CHAPTER 4

Gait six month and one-year after computer assisted Femur First THR vs. conventional THR. Results of a patient- and observer-blinded randomized controlled trial

T. Weber, S. Dendorfer, SK. Bulstra, J. Grifka, GJ. Verkerke and T. Renkawitz- ‘Gait six month and one-year after computer assisted Femur First THR vs. conventional THR. Results of a patient- and observer-blinded randomized controlled trial’ - Gait and Posture

Abstract

BACKGROUND: A correct combined orientation of the Total Hip Replacement (THR) implant components leads to a maximized, stable range of motion (ROM) while decreasing the risk of dislocation. A computer-assisted surgical method (CAS) for THR following the concept of ‘femur first/combined anteversion’ (CAS FF) to improve the combined implant positioning has been developed. A patient- and observer-blinded, randomized study is presented that is used to assess whether patient’s postoperative gait parameters is improved by CAS FF operation method for THR in comparison to conventional THR (CON) six months and one year after surgery.

METHODS: 60 patients were enrolled randomized for conventional, freehand THR (n = 32) or the navigated THR (n = 28). All patients underwent a 3D motion-capture gait analysis of the lower extremity at pre-operative (t0), 6 months post-operative (t1) and 12 months post-operative (t2).

RESULTS: We realized a trend for an improved hip flexion angle for the CAS FF group. Dimensionless walking speed as well as range of motion and symmetry thereof did show a clear improvement over the follow-up period, but no statistical differences between the intervention groups were found.

DISCUSSION: While all parameters do increase over the follow-up period for the CAS FF and CON group, there were no significant differences between the groups six month and one year after surgery. Patients undergoing CAS FF showed a trend to improved hip flexion angle compared to CON patients, with a possible long-term benefit of reducing wear in the implant system, which remains to be proven.
Introduction

One of the major problems during Total Hip Replacement (THR) is to find an optimized compromise between the trias of hip biomechanics, tribology and postoperative functionality. In the end, all three elements are dependent on each other: The position of total hip components correlates to the risk for dislocation, implant failure, articular wear and prosthetic range of motion (ROM). Early impingement occurs when contact between the prosthetic femoral neck, the acetabular cup and/or bony parts (e.g. greater trochanter, acetabular rim, resection plane) occurs within a patient’s normal range of motion. Several authors have proposed starting with the preparation of the femur and then transferring the patient-individual orientation of the stem relative to the cup intraoperatively (‘femur first’/‘combined anteversion’) in order to minimize the risk of impingement and dislocation\textsuperscript{1–3}. A novel, computer-assisted surgical method (CAS) for THR following the concept of ‘femur first/combined anteversion’ (CAS FF) has been developed. This incorporates various aspects of performing a functional optimization of the prosthetic stem and cup position in order to improve implant component positioning and orientation\textsuperscript{4–6}. While a number of studies have been conducted in order to determine the objective outcome of conventional THR, no study so far has investigated the effects of CAS FF on gait\textsuperscript{7–9}.

For quantifying gait several parameters can be used. To quantify the patient’s ability to restore walking some researchers measure walking speed as a target parameter, without taking differences in body height into account\textsuperscript{10}. Since taller persons have a greater leg-length they are also capable of walking faster. Therefore normalizing the walking speed to leg length is essential, especially for the comparison of groups\textsuperscript{11,12}. An increasing number of studies also uses joint angles, especially the hip joint angles (hip flexion hf, hip abduction ha, hip rotation - hr) for THR patients, as a measure if gait following surgery is pathological or if the biomechanics and therefore function can be restored\textsuperscript{8,13,14}. Healthy and able-bodied persons walk in a symmetrical way\textsuperscript{15}. Therefore an important outcome after THR is not only magnitude and orientation of joint angles, but also symmetry of active range of motion (ROM) as a measure to what extent gait pattern is pathological.

The aim of this patient- and observer- blinded, randomized study was to assess whether patient’s postoperative gait parameters are improved in comparison between the CAS FF and conventional THR six months and one year after surgery. Our hypothesis were, (i) CAS FF leads to an improved dimensionless walking speed compared to conventional THR, (ii) the active range of motion after CAS FF is improved both in magnitude and in symmetry compared to conventional THR and (iii) CAS FF leads to an improved hip flexion angle (hf) compared to conventional THR.

