**Post-operative findings and patient-reported outcomes in total hip arthroplasty
following the introduction of the minimally invasive direct anterior approach**

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Abbreviations

OA	Osteoarthritis
THA	Total hip arthroplasty
MIDA	Minimally invasive direct anterior
DLA	Direct lateral approach
RCT	Randomized controlled trial
MID	Minimal important difference
OHS	Oxford Hip score
PROMs	Patient-reported outcome measures
AP	Anteroposterior
BMI	Body mass index
VAS	Visual analogue scale
EQ-5D	EuroQol-five dimensions
ANOVA	Analysis of variance
ICC	Intraclass correlation coefficient
CI	Confidence interval
SD	Standard deviation

Summary

To date, the outcomes of the various surgical approaches used in total hip arthroplasty (THA) vary greatly, and there is insufficient data to determine the optimal choice of approach in patients with end-stage osteoarthritis needing elective THA. We therefore conducted trials to explore the department-level learning curve, as well as patient-related outcome measures (PROMs) and post-operative findings following the introduction of the minimally invasive direct anterior (MIDA) approach.

A prospective database study, a retrospective database study, and a level 1 prospective randomised controlled study (RCT) were conducted in mostly elderly patients at two level 2 hospitals in South Eastern Norway. Post-operative PROMs, complications, and radiographically assessed acetabular and femoral component placement were registered and assessed both during and following the introduction of the MIDA approach.

The findings suggest that outcomes improve gradually within a range of good results, especially following the first couple of 100 patients operated. The main difficulty in learning and establishing the MIDA approach; a new and relatively complex orthopaedic surgical technique, might seem to be primarily related to femoral access and femoral component positioning, as indicated by the relatively high frequency of stem subsidence at our department. Fractures of the greater trochanter may impact the outcomes following THA; however, such fractures do not occur more frequently using the MIDA approach compared to the DLA in our study population. In a patient population treated after the learning of the MIDA approach had been established, radiographically assessed component placement showed similar results in the two approaches, suggesting the MIDA approach is both safe and effective in THA.

Introduction

Hip anatomy

The hip joint is a synovial, so-called ball and socket joint, and is made up of the head of the femur (ball) and the acetabulum of the pelvis (socket) [1]. The main function of the hip joint is to stabilize and support the weight of the upper body while allowing a range of motion of the lower extremities in relation to the upper body (Figure 1).

Figure 1. Anatomy of the hip joint.

The head of the femur (the ball) has a slight forward rotation in relation to the rest of the femur as it sets in the acetabulum, called femoral anteversion. The acetabulum (the socket) also has a slight anterior rotation, called the acetabular anteversion [2]. Failure to replicate skeletal hip joint anatomy may cause poor results in total hip arthroplasty [3].

Total hip arthroplasty (THA)

Annually, approximately 1,000,000 patients undergo total hip arthroplasty (THA) worldwide [4]. In THA a damaged hip joint is replaced with a prosthesis, consisting of a femoral and an acetabular component. The femoral components most commonly in use are typically made of metal; titanium alloys, stainless steel, or other high-strength alloys. The acetabular component is normally composed of either metal, ceramics or polymers [5]. At present, the most common reason for THA is osteoarthritis (OA) [6]; a degenerative joint disease found as far back as in ancient skeletons [7]. THA is the most common surgical treatment of OA in patients where non-surgical treatment has been unsatisfactory and in whom symptoms have a substantial impact on quality of life [6, 8]. OA is characterized by progressive damage to articular cartilage and surrounding structures, including loss of joint space, osteophytes, sclerosis, cyst formation and increasing deformity of the femoral head and acetabulum [9] (Figure 2). Currently, the hip joint is the second most commonly affected joint by OA, after the knee [8].

Figure 2. Typical radiological findings in osteoarthritis, i.e. loss of joint space (long black arrows), osteophytes (long white arrows), sclerosis (stars), cyst formation (short black arrows), and increasing deformity of the femoral head and acetabulum. With permission by the patient.

Moreover, THA may be used to treat other causes of pain in the hip joint, including femoral neck fractures, avascular necrosis, dysplasia and inflammatory arthritis [6].

Orthopaedic surgical approaches in THA

Attempts at improving hip arthritis were described as early as in 1891 by Professor Themistocles Gluck [10], who replaced femoral heads with elephant ivory in patients with tuberculosis affecting the hip. His surgical approach; however, was not described in detail. Sir John Charnley is by many thought to have developed THA as we know it today [11]. Presently, different surgical approaches are used in THA, most commonly the direct lateral, the anterior and the posterior approach [12].

The direct lateral approach (DLA)

In 1982, Kevin Hardinge was the first to describe the direct lateral approach as it is known today [13]. In the direct lateral approach (DLA), the patient is normally in a lateral decubital position, but surgery with this approach can also be performed in the supine position. A skin incision formed as a posterior curve is made in line with the femur from a point distal to a point proximal to the limit of the greater trochanter (Figure 3). Thereafter, in line with the skin incision, an incision is made in the fascia lata.

Figure 3. The skin and fascia lata incisions in the direct lateral approach.

After removing the bursa covering the gluteal muscles, an incision is made in the gluteus medius, leaving a small cuff of tendon to facilitate and ease closure (Figure 4). Finally, the gluteus minimus is incised along its attachment to the greater trochanter, and the joint capsule is removed to provide access to the greater trochanter and femoral neck.

Figure 4. The gluteus medius incision and access to the hip joint in the direct lateral approach.

Other orthopaedic surgical approaches in THA

The posterior approach. In the 1950s, the posterior approach was popularised by A. T. Moore as an alternative approach in THA, in an attempt to avoid damage to the abductor muscles [14]. With the patient in the lateral decubitus position, an incision similar to the direct lateral approach is made; however, more posteriorly curved once the incision passes proximally to the greater trochanter (Figure 5).

Figure 5. The skin incision and access to the hip joint in the posterior approach.

After the fascia lata is incised along the skin incision, the muscle fibers of the gluteus maximus are split to localise the fat pad and sciatic nerve [15]. Thereafter, the tendons of the piriformis and other short external rotators are tenotomised at their insertion on the greater trochanter, and a suture is placed for later re-insertion. Finally, the posterior capsule is opened to provide access to the femoral neck.

The anterolateral approach. In the 1970s, an anterolateral approach previously developed by Watson-Jones for the treatment of femoral neck fractures, became an alternative to trochanter osteotomy [16]. In this approach, an incision is made from the anterior superior iliac tubercle extending distal to the greater trochanter. The interval between the tensor fascia lata and the gluteus medius is identified, in order to release the gluteus minimus insertion on the greater trochanter, and finally the distal third of the insertion of gluteus medius on the greater trochanter is partially released [17].

In a minimally invasive version of the anterolateral approach, an incision is made from a point approximately 3 cm distal and 3 cm lateral to the anterior superior iliac spine, towards the greater trochanter. The fascia of the tensor fascia lata is then split in line with the skin incision, and retractors are inserted in the interval between the tensor fascia lata and the gluteus medius following blunt digital dissection at the distal part of the incision [17].

The minimally invasive direct anterior approach (MIDA)

As early as in 1881, Carl Hueter was the first to describe the anterior approach to the hip joint, used in the resection of the femoral head [18]. In 1917, Marius Smith-Petersen advocated for the use of the same approach for treatment of hip dysplasia, and the anterior approach is often referred to as the Hueter or the Smith-Petersen approach [19]. Following the development of various materials for arthroplasty, Smith-Petersen was the first to use the anterior approach for such surgery [20]. The Judet brothers continued developing the same approach for arthroplasty, promoting the use of the orthopaedic traction table to ease exposure [21].

In an attempt to reduce muscle and tendon trauma, blood loss and recovery time, a first version of a minimally invasive direct anterior approach (MIDA) was developed using a two incision technique [22]. In this technique, the first anterior incision was used for cup placement and a second transgluteal incision for femoral component placement.

Later, a single incision version of the MIDA was developed by Siguer and Matta [18, 23], and this is currently the most commonly used version of the MIDA approach. With the patient in either the supine or lateral decubitus position, an incision is made from a point approximately 3 cm distal and 3 cm lateral to the anterior superior iliac spine, towards the greater trochanter (Figure 6) [24].

Figure 6. The skin incision and access to the hip joint in the minimally invasive direct anterior (MIDA) approach.

This incision is shorter than the original Smith-Petersen approach that used an incision starting at the anterior superior iliac spine. Following the skin and subcutaneous incisions, juncture between the tensor fascia lata and sartorius muscle is identified and an incision is made in the

thick fascia over these muscles to identify the fat strip at the medial, distal edge of the tensor fascia lata. The femur is localised manually in the fat strip, and blunt retractors inserted. Finally, the capsule is removed or incised to provide access to the femoral neck.

Complications following THA

THA is a widely established and successful orthopaedic procedure, but complications may occur [7]. Although there is no standardised reporting system for complications in THA, some have categorised complications from grade 1 to 5, with grade 1 complications that require no further treatment and have no clinical relevance, to grade 5 which is death [25]. The most dreaded early surgical complications following THA, are deep prosthetic joint infections, dislocations, and peri-prosthetic fractures of the acetabulum or the femur. The first two complications almost always require readmission and reoperation (grade 3-4), while the latter may range in severeness from grade 1 to 4.

Stem subsidence, another complication in THA, is defined as a distal displacement of >3 mm of the femoral stem compared to the tip of the greater trochanter within the first 8 weeks following surgery [26]. The risk of femoral subsidence following THA has been reported to vary as much as 5 to 60%. The underlying risk factors are not well understood; however, anatomic variations of the femur and disproportionate stem sizes and shapes are considered to play an important role [27].

As a proximal periprosthetic fracture of the femur, fractures of the greater trochanter may be classified as Vancouver A [28]. The other Vancouver classes include fractures of the femur surrounding the prosthesis (B) and fractures of the femur distal to the femoral prosthesis (C)

[29]. Large, dislocated fractures of the greater trochanter may be found per-operatively, whereas small fractures may only be found post-operatively upon radiographic examination [30]. To our knowledge, there exists no standardised categorisation or treatment guidelines for fractures of the greater trochanter.

Learning in orthopaedic surgery

Assessing the learning process of new orthopaedic surgical techniques and approaches may benefit both patient safety and treatment efficacy. Systematic analysis of the learning in surgical has been given increased focus following the so-called Bristol heart scandal in the 1990s, in which poor surgical learning procedures led to high post-operative mortality in young children [31]. The learning of orthopaedic surgery can be measured by either surgical endpoints, such as duration of surgery and complications, or by patient outcomes, such as survival rates and patient-reported outcome measures (PROMs).

The results may be presented as so-called learning curves, where the variables suitable for evaluation depend on the type of surgery [32]; however, there is no generally accepted standardisation of the assessment of learning. Main confounding factors include variations in study populations, prior surgeon experience, complexity of the procedure and amount of surgeon supervision, that may be addressed by using well-defined surgeon competency and experience prior to the assessment, as well as changes in patient specific outcome measurements [32]. In an ideal surgical learning curve, an acceptable standard is reached and maintained following a primary learning curve of an as limited number of patients as possible [33].

Knowledge gap

Following the introduction of the MIDA approach in orthopaedic surgical departments, individual surgeons may need to perform from 1 to 100 THAs to avoid increased per- and/or post-operative complications [34-40]. However, the underlying mechanisms for the differences in such learning curves and complication rates are not well understood, and further research on the learning of the MIDA approach is needed.

Currently, there is no uniformly recommended approach in THA, and the use of different approaches varies greatly between and even within countries [41, 42]. Some argue that the MIDA approach may reduce muscle trauma and thereby facilitate rapid post-operative recovery and rehabilitation [43-45], whereas others have reported variations in complications that may deter orthopaedic surgeons from using the MIDA approach. The benefits of a swift rehabilitation seem favourable; however, such benefits need to be weighed against the potential risk of complications during the learning of a new orthopaedic surgical approach.

