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Computer-navigated minimally invasive total hip arthroplasty

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Computer-navigated minimally invasive total hip arthroplasty

*Effectiveness, clinical outcome and
gait performance*

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Effectiveness, clinical outcome and gait performance

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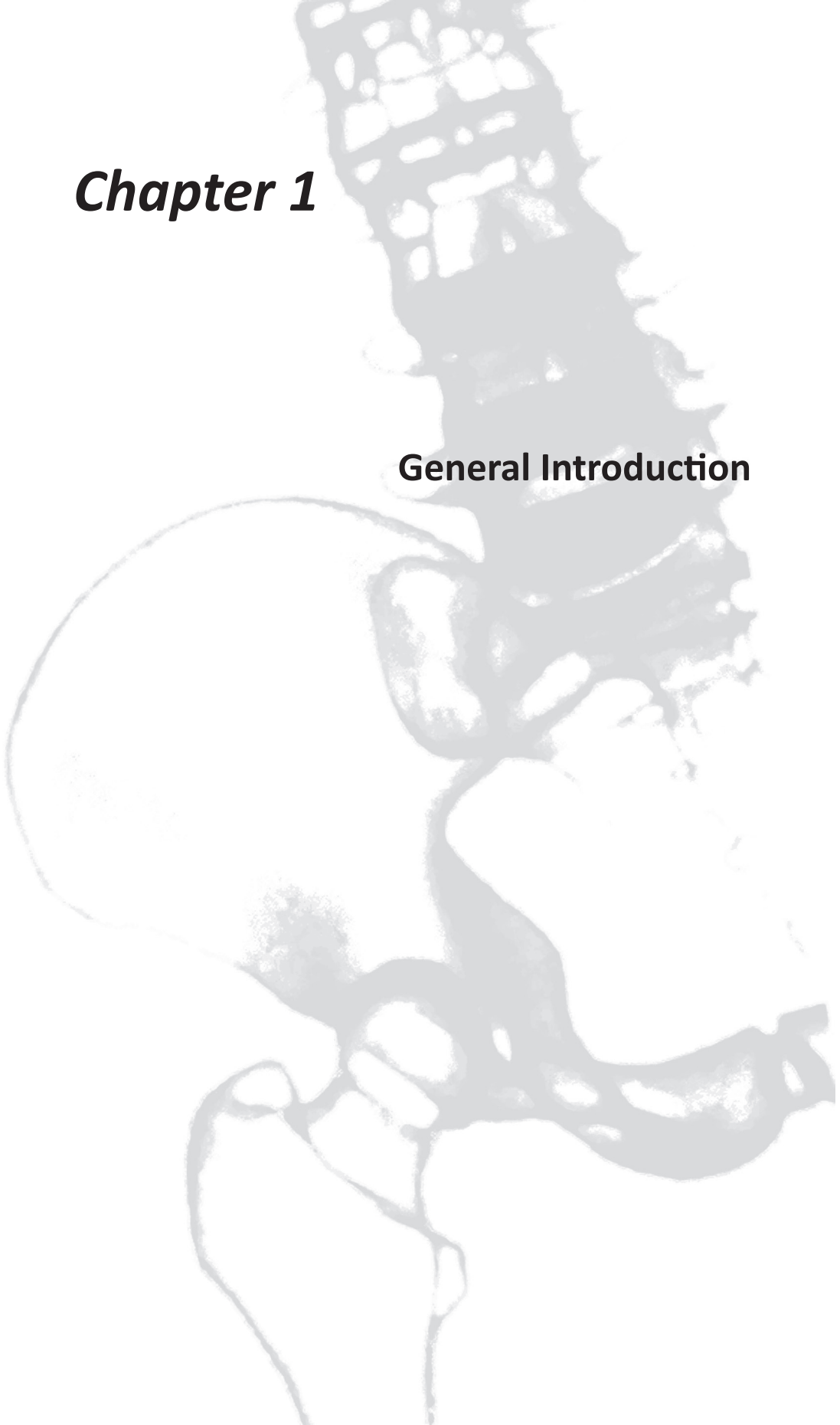
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Chapter 1

General Introduction



Osteoarthritis of the hip, total hip arthroplasty

Osteoarthritis (OA) is one of the leading causes of musculoskeletal pain and an important societal healthcare burden. OA is therefore profiled as one of the major diseases during the World Health Organization (WHO)- and United Nations-endorsed “Bone and Joint Decade (2000 – 2010)”.¹ Furthermore, OA has a major impact on physical functioning in daily life and frequently leads to moderate-to-severe limitations in participation as well as a decreased health-related quality of life.^{2,3}

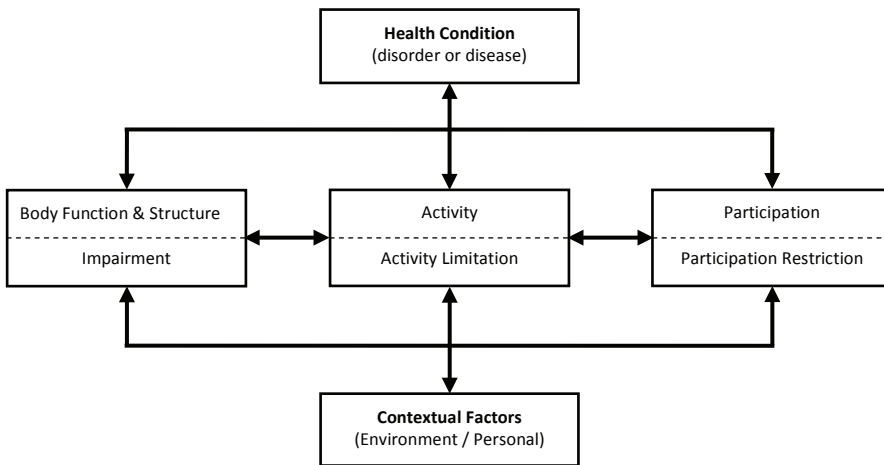
The hip joint is one of the most common sites of OA. Conservative treatment of hip OA involves the use of pain medication and physical therapy. When these treatments are no longer sufficient to alleviate joint pain and functional restrictions in patients with hip OA, a total hip arthroplasty (THA) is the most common surgical treatment option. THA has shown its ability to alleviate joint pain, restore physical functioning and enhance health-related quality of life. It is also considered to be one of the most successful orthopaedic interventions of the past 40 years with 10-year survival rates exceeding 90%.⁴⁻⁶

Due to ageing of the Western population and an increase in the prevalence of obesity, the prevalence of OA is increasing, as has the number of THAs. In 1995, about 14,000 THAs were performed in the Netherlands.⁷ This number rose to approximately 21,500 THAs in 2009.⁸ Based on demographic projections and historical trends it is suggested that 52,000 THAs will be performed in the Netherlands in 2030.⁷ A similar increase in number of THAs is expected in other Western countries.^{9,10}

Although THA has already been proven to be an effective surgical procedure for the treatment of hip OA, there has been considerable effort in recent decades to further improve the component designs, modes of fixation and surgical techniques.¹¹ The concept of minimally invasive surgery (MIS) was adopted recently in the orthopaedic community, leading to the development of minimally invasive techniques for THA. MIS THA aims at decreasing the surgical incision and minimising damage to the underlying soft tissue, in order to accelerate postoperative recovery and an earlier return to normal function.¹² Computer-assisted surgery (CAS) has also gained popularity since it helps the surgeon to precisely visualise and target the surgical site, which may improve the accuracy of orthopaedic procedures.¹³ The use of CAS might be the solution to the limited visibility of anatomical landmarks and vital structures during MIS THA.¹⁴ However, the orthopaedic literature lacks well-designed studies that provide objective evidence on the effectiveness of computer-navigated MIS THA.¹⁵

Measuring outcome after total hip arthroplasty

While outcome assessment in THA has traditionally focused on physician-defined measures of technical success and other surgical outcome measures important to physicians and surgeons,¹⁶ the trend has changed towards measures that evaluate multiple domains that are also important to the patient, such as pain, physical functioning and health-related quality of life.^{17,18} The WHO provides a classification system designed to describe health and health-related problems from biological,

Figure 1. The ICF model²⁰

personal and societal perspectives: the International Classification of Functioning, Disability and Health (ICF).¹⁹ The ICF model identifies three levels of human functioning: functioning at the level of body or body part, the whole person, and the whole person in a social context. Disability therefore involves dysfunction at one or more of these levels: impairments, activity limitations and participation restrictions (Figure 1).¹⁹

The domain *Body Function & Structure* contains aspects of function of body systems or anatomical parts such as joint function, muscle function, gait function and pain. Impairments are problems with (some of) these aspects. Aspects of the domain *Activity* are, for example, activities of daily living such as walking and household tasks. Hence activity limitations are difficulties an individual has in executing such activities or tasks. Involvement in social activities like visiting family and going to work are aspects of the domain *Participation*. Participation restrictions are therefore problems an individual experiences during involvement in social life situations.^{19,21} Consequently, in accordance with the ICF, a complete assessment of outcome for any health condition or intervention requires an evaluation of each domain of the ICF. However, the ICF primarily describes ‘what to measure’ and not ‘how to measure’.²²

The question ‘how to measure’ human functioning in patients with musculoskeletal conditions, including orthopaedic conditions such as hip OA, is addressed by the OMERACT (Outcome Measures in Rheumatology Clinical Trials), where the ICF serves as a basis for the selection of outcome measures based on their content validity.^{17,22,23}

One of the most common assessment methods for measuring outcome of disease or medical interventions are self-reported questionnaires. Advantages of self-reported questionnaires are that they are easy to administer, time-efficient and inexpensive. Furthermore, various aspects of functioning can be assessed

with one questionnaire. The OMERACT group recommends the use of condition-specific and generic health-status questionnaires with which (aspects of) all three domains of the ICF are assessed.¹⁷ However, self-reported questionnaires are not without drawbacks, as they are influenced by patients' expectations and beliefs, the tendency to give socially desirable answers, and recall bias. The addition of performance-based measures such as gait analysis is recommended to gain objective information about physical functioning.²⁴ Gait analysis is often used to discriminate between normal and abnormal gait, and to evaluate progress after interventions to improve gait function such as THA.²⁵⁻²⁷

Gait function is an important aspect of many activities of daily living affected by hip OA and thus may serve as a measure of functional recovery after THA. The ability to independently ambulate indoors and outdoors also plays an important role in health-related quality of life. Gait patterns of patients with osteoarthritis (OA) of the hip are characterised by a decreased walking speed and step length.^{25,28,29} Additionally, these patients frequently show an exaggerated lateral bending of the trunk during gait, which is called a Duchenne limp. In a Duchenne limp, the trunk is inclined in the frontal plane towards the affected hip joint during the stance phase of the gait cycle. With this limp, the mechanical demand for the hip abductor muscles is decreased and the load on the affected hip joint is reduced, which ultimately leads to alleviation of joint pain.³⁰ Gait function can be objectively assessed by means of gait analysis, with which spatiotemporal gait parameters like walking speed and step length can be obtained. Compensatory trunk movements during gait, such as a Duchenne limp, have been scarcely assessed though.

Gait and movements of body segments are usually assessed with optical motion analysis systems that are restricted to a laboratory setting. The disadvantage of such camera-based systems is that they are relatively expensive, time-consuming and labour-intensive, since a specialised and technically educated staff is required. Its use in clinical practice is therefore limited.³¹ A new approach to gait analysis that has gained popularity in recent years, involves the use of body-fixed sensors (BFS), which are based on the use of miniaturised and integrated motion sensors such as accelerometers and gyroscopes. A major advantage of a BFS-based approach is that it can be applied under real-life conditions; no expert laboratory is needed, and measurements can be made over longer periods of time and gait distances.³² Though research has shown that BFS-based gait analysis is an accurate and reliable method for quantifying spatiotemporal gait parameters,³³⁻³⁵ BFS have not been applied to quantify compensatory movements of the trunk during gait in patients with hip OA or after THA.

Aims of the thesis

This thesis encompasses two objectives. The main objective is to assess the effectiveness of computer-navigated MIS THA. To this end, a randomised controlled trial (RCT) was conducted. Patients with end-stage hip OA who were scheduled for a THA were randomly assigned to undergo THA via a computer-navigated MIS technique or the conventional THA technique. The effectiveness of computer-navigated MIS THA and conventional THA is evaluated by means of

clinical outcome measures, self-reported questionnaires on physical functioning and health-related quality of life, and by means of gait analysis.

The second objective of this thesis is the development of a BFS-based gait analysis method, through which insight into the gait function – including compensatory movements of the trunk during gait – of patients with hip OA before and after THA can be obtained during walking outside a laboratory setting.

Outline of the thesis

To gain insight into the scientific evidence of the effectiveness of MIS THA, CAS THA and computer-navigated MIS THA, a qualitative and systematic review of the orthopaedic literature was conducted. **Chapter 2** describes this review. **Chapter 3** presents the design of the RCT on the effectiveness of computer-navigated MIS THA compared to conventional THA.

To gain insight into the gait function of patients with hip OA before and after THA, a BFS-based gait analysis method was developed. With this gait analysis approach compensatory movements of the trunk, such as a Duchenne limp, as well as spatiotemporal gait parameters can be obtained during unconstrained walking outside a laboratory setting. **Chapter 4** presents the accuracy and reproducibility of this BFS-based gait analysis method. **Chapter 5** provides spatiotemporal gait parameters and compensatory movements of the trunk in patients with end-stage hip OA, quantified with this BFS-based gait analysis.

Next, the results of the RCT on the effectiveness of computer-navigated MIS THA compared to conventional THA are presented. **Chapter 6** describes the effect of computer-navigated MIS THA and conventional THA on clinical outcome and physical functioning and health-related quality of life. To this end, clinical parameters and questionnaires are assessed preoperatively, and 6 weeks, 3 and 6 months postoperatively.

Chapter 7 contains a more in-depth analysis of the recovery of gait function after computer-navigated MIS THA or conventional THA, evaluated with BFS-based gait analysis. Gait analysis was performed preoperatively, and 6 weeks, 3 and 6 months postoperatively.

Chapter 8 provides a general discussion of the studies presented in this thesis, addresses some theoretical and practical implications for the professional orthopaedic field, and gives recommendations for future research are given.

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Chapter 2

Minimally invasive and computer-navigated total hip arthroplasty: a qualitative and systematic review of the literature

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BMC Musculoskeletal Disorders, 2010; 11:92.

Abstract

Background: Both minimally invasive surgery (MIS) and computer-assisted surgery (CAS) for total hip arthroplasty (THA) have gained popularity in recent years. We conducted a qualitative and systematic review to assess the effectiveness of MIS, CAS and computer-assisted MIS for THA.

Methods: An extensive computerised literature search of PubMed, Medline, Embase and OVIDSP was conducted. Both randomised clinical trials and controlled clinical trials on the effectiveness of MIS, CAS and computer-assisted MIS for THA were included. Methodological quality was independently assessed by two reviewers. Effect estimates were calculated and a best-evidence synthesis was performed.

Results: Four high-quality and 14 medium-quality studies with MIS THA as study contrast, and three high-quality and four medium-quality studies with CAS THA as study contrast were included. No studies with computer-assisted MIS for THA as study contrast were identified. Strong evidence was found for a decrease in operative time and intraoperative blood loss for MIS THA, with no difference in complication rates and risk for acetabular outliers. Strong evidence exists that there is no difference in physical functioning, measured either by questionnaires or by gait analysis. Moderate evidence was found for a shorter length of hospital stay after MIS THA. Conflicting evidence was found for a positive effect of MIS THA on pain in the early postoperative period, but that effect diminished after three months postoperatively. Strong evidence was found for an increase in operative time for CAS THA, and limited evidence was found for a decrease in intraoperative blood loss. Furthermore, strong evidence was found for no difference in complication rates, as well as for a significantly lower risk for acetabular outliers.

Conclusions: The results indicate that MIS THA is a safe surgical procedure, without increases in operative time, blood loss, operative complication rates and component malposition rates. However, the beneficial effect of MIS THA on functional recovery has to be proven. The results also indicate that CAS THA, though resulting in an increase in operative time, may have a positive effect on operative blood loss and operative complication rates. More importantly, the use of CAS results in better positioning of acetabular component of the prosthesis.

Background

Total hip arthroplasty (THA) is considered to be one of the most successful orthopaedic interventions of the past 40 years, with 10-year survival rates exceeding 90%.^{1,2} In recent decades there has been considerable effort to improve the component designs and modes of fixation of total hip prostheses.³ The concept of minimally invasive surgery (MIS) was adopted recently in the orthopaedic society, leading to the development of minimally invasive techniques for THA. Computer-assisted surgery (CAS) has also gained popularity, since it has the potential to improve the accuracy of orthopaedic procedures.

Despite the increase in use of MIS THA, its risks and benefits are still an ongoing debate issue in the orthopaedic society. Proponents of MIS THA claim that it results in less soft-tissue trauma (smaller skin incision and less muscle damage), reduced blood loss and fewer blood transfusion requirements. Postoperative benefits include less pain, shorter hospital stay, quicker return to function and better cosmetic appearance.^{4,5} Opponents claim that MIS THA introduces additional risks due to limited visibility of anatomical landmarks and vital structures.⁶ Complications involve higher risks for thromboembolism, infection, neurovascular injury, femoral fracture and component malposition, which can result in increased prosthetic wear.^{7,8}

Proper positioning of the hip prosthesis is essential for improving the long-term success of THA. Higher rates of pelvic osteolysis, asymmetric polyethylene wear and component migration have been observed when the acetabular component is malpositioned.⁹ Lewinnek et al.¹⁰ determined a “safe zone” of 5° to 25° of anteversion and 30° to 50° of abduction. They found that the dislocation rate of hip prostheses, where the acetabular components were placed outside this safe range, was approximately four times higher. Most surgeons aim for this safe zone using mechanical alignment guides provided by the manufacturer of the hip prosthesis. However, these mechanical alignment guides have shown clear limitations in terms of accuracy and precision of proper orientation of the hip prosthesis.¹¹

As a result, the interest in computer navigation systems for orientation of the hip prosthesis is increasing, since it may be the solution for the aforementioned problems related to proper prosthetic positioning. Moreover, CAS is not only aimed at an improved alignment of the hip prosthesis, it also provides instant information and feedback to the surgeon, which may make the surgical technique easier to perform and may result in better clinical outcomes. The imaging systems that are used during CAS can be roughly divided into image-based and imageless systems. Image-based systems require the collection of morphological information by preoperative CT scans or MRI, or by means of intraoperative fluoroscopy. Imageless systems use a virtual anatomical model which is embedded in the software and is supplemented by intraoperative registration data of anatomical landmarks.¹²

CAS in THA is not very common nowadays, due to the fact that current CAS systems may involve longer operation times and the introduction of new equipment in the operating room. Other factors that limit the broad application of CAS are costs and complexity of computer navigation systems.¹³ Several studies have

shown however that inaccuracies in prosthetic placement through conventional THA techniques can be significantly reduced by using computer navigation, thereby reducing the risk of various complications such as dislocations.¹⁴⁻¹⁶

The use of CAS may be the solution to the limited visibility of anatomical landmarks during MIS THA. Some even hypothesize that MIS in combination with CAS will result in better positioning of the prosthesis, compared to conventional THA techniques.¹⁸ Combining both techniques with claims of quicker recovery and less pain, together with accurate acetabular component positioning and a minimized risk of dislocation, may result in a more effective procedure for THA compared to the conventional technique. However, there is still controversy concerning the most effective technique for THA because of a lack of scientific evidence on the effectiveness of MIS, CAS and computer-assisted MIS for THA. Hence we performed a systematic review of published evidence on the effectiveness of MIS, CAS and computer-assisted MIS for THA.

Materials and Methods

Search strategy

Following the recommendations of the Cochrane collaborations, an extensive computerised literature search of PubMed, Medline, Embase and OVIDSP was conducted on all studies published between 1995 and May 2009. We used database-appropriate terms, including hip arthroplasty(ies)/replacement(s), minimally invasive/MIS/mini-incision, and/or computer-assisted/navigation/CAS/CAOS. The search strategy was formulated by an experienced medical librarian. To find more studies, the reference lists of all relevant studies were reviewed for potential articles.

Inclusion criteria and procedure

A study was included in the review if 1) a randomized controlled trial or a clinical controlled trial was conducted; 2) the study was published in English, Dutch or German; 3) the study was a full-length published article or fully-written published report; 4) the study population comprised patients aged 18 years or older who were undergoing THA; 5) the study group and control group were similar at baseline with respect to age, gender and BMI; 6) the study contrast was minimally invasive total hip arthroplasty, computer-assisted total hip arthroplasty or a combination of both; and 7) at least one of the following outcome measures was assessed: operative outcome including blood loss and operative time; length of hospital stay; adverse events including intraoperative and postoperative complications; radiographic outcomes including number of outliers of acetabular components outside the desired alignment range; and/or one of the Outcome Measures in Rheumatology Clinical Trials (OMERACT)¹⁹: pain, self-reported physical function and observed physical function, with a follow-up of at least 6 weeks up to one year postoperatively.

The procedure for inclusion of studies was based on the recommendations described by Van Tulder et al.²⁰ The study selection was performed in two stages. The first selection, based on titles and abstracts and taking in consideration the

Table 1. Methodological quality criteria list

Item	Description
1	Was the method of randomization adequate?
2	Was the treatment allocation concealed?
3	Were the groups similar at baseline regarding the most important prognostic indicators?
4	Was the outcome assessor blinded to the intervention?
5	Were co-interventions avoided or similar?
6	Was the drop-out rate described and acceptable?
7	Was the timing of the outcome assessment similar in all groups?
8	Did the analysis include an intention-to-treat analysis?

inclusion criteria, was independently performed by two reviewers (IHFR and BPH). The next stage in the inclusion procedure was performed by the same two reviewers, who independently applied the selection criteria as stated above using the full reports. Disagreement was resolved by discussion. If agreement was not achieved at any stage, a third reviewer was consulted (WZ).

Assessment of methodological quality

The methodological quality of all articles was independently assessed by two reviewers (IHFR and BPH) using a criteria list.²⁰ This list contains 11 criteria related to selection bias, performance bias, attrition bias and detection bias. The requirement of blinding patients or care providers (in this case orthopaedic surgeons) to the intervention (THA) was excluded because such blinding is not possible in this type of research. The question about acceptable compliance in all groups was also excluded, since the question was not applicable to this type of research. All criteria were scored as “yes”, “no” or “unclear”. Studies were considered to be of methodologically high quality when at least six items scored positively; a score of 3 to 5 was medium quality and a score below 3 was considered low quality. Table 1 shows the used criteria list. Disagreement was resolved by discussion and a third reviewer (WZ) was consulted if disagreement persisted.

Statistical analysis

Analysis of the extracted data from the included articles was conducted in line with guidelines for systematic reviews from the Cochrane Collaboration Back Review Group.²⁰ For continuous variables, the standardised mean difference (SMD) with corresponding 95% confidence intervals (95% CIs) was calculated whenever possible. These effect estimates were interpreted according to Cohen: an SMD of 0.2-0.4 was considered a small effect, 0.5-0.7 moderate and ≥ 0.8 large.²¹ For dichotomous outcomes such as postoperative complications and acetabular outliers the odds ratio (OR) and 95% CIs were calculated as the summary statistics. This ratio represents the odds of complications or acetabular outliers occurring in the study group compared with the control group. An odds ratio of less than 1 favours the study group and the point estimate of the odds ratio is considered to be statistically significant if the 95% CI does not include the value of 1. Analysis of the included articles was conducted using Review Manager 5 (version 5.0.18, The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark).

Table 2. Best-evidence synthesis

Strong evidence	Consistent findings among multiple high-quality trials*
Moderate evidence	Consistent findings in multiple low-quality trials and/or one high-quality trial
Limited evidence	Consistent findings in at least one low-quality trial
Conflicting evidence	Inconsistent findings among multiple trials (high- and/or low-quality trials)
No evidence	Findings of eligible trials do not meet the criteria for one of the levels of evidence stated above, or there are no eligible trials available

* Consistent findings were defined as $\geq 75\%$ of the trials showing results in the same direction.

Efforts to retrieve raw data or means and their standard deviations to compute effect sizes or odds ratios by contacting the authors of articles where these data were not reported, were unsuccessful. We therefore chose to summarise the results by means of a qualitative analysis using a rating system that consists of five levels of scientific evidence, taking into account the methodological quality and the outcome of the original studies (best-evidence synthesis) (Table 2).²⁰

Results

Selection of studies

Since the search strategy for MIS, CAS and computer-assisted MIS for THA contained similar components, the results of these search strategies overlapped. After removing double citations, 1842 citations remained. A flow chart of the results of the selection procedure after selection based on title, abstract and full text is shown in Figure 1. The main reasons for exclusion of potentially relevant studies based on full-text articles are also presented in Figure 1.

Eventually, 25 articles were included. In 18 of these articles the study contrast was minimally invasive THA.^{4,17,22-37} A computer navigation system was used during THA during the conventional as well as the MIS approach in two of these studies.^{17,26} Computer-assisted THA was the study contrast in seven articles.^{15,16,18,38-41} In two of these studies, a minimally invasive technique for THA was used in the freehand as well as the CAS group.^{18,39} In the study of Kalteis et al.¹⁵, acetabular components were implanted either freehand or using a CT-based or an imageless computer navigation system. The results of the comparison of the two navigation systems are reported separately in this review. Najarian et al.³⁹ report on the results of the first 49 cases of CAS THA and a second series of 47 cases of CAS THA. Since the first series were used to present data on the learning curve of CAS THA, the results of the second series are reported in this review.

None of the included articles had computer-assisted minimally invasive THA as study contrast. The characteristics of the included studies are presented in Additional file 1.

Methodological quality

The results of the methodological quality assessment of the included articles are presented in Table 3. Overall, the methodological quality of the studies was found to be medium. Four of the studies with MIS THA as study contrast were of high methodological quality^{4,30,31,34} and 14 of medium methodological quality^{17,22-29,32,33,35-37}. Three of the studies with CAS THA as study contrast were

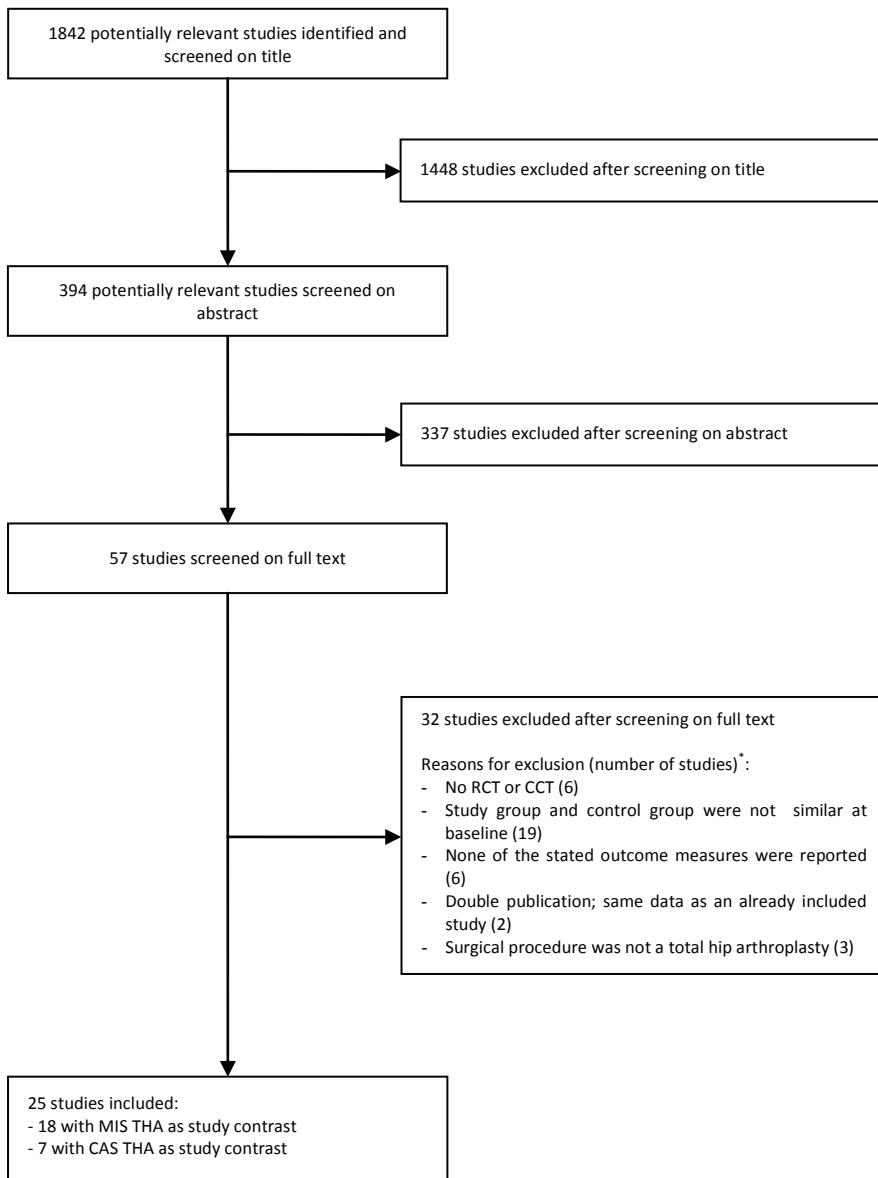


Figure 1. Flow chart of inclusion procedure

* Multiple reasons for excluding were possible per study.

RCT = randomized controlled trial; CCT = controlled clinical trial; MIS THA = minimally invasive total hip arthroplasty; CAS THA = computer-assisted total hip arthroplasty.

of high methodological quality^{15,16,40}, the other four of medium methodological quality^{18,38,39,41}.

