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Daily Physical Activity early after Total Hip Arthroplasty

A comparison of daily physical activity in patients undergoing different surgical approaches in a prospective cohort study

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Abstract

Background: Daily physical activity early after total hip arthroplasty (THA) is important to prevent postoperative complications and reduce negative consequences of inactivity. The extent of muscle weakness after THA caused by the surgical approach is suggested as a factor for how physically active patients are early after surgery. **Purpose:** The purpose of this study was to compare daily physical activity in three groups of THA patients undergoing different surgical approaches in a fast track treatment course early after hospital discharge to home. **Material and Methods:** This prospective cohort study included a total of 63 participants with unilateral hip osteoarthritis under the age of 70 years. Participants were allocated to the direct lateral approach (DLA), the posterior approach (PA), and the anterior approach (AA). Daily physical activity was measured by body-worn activity monitors, activPALs, attached on the participants' thigh during the first four days after hospital discharge. Primary outcome was time in upright positions per 24 hours. Secondary outcomes were time in walking, time in standing, number of steps, and number of upright events per 24 hours. **Results:** A total of 61 (n=23, DLA; n=19, PA; n=19, AA) participants (mean age 56.2, SD 8.4 years) completed the activity monitoring and were included in the final analyses. There were no significant group differences in any of the measures of daily physical activity (p's>0.153). Participants showed a large variation in time in upright positions (median 3.53, IQR 2.91-4.81 hours), as well as the secondary outcome measures of daily physical activity. **Conclusions:** There was no difference in daily physical activity early after surgery between THA patients undergoing DLA, PA and AA in a fast-track treatment course. However, the patients spent a relatively high amount of time being physically active.

Relevance

There is an increasing amount of THA surgeries performed worldwide, and there are constantly improvements regarding implants and surgical techniques. Previous research on the impact of different surgical approaches has mainly focused on complications and various outcomes showing what patients are able to perform early after surgery. The actual amount of physical activity during a day has scarcely been assessed. The present study contributes within the field of orthopedic surgery and rehabilitation with objective measures of daily physical activity early after hospital discharge to home in THA patients undergoing three different surgical approaches in a fast-track treatment course providing supplementary information about the different surgical approaches' impact on early recovery.

Abbreviations

THA	Total hip arthroplasty
HOA	Hip osteoarthritis
DLA	Direct lateral approach
PA	Posterior approach
AA	Anterior approach
HHS	Harris Hip Score
ETUG	Expanded Timed Up and Go
HOOS-PS	Hip Disability and Osteoarthritis Outcome Score - Physical Function Short forms

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1 Background

1.1 Introduction

An increasing amount of total hip arthroplasty (THA) surgeries are performed in people under the age of 70 years. According to the annual report from the Norwegian National Arthroplasty Register, 57% of the THA surgeries in 2013 was performed in patients younger than 70 years (1). THA was initially designed for elderly patients with low mobility, having pain relief as the primary goal (2). But advances in surgical techniques and improved material design have now broadened the indications resulting in an increased amount of younger patients scheduled for surgery. The increasing amount of younger and more mobile patients, leads to different demands regarding physical activity expectations after surgery. In addition to pain relief they want to return to work and a physical active life style as soon as possible after the surgery (3, 4). In the early postoperative phase these patients are concerned about improving temporary limitations in daily life activities, and they desire functional improvements in the ability to walk and move around (5). Early post-operative mobilization, rapid recovery, and reduced hospital stay have gained more attention from a fast-track rehabilitation perspective in THA (6), where the aim is to ensure physically active patients early after surgery and shorten the time required until full recovery. The fast-track treatment course focuses on a multimodal rehabilitation with regional anaesthesia, opioid-sparing postoperative pain management, early mobilization, and thorough information to ensure that the patients play an active role in their own rehabilitation (7). The fast-track treatment course has resulted in a decrease in length of hospital stay after THA from seven-nine days to about two-four days (8, 9). A study from 2014 showed that 82% of the patients operated on at St. Olavs Hospital, Trondheim University Hospital were discharged directly to their homes with a mean of 3.1 days after fast-track THA surgery (10). Thus, it is important to be able to walk and perform daily life activities early after surgery. It is however little knowledge about the patients' actual physical activity early after THA surgery, information that could discover the patients quantity of physical activity including both exercises and activities of daily living. No studies have to our knowledge performed objective measurements on physical activity recognition early after hospital discharge to home.

Physical activity is defined as "any bodily movement produced by skeletal muscles that result in energy expenditure" (11), and is associated with health gain, including a lower risk of

diseases, and higher levels of independence in daily life (12). Bed rest is not desirable as it increases muscle loss and weakness, impairs pulmonary function and predisposes to venous thromboembolism. Short-term hospitalization of five days have shown to reduce patients' upper limb extremity muscular strength by 1.6 kg, forced vital capacity by 0.3 liters, and distance covered in the six-minutes walk test by 38.5 meters, even in patients not restricted to bed, regardless of age or initial functional status (13). A study on healthy older adults with a mean age of 67 years, showed that ten days bed rest lead to a significant reduction in lower extremity muscle strength of 13.2 % in knee extension, maximal aerobic capacity was 12% lower, and the percentage of time spent inactive increased from 54% to 62% on the day after bed rest was completed (14). It is also shown that immobilization following orthopedic surgery could increase the risk of postoperative deep vein thrombosis (15). To reduce the negative consequences of immobilization and prevent postoperative complications, it is therefore important to resume daily physical activity as early as possible after surgery. This is also in line with the rise in demand from younger, more mobile patients, with high expectations regarding early physical activity after surgery (3), and it is an essential element in the fast-track methodology (7).

There are several surgical approaches in THA, and the surgical approach has an impact on the traumatization of the hip muscles during surgery (16). It is believed that the extent of muscle weakness as a result of the trauma during surgery will have an impact on the amount of daily physical activity the patient is able to perform early after surgery. The direct lateral approach (DLA) is the most common method for THA in Norway where the prosthesis is inserted through a transgluteal muscle incision (17). Minimal invasive surgery is a relatively new method which provides an intermuscular and internervous exposure to the hip to decrease the soft tissue dissection and trauma (18). The anterior approach (AA) follows the principles of minimally invasive surgery with a short incision without dissection of muscles (19), while the posterior approach (PA) provides a mini-incision with a dissection of the external rotators of the hip (20). Minimal invasive surgery in combination with multimodal pain management and accelerated rehabilitation in line with the fast-track methodology, has led to a decrease in length of stay, higher rate of discharge directly to home, improvement in function as measured by the Harris Hip Score, and better early recovery in terms of ability to walk with crutches and practicing stairs earlier after THA compared to the traditional DLA (21-24). Further, patients undergoing the PA and AA had less reduction in muscular strength following

THA surgery compared to the patients undergoing the DLA the first postoperative week (25). However, studies have not evaluated the amount of physical activity early after surgery in these patients, which can indicate if the improved early recovery outcomes also have an impact on actual daily physical activity.

New technology with body-worn activity sensors can give information about daily physical activity in a continuous, unsupervised and objective manner throughout the day (26). Activity monitoring will provide information about what the patient actually does during a day. The study by Inoue et al. (2003) included activity registrations by body-worn activity monitors the first postoperative week, where colorectal surgery patients undergoing laparascopic surgery or classical open surgery participated. The study showed that the group receiving laparascopic surgery treatment spent more time being physically active early after surgery, and regained their preoperative physical activity levels three days earlier (third versus sixth day after surgery) as compared to the open surgery group (27). Another study using activity monitors, reported physical activity both before and the first 14 days after total knee arthroplasty surgery (TKA), showing that minimal invasive surgery resulted in more active patients and they spent shorter time regaining 80% of preoperative physical activity levels (third versus seventh day after surgery) compared to standard TKA (28).

Studies on THA patients have investigated the impact of different surgical approaches on clinical outcomes, for example time to mobilization, length of hospital stay and discharge to home versus rehab (22-24, 29-31). Muscle strength and physical function have been measured with various performance-based tests up to twelve weeks postsurgery (22, 24, 25, 29-31), to indicate patients functional status early after surgery. These commonly used outcome evaluations show what patients are able to perform, but what patients actually do during daily life is often not reported. A few studies have used activity monitoring to compare the levels of physical activity preoperatively and six months to four years after surgery (32-36). One study showed that post-discharge levels of daily physical activity early after fast-track total hip and knee arthroplasty was decreased compared to preoperative levels (37). No studies have to our knowledge investigated patients' physical activity in daily life early after different surgical approaches in fast-track THA.

The overall aim of this study was to evaluate daily physical activity early after hospital discharge in three groups receiving different surgical treatment approaches in THA. It was hypothesized that minimal invasive surgery in line with the AA to reduce the muscular trauma during surgery, would result in more physically active patients compared to DLA and PA. The scientific question was as follows:

Is there a difference in daily physical activity early after hospital discharge to home between three groups of total hip arthroplasty patients, undergoing different surgical approaches?

1.2 Theoretical Background

The theoretical framework for this study is presented in what follows. Definitions and introduction to key concepts including activity monitoring, aspects of recovery, daily physical activity both in end-stage hip osteoarthritis (HOA) patients and THA patients, and an introduction to fast-track THA surgery will be outlined.

1.2.1 Recovery after THA

Multiple factors affect early recovery after THA surgery. According to Kehlet and Wilmore (2002), factors that contribute to delayed recovery can be anxiety and fear, surgical stress response, pain, nausea, sleep disturbance and fatigue, while preoperative information, opioid sparing analgesia, minimally invasive operations, early feeding, and disturbance-free sleep time are factors that contribute to accelerated recovery (38).

To date, postoperative quality of recovery lacks a universally accepted definition and assessment technique. According to Bowyer et al. (2014) the term recovery is multidimensional and can be defined as "a return to the pre-surgery state or better". Recovery can be assessed in multiple domains, including function and activities of daily living (39). Hobbs et al. (2011) found that THA patient expectations of surgery focus on recovering valued activities as walking and performing activities of daily living rather than reversal of bodily impairments (4). Common measurements on early recovery in THA have been different outcomes of physical function. Physical function has often been an important factor also to explain daily physical activity for patients. A cross-sectional study in 116 Japanese aged 65-74 showed a significant positive association between physical function measured as

maximal walking speed, and physical activity in daily living measured as steps per day (40). Further, a recent study reported that daily physical activity in cancer patients was related to subjectively scored items of physical functioning and pain (41). In a study on THA and TKA patients early after discharge to home, the patients stated that the decreased function of the affected joint after surgery, was the most debilitating factor for their level of daily physical activity (37). The surgical approach has an impact on the traumatization of hip muscles during surgery (16), and is therefore thought to affect physical function which in turn can affect physical activity in daily life early after surgery.

1.2.2 Activity Monitoring

Several methods are available to collect information about physical activity. Questionnaires and interviews have long been preferred as methods for studying physical activity. The challenge of questionnaires and interviews is that one must rely on the participants' ability to remember correctly and the questions can be perceived differently by different individuals (42). Furthermore, most generic questionnaires are designed to measure physical activity at higher intensities at leisure time, resulting that activities at lower intensities carried out as part of daily physical activity is not measured (43). As THA patients in early postoperative phase are expected to perform physical activity mostly at lower intensities as part of daily life situations, a questionnaire will have important limitations in ability to measure these activities. In recent years new technology has enabled recordings of physical activity by use of activity monitors. Small body worn activity monitors are now available providing objective, real life and continuous measures of persons' physical activity throughout the day.