Adverse events have been reported following the introduction of the MIDA at orthopaedic surgical departments [34, 39, 40, 43, 46-54], including serious complications, such as per-operative haemorrhage and fractures, to few or no post-operative complications. Some reports suggest that iatrogenic fractures of the greater trochanter may affect the outcome of THA; however, the details regarding such fractures are not well understood.

Aims

General aims

In 2008, the orthopaedic surgical department at a level 2 hospital in South Eastern Norway changed the approach used for THA from the DLA to the MIDA approach. In order to further explore the underlying mechanisms of learning curves and potential complications using the MIDA approach in THA, studies were conducted to describe the post-operative findings in the surgical treatment of patients needing elective THA.

Specific aims

At an orthopaedic surgical department, in patients needing elective THA:

1. To explore the department-level learning curve following the introduction of the MIDA approach, defined by patient reported outcome measures (PROMs) and radiological findings.
2. To determine the prevalence and the effect on PROMs of greater trochanter fractures in the MIDA and DLA approaches.
3. To determine the effect of the DLA versus the MIDA approach on component placement.

Materials and methods

Patient populations

All patients were treated with elective THA, the majority being elderly patients with end-stage OA or other chronic hip joint pathology, including avascular necrosis, dysplasia and inflammatory arthritis. The trial population consisted of patients of a Norwegian elderly case mix, where the majority are of Norwegian origin. All patients were recruited at level 2 hospitals, in the first two trials from Drammen hospital, and in the third trial from Sorlandet Hospital Arendal. Table 1 shows the population characteristics in the three trials, respectively.

Table 1. Trial population characteristics

Characteristics	Trial 1	Trial 2	Trial 3
Number of patients	489	26/911	164
Mean age (years)	69	67	66
Sex (male/female)	169/320	5/21	55/109
DLA/MIDA	0/489	13/13	80/84

Trial designs

The first trial was a prospective database study conducted from August 2008 to April 2010.

All patients treated with THA for chronic hip joint pathology using the newly introduced MIDA approach were included in the Drammen Hospital Primary Hip Replacement Quality and Safety Database. All patients were monitored for complications, and all patients provided answers to PROMs questionnaires and underwent post-operative plain anteroposterior (AP)

radiographic images. As all patients were included the quality register, no patients were excluded from the analysis.

The second trial was a retrospective database study conducted between January 2005 and December 2010. All patients treated with THA for chronic hip joint pathology using the DLA and MIDA approaches were included in the Drammen Hospital Primary Hip Replacement Quality and Safety Database. All patients provided radiographs, and all but one patient (who died) provided answers to PROMs questionnaires. As all patients were included the quality register, no patients were excluded from the analysis.

The third trial was a level 1 double-blind, prospective, randomised controlled trial (RCT) conducted between January 2012 and June 2013. All consenting patients with radiologically confirmed chronic hip disease were eligible for inclusion in the trial for THA using either the DLA or the MIDA approach. Excluded were patients in whom other factors could adversely affect outcomes, including previous ipsilateral hip surgery, body mass index (BMI) $>35 \text{ kg/m}^2$ and mental disability, or requested a specific surgical approach. In total, 164 patients were included and 215 patients were excluded (Figure 7). THA procedures were performed by 5 experienced senior orthopedic surgeons, trained in the MIDA approach.

Figure 7. The CONSORT 10 flow diagram for the RCT on the DLA vs the MIDA approach in THA.

Orthopaedic surgical intervention

All trial patients were treated with THA using the same femoral component, but different acetabular components (Table 2), according to the current practice at the respective trial hospitals. In the first and second trials, THAs were performed by 16 different orthopaedic surgeons, from experienced residential surgeons to senior consultants; whereas in the third trial, THAs were performed by 5 senior consultants.

Table 2. Femoral and acetabular implants used in the trials. *Elite plus was the chosen department-level cup component prior to Marathon.

Component	Trial 1	Trial 2	Trial 3
Cup	Marathon, Depuy	Marathon, Depuy Elite Plus, Depuy (DLA*)	Marathon, Depuy
Stem	Corail, Depuy	Corail, Depuy	Corail, Depuy

Outcome measures

The first trial registered PROMs; including the EuroQoL five dimensions (EQ-5D)-five levels questionnaire, the pain visual analogue scale (VAS), the satisfaction VAS, and the Oxford Hip Score (OHS), as well as readmission (yes/no), duration of surgery (minutes), selected complications (per-operative fractures, luxation and infection), and radiographically determined component placement. The second trial registered PROMs and radiographically verified per-operative fractures. In the third trial, cement-mantle thickness, acetabular and femoral component placement, offset and leg length discrepancy was assessed radiographically in all patients.

In the first trial, outcome measures were registered and assessed by 3 senior orthopaedic surgeons, who also performed THAs. In the second trial, registration and assessment was done by 1 senior and 1 resident orthopaedic surgeon. In the third trial, outcome measures were registered and assessed by 2 senior orthopaedic surgeons who were both blinded for the approach and who did not have any other role in the trial, including surgical procedures.

Patient reported outcome measures (PROMs).

Quality of life

EuroQoL five dimensions-5 level questionnaire (EQ-5D)-5LEQ-5D is an assessment tool of quality of life developed by the EuroQol Group. The tool consists of 2 parts (Appendix 1). The first part consists of 5 questions; mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, which in our trials were rated on 5 levels; no problems, slight problems, moderate problems, severe problems, and unable to/extreme problems. In the second part, the patient rates his/her quality of life on a scale from 0 to 100, where 0 equals worst possible life quality and 100 the best life quality possible.

EQ-5D is validated for use in 6 Western European countries, and Denmark was chosen as the closest alternative to Norway. The first score, referred to as the EQ-5D index, ranges from <0 (worse than death) to 0=death and 100=highest possible quality of life, while the patient-rated quality of life value from 0 to 100 is referred to as the EQ-5D VAS (the original EQ-5D index is given as a range between <0 and 1, and in order to facilitate comparison with other PROMs scores, we multiplied the index results by a factor of 100). EQ-5D is validated for several chronic conditions, including arthritis [55, 56], and although EQ-5D has not been validated for hip osteoarthritis, it is often included in studies measuring quality of life outcomes after THA[57]. The minimal important difference (MID) for the EQ-5D index has been estimated to be 7.4 (0.074) [58]. Similar to the pain VAS (see below), a change in the EQ-5D VAS, score of 10 points was considered clinically relevant.

Pain

Pain visual analogue scale (VAS) scores patient-reported pain on a scale from 0 to 100, where 0 equals no pain and 100 the maximal level of pain possible. The scale is widely used and has high reliability [59]. Similar to other patient-reported VAS, pain is also highly multifactorial, and may be influenced by factors such as pain acceptance, tolerance and anxiety. A change in score of 10 points was considered clinically relevant [60].

Satisfaction

The satisfaction VAS scores the patient's satisfaction with THA from 0 to 100, where 100 equals no satisfaction and 0 equals extreme satisfaction (inverse scale). The scale is simple, fast and easy to use, and although satisfaction may be influenced by both physical and emotional factors, the scale has been validated for use after THA [61]. Similar to the pain VAS, we considered a change in score of 10 points as clinically relevant.

Hip function

The Oxford hip score (OHS) is a patient-reported questionnaire that scores responses on a scale from 0 to 48, by assessing pain (6 items) and function (6 items) of the hip in daily activities, such as walking, dressing and sleeping (Appendix 2). The score is designed for evaluation of hip joint replacement and has been found to be both valid and reliable in patients following THA [62, 63]. A high correlation ($r = 0.7$, $P < 0.001$) was found between OHS and the Harris hip score (HHS) [64]. The MID for OHS has been estimated to be 5 points [65].

Component position

Cement-mantle thickness

Cement-mantle thickness was assessed in acetabular zones 1 to 3 by determining the thinnest cement-mantle zone-wise by using a radiological software (Figure 8). The cement-mantle was defined as adequate if ≥ 2 mm in all three zones of the anteroposterior (AP) radiograph [66].

Figure 8. Acetabular zones in AP view

Acetabular component anteversion

The radiographic anteversion angle is defined as the angle between the acetabular axis and the coronal plane [67]. The cup anteversion can be calculated by several methods, including a method developed by Lewinnek used in our trials [68] (Figure 9). An anteversion between 5° and 25° was defined as adequate, i.e. clinically relevant [3].

Figure 9. Calculation of anteversion.

A marathon x-ray marker wire indicates whether the calculated angle is anteverted or retroverted [69] (Figure 10).

Figure 10. Marathon metal x-ray marker in the cup in anteversion (A) and retroversion (B).

Note the “cross-sign” at the top in the anteverted cup.

Acetabular component inclination

The radiographic inclination angle is defined as the angle between the longitudinal axis of the body and projection of the acetabular axis in the coronal plane [70]. Inclination was calculated using the bi-ischial line on AP radiographs (Figure 11); a method that has shown good intra-observer reliability and validity [71-73]. An inclination between 30° and 50° was defined as adequate, i.e. clinically relevant [3].

Figure 11. Inclination measurement in a 70 year old female patient using the bi-ischial line.

The Lewinnek safe zone was defined as a cup anteversion between 5 to 25 degrees and cup inclination between 30 to 50 degrees [3].

Femoral stem position

There is no uniform recommendation of evaluating the lateral view of uncemented femoral stems, other than ensuring the component is centralised in the lateral view [74, 75]. We therefore first assessed the varus/valgus position of the femoral stem on the AP radiograph, where <5 degrees was defined as adequate [76]. Thereafter, the stem position was determined on the lateral radiograph using the THA index, i.e. the distance from the anterior cortex of the femoral wall to the tip of the stem on the lateral radiograph, divided by the distance from the anterior to the posterior wall of the cortex (Figure 12). A THA index between 0.4 and 0.6 was defined adequate.

Figure 12. THA index calculating position of femoral stem in the lateral radiograph.

Femoral and acetabular offset

Offset was assessed by measuring the distance on the AP radiograph between the rotational center and the long axis of the femur (femoral offset), and between the rotational center and the

ilioischial line (acetabular offset) (Figure 13). The sum of these two values was referred to as global offset. The difference between pre- and post-operative offset, i.e. offset restoration, was calculated, and values of ± 5 mm were defined as adequate [77].

Figure 13. Femoral, acetabular, and global offset calculation.

Leg length discrepancy

Pre- and post-operative leg length was measured on the AP radiograph using the distance between the ischial tuberosities and the medial part of trochanter minor. A leg length discrepancy of ± 5 mm was defined as adequate [78].

Statistical analyses

SPSS Statistics version 20 and 25 was used for statistical analysis. A 95% confidence interval (CI) and 5% significance level was used throughout.

In **the first trial**, continuous variables were presented as means, and complications were presented as frequency and percentages. First, the Student's t-test was used to compare PROMs, duration of surgery, and acetabular component placement in the first 250 patients to the last 250 patients. Thereafter, in order to determine the plateau or so-called steady-state, groups of 100 patients were sequentially compared to the remaining patients; i.e. patients 1-100 to the last 400, patients 101-200 to the last 300, and so on. Finally, the same comparisons were done, excluding early reoperations from the analysis.

In addition, the acetabular component placement was defined as safe (value=1) if adequate cup anteversion and inclination (Lewinnek safe zone), otherwise cup placement was defined as unsafe (value=2). The Student's T-test was used to compare the percentage of patients with safe and unsafe cup placement in the first 250 and last 239 patients. The Pearson's chi-squared test showed the same results as the Student's T-test.