Table 3. Results of the methodological quality assessment*

	Fulfilled validity criteria				Unfulfilled validity criteria	Incomplete information for validity assessment	Internal validity score	Methodological quality
	Selection bias (1,2,3)	Performance bias (5)	Attrition bias (6,8)	Detection bias (4,7)				
MIS								
Lawlor et al. ³¹	1,2,3	5	6	4,7	8	-	7	High
Chimento et al. ⁴	1,2,3	5	6	4,7	8	-	7	High
Ogonda et al. ³⁴	1,2,3	5	6	4,7	8	-	7	High
Kim ³⁰	1,3	5	6	4,7	2,8	-	6	High
Bennett et al. ²²	3	5	6	4,7	8	1,2	5	Medium
Chung et al. ²³	3	5	6	4,7	1,2,8	-	5	Medium
Khan et al. ²⁹	3	5	6	4,7	1,2,8	-	5	Medium
Dorr et al. ²⁶	3	5	6	4,7	8	1,2	5	Medium
Ciminiello et al. ²⁴	3	5	6	7	1,2,4,8	-	4	Medium
Dutka et al. ²⁷	3	-	6	4,7	1,2,8	5	4	Medium
Hart et al. ²⁸	3	-	6	4,7	8	1,2,5	4	Medium
Mazoochian et al. ³⁷	3	5	-	4,7	8	1,2,6	4	Medium
Rittmeister & Peters ³⁵	3	5	6	7	1,2,4,8	-	4	Medium
Speranza et al. ³⁶	3	5	6	7	4,8	1,2	4	Medium
DiGioia et al. ¹⁷	3	5	-	4,7	1,2,8	6	4	Medium
De Beer et al. ²⁵	3	-	6	7	1,2,4,8	5	3	Medium
Levine et al. ³²	3	-	6	7	1,2,4,5,8	-	3	Medium
Nakamura et al. ³³	3	-	6	7	1,2,4,5,8	-	3	Medium
CAS								
Leenders et al. ¹⁶	1,2,3	5	6	4,7	8	-	7	High
Parratte & Argenson ⁴⁰	1,2,3	5	6	4,7	8	-	7	High
Kalteis et al. ¹⁵	1,3	5	6	4,7	8	2	6	High
Kalteis et al. ³⁸	1,3	5	6	7	8	2,4	5	Medium
Sugano et al. ⁴¹	3	5	6	4,7	1,2,8	-	5	Medium
Najarjan et al. ³⁹	3	5	6	7	1,2,8	4	4	Medium
Wixson & MacDonald ¹⁸	3	5	6	7	1,2,8	4	4	Medium

* Methodological quality criteria are presented in Table 1.

Operative time

Operative time was reported in 16 studies with MIS THA as study contrast (Table 4). Two high-quality studies and five medium-quality studies reported a moderate to large decrease in operative time for MIS THA.^{23,27,30,32-34,37} One other high-quality study and eight medium-quality studies reported no significant difference in operative time.^{4,17,24-26,28,29,35,36}

Operative time was reported in four studies with CAS THA as study contrast (Table 4). Except for the sub-study of Kalteis et al.¹⁵ on an imageless computer navigation system, all studies reported a moderate increase in operative time for THA when using computer navigation.^{15,38,39,41}

Intraoperative blood loss

Intraoperative blood loss was reported in 14 studies with MIS THA as study contrast (Table 4). Two high-quality studies^{4,34} and eight medium-quality studies^{23,25-27,29,33,36,37} reported a small-to-large decrease in intraoperative blood loss after MIS THA. One high-quality study and three medium-quality studies reported no significant difference.^{24,30,32,35}

Two studies with CAS THA as study contrast reported on intraoperative blood loss (Table 4). Sugano et al. [41] reported no significant effect of the use of

Table 4. Results of perioperative outcome measures*

	Methodological quality	No. of patients	Operative time	Intraoperative blood loss	Length of Stay
			SMD (95% CI)	SMD (95% CI)	SMD (95% CI)
MIS					
Chimento et al. ⁴	High	60	0.03 (-0.48, 0.54)	-0.74 (-1.26, -0.21)	NE (NS)
Ogonda et al. ³⁴	High	219	-0.49 (-0.76, -0.22)	-0.29 (-0.56, -0.03)	NE (NS)
Kim ³⁰	High	140	NE (S, decrease)	NE (NS)	NR
Chung et al. ²³	Medium	120	-0.42 (-0.79, -0.06)	-1.18 (-1.56, -0.79)	-0.73 (-1.10, -0.36)
Khan et al. ²⁹	Medium	200	-0.01 (-0.29, 0.26)	-0.84 (-1.13, -0.55)	NR
Dorr et al. ²⁶	Medium	60	-0.32 (-0.83, 0.19)	-0.41 (-0.92, 0.10)	-0.53 (-1.03, -0.03)
Ciminiello et al. ²⁴	Medium	120	NE (NS)	NE (NS)	NE (NS)
Dutka et al. ²⁷	Medium	120	-0.88 (-1.25, -0.50)	-1.40 (-1.80, -1.00)	NE (NS)
Hart et al. ²⁸	Medium	120	NE (NS)	NR	NR
Mazoochian et al. ³⁷	Medium	52	NE (S, decrease)	NE (S, decrease)	NR
Rittmeister & Peters ³⁵	Medium	152	NE (NS)	NE (NS)	NR
Speranza et al. ³⁶	Medium	100	NE (NS)	NE (S, decrease)	NE (NS)
DiGioia et al. ¹⁷	Medium	70	NE (NS)	NR	NE (NS)
De Beer et al. ²⁵	Medium	60	NE (NS)	-0.77 (-1.30, -0.25)	NE (NS)
Levine et al. ³²	Medium	201	NE (S, decrease)	NE (NS)	NE (S, decrease)
Nakamura et al. ³³	Medium	92	-0.85 (-1.28, -0.42)	-0.42 (-0.84, -0.01)	NR
CAS					
Kalteis et al. ¹⁵ (CT-based)	High	60	NE (S, increase)	NR	NR
Kalteis et al. ¹⁵ (Imageless)	High	60	NE (NS)	NR	NR
Kalteis et al. ³⁸	Medium	45	0.45 (-0.14, 1.04)	NR	NR
Sugano et al. ⁴¹	Medium	180	NE (S, increase)	NE (NS)	NR
Najarjian et al. ³⁹	Medium	100	NE (S, increase)	NE (S, decrease)	NR

SMD = standardized mean difference; 95% CI = 95% confidence interval; NE = SMD not estimable; S = reported differences between groups were significant; NS = reported differences between groups were not significant; NR = outcome measure not reported.

* A negative SMD with 95% CI indicates a decrease in operative time, intraoperative blood loss and length of stay in favor of the study group.

computer navigation during THA on intraoperative blood loss. However Najarian et al.³⁹ reported a significant decrease in intraoperative blood loss.

Length of stay

Ten studies reported on length of stay after MIS THA (Table 4). Three medium-quality studies reported a moderate-to-large decrease in length of hospital stay after MIS THA.^{23,26,32} Two high-quality studies^{4,34} and five medium-quality studies^{17,24,25,27,27,28,35,36} reported no significant differences in length of stay between the MIS THA group and the control group. None of the studies with CAS THA as study contrast reported data on length of stay.

Complications

Seventeen studies with MIS THA as study contrast reported on intraoperative and postoperative complications (Table 5). Two high-quality studies^{4,30} and two medium-quality studies^{35,37} reported higher complication rates after MIS THA, but these rates were statistically non-significant. The results of six medium-quality studies^{23,25,26,29,32,33} showed lower, though statistically non-significant, complication rates after MIS THA. Moreover, two high-quality studies^{31,34} (reporting on the same data) and five medium-quality studies^{17,24,27,28,35} reported no differences in complication rates between the study and control group.

Table 5. Operative complications and acetabular outliers*

	Methodological quality	No. of complications			No. of outliers		
		Study group	Control group	OR (95% CI)	Study group	Control group	OR (95% CI)
MIS							
Lawlor et al. ^{31 †}	High	3/109	4/110	0.75 (0.16, 3.43)			NR
Chimento et al. ⁴	High	3/28	2/32	1.80 (0.28, 11.64)			-
Ogonda et al. ^{34 †}	High	3/109	6/110	0.75 (0.16, 3.43)	16/105	19/109	0.85 (0.41, 1.76)
Kim ³⁰	High	3/70	2/70	1.52 (0.25, 9.40)	13/70	11/70	1.22 (0.51, 2.95)
Chung et al. ²³	Medium	3/57	5/55	0.58 (0.13, 2.54)	0	0	-
Khan et al. ²⁹	Medium	15/100	21/100	0.66 (0.32, 1.38)	3/100	3/100	1.00 (0.20, 5.08)
Dorr et al. ²⁶	Medium	2/30	3/30	0.64 (0.10, 4.15)	0	0	-
Ciminiello et al. ²⁴	Medium	0	0	-	0	0	-
Dutka et al. ²⁷	Medium	1/60	1/60	1.00 (0.06, 16.37)	0	0	-
Hart et al. ²⁸	Medium	1/60	1/60	1.00 (0.06, 16.37)	0	0	-
Mazoochian et al. ³⁷	Medium	4/26	3/26	1.39 (0.28, 6.95)			NR
Rittmeister & Peters ³⁵	Medium	7/76	6/76	1.18 (0.38, 3.70)			NR
Speranza et al. ³⁶	Medium	3/46	0/54	8.77 (0.44, 174.38)	1/46	3/54	0.38 (0.04, 3.76)
DiGioia et al. ¹⁷	Medium	0	0	-	0	0	-
De Beer et al. ²⁵	Medium	1/30	2/30	0.48 (0.04, 5.63)	0	0	-
Levine et al. ³²	Medium	14/126	13/75	0.60 (0.26, 1.35)			NR
Nakamura et al. ³³	Medium	1/50	2/42	0.41 (0.04, 4.67)	4/50	5/42	0.64 (0.16, 2.57)
CAS							
Leenders et al. ¹⁶	High			NR	7/50	14/50	0.42 (0.15, 1.15)
Parratte & Argenson ⁴⁰	High	0	0	-	6/30	17/30	0.19 (0.06, 0.60)
Kalteis et al. ¹⁵ (CT-based)	High	0/30	1/30	0.32 (0.01, 8.24)	5/30	16/30	0.17 (0.05, 0.58)
Kalteis et al. ¹⁵ (Imageless)	High	0/30	1/30	0.32 (0.01, 8.24)	2/30	16/30	0.06 (0.01, 0.31)
Kalteis et al. ³⁸	Medium	0	0	-	2/23	11/22	0.10 (0.02, 0.51)
Sugano et al. ⁴¹	Medium	0/60	7/120	0.13 (0.01, 2.23)	0/59	31/111	0.02 (0.00, 0.36)
Najarian et al. ³⁹	Medium	2/47	2/53	1.13 (0.15, 8.38)	6/47	18/53	0.28 (0.10, 0.80)
Wixson & MacDonald ¹⁸	Medium	2/82	1/50	1.23 (0.11, 13.87)	17/82	18/50	0.46 (0.21, 1.02)

No. = number; OR = Odds ratio; 95% CI = 95% confidence interval; NR = outcome measure not reported. † Articles report on the same study population. * An OR below 1 with 95% CI indicates lower odds for complications and outliers in favor of the study group.

Seven studies with CAS THA as study contrast reported on intraoperative and postoperative complications (Table 5). Both sub-studies of Kalteis et al.¹⁵, which are high-quality studies, reported lower complication rates in the CAS group than in the control group. These results are also shown in a medium-quality study⁴¹, yet in all these studies such differences in complication rates were statistically non-significant. One high-quality study⁴⁰ and three medium-quality studies^{18,38,39} reported no significant difference either.

Acetabular outliers

The number of acetabular components outside the desired alignment range (acetabular outliers) was reported in 13 studies with MIS THA as study contrast (Table 5). The high-quality study of Kim [30] reported more acetabular outliers in the study group, but these rates were statistically non-significant. Fewer acetabular outliers were reported in one high-quality study³⁴ and two medium-quality studies^{33,36}, though this difference was also non-significant. In addition, one high-quality study⁴ and eight medium-quality studies^{17,23-29} reported no differences in acetabular outliers.

All studies with CAS THA as study contrast reported on the number of acetabular outliers (Table 5). Five studies showed significant fewer acetabular

outliers for CAS THA.^{15,38-41} The other two studies also reported fewer acetabular outliers for CAS THA, but this difference was statistically non-significant.^{16,18}

Physical functioning

In order to evaluate physical functioning after THA, several physician-based and self-reported questionnaires are in use. Furthermore, objective assessment of physical function can be done by means of gait analysis. In total, thirteen studies with MIS THA as study contrast reported on physical functioning outcome measures. None of the studies with CAS THA as study contrast assessed physical functioning of patients after THA.

Physician-reported physical functioning

Ten studies with MIS THA as study contrast reported on physician-based physical functioning outcome measures (Table 6). In these studies, two different outcome measures were used, namely the Harris Hip Score^{17,24-27,34,36,37} and the Merle d'Aubigné Hip Score^{28,33}. Six studies reported six weeks postoperatively follow-up data. One medium-quality study²⁷ reported significant improvements in physician-reported physical functioning, and the other five studies (one high-quality and four medium-quality) reported no significant differences^{24-26,34,37}. Five studies reported three months postoperatively follow-up data. Three medium-quality studies^{17,28,37} reported significant improvement in physical functioning scores in favor of MIS THA, and two medium-quality studies^{27,36} showed no significant differences. Six medium-quality studies reported six months postoperatively follow-up data. Only one study¹⁷ reported significant improvement in physical functioning scores six months after MIS THA when compared to conventional THA; the other five studies^{26-28,33,36} showed no significant differences. Two medium-quality studies reported follow-up data one year after THA^{17,28}. Neither study found significant differences in physical function.

Patient-reported physical functioning

Five studies with MIS THA as study contrast reported on patient-reported physical functioning by means of two disease-specific outcome measures, namely the Western Ontario McMaster University Osteoarthritis Index (WOMAC)^{29,34,36,37} and the Oxford Hip Score (OHS)^{25,34} (Table 6). Two of these studies also reported on the physical component of the MOS 36-item Short Form Health Survey (SF-36)²⁹ and the Short Form-12 (SF-12)³⁴, which are both generic questionnaires to assess health-related quality of life. Three studies reported six weeks postoperatively follow-up data. One high-quality study³⁴ and one medium-quality study²⁵ reported no to small but non-significant improvements on patient-reported physical function. However, one medium-quality study³⁷ reported significant effects on the WOMAC in favor of MIS THA. Three medium-quality studies reported follow-up data of three months after MIS THA.^{29,36,37} Two of these studies^{29,37} reported significant effects on the WOMAC in favour of MIS THA and one²⁹ reported no significant difference on the physical component scale of the SF-12. Speranza et al.³⁶ showed no difference on the WOMAC. One medium-quality study [36] reported no significant differences on

Table 6. Results of outcome measures to evaluate physical functioning after MIS THA[†]

	Methodological quality	Follow-up			
		6 weeks	3 months	6 months	1 year
Physician-reported					
Ogonda et al. ^{34*}	High	0.08 (-0.18, 0.35)	NR	NR	NR
Dorr et al. ^{26*}	Medium	NE (NS)	NR	NE (NS)	NR
Ciminiello et al. ^{24*}	Medium	0.26 (-0.10, 0.62)	NR	NR	NR
Dutka et al. ^{27*}	Medium	NE (S) ^a	NE (NS)	NE (NS)	NR
Speranza et al. ^{36*}	Medium	NR	NE (NS)	NE (NS)	NR
Hart et al. ^{28†}	Medium	NR	NE (S) ^a	NE (NS)	NE (NS)
Mazoochian et al. ^{37*}	Medium	NE (NS)	NE (S) ^a	NR	NR
DiGioia et al. ^{17*}	Medium	NR	NE (S) ^a	NE (S) ^a	NE (NS) ^a
De Beer et al. ^{25*}	Medium	0.40 (-0.11, 0.91)	NR	NR	NR
Nakamura et al. ^{33†}	Medium	NR	NR	NE (NS)	NR
Patient-reported					
Ogonda et al. ^{34†}	High	0.03 (-0.23, 0.30)	NR	NR	NR
Ogonda et al. ^{34§}	High	0.13 (-0.13, 0.40)	NR	NR	NR
Ogonda et al. ^{34**}	High	0.01 (-0.26, 0.27)	NR	NR	NR
Khan et al. ^{29‡}	Medium	NR	NE (S) ^a	NR	NE (S) ^a
Khan et al. ^{29††}	Medium	NR	NE (NS)	NR	NR
Mazoochian et al. ^{37‡}	Medium	NE (S) ^a	NE (S) ^a	NR	NR
Speranza et al. ^{36‡}	Medium	NR	NE (NS)	NE (NS)	NR
De Beer et al. ^{25§}	Medium	0.24 (-0.27, 0.74)	NR	NR	NR
Gait analysis^b					
Lawlor et al. ³¹	High	-0.10 (-0.37, 0.16)	NR	NR	NR
Ogonda et al. ³⁴	High	0.19 (-0.07, 0.46)	NR	NR	NR
Bennett et al. ²²	Medium	NE (NS)	NR	NR	NR
Dorr et al. ²⁶	Medium	NE (NS)	NE (NS)	NR	NR

Scores are reported as SMD (95% CI). NE = SMD not estimable; S = reported differences between groups were significant; NS = reported differences between groups were not significant; NR = outcome measure not reported. * scores on the HHS; † scores on the Merle d'Aubigné Hip score; ‡ scores on the WOMAC; § scores on the OHS; ** scores on the physical component of the SF-36; †† scores on the physical component of the SF-12. ^a Improvement in score. ^b Gait velocity is used as outcome measure for gait analysis. [†] A positive SMD with 95% CI indicates better physical functioning in favor of the study group.

the WOMAC six months after MIS THA. Another medium-quality study²⁹ however reported significant differences on the WOMAC one year postoperatively.

Gait analysis

Four studies with MIS THA as study contrast reported gait analysis data to evaluate physical function after THA (Table 6). All four studies reported six weeks postoperatively follow-up data. Two high-quality studies^{31,34} and two medium-quality studies^{22,26} reported no significant effect on gait function. Only one medium-quality study²⁶ reported on three months postoperatively follow-up data. They reported no significant effect on gait function three months after MIS THA. Furthermore, none of the studies reported on follow-up data of six months and one year postoperatively.

Pain

Five studies with MIS THA as study contrast reported on pain (Table 7). One study was of high quality³⁰, the other four studies of medium quality^{17,27,28,33}. These studies used three different measures to assess pain: a Visual Analogue Scale (VAS)^{27,30} for pain, the subscale of the Merle d'Aubigné Hip score^{28,33}, and the pain subscale of the Harris Hip Score¹⁷. Three studies reported six weeks postoperatively follow-up data, reporting a significant moderate decrease²⁷ and no significant effect^{28,30}

Table 7. Results of outcome measures to evaluate pain after THA

	Methodological quality	Follow-up			
		6 weeks	3 months	6 months	1 year
Kim ^{30*}	High	NE (NS)	NE (NS)	NR	NE (NS)
Dutka et al. ^{27*}	Medium	-0.51 (-0.87, -0.15)	-0.13 (-0.49, 0.23)	-0.31 (-0.67, 0.05)	NR
Hart et al. ^{28†}	Medium	NE (NS)	NR	NE (NS)	NE (NS)
DiGioia et al. ^{17‡}	Medium	NR	NE (NS)	NE (NS)	NE (NS)
Nakamura et al. ^{33*}	Medium	NR	NR	NE (NS)	NR

Scores are reported as SMD (95% CI). NE = SMD not estimable; S = reported differences between groups were significant; NS = reported differences between groups were not significant; NR = outcome measure not reported. * score on a VAS for pain; † score on the pain subscale of the Merle d'Aubigné Hip score; ‡ score on the pain subscale of the HHS.

of MIS THA on pain. No significant differences in pain were reported at three months^{17,27,30}, six months^{17,27,28,33} and one year^{17,28,30} postoperatively. None of the studies with CAS THA as study contrast reported on pain after THA.

Best-evidence synthesis

MIS THA

Compared to conventional THA, strong evidence was found for a decrease in operative time and operative blood loss after MIS THA. The evidence for a shorter length of stay was moderate. Strong evidence was also found for no difference in complication rates and position of the acetabular component. Moderate to strong evidence was found for no difference in physical functioning six weeks and six months after surgery. The evidence of a positive effect of MIS THA on physical functioning three months postoperatively was conflicting, as was the evidence for less pain after MIS THA six weeks postoperatively. The evidence for no differences in pain levels three and six months after surgery was strong.

CAS THA

Strong evidence was found for a positive effect of CAS THA on the position of the acetabular component. The evidence for a positive effect on operative blood loss was limited. Strong evidence was found for an increase in operative time and for no significant difference in complication rates after CAS THA.

Discussion

We have reviewed the current literature evaluating the effectiveness of MIS, CAS and computer-assisted MIS for THA. The extensive literature search resulted in 18 articles with MIS THA as study contrast, and seven with CAS THA as study contrast, yet no study with computer-assisted MIS for THA as study contrast was discovered. The results of this systematic review indicate that there were no significant differences in operative complications and acetabular component positioning between MIS THA and the conventional procedure. Furthermore, MIS THA resulted in a reduction in blood loss, operative time and reduced length of stay. The added value of MIS THA over the conventional procedure in terms of a faster functional recovery however remains to be proven. Computer-assisted THA results in better positioning of the acetabular component. It may also have a positive effect on

operative blood loss and complications despite an increased operative time.

Contrary to what proponents of MIS THA stated, this review showed that MIS THA had no effect on physical functioning, as measured by questionnaires as well as gait analysis. Since the main purported benefit of MIS THA is a decrease in the amount of soft-tissue (muscle) damage, it can be postulated that a difference in improvement of physical functioning and pain will only be seen in the early postoperative period. Only eight studies reported data on physical functioning at six weeks postoperatively.^{22,24-27,31,34,37} Six of these studies assessed physical functioning by means of either physician-reported or patient-reported questionnaires.^{24-27,34,37} Although these are shown to be useful for detecting changes in physical functioning over time in patients with osteoarthritis of the hip and after THA^{42,43}, it is arguable whether these questionnaires are sensitive enough to detect subtle differences in improvement of physical functioning after conventional or MIS THA. A possible solution for this problem is to measure physical functioning objectively by means of quantitative gait analysis. However, only four studies assessed physical functioning using gait analysis.^{22,26,31,34} Quantitative gait analysis has been used for numerous applications and has provided insights into functional characteristics not identifiable by clinical exam or other methods. Several studies have compared two surgical techniques for THA, attempting to identify differences in functional outcome.⁴⁴⁻⁴⁶ The studies that used gait analysis^{44,46} revealed differences between the surgical approaches, while this result failed to be identified by means of a questionnaire.⁴⁵

The results for CAS THA demonstrate an increase in operative time and limited evidence for a decrease in operative blood loss, but CAS THA had no effect on operative complication rates. Additionally, the use of CAS during THA had a positive effect on the outliers of the acetabular component position outside the desired range. These results justify use of computer navigation during THA. With improved surgery patients should benefit from having lower morbidity rates, better functional outcome and greater longevity of implants.¹² Wines and McNicol⁴⁷ showed that during conventional THA it is technically difficult to achieve an accurate alignment of the acetabular component intraoperatively. As judged by postoperative CT scans, surgeons' intraoperative estimates of acetabular component positioning were inside the desired range in less than two-thirds of the cases. Since accurate component positioning benefits the longevity of the implanted prosthesis, CAS can help achieve this goal. However, broader application of computer navigation systems is still hindered by increased operative times, partly due to the complexity of the systems, and the accompanying financial costs.

Despite efforts to get an ample overview of the available literature on MIS and CAS for THA, no articles with computer-assisted MIS for THA as study contrast were discovered. Some of the studies included compared computer-assisted MIS for THA with either MIS THA^{18,39} or CAS THA.^{17,26} Their results are in line with the other studies included in this review that compared MIS THA or CAS THA with a conventional approach. Still, an additive effect of the combination of MIS and CAS for THA needs to be established.

Some critical remarks can be made on the included studies. First, a wide variety of

surgical approaches was used in them. We chose to analyse all surgical approaches together, since the aim of this systematic review was to assess the effectiveness of minimally invasive THA, but not of any specific minimally invasive THA approach. Second, the surgical approaches were too heterogeneous and often poorly described to perform subgroup analyses. Studies on image-based and imageless navigation systems were also analysed together, since research has shown that imageless navigation is as reliable as image-based navigation for positioning the acetabular component.¹⁵ Third, the studies included in this review use a variety of definitions of 'minimally invasive THA' or 'mini-incision THA'. The term 'minimally invasive' is clearly open to interpretation. There are patent differences between using an alternate surgical approach intended to gain access to the hip joint through less soft-tissue dissection and using intermuscular planes, and performing the conventional procedure through a smaller skin incision. In the literature, studies use the term 'mini-incision' while, according to the description of the surgical technique, it is a minimally invasive technique which has been used. Conversely, the term 'minimally invasive' is also used in the literature to indicate what appears to be a mini-incision technique. Fourth, the used definitions for the desired range of acetabular component angle varied enormously in the published results of MIS THA and CAS THA. The majority of the studies use the safe zone recommended by Lewinnek et al.¹⁰, including an abduction angle of $40\pm 10^\circ$ and an anteversion angle of $15\pm 10^\circ$. Some studies reported slightly different operation goals, depending on the surgical approach used. The operation goal was nonetheless always the same in the study group and the control group. Finally, not all studies reported the experience of the surgeons with the specific surgical technique. The introduction of a new surgical technique is often accompanied by a learning curve, associated with a temporary increase of adverse events.⁴⁸ To make an objective comparison between conventional technique and a minimally invasive or computer-assisted technique for THA, it is crucial to exclude the cases that are operated on during the time span of the learning curve for the new surgical technique.

Some limitations of this review and its conclusions need to be addressed. In this systematic review, a highly sensitive comprehensive search was conducted following the recommendations of the Cochrane collaboration in order to identify articles of interest. For practical reasons though, only studies published in English, Dutch or German were included in the final review, which might have led to selection bias. Additionally, in order to get a broad overview of all the literature on MIS, CAS and computer-assisted MIS for THA, we chose to include not only RCTs but also CCTs. Shrier et al.⁴⁹ stated that including studies other than RCTs may provide important additional information, thereby improving inference of the results. Moreover, Poolman et al.⁵⁰ suggested that readers should not assume that studies labelled as Level I are of a high reporting quality, or of a better reporting quality than Level II studies. This was also seen in the present review; some CCTs were of a higher methodological quality than several of the included RCTs. Of the studies included, only six were considered of high quality. None of the studies conducted their analyses following the intention-to-treat principle. Furthermore, several RCTs failed to report on the methods of randomisation and treatment allocation. Since

several studies failed to report sufficient data to calculate SMDs, it was not possible to conduct a meta-analysis (quantitative statistics). We therefore used qualitative levels of evidence to summarize the results. Use of a best-evidence synthesis is a next best solution and is a transparent method commonly applied when statistical pooling is not feasible or clinically viable.²⁰

Conclusions

The results of this systematic review indicate that MIS THA is a safe surgical procedure, without increases in operative time, blood loss, operative complications and component positioning when compared to the conventional procedure. However, the surplus value of MIS THA over the conventional procedure in terms of a faster functional recovery remains to be proven. The results of this review also indicate that computer-assisted THA, despite an increased operative time, may have a positive effect on operative blood loss and complications. More importantly, the use of CAS during THA results in better positioning of the acetabular component of the prosthesis. Since minimally invasive THA and the use of computer navigation are becoming increasingly popular in orthopedics, combining 'the best of both worlds' would be a sensible next step to take. With respect to future research, well-designed studies on MIS THA, CAS THA and especially computer-assisted MIS THA are needed, in which the used definitions, surgical technique, study population, outcome measures and study end-points are adequately described.

Competing interests

The authors declare that they have no competing interests.

Author's contributions

IHFR co-coordinated the review, contributed to the literature search, and performed the data extraction, statistical analyses and drafting of the manuscript. BPH contributed to the literature search, data extraction and drafting of the manuscript. MS and WZ participated in the study design and have been involved in, together with SKB, JWG, ALB and RW, critically revising the manuscript. All authors read and approved of the final manuscript.