Activity monitors and outcomes derived from activity monitoring

Activity monitors can include different instruments, but most activity monitors are based on accelerometers. There are several different accelerometers with different specifications, but they have in common an electronic movement sensor which detects acceleration produced by body movement. Activity monitors can capture the frequency of performing activity, duration of performing activity and intensity of performing activity (44). **Activity counts** are often used to express amplitude and frequency of raw acceleration data, and more movement will provide higher value of the activity count (45). The values of activity counts can be analyzed

to provide information on **intensity** (low, moderate, high), and to calculate energy expenditure as kcal/kg/day or estimation of Metabolic Equivalent (MET) values (46). Data measured by accelerometers can also be used to recognize in which **postures** the activity is being performed, activity recognition, as lying, sitting, standing, walking and changing in positions as transitions from sit-to-stand (upright events) (47). In addition, the continuous activity monitoring data also provides possibilities to describe the variation in physical activity more detailed as **activity patterns**. Outcomes that describe activity pattern represent the physical behavior of a person during a certain time period. The "length of events" during daytime is an example of one such outcome (48).

Granat (2012) emphasizes that various outcomes derived from activity monitoring represent different aspects of physical activity (49). Thus, it is necessary that the outcome or outcomes that are chosen represent relevant aspects for the particular target group. One should also have in mind that the results may be dependent on the outcome, and that results not necessarily would be the same if another outcome had been evaluated. One example from the cross-sectional population-based study from Norway, where 2707 participant in the age of 20-64 years completed one week assessments with activity monitors, showed significant gender differences with respect to different intensity measures (50). If looking at time spent in low intensity activity, women spent five hours and men spent 4.5 hours a day in low intensities. For moderate-to-vigorous physical activity (MVPA), men spent significantly more time in MVPA as compared to women, 35 minutes versus 33 minutes a day ($p= 0.01$), respectively. Furthermore, step counts did not show any significant differences between gender (women took 8113 steps and men took 7951 steps per day) (43). Together, this shows that the results were dependent on the chosen outcomes. Measurements of physical activity based on the number of steps resulted in no gender differences, while the intensity-based outcomes revealed gender differences in physical activity.

Most frequent outcomes derived from activity monitoring by accelerometers on patients early postoperatively are time in upright positions (the sum of time standing and walking) and the number of steps during 24 hours (51-56). Other outcomes reported are time in walking during 24 hours (52, 55), the number of upright events during 24 hours (53, 56), time in sedentary (sitting and lying) during 24 hours (51, 55), and intensity based on activity counts (28, 37). THA patients highlight improvements in the ability to walk and move around as important early after surgery (4), and outcomes derived from activity monitoring should therefore be

able to measure this aspect of patients' daily physical activity. Time in upright, time in walking, number of steps, and number of transitions from sit-to-stand could therefore be relevant outcomes for this target group, representing activities that have been affected by the disease, hip osteoarthritis, which is the reason for undergoing THA surgery. These outcomes can give information about recovery early after surgery.

1.2.3 Hip Osteoarthritis

THA is most commonly used to treat joint failure caused by HOA. In a study from 2008, the prevalence of HOA in a Norwegian population aged 28-80 years was 5.5% (57). HOA is a growing problem, which is believed to be associated with increasing life expectancy and the increasing incidence of obesity and inactivity (58). Thus, it is expected that the need for THA surgeries will increase in the coming years (1).

HOA has traditionally been considered as a degenerative disease where the articular cartilage is degenerated due to inflammatory processes eventually resulting in joint failure. Recent evidence shows an additional and integrated role of bone and synovial tissue, and patchy chronic synovitis is evident in the disease (59). Pain is the first and predominant symptom of HOA. The patient will also experience stiffness and loss of movement and function (60). Due to these symptoms the disease also diminish the patient's quality of life (61), and leads to decreased levels of daily physical activity (62, 63), (see more in section "Daily life physical activity in end-stage HOA patients").

There are three treatment modalities for HOA: non-pharmacological, pharmacological and surgical. Non-pharmacological treatments include information and education of the patient, weight reduction if overweight and physical therapy with exercises that strengthen muscles and improve aerobic condition. Paracetamol is the first pharmacological choice as well as NSAIDs for the shortest duration. THA surgery is usually considered only when the other treatment modalities, such as physical therapy and pain medications, no longer are giving satisfactory effect (64).

Daily physical activity in end-stage HOA patients

A few studies have included objective measures to assess physical activity in HOA patients. One Danish study from Holsgaard-Larsen and Roos (2012) included accelerometer measures in their study on end-stage hip or knee osteoarthritis patients scheduled for total joint replacement (62). The 51 patients (mean age 68 years) walked on average 29.3% fewer steps per day compared to a healthy control group, 6632 vs. 8576 steps, respectively. Gender did not influence these results, but age and BMI explained 15.4% and 32.7% of the variation in number of steps per day (62).

A case-control study from the Netherlands aimed to measure the level of daily physical activity in 40 patients (mean age 61.4 years) with end-stage hip or knee osteoarthritis, and to compare the results with a matched group of healthy controls (63). Activity monitoring was performed 48 hours on two consecutive weekdays. The healthy, matched controls were significantly higher movement-related active compared to the hip and knee osteoarthritis patients (about 11.0 %). The HOA patients spent 20.7% of the time in upright positions, which is equal to 4.9 hours of activity per 24 hours period. Physical activity was not associated with pain, but a decrease in physical activity was seen with older age and increasing BMI (63).

1.2.4 Total Hip Arthroplasty

In the end-stage HOA, surgical replacement of the joint by a prosthetic implant is a relevant treatment modality for most patients. Hip joint replacement is currently the most common orthopedic surgery, and the total amount of primary THA surgeries in Norway was 7983 in 2013 (1) About 600 patients are operated annually at St. Olavs Hospital, Trondheim University Hospital (10). According to Crowninshield et al. (2006) the demand for THA in the USA is supposed to increase by 174% within 2030, not only in the elderly, but also in the population of people younger than 65 years (65).

The acetabulum and the femoral head are replaced by a stem and a head which makes the femoral component and a cup which replaces the acetabulum. The components can be fixed with or without bone cement, or as a combination of these two. The cementless components are being attached as the bone is prepared to fit the chosen prosthesis, while cemented components is fixed to the bone with a special bone cement (66). With respect to prosthesis

survival it is found impaired results in patients over the age of 65 with cemented components as compared to cementless components (67). Thus, younger patients usually receive cementless components, and in patients older than 65 - 70 years cemented components are used.

The main aims for the THA surgery are pain relief and improvement in hip function. About 95% of patients operated with primary THA are satisfied one year after surgery, reporting better hip function and increased quality of life, and 80% report no symptoms from the hip (68). A recent study from St. Olavs Hospital, Trondheim University Hospital in Norway, showed that THA patients improved their physical function measured by Harris Hip Score (69) (range 0-100 points with 100 points as the optimal score, and 20 points postoperative increase is graded as successful result after THA surgery (70)), from 53 points preoperatively to 82 points three months postoperatively (10). In addition, activity monitoring studies can evaluate how THA surgery affects daily physical activity early after surgery.

Daily physical activity early after THA

Few studies have used activity monitoring to evaluate daily physical activity early after surgery (28, 53-56), and to our knowledge there are only two studies in THA patients (37, 52). A study from 2013 showed that patients receiving inpatient rehabilitation after lower limb orthopedic surgery (THA, TKA, and fractures), do much less than the 30 minutes of moderate intensity physical activity per day recommended for healthy older adults (71). The 54 patients in the study (mean age 74 years) performed on average 398 (IQR 140 - 993) steps per day and spent eight (IQR 3 - 15) minutes per day in walking early after surgery (median length of nine days after surgery) (52).

A study from Denmark reported daily physical activity pre-and postoperatively in 20 THA and TKA patients with a mean age of 70 years. Total activity counts per day decreased from a mean of 209,861 preoperatively to 163,007 (78% relative to preoperative level) after hospital discharge to home the fourth day postsurgery (37).

1.2.5 Surgical Approaches in Total Hip Arthroplasty

The surgical approach used, is one of many factors crucial for a good postoperative result. Results based on work from our research group showed that patients undergoing the PA and AA had preserved their lower limb muscular strength significantly better than the patients undergoing the DLA the first week after surgery (25). However, it is unknown whether the muscular strength influences physical activity early after surgery. In this study, we wanted to investigate if the surgical approach affects the patients' daily physical activity within the first week postsurgery.

The orthopedic surgeons preferences and experience is mainly decisive for the approach chosen, and the surgeons at a hospital often decide to use one particular approach. The patients unique anatomy may also influence the choice of surgical approach (66). The surgical approaches most commonly used in Norway are the direct lateral approach, posterior approach, anterolateral approach and anterior approach (1). The differences between the approaches are primary which muscles are divided during surgery or if the surgery is performed mini-invasive without dissection or loosening of muscles. Generally all approaches are conducted by an incision through the skin, then dividing or pulling aside muscles so the capsule appears. After capsuleectomi the hip is luxated and the prosthetic components are inserted (66). In the present study the direct lateral, posterior and anterior approaches were used.

The direct lateral approach

The DLA is the most common surgical approach for THA surgery in Norway and amounted 44.4 % of the surgeries in 2013 (1). DLA follows a posterior curved lateral incision and the hip is exposed as described by Hardinge (1982) (17). The DLA is associated with a low risk of dislocation (72). The disadvantage of the approach is that a potential damage of the superior gluteal nerve or failure to reattach the abductor musculature to the greater trochanter, can lead to permanent postoperative weakness and limping (73).

The posterior approach

The PA is the second most used surgical approach in Norway and accounted 30.8% of the THA surgeries in 2013 (1). The PA was first described by Kocher and Langenbech, and later modified by Gibson (20). The advantage of the PA is that the gluteus medius muscle as the most important abductor of the hip, is not affected by the approach (74). The PA has previously been associated with post-operative dislocations (73, 75), mainly owing to the small femoral heads used to prevent wear (76). However, the introduction of highly cross-linked polyethylene liner into the articulation has reduced wear independently of the head diameter (77), leading to increased use of larger head diameter which have contributed to lower dislocation rates (78).

The anterior approach

According to the Norwegian Arthroplasty Register the AA was used in 4.3% of the THA surgeries in 2013 (1). The approach used in the present study was the modified Smith-Peterson approach as described by Berend et al. (2009) (22). This approach provides a intermuscular and internervous exposure to the hip, leading to decreased soft tissue dissection and trauma (79). Some studies have found that this approach can result in reduced postoperative pain and better clinical outcomes compared to the DLA (21-24). However, concerns have been related to higher complication rates owing to wound complications, intra-operative fracture and compromised fixation, with increased risk of early revision surgery (80).

How the surgical approaches affect hip muscles during surgery, can explain the differences seen in how the patients preserve their lower limb muscular strength early after surgery (25). To assess if the surgical approach also affects daily physical activity, we performed activity monitoring early after surgery. It is important to ensure that other postoperative factors also influencing physical activity during this period, such as pain, postoperative mobilization and patient information are equal between patients. This is highly taken care of through the standardized fast-track treatment course for patients undergoing THA surgery.

1.2.6 The Fast-track Treatment Course in THA

The accelerated recovery program in THA surgery called "fast-track" is an optimized perioperative care program which combines various evidence-based techniques used in the care of the patients. According to Douglas and Kehlet (2001) the methods used include thorough preoperative patient information, epidural or regional aneasthesia, optimal pain control, and very early postoperative mobilization (81). The preoperative information and the thorough level of information throughout the perioperative period ensure that the patients play an active role in their own rehabilitation. In addition, a multimodal opioid-sparing approach to analgesia obtains only moderate pain during activity, leading to reduced needs for opioids and enables the patients to enforce the mobilization (82). Main focus is to reduce the level of physical stress related to the surgical treatment enabling early postoperative mobilization with short hospitalization. The fast-track methodology was initially developed within abdominal surgery and key elements have now successfully been implemented in major orthopaedic surgeries, and led to high patients satisfaction, a decrease in morbidity and mortality, and shorter lengths of hospital stay (7, 38, 83). The fast-track methodology was adopted in the total hip and knee arthroplasty patient pathway at the Department of Orthopaedic Surgery at St. Olavs Hospital, Trondheim University Hospital in 2010, and has now become a well-established treatment course for these patients. The One-year follow-up study by Winther et al. (2014) evaluating this implementation, found reduced length of stay, a high level of patient satisfaction and low revision rates, together with improved health-related quality of life and physical function scores three months and one year after surgery in THA patients undergoing the DLA (10). The present study aims to investigate whether the less invasive surgical approaches PA and AA contribute to make the patients more physically activity in daily life early after surgery compared to the DLA.