Patients and Methods

Patients

During a registered, prospective randomized controlled trial (DRKS00000739, German Clinical Trials Register) we randomized patients for surgery with or without the use of an imageless navigation
system. The random allocation sequence was computer-generated in a permuted block randomization design by statisticians of the Institute of Medical Statistics and Epidemiology Munich using certificated randomization software (Rancode 3.6 Professional, IDV, Gauting, Germany). Permutated blocks of four, six, and eight participants were used to ensure a balanced allocation sequence. This sequence then was placed in sealed, consecutively numbered, opaque envelopes. These envelopes were kept in a locked filing cabinet in the office of the surgeon who opened the envelopes in order of participant recruitment on the day of surgery. This investigation was approved by the local Ethics Commission (No.: 10-121-0263). A sovereign power calculation was performed for investigation of the three primary endpoints in this subgroup gait analysis: t0 (preop), t1 (6 month post-operative) and t2 (12 month post-operative). Consequently, each of the corresponding hypotheses was tested on a Bonferroni-adjusted, two-sided \( \frac{5}{3} = 1.7\% \) significance level. The relevant difference between navigation and conventional THR was set at 0.3. Based on these considerations, a sample size of 30 in each group achieved a power of 77% using two-sample t-tests (nQuery Advisor 7.0, Statistical Solutions Ltd, Cork, Ireland). Patients characteristics according to allocation are presented in table 1.

<table>
<thead>
<tr>
<th>Intervention group</th>
<th>Sample size (male/female)</th>
<th>Age in years: Mean(SD)</th>
<th>Age range: min/max</th>
<th>BMI ((kg/m^2)): Mean(SD)</th>
<th>BMI range: min/max</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS FF</td>
<td>28(10/18)</td>
<td>60(7)</td>
<td>50/74</td>
<td>26.73(4.26)</td>
<td>19.45/35.22</td>
</tr>
<tr>
<td>CON</td>
<td>32(19/13)</td>
<td>62(8)</td>
<td>50/74</td>
<td>27.58(3.08)</td>
<td>21.64/33.68</td>
</tr>
</tbody>
</table>

Table 1: Patient characteristics by intervention group

Methods

Computer Assisted Femur First THR (CAS FF)

In the navigated group, an imageless navigation system (BrainLAB Prototype Hip 6.0 Femur First, Feldkirchen, Germany) with newly developed “Femur First” prototype software was used (Renkawitz et al. 2012b).

Conventional THR (CON)

Acetabular components were placed freehand without the use of any alignment guides. The target acetabular component position for all patients was within the ‘safe zone’ as defined by Lewinnek et al. \( (40^\circ \pm 10^\circ \) inclination and \( 15^\circ \pm 10^\circ \) anteversion \)\(^{16}\).

Gait analysis (GA)

All patients performed a 3D motion-capture (MoCap) gait analysis of the lower extremity (SimiMotion®, Unterschleissheim, Germany) at three time points (pre-operative (t0), 6 months post-operative (t1) and 12 months post-operative (t2) Figure1a). A bony and anatomical landmark based marker-set
consisting of 27 retro-reflective markers (Figure 1b) was used to record the patient-specific gait pattern by means of six digital video cameras with a video sample rate of 70Hz. The patients walked at self-selected speed on a 10m walkway, while the ground reaction forces were recorded simultaneously using two force plates (Kistler®, Winterthur, Schweiz; sample rate: 1000Hz). In order to calculate joint positions based on marker data, a static trial was conducted before the gait experiment started. Prior to recording, the patients were asked to walk on the walkway three to five times in order to acquaint themselves with the laboratory situation. One patient missed t1-gait analysis, but returned for the t2-analysis. GA data was processed with a commercial software package that is used for musculoskeletal modeling of gait (AnyBody A/S, Aalborg, Denmark). A generic virtual human body model (AnyGait, AMMR1.6) was first scaled based on anthropometric measurements as an initial guess. This was followed by a nonlinear scaling algorithm based on the marker data gathered during the static trial, further adapting the model to the patient specific anatomy. This model is streamlined for gait analysis and employs standard gait analysis approaches to compute the patient-specific gait pattern by means of a marker driven kinematic model (Figure 1c).

Method verification

Three healthy volunteer male subjects were invited for method verification experiments (S1: 19 years, 79.4kg, 1.73m; S2: 25 years, 70.4kg, 1.69m; S3: 31 years, 73.4kg, 1.82m). The scope of the verification study was to evaluate the measurement chain and not to conduct a population study; hence such a narrow patient collective was acquired. Three sub-studies for the method verification were conducted which are divided in (i) dependency of hip flexion (hf) results on MoCap Analyst (ii) dependency of hf results on marker-placement (iii) repeatability of hf results obtained. To answer (i) three different examiners (A(experienced), B(experienced), C(not-experienced)) evaluated one gait analysis conducted by a healthy subject (S1) ten times. To answer (ii) one healthy subject conducted ten gait experiments (S1) and two experienced examiners (A, B) applied the marker set in an alternating manner. For the robustness experiments the three healthy subjects (S1, S2, S3) conducted ten gait experiments each, which were evaluated by one experienced examiner (A). Data was processed with the same workflow as for the patient study. To evaluate the measurement chain the standard error of mean (SEM) of the respective target parameter was computed according to (2) with n samples and a sample standard deviation $\sigma$.