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Additional file 1. Study characteristics

Study	n	Method	Participants	Interventions		Outcome measures	Follow-up
				MIS			
Bennett et al. ²²	17	RCT	Chosen at random from a larger study cohort of 200 patients who were on the waiting list for THA. Exclusion criteria: previous surgery to ipsilateral hip, or polyarthrits	S: minimally invasive posterior approach (<10 cm) C: standard posterior approach (16 cm)	Gait velocity	6 weeks	
Chimento et al. ⁴	60	RCT	Patients undergoing THA between Nov. 15, 1999 and July 15, 2000. Exclusion criteria: BMI >30, and a hip pathology that would require a more extensive exposure to reconstruct the hip	S: minimally invasive posterolateral approach (± 8 cm) C: standard posterolateral approach (± 15 cm)	Operative time; intraoperative blood loss; length of hospital stay; complications; radiographic evaluation	6 weeks	
Chung et al. ²³	120	CCT	Patients with OA. Exclusion criteria: weight > 100kg, semi-an kylosed joints, severe protrusio or dysplasia. Matched for age, weight, and diagnosis	S: mini-incision posterolateral approach C: standard posterior approach	Operative time; intraoperative blood loss; length of hospital stay; complications; radiographic evaluation	6 weeks	
Ciminiello et al. ²⁴	120	CCT	Patients with OA, assigned by a surgeon to one of the two groups. Matched for age, gender, BMI, ASA-score, diagnosis, prosthesis, type of fixation, anaesthesia, surgical approach, and intraoperative patient positioning	S: small incision (< 5 inches) C: conventional incision (≥ 5 inches)	Operative time; intraoperative blood loss; length of hospital stay; complications; radiographic evaluation; HHS	6 weeks	
De Beer et al. ²⁵	60	CCT	Patients undergoing primary unilateral THA. Matched for gender, age, BMI, and preoperative diagnosis of osteoarthritis	S: minimally invasive direct lateral approach (≤ 10 cm) C: standard direct lateral approach	Operative time; intraoperative blood loss; length of hospital stay; complications; radiographic evaluation; HHS, OHS	6 weeks	
DiGirola et al. ²⁷	70	CCT	Patients with osteoarthritis. Matched for gender, age, and diagnosis	S: minimally invasive posterior approach with computer-assisted navigation (CT-based) C: standard posterior approach with computer-assisted navigation (CT-based)	Length of hospital stay; HHS	3,6, and 12 months	
Dorr et al. ²⁶	60	RCT	Patients undergoing primary unilateral THA between Jan. 2004 and Oct. 2005. Exclusion criteria: previous surgery on the affected hip, a pathological condition of the hip that required an extensive exposure, same-day bilateral THA, and inflammatory polyarthrits	S: mini-incision posterior approach with computer-assisted navigation (imageless) (10 ± 2 cm) C: standard posterior approach with computer-assisted navigation (imageless) (20 ± 2 cm)	Operative time; intraoperative blood loss; length of hospital stay; complications; radiographic evaluation; HHS	6 weeks	
Dutka et al. ²⁷	120	RCT	Patients undergoing THA.	S: minimally invasive direct lateral approach (6-8 cm) C: standard direct lateral approach (20-25 cm)	Operative time; intraoperative blood loss; length of hospital stay; complications; radiographic evaluation; HHS; VAS pain	6 weeks, 3 and 6 months	

Study	n	Method	Participants	Interventions	Outcome measures	Follow-up
Hart et al. ²⁸	120	RCT	Patients undergoing THA between Sept. 2000 and Feb. 2002, with an age >65 years and a BMI <35. Exclusion criteria: patients affected by coagulation disorders, and a Hb < 12 g/dl.	S: minimally invasive posterolateral approach (9-10 cm) C: standard posterolateral approach (20 cm)	Operative time; complications; radiographic evaluation; Merle d'Aubigné-Charrière score	6 weeks, 6 and 12 months
Khan et al. ²⁹	200	CCT	Patients with osteoarthritis or rheumatoid arthritis, undergoing THA. Exclusion criteria: revision arthroplasty, congenital hip anomaly, previous hip surgery or infection, and iatrogenic damage to the piriformis. Matched for age, gender, ASA, BMI, and primary diagnosis. Retrospective control group.	S: less-invasive posterior approach C: standard posterior approach	Operative time; intraoperative blood loss; complications; radiographic evaluation, WOMAC, SF-36	6 weeks, 3 and 12 months
Kim ³⁰	140	RCT	Patients undergoing bilateral THA; 1 minimally invasive and 1 standard THA.	S: minimally invasive modified posterolateral approach (8 cm) C: standard posterolateral approach (15-20 cm)	Operative time; intraoperative blood loss; complications; radiographic evaluation	6 weeks, 3, 6 and 12 months
Lawlor et al. ³¹	210	RCT	Patients undergoing THA. Exclusion criteria: previous surgery to affected hip, and inflammatory polyarthritis if the severity of the disease was likely to compromise postoperative mobility.	S: minimally invasive posterior approach (< 10 cm) C: standard posterior approach (16 cm)	Gait velocity	6 weeks
Levine et al. ³²	201	CCT	Primary THA. Inclusion criteria for MIS: BMI <35, adequate home support and motivation for accelerated rehabilitation, no significant deformity. Standard operation: all other patients. Retrospective control group.	S: minimally invasive two-incision anterior approach (one incision of 5cm and one of 2-3 cm) C: modified Hardinge approach (10-15 cm)	Operative time; intraoperative blood loss; length of hospital stay, complications	6 weeks and 3 months
Mazoochian et al. ³⁷	52	RCT	Patients with the indication for a cementless THA. Exclusion criteria: patients in which an acetabular plastic had to be performed or patients with a malignancy.	S: modified Hardinge approach (8 cm) C: standard lateral approach by Bauer	Operative time; intraoperative blood loss; complications; HHS; WOMAC	6 weeks and 3 months
Nakamura et al. ³³	92	CCT	Patients with osteoarthritis or avascular necrosis. Retrospective control group.	S: mini-incision posterior approach (15-20 cm) C: standard posterior approach (15-20 cm)	Operative time; intraoperative blood loss; radiographic evaluation	6 weeks
Ogonda et al. ³⁴	219	RCT	Patients undergoing THA. Exclusion criteria: history of previous surgery on the affected hip, and inflammatory polyarthritis if the severity of the disease was likely to compromise postoperative mobility.	S: mini-incision posterior approach C: standard posterior approach	Operative time; intraoperative blood loss; length of hospital stay; complications; radiographic evaluation; HHS; OHS; WOMAC; SF-36	6 weeks
Rittmeister & Peters ³⁵	152	CCT	Patients undergoing THA. Retrospective control group.	S: minimally invasive posterior approach C: standard anterolateral approach	Operative time; intraoperative blood loss; complications	6 weeks

Study	n	Method	Participants	Interventions	Outcome measures	Follow-up
Speranza et al. ³⁶	100	RCT	Patients undergoing THA.	S: mini-incision lateral approach C: standard lateral approach	Operative time; intraoperative blood loss; length of hospital stay; complications; radiographic evaluation; HHS; WOMAC	3 and 6 months
CAS						
Kalteis et al. ³⁸	45	RCT	Patients with primary osteoarthritis undergoing THA.	S: standard anterolateral approach with computer-assisted navigation (CT-based) C: standard anterolateral approach	Operative time; complications; radiographic evaluation	
Kalteis et al. ¹⁵	90	RCT	Patients with osteoarthritis undergoing THA. Exclusion criteria: arthritis secondary to hip dysplasia, post-traumatic deformities of the pelvis, or age <50 years.	S1: modified transgluteal approach with computer-assisted navigation (CT-based) S2: modified transgluteal approach with computer-assisted navigation (Imageless) C: modified transgluteal approach	Operative time; radiographic evaluation	
Leenders et al. ¹⁶	100	RCT	Patients with osteoarthritis undergoing THA.	S: anterolateral approach with computer-assisted navigation (CT-based) C: standard anterolateral approach	Radiographic evaluation	
Najarjan et al. ³⁹	100	CCT	Patients undergoing THA.	S: minimally invasive single-incision posterior approach with computer-assisted navigation (Imageless) C: minimally invasive single-incision posterior approach	Operative time; intraoperative blood loss; complications; radiographic evaluation	
Parratte & Argenson ⁴⁰	60	RCT	Patients undergoing THA. Inclusion criteria: age 20-80 years and weight of <100kg. Exclusion criteria: trochanteric osteotomy or revision hip surgery. Matched for gender, age, pathological condition, operatively treated side and BMI.	S: anterolateral approach with computer-assisted navigation (Imageless) C: anterolateral approach	Radiographic evaluation	
Sugano et al. ⁴¹	180	CCT	Patients undergoing THA.	S: posterolateral approach with computer-assisted navigation (CT-based) C: posterolateral approach	Operative time; intraoperative blood loss; radiographic evaluation	
Wixson & MacDonald ¹⁸	132	CCT	Patients undergoing THA. Retrospective control group.	S: limited posterior approach with computer-assisted navigation (Imageless) C: limited posterior approach	Radiographic evaluation	

Chapter 3

Effectiveness of computer-navigated minimally invasive total hip surgery compared to conventional total hip arthroplasty: design of a randomized controlled trial

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Abstract

Background: Moderate to severe osteoarthritis is the most common indication for Total Hip Arthroplasty (THA). Minimally Invasive Total Hip Surgery (MIS) and computer-navigated surgery were introduced several years ago. However, the literature lacks well-designed studies that provide evidence of superiority of computer-navigated MIS over a conventional THA technique. Hence, the purpose of this study is to compare (cost-) effectiveness of computer-navigated MIS with a conventional technique for THA. It is our hypothesis that computer-navigated MIS will lead to a quicker recovery during the early postoperative period (3 months), and to an outcome at least as good 6 months postoperatively. We also hypothesize that computer-navigated MIS leads to fewer perioperative complications and better prosthesis positioning. Furthermore, cost advantages of computer-navigated MIS over conventional THA technique are expected.

Methods/design: A cluster randomized controlled trial will be executed. Patients between the ages of 18 and 75 admitted for primary cementless unilateral THA will be included. Patients will be stratified using the Charnley classification. They will be randomly allocated to have computer-navigated MIS or conventional THA technique. Measurements take place preoperatively, perioperatively, and 6 weeks and 3 and 6 months postoperatively. Degree of limping (gait analysis), self-reported functional status and health-related quality of life (questionnaires) will be assessed preoperatively as well as postoperatively. Perioperative complications will be registered. Radiographic evaluation of prosthesis positioning will take place 6 weeks postoperatively. An evaluation of costs within and outside the healthcare sector will focus on differences in costs between computer-navigated MIS and conventional THA technique.

Discussion: Based on studies performed so far, few objective data quantifying the risks and benefits of computer-navigated MIS are available. Therefore, this study has been designed to compare (cost-) effectiveness of computer-navigated MIS with a conventional technique for THA.

Background

Moderate to severe osteoarthritis is the most common indication for total hip arthroplasty (THA). Incidence of THA in 2005 was 124 per 100,000 inhabitants (20,281 operations) in the Netherlands.¹ Over the past 40 years, THA has proven to be one of the most successful orthopedic interventions. The 15-year prosthesis survival rate exceeds 90%.² Thanks to excellent long-term results and technical improvements, more elderly people who were previously judged to be too old or too sick are considered suitable for THA. Moreover, the number of older adults is increasing.³ Consequently, a boost will be seen in the demand for THA. Together with the shift toward greater cost effectiveness in healthcare, this growing demand triggers the introduction of potentially cost-saving procedures such as Minimally Invasive Total Hip Surgery (MIS).

MIS was introduced in the orthopedic community several years ago. Compared to the conventional incision technique for THA, a shorter incision is made. Proponents of MIS claim that it results perioperatively in less soft-tissue trauma (smaller skin incision and less muscle damage), reduced blood loss and fewer blood transfusion requirements. Postoperative benefits include less pain, quicker recovery (e.g. earlier return to normal gait) and better cosmetic appearance.⁴⁻⁷ Opponents of MIS argue that it leads to more complications, mainly due to poorer operative visualization of landmarks and vital structures.⁸ Among the complications are neurovascular injury, femoral fracture and component malposition, which can result in more wear of the prosthesis. A higher risk for thromboembolism and infection is claimed, due to a longer operation time for MIS.

A solution to the poorer operative visualization is to consider using MIS in combination with computer navigation.⁷ Several studies have shown that inaccuracies in prosthesis placement by means of conventional THA techniques can be significantly reduced by using computer navigation.⁹⁻¹¹ Some even hypothesize that MIS in combination with computer navigation will result in better positioning of the prosthesis, compared to conventional THA techniques.¹²

In terms of cost effectiveness, MIS enthusiasts claim cost reduction due to earlier discharge from the hospital and sooner return to work, as MIS leads to a quicker recovery.^{13,14} Opponents argue a cost increase as specialized equipment (e.g. computer navigation) is needed and operation time is longer.¹⁵

Due to pressure from the industry as well as patients, the orthopedic community has widely embraced MIS. MIS and computer navigation are considered to be potential steps forward in the treatment of THA patients. The orthopedic literature however lacks well-designed studies that provide objective evidence on the effectiveness of computer-navigated MIS, especially in the early postoperative period (first 3 months), when its potential benefits are claimed to be substantial.

Hence, the purpose of this study is to conduct a randomized controlled trial to compare (cost) effectiveness of two THA techniques: computer-navigated MIS and a conventional technique. It is our hypothesis that computer-navigated MIS will lead to a quicker recovery during the early postoperative period (3 months), and to an outcome at least as good at 6 months postoperatively. We also hypothesize that computer-navigated MIS leads to fewer perioperative complications and better

prosthesis positioning. From an economic perspective, cost benefits of computer-navigated MIS over conventional THA technique are expected. The present paper reports on the methodological design of the study.

Methods/Design

Study design

A cluster randomized controlled trial will be conducted. Patients will be stratified into 3 groups based on the Charnley classification, by means of which total hip arthroplasty patients can be subdivided by degree of comorbidity affecting the function of walking. The Charnley classification recognizes three categories. Category A denotes patients with only one hip involved, in whom no other condition interferes with walking. Category B denotes patients with both hips involved but the rest of the body normal and therefore not responsible for any defect in walking. Category C denotes patients with some factors contributing to failure to achieve normal locomotion, such as polyarthritis or rheumatoid arthritis, or cardiovascular or respiratory disability.¹⁶ By using this stratification, the influence of factors other than the THA affecting normal walking will be accounted for.

Within the strata, patients will be randomly allocated to have computer-navigated MIS or the conventional THA procedure by means of cluster randomization to avoid interaction between both patient groups. The random allocation sequence will be computer-generated by an independent planner of the Medical Assessment Office of University Medical Center Groningen (UMCG). The study design, procedures and informed consent are approved by the Medical Ethics Committee of UMCG.

Study population

The study will be conducted at the Orthopedic Department of the UMCG. Patients between the ages of 18 and 75 who are admitted for primary cementless unilateral THA due to primary or secondary osteoarthritis will be included. Patients with inflammatory polyarthritis or with a history of previous surgery on the affected hip will be excluded. Participation in the study is voluntary and patients have to provide informed consent before participation. The inclusion period is planned from March 2007 to May 2008.

Intervention

Computer-navigated MIS

Patients in the MIS group will have surgery using the minimally invasive single-incision anterior approach.¹⁷ The anterior approach is one of several possible approaches to the hip joint. Using special retractors, reamers and insertion handles it is possible to perform this procedure in a minimally invasive way, limiting the skin incision from about 15 cm. to about 8 cm. Advantage of the anterior approach is the possibility of using intermuscular spaces, avoiding muscle damage by cutting or detaching muscles and adding to the minimally invasive character of the approach.

An anterior incision centered over the hip joint is made in a supine patient. After division of skin and subcutis, the intermuscular space between the m. tensor

fascia latae and the m. sartorius is identified and the overlying fascia is opened. The intermuscular plane between the m. tensor fascia latae and the m. sartorius is developed further down to the hip capsule. Subsequently the hip capsule is opened, allowing access to the hip joint. Preparation of the hip for implantation of a hip prosthesis can take place now, by in situ performance of osteotomy of the femoral neck, removal of the femoral head and reaming of the acetabulum, followed by insertion of an uncemented acetabular cup. After reaming of the femur an uncemented femoral component can be placed, followed by placement of a head on the femoral component, repositioning of the joint and closure in layers.

To optimize placement of the acetabular and femoral components of the total hip prosthesis, a computer navigation system (Stryker® Navigation System iNStride Hip, Stryker Corporation, Kalamazoo, MI, U.S.A.) will be used. In order to use computer navigation it is necessary to place two trackers on the patient, which are used by the computer for referencing. These trackers are temporarily fixed on the patient by a small anchoring pin in the iliac crest and on the lateral side of the distal femur. These pins will cause no additional morbidity.

Conventional technique

Patients in the conventional technique group will have surgery using a standard posterolateral approach, in which the patient is placed in a lateral position. After transection of the subcutis, the fascia latae and gluteae are split. Next, the short external rotators are cut at the level of their insertion at the greater trochanter, so this approach is not muscle-sparing. After retraction of the short external rotators backwards, the hip capsule becomes visible and can be incised, allowing access to the hip joint. The rest of the operation will essentially take place in the same manner as the minimally invasive surgical technique.

In the computer-navigated MIS group as well as in the conventional technique group, the same femoral component (ABG II, Stryker Corporation) and acetabular cup (Trident® Cup with X3 or Ceramic inlay, Stryker Corporation) will be used. The anesthetic, analgesic and postoperative physical therapy protocols will be standardized in both groups.

Measurements

In this study, recovery is operationalized as the proportion of subjects with normal gait (no limping during walking) and as the self-reported functional status and health-related quality of life. Measurements will take place preoperatively (day of admission) and perioperatively, and 6 weeks and 3 and 6 months postoperatively. The amount of limping and self-reported functional status and health-related quality of life will be assessed preoperatively as well as postoperatively. Perioperative complications will be registered. Evaluation of prosthesis positioning will take place 6 weeks and 6 months postoperatively. The economic evaluation will focus on differences in costs between computer-navigated MIS and conventional THA technique. The evaluation will be performed from a societal perspective; costs within and outside the healthcare sector will be registered over a period of 6 months. Demographic data, diagnosis, height, weight and BMI, and ASA and

Charnley classifications will also be recorded preoperatively.

Gait analysis

Functional status will be recorded objectively by means of gait analysis using body-fixed sensors. A major advantage of the body-fixed sensor-based approach is that these methods can be applied under real-life conditions; no expert laboratory is needed, and measurements can be made over longer periods of time and gait distances.¹⁸

As walking is by far the most important aspect of functional status, the focus will lie on it - especially the extent of limping during walking (Duchenne limp), given that this is an evident indication of return to a normal gait. Gait parameters, such as accelerations and angular velocities of the upper trunk and pelvis, walking speed and step length, will be assessed while walking at slow, preferred and fast speeds, and while performing an additional attention-demanding task.

Limping can be measured by new methods and new hardware, both of which have been used in ongoing UMCG projects where gait function together with other measures are studied in patients after a hip or knee arthroplasty. Recent pilot work¹⁹ has resulted in a new approach to assess compensatory movements of the trunk during walking. After the accuracy of this new method was confirmed by laboratory experiments, a field experiment showed that measures of pelvic and thoracic movements were related to (mean) walking speed, step length and step duration. The mean peak amplitudes in patients with and without Duchenne limp showed small but systematic differences.¹⁹ It can be concluded that the new method is valuable for the assessment of compensatory trunk movements during gait. The approach allows for the simultaneous assessment of gait parameters and movements of the upper and lower trunk based on a combination of movement sensors.

Self-reported functional status and health-related quality of life

Self-reported functional status and health-related quality of life will be measured with questionnaires. The WOMAC will be used as a disease-specific outcome instrument to measure functional status. The SF-36 and EuroQol 5D are generic questionnaires and will be used to measure health-related quality of life. Patients' satisfaction with the results of the surgical procedure will be measured with the Patient Satisfaction Scale.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) consists of three subscales measuring pain, stiffness and physical functioning. Patients have to score on a five-point Likert scale. The WOMAC has shown high validity and reliability.²⁰ The Dutch version of the WOMAC has also been considered valid and reliable.²¹ The MOS 36-item Short Form Health Survey (SF-36) gives an indication of health-related quality of life, and is considered to be valid, reliable and reproducible.²² The SF-36 is composed of 36 questions, organized into 8 multi-items scales: physical functioning, role limitations due to physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems and general mental

health.²² The WOMAC and SF-36 are the most widely used questionnaires in THA research.^{23,24} The EuroQol 5D is a widely used and validated generic instrument that consists of 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.²⁵ The EuroQol 5D has to be seen as additional to the SF-36 and is embedded in this study protocol, as it is especially useful in combination with the economic evaluation that will be performed. The Patient Satisfaction Scale comprises 4 questions about satisfaction with pain relief, with improvement in function for home/yard work and with improvement in function for recreational activity, as well as overall satisfaction with surgery.²⁶

Perioperative measurements

Perioperatively, average surgical time, intraoperative blood loss, in-hospital transfusion rate and length of skin incision will be recorded.

Radiographic evaluation

At the Orthopedic Department of the UMCG a new digital measurement method has been developed with which postoperative measurements can be executed to objectify and quantify parameters of the quality of positioning of a total hip prosthesis.²⁷ The new procedure employs digital measurement techniques, which are far more reliable than conventional analogue techniques.²⁸⁻³⁰ A radiographic evaluation of several parameters will take place by means of this new digital measurement method. Leg length differences, varus and valgus positioning of the stem, and inclination and anteversion of the acetabular component will be determined.

Economic evaluation

Outcomes of the above-mentioned measurements will be related to costs in additional economic analyses. These analyses will provide information on the probable cost effectiveness of computer-navigated MIS compared to conventional THA technique in the Dutch healthcare system.

Direct medical costs to be assessed include costs of computer-navigated MIS and conventional THA technique, blood transfusions, hospital admissions and costs related to length of hospital stay. In order to facilitate comparisons with other economic evaluations, unit prices (the price of one unit of each cost type included) will be based mainly on Dutch standard prices.³¹ A questionnaire on medical costs outside the hospital (including physiotherapy, visits to general practitioners, nursing care and medication) and other (nonmedical) costs (e.g. absence of work) will be administered to the patients.

Sample size

It is our hypothesis that computer-navigated MIS will lead to better recovery during the early postoperative period (3 months), and at least as good at 6 months postoperatively. In order to detect a difference of 0.254 in the proportion of subjects with normal gait after 3 months of follow-up with 80% power at a significance level of 0.05 in a one-sided test of a difference between two proportions, two groups

of 50 subjects are required. With an expected dropout rate of 10%, a total of 110 patients is needed. At 6 months, the effect of MIS and conventional THA technique on gait (limping) will be compared in a non-inferiority setting. To establish non-inferiority, the lower bound of the 95% confidence interval of the difference between the two treatment groups will be compared with a non-inferiority margin delta. If the whole confidence interval of the difference between the two treatments is smaller than the non-inferiority margin delta, non-inferiority is established. The non-inferiority margin delta is chosen in this study at a value of 0.10, indicating that a difference in proportion of subjects with a normal gait of 0.10 is considered clinically equivalent. To deduce non-inferiority with 80% power at a significance level of 0.05 with expected proportions of subjects with normal gait of 0.95, using a non-inferiority margin delta of 0.10, two groups of 60 subjects are required. With an expected dropout rate of 10%, a total of 132 patients is needed.

Statistical analysis

All statistical analyses will be computed using the Statistical Package for the Social Sciences (SPSS, Inc., Version 12.0, 2003, Chicago). Descriptive statistics will be used to describe both research groups. Analysis of variance (ANOVA) and chi-square procedures will be used to evaluate between-group differences at baseline. Random effect models will be applied for longitudinal analyses. In order to enable statistical conclusions on differences in (skewed distribution of) costs between groups during the study, nonparametric confidence intervals will be constructed based on results of bootstrap analyses. For all test procedures, a probability value of less than 0.05 will be considered as statistically significant.

Discussion

Over the last few years, MIS has become a widely used technique for THA. Several authors^{5,6,32} have concluded that MIS is a safe and reproducible procedure. Chimento et al.⁶ executed a randomized prospective study comparing MIS to a standard approach. There was no difference between the groups in number of patients being able to achieve rehabilitation milestones. However, patients who underwent MIS demonstrated decreased blood loss and limped less 6 weeks postoperatively, indicating a quicker return to a more normal gait. An objective gait analysis was not performed though. In a retrospective cohort study, Woolson et al.³³ attempted to determine whether there was a difference in surgical parameters and component positioning of MIS compared to a standard THA technique. The results showed no differences with respect to surgical parameters. It was concluded that there were no benefits associated with MIS except for a smaller scar. However, more malpositions of the acetabular and femoral components were seen in the MIS group. Malpositioning is a potential complication of MIS due to poorer operative visualization. Computer navigation can be a preventive tool as it permits accurate orientation and fixation of the prosthesis without the need for visualization of bony landmarks. Computer navigation has proved to decrease inaccuracies in prosthesis placement by means of conventional THA technique.⁹⁻¹¹

Wixson and MacDonald¹² found more reproducible acetabular component

placement in a series of computer-navigated MIS as compared to a cohort of a conventional THA technique. They concluded that using MIS in combination with computer navigation can improve the accuracy of component placement. DiGioia and colleagues⁷ compared MIS and conventional surgery, both with the help of computer navigation. At 3 months, MIS patients had significantly better results in limping and stair-climbing, and at 6 months in limping, walking and stair-climbing as determined with the Harris hip score. They used a matched control group and patients were not randomized.

The literature lacks well-designed studies that provide objective evidence to conclude that computer-navigated MIS is superior to a conventional procedure for THA. Additionally, there are conflicting reports on the cost advantages of (computer-navigated) MIS over conventional THA techniques.¹³⁻¹⁵

Purpose of the study presented in this article is to compare (cost) effectiveness of two THA techniques: computer-navigated MIS and a conventional technique. Since computer-navigated MIS is less invasive to muscles and skin, advantages are expected in the early postoperative phase in terms of a quicker recovery. We also hypothesize that it leads to fewer perioperative complications, better prosthesis positioning and cost savings.

Competing interest

The author(s) declare that they have no competing interests.

Authors' contributions

MS and RW originated the idea for the study, led on its design, and will supervise the project. JWG and SKB were co-applicants on the successful funding proposal. MS, RW, WZ, JWG, SKB, ADS and IAS participated in the design of the study and in developing the research protocols. ADS provided statistical consultation. IHFR will coordinate the trial and is responsible for data acquisition. All authors read and corrected draft versions of the manuscript and approved the final manuscript.

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Chapter 4

Compensatory trunk movements in patients with hip osteoarthritis. Accuracy and reproducibility of a body-fixed-sensor based assessment

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Abstract

This study examined the accuracy and reproducibility of a body-fixed-sensor (BFS) based assessment for quantifying frontal plane angular movements of the (upper) thorax and pelvis at different walking speeds of patients with hip osteoarthritis. To evaluate accuracy, angular movements of sensors attached to thorax and pelvis of 3 patients were compared with results based on an optical motion analysis system (OMAS). Accuracy was high, with small and consistent mean differences ($< 1.0^\circ$) and corresponding standard deviations ($< 1.3^\circ$) between OMAS and BFS data. To evaluate reproducibility, angular trunk movements were assessed twice in 15 patients. Reproducibility was high (ICCs ranged from 0.86 to 0.97) and the values of the mean differences between test and retest were small with the 95% CI containing zero. This BFS-based assessment is an accurate and reproducible method for quantifying frontal plane compensatory trunk movements during gait at different walking speeds of patients with hip osteoarthritis.

Introduction

Compensatory movements of the trunk are often seen in patients with end-stage osteoarthritis of the hip. These patients suffer from pain and decreased hip abductor function. Loading of the hip joint can be altered and deficits in muscle strength can be compensated for by means of adaptations in lateral bending of the trunk such as observed during gait with a Duchenne limp.^{1,2} By bending the trunk laterally towards the affected limb during the stance phase, the line of gravity of the body shifts closer to the hip joint of the affected limb. This decreases the mechanical demand for the hip abductor muscles by shortening the moment arm between hip and centre of mass of the upper body, thus reducing the internal joint reaction force at the hip joint, resulting in pain relief of the osteoarthritic hip joint.^{3,4}

Gait analysis can be used to discriminate between normal and abnormal gait, and to evaluate improvements after (surgical) interventions to improve gait performance.^{5,6} Laboratory-based gait analysis techniques are often taken as the gold standard, despite some serious limitations.^{7,8} Gait assessments with these techniques are restricted to a laboratory setting and are labour-intensive, since a specialised and technically educated staff is required. Because of time expenditure and financial constraints their use in clinical practice is limited.⁹ An alternative approach involves the use of body-fixed-sensors (BFS), which are based on the use of miniaturised and integrated sensors such as accelerometers and gyroscopes.⁸ These BFS are practical in use and lightweight, and can be carried on the body, which facilitates unconstrained walking outside a laboratory setting.¹⁰ Previous research has shown that spatiotemporal gait parameters can be accurately measured by means of BFS, mounted to the lower trunk.^{11,12}

There is a lack of information about compensatory movements of the trunk during gait of patients with end-stage hip osteoarthritis or after total hip arthroplasty. We therefore developed a BFS-based gait assessment protocol with which frontal plane angular movements of the thorax and pelvis during gait as well as spatiotemporal gait parameters can be measured simultaneously. However, before this assessment can be used as part of the clinical assessment of patients with end-stage hip osteoarthritis, its accuracy and reproducibility for the population in question should be established. Hence the objective of this study was to determine the accuracy and reproducibility of this BFS-based assessment to measure frontal plane angular movements of sensors attached to thorax and pelvis of patients suffering from end-stage osteoarthritis of the hip while walking. Additionally, the reproducibility of spatiotemporal gait parameters measured with this BFS-based assessment was investigated.

Materials and Methods

The local Medical Ethics Committee approved the procedures employed in this study. All subjects gave written informed consent prior to testing.

Accuracy of BFS-based assessment of trunk movements

Participants

Three patients with end-stage osteoarthritis participated in this part of the study. These patients were on the waiting list for a primary cementless total hip arthroplasty. Two of these patients showed a clearly visible Duchenne limp and one patient showed no distinct Duchenne limp.

Apparatus

The angular movements of the pelvis and the trunk as measured with BFS were validated against the angular changes of the BFS-units as determined by a highly accurate optical motion analysis system (OMAS). As BFS two hybrid triaxial sensor units were used that contained gyroscopes, accelerometers and magnetometers (MTx Motion Tracker, Xsens Technologies B.V., Enschede, The Netherlands). Hence, changes in orientation were measured in 3D. Size of these units was 3.8 x 5.3 x 2.1 cm, weight 30 g. One of the sensor units was positioned at the dorsal side of the pelvis between the posterior superior iliac spines (PSIS). The other sensor unit was positioned on the midline of the upper thorax, just below the seventh cervical vertebra (C7). The BFS were connected with a portable device that sampled digital data from and supplied power to the BFS (Xbus, Xsens Technologies B.V., Enschede, The Netherlands). The Xbus was fastened around the waist with a belt. A rigid triangle (16 x 16 x 11.2 cm) was attached to the BFS with double-sided adhesive tape. Three markers of the OMAS (Optotrak, Northern Digital Inc., Waterloo, Canada) were placed at the corners of the triangle. The Optotrak system has an RMS positional accuracy of 0.1 mm and a resolution of 0.01 mm. With the subject standing in anatomical position, the orientation of the local reference frame of the sensor units on the pelvis matched the global reference frame of the OMAS; the *x*-axis pointing in forward (anterior) direction, the *y*-axis pointing upward along the vertical, and the medio-lateral *z*-axis pointing to the right. Both BFS and OMAS were connected to a PC via a serial cable. Data from the BFS and OMAS were synchronised by using a control switch that generated a voltage switch in the OMAS data stream and gave a signal to the BFS, starting data recording. Data of BFS and OMAS were simultaneously collected with a sample rate of 100 Hz.

Procedure

Measurements took place in a Human Movement Laboratory. Subjects were instructed to walk a distance of 8 m at a self-selected low, preferred and high speed, three times per walking speed. Before data collection, the subjects performed one walking trial at a self-selected pace to familiarise themselves with the measurement procedure.

Data analysis

Data analysis focussed on a comparison of frontal plane angles of the sensors on the thorax and pelvis as calculated based on BFS and OMAS data. All data-samples obtained during the middle 3 m of the 8-m track were used for further analysis. Thus excluding irregular stride cycles due to gaining speed at the start of a walking

trial and slowing down at the end, and excluding inaccurate position data which were obtained outside of the workspace of the OMAS.

Position data of the OMAS were used to calculate the orientation of the local reference frame of the sensor units against the vertical. BFS based angles were calculated by fusing accelerometer and gyroscope data by means of a Kalman filter.¹³ BFS data fusing was performed by means of Xsens software (MT software version 2.8.5, Xsens Technologies B.V., Enschede, The Netherlands). BFS angles were calculated with Xsens software. All data of BFS and OMAS were processed with Matlab (Version 7.0, The Mathworks Inc., Natick, MA, USA). The range of motion (RoM) of the segments was determined by subtracting the maximum and minimum angle of the segments.

Per subject, all data-samples obtained during the three walking trials per walking speed were used together to calculate the differences between the angular movements of the pelvis and thorax as determined from the BFS system and the OMAS. Mean difference and standard deviation of differences were calculated after subtracting the BFS data from the OMAS data.

Reproducibility of BFS-based assessment of trunk movements

Participants

Fifteen patients with end-stage osteoarthritis participated in this part of the study. All patients were on the waiting list for a primary cementless total hip arthroplasty. The subjects had a mean age of 61 ± 9 years, with a mean weight of 74 ± 11 kg and a mean height of 170 ± 8 cm. Their mean score on the Harris Hip Score¹⁴ was 56.5 (range 24-75). To establish test-retest reliability, subjects performed the gait analysis twice: once in the week prior to admission to the hospital for a total hip arthroplasty, and once on their day of admission.

Apparatus

For gait analysis the same BFS system was used as in the first part of this study. One of the sensor units was positioned on the dorsal side of the pelvis between the PSIS. The other sensor unit was positioned on the midline of the upper thorax, just below C7. The portable device (Xbus) supplied power to the BFS, sampled the BFS data, and transmitted these data in real-time to a PDA by means of a wireless connection (Bluetooth). With this PDA, the researcher could start and stop a measurement, and also manually place markers during data collection. All data were collected with a sample rate of 100 Hz.

Procedure

All measurements took place in a hospital corridor. Subjects were instructed to walk a distance of 25 m back and forth on a self-selected low, preferred and high walking speed. During these measurements, markers were recorded in an additional measurement channel every time the subject passed the 2.5-m and 22.5-m point of the 25 m. Before data collection, all subjects walked the corridor on a self-selected pace to familiarise themselves with the measurement procedure.