2 Material and Methods

2.1 Study Design

The present study was a prospective cohort study evaluating daily physical activity early post-discharge in three groups receiving different surgical treatment approaches in total hip arthroplasty (THA). The participant received one of the following surgical approaches; direct lateral approach (DLA), posterior approach (PA) and anterior approach (AA).

This study was part of an ongoing project at the Orthopaedic Research Centre at St. Olavs Hospital, Trondheim University Hospital and Norwegian University of Science and Technology (NTNU), called: "Minimal Invasive Surgery in Total Hip Arthroplasty Patients; Short and Long Term Results" (ClinicalTrials.gov: NCT01506024).

The study was approved by the Regional Committee of Medical and Health Research Ethics (REC no. 2011/450).

2.2 Participants and Recruitment

Patients younger than 70 years old with a body mass index (BMI) less than 34 who lived near Trondheim, had a diagnosis of unilateral hip osteoarthritis (HOA) and were scheduled for primary THA, were assessed for eligibility in the main study "Muscular Strength after Total Hip Arthroplasty: comparison of three surgical approaches in a prospective cohort study". Exclusion criteria were any other disease or illness entailing difficulty with physical testing.

The 63 first participants giving an informed consent were included and scheduled for one of three surgical approach groups; DLA group, PA group and AA group. Participants were allocated to the different treatment groups by the order in which they were included in the study; the first 23 participants were allocated to the DLA group and the next 40 participants were allocated to the PA group (20 participants) or the AA group (20 participants) dependent on the availability of the surgeons. Participants were included from June 2011 to June 2013 from the Orthopaedic Outpatient Clinic at St. Olavs Hospital, Trondheim University Hospital by two orthopaedic surgeons. Participants performing activity monitoring were included in the present study.

2.3 Procedure

2.3.1 Preoperative Procedure

After inclusion all participants followed the same standardized fast-track treatment course organized for knee- and hip arthroplasty as described by Winther et al. (2014) (10). Before surgery the participants received oral and written information about the procedure (84), and participants and their next of kin were invited to a multidisciplinary education class where

each part of the treatment-chain from admission until discharge were presented by an orthopedic surgeon, an anesthetist, a nurse and a physiotherapist. The participants practiced walking with crutches in the stairway, and were shown the fast-track unit in which they would be staying during the hospitalization. All participants were admitted the same day as surgery (10).

2.3.2 Implants

All operations used uncemented, double-tapered, fully HA coated stem (Profemur Gladiator, Wright Medical Technology Inc, Memphis, TN). The acetabular component was an uncemented, porous cup with a highly cross-linked polyethylene insert (Reflection, Smith and Nephew, London, UK). All implants had a modular neck and a ceramic head. All participants in the DLA group and the three first participants in the PA group received a head with 28 mm articulation, while the remaining participants in the PA group and all the participants in the AA group received 32 mm articulations. A team of three experienced surgeons was in charge of the surgeries, each with the expertise in one of the approaches (25). The participants were operated under spinal anesthesia by one of the surgical approaches DLA, PA and AA.

2.3.3 Surgical Approaches

Direct lateral approach

The deep fascia was split proximally in the direction of the anterior fibers of gluteus maximus, and the common muscle plate of the anterior one-third of gluteus medius and vastus lateralis was dissected subperiostically from the greater trochanter. During reconstruction of the abductor muscles, the common muscle plate was reinserted into the greater trochanter with two non-resorbable osteosutures (PremiCron, B. Braun, Melsungen, Germany). This fixations was reinforced with a continuously sewn slowly resorbable looped monofilament suture (MonoPlus, B. Braun, Melsungen, Germany) (25).

The posterior approach

Following a curved skin incision with the top point slightly posterior to the greater trochanter, the incision in the fascia lata was begun in the distal wound. Proximally, the deep fascia was incised in the direction of the anterior fibres of gluteus maximus. The external rotators (piriformis and gemelli muscles) were divided close to the greater trochanter. From their insertion on the greater trochanter (marked with a suture) they were folded posteriosly to protect the sciatic nerve. The capsule was incised in the same direction. For closure the

capsule was sutured and the external rotators were reinserted with a non-resorbable osteosuture (25).

The anterior approach

The AA treatment used in the present study was the modified Smith-Peterson approach as described by Berend et al. (2009) (22). The surgeons used the internervous plane between the tensor fascia lata and sartorius muscles, and moved laterally to rectus femoris for the deep dissection. In this way there was no dissection or loosening of any muscles. For closure a continuously resorbable suture was used in the fascia (25).

2.3.4 Postoperative Procedure

After the surgery all participants, with exception of one participant in the AA group who had revision surgery within the first day post-surgery, followed the standardized fast-track treatment course during hospital stay for two-four days (10, 84). The fast-track treatment course included early mobilization at the intensive care ward at the operation day as soon as the block from the spinal anesthesia disappeared. Thereafter the participants were transferred to a specialized hip and knee arthroplasty unit with a well-defined and experienced program for multimodal rehabilitation. The program included advice on minimally bed rest from the first day after surgery. The participants were recommended to perform daily life activities during the hospital stay, to use private clothing and have meals in the dining room at the patient ward. From day one after surgery the participants were instructed by the physiotherapist in standing position exercises, and they received instructions in walking with crutches including in the stairways. They were instructed to do the exercises three times a day and to walk with crutches in the hallway several times a day. Further, the participants participated in an activity group with a physiotherapist every day during the hospitalization. Multimodal, orally administered opioid-sparing analgesia was given to all participant, and Oxycodone was given if needed (25).

Before discharge, specific discharge criteria had to be fulfilled; when mobilized, the pain level had to be three or less on the pain numeric rating scale (NRS) (85), there should be no wound secretion, the participants had to be self-reliant in activities of daily living, and they had to be able to walk with crutches in stairways (84).

After discharge the patients were prescribed Paracetamol and Tramadol. All participants were discharged to their homes, and got advice on starting outpatient physiotherapy about two weeks postsurgery after the activity monitoring period. During the activity monitoring period they were instructed to continue with the exercises, to perform their activities of daily living and to walk with crutches as much as they felt comfortable with allowing their hip symptoms be the guide (84).

2.4 Outcome Measures

2.4.1 Demographic Data

Preoperative experienced pain at rest and during mobilization was registered in an eleven point (0-10) numeric rating scale (NRS) where 0 is no pain and 10 is worst pain imagine (85). Other demographic variables recorded for each participant included age, gender, BMI and any use of crutches.

2.4.2 Other Preoperative Outcomes

Harris Hip Score (HHS) was assessed to measure physical function preoperatively (69). HHS is a disease-specific therapeutic-administrated score system with four domains: function, pain, deformity, and range of motion, allowing a total score ranging from 0 to 100 points (low-high), which are categorized as follows: 0 to 70 points, poor; 70 to 80 points, fair; 80 to 90 points, good; 90 to 100 points, excellent (86). HHS is frequently used to measure outcome after THA, and has shown to have high validity and reliability (87).

The self-administered disease specific questionnaire Hip Disability and Osteoarthritis Outcome Score - Physical Function Short forms (HOOS-PS) was used to assess the participants opinion about hip-associated problems in daily life activities preoperatively. HOOS-PS has a score from 0 to 100 with zero as the optimal score representing no difficulty to perform specific daily life activities including sitting, running, descending stairs, getting in/ out of bath/ shower, and twisting on loaded leg (88).

Performance-based function preoperatively was assessed using The Expanded Timed Up & Go (ETUG) (89) by measuring the time (in seconds using a stopwatch) required to perform each of the subtasks of The Timed Up & Go (TUG) (90) in a series, but with a stop and a new instruction before the next subtask was undertaken. The five subtasks include to rise from a chair, walk three meters at preferred speed, make at turn, walk three meters maximal speed,

and to turn around and sit down on the chair. The ETUG total time was calculated by adding up the time for all five subtasks.

Maximal walking speed was measured over a distance of five meters. The participants were asked to walk along a nine-meter, straight, flat walkway as fast as possible. Time (in seconds using a stopwatch) was recorded for the middle five meters. Start and stop times were registered when the participants' hips passed two lines on the floor, one at the beginning and the other at the end of the central five-meter region of the walkway. There were two trials and the highest velocity was accepted as value for maximal walking speed. It is previously found that maximal walking speeds are positively associated with the extent of habitual physical activity measured by steps per day (40)

2.4.3 Measures of Daily Physical Activity

Daily physical activity was assessed by activPAL™ (PAL Technologies Ltd., Glasgow, United Kingdom) (91). ActivPAL is a small, body-worn, single-axis accelerometer-based activity monitor. The sensing component is a compact and lightweight (35 x 53 x 7 mm and 20 g) meter that identifies three posture/ activity categories: sitting/ lying, standing and walking. The outputs from this device can define time in upright positions by combining time in standing and time in walking. The number of steps and the number of transitions from sit-to-stand (upright event) are also reported. Data are transferred by a USB interface, and the proprietary software (activPAL™ Professional Research Edition) performs data analysis (92). Figure 2 illustrates the outputs from the activPALs. The device has a memory and battery capacity allowing activity and posture to be recorded continuously for periods up to ten days (93). The activPALs were attached to the front of the participants' non-operated thigh with waterproof tape on the second or third day after surgery (figure 1). The activity monitors were worn continuously (including showering) 24 hours a day until the participants returned to the hospital on the eighth day after surgery, and the activity monitors were removed.

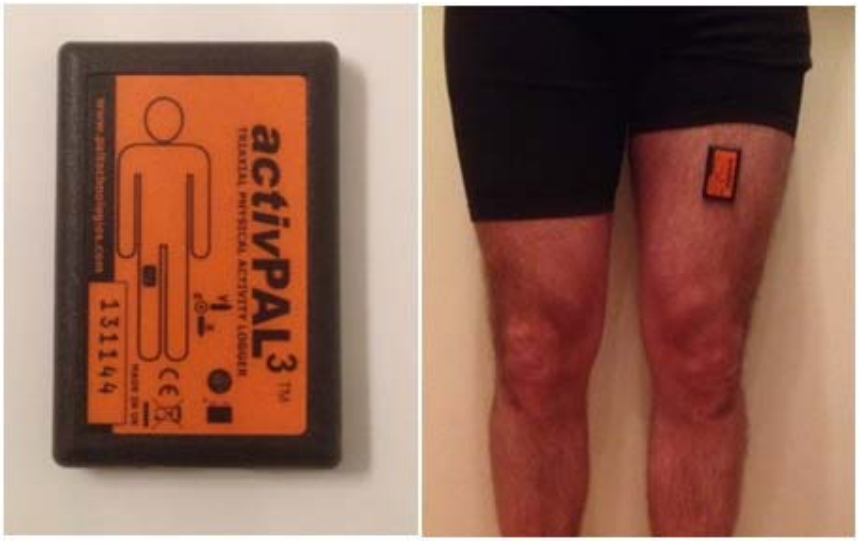

Figure 1. The activPAL activity monitor (left) and a participant with the device attached to the front of his non-operated thigh (right). (Illustration photo).

