic Information

Preoperative demographic characteristics and comorbidities were similar between the two groups (Table 1).

Table 1: Baseline demographics for inpatient and outpatient total hip arthroplasty

Characteristic	Inpatient (n=21)	Outpatient (n=22)
Sex, n (%) Male	12 (57)	12 (55)
Mean Age ± SD, y (min-max)	62.1 ± 8.5 (45-79)	60.2 ± 9.1 (37-75)
Mean BMI ± SD, kg/m^2 (min-max)	27.6 ± 5.9 (18-39)	26.5 ± 4.8 (16-37)
Operative Hip, n (%) Right	9 (43)	12 (55)
Symptoms in Other Hip, n (%)	5 (24)	8 (36)
Dominant Side, n (%) Right	18 (86)	17 (77)
Employment Status, n (%)		
Currently Working	10 (48)	13 (59)
Unemployed	2 (9)	1 (5)
Retired	9 (43)	8 (36)
Previous Joint Replacement, n (%)	4 (19)	7 (32)
ASA Status, n (%)		
1	3 (16)	4 (18)
2	11 (52)	14 (64)
3	7 (33)	4 (18)
4	0 (0)	0 (0)
Pain Catastrophizing Mean Score ± SE	15.2 ± 2.9	14.9 ± 2.7
Self-Efficacy Mean Score ± SE	7.2 ± 0.5	7.3 ± 0.4

Abbreviations. SD = standard deviation. BMI = body mass index. ASA = American Society of Anesthesiologists physical status.

5.3 Surgical Characteristics

All participants underwent a primary THA through the direct anterior approach with general anaesthesia. Surgical characteristics were similar between the two groups (Table 2).

Table 2: Surgical characteristics for inpatient and outpatient total hip arthroplasty

Characteristics	Inpatient (n=21)	Outpatient (n=22)
Releases, n (%)ǂ		
Conjoint Tendon	9 (43)	11 (50)
Piriformis	3 (14)	3 (14)
TFL	1 (5)	2 (9)
Posterior Capsule	1 (5)	2 (9)
Mean Operative Time ± SD, min§	72.3 ± 9.2	73.5 ± 10.5

Abbreviations. SD = standard deviation. ǂTwo patients in the inpatient group received two intraoperative releases, while three patients in the outpatient group received two intraoperative releases. §Operative time calculated from first incision to application of dressing.

5.4 Pathway Flow: Admission to Discharge

Table 3 presents the length of stay in the hospital and time in post-anesthesia care unit (PACU) for both groups. Patients in the inpatient group recovered in the ward after being discharged from PACU, whereas patients in the outpatient group recovered in day surgery after being discharged from PACU. The inpatient group experienced a longer stay in PACU because they were often required to wait for a bed to become available, whereas the outpatient group simply needed to wait until the day surgery unit was ready for them. The median length of stay on the ward for the inpatient group was 22.5 hours (IQR=7.6), while the median length of stay in the day surgery unit for the outpatient group was 3.3 hours (IQR=1.1)

Two patients in the inpatient group were discharged on the second post-operative day. One patient had a vasovagal episode and persistent dizziness post-operatively and remained in hospital an extra day for observation. The second patient presented with hypotension post-surgery which slowed their progression to gain mobility. This patient was kept in the hospital an extra day and declared fit for discharge by the physiotherapist on the second post-operative day.

Table 3: **Pathway flow from admission to discharge for inpatient and outpatient total hip arthroplasty**

	Inpatient (median ± IQR)	Outpatient (median ± IQR)	p-Value
Length of stay (hrs)	29.1 ± 6.0	8.4 ± 1.1	<0.001
Time in PACU (hrs)	2.3 ± 3.3	1.8 ± 1.0	0.01

Abbreviations. IQR = interquartile range. PACU = post anaesthesia care unit

5.5 Primary Outcome

5.5.1 Serious Adverse Events

The relative risk for serious adverse events was similar between groups (RR = 0.96, 95% CI = 0.11 to 8.52, p = 0.97). Specifically, one patient in the inpatient group and one patient in the outpatient group suffered a serious adverse event (Table 4). In the inpatient group, one patient developed an infection approximately one week post-surgery and was prescribed antibiotics for one week (Keflex). Unfortunately the infection did not resolve and the incision continued to breakdown inciting an irrigation and debridement poly exchange revision surgery three weeks following the primary hip replacement. The patient was subsequently discharged after five days. Intraoperative cultures were positive for Staphylococcus aureus and the patient was treated with Ancef for six weeks. The infection resolved following this treatment.

One patient in the outpatient group misunderstood the prescription for analgesia and presented to the emergency room by ambulance suffering an overdose two days post-surgery. The symptoms resolved quickly. At the two-week follow-up visit, this patient had no significant pain control issues.

Table 4: Serious adverse events for inpatient and outpatient total hip arthroplasty

Group	Age	Gender	BMI	Complication
Inpatient	68	Female	30.6	Deep infection
Outpatient	62	Female	24.3	Analgesia overdose

Abbreviations. BMI = Body mass index

5.6 Secondary Outcomes

5.6.1 Cost

The outpatient group was significantly less expensive than the inpatient group from the perspective of the hospital (mean difference = $766; 95% CI = $68.82 to $1466.30) and the Ministry of Health (mean difference = $850.77, 95% CI = $21.07 to $1680.47). However, there was no statistically significant difference between the two groups from the societal perspective (Table 5). Similar results were found with non-parametric Mann-Whitney U tests. There were no statistically significant differences between groups regarding days off of work, days off of homemaking activities and caregiver assistance (Table 6).

We originally planned to calculate the incremental cost-effectiveness ratio (ICER), with early postoperative complications as the effectiveness measure. However, since there were no differences in the rate of serious adverse events between the two groups, our analysis simplified to a cost-minimization analysis.

Table 5: Cost from the perspective of the Ministry of Health, the hospital and society for inpatient and outpatient total hip arthroplasty

Perspective	Inpatient (mean ± SE)	Outpatient (mean ± SE)	Mean Difference (95% CI)	p-value
Hospital	5169.76 ± 348.56	4403.20 ± 63.41	766.56 (68.82 to 1466.30)	0.03
Ministry of Health	6751.59 ± 412.96	5900.82 ± 76.82	850.77 (21.07 to 1680.47)	0.04
Society	12792.46 ± 1355.52	14483.08 ± 1857.52	-1690.62 (-6345.74 to 2964.50)	0.47

Abbreviations. SE = standard error, CI = Confidence interval

Table 6: Days off of work, days off of homemaking activities, and caregiver assistance for inpatient and outpatient total hip arthroplasty

	Inpatient (mean ± SE)	Outpatient (mean ± SE)	Mean Difference (95% CI)	p-value
Days off of work (days)	21.1 ± 6.1	32.7 ± 8.2	-11.6 (-32.6 to 9.3)	0.28
Days off of homemaking (days)	5.8 ± 1.5	4.6 ± 1.6	1.2 (-3.2 to 5.6)	0.59
Caregiver assistance (hours)	24.9 ± 4.2	28.2 ± 5.7	-3.4 (-17.7 to 10.9)	0.74

Abbreviations. SE = standard error, CI = Confidence interval

5.6.1.1 Sensitivity Analyses

Our results were similar when we assigned the wage for patient days off of work as the patient reported household income per 8 hour work day, when we assigned minimum wage ($11.25 per hour, $90 per 8 hour work day) to caregiver time off of work and when we assigned $0 to patient days off of homemaking activities. However, the mean difference between groups from the societal perspective became more similar when we assigned minimum wage ($11.25 per hour, $90 per 8 hour work day) as the wage for patient days off of work (mean difference = $77.51, 95% CI = $-1876.36 to $2031.39).

5.6.2 Patient Satisfaction

We split the results of our 20-item questionnaire into two tables; Table 7 illustrates the results of the five questions with a VAS response option format and Table 8 reports the results of the 15 items with Likert-type response options. There were no differences between the two groups for any of the questions. Notably, almost all study participants in both groups felt very strongly about recommending this procedure to a friend or family member.

Table 7: Patient satisfaction on a visual analog scale (VAS) at two weeks post-operatively following inpatient and outpatient total hip arthroplasty. Lower values indicate greater satisfaction.

Question	Inpatient (median ± IQR)	Outpatient (median ± IQR)	p-Value
1. How much stress did you experience due to uncontrolled pain after your surgery?	10 ± 37	5 ± 50	0.95
2. How bad were the side effects from the pain medication?	36 ± 57	39 ± 72	0.81
3. Overall, I would rate the quality of care that I received **before** surgery as:	2 ± 9	1 ± 2	0.10
4. Overall, I would rate the quality of care that I received **after** surgery as:	3 ± 11	1 ± 3	0.24
5. How strongly would you feel about recommending this procedure (THA) to a friend or family member?	1 ± 0	1 ± 1	0.45

Abbreviations. IQR = interquartile range. All questions scored on a visual analog scale between 0-100.

Most interestingly, 18/21 inpatients and 19/22 outpatients felt that their stay was the right length and 20/21 inpatients and 22/22 outpatients were either mostly or completely satisfied with all factors of the surgical experience. All patients enrolled in the study indicated that they were either very likely or completely likely to have this procedure again in the future in the same manner.