In **the second trial**, the prevalence of complications and PROMs were given as percentages. The prevalence of fractures was compared between patients operated using the MIDA and DLA approaches using the Student's t-test. The mean PROMs values was compared between patients included in this trial and patients included in Sweden's (mean EQ-5D index, satisfaction VAS, and pain VAS) and New Zealand's (mean OHS) hip registers using the Student's t-test.

Analysis of variance (ANOVA) was used to assess the PROMs obtained in this trial in the 3 categories of fractures of the greater trochanter. The variables are considered significantly different when the values within their 95% confidence intervals lie outside the common mean.

In **the third trial**, continuous variables were presented as means. The Student's t-test was used to compare means between trial groups. Categorical variables were given as frequency and percentage, and were compared using Pearsons Chi Squared test. The intra-observer reliability of assessments was determined by calculating the intraclass correlation coefficient (ICC), and values >0.9 were considered to be very good.

Ethical considerations

THA, the chosen trial intervention in all three studies included in this thesis, is proven to be a safe and effective orthopaedic surgical intervention for the treatment of OA [6, 7]. The MIDA approach is an established means of access to the hip joint in THA; however, the characteristics of the learning curve following the introduction of the MIDA approach in THA are not fully understood [38, 39, 47, 79-81]. Importantly, national arthroplasty registry data have shown similar revision rates in THA using the MIDA approach compared to other approaches used in THA[41, 42].

The first trial enrolled patients who were included in the Drammen Hospital Primary Hip Replacement Quality and Safety Database; an anonymised internal data register established for research and quality purposes at a level 2 hospital in South Eastern Norway. Thus, the first trial was part of a hospital-based quality assurance project in line with current regulations. The trial patients were diagnosed and treated as part of regular clinical practice, in line with standardised quality measures, and at no additional costs or procedures beyond regular follow-up. The patients provided answers to questionnaires with regard to patient-reported outcome measures (PROMS), taking an average of 30 minutes each. In order to ascertain that the trial patients were not subject to significant risk of unintended complications, the department and individual

orthopaedic surgeons undertook theoretical and practical preparations, including participation by 2 surgeons at courses in the use of the MIDA approach and live surgery learning sessions taught by external experts in the use of the MIDA approach. For quality assurance, the first 6 operations were supervised by an external expert in the use of the MIDA approach.

The second trial included patients from the same quality register as in the first study. The trial patients were diagnosed and treated as part of regular clinical practice, in line with standardised quality measures, and at no additional costs or procedures beyond regular follow-up. The patients provided answers to PROMS questionnaires, taking an average of 30 minutes each.

The third trial was approved by the regional ethical committee (REK). All patients were enrolled in the trial following free and informed consent, and could withdraw from trial at any point without any consequences for quality or level of treatment or follow-up. All patients were diagnosed and treated as part of regular clinical practice, in line with standardised quality measures, and at no additional costs or procedures beyond regular follow-up.

Results

Trial 1. Department-level learning curve for the MIDA approach

In total, 522 patients were included in this trial. For AP radiographs taken the first post-operative day and responses to PROMs and 6 months following surgery, 6% (33/522) were lost to follow-up. Based on previous clinical experience, loss to follow-up is thought to be related to geographical distances between the trial hospital and some patients' residence, but this data was not registered in this trial. We registered 41 readmissions during the first 90 days, 17 of which were due to THA related issues (including reoperations), and 24 due to elective or other medical illnesses not related to the THA.

Complications

In total, 4.6% (24/522) of patients required reoperation within the first 6 months following surgery (Table 3).

Table 3. Summary of registered complications. *Stem position was not registered and only reoperated stem subsidence was included.

Complications	Number reoperated	Number conservatively treated	Total
Stem subsidence	14	*	14 (needing reoperation)
Other femoral stem pathology	4 (2/4 were trochanteric fractures)	2 (2/2 were trochanteric fractures)	6 (2 perforated femoral canals due malposition of the femoral component + 4 fractures of the greater trochanter (Type 3))
Deep prosthetic infection	5	0	5
Dislocation	3	2 (closed reduction)	5
Acetabular component pathology	3	0	2 cup loosening + 1 iliopsoas impingement

Figure 14 shows the distribution of operated patients, including reoperations due to complications per orthopaedic surgeon.

Figure 14. The distribution of operated patients per orthopaedic surgeon. Red markers indicate patients who underwent revision surgery due to complications.

PROMs

Patients from number 251 and onwards reported significantly better results with regard to all PROMs apart from OHS (close to significant) compared to the first 250 patients (Table 4).

Table 4. Patient-reported outcome measures (PROMs) in patients 1-250 compared to patients >250. SD = standard deviation, EQ-5D = EuroQol 5 dimensions, VAS = visual analogue scale. p values <0.05 were considered statistically significant.

PROMs	Patients 1-250	Patients 251-489	p
	Mean (SD)	Mean (SD)	
EQ5D index	78.1 (26.2)	83.7 (20.4)	0.008
EQ5D VAS	72.0 (21.6)	79.9 (17.7)	0.000
Oxford hip score	40.5 (9.5)	42.0 (7.5)	0.055
Satisfaction VAS	22.5 (23.3)	15.8 (15.6)	0.000
Pain VAS	18 (20.9)	13.8 (15.3)	0.011

Patients operated following patient number 100 reported significantly better PROMs across all scores, whereas patients operated after patient number 200 reported significantly better on EQ-5D VAS, satisfaction VAS and pain VAS (Table 5). Patients following number 301 showed no significant differences on PROMs compared to the previous 100 patients.

Table 5. Comparison of patient-related outcome measures (PROMs), Lewinnek zone, and procedure time in 100 patients at a time. EQ-5D = EuroQol 5 dimensions, VAS = visual analogue scale, Lewinnek = Lewinnek safe zone, i.e. a cup anteversion between 5 to 25 degrees and cup inclination between 30 to 50 degrees. The mean PROMs and procedure time values were analysed using the Student's t-test, Lewinnek safe zone was analysed using Pearson's chi-squared test and p values <0.05 were considered statistically significant.

Outcomes	Mean 1st group of 100			Mean 2nd group of 100			Mean 3rd group of 100			Mean 4th group of 100		
	0- 100	101- 500	P	101- 200	201- 500	P	201- 300	301- 500	P	301- 400	401- 500	P
EQ-5D index	72.2	83.1	0.003	79.8	84.1	0.26	85.5	83.5	0.62	84.3	82.8	0.71
EQ-5D VAS	68.8	77.9	0.001	72.6	79.6	0.008	79.2	79.7	0.85	81.0	78.7	0.38
OHS	38.6	42	0.009	41.2	42.2	0.44	42.9	41.9	0.44	42.1	41.7	0.76
Satisfaction VAS	26.5	17.2	0.002	21.9	15.7	0.04	15.5	15.8	0.92	15.4	16.2	0.79
Pain VAS	20.9	14.6	0.039	17.7	13.6	0.047	12.9	13.9	0.63	13.3	14.3	0.63
Lewinnek	1.3	1.1	0.041	1.2	1.1	0.049	1.1	1.0	0.049	1.0	1.0	0.99
Procedure time	113.3	76.6	0.0001	81.1	75.2	0.046	76.0	74.9	0.71	70.1	78.8	0.004

Excluding early reoperations, patients operated following patient number 100 reported significantly better PROMs across all scores, whereas patients operated after patient number 200 reported significantly better on EQ-5D index, EQ-5D VAS and satisfaction VAS (Table 6). Patients following number 301 showed no significant differences on PROMs compared to the previous 100 patients.

Table 6. Comparison of 100 patients at a time excluding early reoperations. EQ-5D = EuroQol 5 dimensions, VAS = visual analogue scale, Lewinnek = Lewinnek safe zone, i.e a cup anteversion between 5 to 25 degrees and cup inclination between 30 to 50 degrees. The mean PROMs and procedure time values were analysed using the Student's t-test, Lewinnek safe zone was analysed using Pearson's chi-squared test and p values <0.05 were considered statistically significant.

Outcomes	Mean 1st group of 100			Mean 2nd group of 100			Mean 3rd group of 100			Mean 4th group of 100		
	0- 100	101- 500	p	101- 200	201- 500	p	201- 300	301- 500	p	301- 400	401- 500	p
EQ-5D Index	73.7	83.5	0.000	79.9	84.6	0.004	87.0	83.5	0.14	84.3	82.8	0.53
EQ-5D VAS	70.0	78.3	0.0001	72.8	79.9	0.0009	80.2	79.7	0.81	81.0	78.7	0.28
Oxford hip score	39.8	42.2	0.008	41.6	42.3	0.42	43.4	41.9	0.092	42.1	41.7	0.65
Satisfaction VAS	22.1	16.7	0.038	20.7	15.5	0.039	14.7	15.8	0.71	15.4	16.2	0.83
Pain VAS	18.5	14.2	0.042	17.0	13.4	0.082	12.2	13.9	0.59	13.3	14.3	0.76
Lewinnek	1.3	1.1	0.041	1.2	1.1	0.049	1.1	1.0	0.049	1.0	1.0	0.99
Procedure time	111.2	77.0	0.0001	81.6	75.6	0.047	76.4	75.3	0.79	70.1	79.6	0.003

Figure 15 shows the distribution of individual PROMs scores and corresponding learning curves, i.e. regression lines. The curves indicate a plateau or steady state following accumulated department-level learning of the first 200 and 300 THAs using the MIDA approach.

Figure 15. The learning curves, i.e. regression lines and 95% CI, for the MIDA approach as determined by patient-reported outcome measures; EQ-5D index (A), EQ-5D visual analogue scale (VAS) (B), Oxford hip score (OHS) (C), satisfaction VAS (D), and pain VAS (E).

Duration of surgery

Duration of surgery was significantly longer in the first 250 patients (91.9 versus 75.3 minutes, $p < 0.001$); however, operations of patients 401 to 522 lasted significantly longer than operations of patients 301 to 400 (70.1 versus 78.8 minutes, $p = 0.004$) (Figure 16).

Figure 16. The learning curve, i.e. regression line and 95% CI, for the MIDA approach as determined by duration of surgery.

Acetabular component position

There was a statistically significant difference in the acetabular component position, as determined by the Lewinnek safe zone, in the first 250 patients compared to patient numbers >250 (80.0% vs 94.5 %, $p < 0.0001$) (Table 7).

Table 7. Distribution of acetabular component position as defined by the Lewinnek safe zone.

		<250	>250
Lewinnek zone	Safe	80.0%	94.5%
	Unsafe	20.0%	5.5%

The mean anteversion in the first 250 patients was 17.4 (SD 5.8) and 12.7 (SD 4.8) from patient 251, whereas the mean inclination was 45.2 (SD 7.6) and 44.2 (SD 4.9), respectively (Figure 17). Of note, there were a larger number of outliers in the first 250 patients with high anteversion values compared to the last patients.

Figure 17. The acetabular component placement in the MIDA approach as determined by the the Lewinnek safe zone (grey area) in patients by groups of 100.

Trial 2. Fractures of the greater trochanter following THA

Prevalence and fracture classification

In total, iatrogenic fractures of the greater trochanter were found in 3% (26/911) patients assessed for eligibility in this trial. The prevalence did not differ significantly between patients operated with the DLA (13/486) and the MIDA (13/425) approaches ($p=0.78$).

The fractures were divided into 3 groups, based on distinct characteristics (Figure 18). Type 1 were osteotomy-induced fractures of the superior, medial aspect of the trochanter, type 2 were small avulsion fractures of the superior, posterior tip of the greater trochanter, and type 3 were complete fractures of the greater trochanter.

Figure 18. The different types of fractures of the greater trochanter.

PROMs

Twenty-five patients provided responses to PROMs, whereas 1 patient was lost to follow up (death). Patients operated with THA and who had confirmed fractures of the greater trochanter reported on average significantly lower quality of life, reduced hip function, lower satisfaction, and more pain than patients included in Sweden's and New Zealand's hip registers (Table 8).