No data on validity and reliability exists on the present patient group. However, the activity monitor is a valid and reliable measure of walking in healthy older adults (93). It is also found to be a valid and reliable measure of the time spent in upright position during daily physical activities (92). Outcomes from activPALs have also been validated on a population of older people with impaired function and walking mobility, showing perfect accuracy of time spent in upright positions, time in sitting/ lying positions, and number of upright events (94). Problems with accuracy of number of steps at low walking speeds was however present (≤0.47 meters/sec.) (94). The participants' walking speed in the present study was calculated from subtask two (three meters walk at preferred speed) in the ETUG on the day of attaching the activPALs. To estimate daily physical activity in terms of time in upright position in community-dwelling older persons after hip-fracture, on a group level a single recording day is found to provide a reliable estimate (95). In this study the activity monitoring for four consecutive days (with 24-hours recording = 96 hours) the first to the fourth day after discharge to home, were used. Mean activity per 24 hours was calculated and used in the subsequent analysis.

Primary and secondary outcome variables

As primary outcome for daily physical activity, time in upright positions defined as the total time in standing and walking during 24 hours was used. Secondary outcomes were time in

walking, time in standing, number of steps and number of upright events (number of transitions from sit-to-stand), all during 24 hours.

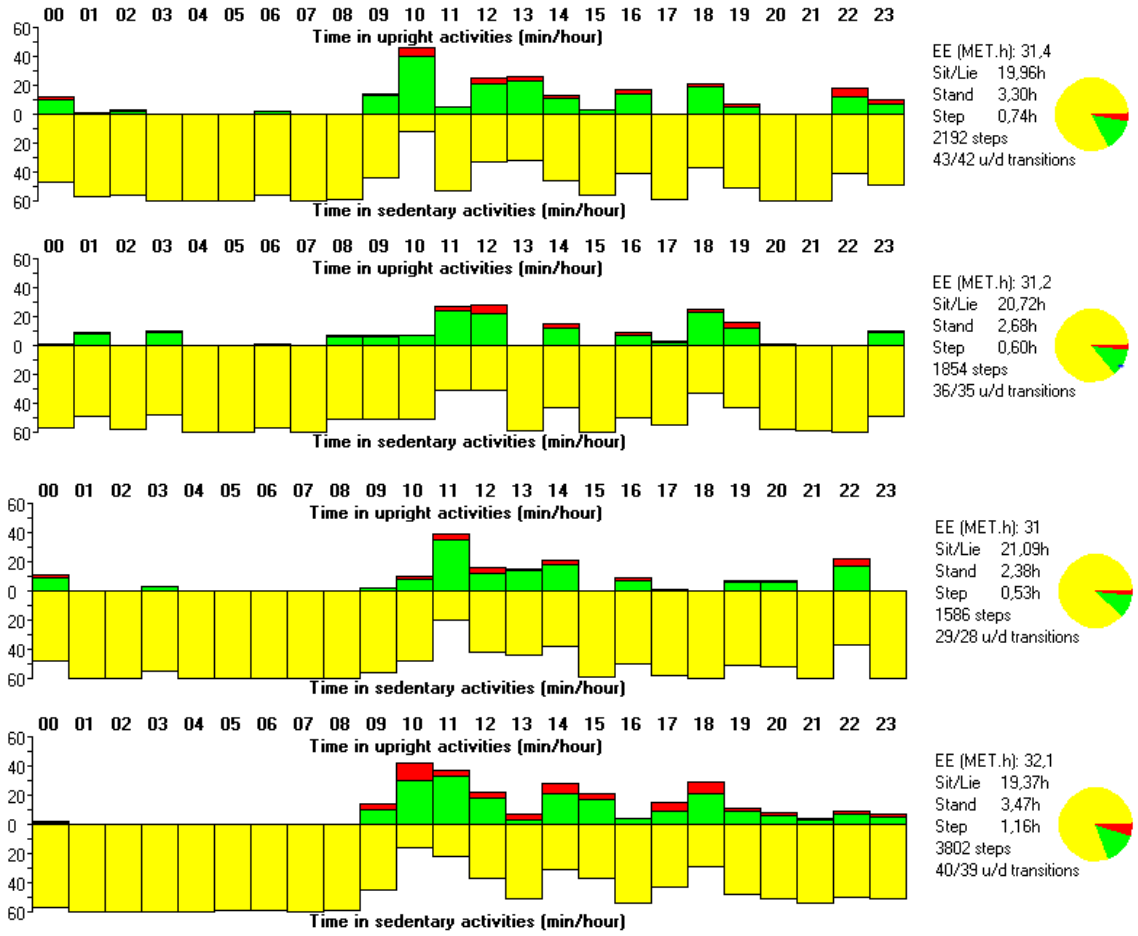

Figure 2. Illustration s of a participant's physical activity during 24 hours activity monitoring the first to fourth day after hospital discharge. Each block represents one hour. Sitting/ lying is shown in yellow, standing is shown in green and walking is shown in red, whereas upright is illustrated by both the green and red together. To the right of each 24 hours of activity monitoring, there is a summary of time (hours) in sitting/ lying, standing and walking, and the number of steps and upright events (transitions from sit-to-stand).

2.5 Sample Size

The sample size in the present study, was determined by the calculations performed for the primary outcome in the main study "Muscular Strength after Total Hip Arthroplasty: comparison of three surgical approaches in a prospective cohort study", which was lower limb muscular strength as measured by 1RM leg press. All participants included in that study were asked to wear activity monitors, and participants with complete activity monitoring from the first to the fourth day after hospital discharge, were included in the analyses in the present study.

2.6 Statistical Analyses

Statistical analyses were performed using IBM SPSS Inc. (SPSS Statistics for Windows, Version 22, Chicago: SPSS Inc.). The distribution of both preoperative, demographic and clinical data were tested for normality by Shapiro-Wilk`s tests and visual inspection of Q-Q plots and histograms. Subsequently, non-parametric statistics were chosen for variables not meeting the assumptions of normal distribution. Demographic and preoperative data were analyzed by descriptive statistics. Chi Squared test was used to detect statistical significant differences between the groups regarding gender, whereas Analysis of variance (ANOVA) was used to detect other statistical significant differences between the groups preoperatively. When detecting background differences between the groups, a significance level of 0.05 was chosen.

The outcome measures of daily physical activity did not meet the assumptions of normal distribution, and the non-parametric Kruskal-Wallis test was therefore used to analyze statistical significant differences between the groups. The Kruskal-Wallis test was also used to detect statistical significant differences between the groups regarding the length of hospital stay. ANOVA was used to detect statistic significant differences regarding pain at day 2 and day 8 after surgery. Bonferroni corrections were used to account for multiple comparisons between the groups. The Mann-Whitney U test was used to analyze statistical significant differences between genders.

With assistance, in the final analyses the differences in outcome measures of daily physical activity between the three groups were analyzed by use of Mixed Linear Models, and adjustments for gender and preoperative pain in rest were included. The covariates appearing

in the model were evaluated at the following values; gender = 1.61 and preoperative pain in rest = 4.77.

A significant level of 0.05 was chosen. The outcome measures of daily physical activity are presented as median per group and adjusted group differences in Table 2.

2.7 Ethical Aspects

This study was conducted in accordance with ethical standards given by the Norwegian National Committee for Medical and Health Research Ethics (96). The study was performed in accordance with the declaration of Helsinki (97). Participation was voluntary and all participants enrolled in the present study had already agreed to participate in the project: "Minimal Invasive Surgery in Total Hip Arthroplasty; Short and Long Term Results". They had signed an informed consent form including information about the activity monitoring (appendix III). Collected data was anonymized before being securely stored. The three surgical approaches used in the study are widely recognized and used in Norway as well as worldwide (1).

2.8 Recourses and Author's Role

Expenses of the present study involved nothing else than relevant office supplies.

Employed as a research assistant during two periods in 2012 and 2013, the author of this thesis participated in collecting the activity monitoring data. Main responsibilities have been testing the participants and administered the activPALs. During working with this master thesis further responsibilities have been organizing, processing and analyzing data.

2.9 Time Schedule

The Master thesis was planned and written during the second, third and fourth semesters of the Masters Program in Clinical Health Science at The Faculty of Medicine, NTNU (2014-2015). Data were collected during 2011-2013. The final thesis was finished by the submission date of 1st of June 2015.

3 Results

3.1 Preoperative Characteristics and Participant Flow

A total of 63 participants (60.3% women) with a mean age of 56.2 (SD 8.4) years were included in the study. One participant (AA group) was excluded owing to revision surgery, and one (PA group) withdraw from participation for personal reasons. The flow diagram (Figure 3) illustrates the flow of participants through the study. A total of 61 participants completed the continuous activity monitoring the first to the fourth day after hospital discharge (96 hours), and were included in the final analyses. Mean activity per 24 hours was calculated and used in the subsequent analysis.

Preoperative characteristics for the participants in the three groups are presented in Table 1. There were no statistical significant differences between the groups in any of the preoperative characteristics, except for experienced preoperative pain at rest (p=0.021), where the AA group reported more pain on the NRS than the other groups (DLA-group, 3.7; PA group, 4.3; AA group 6.1). There was a difference in gender distribution between groups with a majority of women in the DLA and AA groups (60.8% and 75%, respectively) and a minority of women in the PA group (45%), this was not statistically significant (p=0.152). Except for one of the participants in the DLA group who used crutches, there was no use of walking aids preoperatively.

The mean length of hospital stay after surgery for all the participants was 2.65 days (range 2-4 days), with no group differences (DLA group, 2.81 days (range 2-3 days); PA group, 2.47 days (range 2-3 days); AA group, 2.65 days (range 2-4 days), (Kruskal-Wallis Test, p=0.106).