Data analysis

After the measurements, data were transmitted from the PDA to a PC, where the data were processed further with MT software. Next, all data were transferred and processed with Matlab. Data recording of the middle 20m were used for further analysis. By discarding the data of the first and last 2.5m of the trajectory, fluctuations in speed due to gaining speed at the start of a walking trial and slowing down at the end were therefore excluded.¹⁵ The mean of the back-and-forth walks per walking speed were used for further analysis.

For each walking trial, mean peak-to-peak amplitude of the trunk was determined based on 10 subsequent stride cycles. Stride cycles were selected based on initial foot contact as determined from forward pelvic accelerations.^{12,16} The RoM of the thorax and pelvis was determined by subtracting the maximum and minimum angle of the segments.

Additionally, reproducibility of several spatiotemporal variables was assessed. The spatiotemporal variables analysed included walking speed, step length and step duration. For each subject, mean walking speeds were determined for each walking trial. A trajectory of 20m was identified by means of data placed on the electronic data. Mean walking speed was determined based on intermarker distance (20m) and intermarker duration.

Statistical analysis

Relative reliability was determined with Intraclass Correlation Coefficients (ICCs) of the type 3,1 (absolute agreement) and the 95% confidence intervals (CIs)¹⁷ The benchmarks suggested by Fleiss were used to interpret the ICC values: >0.75 represents an excellent correlation, 0.40–0.75 a fair-to-good correlation and <0.40 a poor correlation.¹⁸ Absolute reliability was assessed using the Bland & Altman method. With this method the agreement between the two test sessions is assessed, which includes calculation of the mean difference between test sessions 1 and 2 with a 95% CI. Mean differences within 5% were considered to be small differences. Zero lying within the CI of the mean difference can be seen as a criterion for absolute reliability. Consequently, when zero lies outside the CI a bias in the measurements is indicated.^{19,20} To test whether there was a statistically significant difference between the first and second test session, a Wilcoxon Signed Rank test was performed. A level of $p < 0.05$ was chosen to indicate statistical significance.

Results

Accuracy of BFS-based assessment of trunk movements

Table 1 presents the mean difference in angular movements of the thorax and the pelvis measured by OMAS and BFS, and RoM of the thorax and pelvis measured by BFS. The mean differences between OMAS and BFS data were small and consistent over the different walking speeds and subjects. Generally, SD of differences were somewhat higher for the pelvis as well as for the thorax, when subjects were instructed to walk at high speed. Subjects with a visible Duchenne limp showed a larger RoM of the thorax at all walking speeds.

Table 1. Mean difference between OMAS and BFS-based measurements of angular movements of thorax and pelvis during gait at different speeds

Walking condition		e_{mean} (°)	SD (°)	RoM (°)
Subject 1 (58 yrs, 171 cm, 88 kg)				
Thorax	Low speed	0.17	0.75	13.50
	Preferred speed	-0.15	0.80	11.00
	High speed	-0.79	1.29	11.70
Pelvis	Low speed	-0.38	0.49	7.93
	Preferred speed	-0.42	0.51	6.25
	High speed	-0.06	0.59	7.45
Subject 2 (68 yrs, 169 cm, 70 kg)				
Thorax	Low speed	0.31	0.83	10.50
	Preferred speed	0.27	0.73	9.68
	High speed	0.72	0.69	11.10
Pelvis	Low speed	-0.29	0.58	6.25
	Preferred speed	-0.33	0.51	5.21
	High speed	-0.47	0.84	5.97
Subject 3 (57 yrs, 178 cm, 79 kg)				
Thorax	Low speed	-0.28	0.82	8.23
	Preferred speed	-0.44	0.73	8.32
	High speed	-0.36	0.93	8.87
Pelvis	Low speed	-0.03	0.78	4.04
	Preferred speed	-0.13	0.80	4.96
	High speed	-0.48	0.88	5.18

Subject 1 and 2 showed a clearly visible Duchenne limp, subject 3 showed no distinct Duchenne limp.
 e_{mean} : mean difference; SD: standard deviation of differences; RoM: range of motion, measured by BFS.

Reproducibility of BFS-based assessment of trunk movements

Measures of absolute and relative reliability of BFS-based gait assessment are given in Table 2. Relative reliability of the frontal plane angular movements of thorax and pelvis was excellent, with ICCs ranging from 0.86 to 0.97 and no significant differences between test and retest ($p > 0.05$). In general, the mean differences between test and retest were small when compared with the means of test and retest, and zero lay within the 95% CI of all test parts, which indicates good absolute agreement between the two test sessions.

Reproducibility of the spatiotemporal parameters was also excellent (ICCs ranging from 0.77-0.97) and no significant differences between test and retest ($p > 0.05$). Zero lay within the 95% CI of the mean difference between test and retest, indicating good absolute agreement.

Discussion

Patients with end-stage osteoarthritis of the hip joint often show compensatory movements of the trunk during gait. Increased frontal plane angular movements during gait are used to unload the hip joint¹ and to compensate for weakened hip abductor muscles.²¹ Frontal plane angular movements of the trunk are not a direct measure of hip (un)loading during gait. However, an earlier study estimated hip abduction moments during gait based on a similar sensor configuration as in our study, and demonstrated that compensatory movements in the frontal plane were associated with unloading of the hip.²² The latter finding underlines the relevance of measuring compensatory movements during gait.

This study demonstrates good accuracy of the BFS-based assessments of angular movements of sensors on the thorax and pelvis, with small mean

Table 2. Measures of absolute and relative reliability of BFS-based gait assessment

	Test Mean (Range)	Retest Mean (Range)	Test-retest difference Mean (95% CI)	t-Test statistics for test- retest differences	ICC (95% CI)
Walking speed					
Low speed	0.93 (0.78 – 1.08)	0.94 (0.73 – 1.20)	-0.01 (-0.05 – 0.03)	-0.50 ($p = 0.62$)	0.88 (0.63 – 0.96)
Preferred speed	1.23 (0.96 – 1.54)	1.19 (0.96 – 1.48)	0.04 (-0.01 – 0.09)	2.01 ($p = 0.06$)	0.92 (0.73 – 0.97)
High speed	1.41 (1.10 – 1.76)	1.35 (1.06 – 1.69)	0.05 (-0.03 – 0.14)	2.05 ($p = 0.06$)	0.97 (0.68 – 0.97)
Step length					
Low speed	0.71 (0.58 – 0.88)	0.71 (0.60 – 0.85)	0.00 (-0.04 – 0.04)	0.08 ($p = 0.94$)	0.79 (0.35 – 0.93)
Preferred speed	0.79 (0.62 – 0.98)	0.77 (0.64 – 0.91)	-0.02 (-0.07 – 0.04)	0.86 ($p = 0.40$)	0.77 (0.32 – 0.92)
High speed	0.84 (0.74 – 0.97)	0.82 (0.66 – 0.98)	-0.02 (-0.06 – 0.02)	1.08 ($p = 0.30$)	0.82 (0.45 – 0.94)
Step duration					
Low speed	0.63 (0.51 – 0.75)	0.62 (0.50 – 0.78)	0.01 (-0.02 – 0.03)	0.49 ($p = 0.63$)	0.86 (0.64 – 0.95)
Preferred speed	0.53 (0.47 – 0.58)	0.54 (0.46 – 0.61)	-0.01 (-0.02 – 0.01)	-2.09 ($p = 0.06$)	0.90 (0.70 – 0.97)
High speed	0.49 (0.44 – 0.57)	0.51 (0.43 – 0.61)	-0.02 (-0.04 – 0.01)	-2.07 ($p = 0.06$)	0.81 (0.42 – 0.94)
RoM Pelvis					
Low speed	5.45 (2.89 – 11.34)	5.71 (3.22 – 9.24)	-0.26 (-1.15 – 0.63)	-0.62 ($p = 0.54$)	0.86 (0.58 – 0.95)
Preferred speed	6.01 (3.32 – 9.13)	6.09 (2.99 – 10.07)	-0.08 (-0.64 – 0.77)	-0.30 ($p = 0.77$)	0.90 (0.73 – 0.97)
High speed	6.26 (3.05 – 10.00)	5.99 (2.95 – 10.00)	0.20 (-0.22 – 0.62)	1.02 ($p = 0.33$)	0.95 (0.86 – 0.98)
RoM Thorax					
Low speed	6.81 (3.05 – 13.59)	6.78 (2.90 – 16.91)	0.03 (-0.76 – 0.82)	0.08 ($p = 0.94$)	0.91 (0.75 – 0.97)
Preferred speed	6.00 (2.74 – 14.83)	6.25 (2.96 – 15.39)	-0.26 (-0.68 – 0.16)	-1.32 ($p = 0.21$)	0.97 (0.91 – 0.99)
High speed	6.41 (3.01 – 14.93)	6.10 (3.19 – 13.76)	0.31 (-0.24 – 0.85)	1.21 ($p = 0.25$)	0.94 (0.83 – 0.98)

Walking speed is expressed in $m \cdot s^{-1}$, step length is expressed in m, step duration is expressed in s, and RoM of the pelvis and thorax are expressed in degrees. Abbreviations: CI, confidence interval; ICC, Intraclass Correlation Coefficient; RoM, range of motion.

differences ($< 1.0^\circ$) and standard deviations of differences ($< 1.3^\circ$) from the angular movements assessed with OMAS. In order to obtain patterns of angular changes which are realistic for the intended application of the BFS-based assessment (i.e. to quantify trunk movements in relation to spatiotemporal gait parameters in patients with hip OA), patients with observable differences in angular trunk movements are measured. The results demonstrate that patients with a Duchenne limp showed a clearly larger RoM of the thorax than the patient without a Duchenne limp. These results are in line with the results of an earlier study.²³ This indicates that compensatory movements of the trunk (e.g. a Duchenne limp) during gait can be quantified with this BFS-based assessment.

Despite the different measurement approach, the results of the BFS-based assessment seem to correspond well to results of a camera-based gait analysis system to capture frontal plane angular movements of the pelvis in patients with early-stage hip osteoarthritis.⁴ Compared to healthy subjects²⁴⁻²⁶, the RoM of the pelvis in our patients was somewhat smaller, but the RoM of the thorax was larger.

Previous research has demonstrated that analysis of gait at different walking speeds provides valuable information on (abnormalities in) gait function, which would remain undiscovered if only walking at preferred speed was analysed.²⁷ The results of this study underline this statement. The RoM of the thorax and pelvis of the patient without a distinct Duchenne limp increased slightly with increasing speed. In contrast, in patients with a Duchenne limp the RoM of the thorax and pelvis was the smallest at walking at preferred speed. The RoM of the thorax and pelvis of these patients became larger when they walked at a speed other than their preferred speed. Apparently, less compensatory movements were needed at walking at preferred speed. A possible explanation for this phenomenon may be that, when walking at low speed, the duration of involvement of the hip abductor muscles and weight bearing on the hip joint is longer due to a longer stance phase, resulting in an increased lateral trunk bending to reduce the pain in the hip joint.

This study shows good reproducibility of the BFS-based assessment to measure frontal plane angular movements of the thorax and pelvis in patients with end-stage hip osteoarthritis, with high ICCs (0.86–0.97) that were excellent according to the benchmarks of Fleiss.¹⁸ Furthermore, no statistically significant differences were found between test and retest. The reproducibility of the BFS-based gait assessment to determine spatiotemporal parameters was also excellent, with high ICCs (0.77–0.97) and no statistically significant differences between the two test sessions.

There are two components of variability associated with each assessment of measurement error: systematic bias (i.e. changes in a measure over time such as learning effects) and random errors.²⁸ Learning effects may occur when subjects have not had experience or practice with the test before being measured. The measurement protocol used in this study comprised familiarisation trials to control for these learning effects. A change in the patients' gait performance in a period of 1 week between the test and retest sessions was not expected, since hip osteoarthritis is a chronic disease and concomitant symptoms increase only

gradually over time. Random errors are often due to changes in measurement equipment and location of the measurements. All tests were conducted in the same corridor, and the same test leader instructed the patients and mounted the BFS units. These aspects of absolute reliability were also proven to be good. The results of the Bland & Altman method indicate that there was no significant bias, since the 95% CI of the mean difference of all parameters contained zero. These findings are also supported by the small (non-significant) mean difference between test and retest.

Speed is often determined by means of optoelectronic photocells that measure the time needed to walk a certain distance.^{29,30} In this study, no additional timing equipment was needed, since markers were placed manually in the data. The results show that this is a reproducible method for determining walking speed.

Overall, this study shows that this BFS-based gait assessment is an easy-to-use and reproducible method to determine compensatory movements of the trunk, without requiring additional timing equipment. As far as we know, this is the first article to evaluate the accuracy and reproducibility of a BFS-based assessment of compensatory angular movements of the trunk, especially of the upper thorax as observed during gait with a Duchenne limp, of patients suffering from end-stage hip osteoarthritis. It is therefore not possible to compare the results of this study with other literature about this subject and about the same population. The reproducibility of gait parameters assessed with BFS in the present study was comparable to that reported previously in healthy subjects.^{10,29-32} This is an important finding, as our (clinical) study population is likely to be less homogeneous than a healthy study population. The high ranges, especially in RoM of the thorax and the pelvis, confirm that our study population is heterogeneous in terms of their gait behaviour.

Conclusion

The results of this study demonstrate that this BFS-based gait analysis system is an accurate and reproducible method for quantifying frontal plane compensatory movements of the trunk during gait over a range of walking speeds in patients suffering from end-stage hip osteoarthritis. The assessment of spatiotemporal gait parameters with this method is also proven to be reliable. This BFS-based gait analysis system aids the clinician by means of its user-friendliness, and the fact that compensatory frontal plane angular movements of the trunk during gait as well as spatiotemporal gait parameters can be measured simultaneously. Since the BFS units are placed on the trunk, there is little to no interference with gait which facilitates unconstrained walking outside a laboratory setting. This, together with the promising results, makes the gait analysis protocol highly applicable in real-life (non-laboratory) settings such as hospitals for monitoring changes in gait performance due to (surgical) interventions in patients with hip osteoarthritis.

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Chapter 5

Patients with end-stage hip osteoarthritis show distinctive patterns of trunk movements during gait: a body-fixed-sensor based analysis

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Abstract

Background. Compensatory trunk movements such as a Duchenne limp are observed frequently in patients with osteoarthritis of the hip, yet angular trunk movements are seldom included in clinical gait assessments.

Objective. To quantify compensatory trunk movements during gait in patients with hip osteoarthritis, outside a gait laboratory, using a body-fixed-sensor based gait analysis. Frontal plane angular movements of the pelvis and thorax and spatiotemporal parameters of patients who showed a Duchenne limp during gait were compared to healthy subjects and patients without a Duchenne limp.

Design. A case-control design.

Methods. Two body-fixed sensors were positioned at the dorsal side of the pelvis and on the upper thorax. Peak-to-peak frontal plane range of motion (ROM) and spatiotemporal parameters of patients with a Duchenne limp during gait were compared to healthy subjects and patients without a Duchenne limp.

Results. No differences in spatiotemporal parameters were found between patients and healthy subjects, after correction for differences in walking speed. Patients with a Duchenne limp showed a significantly larger thoracic ROM during walking compared to healthy subjects and to patients without a Duchenne limp. In both groups of patients, pelvic ROM was lower than in healthy subjects. This difference however only reached significance in patients without a Duchenne limp. The ratio of thoracic ROM relative to pelvic ROM revealed distinct differences in trunk movement patterns.

Conclusions. Distinctive patterns of frontal plane angular trunk movements during gait could be objectively quantified in healthy subjects and in patients with hip osteoarthritis using a body-fixed-sensor based gait analysis approach. Therefore, frontal plane angular trunk movements should be included in clinical gait assessments of patients with hip osteoarthritis.

Background

Gait patterns of patients with osteoarthritis (OA) of the hip are characterized by a decreased walking speed and step length.¹⁻³ Additionally, these patients frequently show an exaggerated lateral bending of the trunk during gait, which is called a Duchenne limp.^{4,5} By bending the trunk laterally towards the affected limb during the stance phase, the line of gravity working on the centre of mass (COM) of the upper body shifts closer to the affected hip joint. This decreases the mechanical demand for the hip abductor muscles by shortening the moment arm between hip and COM of the upper body, thus lowering the mechanical burden of the hip joint, resulting in pain relief.^{1,5} An alternative reason for compensatory movements of the trunk during gait is that patients with hip OA often experience weakness of the hip abductor muscles.^{6,7} Consequently, they are unable to achieve stabilization of the pelvis in the frontal plane, which can be compensated for by lateral bending of the trunk.⁵

Gait analysis is often used to quantify lower extremity musculoskeletal pathologies, and to evaluate progress after (surgical) interventions to improve gait function.^{2,8,9} As many interventions for hip OA are aimed at regaining normal gait function¹⁰, quantifying compensatory trunk movements in patients with hip OA is valuable for optimal rehabilitation. Studies on compensatory trunk movements during gait of patients with hip OA are scarce though and focus mainly on compensatory movements of the pelvis during gait^{1,11}, leaving the compensatory movements of the upper trunk out of sight.

Movements of body segments are usually assessed with camera-based gait analysis systems that are restricted to a laboratory setting. Therefore objective gait analysis is, until now, not feasible in clinical practice, since most clinics do not have a gait laboratory at their disposal. A disadvantage of these camera-based gait analysis systems is that they are relatively expensive, time-consuming and labor-intensive since a specialized and technically educated staff is required. As the workspace of these systems is restricted, data of only a few gait cycles can be captured. Hence, the assumption is made that data measured from only a few steps are representative of usual gait performance. Laboratory gait analysis can be viewed as inefficient and uneconomical, and its use in clinical practice is limited.¹² An alternative approach involves the use of body-fixed-sensors (BFS), which are based on the use of miniaturized and integrated motion sensors such as accelerometers and gyroscopes.¹³ These BFS are relatively inexpensive, user-friendly, and lightweight, and can be carried on the body, facilitating unconstrained walking.¹³ In this way data from many gait cycles can be collected outside a laboratory setting under real-life conditions. BFS-based gait systems are therefore relevant for application in clinical settings such as hospitals to monitor the effect of disease progression, (surgical) interventions, and rehabilitation on gait function. Research has shown that spatiotemporal gait parameters can be accurately measured by means of BFS.¹⁴⁻¹⁷ Although a previous study which estimated hip abduction moments based on BFS demonstrated that frontal plane compensatory movements of the trunk were associated with unloading of the hip joint¹⁸, BFS have not been applied to quantify pelvic and thoracic compensatory movements

in patients with end-stage hip OA.

The aim of the present study was therefore to quantify frontal plane compensatory movements of the trunk during gait in patients with end-stage hip OA by means of BFS. To this end, frontal plane angular movements of the pelvis and thorax and spatiotemporal parameters of patients who showed a Duchenne limp during gait were compared to healthy subjects and patients without a Duchenne limp.

Methods

Participants

Sixty patients with end-stage hip OA were included in the study. These patients were scheduled for a primary total hip arthroplasty (THA). Video recordings of gait analyses were used to determine whether patients showed a Duchenne limp during gait. Visual inspection of gait was performed according to the standard physical examination used in clinical practice.^{4,5} Ten of these patients (1 man, 9 women) were classified as patients with a clearly visible Duchenne limp. They had a mean age of 63 (7) years, a mean weight of 76 (10) kg and a mean height of 1.70 (0.05) m. The other 50 patients (14 men, 36 women) showed no distinct Duchenne limp. They had a mean age of 59 (9) years, a mean weight of 78 (12) kg and a mean height of 1.71 (0.08) m. Members of several senior citizens' groups and spouses of included patients were invited to take part in the study to form the healthy control group. Thirty healthy subjects (8 men, 22 women) without clinical signs of hip OA or other conditions likely to impair gait function were included. They had a mean age of 66 (6) years, a mean weight of 69 (12) kg and a mean height of 1.70 (0.09) m. The local Institutional Review Board approved the procedures employed in this study. All subjects gave written informed consent prior to testing.

Apparatus

Two hybrid triaxial sensor units were used that contained gyroscopes, accelerometers and magnetometers (MTx Motion Tracker, Xsens Technologies B.V., Enschede, The Netherlands). Size of these units was 3.8 x 5.3 x 2.1 cm, weight 30 g. One of the sensor units was positioned at the dorsal side of the pelvis between the posterior superior iliac spines. The other sensor unit was positioned on the midline of the upper thorax, just below the spinal process of the seventh cervical vertebra. The BFS were connected with a portable device (Xbus, Xsens Technologies B.V., Enschede, The Netherlands) fastened around the waist with a belt that supplied power to the BFS, sampled the BFS data, and transmitted these data in real-time to a Personal Digital Assistant (PDA) through a wireless connection (Bluetooth). With this PDA, the researcher could start and stop a measurement as well as manually place markers during data collection. All data were collected with a sample rate of 100 Hz.

Procedure

All measurements took place in a hospital corridor, on the day of admission to the hospital for a THA. Subjects were instructed to repeatedly walk a distance of 25 m

back and forth. Subjects were instructed to walk on a self-selected low, preferred and high walking speed. During these measurements, markers were recorded in an additional measurement channel every time the subject passed the 2.5-m and 22.5-m point of the 25 m. Before data collection, all subjects walked the corridor on a self-selected preferred walking speed to familiarize themselves with the measurement procedure. Previous research has shown this gait analysis protocol to be reliable.¹⁷

Data analysis

Data were transmitted from the PDA to a PC, where the data were processed with Xsens software (MT software version 2.8.5, Xsens Technologies B.V., Enschede, The Netherlands). Next, data were further processed with Matlab (Version 7.0, The Mathworks Inc., Natick, USA). Lindemann et al.¹⁹ recommended excluding gait data from the first 2.5 m of a walking trial in older adults to assess steady state gait, so gait data from the first and last 2.5 m of the walking trials were excluded and the middle 20 m, as identified by markers placed on the data, was used for further analysis.

For each walking trial, mean peak-to-peak amplitude of the pelvis and the thorax was determined based on 10 subsequent stride cycles. Stride cycles were selected based on initial foot contact as determined from forward pelvic accelerations.¹⁶ The peak-to-peak frontal plane range of motion (ROM) of the thorax and the pelvis was determined by calculating the difference between the minimum and maximum angles of the segments. The ratio of thoracic ROM relative to pelvic ROM was calculated (thoracic ROM / pelvic ROM).

The spatiotemporal variables analyzed included walking speed, step length and cadence (steps/min). Mean walking speed was determined based on intermarker distance (20 m) and intermarker duration. The mean of the back-and-forth walks per instructed walking speeds were used for statistical analysis.

Statistical analyses

Statistical analysis was done using the PASW software package (version 18, SPSS, Chicago, USA). To assess group differences between patients with a Duchenne limp (DL), without a Duchenne limp (NDL) and the healthy control group (HC), generalized estimating equations (GEE) analyses were used (exchangeable working correlation structure and robust estimation of the covariance matrix). This analysis accurately controls for the effect of differences in walking speed and in patient characteristics such as age, body height, and body weight on the outcome variables by including these variables as covariates. Walking speed was centered on the patients' mean walking speed, 1.1 m/s, by subtracting this value from the measured walking speed. Centering allowed for a meaningful interpretation of main effects, i.e. the main effect can be interpreted as the effect of group at a walking speed of 1.1 m/s. The healthy control group was set as the reference group in the GEE models. Post hoc analyses were conducted to determine significant differences in outcome measures between DL and NDL. P-values of less than .05 were considered to be statistically significant.

Table 1. ROM and ratio of thoracic ROM to pelvic ROM

Instructed walking speed		HC	NDL	DL
Pelvic ROM	Low speed	6.9 (1.5)	5.0 (1.5)	6.1 (1.8)
	Preferred speed	8.2 (1.7)	5.4 (1.6)	5.9 (2.1)
	High speed	9.7 (1.8)	5.8 (1.9)	6.0 (1.8)
Thoracic ROM	Low speed	4.6 (1.2)	5.3 (1.6)	10.7 (2.1)
	Preferred speed	4.9 (1.2)	5.3 (1.4)	9.1 (2.8)
	High speed	5.4 (1.3)	5.4 (1.4)	8.7 (2.0)
Ratio	Low speed	0.7 (0.2)	1.2 (0.5)	1.8 (0.5)
	Preferred speed	0.6 (0.2)	1.1 (0.5)	1.7 (0.6)
	High speed	0.6 (0.1)	1.0 (0.5)	1.7 (0.6)

Values are given as mean (SD). Abbreviations: ROM, Range of Motion; HC, healthy control group; NDL, patients without a Duchenne limp; DL, patients with a Duchenne limp. Thoracic and pelvic ROM are expressed in degrees (°).

Results

Range of Motion

Mean ROM and ratio of the ROM of the thorax to the pelvis are presented in Figure 1 and Table 1. Table 2 shows the results of the GEE analysis of thoracic ROM, pelvic ROM and ratio of thoracic ROM to pelvic ROM.

In HC, pelvic ROM showed a large increase with higher walking speed. Thoracic ROM increased slightly with higher walking speed. Overall, pelvic ROM was larger than thoracic ROM, which is reflected in a ratio lower than 1. The ratio slightly decreased with increasing speed.

In DL, pelvic ROM was slightly smaller compared to HC, though this difference was not statistically significant. Pelvic ROM remained constant with increasing walking speed. The significant (negative) group by walking speed interaction indicates that the development of pelvic ROM with increasing speed differed significantly from HC, i.e. compared to HC it increased less (2.4 degrees) when walking speed increased with 1.0 m/s (Table 2). Thoracic ROM was significantly larger in DL than in HC; at a (centered) walking speed of 1.1 m/s, the difference in thoracic ROM was 5 degrees (Table 2). Thoracic ROM decreased with higher walking speed. Thoracic ROM was larger than pelvic ROM: the ratio was larger than 1.0 at all walking speeds. At a walking speed of 1.1 m/s, the ratio of DL was 1 point higher than the ratio of HC. Furthermore, the ratio decreased significantly more (0.5 points) per 1.0 m/s increase in walking speed compared to HC, as indicated by the significant group by walking speed interaction (Table 2).

In NDL, pelvic ROM was significantly smaller and increased less with higher walking speed, compared to HC. No difference was found in pelvic ROM between NDL and DL. Thoracic ROM was slightly larger compared to HC (1 degree), but significantly smaller compared to DL. Thoracic ROM retained the same magnitude with increasing walking speed. The magnitudes of thoracic and pelvic ROM were comparable, with a ratio of around the value 1 at all walking speeds. The difference in ratio was significant between all groups (Table 2). At a (centered) walking speed of 1.1 m/s, the ratio of DL was 0.5 point higher than the ratio of HC (Table 2). There was no significant difference in the development of the ratio with increasing walking speed between NDL and HC.

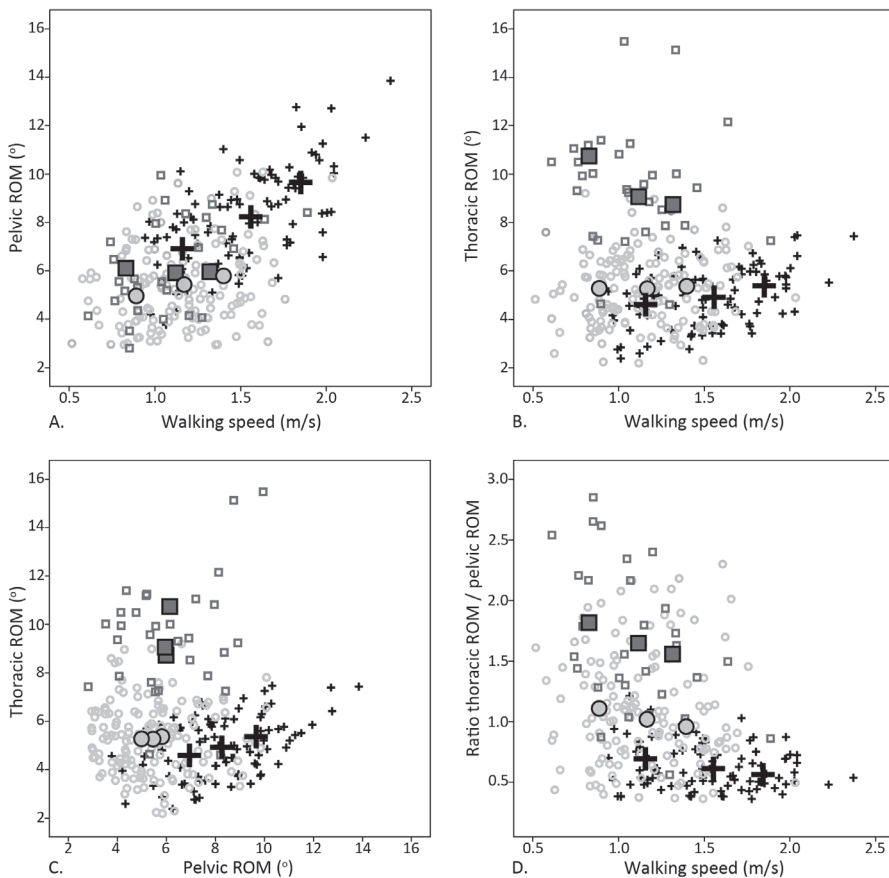


Figure 1. Pelvic and thoracic ROM versus walking speed (A. and B.), thoracic ROM versus pelvic ROM (C.) and ratio of thoracic ROM to pelvic ROM versus walking speed (D.). All data are presented for low, preferred and high walking speed. Small figures indicate individual values, large figures indicate mean values. Healthy controls (+); patients with a Duchenne limp (□); patients without a Duchenne limp (○). Abbreviations: ROM, Range of Motion.

Table 2. GEE analysis of pelvic and thoracic ROM and ratio of thoracic ROM to pelvic ROM^a

Outcome	Group	Group effect (95% CI)	P value	Group by walking speed effect (95% CI)	P value
Pelvic ROM	HC	0 ^b		0	
	NDL	-1.5 (-2.3, -0.7)	<.001	-2.4 (-3.4, -1.4)	<.001
	DL	-0.6(-1.8, 0.5)	.29	-3.0 (-4.7, -1.2)	.001
Thoracic ROM	HC	0		0	
	NDL	1.0 (0.4, 1.7) [†]	.002	-1.0 (-1.7, -0.3) [†]	.005
	DL	5.0 (3.5, 6.4)	<.001	-4.4 (-6.4, -2.4)	<.001
Ratio	HC	0		0	
	NDL	0.5 (0.3, 0.7) [†]	<.001	-0.0 (-0.2, 0.1) [†]	0.64
	DL	1.0 (0.7, 1.3)	<.001	-0.5 (-0.9, -0.1)	.007

Reference group: healthy control group.

^a Adjusted for walking speed, age, body height and body weight.

^b Set to zero because HC was used as reference group.

[†] indicate significant difference between NDL and DL.

Abbreviations: GEE, generalized estimating equation; HC, healthy control group; NDL, patients without a Duchenne limp; DL, patients with a Duchenne limp. Thoracic and pelvic ROM are expressed in degrees (°).