Table 8: Patient Satisfaction two weeks postoperatively following inpatient and outpatient total hip arthroplasty

Patient Satisfaction	Inpatient (n=21)	Outpatient (n=22)
Upon discharge from the hospital, how safe did you feel moving about the house, including going to the bathroom?		
Completely Unsafe	0 (0)	1 (4)
Unsafe	0 (0)	1 (4)
Somewhat unsafe	4 (19)	0 (0)
Neither safe nor unsafe	0 (0)	1 (4)
Somewhat safe	3 (14)	5 (24)
Safe	6 (29)	6 (27)

Completely safe	8 (38)	8 (37)
After surgery, the overall effectiveness of the pain control medication received **in the hospital** were…?		
Completely ineffective	0 (0)	0 (0)
Mostly ineffective	0 (0)	0 (0)
Somewhat ineffective	1 (5)	0 (0)
Neither effective nor ineffective	0 (0)	0 (0)
Somewhat effective	3 (14)	1 (4)
Mostly effective	12 (57)	7 (32)
Completely effective	5 (24)	14 (64)
After surgery, the overall effectiveness of the pain control medication taken **at home** were…?		
Completely ineffective	0 (0)	0 (0)
Mostly ineffective	0 (0)	0 (0)
Somewhat ineffective	0 (0)	0 (0)
Neither effective nor ineffective	0 (0)	0 (0)
Somewhat effective	3 (14)	5 (23)
Mostly effective	13 (62)	8 (36)
Completely effective	5 (24)	9 (41)
How would you rate the overall quality of nursing care that you received in the hospital?		
Completely dissatisfied	1 (5)	0 (0)
Mostly dissatisfied	0 (0)	0 (0)
Somewhat dissatisfied	0 (0)	0 (0)
Neither satisfied nor dissatisfied	0 (0)	0 (0)
Somewhat satisfied	1 (5)	0 (0)
Mostly satisfied	3 (14)	3 (14)
Completely satisfied	16 (76)	19 (86)
Did you have any questions or concerns about your surgery or postoperative care that were not addressed **before** surgery?		
Yes	2 (10)	2 (9)
No	19 (90)	20 (91)
Did you have any questions or concerns about your surgery or postoperative care that were not addressed **after** your surgery, but **before** discharge from hospital?		
Yes	3 (14)	3 (14)
No	18 (86)	19 (86)
Do you feel you were given enough information to know what to expect after you were discharged in terms of **rehabilitation?**		
Completely dissatisfied	1 (5)	1 (4)
Mostly dissatisfied	0 (0)	1 (4)

Somewhat dissatisfied	0 (0)	0 (0)
Neither satisfied nor dissatisfied	0 (0)	0 (0)
Somewhat satisfied	1 (5)	1 (4)
Mostly satisfied	11 (52)	7 (32)
Completely satisfied	8 (38)	12 (56)
Do you feel you were given enough information to know what to expect after you were discharged in terms of **dressing change?**		
Somewhat dissatisfied	0 (0)	1 (5)
Neither satisfied nor dissatisfied	1 (5)	0 (0)
Somewhat satisfied	2 (10)	1 (5)
Mostly satisfied	7 (33)	6 (27)
Completely satisfied	11 (52)	14 (63)
Do you feel you were given enough information to know what to expect after you were discharged in terms of **the amount of pain?**		
Completely dissatisfied	0 (0)	1 (5)
Mostly dissatisfied	0 (0)	0 (0)
Somewhat dissatisfied	1 (5)	2 (9)
Neither satisfied nor dissatisfied	0 (0)	2 (9)
Somewhat satisfied	0 (0)	2 (9)
Mostly satisfied	12 (57)	7 (32)
Completely satisfied	8 (38)	8 (36)
Consider the length of time you stayed in the hospital. My length of stay was:		
I would have preferred to stay another day or two	0 (0)	1 (5)
I would have preferred to stay a few more hours to another day	1 (5)	2 (9)
My stay was just right	18 (85)	19 (86)
I would have preferred to go home a day or a few hours sooner	0 (0)	0 (0)
I would have preferred to go home the same day as my procedure	2 (10)	0 (0)
Did you receive adequate feedback from your surgeon regarding the results of your surgery (i.e., in the recovery room, ward)?		
Completely dissatisfied	0 (0)	3 (13)
Mostly dissatisfied	1 (5)	0
Somewhat dissatisfied	0 (0)	1 (5)
Neither satisfied nor dissatisfied	1 (5)	1 (5)
Somewhat satisfied	1 (5)	0
Mostly satisfied	5 (24)	2 (9)
Completely satisfied	13 (61)	15 (68)
Was your surgeon available and easily accessible if you needed him or her after your surgery?		
Completely dissatisfied	0 (0)	2 (9)
Mostly dissatisfied	0 (0)	0 (0)

Somewhat dissatisfied	0 (0)	0 (0)
Neither satisfied nor dissatisfied	1 (5)	2 (9)
Somewhat satisfied	0 (0)	0 (0)
Mostly satisfied	5 (24)	3 (14)
Completely satisfied	15 (71)	15 (68)
Please comment on the quality of sleep you achieved on the first night following your surgery:		
I didn't get any sleep	1 (5)	2 (9)
I awoke feeling very unrested	5 (24)	1 (4)
I awoke feeling somewhat unrested	7 (33)	3 (14)
Neutral	3 (14)	3 (14)
I awoke feeling somewhat rested	3 (14)	7 (32)
I awoke feeling very rested	2 (10)	6 (27)
Considering all factors (i.e., preoperative teaching, nursing, doctors, hospital), how satisfied were you as a patient with the arthroplasty surgery, from the time you first met the surgeon and including up until the second week after your surgery?		
Completely dissatisfied	1 (5)	0 (0)
Mostly dissatisfied	0 (0)	0 (0)
Somewhat dissatisfied	0 (0)	0 (0)
Neither satisfied nor dissatisfied	0 (0)	0 (0)
Somewhat satisfied	0 (0)	0 (0)
Mostly satisfied	6 (28)	4 (18)
Completely satisfied	14 (67)	18 (82)
If you had a choice, how willing would you be to have this procedure (THA) done again under the same circumstances?		
Not at all likely	0 (0)	0 (0)
Slightly likely	0 (0)	0 (0)
Moderately likely	0 (0)	0 (0)
Very likely	2 (10)	3 (14)
Completely likely	19 (90)	19 (86)

Finally, we assessed patient satisfaction regarding pain and function levels at six weeks and three months post-operatively (Table 9). There were no significant differences found between the two groups at either time-point. Responses to all questions were similar between six weeks and three months post-operatively for both groups.

Table 9: Patient satisfaction at six weeks and three months following inpatient and outpatient total hip arthroplasty

Time	Patient Satisfaction	Inpatient (n=21)	Outpatient (n=22)
6 Weeks	Pain level while sitting?		
	Very Dissatisfied	0 (0)	0 (0)
	Dissatisfied	0 (0)	0 (0)
	Neutral	0 (0)	1 (5)
	Satisfied	7 (33)	4 (18)
	Very Satisfied	14 (67)	17 (77)
	Pain level while lying in bed?		
	Very Dissatisfied	0 (0)	0 (0)
	Dissatisfied	1 (5)	0 (0)
	Neutral	0 (0)	1 (5)
	Satisfied	6 (29)	8 (36)
	Very Satisfied	14 (67)	13 (59)
	Pain level while getting out of bed?		
	Very Dissatisfied	0 (0)	0 (0)
	Dissatisfied	0 (0)	0 (0)
	Neutral	2 (10)	1 (5)
	Satisfied	8 (38)	7 (31)
	Very Satisfied	11 (52)	14 (64)
	Pain level while performing light household duties?		
	Very Dissatisfied	0 (0)	0 (0)
	Dissatisfied	0 (0)	0 (0)
	Neutral	1 (5)	3 (14)
	Satisfied	8 (38)	6 (27)
	Very Satisfied	12 (57)	13 (59)
	Pain level while performing leisure recreational activities?		
	Very Dissatisfied	0 (0)	0 (0)
	Dissatisfied	1 (5)	0 (0)
	Neutral	4 (19)	7 (32)
	Satisfied	4 (19)	5 (23)
	Very Satisfied	12 (57)	10 (45)
3 Months	Pain level while sitting?		
	Very dissatisfied	0 (0)	0 (0)
	Dissatisfied	0 (0)	0 (0)
	Neutral	1 (5)	1 (5)
	Satisfied	4 (19)	5 (23)
	Very Satisfied	16 (76)	16 (73)
	Pain level while lying in bed?		

	Very dissatisfied	0 (0)	0 (0)
	Dissatisfied	0 (0)	0 (0)
	Neutral	1 (5)	1 (5)
	Satisfied	8 (38)	7 (31)
	Very Satisfied	12 (57)	14 (64)
	Pain level while getting out of bed?		
	Very dissatisfied	0 (0)	0 (0)
	Dissatisfied	1 (5)	0 (0)
	Neutral	1 (5)	1 (5)
	Satisfied	5 (23)	6 (27)
	Very Satisfied	14 (67)	15 (68)
	Pain level while performing light household duties?		
	Very Dissatisfied	1 (5)	0 (0)
	Dissatisfied	1 (5)	0 (0)
	Neutral	1 (5)	1 (5)
	Satisfied	4 (18)	8 (36)
	Very Satisfied	14 (67)	13 (59)
	Pain level while performing leisure recreational activities?		
	Very Dissatisfied	1 (5)	0 (0)
	Dissatisfied	1 (5)	1 (5)
	Neutral	2 (10)	1 (5)
	Satisfied	6 (28)	9 (40)
	Very Satisfied	11 (52)	11 (50)

5.6.3 Expectations

Pre-operatively, expectations were not significantly different between the two groups (Table 10). Regarding pain relief, 21/21 inpatients and 21/22 outpatients expected the surgery to help a lot; in terms of improving their ability to carry out normal activities of daily living, 20/21 inpatients and 19/22 outpatients expected the surgery to help a lot.

Table 10: Expectations pre-operatively for patients undergoing inpatient and outpatient total hip arthroplasty

Expectations	Inpatient (n=21)	Outpatient (n=22)
Do you expect your surgery will help with pain relief?		
A lot	21 (100)	21 (95)
Somewhat	0 (0)	1 (5)
Just a little	0 (0)	0 (0)
No, I do not expect the surgery to help with my pain	0 (0)	0 (0)
Not applicable as I do not have pain	0 (0)	0 (0)
Do you expect your surgery will improve your ability to carry out the normal activities of daily living?		
A lot	20 (95)	19 (86)
Somewhat	1 (5)	3 (14)
Just a little	0 (0)	0 (0)
No, I do not expect surgery to improve my ability	0 (0)	0 (0)
Not applicable as I do not have problems with daily living	0 (0)	0 (0)
Do you expect following surgery you will be able to participate in similar activities you did before you started having problems?		
As much as before	16 (76)	18 (82)
Not as much as before	5 (24)	4 (18)
No, I do not expect surgery to improve my participation	0 (0)	0 (0)
Not applicable as I do not do sports or recreational activities	0 (0)	0 (0)
Do you expect following surgery the area operated upon will be back to the way it was before you began having problems?		
Completely	17 (81)	17 (77)
Somewhat improved	4 (19)	5 (23)
A little improved	0 (0)	0 (0)
Not improved	0 (0)	0 (0)

Post-operatively, there were no significant differences regarding the degree to which expectations were met between the two groups at either six weeks or three months (Table 11). At three months, 16/21 inpatients and 18/22 outpatients believed their expectations were either met or were too low regarding pain relief, while 17/21 inpatients and 19/22 outpatients believed their expectations were either met or were too low regarding ability to carry out normal activities.