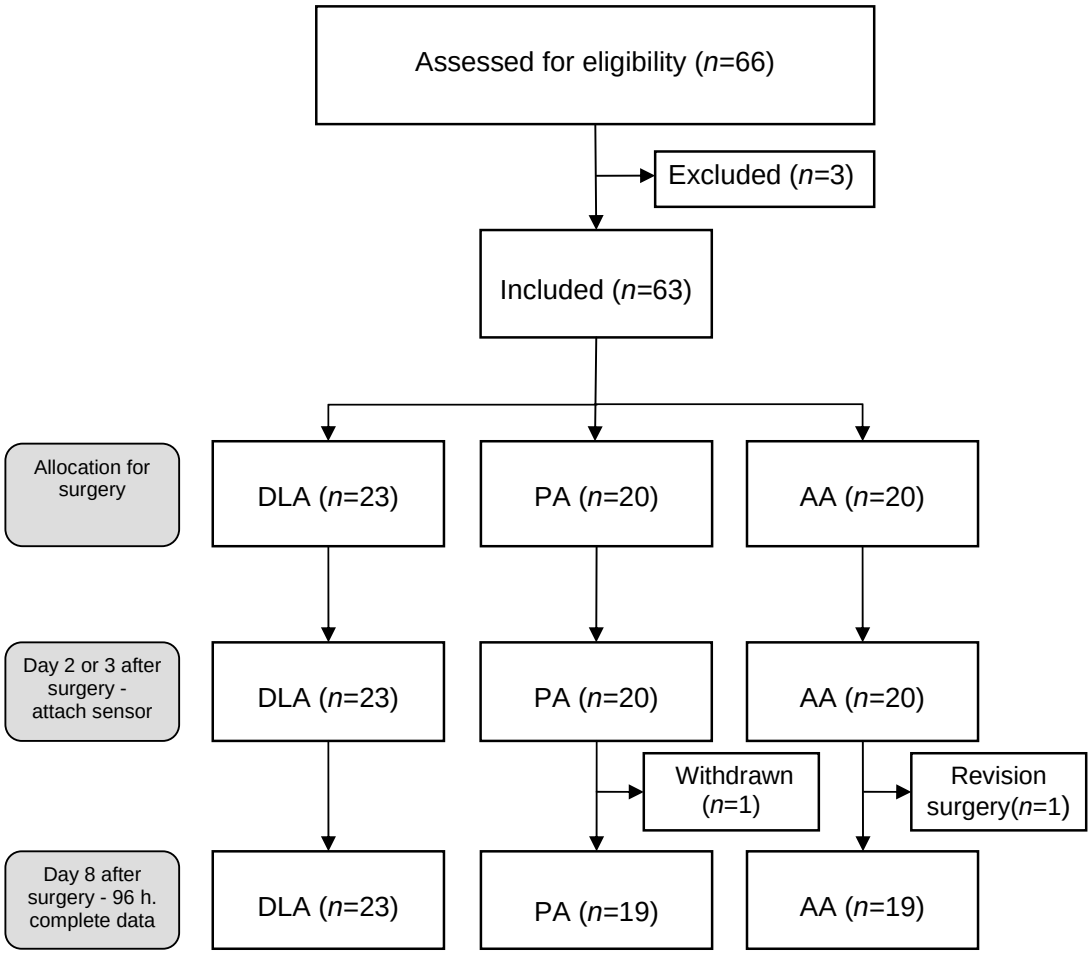

Figure 3. Study flow diagram

Table 1. Demographics and Preoperative Characteristics of the Participants

	Total sample ***n*=63**	**DLA** ***n*=23**	**PA** ***n*=20**	**AA** ***n*=20**	***p*-value**
Age (years)					
Mean (SD)	56.2 (8.4)	56.3 (7.8)	56.2 (7.4)	55.9 (10.1)	0.979[1]
Range	30-69	45-68	44-69	30-69	
Gender, *n* (%)					
Female	38 (60.3)	14 (60.8)	9 (45.0)	15 (75.0)	0.152[2]
BMI (kg/m²)					
Mean (SD)	26.1 (3.3)	25.8 (2.7)	26.7 (3.7)	25.8 (3.4)	0.645[1]
Range	18.9-34.0	22.1-32.1	22.3-34.0	18.9-31.5	
Pain NRS rest, range 0-10					
Mean (SD)	4.7 (2.7)	3.7 (3.0)	4.3 (2.2)	6.1 (2.3)	0.021[1]*
Pain NRS mobilization, range 0-10					
Mean (SD)	6.0 (1.8)	5.7 (1.9)	6.0 (1.8)	6.5 (1.6)	0.301[1]
Harris Hip Score, max=100, min=0					
Mean (SD)	60.5 (11.1)	60.3 (10.3)	61.1 (13.3)	60.2 (10.3)	0.964[1]
HOOS-PS, max=0, min=100					
Mean (SD)	40.2 (14.2)	38.7 (13.0)	40.0 (15.8)	42.0 (14.4)	0.750[1]
ETUG (sec)					
Mean (SD)	11.6 (2.5)	11.4 (2.7)	11.0 (2.5)	12.3 (2.5)	0.239[1]
Max. walking speed (m/sec)					
Mean (SD)	2.08 (0.61)	2.18 (0.62)	2.15 (0.65)	1.88 (0.56)	0.229[1]
Season of surgery, *n* (%)					
Vintertime	22 (36)	5 (21.7)	4 (21.1)	13 (68.4)	

Notes: BMI = Body Mass Index; NRS = Numeric Rating Scale; HOOS-PS = Hip Disability and Osteoarthritis Outcome Score - Physical Function Short forms; ETUG = Expanded Timed Up and Go.
[1]Analysis of variance (ANOVA); [2]Chi Squared test. *Significant at $p<0.05$.

3.2 Outcome Measures of Daily Physical Activity

Results for the total sample of participants and the three groups on the five measures of daily physical activity from the first four days after hospital discharge; time in upright positions, time in walking, time in standing, number of steps, and number of upright events all calculated as mean of 24 hours, are presented in Table 2. Both before and after adjustments for gender and preoperative pain in rest, no differences between the groups was found (*p*'s>0.254 and *p*'s>0.153, respectively). There was a wide range in all measures of daily physical activity between the participants.

3.3 Gender Differences

Men spent almost twice as much time in walking compared to women, 0.91 (IQR 0.59 - 1.20) hours versus 0.49 (IQR 0.36 - 0.87) hours per 24 hours, respectively (Mann-Whitney U test, *p*=0.003). The same was shown for number of steps, where men took more than twice as many steps as women, 3148 (IQR 1921 - 4179) steps versus 1486 (IQR 948 - 2853) steps per 24 hours, respectively (Mann-Whitney U test, *p*=0.001). There were no gender differences for the three other measures of daily physical activity (Mann-Whitney U test, *p*'s>0.294,). There were no statistical significant differences between genders in any of the preoperative characteristics (Independent Samples T-tests, *p*'s>0,056), except for maximal walking speed, where men walked 2.38 (SD 0.70) m/sec. versus women walked 1.88 (SD 0.47) m/sec. (Independent Samples T-tests, *p*=0.001).

3.4. Preferred Walking Speed

On the second day postsurgery, the day the activity monitors were attached, calculations from subtask two in the ETUG showed that all participants walked with a preferred walking speed of 0.47 m/sec. or more (mean 0.84, range 0.47-1.46 m/sec.) with crutches.

3.5 Pain

ANOVA-analyses showed no differences between the groups regarding reported pain on NRS at rest or during mobilization the second and eighth day after surgery (*p*'s>0.379). The second day after surgery mean (SD) pain at rest and during mobilization for all groups was 2 (1.5)

and 3.1 (1.6), respectively. The eighth day after surgery mean (SD) pain at rest and during mobilization for all groups was 2.5 (1.8) and 3 (1.9), respectively.

3.6 Adverse Events

One patient in the AA group had the liner dislocated per-operatively and was excluded due to revision surgery. One patient in the AA group had a cardiac arrest during surgery and was successfully resuscitated with no sequelae and able to wear the monitor for the first four days after discharge. There were no other trial-related adverse events.

Table 2. Measures of Daily Physical Activity during 24 Hours the First Four Days after Hospital Discharge to Home following THA.

	TOTAL SAMPLE Median (25-75 percentile)	**GROUP** Median (25-75 percentile)			**ADJUSTED GROUP DIFFERENCES***			**ADJUSTED *p*-VALUE***
		DLA	**PA**	**AA**	**AA - DLA**	**AA - PA**	**PA - DLA**	
Time upright positions (hrs)	3.53 (2.91-4.81))	3.72 (3.29-5.41)	3.15 (2.84-4.67)	3.68 (2.03-4.63)	-0.67	-0.05	-0.62	0.247
Time walking (hrs)	0.62 (0.39-0.95)	0.70 (0.37-0.93)	0.79 (0.5-1.16)	0.51 (0.4-0.94)	-0.10	-0.18	0.08	0.328
Time standing (hrs)	2.83 (2.22-3.97)	2.96 (2.2-4.54)	2.55 (2.08-3.52)	2.79 (1.64-3.88)	-0.23	-0 02	-0.21	0.206
No of steps	2122 (1154-3526)	2359 (1079-3554)	2799 (1561-3769)	1874 (1208-3404)	-386	-597	211	0.433
No of upright events	35 (30-42.5)	37 (31-49)	38 (33-42)	32 (25-37)	-8.8	-1.5	-7.4	0.153

Notes: DLA = direct lateral approach group; PA = posterior approach group; AA = anterior approach group; Time upright positions = time in standing and walking; No. of upright events = number of transitions from sit-to-stand. *Group differences and *p*-values adjusted for gender and preoperative pain at rest by use of Mixed Linear Models.

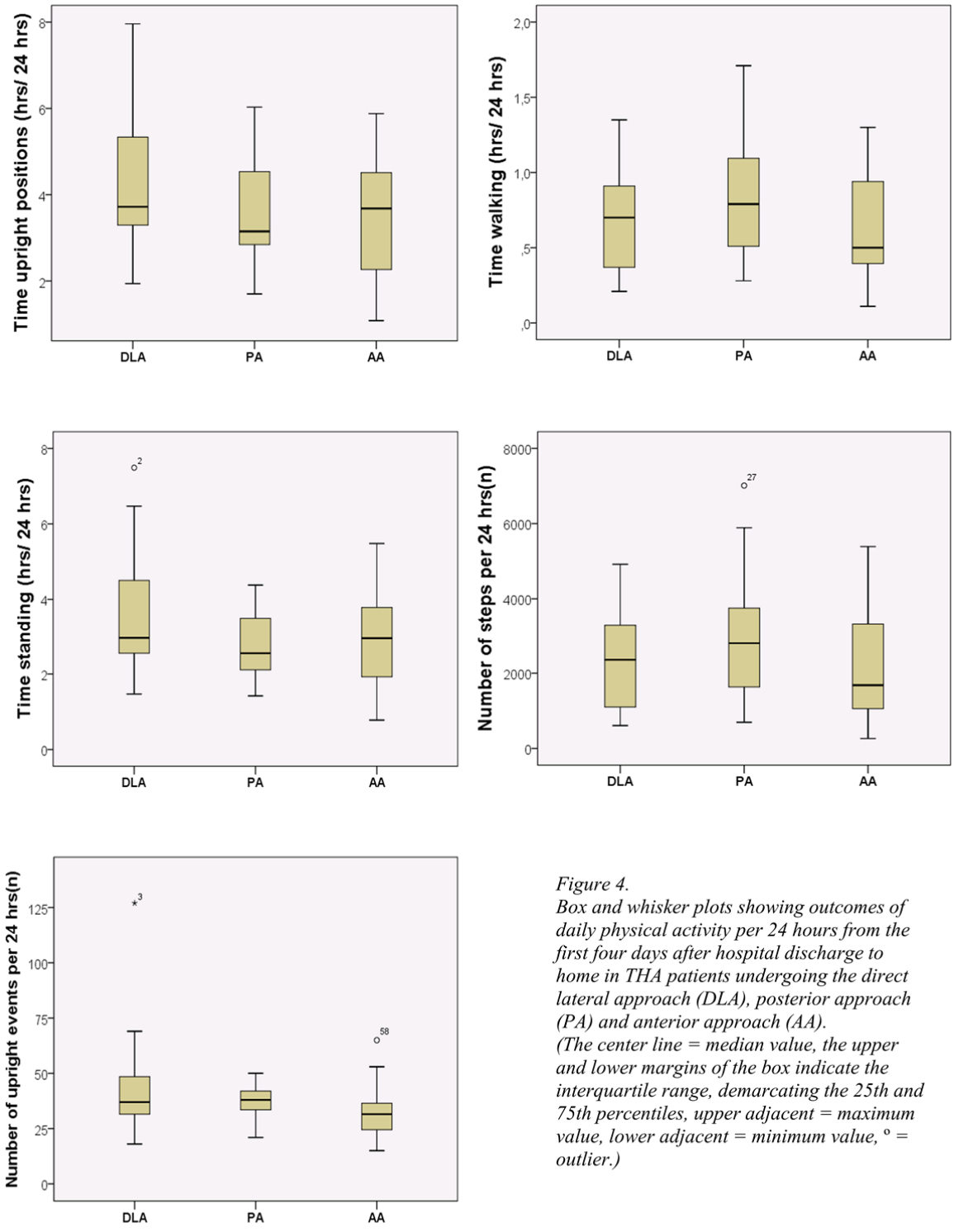

Figure 4.
Box and whisker plots showing outcomes of daily physical activity per 24 hours from the first four days after hospital discharge to home in THA patients undergoing the direct lateral approach (DLA), posterior approach (PA) and anterior approach (AA).
(The center line = median value, the upper and lower margins of the box indicate the interquartile range, demarcating the 25th and 75th percentiles, upper adjacent = maximum value, lower adjacent = minimum value, º = outlier.)