$$SEM(\bar{X}) = \frac{\sigma}{\sqrt{n}}$$  \hspace{1cm} (1)

Subjective outcome measures

At all time points (t0, t1, t2) all patients answered the widely accepted clinical outcome scores the Hip Osteoarthritis Outcome Score (HOOS) and the Harris Hip Score (HHS).
Patients and Methods

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acquisition of volunteer patients
- anthropology
- anatomy

gait analysis
- motion capture (marker trajectories)
- ground reaction forces

input for...

kinematic analysis:
input:
scaling, gait analysis
output:
gait pattern
(joint angles)

scaling
input:
anthropometrics,
MoCapData
output:
segment lengths & masses
joint positions

anthropometry
MM

input:
anthropometrics,
MoCapData
output:
segment lengths & masses
joint positions

a) workflow

b) marker set
c) kinematic model

Figure 1: Gait analysis overview. a) patient/study workflow; b) marker set; c) kinematic and marker driven model
Post-processing

Post-processing of data was done using MATLAB (MATLAB Release 2013a, The MathWorks, Inc., Natick, Massachusetts, United States.). Typical signals (TS) of hip flexion angles for every group (CAS FF and CON) have been computed by means of dynamic time warping (dtw) and according to Bender et al\textsuperscript{22}. Dimensionless walking speed was computed according to Hof\textsuperscript{11} and according to (2)

\[ \hat{v} = \frac{v}{\sqrt{g \cdot l_0}} \]  

(2)

The range of motion (ROM) depicts the active range of motion during of the patient during walking. ROM symmetry is computed according to (3)

\[ ROM_{sym} = \frac{ROM_{op}}{ROM_{noop}} \]  

(3)

Statistics

Statistical testing for significance (\( \alpha \leq 0.017 \)) between CAS FF and CON for dimensionless parameters at different time points was done using two-way ANOVA in MATLAB. If data was not normal distributed the non-parametric Kruskal-Wallis test for unequal sample sizes with \( \alpha \leq 0.017 \) was used\textsuperscript{23}.

Results

Method verification

Figure 2 displays the verification study results (hip flexion, standard error of mean SEM). The influence of MoCap Analyst should be noted. Marker Placement has the greatest influence on the target parameters. The repeatability study shows that results are indeed robust, but care must be taken when conducting experiments. A SEM of \( \pm 2.5^\circ \) is an estimate of how accurate the hf during walking can be computed, hence differences that are greater than \( 2 \cdot hf_{SEM} = 5^\circ \) are indeed measurable. This is in agreement with literature data\textsuperscript{24}.

Dimensionless walking speed

Figure 3 displays the dimensionless walking speed as calculated due to (2). The walking speed increases significantly over the follow-up until reaching magnitude as measured in other studies\textsuperscript{25}. There is no significant difference between the intervention groups.
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Results

Figure 2: Method verification results

Figure 3: Dimensionless walking speed on the operated side including literature data
Kinematic parameters

Figure 4a displays the hip flexion range of motion (hfROM) at the different follow-up points and divided in intervention groups. Figure 4a also includes a benchmark ROM taken from literature\(^{26,27}\) that represent a ROM from young and healthy subjects and from fit and healthy older subjects. The ROM increases over the follow-up period significantly, there were no differences between intervention groups. We also tested hip abduction/adduction (ha) and hip rotation (hr). Ha also showed a significant increase over the follow-up period between t0 and t1, while the increase between t1 and t2 was not-significant. Figure 4b shows the hfROM symmetry (\(ROM_{sym}\)) as calculated by 3. \(ROM_{sym}\) increases over the follow-up period significantly, there were no differences between intervention groups. The TS of hf as a function of 1 100% gait cycle as computed by dtw is displayed in Figure 4c). Hf increases over the follow-up period and both groups reach normal kinematics at t2. The CAS FF group seems to improve faster from t0 to t1 compared to the CON group; however this difference is not significant. Most patients perform with normal kinematics at t1, but some still improve measurable until t2, as indicated by the TS at t1 and t2.