Table 11: Expectations post-operatively following inpatient and outpatient total hip arthroplasty

Time	Expectations	Inpatient (n=21)	Outpatient (n=22)
6 Weeks	My expectations for pain relief were…?		
	Too High – I'm a lot worse than I thought	0 (0)	0 (0)
	Too High – I'm somewhat worse than I thought	2 (10)	2 (9)
	Just Right – My expectations were met	10 (47)	9 (41)
	Too Low – I'm somewhat better than I thought	2 (10)	1 (5)
	Too Low – I'm a lot better than I thought	7 (33)	10 (45)
	My expectations for being able to do my normal activities were…?		
	Too High – I'm a lot worse than I thought	0 (0)	0 (0)
	Too High – I'm somewhat worse than I thought	2 (10)	1 (5)
	Just Right – My expectations were met	10 (47)	8 (36)
	Too Low – I'm somewhat better than I thought	1 (5)	4 (18)
	Too Low – I'm a lot better than I thought	8 (38)	9 (41)
3 Months	My expectations for pain relief were…?		
	Too High – I'm a lot worse than I thought	0 (0)	0 (0)
	Too High – I'm somewhat worse than I thought	5 (24)	3 (14)
	Just Right – My expectations were met	7 (33)	8 (36)
	Too Low – I'm somewhat better than I thought	3 (14)	2 (9)
	Too Low – I'm a lot better than I thought	6 (29)	9 (41)
	My expectations for being able to do my normal activities were…?		
	Too High – I'm a lot worse than I thought	0 (0)	0 (0)
	Too High – I'm somewhat worse than I thought	4 (19)	3 (14)
	Just Right – My expectations were met	8 (38)	9 (41)
	Too Low – I'm somewhat better than I thought	3 (14)	3 (14)
	Too Low – I'm a lot better than I thought	6 (29)	7 (31)

5.6.4 Patient Reported Outcome Scores

There were no significant differences between the groups at any time point for EQ-5D, EQ-5D VAS, WOMAC, Harris Hip, SF-12 and Pain NRS (Table 12). Similar results were found with non-parametric tests. For each of the scoring measures, both groups continued to improve at each successive time point, with the exception the MCS subsection of SF-12, which remained constant throughout the study. Figure 7 presents unadjusted mean PCS and MCS scores with 95% confidence intervals at baseline, two weeks, six weeks and three months post-surgery. Figure 8 displays unadjusted mean VAS

scores with 95% confidence intervals at baseline, discharge, two weeks, six weeks and three months post-surgery. Mean pain scores improved for both groups at each time point up until six weeks following surgery. No differences were found when using baseline pain catastrophizing and self-efficacy scores as a covariate for any of the outcome scores. Furthermore, there was a weak correlation between LOS and pain catastrophizing scores for both the inpatient (r = -0.14) and outpatient (r = 0.09), as well as for the self-efficacy scores for both the inpatient (r = 0.17) and outpatient (r = 0.10).

Table 12: Patient reported outcomes for inpatient and outpatient total hip arthroplasty (adjusted means). Outcomes include EQ-5D, EQ-5D VAS, WOMAC, Harris Hip, SF-12 and Pain NRS.

Questionnaire	Inpatient (mean ± SE)	Outpatient (mean ± SE)	Adjusted Mean Difference (95% CI)	p-Value
EQ-5D				
Baseline	0.79 ± 0.02	0.77 ± 0.03	0.02 (-0.04 to 0.09)	
6 Weeks	0.87 ± 0.01	0.88 ± 0.01	-0.01 (-0.04 to 0.02)	0.56
3 Months	0.89 ± 0.02	0.91 ± 0.02	-0.02 (-0.08 to 0.03)	0.44
EQ-5D VAS				
Baseline	70.1 ± 4.1	71.7 ± 4.5	-1.6 (-14.0 to 10.7)	
6 Weeks	86.8 ± 2.6	87.2 ± 2.5	-0.3 (-7.6 to 7.0)	0.93
3 Months	85.7 ± 3.4	93.0 ± 3.3	-7.3 (-16.9 to 2.3)	0.13
WOMAC Pain				
Baseline	52.4 ± 3.5	47.7 ± 3.9	4.7 (-6.0 to 15.3)	
3 Months	88.4 ± 2.6	90.8 ± 2.6	-2.4 (-9.8 to 5.1)	0.52
WOMAC Stiffness				
Baseline	46.4 ± 4.5	41.8 ± 3.3	4.7 (-6.6 to 15.9)	
3 Months	77.7 ± 3.9	82.0 ± 3.8	-4.3 (-15.3 to 6.7)	0.43
WOMAC Function				
Baseline	52.9 ± 4.1	47.9 ± 3.3	4.9 (-5.7 to 15.5)	
3 Months	86.5 ± 2.6	91.5 ± 2.5	-4.9 (-12.2 to 2.3)	0.18
WOMAC Total				
Baseline	51.3 ± 3.7	46.6 ± 2.9	4.8 (-4.7 to 14.1)	
3 Months	85.5 ± 2.6	89.2 ± 2.6	-3.7 (-11.2 to 3.8)	0.32
Harris Hip				
Baseline	59.8 ± 2.1	59.8 ± 1.5	0.0 (-5.1 to 5.1)	
3 Months	94.7 ± 1.2	97.0 ± 1.2	-2.3 (-5.8 to 1.2)	0.19
SF-12 PCS				
Baseline	31.5 ± 1.9	32.5 ± 2.0	-1.0 (-6.7 to 4.6)	

2 Weeks	35.0 ± 2.2	37.9 ± 2.1	-3.0 (-9.2 to 3.2)	0.34
6 Weeks	46.8 ± 1.7	45.8 ± 1.7	1.0 (-3.9 to 5.9)	0.67
3 Months	48.0 ± 1.7	49.9 ± 1.6	-1.9 (-6.6 to 2.7)	0.41
SF-12 MCS				
Baseline	55.1 ± 2.4	54.2 ± 2.2	0.9 (-5.6 to 7.4)	
2 Weeks	53.5 ± 2.0	55.7 ± 1.9	-2.2 (-7.8 to 3.4)	0.43
6 Weeks	56.7 ± 1.5	56.9 ± 1.5	-0.2 (-4.5 to 4.2)	0.94
3 Months	57.2 ± 1.7	59.2 ± 1.7	-2.0 (-6.8 to 2.8)	0.41
Pain VAS				
Baseline	4.5 ± 0.5	6.0 ± 0.5	-1.4 (-2.8 to -0.1)	
Discharge	3.7 ± 0.5	2.6 ± 0.5	1.13 (-0.24 to 2.49)	0.10
2 Weeks	2.2 ± 0.5	1.9 ± 0.5	0.27 (-1.29 to 1.84)	0.72
6 Weeks	0.9 ± 0.2	0.3 ± 0.2	0.62 (-0.06 to 1.31)	0.07
3 Months	1.0 ± 0.4	0.6 ± 0.4	0.47 (-0.74 to 1.67)	0.44

Abbreviations. SE = standard error, CI = confidence interval, PCS = physical component score, MCS = mental component score

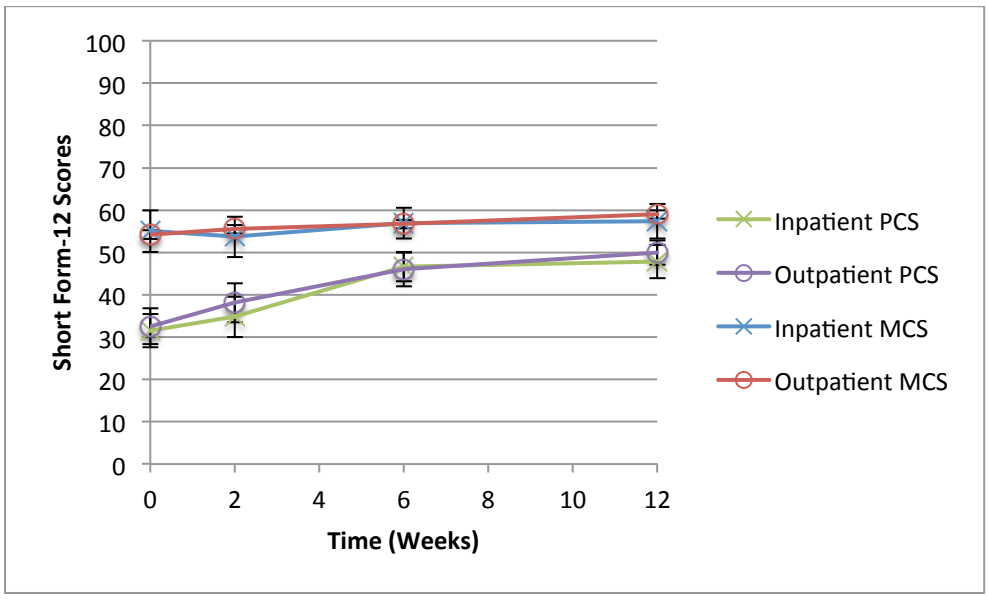

Figure 7: Short Form-12 scores following inpatient and outpatient total hip arthroplasty (unadjusted means, 95% confidence intervals), PCS = physical component score, MCS = mental component score

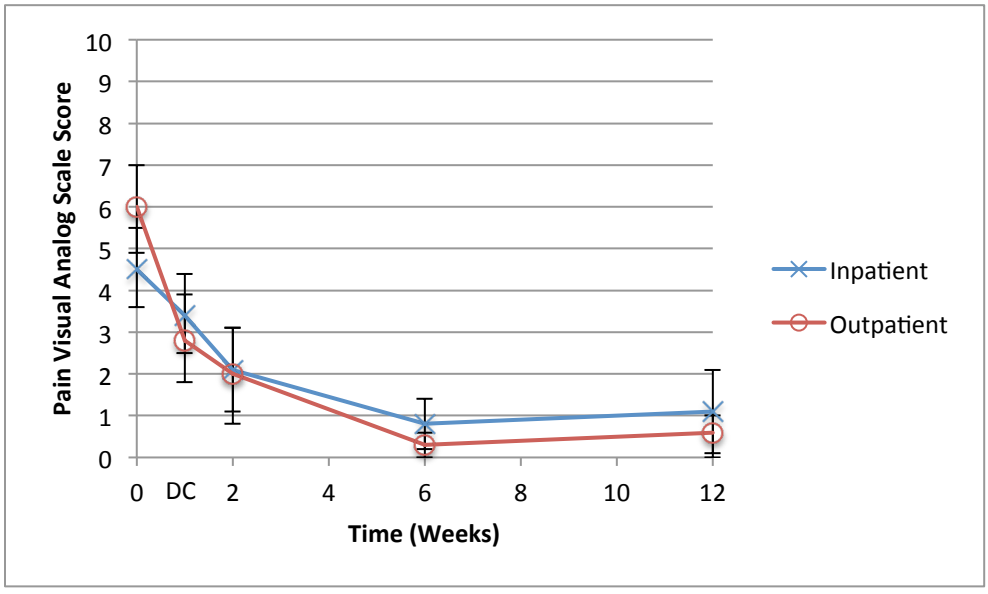

Figure 8: Pain Visual Analog Scale (VAS) scores following inpatient and outpatient total hip arthroplasty (unadjusted means, 95% confidence intervals), DC = discharge

5.7 Gait Aid Use

Mean time to discontinue the use of gait aids was 25.5 days ± 23.5 (0 – 95 days) for the inpatient group and 22.0 days ± 20.1 (0 – 71 days) for the outpatient group. One patient in the inpatient group and two patients in the outpatient group were still using their gait aid at their three-month visit post-operatively. One patient in the inpatient group discontinued the use of gait aids 21 days post-operatively, but presented with a gait aid at the three-month visit due to pain control issues.