Table 8. Mean (standard deviation (SD)) patient-reported outcome measures (PROMs) in trial patients with verified fractures of the greater trochanter compared to mean PROMs in hip registers.

PROMS	Country	Trial data	Hip register data	p
EQ-5D index	Sweden	60 (24-10)	76	0.01
OHS	New Zealand	32 (8-48)	41	0.00
Satisfaction VAS	Sweden	47 (0-100)	18	0.00
Pain VAS	Sweden	32 (0-73)	15	0.00

Patients with type 3 fractures reported on average significantly lower quality of life ($p<0.001$), reduced hip function ($p<0.001$), less satisfaction ($p=0.02$), and less pain ($p=0.02$) compared to patients with type 1 (Figure 19, Appendix 3). Patients with type 2 fractures did not report statistically significant different PROMs compared to patients with the other two categories of fractures.

Figure 19. Patient-reported outcome measures (PROMs) in patients with fractures of the greater trochanter types 1 to 3. EQ-5D = EuroQol 5 dimensions, OHS = Oxford hip score.

Trial 3. Component placement in the DLA versus the MIDA approaches

In this trial, 80 patients were randomised to THA using the DLA approach and 84 patients to THA using the MIDA approach. The interobserver variability was very good in the assessment of all outcomes (intraclass correlation coefficient (ICC) range 0.92-0.98).

Cement-mantle thickness

The mean cement-mantle was statistically significantly thicker in zone 1 in patients treated using the MIDA approach compared to patients treated with the DLA approach (mean difference = 0.51 mm, 95% confidence interval (CI)= 0.09-0.93, $p=0.018$). However, there was

no clinically significant difference in cement-mantle thickness between the MIDA and the DLA approaches in any of the zones (Table 9).

Table 9. Cement-mantle thickness and acetabular component (cup) position in patients treated with THA using the DLA versus the MIDA approaches.

Outcome	Mean (SD)		p	Adequate results (%)		p
	DLA	MIDA		DLA	MIDA	
Cement-mantle thickness (mm)						
Zone 1	0.44 (0.86)	0.95 (1.69)	0.018	6/72 (7.7)	14/82 (17.1)	0.07
Zone 2	1.56 (1.79)	1.98 (1.91)	0.15	29/78 (37.2)	40/82 (48.8)	0.14
Zone 3	3.77 (2.06)	3.85 (2.20)	0.83	66/78 (84.6)	71/82 (86.6)	0.72
Cup position						
Inclination (°)	47.0 (6.0)	49.5 (7.4)	0.023	53/78 (67.9)	43/82 (52.4)	0.045
Anteversion (°)	5.8 (4.3)	9.4 (4.8)	0.000	8/80 (10.0)	10/84 (11.9)	0.70

Acetabular component position

Patients operated with the MIDA approach had significantly higher degrees of cup inclination and anteversion than patients treated with the DLA approach (mean difference = 2.5°, 95% CI= 0.3-4.6, p=0.023 and mean difference = 3.6°, 95% CI= 2.2-5.0, p<0.0001, respectively) (Table 9). Only cup inclination was clinically significantly different in patients treated using the DLA group compared to the MIDA group (p=0.045).

Femoral stem position

The femoral stem tended to be statistically significantly more centrally positioned on the lateral view in patients treated with the MIDA approach; however, there were no statistical or clinical differences in the frontal or lateral position of the femoral stem in patients treated with the MIDA approach compared to patients treated with the DLA approach (Table 10).

Table 10. Femoral stem position, global offset restoration and leg length discrepancy in patients treated with THA using the DLA versus the MIDA approaches.

Outcome	Mean (SD)		p	Adequate results (%)		p
	DLA	MIDA		DLA	MIDA	
Femoral stem position						
Frontal view (varus (°))	2.9 (1.1)	3.1 (1.5)	0.44	73/78 (93.6)	74/82 (90.2)	0.44
Lateral view (THA index)	0.53 (0.17)	0.55 (0.15)	0.36	24/77 (31.2)	37/82 (45.1)	0.07
Global offset restoration	2.17 (7.83)	1.75 (7.50)	0.73	43/79 (54.4)	39/82 (47.6)	0.38
Leg length discrepancy	1.41 (7.87)	0.30 (8.04)	0.16	65/79 (82.3)	73/82 (88.0)	0.31

Overall component position

There were no statistical or clinical differences in global offset restoration or leg length discrepancy between the two trial groups (Table 10).

Discussion

At present, there is insufficient data to determine the optimal choice of approach in the surgical treatment of patients with end-stage OA needing elective THA [82]. We have described a department-level learning curve based on the post-operative findings and patient-reported outcomes following the introduction of the MIDA approach at a level 2 hospital with a patient population representative for THA patients in Norway.

The findings suggest that outcomes improve gradually within a range of good results, especially following the first couple of 100 patients operated. The main difficulty in learning and establishing the MIDA approach; a new and relatively complex orthopaedic surgical technique, might seem to be primarily related to femoral access and femoral component positioning, as indicated by the relatively high frequency of stem subsidence at our department. Fractures of the greater trochanter may impact the outcomes following THA; however, such fractures do not occur more frequently using the MIDA approach compared to the DLA in our study population. In a patient population treated after the learning of the MIDA approach had been established, radiographically assessed component placement showed similar results in the two approaches, suggesting the MIDA approach is both safe and effective in THA.

The learning curve

To our knowledge, there are no previously published trials on department-level learning curves following the introduction of the MIDA approach in THA [34, 39, 43, 46-52, 83]. Rigorous evaluation of learning curves in surgery may be challenging [32, 33], and variations in results may to depend on individual surgeon training and experience [33, 40, 81, 84].

There is no common agreement on how learning curve data should be analysed, and some have argued that group-wise analysis is the most appropriate approach [32]. We used the arithmetic mean as an outcome measure in the analyses of sequential groups of patients operated, thus allowing us to determine the so-called steady state of learning.

Our findings, with and without reoperations, as well as in both broader and finer group subdivisions, indicate that learning occurred within a relatively limited range of good results following the introduction of the MIDA approach. The results, as determined by both PROMs, Lewinnek safe zone, and duration of surgery, suggest that the MIDA approach is safe and effective already from an early point following the introduction of this new orthopaedic surgical technique. Our findings are in line with hip register data of 12 month post-operative PROMs following THA in Sweden and New Zealand [42, 85, 86], and real-time monitoring of learning curves could help minimise risk to patients and optimise improvement during the introduction of the MIDA approach.

Patient-reported outcomes

The PROMs-related learning curve at our department reached a plateau or so-called steady state between 200 and 300 patients. These initial results are similar to PROMs from comparable hip registers [42, 57, 86, 87], and are from a clinical point of view regarded as good. Quality of life and satisfaction improved both statistically and clinically significantly with increasing numbers of patients treated, and reported hip function and pain as a single score showed a tendency towards improvement as well. The learning curves as determined by PROMs, suggest that learning occurred within a range of good results. Although our data were representative at the

department-level, the findings seem to suggest that individual learning curves may vary within the lower range of previously reported number of patients required for learning [34-40].

Orthopaedic surgical outcomes

The duration of surgery decreased significantly with the number of patients treated, probably reflecting increased surgeon experience [44]. If taken as a proxy measure of objectively assessed learning, the steep curve of the duration of surgery suggests that learning was achieved already during the first hundred patients. The findings further support the notion that individual learning curves may vary within the lower range of previously reported number of patients required for learning [34-40].

It is essential that a cement-less femoral stem is stabilized for optimal osseointegration, otherwise stem subsidence may occur, causing leg length discrepancy, reduced offset restoration, instability, and pain, as well as late aseptic loosening and revision [88]. The high frequency of stem subsidence at our department suggests that intra-operatively unstable femoral components may have been an issue in the early phases of learning. An attempt at solving stem subsidence was made by changing the Corail stem to a collared version of the same stem. However, recently published data did not find that the Corail stem was associated with higher subsidence rates, indicating that subsidence in our data might have been caused by suboptimal positioning of the femoral component in the early phases of learning [89, 90].

The occurrence of per-operative fractures at our department were comparable to previously published data, suggesting higher complication rates following the introduction of the MIDA approach in THA [43, 44]. Hip dislocations are rare following THA using the MIDA approach

[45], and the slightly higher frequency of dislocations in our data might be explained by the high occurrence of stem subsidence.

Our findings of femoral stem subsidence and femoral stem perforation suggest that the femoral access, manipulation of soft tissue, and insertion of the femoral component may be associated with complications during learning of the MIDA approach [34, 39, 47]. Furthermore, revisions due to dislocations were due to stem-related problems and corrected by stem reoperation alone, and only three patients were re-operated due to cup component loosening or impingement on the iliopsoas. Brought together, these findings indicate that the main challenge in learning the MIDA approach may be related to suboptimal access to the femur and challenging insertion of the femoral component. In fact, recently published data suggest that cadaver training with femoral access may improve the learning of the MIDA approach {McGee, 2020 #341

Iatrogenic fractures of the greater trochanter

Our findings suggest that fractures of the greater trochanter may have a larger impact on the impact of THA than previously assumed [91]. Our findings suggest that a subdivision of fractures of the greater trochanter might lead to a better understanding of the impact of trochanteric fractures in THA. In contrast to previously published data of computerized tomography (CT) scan-detected fractures, the prevalence of trochanteric fractures occurred relatively infrequent at our department [30, 39, 47]. This may explain the low occurrence of reoperations due to fractures of the greater trochanter in the learning curve study.

The reason for the lower number trochanteric fractures in our data is unclear. The retractors required for adequate femoral visualisation and the femoral component insertion devices used

at our department were specifically designed for the MIDA approach. Based on clinical experience, other retractors and/or insertion devices, as well as a more lateral access point for femoral components, might increase the risk of iatrogenic trochanteric fractures. This would further support the notion that femoral access, manipulation and insertion of the femoral component may be the challenging part of learning the MIDA approach.

Component placement

Our findings show that the acetabular component position, as determined by the Lewinnek safe zone, was significantly more often unsafe in the first 250 patients operated compared to patient number 251 and onwards. However, there were no dislocations due to cup malpositioning, and the clinical relevance of these findings are therefore questionable. The statistically significant improvement in acetabular component position, as determined by the Lewinnek safe zone, found following the operations of the first 250 patients, suggests that an optimisation of the surgical technique may be possible within a range of good results.

In a separate study population at a hospital with established use of the MIDA approach, radiographically assessed acetabular component placement showed no clinically relevant differences between patients treated using the DLA compared to those treated with the MIDA approach. The higher inclination values found in patients operated using the MIDA approach have been reported also by others [92]; however, the mean inclination values <50 degrees and absence of hip dislocations in the study population [93] might suggest that a higher degree of cup inclination did not have any clinical implications [94].

Previously published data of the acetabular component placement in the MIDA approach show conflicting data, and confounding factors such as study design, surgeon experience and learning could have affected these results [95, 96]. Our findings based on the comprehensive assessment and analyses of cement-mantle thickness, acetabular and femoral component placement, including the THA index, offset restoration, and leg length discrepancy, are in line with previously published data that indicate adequate acetabular and femoral component placement using the MIDA approach. This further strengthens the notion that this approach provides adequate access to and exposure of the hip joint for safe use in THA [43-45].

Strengths and limitations

The trials had several strengths and limitations. To our knowledge, the learning curve trial is the first trial to analyse learning of the MIDA approach at a department-level using PROMs as outcome measures, as well as to comprehensively report and analyse complications. Furthermore, the trial included operations representative of a level 2 orthopedic surgical department and performed by a number of surgeons who were new to the procedure, thereby probably resulting in authentic learning curves. The second trial is the first to assess PROMs in relation to fractures of the greater trochanter, and further to differentiate between various types of such fractures. Finally, the third trial was a rigorously conducted, level 1 double-blind, prospective RCT that is the only trial to comprehensively have assessed component placement in the DLA versus the MIDA approach.