4 Discussion

This study evaluated objectively measured daily physical activity of THA patients under the age of 70 years early after hospital discharge to home after a fast-track treatment course. The aim was to compare daily physical activity in three groups of THA patients undergoing different surgical approaches, DLA, PA and AA. Results showed no group differences in the primary outcome time in upright positions, or the secondary outcomes time in walking, time in standing, number of steps, and number of upright events in the first four days post-discharge. Overall, there was considerable variation in all outcomes of daily physical activity, indicating a heterogeneous sample of recently operated THA patients in terms of daily physical activity.

The present study is unique in that it is the first to assess objectively measured daily physical activity in patients after fast-track THA early after hospital discharge in a trial comparing different surgical approaches. Contrary to the hypothesis, the participants undergoing minimal invasive surgery in line with the AA did not have a higher amount of daily physical activity early after hospital discharge compared to the other groups undergoing more invasive surgical approaches in terms of the extent of muscle dissection. Previous studies have shown that THA by use of AA results in improved clinical outcomes of early recovery when compared to DLA (21, 22, 24) and PA (23). It was therefore surprising that patients in the AA group did not spend a higher amount of time being physically active early after surgery.

All three groups in this study did spend a relatively high amount of time being physically active, and this could partly explain why we did not find any group differences. Overall, the median participant spent 3.35 hours in upright positions and took 2122 steps per 24 hours. This shows that already within the first week postsurgery, participants were back to about 70% of the time in upright positions found in end-stage HOA patients with a mean age of 61.4 years (63). In the absence of previous activity monitoring studies on THA patients early after surgery, a comparison is made with other patient groups' amount of daily physical activity at the same period of time after major surgery. The amount of daily physical activity in the present study corresponds to almost seven times as much time in upright positions, compared to patients with a mean age of 61 years undergoing upper abdominal surgery the fourth postoperative day (median of 34.4 minutes in upright positions) (53). Further, another study showed that patients undergoing heart surgery took a median of 804 steps the fifth day after intensive care unit discharge, less than half as many steps than the recently operated THA patients in the present study (54). The patients in these two studies were still hospitalized, and therefore not entirely comparable to the patients in our study. However, it could indicate that just a few days after THA in a

fast track treatment course, patients spend a higher amount of time being physically active as compared to other patients groups undergoing major surgery. Regardless of surgical approach the relatively high amount of daily physical activity demonstrated in this study, indicates that the surgical approach may not be a limiting factor for the amount of physical activity early post-surgery. Thereby, other factors in the fast-track treatment course may be more important in terms of influencing daily physical activity early after surgery.

Early after surgery, multiple factors such as pain, nausea, stress response with subsequent organ dysfunction, and fatigue may affect early postoperative mobilization (98), which in turn may influence the patients' daily physical activity. The fast-track methodology in THA surgery combines various evidence-based methods in order to optimize treatment and reduce the negative consequences of surgery in order to prevent delayed recovery. The concept includes optimal pain control, regional anesthesia, and aggressive postoperative rehabilitation including early oral nutrition and ambulation. The combination of these elements reduces the postoperative physical stress response, pain, nausea and fatigue, which in turn facilitate physical activity and early recovery after surgery (38). In the present study, all participants regardless of surgical approach received the same fast-track care organized for total hip- and knee arthroplasty patients at the hospital. In addition to equal and extensive preoperative information and perioperative care, they also underwent the same rehabilitation protocol including early mobilization and instruction in exercises and encouragement in resumption of daily physical activity as much as they felt was comfortable. The results showing no group differences in the amount of time being physically active, may suggest that the fast-track treatment course itself optimizes the factors affecting the patients' daily physical activity early after surgery to such an extent, including low levels of pain (3 or below on NRS), that the surgical approach used does not seem to have a further impact on the amount of physical activity during the first postoperative week. The surgical stress response might have a greater influence on daily physical activity early postsurgery. However, later in the rehabilitation period when the surgical stress response is less prominent, one can question if the surgical approaches' various degrees of muscle trauma might affect the patient's daily physical activity.

The participants in our study had no restrictions regarding exercise or performance of daily physical activity, except to avoid contact sports. Participants were encouraged to be as physically active as they felt was comfortable, and instructed to proceed with activities as tolerated, allowing their hip symptoms to be the guide. Although there was no difference between the groups in the amount of daily physical activity, there was a considerable variation in all outcomes of daily physical activity. The number of steps can illustrate the variation, where the median participant took 2122 steps per 24 hours. The wide interquartile range from 1154 to 3526 steps shows that 25% of the participants took less than 1154 steps

per 24 hours, while the 25% most active participants took more than 3526 steps per 24 hours. The same pattern was present in all outcome measures of daily physical activity. This could indicate that the patient's daily physical activity early after THA surgery might be more influenced by patient-specific factors present prior to surgery rather than the surgical approach itself. Studies have shown that age and BMI can influence the amount of daily physical activity in end-stage HOA patients (62, 63). In the present study, there were no differences regarding BMI and age between the groups. However, there was a wide range in age from 30-69 years and a range in BMI from 18.9- 34.0. This could have affected the amount of daily physical activity, and explain some of the large variability seen in the number of steps and the other measures of daily physical activity early after surgery. There is reason to assume that the amount of daily physical activity a patient performs before surgery also is determinative for the amount of daily physical activity early after surgery regardless of the approach treatment, as long as postoperative factors reducing physical activity are minimized through the fast-track treatment course.

It was believed that the extent of muscle weakness as a result of the trauma during surgery, has an impact on the amount of daily physical activity the patient is able to perform early after surgery. According to a recently accepted study from our research group, the participants in the present study undergoing the PA and AA had less reduction in lower limb muscular strength following surgery than did participants undergoing the DLA at days two and eight postsurgery. The second day postsurgery, when the activPALs were attached, the DLA group had a halving of lower limb muscular strength relative to preoperative values (49-57%), while the AA and PA groups had reduced lower limb muscular strength to 76-80% relative to preoperative values. The eighth day postsurgery, upon completion of the activity monitoring period, the AA and PA groups had almost completely regained their preoperative lower limb muscular strength (89-107% relative to preoperative values), while the DLA group still had a substantial reduction in lower limb muscular strength (63-69% relative to preoperative values) (25). The fact that the participants in the DLA group in the activity monitoring period had a significantly larger reduction in lower limb muscular strength, did not affect the amount of daily physical activity performed early after surgery compared to the other groups. The extent of muscle weakness as a result of the trauma during surgery, did not have an impact on the amount of daily physical activity, which again indicates that the surgical approach may not be a limiting factor for how physically active THA patients are this early after surgery. Instead, it points out other postoperative factors, such as the various components of the surgical stress response, as mentioned by Kehlet (1997) (98), to be more important in affecting daily physical activity early after surgery. The surgical stress response can be the reason why the patients in the PA and AA groups did not utilize the more preserved lower limb muscular strength to spend a higher amount of time being physically activity early after surgery compared to the DLA group.

The surgical approach did not affect the amount of daily physical activity early after hospital discharge to home in a population of relatively young (mean 56.2, range 30-69 years) and well-functioning THA patients in our study. A Danish study evaluated daily physical activity based on activity counts in hip and knee arthroplasty patients with mean age of 70.5 years (range 61-89 years) early after hospital discharge to home. In this study the patients reported that the most debilitating factor hindering their movements and ambulating was a feeling of weakness in the operated limb. The researchers attributed this to the profound reduction in muscle strength after surgery reported in other studies of this population (37). In an older population of THA patients with more profound impaired function and marginal preoperative muscle strength, the extent of muscle strength reduction caused by different approaches during surgery, might affect the amount of daily physical activity early after surgery, but this is a hypothesis to be further investigated in future studies.

Few years ago, hospital discharge after THA surgery was usually followed by inpatient rehabilitation. Today the majority of the THA patients are discharged from hospital directly to home (10). Therefore, it is interesting to compare the THA patients' daily physical activity at an inpatient rehabilitation facility to the findings in our study. A study from Peiris and colleagues (2013) has shown that patients with a mean age of 73 years, median nine days after surgery, receiving inpatient rehabilitation for lower limb orthopaedic conditions, only spent a median of 58 minutes in upright positions, a median of 8 minutes in walking, and took a median of 398 steps per day (52). The values are about one fifth of the overall daily physical activity performed by the participants in our study. Even though the participants were not entirely comparable to our participants, due to older age and half of them elective THA and TKA patients (the other patients had a traumatic fracture), it indicates that THA patients discharged directly to home perform a higher amount of daily physical activity compared to patients discharged to an inpatient rehabilitation facility. A subgroup analysis of the rehabilitation study data showed that the participants who underwent THA and TKA spent 0.8 more hours in upright positions per day than participants who had traumatic fracture (51), but these arthroplasty patients still performed much less daily physical activity than shown in our study. The difference in the amount of daily physical activity between THA patients discharged to a rehabilitation facility and those who are discharged directly to home, indicate that there is a lack of stimulation to habitual daily physical activity in rehabilitation facilities compared to what the patients are stimulated to do if they have to manage on their own at home. To fend for themselves at home could also stimulate earlier regaining of ADL-functions. This demonstrates that the common routine of discharging independently mobile THA patients directly to home early after surgery is beneficial for their daily physical activity and could also be beneficial for recovery of ADL-functions.

We found an interesting gender difference for two of the outcomes in our study, where men spent almost twice as much time in walking and took more than twice as many steps compared to women. This finding was somewhat surprising, because many activity monitoring studies on various populations show no gender differences. A study on end-stage HOA patients showed no gender difference in number of steps taken (62). Neither in a Norwegian population-based study on physical activity in adults there was found gender difference with respect to the number of steps taken (43). However, the population study showed that men spent significantly more time in MVPA compared to women, while women spent significantly more time in low intensity activity. In the present study we did not measure the intensity of activities. The difference seen in time in walking, while there was no difference in time in upright positions, indicate that men had a higher intensity in their daily physical activity compared to women. Men spent more of their upright time in walking, compared to women, while women spent more of their upright time in standing. Thus, the differences between gender seen in the number of steps and time in walking which did not appear in the other outcome measures, means that different outcome measures can display different aspects of daily physical activity. Therefore the results can be dependent on the chosen outcomes.

4.4 Methodological Considerations

With regard to research exploring daily physical activity in THA patients early after hospital discharge, the present study contributes with objective collected data from activity monitors. By allocating the participant in groups undergoing different surgical approaches, the outcome measures derived from the activity monitoring were able to examine whether there was a difference between the groups in daily physical activity. At current date, daily physical activity early after surgery is scarcely reported in prior research for this patient group although such information can give additional knowledge about different surgical approaches' impact on early recovery. The methodological considerations of the present study are debated in the following.

4.4.1 Internal Validity

There are some factors that might have threatened the internal validity of the findings in the present study. This study was a prospective cohort study, and issues with no randomization to group allocation and the lack of preoperative outcome measures of daily physical activity, are of particular concern.

Randomized controlled trials are considered to be the gold standard of true experimental designs to examine the effect of a treatment or intervention on a particular disease or condition (99). Randomization was not suitable in our study because of practical reasons. The surgeons performing the

AA and the PA surgeries worked at other hospitals, and participants were allocated to the surgical approach dependent on the availability of the surgeons. The allocation of participants resulted in a difference in gender distribution between the groups as can be seen in the baseline data. Further, there was also a significant group difference in pain at rest preoperatively, where the participants in the AA group reported more pain than the other two groups. A randomization procedure could have eliminated sources of systematic variation by ensuring an equal distribution of confunding factors, and could have made study groups as similar as possible at baseline, which is especially important at a small sample size. This is important so that potential differences in daily physical activity should be due to the different surgical approaches and not be influenced by initial differences. In the final analyses using Linear Mixed Models, adjustments were made for differences in gender and preoperative pain at rest to control for possible influence. Nevertheless, group differences did not change after controlling for gender and preoperative pain at rest, which means that the group differences seen at baseline did not affect the main results.