5.8 Phone Calls

There was no statistically significant difference between the two groups regarding the number of phone calls made to the hospital in the first two weeks post-operatively. The mean ± SE for the number of calls was 1.1 ± 0.5 (range: 0-11) for the inpatient group and 0.7 ± 0.3 (range: 0-6) for the outpatient group.

5.9 Caregiver Assistance

There was no statistically significant difference between the two groups regarding caregiver assistance in the first two weeks post-operatively. Most interestingly, on a seven-point scale, caregivers in both groups reported similar levels of assistance for transportation (5.2 ± 0.2 vs. 4.9 ± 0.3, mean difference 0.3, 95% CI, -0.5 to 1.1, $p = 0.93$) and for household responsibilities (5.0 ± 0.2 vs. 3.7 ± 0.5, mean difference 1.2, 95% CI, 0.2 to 2.3, $p = 0.13$).

Chapter 6

6 Discussion

The purpose of this study was to compare serious adverse events and early postoperative outcomes in patients being discharged either on day 0 (outpatient) or admitted to the hospital overnight (inpatient) following a primary direct anterior total hip arthroplasty (THA). We assessed serious adverse events, cost, patient satisfaction, expectations, functional outcomes, quality of life and pain. In this preliminary analysis of an ongoing randomized control trial, we found no statistically significant differences in serious adverse events, whereas the outpatient group had a significantly shorter length of stay (LOS) in the hospital and was significantly less costly from the perspectives of the hospital and the Ministry of Health (MoH). No other statistically significant differences were found between the two groups for any other outcome measures.

The major deterrent for outpatient joint replacements is patient safety, with the fear of additional adverse events and increase in hospital readmissions. Previous literature that cautions against outpatient joint replacements advocates that the majority of complications following surgery occur within the time-frame of the typical hospital stay[100]. However, in accordance with research investigating the safety and feasibility of outpatient joint replacements[5,16,101,102], our results illustrate that outpatient THA can be safely performed with comparable complication rates to similar inpatient procedures. One patient in the inpatient group (1/21) and one patient in the outpatient group (1/22) suffered a serious adverse event. Although the sample size is small and definitive conclusions cannot be made, these results are encouraging.

We compared the cost of inpatient versus outpatient THA from the perspective of the hospital, MoH and society. Our results illustrate that outpatient THA is significantly less expensive from the perspective of the hospital ($5,169.76 versus $4,403.30; $p = 0.03$) and the MoH ($6,751.59 versus $5,889.92; $p = 0.04$), while there was no statistically significant difference from the societal perspective ($12,792.46 versus $14,483.08; $p =$

0.47). Following recovery in PACU, the outpatient group recovered in day surgery ($1.75/min) for an average of 3.3 hours, whereas the inpatient group recovered on the ward ($0.44/min) for an average of 22.5 hours. Furthermore, the inpatient group had to stay in PACU ($1.87/min) longer to wait for an available room. The outpatient group was less expensive primarily due to the decreased LOS ($p < 0.001$), decreased time in PACU ($p = 0.01$) and decreased time in recovery following discharge from PACU ($p < 0.001$).

Societal costs were similar between the inpatient and outpatient cohorts ($12,792.46 versus $14,483.08; $p = 0.47$). Although not statistically significantly different, the outpatient group had more days off of work (32.7 ± 8.2) compared to the inpatient group (21.1 ± 6.1). Eleven patients in the outpatient group were employed full time, whereas only eight patients in the inpatient group were employed full time. Furthermore, six patients in the outpatient group and two patients in the inpatient group reported that they took three months off of paid employment post-operatively. These discrepancies skewed the data in favour of the inpatient group but we suspect this difference can be attributed to our small sample size and that because this is an ongoing randomized trial, these differences will disappear once the full sample size is achieved. However, in this preliminary analysis, the cost attributed to days off of work offset the cost savings from the perspectives of the hospital and the MoH. To make sure any assumptions or estimates were not influencing the final results, we conducted sensitivity analyses to examine the degree of uncertainty in the societal costs. We did not find any statistically significant differences in any of the sensitivity analyses. The only sensitivity analysis that made the mean difference between groups more similar was when we assigned minimum wage ($11.25 per hour, $90 per 8 hour work day) as the monetary value for patient days off of work. Time off of paid employment will be important to investigate further in the final analysis.

At our institution, Petis et al.[66] reported that from the perspective of the MoH, the average total cost of a direct anterior THA (n=40) was $7300.22 (95% CI = 7064.49-7535.95). Our findings were similar for the inpatient ($6751.59; 95% CI = 5889.10-7611.79) cohort

and less expensive for the outpatient ($5900.82; 95% CI = 5741.99-6059.66) cohort. The average LOS reported by Petis et al.[66] was 33.9 hours (95% CI = 29.6-38.2), whereas in our study the median LOS was similar for the inpatient group (29.1 hours; IQR = 6.0), but shorter for the outpatient (8.4 hours; IQR = 1.1) group.

At our institution, the standard-of-care for THA is a direct lateral approach, which Petis et al.[66] reported as $7853.10 (95% CI = 7577.29-8128.91) with an average LOS of 64.2 hours (95% CI = 56.7-71.7). For this study, we used a direct anterior approach, which has been shown to allow for accelerated mobility milestones and may therefore be more amenable to earlier discharge. Indeed, the average LOS for both our inpatient and outpatient groups was shorter than the direct lateral approach in the Petis study[66]. Further, our outpatient group was able to be safely discharged to home on the same day, which is why the direct anterior approach care pathway with outpatient protocol offer a significant cost savings over the standard of care direct lateral approach care pathway.

To our knowledge, this is the first economic analysis on outpatient THA conducted in Canada. Our study found less cost savings compared to other outpatient THA economic analyses completed in the United States, which can likely be attributed to the significantly shorter LOS of our inpatient group (24.6 ± 8.9 hours). In 2005, Bertin et al.[10] conducted a non-randomized cohort study with 20 patients (10 patients per group) and found that the average hospital bill was US$4000 less ($p < 0.007$) and the average total charge was US$2465 less ($p = 0.02$) for outpatients compared to inpatients (LOS = 3.2 days). In our study, the mean difference from the perspective of the hospital was $766.56 and the mean difference from the perspective of the MoH was $850.77 less for the outpatients. Other than the longer length of stay in the Bertin study[10], four patients in the inpatient group suffered a complication, whereas there were no complications in the outpatient group.

A second study by Aynardi et al.[3] that used a case-control design to compare inpatients (n=78) to outpatients (n=119) found that the average overall cost for the outpatient group was significantly lower than the inpatient group (US$24,529 versus US$31,327; p >

0.0001). As with the Bertin study[10], the average LOS for inpatients in the Aynardi study[3] was 73.8 ± 24.1 hours and the average LOS for the outpatients was 24.6 ± 8.9 hours; much longer than our institution's practice. Other possible contributions to the differences between groups (attributed to the study design) include a significantly lower average BMI ($p > 0.0001$) and younger age ($p=0.07$) in the outpatient group[3].

One purported advantage of outpatient hip replacements is the increase in patient autonomy and satisfaction; the majority of patients do not want to remain in hospital and would prefer to recover in the comfort of their own home[16]. However, our study found there was no difference between the two cohorts in any of the satisfaction questions. This may be a result of our modified Zelen design that blinded patients to the fact that they were in an RCT and randomized to inpatient or outpatient care, ensuring that satisfaction was not influenced by positive or negative feelings related to group assignment. It is worth highlighting, however, that in the outpatient group, two patients indicated that they felt completely unsafe and unsafe (respectively) upon discharge when moving about the house or using the bathroom. As our sample size grows we will be better situated to estimate the magnitude of the problem and whether we need to make changes to patient, and perhaps caregiver, education material.

Similar improvements were seen between groups in functional ability and quality of life outcomes. These results were comparable to other outpatient hip replacement studies assessing clinical outcomes such as EQ-5D, WOMAC, HHS, SF-12 and Pain VAS[8,14,80,102,103]. Contrary to our results, Hoeffel et al.[104] recently reported significantly greater improvements in functionality at three months post-operative in outpatients (n=96) compared to inpatients (n=152). Specifically, outpatients had a significantly higher improvement using the Oxford Hip score Questionnaire (20.9 vs. 17.0; $p < 0.01$), significantly higher improvement in VAS pain score (84.5% vs. 66.2%; $p < 0.01$), significantly higher score when rating how normal their joint felt on an 100 point scale (85.0 vs. 76.8; $p = 0.022$), and significantly higher percentage of patients reporting their pain relief (71.7% vs. 56.3%; $p < 0.01$) and ability to perform regular activities (57.7%

vs. 30.6%; p = 0.002) as "excellent"[104]. At the time of our study, Hoeffel's study was only a published abstract, which meant that the patient demographics were not explicitly reported[104]. In addition, the Hoeffel study was a prospective cohort study without randomization that compared outpatients undergoing a THA at a newly opened ambulatory surgery center versus inpatients undergoing a THA in a hospital setting, any of which could explain the inconsistency in their findings compared to the existing literature and to our study.

It's our opinion that patient selection is imperative to ensure outpatient THA is safe. Kort et al.[18] performed a review of the literature to determine the patient selection criteria for outpatient joint arthroplasty and found that there is no general consensus. The most common patient selection criteria however included patients who are willing to go home the same day of surgery, with a low ASA classification (<III), age <75, and sufficient support at home[16,18]. Extensive pre-existing comorbidities are a contraindication for outpatient procedures[16,18,76].