Including pre-operative data on patients in the first trial would have strengthened the analysis and results interpretation. Adaptive changes made during the trial period were clinically and ethically necessary; however, the changes may have affected the results. The registered data

did not allow more detailed comparative analyses of the patients' and/or orthopaedic surgeons' potential impact on the learning curve, including factors such as patient BMI and level of surgeon experience and number of operations performed per surgeon. Some argue that obese patients should not be operated using the MIDA approach, and excluding such patients might mean the results may not be applicable to patients with a BMI >35 kg/m² [97, 98].

Assessment of intraobserver reliability, as well as including a second outcome assessor in the second trial could have strengthened the results' validity. Moreover, only plain radiographs were assessed for data collection, and investigating operation journals for any intra-operatively observed fractures and/or including CT scan assessments might have strengthened the data. Finally, the sample size was limited, increasing the risk of impact of outlier values in the parametric analyses of the data.

In the third trial, 5 radiographs that were challenging to measure were excluded from the analysis, potentially introducing selection bias. Including CT scan assessments might have strengthened the data accuracy and analyses, in particular with regards to cement-mantle thickness, femoral stem anteversion, and leg length [99, 100]. Recently published data suggest that dislocation may be more multifactorial than assessed by the Lewinnek safe zone, and thus some may argue that CT scan-assessed femoral anteversion should be considered together with acetabular anteversion [101]. However, CT scans would have exposed patients to excessive and potentially unnecessary radiation [100].

Conclusions

There is insufficient data to determine the optimal choice of approach in the surgical treatment of patients with end-stage OA needing elective THA [82]. We have described a department-level learning curve based on the post-operative findings and patient-reported outcomes following the introduction of the MIDA approach at a level 2 hospital with a patient population representative for THA patients in Norway.

The findings suggest that outcomes improve gradually within a range of good results, especially following the first couple of 100 patients operated. The main difficulty in learning and establishing the MIDA approach; a new and relatively complex orthopaedic surgical technique, might seem to be primarily related to femoral access and femoral component positioning, as indicated by the relatively high frequency of stem subsidence at our department. Fractures of the greater trochanter may impact the outcomes following THA; however, such fractures do not occur more frequently using the MIDA approach compared to the DLA in our study population. In a patient population treated after the learning of the MIDA approach had been established, radiographically assessed component placement showed similar results in the two approaches, suggesting the MIDA approach is both safe and effective in THA.

Outstanding research

Further research is needed to determine the most suitable approach in THA. This would include further research in other study populations of both patients and orthopaedic surgeons on department-level learning of the MIDA approach, as well as other approaches, including the increasingly popular posterior approach. Further studies should determine the longevity of THA using the MIDA approach compared to other approaches [45]. Additionally, aspects of femoral access should be evaluated as a possible issue during early learning of the MIDA approach. Moreover, further research is needed to determine the appropriate treatment options of trochanteric fractures, including the preferred type of osteosynthesis [102].

Following the experiences at our department, we recommend that future assessments following the introduction of the MIDA approach should aim to limit change to the approach only. Without introducing other components, rehabilitation or other possible confounders, and should ensure background research, rigorous training on cadavers, attendance at courses, as well as supervisors trained in using the MIDA approach during the first XX operations. Any changes in protocol should be based on evidence or at least data-based, and any changes in approach should be based on appropriate and adequate data assessment and analyses. Learning curve studies should monitor for unexpected complications and changes addressed appropriately.

Appendices

Appendix 1. EQ-5D sample form

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagine

The worst health
you can imagine

Under each heading, please tick the ONE box that best describes your health

MOBILITY

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

SELF-CARE

- I have no problems washing or dressing myself ☐
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

PAIN / DISCOMFORT

- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐
- I am extremely anxious or depressed ☐

Appendix 2. Oxford hip score (OHS)

Please answer the following 12 questions. Choose only one answer per question. The value for each answer is indicated to the left of the answer. Total up all of your answers to obtain a total score out of 48 points.

During the past 4 weeks:

1. How would you describe the pain you usually have in your hip?

- 4) None
- 3) Very mild
- 2) Mild
- 1) Moderate
- 0) Severe

2. Have you been troubled by pain from your hip in bed at night?

- 4) No nights
- 3) Only 1 or 2 nights
- 2) Some nights
- 1) Most nights
- 0) Every night

3. Have you had any sudden, severe pain-' shooting ', 'stabbing', or 'spasms' from your affected hip?

- 4) No days
- 3) Only 1 or 2 days
- 2) Some days
- 1) Most days

0) Every day

4. Have you been limping when walking because of your hip?

4) Rarely/never

3) Sometimes or just at first

2) Often, not just at first

1) Most of the time

0) All of the time

5. For how long have you been able to walk before the pain in your hip becomes severe (with or without a walking aid)?

4) No pain for 30 minutes or more.

3) 16 to 30 minutes

2) 5 to 15 minutes

1) Around the house only

0) Not at all

6. Have you been able to climb a flight of stairs?

4) Yes, easily

3) With little difficulty

2) With moderate difficulty

1) With extreme difficulty

0) No, impossible

7. Have you been able to put on a pair of socks, stockings or tights?

- 4) Yes, easily
- 3) With little difficulty
- 2) With moderate difficulty
- 1) With extreme difficulty
- 0) No, impossible

8. After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your hip?

- 4) Not at all painful
- 3) Slightly painful
- 2) Moderately painful
- 1) Very painful
- 0) Unbearable

9. Have you had any trouble getting in and out of a car or using public transportation because of your hip?

- 4) No trouble at all
- 3) Very little trouble
- 2) Moderate trouble
- 1) Extreme difficulty
- 0) Impossible to do

10. Have you had any trouble with washing and drying yourself (all over) because of your hip?

- 4) No trouble at all

- 3) Very little trouble
- 2) Moderate trouble
- 1) Extreme difficulty
- 0) Impossible to do

11. Could you do the household shopping on your own?

- 4) Yes, easily
- 3) With little difficulty
- 2) With moderate difficulty
- 1) With extreme difficulty
- 0) No, impossible

12. How much has pain from your hip interfered with your usual work, including housework?

- 4) Not at all
- 3) A little bit
- 2) Moderately
- 1) Greatly
- 0) Totally

Appendix 3. Analysis of variation (ANOVA) comparing trochanteric fracture types

Dependent Variable	(I) Type	(J) Type	Sig.	95% Confidence Interval	
				Lower Bound	Upper Bound
OHS	Type 1	Type 2	.06	-.55	23.80
		Type 3	.00	9.20	33.55
	Type 2	Type 1	.06	-23.80	.55
		Type 3	.13	-2.42	21.92
	Type 3	Type 1	.00	-33.55	-9.20
		Type 2	.13	-21.92	2.42
Pain_VAS	Type 1	Type 2	.29	-48.28	11.74
		Type 3	.02	-66.28	-6.26
	Type 2	Type 1	.29	-11.74	48.28
		Type 3	.28	-46.99	10.99
	Type 3	Type 1	.02	6.26	66.28
		Type 2	.28	-10.99	46.99
Satisfaction_VAS	Type 1	Type 2	.15	-59.86	7.86
		Type 3	.02	-77.05	-6.95
	Type 2	Type 1	.15	-7.86	59.86
		Type 3	.49	-51.05	19.05
	Type 3	Type 1	.02	6.95	77.05
		Type 2	.49	-19.05	51.05
EQ_5D	Type 1	Type 2	.08	-2.95	62.45
		Type 3	.00	19.92	85.32
	Type 2	Type 1	.08	-62.45	2.95
		Type 3	.21	-9.82	55.57
	Type 3	Type 1	.00	-85.32	-19.92
		Type 2	.21	-55.57	9.82

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Published papers

The direct anterior minimal invasive approach in total hip replacement: a prospective departmental study on the learning curve

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ABSTRACT

Introduction: Introduction of new surgical techniques is normal, but seldom monitored in real time. The purpose of this study was to monitor the learning curve when introducing a new surgical technique to a department. We did a prospective evaluation of the learning curve when introducing the minimally invasive direct anterior approach in total hip arthroplasty. We wish to investigate whether there is a learning curve for the direct anterior minimal invasive approach in total hip replacement and what are the early complications to this approach.

Methods: The department changed from the direct lateral approach to the minimally invasive direct anterior approach. We monitored the first 522 patients operated using this approach with regards to patient outcome scores and complications 6 months postoperatively.

Results: The last 250 patients operated all had significantly better results with regard to patient outcome scores and cup placement. We investigated 100 patients at a time and compared them with the rest of the patient and found the same pattern. This pattern ends when we reach patients somewhere between 200-300.

Discussions: We established the learning curve on a departmental level with regards to introduction of the minimal invasive direct anterior approach. We see a steady improvement in scores with regards to patient outcome scores and cup positioning until we reach a steady-state. The learning curve here flattens out. Departments must understand that one should expect early complications and somewhat less than optimal results at first when introducing this new surgical technique.

Keywords: Complications in THA, Direct anterior minimal invasive approach, Learning curve, Stem subsidence, THA

Introduction

Whenever new health care technology is introduced, health care providers need to learn how to use this new technology. In surgical specialties learning is complex and consists of multiple factors, in which surgical skills, surgical experience, volume of surgery and knowledge of safety hazards are of vital importance (1, 2).

Improvements are often rapid at first and then tail off until a “steady state” is reached (Fig. 1). In manufacturing the curve is often s-shaped and it seems logical that this could also be true for surgical technique (3). Learning curve assessment

and evaluation is however complex and difficult in health care technology. Results vary naturally with experience and at what part of the learning curve one is at the moment (2, 4). One may argue that identifying the point at which the curve flattens should solve subsequent evaluation of the learning curve, however the evaluation and statistical analysis of how to do this remains unclear.

Primary total hip replacement (THR) is a common major surgical procedure and it has been referred to as “the operation of the century” (5). Globally, there has been a steady increase in the incidence of total hip replacement. When performing THR there are several different approaches to the hip joint. In recent years muscle-sparing approaches to utilise intramuscular planes has gained popularity as access to the hip joint (6, 7). One such approach is the direct anterior muscle-sparing approach in which the plane between the tensor fascia lata muscle and the sartorius muscle is accessed. The proponents of muscle-sparing approaches argue that this surgical technique results in earlier rehabilitation and improved function, but so far there is limited evidence to support this notion (8, 9). In fact, some argue that this and other minimal invasive approaches are associated with an increased risk of early complications (10-12). Little is known regarding the

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Fig. 1 - Typical learning curve.

learning curve for the minimally invasive approach for THR. Most studies are single surgeon trials describing a single surgeons' results. They seldom state at what point in the surgeons training the results derive from. Muller et al published data at a departmental level stating that a surgeon needs roughly 20 cases before normalisation of revision risk (13). However, the study only included 150 patients and the main endpoint was revision, not functional scores. In fact, authors claim there is a high complication rate at start-up when using the minimally invasive direct anterior approach (14). De Steiger et al (15) published data regarding the learning curve for the anterior approach comparing new surgeons to experienced surgeons. They found that one needs 50 procedures before the revision rate is similar to experienced surgeons. Seng et al (16) reported results indicting approximately 40 cases or 6 months of training after 6 weeks follow-up. Recently, a systematic review was published regarding the less invasive anterior approach and in conclusion it states that the learning curve is "still not clear" (17). It seems of vital importance that both surgeons and departments performing this procedure should know the learning curve in order to predict and understand outcome. There is some information regarding single-surgeon learning curves, but on a departmental level there is lack of knowledge. In addition, all studies lack functional scores as outcome and solely rely on revision rates as their endpoint.