A shortcoming in this study was the lack of preoperative activity monitoring data of daily physical activity. With the same outcome measures of daily physical activity preoperatively, it would have been possible to examine whether the groups were equal in relation to the amount of daily physical activity prior to surgery. Therefore, we cannot exclude if the outcomes were influenced by group differences in physical activity behavior prior to surgery. However, in the lack of sufficient randomization and preoperative objective measures of daily physical activity, the function tests as the Harris Hip Score and the HOOS-PS showed that there were no preoperative group differences in physical function or the participants' opinion about hip-associated problems in daily life activities. In addition, there were no group differences in values for maximal walking speed. Previous findings show that maximal walking speeds are positively associated with the extent of habitual physical activity measured by steps per day (40). Further, there were no differences between the groups regarding age and BMI, which is previously found to be associated with the number of steps per day in patients with end-stage hip or knee osteoarthritis (62). The similarity in relation to these preoperative data suggests that the participants may have been similar also in daily physical activity prior to the surgeries, although one should be cautious to draw such a conclusion.

The standardized fast-track patient pathway minimizes the risk of possible confounding factors, such as different pain management, rehabilitation, or patient education, which could have affected the amount of daily physical activity early after surgery (100). As described earlier (section 2.3.4) all participants were given the same information and recommendations regarding daily physical activity. They received analgesia which ensured low levels of pain, and they were all discharged to home within day three or

four (only two participants were discharged the fourth day) after surgery. The surgeons in charge of the surgeries were highly skilled and with long experience in performing surgeries with the current approach. Thereby there was no learning curve involved in the series of any of the surgeons that could have affected the results of the surgeries and influenced the patients' daily physical activity. Pain was not monitored during the period the participants were wearing the activity monitors at home. However, there were no differences in pain between the participants when they were asked to report pain at rest and during mobilization at the second and eighth day postsurgery when the activity monitors were attached and collected. As the activity monitoring was conducted in the period between these two days, pain was considered unlikely to influence the results. All these factors contribute to ensure that the participants were treated equally with respect to factors that could have influenced daily physical activity early after discharge to home, which increases the likelihood that any difference between the groups was caused by the surgical approach used.

The activity monitor used in the present study is not validated on THA patients. However, the activPAL is found to give a valid and reliable measure of the time in walking and time spent in upright positions during daily physical activities in healthy older adults (92, 93). Further, in a population of older people with impaired function and walking mobility, it is found to show perfect accuracy in the time spent in upright positions and the number of upright events (94), and therefore it is reasonable to believe that the activPAL gives a valid and reliable measure of these outcomes also in a population of recently operated THA patients. The activPAL is found to have problems with registering number of steps especially at slow walking speeds (≤0.47 m/s) (94). To explore if the number of steps measured in the present study were reliable, the participants' walking speed was calculated from subtask two (three meters walk at preferred speed) of the Expanded Timed Up and Go on the day of attaching the activity monitors . The calculations showed that all the participants had a preferred walking speed of 0.47 m/sec. or more (mean 0.84 m/sec., range 0.47-1.46 m/sec.). Thus, the participants' preferred walking speed was fast enough to assume that the outcome number of steps between groups were reliable.

Outcomes derived from activity monitoring represent different aspects of daily physical activity (92). In this study the time in upright positions was chosen as primary outcome measure, because the ability to walk and move around represent activities which are important for THA patients early after surgery (4).The time in upright positions was therefore considered to be able to capture activities which are relevant for the particular target group. It may have been a weakness in the study that it lacks an outcome measure based on intensity of activity to distinguish between the groups.

The length of the data collection period and whether weekend days should be included, should be related to what is required to get a reliable outcome (101). The number of recording days in accelerometer studies is usually found to be between three to seven days (102). As long as the activity monitor is not validated on this particular target group, the number of recording days must be based on conclusions from validations on similar groups. It is found that in older persons with mobility limitations, at least four days with activity recordings is needed to provide a reliable estimate on activity patterns for individual persons. On a group level one single recording day provides a reliable estimate of daily physical activity in terms of time in upright positions (95). In this study the activity monitoring for the first four days after discharge to home, were used. All the participants were monitored two weekdays in addition to the weekend as all participants were operated on Mondays or Tuesdays and were discharged on Wednesdays, Thursdays or Fridays. This made the activity monitoring periods as similar as possible for all groups, and strengthens the reliability of the outcome.

Seasonal changes can affect a person's daily physical activity (50). In the DLA and PA groups about 20% of the participants underwent surgery during the winter, while in the AA group 68% of the participants underwent surgery during the winter. The seasonal changes may have affected the participants' daily physical activity, where the AA group spent less time in walking and took fewer steps than the other two groups. It is less likely that patients go outdoor with crutches just a few days after surgery during wintertime with possibly slippery conditions than during summertime.

4.4.2 External Validity

Sample size was calculated for the primary outcome in the main study, which was lower limb muscular strength measured by 1RM leg press (25). With the relative small sample size of 19 to 23 participants in each group and a large variability within the groups, one should be aware of the possibility of non-significant results due to insufficient power. Hence, the possibility of committing a Type II-error, that is obtaining a non-significant result when in fact the null-hypothesis is not true, is present (99). When a statistical test does not result in a statistically significant outcome, but the effect size is clinically meaningful, we should be aware of the possibility of Type II-error. However, further studies are needed to conclude on thresholds for clinically relevant differences of upright time early after surgery.

The sample in this study was individuals with unilateral HOA under the age of 70 years with a BMI less than 34. The age criteria was set to make it possible to use the same type of cementless components for all participants. The BMI restriction was set because the AA is not suitable for persons with BMI>34. The results can therefore not be generalized to a population of patients with higher BMI or a population

of patients older than 70 years. However, the age of the participants in this study is in accordance with the majority of THA patients operated on in Norway (1), meaning that the results of the present study can be generalized to a large part of the population of THA patients.

4.5 Implications for Clinical Work

Daily physical activity early after surgery is important to prevent postoperative complications and reduce negative consequences of immobilization. The present study contributes with objectively measured outcomes of daily physical activity in THA patients early after surgery in a fast-track treatment course. The results from the present study suggest that the surgical approach used may not be a limiting factor for the amount of physical activity early postsurgery. The choice of surgical approach should therefore be based on other criteria giving THA patients the most beneficial short and long term results.

Further, the results showed that the participants spent a relatively high amount of time being physically active the first week after discharge to home regardless of the surgical approach used, compared both with other patient groups undergoing major surgery as well as THA patients undergoing inpatient rehabilitation. This indicates that our sample of independent mobile THA patients who were discharged to home just 2-3 days after fast-track surgery, were relatively physically active in their daily life. Thus, the THA treatment course with early discharge directly to home only a few days after surgery is appropriate for this patient group.

5. Conclusions

This study on THA patients undergoing three different surgical approaches with varying degrees of muscle trauma, showed no group differences in the amount of time in upright positions, time in standing position, time in walking, number of steps, and number of upright events, indicating that the surgical approach may not be a limiting factor for daily physical activity during the first week after surgery in a fast-track treatment course. Recently operated THA patients under the age of 70 years showed considerable variations in the amount of daily physical activity, where the median patient spent a relatively high amount of time being physically active the first four days after discharge to home.

The study results suggest that the fast-track treatment course itself optimizes the factors affecting the patients' daily physical activity to such an extent that the surgical approach does not seem to have a further impact on daily physical activity in this population of relatively young and well-functioning THA patients early after surgery. More research on a larger sample size is needed to confirm these

results. How different surgical approaches impact daily physical activity later in the rehabilitation should also be evaluated. Future research should also include older THA patients with preoperatively more profound impaired functioning in activities of daily living, to investigate if the muscle trauma during surgery performed by different surgical approaches affects the amount of daily physical activity after surgery in this population.

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Appendices

I Harris Hip Score

II HOOS-PS

III Patient information and informed consent

Harris hip score - prepol

☐ Primæroperasjon ☐ Reoperasjon

Smerte

☐ Ingen
☐ Svak, lett verking/smerte uten innvirkning på funksjon
☐ Lett, noe vondt etter mye aktivitet, behov for reseptfri smertestillende
☐ Moderat, tolerabel men pasienten plages jevnlig. Kan hemme vanlig aktivitet, kan trenge sterkere smertestillende enn paracet
☐ Sterk, sterke smerter, men oppegående, hemmer aktivitet betydelig, behov for smertestillende sterkere enn paracet, noe nattsmerter
☐ Invalidiserende, betydelig natt smerte, klarer knapt å gå pga smerte

Gangfunksjon

Halting
☐ Ingen
☐ Lett
☐ Middels
☐ Svær

Støtte
☐ Ingen
☐ Stokk/gåstav for lengere tur
☐ Stokk/gåstav vanligvis
☐ En krykke
☐ To stokker/gåstaver
☐ To krykker/umulig å gå

Gangdistanse
☐ Ubegrenset
☐ 600 m
☐ 200-300 m
☐ Kun inne
☐ Bare seng og stol

Funksjon, daglige gjøremål

Trappegang
☐ Normal uten å bruke rekkverk
☐ Normalt med støtte til rekkverk
☐ Ett trinn av gangen ved hjelp av rekkverk
☐ Umulig

Påkledning
☐ Ingen problemer med sko/sokker
☐ Problemer med sko/sokker
☐ Umulig å ta på sko/sokker

Sitting
☐ Komfortabel i vanlig stol 1 time
☐ Komfortabel i høy stol halv time
☐ Ikke komfortabel i noen stoler

Transport
☐ Kan bruke kollektiv (buss)
☐ Umulig å bruke kollektiv (buss)

Deformitet

☐ Ingen
☐ Fleksjonskontraktur over 30°
☐ Adduksjonskontraktur over 10°
☐ Innrotasjon i ekstensjon over 10°
☐ Benlengdeforskjell over 3 cm

Totalt bevegelsesutslag

Grader fleksjon
☐ Ingen
☐ 1 - 7
☐ 8 - 15
☐ 16 - 23
☐ 24 - 31
☐ 32 - 39
☐ 40 - 44
☐ 45 - 54
☐ 55 - 64
☐ 65 - 69
☐ 70 - 74
☐ 75 - 79
☐ 80 - 89
☐ 90 - 99
☐ 100 - 110

Grader ext rotasjon
☐ Ingen
☐ 1 - 4
☐ 5 - 9
☐ 10 - 15

Grader abduksjon
☐ Ingen
☐ 1 - 4
☐ 5 - 9
☐ 10 - 14
☐ 15 - 20

Grader adduksjon
☐ Ingen
☐ 1 - 4
☐ 5 - 9
☐ 10 - 15

Hip dysfunction and Osteoarthritis Outcome score (HOOS) Physical Function Shortform (PS) - prepol

Spørreskjema til pasienter med hofteproblemer

Veiledning: dette spørreskjemaet inneholder spørsmål om hvordan din hofte fungerer. Svarene vil hjelpe oss til å følge med på hvordan du har det og hvor godt du fungerer i hverdagen. Besvar spørsmålene ved å krysse av for det alternativet du synes passer best for deg (kun ett kryss ved hvert spørsmål). Du skal besvare ALLE spørsmål. Hvis du er usikker, kryss likevel av for det alternativet som føles mest riktig.

Følgende spørsmål handler om din fysiske funksjon ved hverdagslige aktiviteter og ved aktiviteter som er litt mer krevende. Angi **graden av vanskeligheter du har opplevd den siste uken** ved følgende aktiviteter på grunn av dine hofteproblemer.