Table 3. Walking speed, step length and cadence data

	Instructed walking speed	HC	NDL	DL
Walking speed	Low speed	1.2 (0.1)	0.9 (0.1)	0.8 (0.1)
	Preferred speed	1.6 (0.2)	1.2 (0.2)	1.1 (0.2)
	High speed	1.9 (0.2)	1.4 (0.2)	1.3 (0.3)
Step length	Low speed	68.6 (8.6)	60.1 (8.6)	57.3 (8.0)
	Preferred speed	79.7 (11.6)	70.0 (10.9)	65.0 (8.9)
	High speed	90.5 (11.6)	76.6 (12.8)	72.8 (11.3)
Cadence	Low speed	102.3 (9.4)	88.7 (11.4)	89.1 (8.4)
	Preferred speed	119.0 (16.4)	99.8 (15.1)	101.3 (20.2)
	High speed	123.6 (11.8)	107.8 (14.0)	110.7 (14.5)

Values are given as mean (SD). Abbreviations: HC, healthy control group; NDL, patients without a Duchenne limp; DL, patients with a Duchenne limp. Walking speed is expressed in m/s, step length in cm and cadence in steps/min.

Spatiotemporal parameters

Mean walking speed, step length and cadence data are presented in Table 3. Table 4 shows the results of the GEE analysis of walking speed, step length and cadence. Compared to HC, DL and NDL walked at a significantly lower speed. No differences were found in walking speed between NDL and DL. There were no significant differences in step length or cadence between the groups, after correction for walking speed.

Table 4. GEE analysis of walking speed, step length and cadence^a

Outcome	Group	Group effect (95 % CI)	P value
Walking speed	HC	0 ^b	
	NDL	-0.4 (-0.4, -0.3)	<.001
	DL	-0.4 (-0.5, -0.3)	<.001
Step length	HC	0	
	NDL	0.4 (-2.5, 3.3)	.79
	DL	-1.0 (-5.0, 3.0)	.63
Cadence	HC	0	
	NDL	-0.1 (-4.4, 4.4)	.99
	DL	1.5 (-4.9, 8.1)	.64

Reference group: healthy control group.

^a Adjusted for walking speed, age, body height and body weight (walking speed: adjusted for age, body height and body weight).

^b Set to zero because HC was used as reference group.

Abbreviations: GEE, generalized estimating equation; HC, healthy control group; NDL, patients without a Duchenne limp; DL, patients with a Duchenne limp.

Walking speed is expressed in m/s, step length in cm and cadence in steps/min.

Discussion

The present study quantified compensatory movements of the trunk during gait in subjects with end-stage hip OA by means of BFS. Frontal plane angular movements of the pelvis and thorax and spatiotemporal parameters of patients with a Duchenne limp during gait were compared to healthy subjects and to patients without a Duchenne limp. The results showed that, over a range of instructed walking speeds, all patients walked at a significantly lower speed, along with a shorter step length and lower cadence. However, after correction for walking speed, these differences in spatiotemporal parameters disappeared. Patients with a Duchenne limp showed a significantly larger thoracic ROM during walking

compared to healthy subjects and to patients without a Duchenne limp. The ratio of thoracic ROM to pelvic ROM revealed distinct differences in trunk movement patterns.

Several studies reported on frontal plane ROM of the pelvis and thorax during walking on a preferred walking speed in healthy subjects of different age groups, captured with camera-based gait analysis systems.^{11,20-24} Values for mean pelvic ROM ranged from 5.7° to 11.5°. Values for mean ROM of the trunk ranged from 3.3° to 7.0°. Our results for healthy subjects are in line with these findings.

A few studies have quantified the pelvic frontal plane ROM during walking of patients with mild to end-stage hip OA, measured with camera-based gait analysis systems during overground walking on a preferred walking speed.^{1,11,21} Values for mean pelvic ROM ranged from 4.0° to 6.1°. Only Thurston²¹ reported a mean thoracic frontal plane ROM of 7.2°. None of these studies distinguished between patients with and without a Duchenne limp though. Our results are in line with these findings, when the results of the patients with and without a Duchenne limp are combined.

The hip abductor muscles control frontal plane pelvic movement during gait and re-establish the pelvis as a platform on which the trunk rests during the stance phase.²⁵ In the present study, a large pelvic ROM and a smaller thoracic ROM were observed in healthy subjects. Additionally, pelvic ROM greatly increased with higher speed, while only a slight increase in thoracic ROM was discerned. These observations indicate that with increasing walking speed the upper trunk maintains its approximately vertical orientation, while angular movements of the pelvis steadily increase. Obviously the latter requires a mounting effort by the hip abductor muscles. However, patients with hip OA have a substantial loss of hip abductor muscle strength in the affected limb, compared to healthy age-matched controls.^{6,7} Patients with a Duchenne limp showed a larger thoracic ROM, but, in contrast to those patients without a limp, their pelvic ROM did not differ significantly from healthy controls. This finding may indicate that an excessive lateral bending of the trunk reduces the loading of the hip and hip abductor muscles, thus helping to maintain the angular movements of the pelvis. Patients with a Duchenne limp showed a decrease of thoracic ROM with higher walking speed. This may be due to the fact that with increasing speed less time is spent in single stance; thus there may be less need for compensatory movements, but also the available time to perform such an excessive lateral movement is shorter. It should be noted that patients without a Duchenne limp also showed a slightly increased thoracic ROM, but it was significantly smaller than that of patients with a Duchenne limp.

The different patterns of angular movements of the pelvis and thorax during gait can be quantified by the ratio of thoracic ROM to pelvic ROM. In healthy subjects, thoracic ROM was smaller than pelvic ROM, which is reflected in a ratio lower than 1. The ratio of patients without a Duchenne limp was around 1, that of patients with a Duchenne limp was greater than 1. The ratio of patients without a clearly visible Duchenne limp was also significantly higher compared to healthy subjects. However, in these patients, compensatory movements could not be

recognized by clinical examination.

Some may consider differences in walking speed between subjects as a limitation of this study due to the confounding effects these differences might have on angular movement of the trunk and on spatiotemporal parameters. By instructing the subjects to walk at their self-chosen speed allowed each subject to walk as naturally as possible, thereby obtaining the best representation of their true (real-life) gait behavior. Furthermore, a previous reproducibility study of this gait analysis protocol has shown that, by instructing the subjects to walk at a self-chosen speed, reproducible and reliable results are obtained.¹⁷ We therefore used statistical procedures to adjust the gait data for differences in walking speed, as recommended in the literature.²⁶

A decreased walking speed with shorter steps and lower cadence, as observed in this study, are typical gait adaptations in patients with hip OA.¹⁻³ Reducing cadence and step length might be a compensatory strategy to lower the duration of single stance, as it results in spending a proportionally longer time in the double-support phase of the gait cycle.²⁷ After controlling for walking speed and several patient characteristics, our study did not find significant differences in step length or cadence between patient groups and healthy subjects. By contrast, other studies reported shorter step length and an increased cadence in patients with hip OA compared to their healthy counterparts, while walking overground¹¹ or on a treadmill²⁸. However, unlike the present study, Kubota et al.¹¹ did not (mathematically) control for differences in walking speed, and the results of Bejek et al.²⁸ may deviate from our results since spatiotemporal parameters obtained during treadmill walking may differ from those for overground walking²⁹.

The classification system that was used in this study to determine whether a subject showed a Duchenne limp might also be seen as a limitation of the study. In this study, patients were classified as having a Duchenne limp by means of visual inspection of gait according to standard physical examination used in clinical practice. This is a subjective, qualitative measure. There may have been patients that use frontal plane compensatory movements of the trunk that remain unnoticed by visual inspection. Consequently, these patients might have been classified as not having a Duchenne limp. To our knowledge, there presently is no objective clinical measure to quantify a Duchenne limp. However, despite the fact that there may have been misclassifications in the non-Duchenne limp group, the results of this study were very clear. This study showed that frontal plane compensatory trunk movements, as well as spatiotemporal gait parameters, can be objectively quantified by means of a BFS-based gait analysis system. The ratio of thoracic ROM to pelvic ROM appeared to be a powerful measure to distinguish between the patterns observed in healthy subjects and in hip OA patients with and without a clearly visible Duchenne limp.

Until now, the primary choice of measurement to objectively monitor the effect of disease progression, (surgical) interventions, and rehabilitation on gait function is the use of a camera-based gait analysis system which is restricted to a laboratory setting. This makes it, in clinical practice, difficult to objectively quantify gait function. The easy-to-use BFS-based gait analysis system used in this

study demonstrated a great potential to evaluate and objectively quantify in a clinical setting the compensatory trunk movements as well as spatiotemporal gait parameters in patients with lower limb OA.

There is a growing base of knowledge on compensatory angular trunk movements during gait in patients with OA of the lower limb.³⁰⁻³² This has led to the development of gait retraining interventions, which use frontal plane angular trunk movement during gait to reduce joint loading of the hip and knee in patients with hip or knee OA.^{33,34} Real-time biofeedback methods appeared to be effective for gait retraining.³⁵ Hunt et al.³³ showed that the use of biofeedback to control the amount of trunk lean during gait retraining in patients with knee OA is successful. However, they used a camera-based gait analysis system, which was bound to a gait laboratory, as a biofeedback system. Previous research has shown the feasibility of BFS as a wireless real-time auditory or visual biofeedback system during interventions to enhance balance and gait function in patients with various mobility disorders.^{36,37} This application of BFS may enhance a broad implementation of biofeedback-based gait retraining interventions focused on increased frontal plane trunk movement in patients with hip and knee OA.

Conclusions

The present study is, to our knowledge, the first to have investigated frontal plane compensatory movements of the trunk during gait of patients with end-stage hip OA by means of a body-fixed-sensor based gait analysis system. Distinctive patterns of frontal plane angular trunk movements during gait could be objectively quantified in healthy subjects and in hip OA patients. The ratio of thoracic ROM to pelvic ROM appeared to be a powerful measure to distinguish between the patterns observed in healthy subjects and in hip OA patients with and without a clearly visible Duchenne limp. No differences in spatiotemporal parameters were found, after correction for differences in walking speed. The findings of the present study suggest that frontal plane angular trunk movements should be included in clinical gait assessments of patients with hip OA. Since this BFS-based gait analysis approach is not confined to a laboratory and is user-friendly, it is a useful method to objectively assess gait function in a clinical (outpatient) setting.

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Chapter 6

Minimally invasive total hip arthroplasty with computer navigation: a randomized controlled trial

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Abstract

Background: Both minimally invasive surgery (MIS) and computer-assisted surgery (CAS) for total hip arthroplasty (THA) has gained popularity. Combining MIS and CAS for THA may result in a more effective procedure compared to the conventional technique. Hence the objective of this study was to compare the effectiveness of a MISCAS and a conventional THA technique in terms of clinical and radiographic results and patients' functional outcome until 6 months after surgery.

Methods: Seventy-five patients were randomly allocated to have total hip arthroplasty (THA) with a minimally invasive technique in combination with computer navigation (MISCAS THA, n=35) or a conventional technique (n=40). Anesthetic, analgesic, postoperative physiotherapy protocols were similar in both groups. Discharge criteria were also identical. Next to surgical outcome, physical functioning was assessed preoperatively, and 6 weeks, 3 and 6 months postoperatively.

Results: Surgical time and red blood cell volume loss were significantly higher after MISCAS THA. Average length of stay however was significantly shorter after MISCAS THA (5.2 ± 1.9 days) than after conventional THA (6.9 ± 2.1 days). No difference in complication rate was found. The position of the acetabular component position was similar. Physical functioning, as measured with a questionnaire as well as with gait analysis was also comparable between the groups.

Conclusions: Overall, MISCAS THA results in a shorter length of stay despite the increase in surgical time and blood loss. No difference in number of complications was found. By using computer navigation, an accurate placement of the prosthesis was assured. No differences in (the recovery of) physical functioning after MISCAS THA or conventional THA were found.

Level of Evidence: A level I study.

Introduction

The current trend in orthopedic surgery towards minimally invasive surgical techniques (MIS) for joint replacement procedures such as total hip arthroplasty (THA) has been adopted recently in the orthopedic community. Main goals in THA are to relieve pain and enhance joint function. Accurate fit and fixation of the prosthetic components and good overall limb alignment are prerequisites for the long-term success of THA.¹

Advocates of minimally invasive total hip arthroplasty (MIS THA) emphasize the potential of this method to reduce soft tissue trauma and thereby reduce operative blood loss, postoperative pain and hospitalization time, and to speed the return to normal function.² Opponents are concerned that MIS THA introduces additional risks related to a reduced visualization of anatomic landmarks and vital structures during surgery.³

Computer-assisted surgery (CAS) has also gained popularity, since it has the potential to improve the accuracy of THA. Several studies have shown that inaccuracies in prosthetic placement through mechanical alignment aids can be significantly reduced by using computer navigation.^{4,5} CAS may therefore be the solution to the limited visibility of anatomical landmarks during MIS THA.¹ CAS in THA is not very common yet though. This is mainly due to the fact that CAS systems may involve longer surgical times and the introduction of new equipment in the operating room. Other factors that limit the broad application of CAS are costs and complexity of computer navigation systems.⁵

Combining MIS and CAS for THA may result in a more effective procedure compared to the conventional technique. However, the orthopedic literature lacks well-designed studies that provide objective evidence on the effectiveness of MISCAS THA, especially in the early postoperative period, when its potential benefits are claimed to be substantial.⁶ Hence the objective of this study was to compare the effectiveness of a MISCAS and a conventional THA technique in terms of clinical and radiographic results and patients' functional outcome until 6 months after surgery.

Materials and Methods

Patient selection

Between July 2007 and February 2010, 97 patients who were placed on the waiting list for a THA were found eligible for the present study. Inclusion criteria were age 18-75, admitted for primary cementless unilateral THA due to primary or secondary osteoarthritis. Exclusion criteria were a history of previous surgery on the affected hip, a pathological condition of the hip joint that required an extensile exposure of the joint during surgery, and obesity expressed as a body mass index above 32. Fifteen patients declined to participate. Eventually, 82 patients were included in the study. Informed consent was obtained from all patients. Patients were randomly allocated to undergo THA through either a MISCAS or a conventional technique. The random allocation sequence was computer-generated by an independent planner of the local Trial Coordination Center. In the MISCAS THA group, three patients did not undergo THA. Two patients decided to go to another

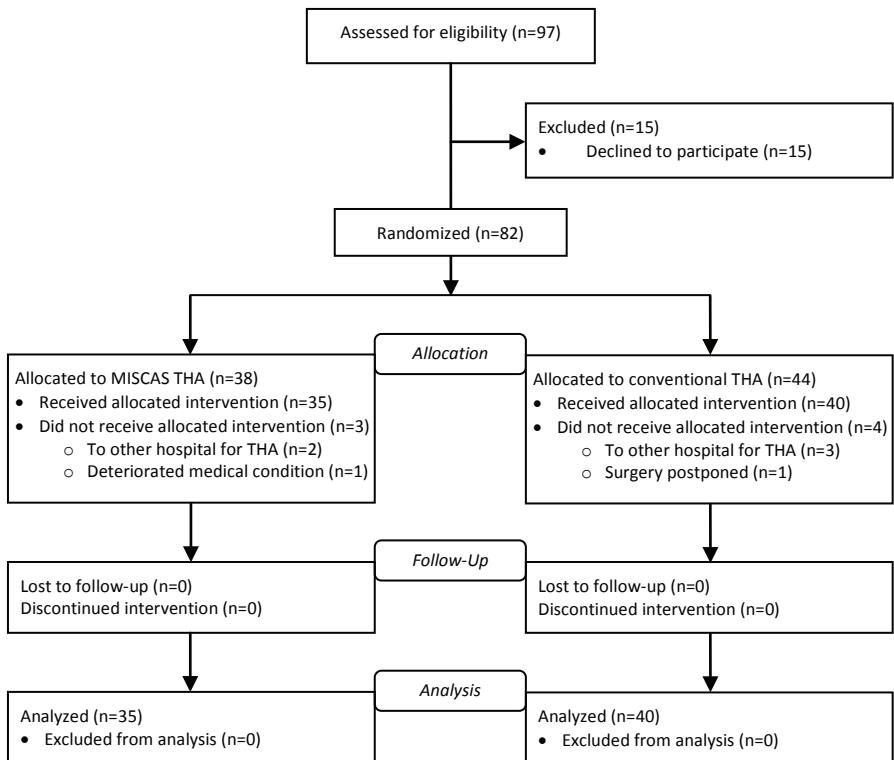


Figure 1. CONSORT flow diagram for enrollment in the study

hospital for THA, and the medical condition of one patient deteriorated while he was on the waiting list. Consequently he did not meet the inclusion criteria for this study anymore. In the conventional THA group, four patients were not operated. Three patients decided to go to another hospital for THA, and one patient decided to postpone the surgery. The CONSORT^{7,8} flow diagram for this study is shown in Figure 1. The study was approved by the Institutional Review Board. The study was registered in the International Standard Randomized Controlled Trial Number Register (ISRCTN52538512).

Surgical technique

Patients in the MISCAS THA group had surgery using the minimally invasive single-incision anterior approach.^{9,10} Using special retractors, reamers and insertion handles it was possible to perform this procedure in a minimally invasive way, by using intermuscular planes, thereby avoiding muscle damage. To optimize placement of the acetabular and femoral components of the total hip prosthesis, an imageless computer navigation system (Stryker® Navigation System iNstride Hip, Stryker Corporation, Kalamazoo, Mi, USA) was used. Two trackers were placed on the patient, which were used by the computer navigation system for referencing.

These trackers were temporarily fixated with two 3.5 mm anchoring pins in the iliac crest and two in the distal femur. The pins caused no additional morbidity.

For the conventional technique a standard posterolateral approach was used. In the MISCAS THA group as well as in the conventional THA group, the same acetabular cup (Trident® Cup with polyethylene (X3) or ceramic (Alumina) inlay, Stryker Corporation) and femoral component (ABG II, Stryker Corporation) were used. The safe zone defined by Lewinnek et al.¹⁰, an anteversion angle of $15\pm 10^\circ$ and an inclination angle of $40\pm 10^\circ$, was the surgical goal for the orientation of the acetabular component in both techniques.

The anesthetic, analgesic and postoperative physical therapy protocols were identical in both groups. Functional rehabilitation started on the day following surgery. Patients started walking on the first postoperative day. Discharge criteria were also identical. A score of 90 or more on the Modified Barthel Index had to be achieved before a patient was considered sufficiently independent for safe hospital discharge.¹¹ Patients were instructed to use two elbow crutches until six weeks postoperatively, and one elbow crutch until three months postoperatively. No physical therapy following discharge was prescribed.

Data collection

On the day of admission to the hospital, demographic data and ASA¹² (American Society of Anesthesiologists) grade were recorded. Surgical time, intra- and postoperative complications and length of hospital stay (from day of surgery to day of discharge) were also recorded. All patients had a full blood count, including haematocrit (Hct) preoperatively and on the first postoperative day. Red blood cell (RBC) volume loss was calculated with these data. Patient's blood volume (PBV) was calculated using the formula of Nadler et al.¹³ Multiplying the PBV by the Hct will give an estimation of the total RBC volume.¹⁴ If a blood transfusion was performed, a unit of blood containing 275 ml of RBC with an Hct of 0.60 was used. The RBC volume of this unit of blood was therefore $(0.275 \times 0.60 =) 0.165$ L. This transfused RBC volume was then added to the RBC volume loss. The loss of RBC volume was therefore calculated from the change in Hct:

$$\text{RBC volume loss (L)} = \text{PBV} \times (\text{Hct}_{\text{pre-op}} - \text{Hct}_{\text{post-op}}) + \text{number of transfused units of blood} \times 0.165$$

Complications related to the THA were collected during the patient's stay in the hospital, and during the postoperative follow-up visits to the outpatient clinic at six weeks, three and six months postoperatively.

The position of the acetabular component was determined by means of standardized anteroposterior radiographs of the pelvis, made six weeks postoperatively. The first author (IHFR) performed the measurements. Anteversion and inclination angle of the acetabular component were measured according to the radiographic definition.¹⁵ In order to measure these angles, an ellipse was fitted to its rim as projected on the anteroposterior radiographs. The anteversion angle was measured as the angle produced by the cup's long axis and the line perpendicular

to that axis. The inclination angle was measured as the angle produced by the cup's long axis and the line crossing the lowest points of the ischium bilaterally.¹⁶

To reduce intraobserver variability, measurements were made twice and the average value was used. Intraobserver reliability was high, with Intraclass Correlation Coefficients (ICCs) of 0.99 and 0.96 for inclination and anteversion angles, respectively. To determine interobserver reliability, 30 hips were also measured by one of the other authors (WCHL). Interobserver reliability was also high, with ICCs for inclination and anteversion angles of 0.92 and 0.90, respectively. The position of the acetabular component was considered an outlier when it was positioned outside the safe zone.¹⁰

Physical functioning was assessed preoperatively and during the follow-up visits to the outpatient clinic at six weeks, three and six months postoperatively, by means of the Western Ontario McMaster University Osteoarthritis Index (WOMAC)¹⁷ and gait analysis. Gait analysis was performed by means of a body-fixed sensor-based gait analysis method.¹⁸ A major advantage of this approach is that it can be applied under real-life conditions, and no expert laboratory is needed.¹⁹ All gait analysis measurements took place in a hospital corridor. Patients were instructed to repeatedly walk a distance of 25 m back and forth, on a self-selected (preferred) walking speed. Previous research has shown this gait analysis protocol to be reliable and applicable to patients with osteoarthritis of the hip joint.¹⁸ Walking speed and step length were recorded.

Statistical analysis

Enrollment was stopped after the inclusion of the 82nd patient because of difficulty of finding eligible patients. However this sample size has been showed to be sufficient to detect a difference on the physical functioning subscale of the WOMAC between the MISCAS THA and conventional THA group at 6 weeks postoperatively. As the potential benefit of MISCAS THA over conventional THA is expected in the early postoperative period, scores on this subscale of the WOMAC of patients 6 weeks after THA, reported by van den Akker-Scheek et al.²⁰, have been used in the sample size calculation. Quintana et al.²¹ reported a minimal detectable change of 12 points on the physical functioning subscale of the WOMAC after THA. By an 80% statistical power with an alpha level of 0.05, 32 patients in each group would be sufficient to detect this change in WOMAC score.

Statistical analysis was done using the PASW software package (version 18, SPSS, Chicago, USA). For the clinical parameters, t-tests were used for continuous values or the Mann-Whitney U test when the variables were not normally distributed. A Chi-square test and a Fisher's Exact test was used for dichotomous values. To assess differences in (the recovery of) physical functioning between the MISCAS THA and conventional THA group, generalized estimating equations (GEE) analyses were performed (exchangeable working correlation structure and robust estimation of the covariance matrix). Longitudinal data are characterized by repeated observations of the same subjects. GEE analysis was developed to correct for repeated outcomes within the same subject.²² With a GEE analysis, adjustments for the effect of differences in patient characteristics on the outcome variables can

Table 1. Patient demographics and characteristics*

	MISCAS THA	Conventional THA
No. of patients (M/F)	35 (11/24)	40 (8/32)
Age (yr)	60.3 ± 7.6	60.5 ± 9.6
Height (m)	1.7 ± 0.1	1.7 ± 0.1
Weight (kg)	80.2 ± 10.7	75.3 ± 12.5
Body Mass Index*	27.2 ± 3.6	26.2 ± 3.5
ASA grade (1/2)	7/28	10/30

* Values are given as mean ± standard deviation.

also be made by including these variables as covariates. Age, BMI and ASA score were therefore included in the analysis of the WOMAC. Body height was included in the analysis of walking speed. Additionally, preoperative values of the outcome variables were added to the analyses. Not correcting for preoperative differences between the MISCAS THA and conventional THA group can lead to either over- or underestimation of the estimated intervention effect.²³ A p-value of <.05 was considered to indicate statistical significance.

Results

Patient demographics are presented in Table 1. Thirty-two in the MISCAS THA group and 37 in the conventional THA group had a diagnosis of primary osteoarthritis, the remaining patients were diagnosed with secondary osteoarthritis due to osteonecrosis or rheumatoid arthritis.

Table 2. Operative results, complications and length of stay*

	MISCAS THA	Conventional THA	P-value
Surgical time (min)	193 (110 – 265)	96 (30 – 275)	<.001
Calculated RBC volume loss (L)	0.6 (0.3 – 1.2)	0.5 (0.2 – 0.9)	.05
Intraoperative complications	6	3	.20
Postoperative complications			
Until discharge	2	8	.07
6 weeks postoperatively	1	2	.64
3 months postoperatively	0	0	1.00
6 months postoperatively	0	0	1.00
Length of stay (days)	5.2 (3 – 11)	6.9 (4 – 12)	<.001
Barthel Index at discharge*	97.3 (92-100)	97.4 (93-100)	.90

* Values are given as mean (range).

Surgical time and mean RBC volume loss of the MISCAS THA technique were significantly higher than those of the conventional THA technique ($p < .001$) (Table 2). There were six intraoperative complications in the MISCAS THA group and three in the conventional THA group (Table 2); this difference was not significant ($p = .20$). In the MISCAS THA group one patient sustained a fissure of the medial calcar, for which a cemented femoral component (Exeter, Stryker Corporation) was inserted. In another patient a small part, probably an osteophyte, of the greater trochanter broke off, which did not need additional operative treatment. Another patient had a proximal femoral fracture, which was treated intraoperatively with cerclage cables and deeper insertion of the femoral component. In three patients the m. tensor fascia latae was macroscopically damaged, which did not need additional treatment. In the conventional THA group two patients had a fracture of the acetabulum, of which one was stabilized intraoperatively by means of

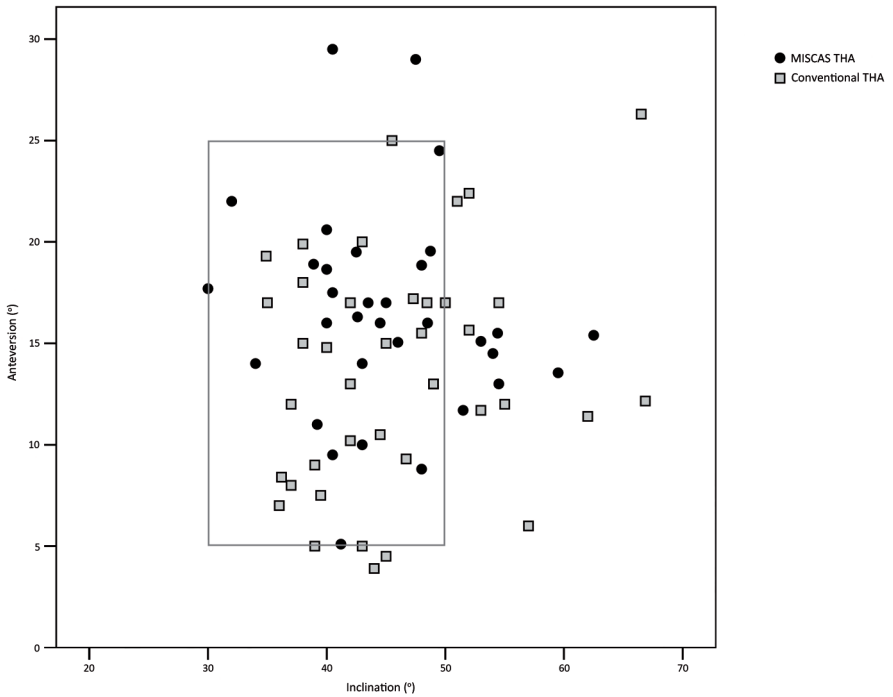


Figure 2. Positions of the acetabular component relative to Lewinnek's Safe Zone (grey frame)

plate osteosynthesis and a central mesh. In both patients, a cemented acetabular component (Contemporary, Stryker Corporation) was inserted. One other patient sustained a fissure of the femoral neck, which was fixated intraoperatively by means of cerclage cables.

The number of postoperative complications until discharge was higher in the conventional THA group than in the MISCAS THA group (8 and 2 complications, respectively), though this difference was not significantly different ($p=0.07$). In the MISCAS THA group one patient suffered from atrial fibrillation directly postoperatively. The patient, known to have cardiac problems, was treated with medication. One patient experienced loss of sensibility of the skin of the upper leg, probably caused by damage to the femoral lateral cutaneous nerve. In the conventional THA group one patient was temporarily transferred to the cardiac care unit because of a diminution of consciousness, which appeared to be a postoperative vasovagal reaction. Furthermore, four patients sustained prolonged wound leakage, one patient developed an eczematous rash on the lower limb, and one patient sustained a urinary tract infection. Additionally, one patient in the conventional THA group developed a deep wound infection, which was treated with irrigation and débridement with retention of the components of the prosthesis, followed by oral antibiotics. Between discharge from the hospital and six weeks postoperatively, one patient in the MISCAS THA group sustained a fracture of the greater trochanter, which needed a re-operation in which the fracture was fixated by means of a trochanter grip plate and cerclage cables. Two

Table 3. Orientation and number of outliers of the acetabular component outside the Safe Zone in the MISCAS THA group and conventional THA group^a

		MISCAS THA	Conventional THA	P-value
Inclination ^a (°)		44.9 ± 7.1	45.7 ± 8.3	.66
Anteversion ^a (°)		16.6 ± 5.1	13.6 ± 5.7	.02
Outliers	Inclination	7/35	10/39	.57
	Anteversion	2/35	3/39	.74
	Total	9/35	12/39	.63

^a Values are given as mean ± standard deviation.

patients from the conventional THA group developed a deep wound infection. Both infections were treated with irrigation and débridement with retention of the components of the prosthesis, followed by oral antibiotics. At three months and six months postoperatively no other complications were reported. No difference in total number of complications was found ($p=.73$).

At discharge from the hospital, all patients had a Barthel Index score of higher than 90. The length of hospital stay was significantly shorter following MISCAS THA when compared to conventional THA ($p<.001$). Twenty-five (71%) of the 35 patients in the MISCAS THA group met the discharge criteria on day 5 compared with 11 (28%) of the 40 patients in the conventional THA group.

The orientation of the acetabular component of one patient from the conventional THA group could not be evaluated, since intraoperatively a fracture of the medial wall of the acetabulum occurred which needed reconstruction. The mean anteversion angle of the acetabular cup was significantly lower after conventional THA ($p=.02$), but the mean inclination angle did not significantly differ between the two groups ($p=.66$) (Table 3, Figure 2). Though the number of outliers outside the safe zone was lower after MISCAS THA, this difference was not statistically significant.