The patient demographics of our study were similar to those of a systematic review we conducted investigating the safety and feasibility of outpatient joint replacements[16]. In the systematic review, the mean age for hip replacements ranged from 53-63 years old[16]. In the current study, the average age for the inpatient group was 62 ± 8 years (range: 45-79 years) and the average age for the outpatient group was 60 ± 9 years (range: 37-75 years). However, the average age of the general population undergoing a hip replacement is 68 years[16,105], highlighting younger age as an important factor when considering outpatient care for patients undergoing THA.

The majority of the studies included in the systematic review reported more males than females[16]. This is similar to our study, which includes 12 males out of 21 patients in the inpatient group and 12 males out of 22 patients in the outpatient group. The fact that studies investigating outpatient care for this patient group have tended to include slightly more males than females is inconsistent with the fact that slightly more females (56.8%)[16,105] undergo hip replacement than males, which may indicate a surgeon bias

toward males being better candidates for outpatient surgery. Interestingly, Abbas et al.[106] used a multiple regression and found that female gender ($p < 0.05$) predicted a longer LOS in the hospital following a total hip replacement. It's possible that the gender difference in outpatient joint replacement is due preconceived ideas about sex differences in societal roles of caregiving where females are thought to more often play a caregiving rather than care-receiving role[16]. Although there is no definitive evidence to support this finding, it is a fascinating trend that should to be examined further.

As Shah *et al*.[107] demonstrated a potential disadvantage to outpatient joint arthroplasty is the increase in telephone calls from patients to clinicians. Patients admitted to the hospital following surgery have nurses, physical therapist, occupational therapists and clinicians available to answer questions as they arise. However, patients who are discharged from the hospital as an outpatient do not have this same access[107]. We were cognizant that the earlier discharge from the hospital might lead to an increase in telephone calls to the surgeon's office. However, similar to Goyal et al.[102], there was no statistically significant difference in the number of phone calls between the two groups throughout the first two weeks post-operatively. The mean number of calls from the inpatient group was 1.5 ± 0.5 (range: 0-11), while the outpatient group was 1.0 ± 0.3 (range: 0-6).

Another perceived disadvantage of outpatient discharge pathway is the fear of shifting the burden from experienced health professionals to the patient's caregiver. This theory was not supported by our data, as the reported number of hours of caregiver assistance was similar between inpatients and outpatients (25.3 ± 4.2 versus 28.0 ± 5.7; $p = 0.71$ respectively). One explanation for our findings may be that we only included patients with an ASA score ≤ 3 (inpatient: 2.2 ± 0.2, outpatient: 2.0 ± 0.1; $p = 0.34$); patients with a low ASA score tend to be more self-sufficient and capable of taking care of themselves[108].

We used the Pain Catastrophizing Scale[97] and the Self-Efficacy For Managing Chronic Disease 6-Item Scale[98] to potentially explain which patients may encounter greater difficulty with same day discharge. Sullivan et al.[97] found that high scores on the Pain

Catastrophizing Scale predicted a higher degree of patient-reported pain following surgery and contributed to a longer duration of disability immediately following the surgery. Furthermore, individuals who scored high on measures of pain catastrophizing tended to require a prolonged stay when hospitalized[97]. However, our study did not support an association between longer LOS and higher pain-catastrophizing scores for both the inpatient ($r = -0.14$) and outpatient ($r = 0.09$) groups.

Regarding self-efficacy, higher scores indicate patients that are more confident in their ability to deal with health problems[98], which is a crucial trait for outpatients. Our data did not support an association between longer LOS and lower self-efficacy scores for both the inpatient ($r = 0.17$) and outpatient ($r = 0.10$) groups. However, it's possible that our current small sample size and large variability between subjects in self-efficacy ratings, makes statistically finding a significant association more difficult.

This study is unique for its randomized methodological design, and emphasis on safety, cost and patient reported outcomes. To our knowledge, this is the first study to randomize patients undergoing a total hip replacement to either an inpatient or outpatient discharge pathway. The limited research comparing inpatient to outpatient THA include case series and non-randomized comparison groups which have a greater potential to introduce significant bias[3,10]. Furthermore, the two previous economic analyses involving outpatient THA had methodological flaws (i.e. non-randomized cohorts, small sample size and imbalance in patient demographics) and were conducted in the United States[3,10]. We conducted an economic analysis from multiple payer perspectives to understand specifically where cost savings occur. Therefore, this study is important for comparing inpatient and outpatient THA and can provide surgeons and associated health professionals with the information needed to make an informed decision when developing a same-day discharge pathway for patients undergoing a THA.

6.1 Limitations

The most prevalent limitation was the small sample size, which decreased the precision of the results. However, this was a preliminary analysis of a larger ongoing study.

Another limitation of our study was that it was completed at a single center with a single surgeon performing all of the surgeries. The median LOS in Canada following a THA is four days[46], while we used a comparison group with a median LOS of 29.1 hours (IQR=6.0), which reduces the external validity of our study, as our results may not be generalizable to the average health care center with longer LOS as part of standard of care. Furthermore, the use of a single surgeon introduces the possibility of expertise bias, which can impact procedure time and the availability of a specialized traction table.

With the small sample size of 43 patients, our analysis was overly sensitive to extreme cases. To avoid presenting a biased estimate of LOS, we were forced to remove one patient who suffered an intraoperative periprosthetic fracture and required hospitalization at Parkwood Hospital for over 12 weeks. Since a perioperative fracture is unrelated to the intervention, this patient was excluded from this analysis and was not analyzed according to intention-to-treat. Once the study has reached its full sample size, through the process of randomization, we expect similar proportions of patients within each group to suffer these types of unrelated complications; leaving the comparison of LOS between groups uninfluenced.

Logistically, outpatients were scheduled at 8:00 am or 10:00 am to give the patient sufficient time to meet discharge criteria during the day shift, whereas some inpatients were scheduled for 12:00 pm. Because at our institution inpatients are usually discharged at 11:00 am, a surgery at noon for inpatients meant that the LOS for these patients is shorter than patients scheduled for surgery in the morning (like all outpatients). Thus, the average inpatient LOS is decreased because of logistics rather than any effect of inpatient versus outpatient. However, even with this limitation outpatients had a statistically significant shorter LOS.

Finally, we originally asked caregivers to complete a questionnaire regarding caregiver burden following the hip replacement. However, this questionnaire was developed for caregivers of patients who had suffered a stroke[99], which meant that the majority of items were not relevant to the caregivers in our study since the degree of disability within our sample was not as great as patients post-stroke. For these reasons, we only reported the results of questions that we felt were relevant to our population and added a more suitable questionnaire part way through the study.

Chapter 7

7 Conclusion

We found no significant differences in serious adverse events between patients who followed an inpatient versus outpatient care pathway following THA. The outpatient group had a significantly shorter LOS than the inpatient group, which resulted in significantly lower costs from the perspective of the hospital and the MoH. Both groups reported similar scores for satisfaction, pain, quality of life and general health measures. A larger sample size is required to make any definitive conclusions.

7.1 Future Directions

For this study, we will complete the data collection to include 70 patients in each group for a total of 140 patients. The larger sample size will strengthen our results and provide more certainty around our estimates of effect size. Furthermore, we will introduce additional surgeons at our institution and additional health care centers to limit expertise bias, improve knowledge translation and increase the study's applicability.

Future research should include care centers with different patient volumes to ensure that outpatient THA discharge pathways are manageable across multiple settings and not strictly within academic centers. Another improvement is to include a caregiver component that properly assesses whether outpatient caregivers suffer an increased burden over their inpatient counterparts. Finally, previous research has reported that numerous surgical techniques can be used to safely and effectively perform outpatient joint replacements[16]. In the future, including surgeons that use different surgical techniques would be beneficial to assess the generalizability of outpatient hip replacement discharge pathways.

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Appendices

Appendix A: Lawson Final Approval Notice

LAWSON
HEALTH RESEARCH INSTITUTE

LAWSON FINAL APPROVAL NOTICE

LAWSON APPROVAL NUMBER: R-15-082

PROJECT TITLE: Patient satisfaction and costs associated with total hip arthoplasty

PRINCIPAL INVESTIGATOR: Dr. Brent Lanting

LAWSON APPROVAL DATE: May 27, 2015

Health Sciences REB#: 106362

Please be advised that the above project was reviewed by the Clinical Research Impact Committee and 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, [redacted]

cc: Administration

Appendix B: UWO REB Approval

Western Research

Research Ethics

Western University Health Science Research Ethics Board
HSREB Full Board Initial Approval Notice

Principal Investigator: Dr. Brent Lanting
Department & Institution: Schulich School of Medicine and Dentistry\Orthopaedic Surgery,London Health Sciences Centre

HSREB File Number: 106362
Study Title: Patient Satisfaction and Costs Associated with Total Hip Arthroplasty
Sponsor:

HSREB Initial Approval Date: May 11, 2015
HSREB Expiry Date: May 11, 2016

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Letter of Information & Consent	Clean LOI	2015/04/14
Data Collection Form/Case Report Form	Section I - Cost	2015/02/06
Data Collection Form/Case Report Form	Section J - Cost	2015/02/06
Data Collection Form/Case Report Form	Section G - Cost	2015/02/06
Data Collection Form/Case Report Form	Section H - Cost	2015/02/06
Data Collection Form/Case Report Form	Section D - cost	2015/02/06
Data Collection Form/Case Report Form	Section E - Cost	2015/02/06
Data Collection Form/Case Report Form	Section F - Cost	2015/02/06
Data Collection Form/Case Report Form	Section C - cost	2015/02/06
Data Collection Form/Case Report Form	Section A - Cost	2015/02/06
Data Collection Form/Case Report Form	Section B - Cost	2015/02/06
Data Collection Form/Case Report Form	Patient Flow	2015/02/06
Data Collection Form/Case Report Form	Patient Satisfaction	2015/02/06
Data Collection Form/Case Report Form	Screening Form	2015/02/06
Data Collection Form/Case Report Form	Numeric Pain Rating Score	2015/02/06
Data Collection Form/Case Report Form	Pain Catastrophizing	2015/02/06
Data Collection Form/Case Report Form	Patient Demographics	2015/02/06
Data Collection Form/Case Report Form	Expectations Post	2015/02/06
Data Collection Form/Case Report Form	Expectations Pre	2015/02/06
Data Collection Form/Case Report Form	Harris Hip Score	2015/02/06
Data Collection Form/Case Report	Charlson Comorbidity	2015/02/06

[redacted]

Western Research

Research Ethics

Form	Index	
Data Collection Form/Case Report Form	Daily Diary	2015/02/06
Data Collection Form/Case Report Form	Caregiver Burden	2015/01/21
Data Collection Form/Case Report Form	CAS	2015/02/06
Other	Revised Debriefing - clean	2015/03/16
Data Collection Form/Case Report Form	Adverse Events Follow Up	2015/02/06
Data Collection Form/Case Report Form	Adverse Events Report	2015/02/06
Data Collection Form/Case Report Form	Surgical Information Form	2015/02/06
Data Collection Form/Case Report Form	WOMAC	2015/02/06
Data Collection Form/Case Report Form	SF-12	2015/02/06
Data Collection Form/Case Report Form	Self Efficacy	2015/02/06
Western University Protocol	Received March 17/15	

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

[redacted]

Ethics Officer to Contact for Further Information

Erika Basile	Grace Kelly	Mina Mekhail	Vikki Tran

[redacted]

This is an official document. Please retain the original in your files.