	Ingen	Noe	Moderat	Betydelig	Svært stor
1. Gå ned trapper	☐	☐	☐	☐	☐
2. Gå inn og ut av dusj/badekar	☐	☐	☐	☐	☐
3. Sitte	☐	☐	☐	☐	☐
4. Løpe	☐	☐	☐	☐	☐
5. Snu/vende kroppen når du står på benet	☐	☐	☐	☐	☐

Forespørsel om deltakelse i forskningsprosjektet:

"Miniinvasiv kirurgisk tilgang hos pasienter med hofteleddslitasje; kort- og langtidseffekter"

og

"Effekt av kirurgisk tilgang på beintetthet rundt kunstige hofteledd"

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie som sammenligner hofteleddets funksjon, plassering av hofteprotesen og beintettheten rundt hofteprotesen hos pasienter med standard hofteprotese etter at de er operert med ulik kirurgisk tilgang til leddet. Dette vil gi verdifull informasjon om hvordan man kan bevare beintettheten hos hofteprotesepasienter og valg av operasjonsmetode for pasienter med hofteleddsslitasje i framtida. Studien utføres i nært samarbeid mellom ortopedisk avdeling ved St. Olavs Hospital, Nasjonalt kompetansesenter for Ortopediske implantater ved seksjonsoverlege Dr. Med. Olav Foss og Norges teknisk naturvitenskapelige Universitet (NTNU). Medisinsk ansvarlig er seksjonsoverlege for proteseseksjonen ved ortopedisk avdeling, Dr. Med. Otto Schnell Husby. Faglig ansvarlig er PhD. Siri Bjørgen ved Institutt for Nevromedisin og PhD Tina S Wik ved ortopedisk avdeling. Som deltaker har du krav på å bli informert om studiet, og hva deltakelsen innebærer.

Hva innebærer studien?

Deltakerne vil bli tilfeldig fordelt til å opereres med en av tre vitenskapelige anerkjente kirurgiske tilganger som gir ulik grad av muskelskade i forbindelse med inngrepet. Som deltaker i studien vil du følge det ordinære behandlingsforløpet for pasienter operert med totalprotese i hofte/kne ved ortopedisk avdeling før, under og etter operasjonen. I tillegg vil det bli foretatt tester både før og gjentatte ganger etter operasjonen. De fysiske testene innebærer målinger av styrke i beina. Disse foretas ved hjelp av et beinpress apparat og et trekkapparat. Det vil også bli gjennomført andre fysiske tester som måler hvordan hofteleddet fungerer. I tillegg vil beintettheten rundt protesen og bevegeligheten i hofteleddet måles ved hjelp av standardiserte prosedyrer, samt at du vil bli bedt om å besvare noen spørreskjema som omhandler hvordan du selv opplever smerte og funksjon i forbindelse med hofteleddet.

Mulige fordeler og ulemper

Som deltaker i studien får du tett oppfølging av lege og treningsfysiolog gjennom hele prosjektperioden med ekstra konsultasjoner, og skulle du ha behov for å komme i kontakt med lege utenom de planlagte møtene kan dette ordnes direkte via prosjektansvarlig. I tillegg til de standardiserte etterkontrollene ved ortopedisk avdeling etter 3 mnd og 1 år, vil du bli bedt om å møte til undersøkelse/testing etter 1 dag, 1 og 6 uker samt 6 mnd og 3 år. Det vil i tillegg til å bli tatt røntgen av hoftene dine etter operasjonen og ved etterkontrollene, også bli tatt røntgen etter 1 og 6 uker, 6 mnd samt etter 2 og 5 år. Ved røntgen blir kroppen utsatt for ioniserende stråling, men denne dosen er så liten at det ikke utgjør noen kjent risiko for deg som pasient. Beintetthets-undersøkelsen vil ta ca 15 minutter, og du vil ligge i ro på ryggen under hele undersøkelsen. Dette vil ikke medføre noe ubehag. Undersøkelsen vil tidsmessig legges til de undersøkelsene og kontrollene du likevel skal til ved sykehuset. Beintetthetsmålingen er en slags røntgenundersøkelse med svært lite stråling, og utgjør ingen kjent helserisiko. Deltakere i studien vil få oppfølging av lege og forskningsmedarbeider dersom beintetthetsmålingene skulle vise noe unormalt.

Hva skjer med informasjonen om deg?

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle personopplysninger om deltakere oppbevares utilgjengelig for andre enn forsøksleder og samarbeidspartnere. Alle prosjektmedarbeidere har taushetsplikt i henhold til hfl. § 7. Resultater og målinger vil bli behandlet konfidensielt. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Dette gjør vi slik at vi eventuelt på et senere tidspunkt skal kunne tilbakeføre identiteten hvis dette er nødvendig som følge av nye oppdagelser som kan komme deg som pasient tilgode. Prosjektslutt er 290616, og dette er den siste dato du kan bli kontaktet for en eventuell oppfølgingsstudie. Etter at prosjektet er avsluttet vil opplysningene om deg bli oppbevart i 5 år. Involverte ledere i studiet har også taushetsplikt i henhold til Forvaltningslovens § 13 og Helsepersonellovens § 21. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Prosjektet er godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk.

Frivillig deltakelse

Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte prosjektleder Siri Bjørgen, tlf; 725 73669/ 915 31150, e-post: siri.bjorgen@ntnu.no. Har du spørsmål om beintetthetsundersøkelsen kan du kontakte prosjektleder Tina Strømdal Wik, tlf: 72826521/98886991, e-post: tina.s.wik@ntnu.no

Ytterligere informasjon om studien finnes i kapittel *A* – *utdypende forklaring av hva studien innebærer.*
Ytterligere informasjon om biobank, personvern og forsikring finnes i kapittel B – *Personvern, biobank, økonomi og forsikring.*

Samtykkeerklæring følger etter kapittel B.

Kapittel A- utdypende forklaring av hva studien innebærer

Kriteriene for å delta i prosjektet er følgende:

- Alder <70 år

- Ikke ha sykdommer som er ***funksjonsnedsettende*** og vanskeliggjør gjennomføring av testing

    - i skjelett- og muskelapparatet

    - aktuell hjerte- lungesykdom

    - aktuell maligne sykdommer

Bakgrunnsinformasjon om studien

Når det settes inn et kunstig hofteledd hos pasienter med hofteleddslitasje er målet i tillegg til å redusere smerte, å bevare biomekanikken i hoften slik at funksjonen blir minst mulig redusert og at protesen varer lengst mulig. Mange pasienter som er operert med totalprotese i hoften opplever svekkelse i hoften også etter at de er operert. Svekkelsene innebærer smerte, svakhet i de omkringliggende musklene, redusert bevegelighet og nedsatt gangfunksjon. Disse problemene kan føre til komplikasjoner som løsning av protesedeler og ustabilitet i leddet. Det er derfor viktig å studere betydningen av hvilken kirurgisk tilgang til hofteleddet man velger for å redusere risikoen for dette.

Etter innsetting av kunstig hofteledd kan det oppstå beintap rundt protesen. Dette beintapet kan være synlig på røntgen, og det kan måles ved hjelp av beintetthetsmåling. Vi vet ikke om noen dramatiske konsekvenser av dette beintapet, men man mistenker at det i ekstreme tilfeller kan føre til brudd i nærheten av protesen og det kan vanskeliggjøre en reoperasjon om nødvendig. Det kommer stadig nye protesekonsepter på markedet, hvor en del av dem retter seg mot å redusere beintapet rundt protesen. Det er derfor viktig å studere forhold som kan påvirke dette. Hensikten med denne studien er å undersøke om bruk av ulike kirurgiske tilganger påvirker beintettheten rundt det kunstige hofteleddet.

Undersøkelser

Du vil i tillegg til å møte til de standardiserte timene ved ortopedisk avdeling i forbindelse med innsettingen av det nye hofteleddet bli bedt om å møte til undersøkelser/tester både før, og gjentatte ganger etter operasjonen. Undersøkelsene innebærer testing av styrke og funksjonalitet i hoften. Du vil også måtte svare på spørsmål og fylle ut spørreskjema angående hoften din. Fra dag to til åtte vil du gå med en aktivitetssensor som registrerer hvor aktiv du har vært den første uka etter operasjonen.

Vi vil undersøke deg med en beintetthetsmåling (DEXA-scanning) før og etter operasjonen, samt i forbindelse med kontroller på sykehuset for det kunstige hofteleddet. Dette er en slags røntgenundersøkelse hvor vi får et tall på beintettheten rundt det kunstige hofteleddet. Vi vil sammenligne verdiene mellom gruppene som er operert med ulik kirurgisk tilgang til hofteleddet. Vi vet at denne verdien forandrer seg mest den første tiden etter operasjonen og derfor er

undersøkelsene tettere i det første halve året. Deretter vil vi undersøke beintettheten etter 1 og 3 år. Vi vil også få informasjon om de generelle beintetthetsverdiene i kroppen, og du vil få vite om du er beinskjør eller ikke. Dersom vi finner unormale verdier vil vi igangsette behandling for dette.

Tidsskjema – hva skjer og når skjer det?

De samme undersøkelsene/testene vil bli gjentatt på de følgende oppmøtene forbindelse med studien.

Disse innebærer;

- Styrke i muskulaturen rundt hofteleddet
- Fleksibilitet i hofteleddet
- Mobilitet og funksjonalitet
- Grad av smerte
- Livskvalitet
- Fra dag 2 til 8 etter operasjonen vil aktivitetsnivået bli registrert

Og vil bli foretatt;

- Før operasjonen
- 2 og 8 dag etter operasjonen
- 6 uker etter operasjonen
- 3 og 6 mnd. etter operasjonen
- 1 og 3 år etter operasjonen

Røntgenundersøkelsene i forbindelse med studien vil bli tatt;

- Første og 8 dag etter operasjonen
- 6 uker etter operasjonen
- 3 og 6 mnd. etter operasjonen
- 1, 2 og 5 år etter operasjonen

Beintetthetsundersøkelsen foregår på ortopedisk poliklinikk. Vi vil samordne med de undersøkelsene fra den andre studien du deltar i. Det vil bli beintetthetsundersøkelse

- før operasjonen
- etter operasjonen mens du fortsatt er innlagt på sykehuset
- 6 uker etter operasjonen
- 3 og 6 måneder etter operasjonen
- 1 år og 3 år etter operasjone

Ny informasjon/situasjon: Du vil bli orientert så raskt som mulig dersom ny informasjon blir tilgjengelig som kan påvirke din villighet til å delta i studien, dette gjelder også dersom det oppstår mulige beslutninger/situasjoner som gjør at din deltagelse i studien kan bli avsluttet tidligere enn planlagt.

Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern

Opplysninger som registreres om deg er data som samles inn på poliklinikken før operasjonen; høyde, vekt, røykevaner, medisinbruk og bruk av gangredskaper. I tillegg vil opplysninger som

funksjonalitet/mobilitet i hoften, opplevelse av smerte og din fysiske tilstand i tilknytning til hoften samles inn på poliklinikken og ved etterkontrollene. St. Olavs Hospital ved administrerende direktør er databehandlingsansvarlig.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien kan du kreve å få slettet opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi

Studien er finansiert gjennom forskningsmidler fra Samarbeidsorganet (Helse Midt-Norge RHF og NTNU) og Nasjonalt kompetansesenter for ortopediske implantater (NKSOI) ved St. Olavs Hospital. Prosjektet er et ”investigator-initiated study” og data samlet inn i prosjektet eies av NTNU og St. Olavs Hospital. Det vil derfor ikke være noen interessekonflikter knyttet til prosjektet.

Forsikring

Skulle noe skje med deg som pasient i forbindelse med deltakelsen i studien, er du forsikret gjennom pasientskadeloven.

Informasjon om utfallet av studien

Som deltaker i prosjektet har du rett til å få informasjon om utfallet/resultatet av studien.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)