![Figure 4](image_url)

**Figure 4**: Kinematic parameters. a) hf ROM including benchmarks for healthy, young and fit, elderly subjects; b) hf symmetry index including perfect symmetry c) hf at different follow up points for the CAS FF and the conventional group; the gray shaded area indicates a healthy hf time series as gathered during the method verification experiments.
Discussion

To the best of our knowledge this is the first study that investigated if gait performance can be improved by CAS FF utilizing a combined workflow of experimental and computational methods. In detail our hypotheses were (i) the dimensionless walking speed of the CAS FF group is improved compared to conventional THR, (ii) the active range of motion is improved compared to conventional THR and (iii) the walking pattern is more symmetrical in the CAS FF group when compared to conventional THR group.

Our results indicate that the CAS FF patients perform with the same gait performance after THR compared to the CON group. We realized a trend for improved hf for CAS FF at six month after surgery but the differences did not reach statistical significance. While all parameters do increase over the follow-up period for both of the groups, there were no significant differences between the groups six month and one year after surgery. The results also show that the full walking ability of patients is mostly restored six month after surgery regardless of the intervention technique. There are several reasons why we could not accept our hypothesis that postoperatively CAS FF leads to an improved walking performance when compared to conventional THR. First, six month after surgery could be too late to measure early effect of CAS FF on walking ability. There might be an effect on the target parameters before six month after the intervention, but there is no data available at that time-point. We chose six months since our clinical experience is that patient compliance seems to be good. Our drop-out rate supports this, only 2.56% patients eligible for pre-op analysis did not return for the follow-up analysis. Second, a main goal of CAS FF is minimizing the risk for impingement and dislocation by optimizing the implant position and orientation in order to prevent impingement and decrease the risk for dislocation\(^1\). This is not necessarily related to walking ability, as it is supported by our study. Walking ability is only restricted if impingement occurs. The implant positions and orientations of the implant system that the surgeons achieved during the different interventions are not critical for walking in terms of impingement. Third, gait is not a critical motion. Impingement or dislocation is most likely to occur during critical motion such as a squat or sit to stand maneuvers\(^28,29\). It is however unethical to invite patients for experiments that might obviously result in failure of the implanted joint. Such research is best carried out by facilitating a computational approach\(^30–32\). Patients may benefit the most from CAS FF during critical motions but such research can only be carried out in silico, which is a scope for further research. The reason why we chose walking is that it is the most common activity of daily living (ADL) in THR patients\(^33\). Fourth, the effect may not be measurable or the method is not sensible enough. Results gathered by means of gait analysis are subject to variation which results on one hand from intra-individual differences in walking patterns. While such intra-individual deviations can be countered by repeating the experiments several times and choosing a representative experiment\(^34\), gait analysis is still subject to soft-tissue artifacts (STA) of the attached markers during walking\(^35\). This might bias the results even if we tried to counter that effect by defining the joint centers using a static trial, therefore canceling out the influence of walking dynamics on STA. Previous studies have found a higher precision and fewer outliers in terms of implant positioning for standard navigation algorithms for THR\(^3,36–38\). The navigated Femur First technique takes this step even further by adjusting the acetabular cup relative to the
femoral components. Investigating the long-term benefit of CAS FF is a scope for further research and remains to be proven. While this is the first study conducted to research the walking ability after CAS FF, several studies investigate the influence of different surgical techniques for THR. These studies also find an overall improvement of gait performance after surgery, but no difference in gait performance when operated with different surgical THR techniques (MIS vs. conventional, CAS vs. conventional) has been found. Strength of this study is the rather larger patient number when using highly accurate 3D MoCap video based gait analysis. This method is rather costly in terms of resources; so not many studies with such a large collective have been conducted so far. There are other systems available that are not as laborious, with the disadvantage of being not as accurate as 3D MoCap systems. We also conducted detailed and careful verification experiments in order to determine the limits and capabilities of our system. Our patient collective was also randomized as well as blinded, to the greatest extent. This fact cancels out placebo effects as well as observer bias. Limiting is the fact that we did not include physical activity in particular. Patients that are more active during their everyday life may recover faster than others. This may result in a better walking ability. Since the participants were asked to walk the same way they normally do we included this effect in the experiments. Also gait analysis is an objective measurement method, therefore canceling out any psychological effects that might influence walking ability. By means of clinical outcome scores (Hip Osteoarthritis Outcome Score, Harris Hip Score) we tried to counter such effects. The scores also did not reveal any difference between the intervention groups at t0, t1 and t2.

Conclusion

THR in general leads to an improved ability to walk six month after surgery. Patients undergoing CAS FF showed a trend to an improved hip flexion angle compared to CON patients. The results suggest that CAS FF may lead to a better performance. CAS FF delivers the same functional and biomechanical outcome as CON, with a possible long-term benefit of reducing wear in the implant system, which remains to be proven.

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References