[redacted]

Appendix C: Letter of Information

Letter of Information

Study Title: Patient Satisfaction and Costs Associated with Total Hip Arthroplasty

Principle Investigators:

Brent Lanting, MD FRCSC
London Health Sciences Centre
University Hospital
London, ON
[redacted]

James Howard, MD FRCSC
London Health Sciences Centre
University Hospital
London, ON
[redacted]

INTRODUCTION
You are being invited to participate in a research study because you are undergoing total hip arthroplasty (THA).

In order to decide whether or not you want to be part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your family physician.

PURPOSE
The purpose of this study is to evaluate costs and early complications associated with hip replacement surgery. There will be 70 patients enrolled in this study. Your participation will last approximately 3 months. Each visit with the surgeon will take approximately 60 minutes of your time. The length of the visit is not affected by your decision to participate in this study.

DESCRIPTION OF STUDY
The total time commitment of the study is 3 months. Visits for this study will coincide with follow-up visits that you would already attend with your surgeon after your surgery. We will ask you to fill out questionnaires that will assess satisfaction, functional ability, quality of life, pain and any complications. Furthermore, you will be required to keep a diary to capture costs for the first 2 weeks following discharge from the hospital. This diary will ask you to report any emergency room visits, any hospitalizations; visits to various healthcare professionals; tests, procedures, surgeries; medications and any cost incurred by your caregiver.

_____
Participant's Initials

RISKS
There are no known risks to your participation in this study. Participation is voluntary. Standard anesthetic and surgical risks that apply in standard practice will apply to study participants. There is no additional imaging, follow-up visits coincide with our standard visit schedule and participants can opt out of any questionnaires that make them uncomfortable.

BENEFITS
There are no known benefits to you for participating in this study; however, possible benefits may include decrease in pain levels and increase in function of the hip joint. The findings from this study will contribute to our improvement in the treatment of future patients undergoing THA. This study will identify if there is a new, safe and efficient method to THA that can improve satisfaction, while also minimizing costs.

CONFIDENTIALITY
Any personal health information collected or other information related to you will be coded by 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.

The data that is collected from you is managed by a company called EmPower Health Research. Any information provided by you is protected by a username and password. It travels in a scrambled format to a server (storage computer) that is located in Montreal, Canada. Your email address and your date of birth are part of this database. The database will send automatic reminder emails to you if you are required to login and answer questions. Instructions for logging into the database will be provided by the research assistant. The company that houses the database is a professional company with extremely high standards of physical and virtual security. We want to let you know however, that even with this high level of security, there is always a remote chance that your information could be accessed or "hacked" by someone who is not supposed to have your information. If we became aware that this had happened, we would inform you immediately.

Study data will be kept for seven 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: Michael Pollock, a[redacted]

_____
Participant's Initials

London Health Sciences Centre

COST/COMPENTSATION
There are no additional costs to you for participating in this study. There is no compensation for participating in this study. The assessments for this study will coincide with your routine follow-ups with your surgeon.

CONTACT FOR QUESTIONS
If you have any questions about your rights as a research participant or the conduct of this study, you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute [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 research assistant Michael Pollock, at [redacted]

This letter is yours to keep for future reference. Thank you for considering participation in this study. We appreciate your time and interest.

Sincerely,

Dr. Brent Lanting, MD
Dr. James Howard, MD
Dr. Dianne Bryant, PhD
Michael Pollock, MSc (can.)

_____
Participant's Initials

Letter of Consent

Study Title: Patient Satisfaction and Costs Associated with Total Hip Arthroplasty

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.

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date
_____	_____	_____
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

_____
Participant's Initials

Appendix D: Letter of Debriefing - Inpatient

Letter of Information

Study Title: Patient Satisfaction and Costs Associated with Total Hip Arthroplasty

Principle Investigators:

Brent Lanting, MD FRCSC
London Health Sciences Centre
University Hospital
London, ON
[redacted]

James Howard, MD FRCSC
London Health Sciences Centre
University Hospital
London, ON
[redacted]

YOU WERE RANDOMIZED TO: Inpatient

BACKGROUND INFORMATION AND PURPOSE
Patient satisfaction is one of the key components to a successful total hip arthroplasty (THA). Satisfaction refers to the feeling of achieved expectations with regards to pain and functional outcome. Furthermore, although THA is an established and proven treatment that frequently yields excellent results, shortening hospital stays is an important solution to the high cost of hip replacement surgery. Many important strides have been recently made in arthroplasty, such as smaller incisions and rapid recovery. The goal of these changes is to provide patients with earlier control of their independence, while also providing greater relief of anxiety. Rapid rehabilitation and earlier discharge protocols have allowed patients to feel more control of their body and ultimately improve their satisfaction. A further potential advantage of shortened length of stay in hospitals is the decreased cost to the patient and to the healthcare system.

We are interested in evaluating patient satisfaction and costs associated with outpatient versus inpatient THA. In order to test the effectiveness of length of stay following THA, we must compare the outcomes of similar patients who receive usual care. The study that you took part in was part of this clinical trial. A random selection process (similar to flipping a coin) allocated you to the inpatient group. At the beginning of the study, you were not informed that the random selection process had taken place as it was felt that this information may influence your perception of the care you were receiving and your perception of your outcome. Let us reassure you that you received the same care as patients who were not research participants (usual care). 70 patients took part in this study, 35 stayed overnight following THA (inpatient) and the other 35 were discharged the same day (outpatient).

_____
Participant's Initials

London Health Sciences Centre

RISKS
Standard anesthetic and surgical risks that apply in standard practice will apply to study participants. Both procedures are currently being conducted in North America and do not represent a new or novel technique that has not been tested in humans. There is no additional imaging, follow-up visits coincide with our standard visit schedule and participants can opt out of any questionnaires that make them uncomfortable.

BENEFITS
You may receive benefit from being part of the outpatient group. The findings from this study will contribute to our improvement in the treatment of future patients undergoing THA. This study will identify if there is a new, safe and efficient method to THA that can improve satisfaction, while also minimizing costs.

CONFIDENTIALITY
If you would like a copy of the study results, please indicate this on the consent form. All information obtained during the course of this study is strictly confidential and your identity is protected at all times. You will be identified by a code based on the date of entry into the study and a project identifier. Data is stored in locked files and is available only to the investigators associated with this study. You will not be identified in any publication, presentation or reports. Unless your consent is given, the information or data collected for this study will not be used for any other purpose than for research. 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.

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: Michael Pollock, at[redacted]

COST/COMPENTSATION
There are no additional costs to you for participating in this study. There is no compensation for participating in this study. The assessments for this study will coincide with your routine follow-ups with your surgeon.

_____
Participant's Initials

London Health Sciences Centre

CONTACT FOR QUESTIONS

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 research assistant Michael Pollock, at [redacted]

This letter is yours to keep for future reference. Thank you for considering participation in this study. We appreciate your time and interest.

Sincerely,

Dr. Brent Lanting, MD
Dr. James Howard, MD
Dr. Dianne Bryant, PhD
Michael Pollock, MSc (can.)

_____
Participant's Initials

TITLE OF PROJECT: Patient Satisfaction and Costs Associated with Total Hip Arthroplasty

I have read the debriefing letter of information, have had the nature of the study explained to me, and I agree for my data to be used in the study. All questions have been answered to my satisfaction.

Printed Name of Participant	Signature of Participant	Date
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Possibility of future research

There may be future opportunities for you to participate in ongoing research. If you are interested in being contacted, please check the appropriate box below. If contacted, you will be asked to read a new letter of information and sign a new consent form.

□ Please do not keep my name and contact information. I do not wish to be contacted in the future.
□ Please keep my name and contact information so that I may be contacted to learn about future research opportunities or have access to my data in the future.

Copy of Study Results

I would like a copy of the study results. Yes ☐ No ☐
If yes, please write your mailing address below.

_____
_____
_____
_____

_____
Participant's Initials

Appendix E: Letter of Debriefing - Outpatient

Letter of Information

Study Title: Patient Satisfaction and Costs Associated with Total Hip Arthroplasty

Principle Investigators:

Brent Lanting, MD FRCSC
London Health Sciences Centre
University Hospital
London, ON
[redacted]

James Howard, MD FRCSC
London Health Sciences Centre
University Hospital
London, ON
[redacted]

YOU WERE RANDOMIZED TO: Outpatient

BACKGROUND INFORMATION AND PURPOSE
Patient satisfaction is one of the key components to a successful total hip arthroplasty (THA). Satisfaction refers to the feeling of achieved expectations with regards to pain and functional outcome. Furthermore, although THA is an established and proven treatment that frequently yields excellent results, shortening hospital stays is an important solution to the high cost of hip replacement surgery. Many important strides have been recently made in arthroplasty, such as smaller incisions and rapid recovery. The goal of these changes is to provide patients with earlier control of their independence, while also providing greater relief of anxiety. Rapid rehabilitation and earlier discharge protocols have allowed patients to feel more control of their body and ultimately improve their satisfaction. A further potential advantage of shortened length of stay in hospitals is the decreased cost to the patient and to the healthcare system.

We are interested in evaluating patient satisfaction and costs associated with outpatient versus inpatient THA. In order to test the effectiveness of length of stay following THA, we must compare the outcomes of similar patients who receive usual care. The study that you took part in was part of this clinical trial. A random selection process (similar to flipping a coin) allocated you to the outpatient group. At the beginning of the study, you were not informed that the random selection process had taken place as it was felt that this information may influence your perception of the care you were receiving and your perception of your outcome. Let us reassure you that you received the same care as patients who were not research participants (usual care). 70 patients took part in this study, 35 stayed overnight following THA (inpatient) and the other 35 were discharged the same day (outpatient).