The purpose of this study was to examine the learning curve for the direct anterior approach in the supine position looking at short-term outcome measurements in primary THR at a single institution.

In addition, we would like to examine whether we could identify a point at which the learning curve flattens, hence the number needed to reach a «steady state».

Methods

This was a prospective departmental study in which all patients treated at Drammen Hospital with primary total hip replacement within the period from August 2008 until April 2010 were evaluated (Tab. I). In all patients, a muscle-sparing direct anterior approach was utilised. The department had previously used the lateral approach during THR. The learning curve and data collected is therefore

TABLE I - Patient demographics and prosthetic implants used

Age, mean (range) (y)	67 (31-94)	
	Number	Percent
Women	320	66%
Men	169	34%
ASA III	59	13%
Primary osteoarthritis	410	84%
Stem		
Corail uncemented stem (DePuy)	450	92%
Corail cemented stem (DePuy)	13	2.7%
KAR un-cemented stem (DePuy)	2	0.4%
Accolade uncemented stem (Stryker)	22	4.5%
Cup		
Trident uncemented cup (Stryker)	25	5.1%
Elite plus cemented cup (DePuy)	35	7.2%
Marathon cemented cup (DePuy)	411	84%
Pinnacle uncemented cup (DePuy)	16	3.3%

after introduction of a new surgical technique. All surgeons were new to the procedure, only 2 surgeons attended a course in advance and an experienced surgeon from abroad participated in the first 6 operations. Operations were performed with the patient in a supine position on an ordinary operation table. Both standard cemented and uncemented implants were used (Tab. I). All consultants and residents assigned to the joint replacement unit took part in the operations. Resident and consultant doctors took turns every other surgery being the primary surgeon. A total of 15 surgeons performed the surgeries. Intraoperative x-ray imaging was not performed.

Patient demographics, perioperative data, complications and patient-reported outcomes were collected from the Drammen Hospital Primary Hip Replacement Quality and Safety Database. As a part of the Department's follow up regime, patients received a survey approximately 6 months' postoperative. The survey consisted of the EuroQOL five dimensions questionnaire (EQ-5D) (a general health score, where 100 is the best), Pain visual analogue scale (VAS) (0-100, where 0 is the best), satisfaction VAS (0-100 where 0 is the best), Oxford Hip Score (OHS) (0-48, where 48 is the best) and also a question about re-admission. No patients were excluded from the analysis.

We also reviewed component placement using plain radiographs, including cup anteversion and cup inclination. This is done using plain anteroposterior (AP) radiographs and the ellipse formed by the cup positioning as described by Lu et al (18).

A total of 522 patients were included in the study.

Results

There were 522 THR surgeries included in the main analysis. Of these, 489 (93%) patients returned to follow-up after 6 months. Patient demographics and prosthetic implants used are summarised in Table I.

Within the first 6 months 24 patients had to be reoperated (4.5%). We also had 5 infections and 5 dislocations, all dislocations anterior. The last patient reoperated within the first 6 months was patient number 285, and only 2 patients were reoperated after 250 cases. Stem problems, mainly stem subsidence, was a major cause of reoperations and there was a total of 14 reoperations done due to this problem.

Comparing the first 250 patients with the last 250 we found significantly better scores for patient outcome (Tab. II). Lewinnek scores are either safe given the value 1 or unsafe given value 2 in this analysis for simplification in Table II (19). In fact, all patient-outcome scores improve significantly in the last 250 patients except Oxford Hip Score. OHS improves also, but not significantly. For cup placement, we include percent-

age scores with regard to safe and unsafe placement (Tab. III). We had significantly safer cup positioning in the latter 250 patients and significantly more unsafe cup positioning in the first 250 patients.

When comparing results for the first 100 patients with the next 400 patients we found that there were improvements for all outcome scores (Tab. IV). From patient 101-200 compared to the last 300 there were improvements in all scores except for EQ-5D and OHS. For patient 201-300 compared to the last 200 there were only better Lewinnek score. Finally, between patient 301-400 and the last 100 there were no changes. This clearly identifies the pattern of learning curve with regards to improvement. The patient number where improvement stops marks the end of the learning curve or where the curve flattens out.

The same analysis was done excluding the early reoperations, giving the same results (Tab. V). The only difference is that pain VAS is no longer significantly better when comparing patient 101-200 to the last 300 patients.

TABLE II - Statistics comparing the last 250 to the first 250 patients. Bold numbers with stars indicate $p < 0.05$

Patient	0-250 Mean	250-500 Mean
EQ-5D Index	78.1	83.7*
EQ-5D VAS	72.0	79.9*
Oxford Hip Score	40.5	42.0
Satisfaction VAS	22.5*	15.8
Pain VAS	18*	13.8
Lewinnek	1.2*	1.1
Procedure time	91.9*	75.3

EQ-5D = EuroQOL five dimensions questionnaire; VAS = visual analogue scale.

TABLE III - Lewinnek scores in percentages. Bold numbers indicate $p < 0.05$

Patient		>250	250+
Lewinnek	Safe	80.0%	94.5%
	Unsafe	20.0%	5.5%

Discussion

In this prospective single-centre study, we have demonstrated that there is a learning curve for implementing a new approach for primary THR surgery on a departmental level.

Statistical data analysis regarding learning curves is difficult. There is no general agreement how to analyse such data. We chose to split the data into the first 250 and the last 250+ patients initially. This, in order to simplify statistics comparing the last 250 to the first 250 patients (Tab. II).

We found that all results were significantly better in the last 250+ patients compared to the first 250 patients on patient-reported outcome, except for the OHS. The results also showed significantly more «unsafe» cup positioning in the first 250 patients compared to the last 250 patients as well as significantly more safe cup positioning in the last 250 patients. From this we can conclude that there is a learning curve.

We then decided to investigate whether we could identify where the change occurred or at which point we achieved a “steady state” in terms of outcome measurements. We did this by comparing the results of 100 patients at a time to the rest. The point at which the results stopped being better, was

TABLE IV - Comparison of 100 patients at a time. Bold numbers with stars are significant ($p < 0.05$)

Patient	0-100 Mean	101-500 Mean	101-200 Mean	201-500 Mean	201-300 Mean	301-500 Mean	301-400 Mean	401-500 Mean
EQ-5D Index	72.2	83.1*	79.8	84.1	85.5	83.5	84.3	82.8
EQ-5D VAS	68.8	77.9*	72.6	79.6*	79.2	79.7	81.0	78.7
Oxford Hip Score	38.6	42*	41.2	42.2	42.9	41.9	42.1	41.7
Satisfaction VAS	26.5*	17.2	21.9*	15.7	15.5	15.8	15.4	16.2
Pain VAS	20.9*	14.6	17.7*	13.6	12.9	13.9	13.3	14.3
Lewinnek	1.3*	1.1	1.2*	1.1	1.1*	1.0	1.0	1.0
Procedure time	111.3*	76.6	81.1*	75.2	76.0	74.9	70.1	78.8*

EQ-5D = EuroQOL five dimensions questionnaire; VAS = visual analogue scale.

TABLE V - Comparison of 100 patients at a time, early reoperations are now excluded. Bold numbers with stars are significant ($p < 0.05$)

Patient	0-100	101-500	101-200	201-500	201-300	301-500	301-400	401-500
	Mean	Mean	Mean	Mean	Mean	Mean	Mean	Mean
EQ-5D Index	73.7	83.5*	79.9	84.6*	87.0	83.5	84.3	82.8
EQ-5D VAS	70.0	78.3*	72.8	79.9*	80.2	79.7	81.0	78.7
Oxford Hip Score	39.8	42.2*	41.6	42.3	43.4	41.9	42.1	41.7
Satisfaction VAS	22.1*	16.7	20.7*	15.5	14.7	15.8	15.4	16.2
Pain VAS	18.5*	14.2	17.0	13.4	12.2	13.9	13.3	14.3
Lewinnek	1.3*	1.1	1.2*	1.1	1.1*	1.0	1.0	1.0
Procedure time	111.2*	77.0	81.6*	75.6	76.4	75.3	70.1	79.6*

EQ-5D = EuroQOL five dimensions questionnaire; VAS = visual analogue scale.

the point at which we reached a “steady state”, or where the learning curve flattened out. This point was reached between 200 and 300 operated (Tab. IV).

We had many early reoperations in the first 250 patients and one might think these could be the cause of the inferior results in the first 300 patients. We therefore did the analysis again after removing these patients. The results when removing the early reoperations were much the same. The only exception being that pain VAS was no longer significantly better from patient 100-200 (Tab. V).

Patient outcome scores were significantly better as far as the first 200 patients. Lewinnek scores were significantly better all the way to patient 300 (Tabs. IV and V).

We therefore conclude that after introduction of the direct anterior muscle sparing approach one needs between 200-300 patients operated before reaching a “steady state” in terms of patient outcome scores and cup placement. This, of course, is on a departmental level and not in terms of single surgeon procedures.

Unfortunately, we did not score the patients before surgery. Changes in patient related scores with regards to comparing preoperative scores to postoperative scores, would have strengthened the evaluation of the learning curve.

This study does however have several strengths. We did not define the end of the learning curve arbitrarily, which has been a common weakness in earlier publications regarding learning curves in hip replacement surgery (1). Also, there was a large number of surgeons, both consultants and residents, performing the surgeries. In every surgery performed, there is both a consultant and a resident, and they take turns being the primary surgeon for every surgery. Therefore, there is a constant amount of surgeries being performed by either a consultant or resident doctor. This strengthens the conclusion of the departmental learning curve, due to the fact that we eliminate the possibility of some of the groups having larger amounts of residents performing the surgeries. Lastly, this study was performed at a public general hospital with a typical Scandinavian case mix.

Throughout the learning curve period there were adaptive changes made to address quality and safety issues. Subsidence of uncemented collarless stems was the leading cause of revisions in this series. To stop this problem, we

changed to a collared version of the same stem. That solved the subsidence problem without any apparent negative effects. In addition, there were several adaptive changes made to the surgical technique during the learning curve period in order to secure acceptable access to the femur.

While reviewing our data set, it became apparent that if one was to utilise only cemented prosthesis, a large proportion of the early revisions may have been avoided altogether (stem subsidence, femoral fractures, and perhaps even the 2 cases with early aseptic loosening).

Based on our findings we consider single surgeon series to be an inferior method to examine the possible negative effects of a learning curve. Single surgeon studies will have obvious weaknesses. Not only because different surgeons will have different learning curves as a result of their different previous surgical experience, but also because different surgeons will differ with respect to surgical skills and thus their ability to learn new surgical procedures. In a systematic review of studies looking at learning curves in surgery, Ramsey et al (20) found that 47% of publications only involved single-surgeon series (3, 20, 21). De Steiger et al (15) examined learning curves of single surgeons in their start-up period and compared them to experienced surgeons, but the only end-point was revision. Patient-outcome scores or other complications were not reported. This would have given us important information on improvements. Using revision as the only measurement to learning curve gives an indication, but is obviously inferior to outcome scores and other complication, which gives a more detailed analysis of the learning curve.

To our knowledge, this is the only study analysing learning curves using changes in outcome scores as end point, and publishing all complications, and of course defining where the surgeons are in their training when starting to analyse the learning curve. All surgeons in this study were new to the procedure.

Based on our findings, we strongly recommend that the introduction and implementation of a new surgical technique should be monitored in real time, preferably at a national or international level. This type of audit would allow optimal quality and safety when introducing a new surgical technique. Such oversight should also enable the surgical community

to interactively learn and adapt to new challenges that may arise with the new surgical technique. An ad hoc monitoring while waiting for new publications in scientific journals has several weaknesses such as long lead-time, lack of external validity and publication bias.

