Gait & Posture 49 (2016) 418–425

Contents lists available at ScienceDirect

Gait & Posture

journal homepage: www.elsevier.com/locate/gaitpost

Full length article

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

Tim Weber[a,b,*], Sebastian Dendorfer[a], Sjoerd K. Bulstra[c], Joachim Grifka[b], Gijsbertus J. Verkerke[d,e], Tobias Renkawitz[b]

[a] Ostbayerische Technische Hochschule Regensburg, Faculty of Mechanical Engineering, Laboratory for Biomechanics, Regensburg, Germany
[b] Regensburg University Medical Center (UKR), Department of Orthopaedic Surgery, Regensburg, Germany
[c] University of Groningen, University Medical Center Groningen (UMCG), Department of Orthopaedic Surgery, Groningen, The Netherlands
[d] University of Groningen, University Medical Center Groningen (UMCG), Department of Rehabilitation Medicine, Groningen, The Netherlands
[e] University of Twente, Department of Biomechanical Engineering, Enschede, The Netherlands

ARTICLE INFO

Article history:
Received 21 July 2015
Received in revised form 22 June 2016
Accepted 25 June 2016

Keywords:
THA
Computer-assisted surgery
Femur first
Combined anteversion
Gait analysis
Biomechanics

ABSTRACT

A prospective randomized controlled trial is presented that is used to compare gait performance between the computer assisted Femur First (CAS FF) operation method and conventional THR (CON). 60 patients underwent a 3D gait analysis of the lower extremity at pre-operative, 6 months post-operative and twelve months post-operative.

Detailed verification experiments were facilitated to ensure the quality of data as well as to avoid over-interpreting of the data. The results confirm a similar data-quality as reported in the literature. Walking speed, range of motion and symmetry thereof improved over the follow-up period, without significant differences between the groups. While all parameters do significantly increase over the follow-up period for both groups, there were no significant differences between them at any given time-point. Patients undergoing CAS FF showed a trend to improved hip flexion angle indicating a possible long-term benefit.

1. 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 [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 [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 [7–9].

In order to quantify gait after THR several parameters of interest can be found in the literature, three of them being: (i) normalized walking speed (ii) hip joint angles (hip flexion – hf, hip abduction – ha, hip rotation – hr) (iii) walking symmetry. If not normalizing the walking speed to body height [10], the comparison between groups becomes very challenging, since taller persons have a greater leg-length which enables them to walk faster [11,12]. An increasing number of studies also uses joint angles (kinematics) as

* Corresponding author at: Ostbayerische Technische Hochschule Regensburg, Faculty of Mechanical Engineering, Laboratory for Biomechanics, Regensburg, Germany.
E-mail addresses: tim.weber@oth-regensburg.de (T. Weber), sebastian.dendorfer@oth-regensburg.de (S. Dendorfer), s.k.bulstra@umcg.nl (S.K. Bulstra), Joachim.Grifka@klinik.uni-regensburg.de (J. Grifka), g.j.verkerke@umcg.nl (G.J. Verkerke), tobias.renkawitz@web.de (T. Renkawitz).

http://dx.doi.org/10.1016/j.gaitpost.2016.06.035
0966-6362/

a measure if gait following surgery is pathological or if the biomechanics and therefore function can be restored [8,13,14]. Healthy and able-bodied persons walk in a symmetrical way [15]. Therefore, an important outcome after THR is not only kinematic measures, 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 hypotheses 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. Detailed verification experiments of our measurement chain have been included in this study to ensure the validity of our approach and avoid misleading interpretations.

2. Patients and methods

2.1. Patients

During a registered, prospective randomized controlled trial (German Clinical Trials Register, Main ID: DRKS00000739) we randomized patients for surgery with or without the use of an imageless navigation system. A flowchart for patient acquisition including eligibility criteria is shown in Fig. 1.

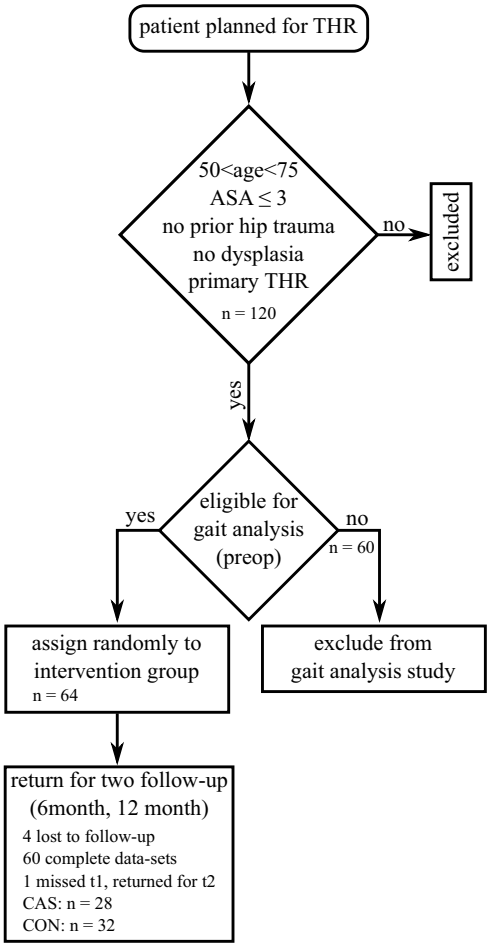

Fig. 1. Flow-chart for the patient acquisition including eligibility criteria.

Fig. 1 The random allocation sequence was computer-generated in a permuted block randomization design by statisticians of the deleted for blinded review using certificated randomization software (Rancode 3.6 Professional, IDV, Gauting, Germany). Permuted 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 5%/3 = 1.7% significance level. The relevant difference between navigation and conventional THR was set at 0.3 given a standard deviation of 0.362. 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. Press-fit acetabular components, uncemented hydroxyapatite-coated stems (Pinnacle cup, Corail stem, DePuy, Warsaw, IN), standard (nondysplastic and nonoffset) polyethylene liners and metal heads with a diameter of 32 mm were used in all patients.

2.2. Methods

2.2.1. 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 [6].

2.2.2. 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 $15 \pm 10^\circ$, anteversion) [16].

2.2.3. Gait analysis (GA)

All patients performed a 3D motion-capture (MoCap) gait analysis (GA) 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) – Fig. 2a). A bony and anatomical landmark based marker-set consisting of 27 retro-reflective markers (Fig. 2b) was used to record the patient-specific gait pattern by means of six digital video cameras with a video sample rate of 70 Hz [9]. The patients walked at self-selected speed on a 10 m walkway, while the ground reaction forces were recorded simultaneously using two force plates (Kistler®, Winterthur, Schweiz; sample rate:1000 Hz). 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 [17]. This was followed by