Table 4. Preoperative and postoperative WOMAC scores^a

		preoperative	6 weeks postoperative	3 months postoperative	6 months postoperative
Pain	CON	51 ± 17	80 ± 17	87 ± 14	87 ± 11
	MISCAS	46 ± 14	82 ± 16	85 ± 18	85 ± 16
Joint stiffness	CON	49 ± 19	64 ± 21	68 ± 18	72 ± 19
	MISCAS	53 ± 20	70 ± 16	69 ± 19	79 ± 19
Physical functioning	CON	46 ± 17	72 ± 16	80 ± 17	84 ± 14
	MISCAS	48 ± 19	74 ± 16	79 ± 20	82 ± 20

^a Values are given as mean ± standard deviation. Abbreviations: MISCAS, MISCAS THA group; WOMAC, Western Ontario McMaster University Osteoarthritis Index.

Preoperative and postoperative scores on the WOMAC are presented in Table 4. The results of the GEE analyses of the WOMAC are given in Table 5. Overall, the scores increased after surgery. No significant differences in scores between the MISCAS THA and conventional THA group were found. The development of the scores over time was also not significantly different between the two groups.

Table 5. Results of GEE analysis of WOMAC scores*

Effect			Regression coefficient (95% CI)	P-value
Pain	Intervention		2.4 (-2.9, 7.7)	.37
	Time	6 weeks	0 ^a	
		3 months	5.3 (1.6, 8.9)	.005
		6 months	7.0 (3.5, 10.5)	<.001
Joint Stiffness	Intervention		5.5 (-0.5, 11.4)	.07
	Time	6 weeks	0	
		3 months	2.1 (-2.3, 6.5)	.35
		6 months	9.2 (4.5, 13.9) [†]	<.001
Physical Functioning	Intervention		-0.85 (-6.0, 7.7)	.81
	Time	6 weeks	0	
		3 months	7.9 (4.3, 11.4)	<.001
		6 months	12.2 (8.5, 15.8) [†]	<.001

Reference group: conventional THA group.

^a Adjusted for age, BMI, ASA score and preoperative scores on the respective outcome variable.

^a Set to zero because the measurement that was made 6 weeks postoperatively was used as reference.

[†] indicates significant difference (p<.05) between 3 and 6 months postoperatively.

Abbreviations: GEE, generalized estimating equations; 95% CI, 95% confidence interval; WOMAC, Western Ontario McMaster University Osteoarthritis Index.

Preoperative and postoperative walking speed and step length are presented in Table 6. The results of the GEE analyses of walking speed and step length, per instructed walking speed, are given in Table 7. At six weeks postoperatively, walking speed and step length were comparable to the preoperative values. After that, walking speed and step length increased significantly at all instructed walking speeds. No significant differences in walking speed and step length were found between the MISCAS THA and conventional THA group. The development of the scores over time was also not significantly different between the groups.

Table 6. Preoperative and postoperative walking speed and step length*

		preoperative	6 weeks postoperative	3 months postoperative	6 months postoperative
Walking speed (m/s)	CON	1.1 ± 0.2	1.1 ± 0.2	1.2 ± 0.2	1.3 ± 0.2
	MISCAS	1.1 ± 0.2	1.1 ± 0.2	1.2 ± 0.2	1.3 ± 0.1
Step length (cm)	CON	68.3 ± 8.8	67.6 ± 10.2	72.7 ± 7.8	75.1 ± 8.5
	MISCAS	67.9 ± 15.3	70.3 ± 11.4	74.7 ± 12.8	77.4 ± 9.4

*The values are given as mean ± standard deviation.

Table 7. Results of GEE analysis of walking speed and step length

Effect			Regression coefficient (95% CI)	P-value
Walking speed ^a	Intervention		0.01 (-0.05, 0.07)	.81
	Time	6 weeks	0 ^a	
		3 months	0.14 (0.11, 0.18)	<.001
		6 months	0.21 (0.17, 0.25) [†]	<.001
Step length ^b	Intervention		1.3 (-0.9, 4.3)	.44
	Time	6 weeks	0	
		3 months	4.9 (2.5, 7.2)	<.001
		6 months	7.1 (4.8, 9.4) [†]	<.001

Reference group: conventional THA group.

^a Adjusted for body length and preoperative walking speed.

^b Adjusted for body length and preoperative step length.

^a Set to zero because the measurement that was made 6 weeks postoperatively was used as reference.

[†] indicates significant difference (p<.05) between 3 and 6 months postoperatively.

Walking speed is expressed in m/s, step length is expressed in cm.

Abbreviations: GEE, generalized estimating equations; 95% CI, 95% confidence interval.

Discussion

To the best of our knowledge, this prospective, randomized controlled trial is the first to determine the effectiveness of a minimally invasive technique in combination with computer navigation for THA compared to a conventional THA technique, in terms of clinical and radiographic results and patients' functional outcome until six months after surgery. The results of this study show that the average length of stay was significantly shorter after MISCAS THA, although surgical time and blood loss were significantly higher compared to conventional THA. No difference in complication rate was found. The position of the acetabular component position was similar. Physical functioning, measured with a self-reported questionnaire as well as with gait analysis, was also comparable between the groups.

The significant increase in surgical time and blood loss is in contrast with the results found in the literature on MIS THA.²⁴⁻²⁶ However, in these studies blood loss was estimated by measuring the volume of blood in the suction bottles weighing the swabs used, and the blood accumulated in a drain. As mentioned by Ogonda et al.²⁶, the weakness of these measurements is that they may be subjective to suggestibility on the part of operating-room staff, who, since they are not blinded to the surgical technique, may have anticipated greater blood loss. Additionally, Sehat et al.²⁷ report that, when estimating blood loss based on visible blood loss (blood in suction bottles and swabs), true blood loss is underestimated by 26% in THA. Presumably, this hidden blood loss can be attributed to perioperative bleeding into tissue compartments.²⁸ In this study these issues were taken into account by calculating blood loss based on the drop in Hct levels after surgery.¹³ Additionally, CAS THA is shown to increase surgical time.^{29,30} Introducing a new surgical technique with its accompanying instruments to the operating room will result in an increased surgical time. Therefore the surgeons gained experience with the MISCAS THA technique before start of this study. Furthermore, surgical time was low for the conventional THA technique, compared to other studies.^{4,24,30}

In contrast with the claims of the opponents of MIS, this study showed that MISCAS THA did not result in an increase of operative complications. We chose to report damage to the m. tensor fascia latae as an intraoperative complication of MISCAS THA, since it aims to cause less muscle trauma. However, the occurrence of muscle trauma is inherent to approaches for conventional THA, where muscles are dissected to gain access to the hip joint. With this in mind, the number of intraoperative complications occurring in this study during either of the other THA techniques would even be lower after MISCAS THA. On the other hand, two cases of intraoperative fractures of the acetabulum were reported in the conventional THA group. In general, an intraoperative fracture of the acetabulum is a rare complication of THA at our department. According to the literature, the use of a press-fit acetabular component as in our series is associated with larger prevalence of this complication.³¹ The cause of the relative high prevalence in the conventional THA group in this study could however not be discovered.

There were two cases of deep wound infection in the conventional THA group. In general, the infection rate after total joint surgery at our department is in line with (inter)national infection rates.³² No particular cause of these infections

could be found. One must therefore bear in mind that this number of acetabular fractures and wound infections is a biased representation, and the number of complications should therefore be considered in light of the aforementioned aspects.

Opponents of MIS THA state that reduced visualization during surgery is a major disadvantage of MIS THA, since it may compromise optimal positioning of the components.³ In the present study this disadvantage is overcome by using CAS. No significant difference in the position of the acetabular component, and in the number of outliers outside the desired range, was found between MISCAS and conventional THA. This indicates that, by using CAS during MIS, an accurate position of the acetabular component is assured.

A significantly shorter length of stay after MISCAS THA was found, despite the longer surgical time and higher blood loss. The standardization of anesthetic, analgesic and postoperative physical therapy protocols ensured that patients recovered at their own pace. All patients had a comparable level of independence at discharge, as they had to achieve a score of 90 or more on the Modified Barthel Index before they were considered sufficiently independent for safe hospital discharge. So, the shorter length of hospital stay after MISCAS THA may be explained by the fact that this technique results in less soft tissue trauma, leading to less wound leakage, and a faster return to independently performing activities of daily living.

One of the main goals of THA is restoration of physical functioning. In this study, reliable and valid measurements of physical functioning were used, namely the WOMAC and gait analysis. Gait analysis is a useful and objective method to evaluate the clinical performance of different THA techniques, though not very often used after MIS THA.⁶ Physical functioning improved significantly after THA. However, no differences in (the recovery of) physical functioning after MISCAS THA or conventional THA were found. These findings are in line with a systematic review on the effectiveness of MIS THA.⁶ The follow-up period in this study was short, but it covered the period in which the potential benefits of MISCAS THA with respect to physical functioning are proposed to be the most substantial.

Since this study shows that MISCAS THA results in a shorter hospital stay, future research is needed that evaluate the potential benefit of MISCAS THA on functional recovery during the first weeks after discharge from the hospital. Additionally, an economic evaluation is recommended that determines whether MISCAS THA is a cost-effective technique, i.e. whether not only the direct medical costs may be lower after MISCAS THA, but also medical costs outside the hospital (including physical therapy, visits to general practitioners, nursing care) and other (nonmedical) costs (e.g. absence of work).

In conclusion, this study showed that MISCAS THA resulted in a shorter length of stay, despite the increase in surgical time and blood loss. No difference in number of complications was found. By using computer navigation, an accurate placement of the prosthesis was assured. No differences in (the recovery of) physical functioning after MISCAS THA or conventional THA were found.

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Chapter 7

Comparison of gait function of patients following computer-navigated minimally invasive and conventional total hip arthroplasty: a randomized controlled trial

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Abstract

Purpose: A randomised controlled trial was conducted to determine the effectiveness of computer-navigated minimally invasive (MIS) total hip arthroplasty (THA) compared to conventional THA on the restoration of physical functioning during postsurgical recovery.

Methods: Thirty-five patients underwent THA using a minimally invasive anterior approach in combination with computer navigation. Forty patients underwent THA using a conventional posterolateral approach. A body-fixed-sensor-based gait analysis was performed preoperatively, and 6 weeks, 3 and 6 months postoperatively. Walking speed, step length and cadence, and frontal plane angular movements of the pelvis and the thorax were assessed. The same data were obtained from 30 healthy subjects.

Results: No differences were found in the recovery of spatiotemporal parameters, nor was there any difference in angular movements of the pelvis and the thorax following computer-navigated MIS THA or conventional THA. Although gait function improved after surgery, small differences in several spatiotemporal parameters and angular movements of the trunk remained at 6 months postoperatively between both patient groups and healthy subjects.

Conclusions: No evidence was found for a faster recovery of gait function following computer-navigated MIS THA. Although patients undergoing THA had considerably improved their gait function 6 months following surgery, small differences remained compared to healthy subjects.

Introduction

Total hip arthroplasty (THA), which has been performed since the late 1960s, has become one of the most frequently performed and successful orthopaedic interventions. An increase in the number of THAs is seen due to an ageing population and increased incidence of obesity.^{1,2} Driven by this growing demand for THA, together with a greater emphasis on cost-effectiveness in health care and patients' higher expectations of shorter hospital stays and a faster recovery, alternative surgical procedures have been developed to improve the success of THA. Minimally invasive surgery (MIS) for THA is one of these developments. MIS THA aims at decreasing the surgical incision and minimising damage to the underlying soft tissues such as muscles and tendons, in order to accelerate postoperative recovery and an earlier return to normal (gait) function.³

In contrast with a conventional technique for THA, surgical exposure of bony landmarks during MIS THA is limited. Proper positioning of the hip prosthesis is essential for the long-term success of THA, hence some authors recommend the use of computer navigation during MIS THA.⁴ Computer navigation allows a more accurate and precise implant alignment without complete visualisation of the bony landmarks during surgery.⁵ MIS and computer navigation are considered to be potential forward steps in the treatment of THA patients. However, there is a lack of scientific evidence on the effectiveness of computer-navigated MIS THA, especially on physical functioning.⁶

Gait function is an important aspect of many activities of daily living, so it is closely linked to overall physical functioning. Gait patterns of patients undergoing THA are characterised by a decreased walking speed and step length.⁷⁻¹⁰ These patients frequently show an exaggerated lateral bending of the trunk during gait, which is called a Duchenne limp.¹⁰⁻¹² This decreases the mechanical demand for the hip abductor muscles by shortening the moment arm between hip and centre of mass of the upper body. Consequently, the mechanical burden of the hip joint is lowered, resulting in pain relief.^{9,12} Since one of the main goals of THA is restoration of gait function, gait analysis is a useful and objective method to evaluate clinical performance of different THA techniques.

A randomised controlled trial (RCT) was performed into the effectiveness of computer-navigated MIS THA compared to a conventional technique for THA.¹³ Gait analyses were performed to determine differences in the restoration of physical functioning during recovery following computer-navigated MIS THA or conventional THA. This study presents the results of these gait analyses.

Methods

Participants and surgical procedure

Patients between the ages of 18 and 75 who were admitted for primary cementless unilateral THA due to primary or secondary osteoarthritis were selected. Exclusion criteria were a history of previous surgery to the affected hip, inflammatory polyarthritis where the severity of multiple joint disease was likely to compromise postoperative mobility and a body mass index $> 32 \text{ kg/m}^2$.

Patients were stratified into three groups based on the Charnley

Table 1. Subject characteristics

	HC	CON	MISCAS
N (men/women)	30 (8/22)	40 (11/32)	35 (11/24)
Charnley classification A/B/C		31/8/1	24/9/2
Age (yr)	65.8 ± 6.0	60.5 ± 9.5	60.3 ± 7.7
Height (cm)	169.4 ± 9.5	169.3 ± 7.2	172.2 ± 8.6
Weight (kg)	69.1 ± 11.8	75.3 ± 12.4	80.8 ± 10.2
BMI	23.9 ± 3.2	26.2 ± 3.5	27.3 ± 3.5

Values are given as means ± SD. Abbreviations: HC, healthy control group; CON, conventional THA group; MISCAS, computer-navigated MIS THA group.

classification¹⁴, which stratifies patients by the presence of OA in one or both hips, or co-morbid conditions that have a negative influence on walking capacity. Within the strata, patients were randomly allocated to have computer-navigated MIS (MISCAS) or the conventional THA (CON) procedure by means of cluster randomisation. The random allocation sequence was computer-generated by an independent planner of the local Trial Coordination Centre.

Patients in the MISCAS group had surgery using the minimally invasive single-incision anterior approach.³ Advantage of the anterior approach is the possibility of using the intermuscular plane between the m. tensor fascia latae and the m. sartorius, avoiding muscle damage by cutting or detaching muscles. This adds to the minimally invasive character of the approach. To optimise placement of the acetabular and femoral components of the total hip prosthesis, a computer navigation system (Stryker® Navigation System iNStride Hip, Stryker Corporation, Kalamazoo, MI, USA) was used. For the conventional technique a standard posterolateral approach was used. The same acetabular cup (Trident® Cup with X3 or Ceramic inlay, Stryker Corporation) and femoral component (ABG II, Stryker Corporation) were used in the MISCAS group and in the CON group. The anaesthetic, analgesic and postoperative physical therapy protocols were identical in both groups. Functional rehabilitation started on the day following surgery. Patients started walking on the first postoperative day. Discharge criteria were also identical. No physical therapy following discharge was prescribed.

The MISCAS group consisted of 35 patients and the CON group of 40 patients. In order to determine whether the patients' gait function returned to normal 6 months after surgery, gait function of these patients was compared to that of healthy subjects. Members of several senior citizens' groups and spouses of patients who were included in the study were invited to take part in the study to form the healthy control group (HC). Thirty healthy subjects without clinical signs of hip OA or other conditions likely to impair gait function formed the HC group. Subject characteristics are presented in Table 1.

The local Medical Ethics Committee approved the procedures employed in this study. All participants gave written informed consent prior to testing.

Gait analysis

Spatiotemporal gait parameters and compensatory trunk movements of patients undergoing THA were assessed by means of a body-fixed-sensor (BFS)-based gait analysis. Two hybrid triaxial sensor units were used that contained gyroscopes, accelerometers and magnetometers (MTx Motion Tracker, Xsens Technologies B.V.,

Enschede, The Netherlands). Size of these units was 3.8 x 5.3 x 2.1 cm, weight 30 g. One of the sensor units was positioned at the dorsal side of the pelvis between the posterior superior iliac spines. The other sensor unit was positioned on the midline of the upper thorax, just below the spinal process of the seventh cervical vertebra. The BFS were connected with a portable device that was fastened around the waist with a belt (Xbus, Xsens Technologies B.V., Enschede, The Netherlands). This portable device supplied power to the BFS, sampled the BFS data, and transmitted these data in real-time to a Personal Digital Assistant (PDA) by means of a wireless connection (Bluetooth). With this PDA, the researcher could start and stop a measurement as well as manually set markers during data collection. All data were collected with a sample rate of 100 Hz.

All measurements took place in a hospital corridor. Gait analyses were performed preoperatively on the day of admission to the hospital for a THA, and 6 weeks, 3 and 6 months postoperatively. Subjects were instructed to repeatedly walk a distance of 25 m back and forth at a self-selected low, preferred and high walking speed. During these measurements, markers were recorded in an additional measurement channel every time the subject passed the 2.5-m and 22.5-m point of the 25 m. Previous research has shown this gait analysis protocol to be valid and reliable in assessing compensatory trunk movements during gait as well as spatiotemporal gait parameters.¹⁰

Data analysis

Data were transmitted from the PDA to a PC, where the data were processed with Xsens software (MT software version 2.8.5, Xsens Technologies B.V., Enschede, The Netherlands). Next, data were further processed with Matlab (Version 7.0, The Mathworks Inc., Natick, MA, USA). Lindemann et al.¹⁵ recommended excluding gait data from the first 2.5 m of a walking trial in older adults to assess steady state gait. Therefore, gait data from the first and last 2.5 m of the walking trials were excluded. For each walking trial, mean peak-to-peak amplitude of the pelvis and thorax was determined based on 10 subsequent stride cycles. Stride cycles were selected based on initial foot contact as determined from forward pelvic accelerations.¹⁶

The spatiotemporal variables analysed included walking speed, step length and cadence (steps/min). Mean walking speed was determined based on intermarker distance (20 m) and intermarker duration. The peak-to-peak frontal plane range of motion (ROM) of the thorax and the pelvis was determined by calculating the difference between the minimum and maximum angle of the segments. In addition, the ratio of thoracic ROM to pelvic ROM was calculated (thoracic ROM/pelvic ROM). The mean of the back-and-forth walks per instructed walking speed were used for further analysis.

Statistical analysis

To assess whether there are differences in (the development of) several spatiotemporal parameters and compensatory trunk movements between the MISCAS and CON group, generalised estimating equations (GEE) analyses were

performed (exchangeable working correlation structure and robust estimation of the covariance matrix). First, GEE analyses were performed to determine differences between the preoperative measurements of the MISCAS and CON groups and healthy subjects. To correct for differences in patient characteristics, body height and weight were included as covariates in the analyses of the spatiotemporal parameters. Since walking speed may vary between subjects irrespective of the instructed walking speed, walking speed was included as a covariate in the analyses of step length, cadence, pelvic ROM, thoracic ROM, and ratio of thoracic ROM to pelvic ROM. Second, GEE analyses were performed per patient group to determine changes in spatiotemporal parameters and angular movements of the trunk compared to preoperative values. Third, GEE analyses were performed to determine whether there were differences in the development of the outcome variables between the MISCAS and the CON group following THA. The same covariates of the first GEE analyses were included. Additionally, not correcting for preoperative differences between the MISCAS and CON groups can lead to either over- or underestimation of the estimated intervention effect.¹⁷ Preoperative values of the outcome variables were therefore added to the analyses. Post-hoc analyses were performed to determine significant differences in outcome variables between subsequent follow-up measurements. To determine whether there were significant differences in the development of the assessed gait variables over time between both groups, interaction terms (group-by-time interaction) were also added to the GEE analyses. If these interaction terms were statistically significant, they were included in the GEE models. Fourth, to assess whether the patients' gait function had returned to normal values 6 months after surgery, differences between the two patient groups and the healthy control group were assessed by means of a GEE analysis. Walking speed, body height and weight were added to the analyses as covariates. Statistical analysis was done using the PASW software package (version 18, SPSS, Chicago). A p-value of <.05 was considered to be statistically significant.

Results

Descriptive statistics of spatiotemporal parameters and angular movements of the trunk of healthy subjects, MISCAS group and CON group are presented in Table 2. Significant differences in preoperative data between the MISCAS group and CON group and healthy subjects as well as changes in these parameters over time per patient group are indicated in this table. Results of the GEE analyses for differences in the development of spatiotemporal gait parameters and angular movements of the trunk over time between the MISCAS group and the CON group are given in Table 3.

Spatiotemporal parameters

Preoperative values of walking speed, step length and cadence did not significantly differ between the MISCAS group and the CON group. Compared to preoperative values, no differences in walking speed were found in either groups 6 weeks postoperatively (Table 2). From that point in time, walking speed improved

Table 2. Means \pm standard deviations of spatiotemporal parameters and angular movements of the trunk

	HC					CON					MISCAS					
	preoperative	6 weeks postoperative	3 months postoperative	6 months postoperative	preoperative	6 weeks postoperative	3 months postoperative	6 months postoperative	preoperative	6 weeks postoperative	3 months postoperative	6 months postoperative	preoperative	6 weeks postoperative	3 months postoperative	6 months postoperative
Walking speed	Low speed	1.2 \pm 0.1	0.8 \pm 0.2	0.9 \pm 0.2*	1.0 \pm 0.1*	0.8 \pm 0.2 ^a	0.8 \pm 0.2	0.9 \pm 0.2*	0.8 \pm 0.2 ^a	0.8 \pm 0.2	0.9 \pm 0.2*	1.0 \pm 0.2*	0.8 \pm 0.2 ^a	0.8 \pm 0.2	0.9 \pm 0.2*	1.0 \pm 0.2*
	Preferred speed	1.6 \pm 0.2	1.1 \pm 0.2	1.2 \pm 0.2*	1.3 \pm 0.2*	1.1 \pm 0.2 ^a	1.1 \pm 0.2	1.2 \pm 0.2*	1.1 \pm 0.2 ^a	1.1 \pm 0.2	1.2 \pm 0.2*	1.3 \pm 0.1*	1.1 \pm 0.2 ^a	1.1 \pm 0.2	1.2 \pm 0.2*	1.3 \pm 0.1*
	High speed	1.9 \pm 0.2	1.4 \pm 0.3*	1.4 \pm 0.2*	1.5 \pm 0.2*	1.3 \pm 0.3 ^a	1.3 \pm 0.2	1.4 \pm 0.2*	1.5 \pm 0.2*	1.3 \pm 0.3 ^a	1.3 \pm 0.2	1.5 \pm 0.3*	1.6 \pm 0.2*	1.3 \pm 0.2	1.5 \pm 0.3*	1.6 \pm 0.2*
Step length	Low speed	68.6 \pm 8.6	60.0 \pm 9.9	61.3 \pm 8.1	64.0 \pm 5.3*	58.5 \pm 11.1	60.3 \pm 10.3	62.5 \pm 11.4*	58.5 \pm 11.1	60.3 \pm 10.3	62.5 \pm 11.4*	65.2 \pm 11.2*	58.5 \pm 11.1	60.3 \pm 10.3	62.5 \pm 11.4*	65.2 \pm 11.2*
	Preferred speed	79.7 \pm 11.6	68.3 \pm 8.8 ^a	72.7 \pm 7.8*	75.1 \pm 8.5*	67.9 \pm 15.3 ^a	70.3 \pm 11.4	74.7 \pm 12.8*	75.1 \pm 8.5*	70.3 \pm 11.4	74.7 \pm 12.8*	77.4 \pm 9.4*	67.9 \pm 15.3 ^a	70.3 \pm 11.4	74.7 \pm 12.8*	77.4 \pm 9.4*
	High speed	90.5 \pm 11.6	75.3 \pm 11.4	79.9 \pm 11.0*	82.9 \pm 11.1*	76.1 \pm 15.4	76.9 \pm 11.5	83.2 \pm 13.5*	82.9 \pm 11.1*	76.9 \pm 11.5	76.9 \pm 11.5	83.2 \pm 13.5*	88.5 \pm 13.5*	76.1 \pm 15.4	76.9 \pm 11.5	83.2 \pm 13.5*
Cadence	Low speed	102.3 \pm 9.4	87.5 \pm 13.8	90.1 \pm 9.8	90.6 \pm 9.4	87.0 \pm 11.1	80.9 \pm 12.4*	87.1 \pm 8.7	87.0 \pm 11.1	80.9 \pm 12.4*	87.1 \pm 8.7	88.7 \pm 8.6	87.0 \pm 11.1	80.9 \pm 12.4*	87.1 \pm 8.7	88.7 \pm 8.6
	Preferred speed	119.0 \pm 16.4	100.4 \pm 11.4*	101.3 \pm 7.9	101.9 \pm 6.3	100.0 \pm 10.2 ^a	93.9 \pm 12.3*	99.6 \pm 9.6	100.0 \pm 10.2 ^a	93.9 \pm 12.3*	99.6 \pm 9.6	102.5 \pm 9.0*	100.0 \pm 10.2 ^a	93.9 \pm 12.3*	99.6 \pm 9.6	102.5 \pm 9.0*
	High speed	123.6 \pm 11.8	107.1 \pm 10.8	106.4 \pm 8.3	109.9 \pm 8.3*	106.9 \pm 12.6	101.3 \pm 12.9*	105.8 \pm 11.3	109.9 \pm 8.3*	106.9 \pm 12.6	101.3 \pm 12.9*	107.0 \pm 8.9	106.9 \pm 12.6	101.3 \pm 12.9*	105.8 \pm 11.3	107.0 \pm 8.9
Pelvic ROM	Low speed	6.7 \pm 1.3	5.0 \pm 1.4*	4.9 \pm 1.4	5.5 \pm 1.4	4.5 \pm 1.3 ^a	3.7 \pm 1.4*	4.3 \pm 1.5	5.5 \pm 1.4	4.3 \pm 1.5	4.3 \pm 1.5	4.8 \pm 1.4	4.5 \pm 1.3 ^a	3.7 \pm 1.4*	4.3 \pm 1.5	4.8 \pm 1.4
	Preferred speed	8.1 \pm 1.2	5.4 \pm 1.4*	5.7 \pm 1.4*	6.4 \pm 1.3*	4.8 \pm 1.3 ^a	4.2 \pm 1.4*	5.1 \pm 1.4	6.4 \pm 1.3*	4.2 \pm 1.4*	5.1 \pm 1.4	5.6 \pm 1.4*	4.8 \pm 1.3 ^a	4.2 \pm 1.4*	5.1 \pm 1.4	5.6 \pm 1.4*
	High speed	9.5 \pm 1.2	5.7 \pm 1.4*	6.2 \pm 1.4	7.0 \pm 1.4*	5.1 \pm 1.4 ^a	4.5 \pm 1.4	5.7 \pm 1.4*	7.0 \pm 1.4*	4.5 \pm 1.4	5.7 \pm 1.4*	6.2 \pm 1.4*	5.1 \pm 1.4 ^a	4.5 \pm 1.4	5.7 \pm 1.4*	6.2 \pm 1.4*
Thoracic ROM	Low speed	4.4 \pm 1.3	5.7 \pm 1.5*	4.5 \pm 1.5*	4.4 \pm 1.4*	6.0 \pm 1.4 ^a	5.3 \pm 1.5*	5.5 \pm 1.4	4.4 \pm 1.4*	5.3 \pm 1.5*	5.5 \pm 1.4	5.1 \pm 1.4	6.0 \pm 1.4 ^a	5.3 \pm 1.5*	5.5 \pm 1.4	5.5 \pm 1.4
	Preferred speed	4.8 \pm 1.3	5.6 \pm 1.4*	4.7 \pm 1.4*	4.8 \pm 1.4*	5.5 \pm 1.4 ^a	4.8 \pm 1.4*	4.7 \pm 1.4*	4.8 \pm 1.4*	4.8 \pm 1.4*	4.8 \pm 1.4	5.1 \pm 1.4	5.5 \pm 1.4 ^a	4.8 \pm 1.4*	4.8 \pm 1.4	5.1 \pm 1.4
	High speed	5.2 \pm 1.3	5.5 \pm 1.4*	4.7 \pm 1.4*	5.0 \pm 1.4*	5.7 \pm 1.4 ^a	4.6 \pm 1.5*	4.7 \pm 1.4*	5.0 \pm 1.4*	4.6 \pm 1.5*	4.7 \pm 1.4*	5.3 \pm 1.4	5.7 \pm 1.4 ^a	4.6 \pm 1.4*	5.3 \pm 1.4	5.7 \pm 1.4
Ratio ROM	Low speed	0.7 \pm 1.4	1.1 \pm 1.6*	0.9 \pm 1.6*	0.8 \pm 1.6*	1.3 \pm 1.5 ^a	1.4 \pm 1.4	1.3 \pm 1.6	0.8 \pm 1.6*	1.4 \pm 1.4	1.3 \pm 1.6	1.1 \pm 1.4	1.3 \pm 1.5 ^a	1.4 \pm 1.4	1.3 \pm 1.6	1.1 \pm 1.4
	Preferred speed	0.6 \pm 1.3	1.0 \pm 1.6*	0.8 \pm 1.6*	0.7 \pm 1.6*	1.1 \pm 1.6 ^a	1.2 \pm 1.4	1.0 \pm 1.5	0.7 \pm 1.6*	1.2 \pm 1.4	1.0 \pm 1.5	0.9 \pm 1.5*	1.1 \pm 1.6 ^a	1.2 \pm 1.4	1.0 \pm 1.5	0.9 \pm 1.5*
	High speed	0.5 \pm 1.3	1.0 \pm 1.5*	0.8 \pm 1.5*	0.7 \pm 1.6*	1.1 \pm 1.6 ^a	1.0 \pm 1.4	0.9 \pm 1.5	0.7 \pm 1.6*	1.0 \pm 1.4	0.9 \pm 1.5	0.9 \pm 1.4*	1.1 \pm 1.6 ^a	1.0 \pm 1.4	0.9 \pm 1.5	0.9 \pm 1.4*

Values are given as means \pm SD. Note: geometric mean \pm SD are given of the pelvic and thoracic ROM and of the ratio. Abbreviations: HC, healthy control group; CON, conventional THA group; MISCAS, computer-navigated MIS THA group. Thoracic and pelvic ROM are expressed in degrees ($^{\circ}$), walking speed in m/s, step length in cm, and cadence in steps/min.
^a Indicates a significant difference ($p < 0.05$) between preoperative value and healthy subjects; * indicates a significant increase ($p < 0.05$) compared to preoperative value; † indicates a significant decrease ($p < 0.05$) compared to preoperative value.

significantly in both groups. No differences in walking speed were found between the MISCAS group and the CON group (Group effect, Table 3). The development of walking speed was also comparable between both groups, as no significant group-by-time interaction effects were found. During the follow-up period, walking speed increased significantly at all instructed walking speeds (Time effect).