The concept of non-maleficence, “first do no harm”, has been in the core of medical ethics since ancient times. However, when considering new surgical techniques, the concept of non-maleficence elicits a catch 22 paradox. In order to conduct large multi-centre randomised clinical controlled trials, that have the propensity to yield evidence towards whether a new technique offers any advantage over an existing technique, a sufficient number of surgeons need to acquire the knowledge of how to master the new technique. A worst-case scenario would arise if one were to harm patients during the learning curve period for a new surgical technique that was inferior to the already existing surgical technique. On the other hand, there is an inherent obligation to coming generations to implement new surgical techniques that may improve the surgical outcome for patients.

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Fractures of the greater trochanter following total hip replacement

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ABSTRACT: *We studied the incidence of greater trochanteric fractures at our department following THR. In all we examined 911 patients retrospectively and found the occurrence of a greater trochanteric fracture to be 3%. Patients with fractures had significantly poorer outcome on Oxford Hip score, Pain VAS, Satisfaction VAS and EQ-5D compared to THR without fractures. Greater trochanteric fracture following THR is one of the most common complications following THR. It has previously been thought to have little impact on the overall outcome following THR, but our study suggests otherwise.*

KEY WORDS: *Greater trochanter fracture, Total hip replacement, Total hip arthroplasty, iatrogenic, Patient reported outcome measures*

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INTRODUCTION

Fracture of the greater trochanter is common following total hip replacement (THR), the incidence possibly as high as 5% (1, 2). It is not thought to have a major effect on overall outcome (3).

We believe that iatrogenic trochanteric fractures have a bigger impact on overall outcome than previously described and therefore studied the relevance and incidence of these in our department.

The existing literature suggests that such injuries have little effect on patient outcome following THR (1-3). However, none of the published work reported patient related scores and all seemed to base conclusions on a number of assumptions.

There is no classification system following this type of iatrogenic fracture and there are no guidelines regarding how to treat and follow-up this complication. Our study aimed to address these issues.

MATERIALS AND METHOD

We studied the incidence of isolated greater trochanter fracture in our department following total hip replacement from 2005-2010. Approximately half of the patients (486) underwent surgery using a transgluteal approach and half (425) had a muscle sparing approach (MSA) direct anterior approach. The age of our patients ranged between 41 and 86. We reviewed the x-rays of all patients who underwent THR in this period.

We included all patients with a greater trochanteric fracture observed on radiographs postoperatively. All patients received hybrid prostheses, consisting of a cemented acetabulum and uncemented femoral component.

All patients followed the department's common rehabilitation programme.

We sent questionnaires to all patients with a trochanteric fracture. The questionnaires included Oxford hip score, Pain VAS, Satisfaction VAS and EQ-5D.

This data were compared to the expected outcome of Oxford hip score, Pain VAS, Satisfaction VAS and EQ-5D from the hip register in Sweden and New Zealand.

RESULTS

We found 26 fractures of the greater trochanter.

Twenty-five out of 26 patients answered the questionnaires, and one patient had died.

Four of the questionnaires were answered by telephone interview since these patients did not send their questionnaires back.

We found iatrogenic fractures in 26 of 911 THR (3%), five of which occurred in males and 21 in females. Seven of the patients were treated with fixation of the fracture, using either Kirschner wires with cerclage or a claw plate.

Overall, 65% of the patients with a fracture, reported limping post operatively, and 46% reported pain. The incidence of either complication being reported was 70%.

There was no difference in the occurrence of iatrogenic trochanteric fractures when comparing MSA to the transgluteal approach (13/425 vs 13/486).

The patients with fractures of the greater trochanter report clinically and statistically significant poorer results on all outcome values; (EQ-5D index 0.60 (0.24-1.0) vs 0.76, Oxford hip score 32 (8-48) vs 41, satisfaction VAS 47 (0-100) vs 18 og pain VAS 32 (0-73) vs 15).

We saw no difference in the outcome irrespective of whether the fracture was fixed primarily, secondarily or not fixed at all.

We decided to compare outcomes of the individual types of fractures from a classification we created, since there was a clear pattern, based on fracture location (Brun-Maanssons classification).

We compared the outcomes of different types of fractures to the expected values from THR found in the hip register in Sweden (2008) (4) and New Zealand (1999-2008) (5).

The grey line in the graphs indicates level of significance $p < 0.05$ (Figs. 1E-H).

The poor results occur mainly after type 3 fractures, which are significant on all outcome values whereas type 1 and type 2 fractures show non-significant changes on all measured values. Figure 1F shows the clearest pattern of all the values with OHS being significantly lower in type 3 fractures whilst type 1 and 2 fractures are non-significant.

Figure 1G also show the same pattern with significantly higher values in pain for type 3 fractures and non significant values for type 1 and 2 fractures.

Finally, the satisfaction values are significantly higher for type 3 fractures whilst type 1 and 2 fractures show non-significant values.

DISCUSSION

Our study is a retrospective study with inherent limitations regarding cause and effect. However, our study is, to our knowledge, the only study including patient related scores. Hendel and Yasin reported that all trochanteric fractures fixed primarily healed without complications (1), but we did not observe this. Such fractures are more common in females, possibly due to osteoporosis. Like us, Pritchett found no difference in the number of isolated trochanter fractures when comparing surgical approaches (the direct lateral and the posterior approach) (2).

Our results suggest that a fracture during THR can greatly affect the outcome. This applies particularly if it is a type 3 fracture. Further research should focus on finding optimal treatment options for this fracture.

However, the best treatment option for type 3 fractures remains unknown. We had only eight type 3 fractures. The outcome was poor on all values and this was irrespective of whether they were treated with fixation or not, either primarily or at a later time.

Further investigation should focus on finding the best treatment option for type 3 fractures and to further investigate type 2 fractures. It seems clear that a fracture caused by cutting off the top part of the trochanter during the femoral neck osteotomy (type 1) has less or no impact on the outcome of THR, possibly because this fracture (and type 2 fractures) do not violate the gluteus medius muscle significantly.

A stem with a lateral insertion point into the femur might produce more trochanteric fractures. All patients in our study had a stem with a low lateral profile (Corail, Depuy). When dealing with isolated fractures of the greater trochanter in adults due to trauma the recommendations are bed rest/crutches with protected weight bearing for 3-4 weeks. Often the fracture is incomplete and intact fibres of the gluteus medius prevent wide separation (6). They heal well and have a good expected outcome.

Pritchett states the indications for operative treatment of greater trochanter fractures following THR to be:

Fig. 1 - A) Type 1: Fracture as a result of the osteotomy. **B)** Type 2: Partial fracture of the greater trochanter. Frontal view. **C)** Type 2: Partial fracture of the greater trochanter. Side view. **D)** Type 3: Complete fracture of the greater trochanter. **E)** The figure shows the relationship between Eq-5d index and the different types of fractures. **F)** The figure shows the relationship between the Oxford Hip Score and the different types of fractures. **G)** The figure shows the relationship between the Pain VAS and the different types of fractures. **H)** The figure shows the relationship between the Satisfaction VAS and the different types of fractures.

1. Dislocation or instability of the prosthesis;
2. Severe limp or pain;
3. Widely displaced trochanter fracture >2 cm.

The specific treatment options for type 3 fractures remain unknown. Further studies must attempt to clarify what osteosynthesis yields the best results following a type 3 fracture.

In cases of non-union with dislocation tension band fixation or a trochanteric claw plate can be effective, so these options should be considered for further evaluation in type 3 injuries (7-9).

Overall, we observed that fractures of the greater trochanter can influence the outcome adversely following THR, and further evaluation of this complication is warranted.

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Primary Arthroplasty

Component Placement in Direct Lateral vs Minimally Invasive Anterior Approach in Total Hip Arthroplasty: Radiographic Outcomes From a Prospective Randomized Controlled Trial

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ABSTRACT

Background: End-stage coxarthrosis is increasingly common; however, limited evidence exists on the effect of direct lateral approach (DLA) and minimally invasive direct anterior approach (MIDA) on component placement in total hip arthroplasty (THA). We therefore conducted a prospective, randomized controlled trial to determine the component placement in DLA vs MIDA in THA.

Methods: Between January 2012 and June 2013, 164 patients with clinically and radiologically confirmed coxarthrosis aged 20–80 years were randomized to either DLA or MIDA (active comparator). Excluded were patients with previous ipsilateral hip surgery, a body mass index >35 kg/m², and/or mental disability. Primary clinical outcomes have been published elsewhere. Secondary outcomes included radiographic assessment of the acetabular component (cement-mantle thickness, inclination, and anteversion), femoral stem position (varus/valgus and THA index), offset restoration, and leg length discrepancy.

Results: The mean cement-mantle was significantly thicker in zone 1 in the MIDA group (mean difference = 0.51 mm, 95% confidence interval [CI] 0.09–0.93, $P = .018$), and the mean degrees of inclination and anteversion were higher in the MIDA group (mean difference = 2.5°, 95% CI 0.3–4.6, $P = .023$ and mean difference = 3.6°, 95% CI 2.2–5.0, $P < .0001$, respectively). According to the defined reference range, cup inclination was more often adequate in the DLA group (67.9% (53/78) in the DLA group vs 52.4% (43/82) in the MIDA group, $P = .045$). There were no differences in frontal or lateral femoral stem position, global offset restoration, or leg length discrepancy.

Conclusion: In this population of Norwegian patients with coxarthrosis, radiographic assessment showed limited differences in component placement between MIDA and DLA. The findings suggest that component placement is similar in the 2 surgical approaches.

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Total hip arthroplasty (THA) is a well-established treatment for end-stage coxarthrosis [1]. In Norway, the most common surgical approach has for many years been the direct lateral approach

(DLA); however, anterior approaches have become more common due to their minimally invasive character [2]. The lateral and anterior approaches might result in different outcomes and complications; however, as of yet, neither has proven superior [3–5].

DLA releases the anterior part of the gluteus medius and gluteus minimus muscles, offering good peroperative exposure of both the acetabulum and femur [5,6]; however, this approach carries the risk of gluteal insufficiency and postoperative pain [7]. In principle, the minimally invasive direct anterior approach (MIDA), using a neutral nervous and muscular plane, would lead to less muscle and tendon trauma, less pain, and improved functional outcome [8,9]. On the other hand, some clinical trials suggest that patients

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operated through MIDA are subject to a higher rate of complications, possibly due to longer operator learning curve and, by consequence, poorer component placement [10–13]. To date, only 1 randomized controlled trial (RCT) has assessed the effect of DLA vs MIDA on component placement, assessing only cup inclination and stem position in the frontal view [5,14].

We therefore conducted a prospective RCT to determine the effect of surgical approach on component placement in THA. Patients were randomized to either DLA or MIDA and component placement was radiographically assessed in both groups.

Materials and Methods

A level I double-blind, prospective, RCT was conducted at Sorlandet Hospital Arendal between January 2012 and June 2013. The trial was approved by the regional ethics committee (REK ID 2011/2581 D), and was registered at clinicaltrials.gov (NCT01578746). This article describes the radiological findings of this trial. The clinical findings have been published [15].

Patients aged 20–80 years, of both genders, and with a clinically and radiographically verified diagnosis of end-stage coxarthrosis were eligible for participation. Patients who provided informed, written consent were included in the trial. Excluded were patients with previous ipsilateral hip surgery, body mass index (BMI) >35 kg/m², and an explicit request for surgical approach. As this trial was part of an RCT that included postoperative follow-up, patients having any mental disability, such as dementia, were also excluded.

During the trial period 379 primary THAs were performed at the trial centre, and of those, 215 patients were excluded (Fig. 1). Patients included in the trial were randomized to either DLA or MIDA using sealed envelopes. Surgery was performed by 5 senior orthopedic surgeons who were experienced in using the DLA approach and who were trained in the department's established use of MIDA [13].