_____
Participant's Initials

RISKS
Standard anesthetic and surgical risks that apply in standard practice will apply to study participants. Both procedures are currently being conducted in North America and do not represent a new or novel technique that has not been tested in humans. There is no additional imaging, follow-up visits coincide with our standard visit schedule and participants can opt out of any questionnaires that make them uncomfortable.

BENEFITS
You may receive benefit from being part of the outpatient group. The findings from this study will contribute to our improvement in the treatment of future patients undergoing THA. This study will identify if there is a new, safe and efficient method to THA that can improve satisfaction, while also minimizing costs.

CONFIDENTIALITY
If you would like a copy of the study results, please indicate this on the consent form. All information obtained during the course of this study is strictly confidential and your identity is protected at all times. You will be identified by a code based on the date of entry into the study and a project identifier. Data is stored in locked files and is available only to the investigators associated with this study. You will not be identified in any publication, presentation or reports. Unless your consent is given, the information or data collected for this study will not be used for any other purpose than for research. 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.

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: Michael Pollock, at[redacted]

COST/COMPENTSATION
There are no additional costs to you for participating in this study. There is no compensation for participating in this study. The assessments for this study will coincide with your routine follow-ups with your surgeon.

_____
Participant's Initials

London Health Sciences Centre

CONTACT FOR QUESTIONS

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 research assistant Michael Pollock, at [redacted]

This letter is yours to keep for future reference. Thank you for considering participation in this study. We appreciate your time and interest.

Sincerely,

Dr. Brent Lanting, MD
Dr. James Howard, MD
Dr. Dianne Bryant, PhD
Michael Pollock, MSc (can.)

_____
Participant's Initials

TITLE OF PROJECT: Patient Satisfaction and Costs Associated with Total Hip Arthroplasty

I have read the debriefing letter of information, have had the nature of the study explained to me, and I agree for my data to be used in the study. All questions have been answered to my satisfaction.

Printed Name of Participant	Signature of Participant	Date
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Possibility of future research

There may be future opportunities for you to participate in ongoing research. If you are interested in being contacted, please check the appropriate box below. If contacted, you will be asked to read a new letter of information and sign a new consent form.

□ Please do not keep my name and contact information. I do not wish to be contacted in the future.
□ Please keep my name and contact information so that I may be contacted to learn about future research opportunities or have access to my data in the future.

Copy of Study Results

I would like a copy of the study results. Yes ☐ No ☐
If yes, please write your mailing address below.

_____
_____
_____
_____

_____
Participant's Initials

Appendix F: Inpatient Pamphlet

What to Expect in Hospital

After surgery, our team will teach and review with you:

- How to safely get in and out of bed. This may occur on the same day as surgery
- Walking and how to properly use the walking aid you will use when you return home
- If you have stairs to manage at home, you will be instructed on the correct technique to safely go up and down
- Exercises you will be responsible for when you leave the hospital
- How to manage your incision, pain medication and blood thinner injections
- Things to watch for when you return home
- Any further equipment needs you may have

Contact Information

Office of Dr. B. Lanting

[redacted]

Rorabeck Bourne Joint Replacement Clinic

[redacted]

[redacted]

[redacted]

NS6941 (Rev. 2014/08/23)

London Health Sciences Centre

Patient Information

Total Hip Replacement

Direct Anterior Approach

Information and Exercises for patients of Dr. Lanting

UNIVERSITY HOSPITAL

ORTHOPAEDIC SURGERY

Direct Anterior Approach

A total hip replacement using the Direct Anterior (modified Heuter or short Smith-Petersen) Approach involves making an incision along the front of the pelvis extending down 8-10cm to the upper thigh and uses x-rays during surgery. Referred to as "muscle sparing", the approach is between muscles, but often requires the release of a small muscle behind the hip and may require a release and repair of the rectus femoris muscle.

After Surgery

When walking, you will be allowed to bear as much weight as you can tolerate through your operated leg. Initially, you may require the use of an aid to assist with your walking, like crutches or a cane. As your walking improves, you may stop using the aids at any time.

If you have had both hips replaced during the same surgical procedure, then use a walker for 4 weeks.

Going Home

It is possible that you will discharged home the same day as your surgery. If you remain in hospital overnight, it is anticipated you will be discharged home the day after surgery.

NO driving until your 6 week follow-up with Dr. Lanting.

Your Incision

The incision will have steri-strips with a clear dressing. This will remain in place until your 2 week follow-up with Dr. Lanting.

NO showering until your 2 week follow-up appointment.

NO baths, pools or hot tubs until your 6 week follow-up appointment.

Once the dressing and steri-strips have been removed, **DO NOT** apply any lotions, ointments or creams over the incision for 4 weeks.

Exercises after Surgery

A physiotherapist will see you after surgery and teach you exercises that are appropriate to begin.

When you are discharged from the hospital, you will follow-up with a physiotherapist within 1-2 weeks and they will instruct you on how to progress with your rehabilitation.

a) Lying on your back or sitting with your legs on the bed –

1. Bend your knee by sliding your heel back as far as you can (You may use a towel or sheet around your foot for assistance)
2. **REPEAT 10x**

b) Lying on your back with your knee straight –

1. Tighten the muscle on the front of your thigh and press the back of your knee into the bed
2. Hold 5-10 seconds
3. **REPEAT 10x**

c) Lying on your back –

1. Place a rolled towel underneath your knee (6 inch diameter)
2. Pull your toes up and lift your heel off the bed keeping your knee on the roll
3. Hold 5-10 seconds
4. **REPEAT 10x**

d) Lying on your back with the big toe on your operated leg pointed towards the ceiling –

1. Slide you operated leg out sideways
2. **REPEAT 10x**

Appendix G: Outpatient Pamphlet

What to Expect in Hospital

After surgery, our team will teach and review with you:

- How to safely get in and out of bed
- Walking and how to properly use the walking aid you will use when you return home
- If you have stairs to manage at home, you will be instructed on the correct technique to safely go up and down
- Exercises you will be responsible for when you leave the hospital
- How to manage your incision and dressing
- How to manage your pain and blood thinning medications
- Things to watch for when you return home
- Any further equipment needs you may have

Contact Information

If you have any problems the evening of your surgery, please call 519-685-8500 and ask to speak to the Orthopaedic Resident ON CALL

Office of Dr. B. Lanting
[redacted]

Office of Dr. J. Howard
[redacted]

Rorabeck Bourne Joint
[redacted]

Physiotherapy Department
[redacted]

www.lhsc.on.ca/jointreplacement

NS7276 (Rev. 2016/05/09)

London Health Sciences Centre

Patient Information

OUTPATIENT
Total Hip Replacement

Direct Anterior Approach

Information and Exercises

London Health Sciences Centre
University Hospital
ORTHOPAEDIC SURGERY

Direct Anterior Approach

A total hip replacement using the Direct Anterior (modified Heuter or short Smith-Petersen) Approach involves making an incision along the front of the pelvis extending down 8-10cm to the upper thigh and using x-rays during surgery. The approach is often called a muscle sparing approach as the approach is between muscles, but does require the release of a small muscle behind the hip and often may require a release and repair of the rectus femoris muscle.

After Surgery

When walking, you will be allowed to bear as much weight as you can tolerate through the surgical leg. Initially, you may require the use of an aid to assist with your walking, like crutches or a cane. As your walking improves, you may stop using the aids at any time.

Going Home

It is anticipated that you will be discharged home the day of your surgery.

NO driving until your 6 week follow-up with your surgeon.

Your Incision

The incision will be closed with either an absorbable suture and steri-strips or staples. The dressing will remain in place until your 2 week follow-up with your surgeon.

NO showering until your 2 week follow-up appointment.

NO baths, pools or hot tubs until your 6 week follow-up appointment.

Once the dressing and steri-strips have been removed, **DO NOT** apply any lotions, ointments or creams over the incision for 4 weeks.

Exercises after Surgery

A physiotherapist may see you after surgery and teach you exercises that are appropriate to begin.

When you are discharged from the hospital, you will follow-up with a physiotherapist within 1-2 weeks and they will instruct you on how to progress with your rehabilitation.

a) Lying on your back or sitting with your legs on the bed –

1. Bend your knee by sliding your heel back as far as you can (You may use a towel or sheet around your foot for assistance)
2. **REPEAT 10x**

b) Lying on your back with your knee straight –

1. Tighten the muscle on the front of your thigh and press the back of your knee into the bed
2. Hold 5-10 seconds
3. **REPEAT 10x**

c) Lying on your back –

1. Place a rolled towel underneath your knee (6 inch diameter)
2. Pull your toes up and lift your heel off the bed keeping your knee on the roll
3. Hold 5-10 seconds
4. **REPEAT 10x**

d) Lying on your back with the big toe on your operated leg pointed towards the ceiling –

1. Slide your operated leg out sideways
2. **REPEAT 10x**

Appendix H: Permission from JBJS to Use Systematic Review

RIGHTS FOR AUTHORS

Permission from The Journal of Bone and Joint Surgery, Inc. (JBJS) is not required for the following uses:

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contact healthpermissions@wolterskluwer.com.

Appendix I: Patient Satisfaction Questionnaire

Patient Satisfaction

Q1. Upon discharge from the hospital, indicate how safe you felt moving about the house, including going to the bathroom or washing yourself?

- ◯ Completely Unsafe
- ◯ Unsafe
- ◯ Somewhat unsafe
- ◯ Neither safe nor unsafe
- ◯ Somewhat safe
- ◯ Safe
- ◯ Completely safe

Q2. After surgery, the overall effectiveness of your pain control medications **received in hospital** at relieving your pain was:

- ◯ Completely ineffective
- ◯ Mostly ineffective
- ◯ Somewhat ineffective
- ◯ Neither effective nor ineffective
- ◯ Somewhat effective
- ◯ Mostly effective
- ◯ Completely effective

Q3. After surgery, the overall effectiveness of your pain control medications **taken at home** in relieving your pain was:

- ◯ Completely ineffective
- ◯ Mostly ineffective
- ◯ Somewhat ineffective
- ◯ Neither effective nor ineffective
- ◯ Somewhat effective
- ◯ Mostly effective
- ◯ Completely effective

Q4. How much stress did you experience due to uncontrolled pain after your surgery? If completing in hard copy, please mark your pain with a slash across the line (/).