Step length significantly increased compared to preoperative values in both groups 3 and 6 months postoperatively. Overall, step length was larger in the MISCAS group after correction for several covariates, including walking speed and body height. This difference was only statistically significant for walking at low speed (Group effect). No significant group-by-time interaction effects were found, indicating that the development of step length over time was comparable in both groups. No significant changes in step length were found during the follow-up period.

Cadence was comparable in both groups, irrespective of walking speed. The development of cadence was also the same in both groups, as no significant group-by-time interaction effects were found. After correction for several covariates, including walking speed, no significant changes in cadence over time were found.

Frontal plane angular movements of the trunk

The pelvic and thoracic ROM and the ratio were not normally distributed. This problem was solved after a logarithmic transformation of the data. Therefore, the logarithmic transformed data of the pelvic and thoracic ROM and the ratio were used for further analysis.

Preoperatively, pelvic ROM was smaller in the MISCAS group compared to the CON group, though this difference was not statistically significant. Compared to healthy subjects, pelvic ROM was significantly smaller in the MISCAS group as well as in the CON group. Six weeks postoperatively, pelvic ROM was smaller in both patient groups compared to preoperative values, and from that point on it started to increase. Overall, pelvic ROM was smaller in the MISCAS group compared to the CON group, though this difference was not statistically significant (Group effect, Table 3). The development of pelvic ROM over time was also comparable, as no significant group-by-time interaction effects were found. After correction for several covariates including walking speed, significant increases in pelvic ROM were found in both groups between 6 weeks and 3 months postoperatively and between 6 weeks and 6 months postoperatively during walking at a preferred or high speed. Pelvic ROM increased also significantly between 6 weeks and 6 months postoperatively while walking at low speed (Time effect).

Preoperatively, thoracic ROM tended to be larger in the MISCAS group compared to the CON group, though this difference was not statistically significant ($.05 < p < .10$). Significant differences were found between the preoperative thoracic ROM of healthy subjects and both groups. After surgery, thoracic ROM decreased significantly in the CON group while in the MISCAS group it remained comparable to preoperative values, except for walking at low and high speed 6 weeks postoperatively. Overall, thoracic ROM was significantly higher after THA in the MISCAS group during walking at low speed (Group effect). No significant

Table 3. Results of GEE analyses for differences in the development of spatiotemporal gait parameters and angular movements of the trunk over time between the MISCAS THA group and the conventional THA group

	Group effect			Time effect		
	Instructed walking speed	β (95% CI)	P-value	6 wk – 3 months	3 – 6 months	6 wk – 6 months
				β (95% CI)	β (95% CI)	β (95% CI)
Walking speed ^a	Low speed	-0.01 (-0.06, 0.05)	.89	0.09 (0.06, 0.13)	0.05 (0.01, 0.08)	0.14 (0.10, 0.18)
	Preferred speed	0.01 (-0.05, 0.07)	.81	0.14 (0.11, 0.18)	0.06 (0.03, 0.10)	0.21 (0.17, 0.25)
	High speed	0.04 (-0.04, 0.12)	.35	0.18 (0.13, 0.23)	0.10 (0.06, 0.14)	0.28 (0.24, 0.32)
Step length ^b	Low speed	1.9 (0.0, 3.8)	.05	-1.0 (-3.0, 1.0)	0.8 (-0.2, 1.8)	-0.2 (-2.3, 1.9)
	Preferred speed	1.3 (-0.9, 3.5)	.26	-0.3 (-2.2, 1.6)	0.0 (-1.0, 1.1)	-0.3 (-2.3, 1.8)
	High speed	1.6 (-1.0, 4.2)	.22	-0.2 (-3.2, 2.8)	-0.2 (-1.7, 1.3)	-0.4 (-4.1, 3.2)
Cadence ^b	Low speed	-2.2 (-4.7, 0.2)	.08	1.8 (-1.1, 4.7)	-0.8 (-2.3, 0.7)	1.0 (-2.2, 4.2)
	Preferred speed	-1.4 (-4.0, 1.2)	.29	1.2 (-1.2, 3.6)	0.0 (-1.5, 1.6)	1.3 (-1.0, 3.5)
	High speed	-2.5 (-5.5, 0.5)	.10	0.5 (-3.6, 4.6)	0.5 (-1.2, 2.3)	1.1 (-3.4, 5.6)
Pelvic ROM ^c	Low speed	-1.1 (-1.2, 1.1)	.29	1.1 (-1.0, 1.2)	1.1 (-1.0, 1.2)	1.2 (1.0, 1.3)
	Preferred speed	-1.0 (-1.2, 1.1)	.42	1.1 (1.1, 1.2)	1.1 (-1.0, 1.2)	1.2 (1.1, 1.3)
	High speed	-1.1 (-1.2, 1.1)	.34	1.1 (1.0, 1.3)	1.1 (-1.0, 1.1)	1.2 (1.0, 1.4)
Thoracic ROM ^c	Low speed	1.2 (1.0, 1.3)	.005	-1.0 (-1.1, 1.1)	-1.0 (-1.1, 1.1)	-1.0 (-1.2, 1.1)
	Preferred speed	1.1 (-1.0, 1.2)	.17	1.0 (-1.1, 1.1)	-1.0 (-1.1, 1.1)	1.0 (-1.1, 1.1)
	High speed	1.1 (-1.0, 1.2)	.10	1.1 (-1.0, 1.2)	1.0 (-1.0, 1.1)	1.1 (-1.0, 1.2)
Ratio ROM ^c	Low speed	1.3 (1.1, 1.5)	.002	-1.1 (-1.2, 1.1)	-1.1 (-1.2, 1.1)	-1.2 (-1.3, -1.0)
	Preferred speed	1.2 (1.0, 1.3)	.04	-1.1 (-1.2, 1.1)	-1.1 (-1.2, 1.0)	-1.2 (-1.3, 1.0)
	High speed	1.2 (1.0, 1.4)	.01	-1.1 (-1.2, 1.1)	-1.0 (-1.1, 1.1)	-1.1 (-1.2, 1.1)

Reference group: conventional THA group.

^a Adjusted for preoperative values, body height and body weight.^b Adjusted for preoperative values, walking speed, body height and body weight.^c Adjusted for preoperative values and walking speed.Abbreviations: β , regression coefficient; GEE, generalised estimating equations; 95% CI, 95% confidence interval.Thoracic and pelvic ROM are expressed in degrees ($^{\circ}$), walking speed in m/s, step length in cm and cadence in steps/min.

group-by-time interaction effects were found, indicating that the development of thoracic ROM over time was comparable in both groups. During the follow-up period, no significant changes in thoracic ROM were found after correction for several covariates.

Preoperatively, no differences were found in the ratio between the MISCAS group and the CON group. The ratio of healthy subjects was significantly smaller compared to both groups, and had significantly decreased compared to preoperative values 3 and 6 months after conventional THA. In the MISCAS group, the ratio had significantly decreased at 6 months postoperatively compared to preoperative values during walking at preferred and high speed. Overall, the ratio was significantly higher in the MISCAS group (Group effect). No significant group-by-time interaction effects were found, which indicates that the development of the ratio over time was comparable in both groups. There was a trend towards a decreasing ratio in both groups over time after correction for walking speed, though this decrease was only significant between 6 weeks and 6 months after THA for walking at low speed (Time effect).

Comparison with healthy subjects 6 months postoperatively

The results of the GEE analysis to determine whether the patient’s gait function returned to normal values 6 months postoperatively are given in Table 4. Compared to healthy subjects, both patient groups walked significantly more slowly at all instructed walking speeds. After correction for several covariates including walking speed, patients walked with a significantly larger step length, but also with a lower

Table 4. Results of GEE analyses of differences in spatiotemporal gait parameters and angular movements of the trunk 6 months postoperatively between patients and healthy subjects

	Instructed walking speed	Group effect			
		MISCAS THA		Conventional THA	
		β (95% CI)	P-value	β (95% CI)	P-value
Walking speed ^a	Low speed	-0.2 (-0.3, -0.1)	<.001	-0.2 (-0.2, -0.1)	<.001
	Preferred speed	-0.3 (-0.3, -0.2)	<.001	-0.2 (-0.3, -0.2)	<.001
	High speed	-0.3 (-0.4, -0.2)	<.001	-0.3 (-0.4, -0.2)	<.001
Step length ^b	Low speed	3.8 (0.4, 7.3)	.03	3.6 (0.9, 6.3)	.008
	Preferred speed	7.1 (3.3, 10.9)	<.001	7.2 (3.6, 10.7)	<.001
	High speed	7.6 (3.3, 11.8)	.001	5.6 (1.5, 9.7)	.007
Cadence ^b	Low speed	-6.0 (-10.6, -1.3)	.01	-5.8 (-9.6, -1.9)	.003
	Preferred speed	-8.2 (-13.6, -2.8)	.003	-9.1 (-14.3, -3.9)	.001
	High speed	-9.5 (-14.8, -4.2)	<.001	-7.5 (-12.7, -2.4)	.004
Pelvic ROM ^c	Low speed	-1.2 (-1.5, -1.0)	.02	-1.0 (-1.3, 1.1)	.50
	Preferred speed	-1.2 (-1.5, -1.1)	.003	-1.0 (-1.3, 1.0)	.18
	High speed	-1.3 (-1.5, -1.2)	<.001	-1.1 (-1.3, -1.0)	.05
Thoracic ROM ^c	Low speed	1.5 (1.3, 1.8)	<.001	1.2 (1.1, 1.4)	.02
	Preferred speed	1.2 (-1.0, 1.4)	.08	1.1 (-1.1, 1.3)	.21
	High speed	1.2 (-1.0, 1.4)	.06	1.0 (-1.1, 1.2)	.63
Ratio ROM ^c	Low speed	1.8 (1.5, 2.2)	<.001	1.3 (1.0, 1.6)	.03
	Preferred speed	1.5 (1.3, 1.8)	<.001	1.2 (-1.0, 1.6)	.07
	High speed	1.6 (1.3, 1.8)	<.001	1.2 (-1.0, 1.5)	.12

Reference group: healthy control group.

^a Adjusted for body height and body weight.

^b Adjusted for walking speed, body height and body weight.

^c Adjusted for walking speed.

Abbreviations: β , regression coefficient; GEE, generalised estimating equations; 95% CI, 95% confidence interval. Thoracic and pelvic ROM are expressed in degrees (°), walking speed in m/s, step length in cm, and cadence in steps/min.

cadence on all instructed walking speeds.

Pelvic ROM was significantly smaller in the MISCAS group compared to healthy subjects. Pelvic ROM was also significantly smaller in the CON group during walking at high speed. Thoracic ROM was significantly higher while walking at low speed, and borderline significant while walking at preferred and high speed in the MISCAS group. In the CON group, thoracic ROM was significantly larger while walking at low speed. The ratio of thoracic ROM to pelvic ROM was significantly higher in the MISCAS group, irrespective of instructed walking speed. Significant differences in ratio were also found between the CON group and healthy subjects during walking at low speed ($p=.03$). The difference in ratio was borderline significant ($p=.07$) while walking at preferred speed.

Discussion

To the best of the authors' knowledge, this is the first study to evaluate differences in the restoration of physical functioning during recovery following computer-navigated MIS THA compared to conventional THA by means of gait analysis. Not only spatiotemporal parameters but also frontal plane angular movements of the trunk were assessed. This study showed that there were no differences in the recovery of spatiotemporal parameters and angular movements of the trunk during rehabilitation after MISCAS THA or conventional THA. Although gait function improved considerably after surgery, significant differences in several spatiotemporal parameters and angular movements of the trunk remained between both patient groups and healthy subjects.

Spatiotemporal parameters

Gait function improved significantly after THA, irrespective of the surgical technique, yet no differences in the recovery of gait function after MISCAS THA or conventional THA were found. In accordance to literature,⁷ large improvements in walking speed and step length were observed. Overall, step length tended to be larger after MISCAS THA compared to conventional THA. This difference was significant during walking at low speed, and cannot be attributed to differences in body height and walking speed between the patient groups and healthy subjects since corrections were made for these parameters in the statistical analyses. An alternative explanation might be that with the conventional technique, glutei muscles are split and external rotator muscles are cut, which may lead to a decreased motion of the hip joint during gait.¹⁸

There is a lack of well-designed studies on computer-navigated MIS THA.⁶ Also, little research has been done into the recovery of gait function after minimally invasive THA compared to conventional THA⁶, and the few studies that assess recovery of gait function after minimally invasive THA use a wide variety of approaches¹⁹⁻²² or compare two minimally invasive approaches for THA.²³⁻²⁵ The results of these studies are also conflicting. Some studies show no benefit of minimally invasive THA over conventional THA in terms of spatiotemporal parameters like walking speed and step length.^{19,22} However, Mayr et al.²¹ found that, after a minimally invasive anterior approach for THA, cadence, stride length

and walking speed had significantly improved 12 weeks postoperatively, while no significant improvements were found following a conventional anterolateral approach for THA. However, they did not correct for differences in preoperative values of these parameters or other variables that may have influenced the outcome.

Frontal plane angular movements of the trunk

Though pelvic ROM tended to be smaller in the MISCAS THA group, no significant differences were found in pelvic ROM between the two groups. Preoperatively, pelvic ROM was significantly smaller compared to healthy subjects in the MISCAS group and the CON group. Six weeks postoperatively, both groups showed a further decreased pelvic ROM, from which it started to increase gradually. Previous research has demonstrated that pelvic ROM increased with increasing walking speed in healthy subjects.²⁶ In the present study, pelvic ROM increased significantly during rehabilitation, even more than what would be expected because of the observed increase in walking speed. Compared to preoperative values, pelvic ROM was significantly higher 6 months postoperatively in both groups. A decrease in pelvic ROM was found 6 weeks postoperatively, irrespective of surgical technique. No difference in pelvic ROM was found between MISCAS THA and conventional THA.

In the present study, thoracic ROM decreased following THA in both groups. However, thoracic ROM tended to be larger in the MISCAS THA group compared to the CON group, though this difference was only statistically significant while walking at low speed. Despite the fact that randomisation of the surgical technique was performed after stratification based on the Charnley classification,¹⁴ it might be that the MISCAS group consisted of a larger number of patients who, before THA, used compensatory trunk movements during gait, such as a Duchenne limp. Research has demonstrated that patients with hip osteoarthritis use such compensatory trunk movements.⁹ By bending the trunk laterally towards the affected limb during the stance phase, the moment arm between hip and centre of mass of the upper body is shortened, thus lowering the mechanical burden of the hip joint and resulting in pain relief.^{9,12} Because the development of thoracic ROM following THA was comparable after computer-navigated MIS THA and conventional THA, the difference in thoracic ROM might be a remnant of preoperative differences in thoracic ROM. After surgery, when patients no longer experience pain during stance on the affected limb, they could still be using these compensatory movements of the trunk out of habit. One might also argue that patients in the MISCAS THA group do not regain their hip abductor muscle strength after surgery because of surgical damage to these muscles, yet a cadaver study has shown that a minimally invasive anterior technique for THA results in minimal damage to hip abductor muscles.²⁷

This study also demonstrated that the ratio of thoracic ROM to pelvic ROM is a sensitive measure to determine differences in frontal plane angular trunk movements. Previous research has shown that this ratio identifies significant differences between healthy subjects and hip osteoarthritis patients who showed

a Duchenne limp during gait and patients without a clearly visible Duchenne limp.²⁶ This stresses the fact that combining information on frontal plane angular movements of the pelvis and the thorax provides additional information that would otherwise remain undiscovered. Ratio of the ROM was significantly higher in the MISCAS THA group, irrespective of walking speed. Ratio of the ROM also tended to decrease following THA, and no differences were found in the postoperative development of the ratio between the MISCAS group and the CON group.

Comparison with healthy subjects 6 months postoperatively

Six months after THA, all patients still walked at a significantly lower walking speed compared to healthy subjects, irrespective of the instructed walking speed. Their step length and cadence was also lower compared to healthy subjects without correction for several covariates including walking speed. Previous studies have shown that deviations in spatiotemporal parameters persist up to one year after THA.^{28,29} These studies also found a persistent decrease in walking speed, shorter step length and higher cadence compared to healthy controls. However, the present study showed that, after correction for walking speed and body height, patients' step length was significantly larger compared to healthy subjects. Also, cadence (steps/min) was significantly lower. This difference in findings might therefore be due to the fact that in these earlier studies no corrections were made for body height and walking speed.

Patients after MISCAS THA tended to maintain a decreased pelvic ROM at 6 months following surgery, compared to healthy subjects. This 'stiff' gait with little motion of the pelvis in the frontal plane was also observed in other studies on patients 6 months following THA.^{18,28} Compared to healthy subjects, thoracic ROM was also larger, mainly in patients following MISCAS THA. Consequently, the ratio of thoracic ROM to pelvic ROM was significantly different from that of healthy subjects in the MISCAS THA group. As stated above, these differences might be remnants of preoperative differences, because the trends in pelvic and thoracic ROM over time are the same following computer-navigated MIS THA and conventional THA.

Conclusion

No evidence was found for a faster recovery of gait function following computer-navigated MIS THA. Although patients undergoing THA had considerably improved their gait function 6 months following surgery, small differences remained compared to healthy subjects. Furthermore, this research demonstrated the importance of assessing not only spatiotemporal parameters but also compensatory trunk movements during gait in patients following THA.

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Chapter 8

General Discussion



Introduction

Main objective of this thesis was to assess the effectiveness of computer-navigated minimally invasive total hip arthroplasty (THA). To gain insight into the scientific evidence of the effectiveness of minimally invasive (MIS) THA, computer-navigated (CAS) THA and computer-navigated MIS THA, a qualitative and systematic review of the orthopaedic literature was conducted (Chapter 2). Next, a randomised controlled trial was designed to assess the effectiveness of computer-navigated MIS THA (Chapter 3). The effectiveness of computer-navigated MIS THA compared to conventional THA was evaluated by means of clinical outcome measures, self-reported questionnaires on physical functioning and health-related quality of life, and by means of gait analysis (Chapters 6 and 7).

The second objective of this thesis was the development of a body-fixed-sensor (BFS)-based gait analysis method with which insight into gait function, including compensatory movements of the trunk during gait, of patients with osteoarthritis (OA) of the hip before and after THA can be assessed objectively during walking outside a laboratory setting under real-life conditions. Research was conducted into the accuracy and reproducibility of the BFS-based gait analysis method (Chapter 4). Next, spatiotemporal gait parameters and compensatory movements of the trunk of patients with end-stage hip OA who showed a Duchenne limp during gait were compared to healthy subjects and patients without a Duchenne limp (Chapter 5). This BFS-based gait analysis method was subsequently used to assess objectively whether computer-navigated MIS THA provided beneficial effects on functional recovery compared to conventional THA (Chapters 6 and 7).

The present chapter provides an overview and discussion about the main findings of the research presented in this thesis. First, the RCT into the effectiveness of computer-navigated MIS THA compared to conventional THA is discussed, and limitations of the conducted RCT will be identified. Second, the BFS-based gait analysis method will be discussed in the light of its potential contribution to clinical assessment of gait function in patients with hip OA before and after THA. Limitations of the developed BFS-based gait analysis method will also be given. Finally, clinical implications and suggestions for future research are given.

Computer-navigated MIS THA

The systematic review underlined the need for further clinical research to assess the effectiveness of computer-navigated MIS THA (Chapter 2). Our research into the effectiveness of computer-navigated MIS THA compared to conventional THA showed that computer-navigated MIS THA resulted in a shorter length of stay despite an increase in surgical time and blood loss. Furthermore, by using computer navigation an accurate placement of the prosthesis was assured. No difference in number of complications was found (Chapter 6), and no evidence was found for a faster recovery of physical functioning after computer-navigated MIS THA (Chapters 6 and 7).

Our systematic review demonstrated a lack of studies on the effectiveness of computer-navigated MIS THA. Discussing the findings of our RCT in the light

of existing literature on computer-navigated MIS THA was thus not possible. The findings will therefore be discussed in the light of existing literature on MIS THA and CAS THA.

MIS THA

MIS THA continues to be of interest to both patients and orthopaedic surgeons because of the claimed benefits of less soft-tissue trauma, less pain, shorter hospital stay, quicker return to function, and better cosmetic appearance. Some issues remain to be subject to debate though. One of these issues regards the definition of a 'minimally invasive' surgical technique for THA. Clearly, there are differences between using a surgical technique intended to gain access to the hip joint through less soft-tissue dissection and using intermuscular planes, and performing the conventional procedure through a smaller skin incision with the same amount of damage to the underlying soft tissues as with the conventional technique. A more proper term for the latter is 'mini-incision', since the only difference with the conventional technique is length of the skin incision. In any case, it is important to make a distinction between those categories of MIS THA.¹ According to the above stated definition is the in our RCT investigated computer-navigated MIS THA technique a real minimally invasive technique, since intermuscular planes were used, thereby avoiding muscle damage.

Secondly, there are various minimally invasive surgical approaches for THA, such as minimally invasive posterior, posterolateral, anterolateral, anterior, and two-incision approaches. The levels of evidence regarding the effectiveness of these approaches are also diverse.² It remains relatively unclear whether good outcomes can be attributed to the minimally invasive surgical techniques themselves or if they are due to strict patient selection, advanced anaesthesia protocols, patient-education interventions, or rapid rehabilitation protocols. Caution is therefore advised when interpreting and generalising outcomes of (different approaches for) MIS THA. In our RCT on the effectiveness of computer-navigated MIS THA compared to conventional THA, the anaesthetic, analgesic and postoperative physical therapy protocols during hospital stay were identical in both groups.

Some have suggested that MIS THA may provide economic benefits due to earlier discharge from the hospital and prompter return to normal daily activities including work, as MIS THA leads to a quicker recovery. Duwelius et al.³ conclude that MIS THA provides economic benefits because of a shortened length of hospital stay and a reduction in overall hospital costs. Not only hospital savings but also savings from a societal perspective – i.e. medical costs outside the hospital (including physiotherapy, visits to general practitioners, nursing care and medication) and other nonmedical costs (e.g. absence from work) – should be included. A cost-effectiveness analysis was conducted by the Canadian Agency for Drugs and Technologies in Health to compare the cost-effectiveness of MIS THA and conventional THA.⁴ The results of this study demonstrated little difference between the techniques in costs and quality-adjusted life-years (QALY) gained. De Verteuil et al.⁵ also investigated the cost-effectiveness of MIS THA. MIS THA was less costly and provided slightly more QALYs gained, therefore dominating

conventional THA in both short-term and long-term analyses. Main findings were a decreased length of hospital stay, shorter operation duration and a 1-month earlier return to daily activities following MIS THA. A shorter hospital stay was also found in our RCT. The results also showed a longer operation duration, but it must be mentioned that in our RCT computer navigation was used during MIS THA which may explain the difference in results compared to the findings of De Verteuil et al.⁵

Since long-term results, such as risk of revision, are not yet available for MIS THA, the uncertainty of the long-term results is substantial. Given that limited visibility of anatomical landmarks and vital structures is considered a major drawback of MIS THA,⁶ one may argue that the risk of revision of the hip prosthesis, because of malpositioned prosthesis components, might be higher following MIS THA. The use of assistive devices to enhance the accuracy of hip prosthesis alignment during MIS THA might thus be inevitable.

CAS THA

It is increasingly recognised in the orthopaedic community that the use of computer navigation is necessary during minimally invasive techniques for total joint arthroplasty.^{7,8} The results of our RCT underline this notion; by using computer navigation during MIS THA, the prosthesis components were as accurately aligned as with the conventional technique for THA. In orthopaedic surgery there is a well-recognised link between accurate alignment of prosthesis components and clinical outcome. Higher rates of pelvic osteolysis, asymmetric wear and component migration have been observed when the prosthesis components are malaligned.⁹ Wear particles can induce a biological response leading to periprosthetic bone loss and aseptic loosening of the prosthesis¹⁰, leading to early revision of the prosthesis.

Most surgeons use mechanical alignment guides provided by the manufacturer of the hip prosthesis. These mechanical alignment guides have shown clear limitations in terms of accuracy and precision of proper alignment of the hip prosthesis.¹¹ As a result, the interest in computer navigation systems is increasing. Computer navigation systems allow accurate intraoperative measurement and real-time surgical feedback. Research has shown that, even in the hands of an experienced surgeon, prosthesis positioning can be improved by using computer navigation during surgery.¹²⁻¹⁴ There is also evidence that experienced surgeons' accuracy in prosthesis positioning by freehand may improve after using computer navigation during surgery.¹³ Furthermore, there are indications that the use of computer navigation reduces the learning curve in joint arthroplasty.^{15,16}

At present, computer navigation is not commonly used during total joint arthroplasty, due to the fact that current computer navigation systems may involve longer operation times. Other factors that limit the broad application of CAS are costs and complexity of computer navigation systems. In a survey of orthopaedic surgeons to collect their opinions on the use of computer navigation systems during total joint arthroplasty, lack of money was cited to be the main barrier faced by surgeons when wanting to change the equipment they used.¹⁷ This notwithstanding, as the evidence-based argument to use computer navigation during THA is becoming stronger because scientific evidence on higher levels of

accuracy associated with navigation techniques is growing, the number of CAS THA procedures is gradually increasing.

Although the added value of using computer navigation during conventional THA is apparent, its potential to enhance the accuracy of MIS THA is even more evident. Accordingly, one might expect that by using computer navigation during MIS THA the alignment of the prosthesis components would always be more accurate than by freehand during conventional THA. However, the results of our RCT demonstrated that the alignment of prosthesis components during computer-navigated MIS THA was just as accurate as by freehand during conventional THA.

Limitations

A few limitations of the RCT into the effectiveness of computer-navigated MIS THA compared to conventional THA need to be addressed. The first is the number of patients included in the study. The intended number of 120 patients was not reached. Despite the fact that the inclusion period was prolonged, it remained difficult to find eligible patients. The initial time frame of the inclusion period was based on historical data for the years 2000–2003 from the department of Orthopaedics of the University Medical Center Groningen. However, the patient population has changed since then. A few years ago, the Dutch government stipulated that the system for registration and invoicing of treatments in hospitals would be changed. Since then, hospitals have worked with Diagnosis Treatment Combinations (DTC) and charge on this basis. A DTC can be defined as a combination of all activities of a hospital and a medical specialist that arise from the patient's request for medical treatment, with a fixed price. Accordingly, a trend became visible in recent years of general hospitals tending to refer patients with multiple health problems to more specialised hospitals such as university medical centres. This increase in complex patients led to a decrease in the number of relatively physically fit patients. This has in turn led to a decrease in the number of eligible patients for the RCT. However, despite this smaller sample size, the research presented in this thesis has resulted in significant findings.

Second, the effects of computer-navigated MIS THA in the early recovery period, i.e. during the first weeks following discharge from the hospital, have not been assessed in the RCT. Based on what was known in the scientific literature on the potential benefits of MIS THA, it was expected that these benefits would be visible in the postoperative period between 6 weeks and 3 months. Following computer-navigated MIS THA, hospital stay was shorter but no differences were found between the effect of surgical technique on physical functioning at 6 weeks and 3 months postoperatively. It can therefore be argued that the beneficial effect of computer-navigated MIS THA on the recovery of physical functioning might have taken place in the period between surgery and 6 weeks postoperatively. The long-term results have also not been assessed, because the beneficial effects of computer-navigated MIS THA were expected in the postoperative period between 6 weeks and 3 months, and our hypothesis was that the outcome after computer-navigated MIS THA and conventional THA would be comparable at 6 months postoperative. Main purpose of long-term follow-up after THA would be to assess

whether problems arise due to potential malpositioning, loosening or wear of prosthesis components. In the present study, prosthesis alignment was assured because computer navigation was used during the minimally invasive technique for THA. Moreover, the same type of hip prosthesis was placed in both study groups.

Body-fixed-sensor based gait analysis for the assessment of physical functioning

The research presented in this thesis demonstrated that not only spatiotemporal parameters such as speed, step length and step duration can be accurately and reliably assessed with BFS-based gait analysis, but also compensatory trunk movements during gait such as a Duchenne limp, when an extended sensor configuration is used (Chapter 4).

In patients with end-stage hip OA as well as in healthy subjects, distinctive patterns of trunk movements during gait could be objectively quantified by means of BFS-based gait analysis (Chapter 5). This research has emphasised that to gain full insight into compensatory movements of the trunk, both angular movements of the pelvis and the thorax should be determined. Moreover, the ratio of the range of motion of thorax to pelvis was shown to be a sensitive measure to distinguish between patterns observed in healthy subjects and in hip OA patients with and without a clearly visible Duchenne limp.

Next, the BFS-based gait analysis method was used to assess whether the recovery of physical functioning following THA was different between patients who underwent MISCAS THA or a conventional technique for THA (Chapter 7). Gait function was assessed preoperatively and 6 weeks, 3 months and 6 months after surgery. No evidence was found for a faster recovery of gait function following computer-navigated MIS THA. Although both patient groups significantly improved their gait function, small differences remained compared to healthy subjects at 6 months following THA.

At present, BFS-based gait analysis methods are mainly used in research to determine effectiveness of various (surgical) interventions on physical functioning.^{18,19} The primary reason for the lack of utilisation of gait analysis in clinical practice is the lack of evidence demonstrating that functional outcomes are improved as a direct result of gait analysis.²⁰ As the emphasis on evidence-based practice is increasing, the need for objective, quantitative methods to demonstrate effectiveness of treatment is also growing. BFS-based gait analysis methods, like the method developed in the research presented in this thesis, are highly applicable in real-life (non-laboratory) settings. In clinical practice, BFS-based gait analysis methods can be used as initial assessment tools or to monitor progress during and after rehabilitation. Additionally, results of gait assessments can be used to make adjustments to the rehabilitation protocol in order to enhance recovery of gait function.

Since BFS units are placed on the trunk, there is little to no interference with gait which facilitates unconstrained walking. Furthermore, by attaching BFS on one or more body segments (e.g. trunk, thigh, and shank), the body posture at rest (i.e. standing, sitting, and lying) can be recognised.²¹ Therefore, BFS-based assessments

of physical functioning can be made over longer periods of time, so that insight can be gained not only into the type of physical activity but also the duration and intensity of that activity.

Limitations

Several robust parameters of gait function such as walking speed, step length and cadence can be easily and objectively assessed in a clinical setting with the BFS-based gait analysis method. Compensatory trunk movements during gait, such as a Duchenne limp, can be objectified with this method. However, the presented BFS-based approach is useful for identifying gait abnormalities rather than for an in-depth analysis of underlying mechanisms of impairments in gait function. With respect to a Duchenne limp, the exact underlying link between hip joint moments, muscle activity and pain cannot be discovered with the BFS-based gait analysis method. A more in-depth gait analysis may be needed to that end. Gait laboratories are usually equipped with camera-based gait analysis systems which can be extended with force plates and electromyography so that more complex data on kinematics, kinetics, electromyography and energy consumption can be obtained. These gait laboratories are very useful for gaining insight into underlying mechanisms of impairments in gait function, but their applicability in clinical settings is low.