Baseline data were recorded prior to surgery, including gender, age, BMI, and American Society of Anesthesiologists grade (Table 1). All THAs were performed using a cemented cup

(Marathon; DePuy, Warsaw, IN), uncemented stem (Corail; DePuy), and ceramic head with a diameter of 32 mm (BIOLOX Forte; CeramTec, Plochingen, Germany). In either approach, the operating surgeons aimed at a preoperative cup anteversion of 0°–10° and an inclination of 45°, using a freehand technique aided by the cup placement device.

Outcome measures were assessed by 2 experienced orthopedic surgeons on radiographs taken presurgery and directly postsurgery. The outcome assessors were blinded for surgical approach and had no other role in the trial, that is, they did not take part in any of the surgical procedures. The radiological examinations were tested for interobserver reliability. Radiographs were assessed for cement-mantle thickness, cup inclination, cup anteversion, varus/valgus position of the femoral stem in the frontal plane, femoral stem positioning in the lateral view (THA index), preoperative and postoperative cup and femoral stem offset (offset restoration), and leg length discrepancy.

Cement-mantle thickness was assessed in acetabular zones 1–3 (Fig. 2), by calibrating the radiograph and measuring the thinnest cement-mantle in each zone using the measurement tool of the radiological software. The cement-mantle was defined as adequate if ≥ 2 mm [16]. Cup positioning was assessed by measuring inclination (the angle between the bi-ischiatic line and projection of the acetabular axis in the frontal view) and anteversion (using Lewinnek's formula $\arcsin$: minor frontal view cup diameter/major frontal view cup diameter) [17]. An inclination between 30° and 50° and an anteversion between 5° and 25° were defined as adequate.

A varus/valgus position of the femoral stem in the frontal view of <5° was defined as adequate. The femoral stem position was further assessed in the sagittal plane using the THA index, that is, the distance from the anterior cortex of the femoral wall to the tip of the stem on the lateral radiograph, divided by the distance from the anterior to the posterior wall of the cortex (Fig. 3). A THA index value between 0.4 and 0.6 was considered adequate midline positioning of the prosthesis. Offset restoration was estimated by measuring the differences in preoperative and postoperative global offset, that is, the sum of the acetabular

Fig. 1. Consort 2010 flow diagram.

Table 1

Baseline Characteristics in the 2 Trial Groups.

Baseline Characteristics	DLA	MIDA
Number of patients	80	84
Age (y) ^a	65.6 ± 8.6	67.2 ± 8.6
Gender (male/female)	30/50	25/59
Body mass index ^a	27.6 ± 3.9	27.7 ± 3.6
ASA grade ^a	1.8 ± 0.7	1.9 ± 0.7

DLA, direct lateral approach; MIDA, minimally invasive direct anterior approach.

^a Data are given as mean and standard deviation.

offset (the distance between the center of rotation of the femoral head and a line bisecting the ilioischial line) and the femoral offset (the distance between the center of rotation of the femoral head and a line bisecting the long axis of the femur) (Fig. 4). A difference in global offset between preoperative and postoperative values of ± 5 mm was considered adequate. Preoperative and postoperative leg length was estimated by measuring the distance between a line tangential to the ischial tuberosities and the medial aspect of the trochanter minor, and a discrepancy of ± 5 mm was considered adequate.

Statistical Analysis

Continuous values were described by mean and standard deviation, and compared between trial groups by the independent sample Student's *t*-test. Categorical values were expressed by frequency and percentage, and results compared between trial groups by Pearson's chi-squared test. Interobserver reliability was assessed by calculating the intraclass correlation coefficient (ICC), and values superior to 0.9 were considered very good. A 5% significance level was used throughout. Statistical analyses were performed using SPSS version 25.

Results

Included in this trial were 80 patients randomized to DLA and 84 patients randomized to MIDA. Assessments of radiographs showed

Fig. 2. Acetabular component (cup) zones for radiographic assessment of cement-mantle thickness. Cement-mantle thickness was assessed by measuring the thinnest cement-mantle in each zone using the measurement tool of the radiological software.

Fig. 3. Calculation of the THA index as a measure of femoral stem position in the sagittal plane.

very good interobserver reliability for all outcome measures (intraclass correlation coefficient range = 0.92–0.98).

Cement-Mantle Thickness

The mean cement-mantle was significantly thicker in zone 1 in patients treated with MIDA compared to patients treated with DLA (mean difference = 0.51 mm, 95% confidence interval [CI] 0.09–0.93, $P = .018$) (Table 2). However, there were no differences in adequacy of cement-mantle thickness between the 2 surgical approaches in any of the zones (Table 3).

Acetabular Component Position

The degrees of both cup inclination and anteversion were significantly higher in the MIDA group compared to the DLA group (mean difference = 2.5° , 95% CI 0.3–4.6, $P = .023$ and mean difference = 3.6° , 95% CI 2.2–5.0, $P < .0001$, respectively) (Table 2, Fig. 5). As shown in Table 3, cup inclination was significantly more often adequate in the DLA group (67.9% (53/78) in the DLA group vs 52.4% (43/82) in the MIDA group, $P = .045$).

Fig. 4. Measurement of global offset.

Table 2

Mean Cement-Mantle Thickness, and Cup Inclination and Anteversion in the 2 Trial Groups.

Outcome	Mean (SD)		P Value
	DLA	MIDA	
Cement-mantle thickness (mm)			
Zone 1	0.44 (0.86)	0.95 (1.69)	.018
Zone 2	1.56 (1.79)	1.98 (1.91)	.147
Zone 3	3.77 (2.06)	3.85 (2.20)	.826
Cup positioning			
Inclination (°)	47.0 (6.0)	49.5 (7.4)	.023
Anteversion (°)	5.8 (4.3)	9.4 (4.8)	.000

DLA, direct lateral approach; MIDA, minimally invasive direct anterior approach; SD, standard deviation.

Femoral Stem Position

There were no differences in mean frontal or lateral femoral stem positions between the 2 trial groups (Table 4). The positioning of the femoral stem was in the majority of patients considered adequate in the frontal view, whereas the THA index suggests that the femoral stem tended to be placed more centralized on the lateral radiographs in the MIDA group (Table 5). However, there was no difference in adequacy of frontal or lateral femoral stem placement between the 2 trial groups.

Overall Component Placement

There was no difference in mean global offset restoration between the 2 trial groups (Table 4). Global offset restoration was considered adequate in half of the patients, and there was no difference in offset restoration between the 2 surgical approaches (Table 5). There was no difference in mean leg length discrepancy between the 2 trial groups (Table 4), neither was there any difference in adequacy of leg length discrepancy between the 2 trial groups (Table 5).

Discussion

In this, to date largest double-blind, prospective RCT of radiologically assessed placement of the acetabular and femoral components in THA showed limited differences in component placement between MIDA and DLA. The findings suggest that component placement is similar in the 2 surgical approaches.

The 2 surgical procedures differ in approach to the hip joint, and some consider DLA to provide a more suitable exposure for THA. We hypothesized that component placement would be superior in the DLA group; however, our trial did not reveal any such difference. As such, this corroborates the findings from limited data in

Fig. 5. Acetabular component positioning in the 2 trial groups.

which radiographically assessed component placement was similar between patients treated with DLA and MIDA [5,18–21].

Other data suggest that MIDA may be associated with both better [4] and poorer cup placement [22]; however, trial design, surgical technique, and surgeon learning curve could have affected these findings [13,23]. The slightly thicker cement-mantle in zone 1 in the MIDA group could be explained by the dorsal decubitus position of the pelvis in the MIDA approach, as opposed to the lateral decubitus position in the DLA approach. However, as noted, there was no difference in adequacy of cement-mantle thickness between the 2 trial groups, and the authors believe that the difference in absolute thickness would be too minor to have any relevant clinical implication.

It is thought that deviating anteversion and inclination values might affect implant wear and/or survival. Previously published data on metal-on-metal implants did not find any correlation between implant wear and excess anteversion of either the cup and/or stem components [24]. Additionally, in our trial, the differences in anteversion between the 2 groups are unlikely to be clinically relevant as the mean values in both groups corresponded to the targeted degree of anteversion between 0° and 10°, as originally described by Charnley [25]. The higher inclination values in the MIDA group as those found in our trial are not uncommon [23]. In latest generation polyethylene cups, such as those used in our trial, inclination values >50° may affect implant wear and/or survival [26–28]. As the mean cup inclination in both trial groups was inferior to this level, the authors would argue that the inclination results were unlikely to have any clinical value. Finally, other consequences, such as hip dislocation, were not found during the 2-year follow-up period of the clinical results trial [15].

Table 3

Adequacy of Cement-Mantle Thickness, and Cup Inclination and Anteversion in the 2 Trial Groups.

Outcome	Adequate Results, n (%)		P Value
	DLA	MIDA	
Cement-mantle thickness			
Zone 1	6/78 (7.7)	14/82 (17.1)	.07
Zone 2	29/78 (37.2)	40/82 (48.8)	.14
Zone 3	66/78 (84.6)	71/82 (86.6)	.72
Cup positioning			
Inclination	53/78 (67.9)	43/82 (52.4)	.045
Anteversion	8/80 (10.0)	10/84 (11.9)	.70

DLA, direct lateral approach; MIDA, minimally invasive direct anterior approach.

Table 4

Mean Femoral Stem Position and Leg Length Discrepancy in the 2 Trial Groups.

Outcome	Mean (SD)		P Value
	DLA	MIDA	
Femoral stem position			
Frontal view (varus [°])	2.9 (1.1)	3.1 (1.5)	.443
Lateral view (THA index)	0.53 (0.17)	0.55 (0.15)	.358
Global offset restoration	2.17 (7.83)	1.75 (7.50)	.731
Leg length discrepancy	1.41 (7.87)	−0.30 (8.04)	.164

The number of patients in each of the trial groups varied according to the number of available radiographs of adequate quality.

DLA, direct lateral approach; MIDA, minimally invasive direct anterior approach; SD, standard deviation; THA, total hip arthroplasty.

Table 5

Adequacy of Femoral Stem Position and Leg Length Discrepancy in the 2 Trial Groups.

Outcome	Adequate Results, n (%)		P Value
	DLA	MIDA	
Femoral stem position			
Frontal view (varus)	73/78 (93.6)	74/82 (90.2)	.44
Lateral view (THA index)	24/77 (31.2)	37/82 (45.1)	.07
Global offset restoration	43/79 (54.4)	39/82 (47.6)	.38
Leg length discrepancy	65/79 (82.3)	73/83 (88.0)	.31

The number of patients in each of the trial groups varied according to the number of available radiographs of adequate quality.

DLA, direct lateral approach; MIDA, minimally invasive direct anterior approach; THA, total hip arthroplasty.

This trial is the second double-blind, prospective RCT to assess component placement in DLA and MIDA for THA [14]. To our knowledge, this is the only trial to include assessment of cement-mantle thickness, THA index, and global offset restoration—assessments that are of value for clinical and patient-reported outcome measures [16,29–32]. This trial has some limitations. Up to 5 patients had radiographs that were challenging to measure, and these patients, equally distributed between the trial groups, were excluded so as not to adversely affect the results. Moreover, patients with a BMI >35 kg/m² were excluded from this trial, and the results may therefore not apply to severely obese patients. Some have argued that MIDA should not be applied to patients with obesity [33,34]. Furthermore, only plain radiographs were analyzed in this trial, and the authors cannot preclude that computed tomography scans would have provided additional data with regard to the anteversion and retroversion of the stem component.

This trial adds to the data that show limited differences in component placement between the DLA and MIDA as surgical approaches to THA. Further research should include large, prospective, multicenter trials to investigate the effect of DLA and MIDA on component survival. Future trials could potentially also include the posterior surgical approach, which is currently gaining popularity as an alternative intervention for THA.

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