No stress 1 _____ 100 Extreme stress

Q5. How bad were the side effects from the pain medications you used either in hospital or at home in the week after surgery (i.e., constipation, inability to void, drowsiness, nausea or vomiting, itching)?

No side effects 1 _____ 100 Extreme side effects

Q6. In your opinion, how would you rate the overall quality of the nursing care that you received in hospital?

- ◯ Completely dissatisfied
- ◯ Mostly dissatisfied
- ◯ Somewhat dissatisfied
- ◯ Neither satisfied nor dissatisfied
- ◯ Somewhat satisfied
- ◯ Mostly satisfied
- ◯ Completely satisfied

Q7. Did you have any questions or concerns about your surgery or postoperative care that were not addressed **before** your surgery?

- ◯ No
- ◯ Yes

So we can improve our education programs in the future, please list your questions:

Q8. . Did you have any questions or concerns about your surgery or postoperative care that were not addressed **after** your surgery, but **before** discharge from hospital?

- ◯ No
- ◯ Yes

So we can improve our education programs in the future, please list your questions:

Q9. Do you feel you were given enough information to know what to expect after you were discharged in terms of your **rehabilitation**?

- ◯ Completely dissatisfied
- ◯ Mostly dissatisfied
- ◯ Somewhat dissatisfied
- ◯ Neither satisfied nor dissatisfied
- ◯ Somewhat satisfied
- ◯ Mostly satisfied
- ◯ Completely satisfied

Q10. Do you feel you were given enough information to know what to expect after you were discharged in terms of your **dressing changes**?

- ◯ Completely dissatisfied
- ◯ Mostly dissatisfied
- ◯ Somewhat dissatisfied
- ◯ Neither satisfied nor dissatisfied
- ◯ Somewhat satisfied
- ◯ Mostly satisfied
- ◯ Completely satisfied

Q11. Do you feel you were given enough information to know what to expect after you were discharged in terms of the **amount of pain**?

- ◯ Completely dissatisfied
- ◯ Mostly dissatisfied
- ◯ Somewhat dissatisfied
- ◯ Neither satisfied nor dissatisfied
- ◯ Somewhat satisfied
- ◯ Mostly satisfied
- ◯ Completely satisfied

Q12. Consider the length of time you stayed in the hospital. My length of stay was:

- ◯ I would have preferred to stay another day or two
- ◯ I would have preferred to stay a few more hours to another day
- ◯ My stay was just right
- ◯ I would have preferred to go home a day or a few hours sooner
- ◯ I would have preferred to go home the same day as my procedure

Q13. Did you receive adequate feedback from your surgeon regarding the results of your surgery (i.e., in the recovery room, ward)?

- ◯ Completely dissatisfied
- ◯ Mostly dissatisfied
- ◯ Somewhat dissatisfied
- ◯ Neither satisfied nor dissatisfied
- ◯ Somewhat satisfied
- ◯ Mostly satisfied
- ◯ Completely satisfied

Q14. Was your surgeon available and easily accessible if you needed him or her after your surgery?

- ◯ Completely dissatisfied
- ◯ Mostly dissatisfied
- ◯ Somewhat dissatisfied
- ◯ Neither satisfied nor dissatisfied
- ◯ Somewhat satisfied
- ◯ Mostly satisfied
- ◯ Completely satisfied

Q15. Please comment on the quality of sleep you achieved on the first night following your surgery

- ◯ I didn’t get any sleep
- ◯ I awoke feeling very unrested
- ◯ I awoke feeling somewhat unrested
- ◯ Neutral
- ◯ I awoke feeling somewhat rested
- ◯ I awoke feeling very rested

Q16. Overall, I would rate the quality of care that I received **before** surgery as:

Best care possible 1 _____ 100 Worst care possible

Q17. Overall, I would rate the quality of care that I received **after** surgery as:

Best care possible 1 _____ 100 Worst care possible

Q18. Considering all factors (i.e., preoperative teaching, nursing, doctors, hospital) **how satisfied were you as a patient** with the arthroplasty surgery, from the time you first met your surgeon and including up until the second week after your surgery?

- ◯ Completely dissatisfied
- ◯ Mostly dissatisfied
- ◯ Somewhat dissatisfied
- ◯ Neither satisfied nor dissatisfied
- ◯ Somewhat satisfied
- ◯ Mostly satisfied
- ◯ Completely satisfied

Q19. How strongly would you feel about recommending this procedure (THA) to a friend or family member?

Recommend to everyone 1 _____ 100 Never recommend to anyone

Q20. If you had a choice, how willing would you be to have this procedure (THA) done again under the same circumstances?

- ◯ Not at all likely
- ◯ Slightly likely
- ◯ Moderately likely
- ◯ Very likely
- ◯ Completely likely

Appendix J: Image Permission

From: **Permissions** Permissions[redacted]
Subject: RE: Permission to Use Copyrighted Material in a Master's Thesis - Michael Pollock
Date: June 20, 2016 at 2:52 PM
To: Michael Pollock [redacted]

Dear Michael,

You have our permission to use the CJS Figures 1 and 2 in your thesis.

The Royalty fee has been waived.

Please provide credit to the full article.

Janis Murrey
Program Manager Journals
La gestionnaire de programme, Journaux

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From: Michael Pollock [mailto[redacted]
Sent: June-20-16 2:18 PM
To: Permissions
Subject: Permission to Use Copyrighted Material in a Master's Thesis

Dear Canadian Journal of Surgery:

I am a University of Western Ontario graduate student completing my Master's thesis entitled "Inpatient versus Outpatient Total Hip Arthroplasty". My thesis will be available in full-text on the internet for reference, study and / or copy. Except in situations where a thesis is under embargo or restriction, the electronic version will be accessible through the Western Libraries web pages, the Library's web catalogue, and also through web search engines.I will also be granting Library and Archives Canada and ProQuest/UMI a non-exclusive license to reproduce, loan, distribute, or sell single copies of my thesis by any means and in any form or format. These rights will in no way restrict republication of the material in any other form by you or by others authorized by you.

I would like permission to allow inclusion of the following material in my thesis: Figure 1 (Example of the specialized table used during a direct anterior approach) and Figure 2 (The skin incision used for the direct anterior approach to the hip) from “Petis S, Howard JL, Lanting BL, Vasarhelyi EM. Surgical approach in primary total hip arthroplasty: anatomy, technique and clinical outcomes, Canadian Journal of Surgery, Vol. 58(2), pp. 128-139, 2015."

The material will be attributed through a citation.

Please confirm in writing or by email that these arrangements meet with your approval.

Sincerely,

Michael Pollock

--

Michael Pollock, BSc
MSc Candidate
Department of Kinesiology
University Hospital
Western University
[redacted]

Curriculum Vitae

Michael Pollock

EDUCATION

Master of Science	Kinesiology, Integrative Biosciences *Collaborative Musculoskeletal Health Research* Western University, London, Ontario, Canada September 2014 – August 2016
Bachelor of Science	Kinesiology Western University, London, Ontario, Canada Class of 2014

RESEARCH EXPERIENCE

Western University Graduate Student 2014-2016	Inpatient versus Outpatient Total Hip Arthroplasty *Supervisors: Dr. Dianne Bryant and Dr. Brent Lanting*
Western University Graduate Student 2014-2016	Femoroacetabular Impingement Randomized Controlled Trial *Supervisors: Dr. Douglas Naudie and Dr. Dianne Bryant*
Western University Graduate Student 2015-2016	A Comprehensive Review of Outpatient Total Hip Arthroplasty via a Qualitative Review of all Involved Stakeholders *Supervisors: Dr. Dianne Bryant, Dr. Brent Lanting and Dr. Debbie Rudman*
Western University Graduate Student 2014-2016	Outpatient Total Hip Arthroplasty, Total Knee Arthroplasty and Unicompartmental Knee Arthroplasty: A Systematic Review of the Literature *Supervisors: Dr. Brent Lanting and Dr. Lyndsay Somerville*
Western University Undergraduate Student 2013-2014	Pulmonary O_2 Uptake Kinetics in Hypoxia: Effect of Hyperventilation-Induced Hypocapnic Alkalosis During Moderate-Intensity Cycling Exercise *Supervisors: Dr. John Kowalchuk and Dr. Daniel Keir*

PUBLICATIONS:

M. Pollock, L. Somerville, A. Firth, B. Lanting. Outpatient total hip arthroplasty, total knee arthroplasty and unicompartmental knee arthroplasty – a systematic review of the literature. *JBJS Reviews*. (In press).

CONFERENCES

Toronto, Ontario May, 2016	Bodies of Knowledge Graduate Student Conference *Oral Presentation:* Inpatient versus outpatient total hip arthroplasty
Amsterdam, The Netherlands April 2016	Osteoarthritis Research Society International 2016 *Poster presentation:* Outpatient total hip arthroplasty, total knee arthroplasty and unicompartmental knee arthroplasty – a systematic review of the literature
London, Ontario April 2016	2016 Canadian Bone and Joint Conference *Poster presentation:* Outpatient total hip arthroplasty, total knee arthroplasty and unicompartmental knee arthroplasty – a systematic review of the literature
London, Ontario April 2015, 2016	Kinesiology Graduate Students Association Symposium *Oral Presentation:* Inpatient versus outpatient total hip arthroplasty *Poster Presentation:* Inpatient versus outpatient total hip arthroplasty
London, Ontario March 2015, 2016	Faculty of Health Sciences Research Day *Poster presentation:* Outpatient total hip arthroplasty, total knee arthroplasty and unicompartmental knee arthroplasty – a systematic review of the literature *Poster Presentation:* Inpatient versus outpatient total hip arthroplasty

London, Ontario May 2015	Western University Bone and Joint Research Retreat *Poster Presentation:* Inpatient versus outpatient total hip arthroplasty

RELATED WORK EXPERIENCE

Western University Teaching Assistant *Fall 2015, Winter 2016*	KIN 3336A/B: Practical Aspects of Athletic Injuries Professor Dave Humphreys *Lecturer:* Major Sport Injuries – Surgical and Alternative Treatments
Western University Teaching Assistant *Winter 2015*	KIN 2236B: Intro to Athletic Injuries Professor Dave Humphreys *Lecturer:* Osteoarthritis and the Injured Athlete
Western University Teaching Assistant *Fall 2014*	KIN 3330F: Lab in Exercise Physiology Professor John Kowalchuk

HONOURS AND AWARDS

Western University 2015-2016	Transdisciplinary Bone and Joint Research Scholarship
Western University 2014-2016	Western Graduate Research Scholarship
Western University 2014	Graduated with Distinction
Western University 2010-2014	Dean's Honour List