In research presented in this thesis, gait analyses were performed on patients with hip OA before, and at 6 weeks, 3 months and 6 months after THA. With this design, insight was gained into the restoration of gait function over a period of time. The assumption has been made that, since walking is an important aspect of functional status, improvements in gait function are indicative of improvements in functional status. Whether patients following THA become physically active again and whether they resume performing activities of daily living has not been objectively investigated though. Therefore, research not only into gait function following THA but also into the type, frequency and intensity of physical activity, and especially activities of daily living, is needed.

Clinical implications

Clinical implications of the findings of the RCT into the effectiveness of computer-navigated MIS THA as well as the results regarding the BFS-based gait analysis method are presented below.

Improvements in (peri-)operative care of THA

In the last decade, many developments have taken place in surgical techniques and assistive surgical devices to improve clinical outcome following THA. MIS THA, CAS THA, and computer-navigated MIS THA are promising developments to optimise surgical outcome and accurate alignment of the prosthesis components. Another evolution of so-called fast-track surgery has taken place. This is a multimodal approach that incorporates not only surgeons but also anaesthesiologists, nurses and physical therapists as active participants of the care team. Fast-track surgery focuses on enhancing recovery and reducing morbidity by implementing

evidence in the fields of anaesthesia, analgesia, reduction of surgical stress, fluid management, minimally invasive surgery and nutrition.²² These principles have also been implemented in the perioperative care of THA. A fast-track THA programme usually consists of patient education, adapted analgesic protocols, nutritional screening and fastened patient mobilisation.²³⁻²⁶ With a fast-track programme the length of hospital stay can be significantly reduced²⁴ therefore embedding computer-navigated MIS THA in such a programme might optimise its beneficial effects.

Physical therapy before and after THA

A certain amount of damage to soft tissues and muscles is intrinsic to THA. It is likely that the surgical damage of THA can be no further reduced than that caused by means of THA performed with a minimally invasive surgical technique. There seems however to be room for improvements to patients' physical condition before and after THA. And although the results of minimally invasive surgery for THA are promising, one must bear in mind that MIS THA may not be suitable for every patient and that the younger, physically fitter patient might profit the most from MIS THA. Clinical evidence suggests that physically fit patients generally recover more quickly after surgery compared to patients who are less physically fit. Enhancing the preoperative physical status of the less-fit patients by means of physical therapy might therefore be rewarding.²⁷⁻²⁹

In the end, these initiatives are aimed at enhancing postoperative functional recovery, so it is important to retain benefits gained in the pre- and perioperative period after hospital discharge in order to speed up the return to normal daily functioning. Intensive physical therapy during the first weeks after discharge might help achieve this goal. Bulthuis et al.³⁰ demonstrated that an intensive physical therapy programme of 3 weeks directly following hospital discharge resulted in significantly better physical functioning compared to usual care, with positive effects present until 6 months after discharge. By tailoring physical therapy to the specific needs and physical problems of the patient, recovery of physical functioning would be further enhanced.

When a patient is fully recovered after THA it is important to maintain a physically active lifestyle, since physical activity results in increased bone density, which improves prosthesis fixation and thereby reduces the risk of loosening.³¹ Research has shown that physical activity increases after THA compared to the preoperative physical activity level.³² However, one year after THA a considerable number of patients were found to be insufficiently physically active.³³ Hence, there is a need for interventions to promote physical activity behaviour of patients after THA.

Body-fixed-sensors and physical therapy

BFS-based gait analysis methods can be used as initial assessment tools and as tools for monitoring progress during and after rehabilitation. Tailoring of physical therapy can be done based on objective information on specific impairments in the patient's gait function, assessed with BFS. Another application of BFS methods is to

use them as a biofeedback system during physical therapy to improve gait function. Biofeedback is a technique that typically uses electronic equipment to provide a patient with auditory signals, visual signals, or both about internal physiological events. During biofeedback for gait rehabilitation patients are provided with additional sensory information on their own movements (e.g. kinematics, kinetics and electromyography). Biofeedback also provides clinicians with a useful tool to give patients instructions on how to modify movement patterns. A major advantage of biofeedback is that the feedback is provided instantaneously, whereas methods of external feedback (e.g. verbal and video feedback) are provided some time after the movement.³⁴ Andriacchi³⁵ proposed that persons with joint pathologies of the lower limb develop compensatory gait patterns that become habitual over time. Biofeedback might therefore be useful in gait rehabilitation following THA in order to relearn normal gait patterns, in particular normal angular movements of the trunk during gait. Hunt et al.³⁶ demonstrated that the use of biofeedback to control the amount of trunk lean during gait retraining in patients with knee OA is successful. For biofeedback they used a camera-based gait analysis system that was bound to a gait laboratory. Previous research has demonstrated the feasibility of BFS as a wireless real-time auditory or visual biofeedback system during interventions to enhance balance and gait function in patients with various mobility disorders.^{37,38}

Recommendations for future research

Ideas for future research, with two main directions, have emerged from this work: improving outcome following THA, and fields of application of BFS.

Improving outcome following THA

Embedding computer-navigated MIS THA in a fast-track programme and combining it with intensive pre- and postoperative physical therapy regimes seem clinically sound developments to improve outcome following THA. However, scientific evidence for its effectiveness is scarce. Research is needed not only into the clinical effectiveness but also into the cost-effectiveness of intensive physical therapy regimes in combination with fast-track computer-navigated MIS THA. An economic evaluation from a societal perspective is recommended,³⁹ in which not only the direct medical costs are assessed but also medical costs outside the hospital (visits to general practitioners, nursing care) and other nonmedical costs (e.g. absence from work).

It is expected that, in the near future, more members of the working population will be undergoing THA due to the facts that more people undergo THA at a younger age, the number of elderly persons in Western society is increasing, and that people are retiring at an older age. So far, little is known about the effectiveness of THA on level of participation, either in work or socially. Only one recent study⁴⁰ has investigated the effect of THA on employment, other studies^{41,42} were conducted more than 15 years ago. More research is thus needed into the effectiveness of THA on regaining participation in both employment and social functioning.

There has been a lack of interventions promoting physical activity behaviour following THA. Such interventions should be aimed at enhancing physical activity during different aspects of daily life. Attention must be given not only to becoming more physically active during activities of daily living and during free time, but also to becoming more physically active at work.

Fields of application of BFS

Several applications of BFS in the field of physical therapy have been suggested earlier in this chapter. One suggested application is to use BFS-based gait analysis for monitoring progress as well as tailoring the physical therapy regime following THA. So far, little is known about using BFS-based gait analysis in a structural manner during physical therapy following THA. Research is needed to assess the feasibility and effectiveness of BFS-based gait analysis as part of the rehabilitation process of patients following THA. Another application is to extend the BFS configuration proposed in this thesis so that it can be used as a biofeedback method. Research is thus needed into the feasibility and effectiveness of BFS-based biofeedback methods in a gait rehabilitation programme focused on compensatory movements of the trunk during gait in patients following THA.

Recent years have witnessed a growing interest in the use of BFS-based physical activity monitors. Postural transitions (sit-to-stand and stand-to-sit), dynamic activity (walking) and static behaviour (sitting, standing, lying) can be identified by means of BFS, and measurements can be made over longer periods of time.^{21,43} Physical activity during activities of daily living as well as during sports activities can therefore be objectively determined by means of BFS. The third proposed application is the use of BFS-based physical activity monitors to objectively quantify physical activity behaviour following THA. Little is known about physical activity behaviour of patients following THA.^{32,33} In general, self-reported questionnaires are used to gain insight into physical activity behaviour,⁴⁴⁻⁴⁶ but patients following THA tend to overestimate their level of physical activity.⁴⁷ To this end, BFS could be applied as activity monitor to assess physical activity behaviour at home as well as during leisure-time activities and during work. Activity monitoring by means of BFS is also highly suitable for home-based interventions to enhance physical activity behaviour. Future research is needed to investigate the feasibility of a home-based intervention with BFS-based activity monitors for the promotion of physical activity behaviour in patients after THA.

Concluding remarks

Research presented in this thesis has provided insight into the effectiveness of computer-navigated MIS THA compared to conventional THA. Although evidence has been found for the effectiveness of computer-navigated MIS THA on several aspects of clinical outcome, the proposed beneficial effect of computer-navigated MIS THA on recovery of physical functioning remains to be proven. The developed BFS-based gait analysis method shows high potential for use in a clinical setting to objectively determine gait function of patients with hip OA before and after THA.

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A detailed botanical illustration of a plant stem. The upper portion of the stem is covered in a dense, grid-like pattern of small, square or rectangular cells, resembling a mesh or a specific type of bark. Below this, the stem becomes more irregular and bulbous, with several rounded, protruding sections that resemble nodes or specialized growths. The overall appearance is that of a thick, woody stem with complex, rounded structures. The word "Summary" is printed in a bold, black, sans-serif font on the right side of the image, overlapping the stem's structure.

Summary

Total hip arthroplasty (THA) is one of the most successful orthopaedic interventions of the past 40 years. The concept of minimally invasive surgery (MIS) was introduced recently in the orthopaedic community, leading to the development of minimally invasive techniques for THA. Computer-assisted surgery (CAS) has also gained popularity, since it helps the surgeon to precisely visualise and target the surgical site, which may improve the accuracy of orthopaedic procedures. Using computer navigation during MIS THA was therefore a sensible next step to take. However, little research has been done into the effectiveness of computer-navigated MIS THA.

This thesis encompasses two objectives. The main objective is to assess the effectiveness of computer-navigated MIS THA compared to conventional THA. The second objective is the development of a body-fixed-sensor (BFS) based gait analysis method through which insight can be obtained into the gait function, including compensatory trunk movements during gait, of patients with hip osteoarthritis (OA) before and after THA.

Chapter 2 describes a qualitative and systematic review of the literature on the effectiveness of MIS THA, CAS THA and computer-navigated MIS THA. Eighteen studies on MIS THA and seven studies on CAS THA were included. No studies on computer-navigated MIS THA were identified. The results of this review indicate that MIS THA is a safe surgical procedure, without increases in surgical time, blood loss, or complications, and with a similar component positioning compared to conventional THA. However, the surplus value of MIS THA over the conventional procedure in terms of a faster recovery of physical functioning remains to be proven. No difference in complication rates was found after CAS THA or the conventional procedure, though CAS THA resulted in higher surgical time. More importantly, the use of computer navigation results in better positioning of the hip prosthesis. Additionally, this review underlines the lack of well-designed studies on the effectiveness of computer-navigated MIS THA.

Chapter 3 describes the design of a randomised controlled trial (RCT) into the effectiveness of computer-navigated MIS THA compared to conventional THA. Patients between the ages of 18 and 75 admitted for primary cementless unilateral THA are included. Patients were randomly allocated to undergo computer-navigated MIS THA or conventional THA. Surgical time, operative blood loss, intra- and postoperative complications and length of hospital stay were recorded. Radiographic evaluation of the prosthetic position took place 6 weeks postoperatively. Physical functioning was assessed preoperatively, and 6 weeks, 3 months and 6 months postoperatively by means of self-reported questionnaires and by gait analysis. The results of the study are reported in Chapter 6.

The next two chapters of this thesis address research into the development of a BFS-based gait analysis method. Such an approach serves to obtain compensatory movements of the trunk, such as a Duchenne limp, as well as spatiotemporal gait parameters during unconstrained walking outside a laboratory setting.

In **Chapter 4** the accuracy and reliability of this BFS-based gait analysis method for quantifying compensatory trunk movements and spatiotemporal gait parameters in patients with hip OA are presented. To evaluate accuracy, angular movements of sensors attached to thorax and pelvis of 3 patients were compared with results based on an optical motion analysis system (OMAS). Accuracy was high, with small and consistent mean differences ($< 1.0^\circ$) and corresponding standard deviations ($< 1.3^\circ$) between OMAS and BFS data. To evaluate reproducibility, angular trunk movements were assessed twice in 15 patients. Reproducibility was excellent (ICCs ranged from 0.86 to 0.97) and the values of the mean differences between test and retest were small with the 95% CI containing zero. It was concluded that this BFS-based assessment is an accurate and reproducible method for quantifying frontal plane compensatory trunk movements during gait at different walking speeds of patients with hip osteoarthritis.

In **Chapter 5** compensatory trunk movements during gait in patients with hip OA were quantified outside a laboratory setting, using the BFS-based gait analysis method. Frontal plane angular movements of the pelvis and thorax and spatiotemporal gait parameters of patients who showed a Duchenne limp were compared to healthy subjects and patients without a distinct Duchenne limp. Distinctive patterns of frontal plane angular trunk movements during gait could be objectively quantified in healthy subjects and in hip OA patients. The ratio of thoracic ROM to pelvic ROM appeared to be a powerful measure to distinguish between the patterns observed in healthy subjects and in hip OA patients with and without a clearly visible Duchenne limp. No differences in spatiotemporal parameters were found after correction for differences in walking speed. The findings of this study suggest that frontal plane angular trunk movements should be included in clinical gait assessments of patients with hip OA.

Next, the results of the RCT into the effectiveness of computer-navigated MIS THA compared to conventional THA are presented in **Chapter 6**. Seventy-five patients were randomly allocated to undergo computer-navigated MIS THA ($n=35$) or conventional THA ($n=40$). Anaesthetic, analgesic and postoperative physiotherapy protocols were similar in both groups. Discharge criteria were also identical. Next to surgical outcome, physical functioning was assessed preoperatively, and 6 weeks, 3 months and 6 months postoperatively by means of a self-reported questionnaire and gait analysis. Surgical time and blood loss were significantly higher during computer-navigated MIS THA. Average length of stay however was significantly shorter after computer-navigated MIS THA (5.2 ± 1.9 days) compared to conventional THA (6.9 ± 2.1 days). No difference in complication rate was found. By using computer navigation during MIS THA, an accurate placement of the prosthesis was assured. No differences in measures representing (the recovery of) physical functioning after MIS THA or conventional THA were found.

Chapter 7 contains a more in-depth analysis of the restoration of gait function after computer-navigated MIS THA and conventional THA, evaluated with the BFS-based gait analysis method. Gait analysis was performed preoperatively and 6 weeks, 3 months and 6 months postoperatively. Walking speed, step

length and cadence as well as frontal plane angular trunk movements were assessed. To determine whether gait function was returned to normal 6 months postoperatively, a comparison with gait function of healthy subjects (n=30) was made. No differences were found in the recovery of spatiotemporal parameters, nor was there any difference in angular movements of the pelvis and the thorax following MISCAS THA or conventional THA. Although gait function improved after surgery, small differences in several spatiotemporal parameters and angular movements of the trunk remained 6 months postoperatively between both patient groups and healthy subjects.

The general discussion in **Chapter 8** provides an overview and discussion about the main findings of the research presented in previous chapters. Although evidence was found for the effectiveness of computer-navigated MIS THA on several aspects of clinical outcome, the proposed beneficial effects of computer-navigated MIS THA on the recovery of physical functioning remain to be proven. Hospital stay was shorter following computer-navigated MIS THA but no differences in physical functioning between computer-navigated MIS THA and conventional THA were found 6 weeks and 3 months postoperatively. It can therefore be argued that the beneficial effect of computer-navigated MIS THA on the recovery of physical functioning might have taken place between discharge from the hospital and the first postoperative measurement 6 weeks postoperatively. Hence to quantify these effects, earlier measurements of physical functioning might be necessary. Furthermore, the developed BFS-based gait analysis method showed high potential for use in a clinical setting to objectively determine gait function of patients with hip osteoarthritis before and after THA.

Several clinical implications of computer-navigated MIS THA are given, such as embedding computer-navigated MIS THA in a so-called 'fast-track' programme to optimise its beneficial effects. To retain these benefits after hospital discharge in order to speed up a return to normal daily functioning, additional physical therapy is recommended. Moreover, promoting a physically active lifestyle after THA is important. BFS can play a role in physical therapy following THA as well as in promoting a physically active lifestyle.

In the general discussion it is emphasised that further research is needed into the clinical effectiveness and cost effectiveness of computer-navigated MIS THA and physical therapy to enhance the recovery of physical functioning and physical activity behaviour after THA. Further research is also needed into the feasibility and effectiveness of applying BFS as part of the rehabilitation process of patients following THA as well as using BFS as physical activity monitors.

A black and white micrograph showing a cross-section of a plant stem. The vascular bundles are arranged in a ring. A prominent vascular cambium is visible, forming a large, circular, shaded area. The cambium is producing secondary xylem on the inner side and secondary phloem on the outer side. The primary xylem is located towards the center, and the primary phloem is towards the periphery. The text "Samenvatting" is overlaid on the image.

Samenvatting

De totale heupartroplastiek (THA) is een van de meest succesvolle orthopedische ingrepen van de laatste 40 jaar. Het concept van minimaal invasieve chirurgie (MIS) is recentelijk geïntroduceerd in de orthopedische gemeenschap, hetgeen heeft geleid tot de ontwikkeling van minimaal invasieve technieken voor THA. Computer genavigeerde chirurgie (CAS) wordt tevens vaker toegepast aangezien het de chirurg ondersteunt bij het in kaart brengen van het operatie gebied, waardoor de nauwkeurigheid van orthopedische ingrepen vergroot kan worden. Het gebruik van computernavigatie tijdens MIS THA is daarom een logische volgende stap. Er is echter weinig onderzoek gedaan naar de effectiviteit van computer genavigeerde MIS THA.

In dit proefschrift staan twee doelstellingen centraal. De hoofddoelstelling is het vaststellen van de effectiviteit van computer genavigeerde MIS THA in vergelijking met conventionele THA. De tweede doelstelling is de ontwikkeling van een gangbeeldanalyse methode op basis van body-fixed-sensors (BFS), waarmee inzicht verkregen kan worden in de loopfunctie, inclusief compensatoire rompbewegingen tijdens lopen, van patiënten met heupartrose vóór en na THA.

Hoofdstuk 2 beschrijft een kwalitatieve en systematische review van de literatuur over de effectiviteit van MIS THA, CAS THA en computer genavigeerde MIS THA. Achttien artikelen over MIS THA en 7 artikelen over CAS THA zijn geïnccludeerd. Er zijn geen artikelen over computer genavigeerde MIS THA gevonden. De resultaten van deze review laten zien dat MIS THA een veilige ingreep is zonder toename in operatietijd, bloedverlies, complicaties en met een vergelijkbare positionering van de prothesecomponenten in vergelijking met conventionele THA. Echter, de meerwaarde van MIS THA in vergelijking met conventionele THA wat betreft snelheid van herstel van het fysiek functioneren moet nog worden aangetoond. Het aantal complicaties verschilde niet tussen CAS THA en conventionele THA, ondanks dat de operatietijd langer was tijdens CAS THA. Nog belangrijker, het gebruik van computernavigatie resulteerde in een betere positionering van de prothese. Tenslotte onderschrijft deze review het tekort aan goed opgezette studies naar de effectiviteit van computer genavigeerde MIS THA.

Hoofdstuk 3 beschrijft de opzet van een gerandomiseerde gecontroleerde trial (RCT) naar de effectiviteit van computer genavigeerde MIS THA in vergelijking met conventionele THA. Patiënten met een indicatie voor een primaire unilaterale ongecementeerde THA en een leeftijd tussen de 18 en 75 jaar, komen in aanmerking voor deelname aan het onderzoek. Via loting wordt bepaald of de patiënt via computer genavigeerde MIS THA of conventionele THA geopereerd wordt. Operatietijd, bloedverlies, intra- en postoperatieve complicaties en ligduur in het ziekenhuis worden geregistreerd. De positie van de prothese wordt gemeten aan de hand van röntgenfoto's die 6 weken na de operatie gemaakt worden. Het fysiek functioneren wordt preoperatief, 6 weken en 3 en 6 maanden na operatie in kaart gebracht door middel van vragenlijsten en gangbeeldanalyse. De resultaten van dit onderzoek zijn beschreven in hoofdstuk 6.

De volgende twee hoofdstukken van dit proefschrift behandelen het onderzoek

naar de ontwikkeling van een BFS-gebaseerde gangbeeldanalyse methode. Met deze gangbeeldanalyse methode kunnen niet alleen spatiotemporele parameters maar ook compensatoire rompbewegingen gemeten worden tijdens het lopen.

Hoofdstuk 4 beschrijft de nauwkeurigheid en betrouwbaarheid van deze BFS-gebaseerde gangbeeldanalyse methode voor het kwantificeren van compensatoire rompbewegingen en spatiotemporele parameters van patiënten met heupartrose. Voor het evalueren van de nauwkeurigheid zijn de hoekbewegingen van sensoren die bevestigd waren op de thorax en de pelvis van 3 patiënten vergeleken met de resultaten van een optisch bewegingsanalyse systeem (OBS). De nauwkeurigheid was hoog, met kleine en consistente gemiddelde verschillen ($<1,0^\circ$) en bijbehorende standaarddeviaties ($<1,3^\circ$) tussen OBS en BFS data. Voor het vaststellen van de test-hertest betrouwbaarheid zijn de hoekbewegingen van de romp van 15 patiënten tweemaal gemeten. De test-hertest betrouwbaarheid was zeer goed (ICCs varieerden van 0,86 tot 0,97) en de gemiddelde verschillen tussen de eerste en tweede meting waren klein met de nul in het 95% betrouwbaarheidsinterval. Er kan geconcludeerd worden dat deze BFS-gebaseerde gangbeeldanalyse een nauwkeurige en betrouwbare methode is voor het kwantificeren van compensatoire rompbewegingen in het frontale vlak van patiënten met heupartrose tijdens het lopen op verschillende snelheden.

In **hoofdstuk 5** zijn compensatoire rompbewegingen tijdens het lopen van patiënten met heupartrose bepaald met behulp van de BFS-gebaseerde gangbeeldanalyse methode. Hoekbewegingen van de thorax en de pelvis en spatiotemporele parameters van patiënten met een Duchennegang zijn vergeleken met gezonde proefpersonen en patiënten zonder een Duchennegang. Kenmerkende patronen van hoekbewegingen van de romp tijdens het lopen konden objectief gekwantificeerd worden in zowel gezonde proefpersonen als patiënten. De ratio van de ROM van de thorax ten opzichte van de ROM van de pelvis bleek een sterke maat te zijn om patronen van gezonde proefpersonen te onderscheiden van die van patiënten met en zonder een Duchennegang. Er werden geen verschillen in spatiotemporele parameters gevonden, na correctie voor verschillen in loopsnelheid. Op basis van de resultaten van dit onderzoek wordt aangeraden om hoekbewegingen van de romp in kaart te brengen tijdens de klinische beoordeling van het looppatroon van patiënten met heupartrose.

Vervolgens worden de resultaten van de RCT naar de effectiviteit van computer genavigeerde MIS THA in vergelijking met conventionele THA gepresenteerd in **hoofdstuk 6**. Via loting is bij vijftenzeventig patiënten bepaald of zij via de computer genavigeerde MIS THA ($n=35$) of conventionele THA ($n=40$) geopereerd zouden worden. De anesthesie-, pijnbestrijdings- en postoperatieve fysiotherapieprotocollen waren hetzelfde in beide groepen, evenals de ontslagcriteria. Naast chirurgische uitkomstmaten is het fysiek functioneren preoperatief, 6 weken en 3 en 6 maanden postoperatief gemeten door middel van vragenlijsten en gangbeeldanalyse. De operatietijd en het bloedverlies waren significant hoger tijdens computer genavigeerde MIS THA. De gemiddelde ligduur in het ziekenhuis was echter significant korter na computer genavigeerde MIS THA

($5,2 \pm 1,9$ dagen) in vergelijking met conventionele THA ($6,9 \pm 2,1$ dagen). Er was geen verschil in het aantal complicaties. Door het gebruik van computernavigatie werd de heupprothese nauwkeurig geplaatst. Er zijn geen verschillen gevonden in de uitkomstmaten voor (het herstel van) het fysiek functioneren na computer genavigeerde MIS THA of conventionele THA.

Hoofdstuk 7 bevat een uitgebreide analyse van het herstel van de loopfunctie na computer genavigeerde MIS THA en conventionele THA, in kaart gebracht met de BFS-gebaseerde gangbeeldanalyse methode. De gangbeeldanalyse is preoperatief, 6 weken en 3 en 6 maanden postoperatief uitgevoerd. Zowel loopsnelheid, staplengte en stapfrequentie als hoekbewegingen van de romp zijn gemeten. Om vast te stellen of de loopfunctie 6 maanden postoperatief weer normaal was, is deze vergeleken met de loopfunctie van gezonde proefpersonen ($n=30$). Er zijn geen verschillen gevonden in het herstel van zowel de spatiotemporele parameters als de hoekbewegingen van de romp na computer genavigeerde MIS THA of conventionele THA. Alhoewel de loopfunctie verbeterde na de operatie bleven er, 6 maanden postoperatief, kleine verschillen bestaan in verscheidene spatiotemporele parameters en hoekbewegingen van de romp tussen beide patiëntengroepen en de gezonde proefpersonen.

De algemene discussie in **hoofdstuk 8** geeft een overzicht en discussie van de belangrijkste resultaten van het onderzoek, beschreven in de voorgaande hoofdstukken. Ondanks dat er bewijs gevonden is voor de effectiviteit van computer genavigeerde MIS THA op verschillende aspecten van klinische uitkomst, moet het veronderstelde gunstige effect van computer genavigeerde MIS THA op het herstel van het fysiek functioneren nog worden aangetoond. Hoewel de ligduur korter was na computer genavigeerde MIS THA, waren er 6 weken en 3 maanden na de operatie geen verschillen in het fysiek functioneren na computer genavigeerde MIS THA of conventionele THA. Een mogelijke verklaring hiervoor kan zijn dat het gunstige effect van computer genavigeerde MIS THA op het herstel van het fysiek functioneren wellicht heeft plaatsgevonden tussen het ontslag uit het ziekenhuis en de eerste postoperatieve meting 6 weken na operatie. Om deze effecten te kwantificeren is het wellicht noodzakelijk om het fysiek functioneren eerder te meten. Verder heeft de ontwikkelde BFS-gebaseerde gangbeeldanalyse methode veel potentie om in een klinische setting objectief de loopfunctie van patiënten met heupartrose vóór en na THA in kaart te brengen.

Verscheidene klinische implicaties van computer genavigeerde MIS THA worden gepresenteerd, zoals het inbedden van computer genavigeerde MIS THA in een verkort opnameprogramma om zodoende haar gunstige effecten te optimaliseren. Om deze effecten na ontslag uit het ziekenhuis te behouden en zo de terugkeer naar het normaal dagelijks functioneren te versnellen, wordt additionele fysiotherapie aangeraden. Bovendien is het belangrijk om een lichamelijk actieve leefstijl na THA te stimuleren. BFS kunnen een rol spelen bij zowel de fysiotherapie na THA als bij het stimuleren van een lichamelijk actieve leefstijl.

In de algemene discussie wordt benadrukt dat verder onderzoek nodig is naar de klinische- en kosteneffectiviteit van computer genavigeerde MIS THA, pre- en postoperatieve fysiotherapie en het lichamelijke activiteitenpatroon na THA.

Tevens is verder onderzoek nodig naar zowel de uitvoerbaarheid en effectiviteit van de toepassing van BFS in de revalidatie van patiënten na THA als het gebruik van BFS als monitors van lichamelijke activiteit.

A detailed black and white micrograph of a plant stem cross-section. The image shows several vascular bundles arranged in a ring. Each bundle contains primary xylem on the inner side and primary phloem on the outer side. A prominent, dark, circular vascular cambium is visible, indicating secondary growth. The cambium is producing secondary xylem (wood) on the inner side and secondary phloem (bark) on the outer side. The outermost layer is the cortex, and the innermost is the pith. The text 'Dankwoord' is overlaid on the right side of the image.

Dankwoord

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Curriculum Vitae

Curriculum Vitae

Inge Hilde Frouwke Reininga was born in Marrum on May 12, 1981. In 1999 she finished high school (Christelijk Gymnasium Beyers Naudé, Leeuwarden) and started to study Human Movement Sciences at the University of Groningen. For her Master's thesis she performed a research project at the Department of Orthopaedics of the University Medical Center Groningen. After graduating in 2003 until July 2004 she attended the college of Physical Therapy of the Hanze University of Applied Sciences of Groningen. In September 2004 Inge started to work at the Department of Orthopaedics of the University Medical Center Groningen on a research project, titled "Measuring functional recovery of athletes after anterior cruciate ligament reconstruction". In January 2007, she started her PhD project, titled "Computer-assisted Minimally Invasive Total Hip Surgery (MIS): a randomised controlled trial into the effectiveness compared to traditional Total Hip Arthroplasty (THA)", where this thesis is based on. Inge started to study Epidemiology at the EMGO Institute for Health and Care Research of the VU University Amsterdam in January 2009. In 2011, she earned her Master of Epidemiology degree.

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Computer-navigated minimally invasive total hip arthroplasty

Effectiveness, clinical outcome and gait performance

Inge H.F. Reininga, 29 juni 2011

1. De grootste winst van computer genavigeerde minimaal invasieve totale heupartroplastiek is een kortere ligduur in het ziekenhuis (*dit proefschrift*).
2. Het gebruik van computernavigatie tijdens minimaal invasieve totale heupartroplastiek geeft een vergelijkbare positie van de heupprothese als bij een conventionele totale heupartroplastiek (*dit proefschrift*).
3. Computer genavigeerde minimaal invasieve totale heupartroplastiek lijkt geen meerwaarde te hebben wat betreft (de snelheid van) herstel van het fysiek functioneren (*dit proefschrift*).
4. Patiënten met en zonder een duidelijk zichtbare Duchennegang maken afwijkende rompbewegingen tijdens het lopen in vergelijking met gezonde personen (*dit proefschrift*).
5. Het in kaart brengen van compensatoire rompbewegingen dient deel uit te maken van de klinische beoordeling van het looppatroon van patiënten met heupartrose, zowel voor als na een totale heupartroplastiek (*dit proefschrift*).
6. Patiënten worden 6 maanden na een totale heupartroplastiek als uitgerevalideerd beschouwd, toch is hun looppatroon op dat moment nog niet vergelijkbaar met die van gezonde personen (*dit proefschrift*).
7. Gegeven het feit dat de totale heupartroplastiek succesvol is gebleken in het herstel van het fysiek functioneren, is de directe noodzaak voor postoperatieve fysiotherapie naar de achtergrond verdwenen.
8. Het zetten van de juiste stappen op het juiste moment is niet alleen belangrijk voor de patiënt met een heupprothese, maar ook voor de promovendus.
9. Voor longitudinaal onderzoek is een lange adem noodzakelijk.
10. Door de toenemende heterogeniteit van de patiëntenpopulatie is onderzoek naar de behandeling van de 'standaard' patiënt steeds moeilijker uitvoerbaar in een universitair medisch centrum.
11. Vergrijzing: de collectieve levenswijshouding is groter dan ooit (*Loesje*).
12. Science is a wonderful thing if one does not have to earn one's living at it (*Albert Einstein*).
13. Life is just what happens to you, while you're busy making other plans (*John Lennon*).