


CHAPTER 7

General Discussion

The general aim of this thesis was to determine the Biomechanical Outcome after Total Hip Replacement in a quantitative manner and especially to evaluate the Biomechanics following Computer-Assisted Femur First THR in a quantitative manner. In the general discussion all results and their indications will be discussed including suggestion how to apply the outcome of this study and followed by the discussion of strengths and limitations. At the end conclusions of this study will be given.

Discussion

Hip joint replacement is becoming increasingly important due to the aging society. The overall survival rate of an artificial hip joint is acceptable, but due to the demographic change, people tend to live longer. Therefore the survival rates of the implant system must be increased. Improving prostheses is challenging, because a lot of scientific effort has been put into this already. After optimizing the implant system, scientific emphasis has shifted to improve implant positioning and surgical techniques. There are several new surgical techniques introduced, but up to now, it is not known which is preferable. It was the objective of this work to research the outcome of Total Hip Replacement (THR) and especially Minimally Invasive Surgery (MIS) THR using patient-specific musculoskeletal models and motion capture gait analysis (GA). A second scope of this work was to provide evidence that MIS approaches are favorable in biomechanical terms compared to conventional surgical approaches during a bilateral squat using \textit{in silico} biomechanical models. A bilateral squat was used in order to research into the biomechanical influences of surgical approach on the contralateral side. A squat was chosen because it can be compared to the ‘sitting down’ motion that is known to be the third most common motion that THR patients perform during their daily life\(^1\). A third goal of this work was to compare another new THR surgical technique with current practice during a prospective, randomized and double blinded clinical trial (prct).

The new surgical technique optimizes the implant component orientation with respect to each other following the concept of ‘combined anteversion/femur first’ and makes use of computer-assisted surgery (computer assisted femur first - CAS FF). The concept of combined anteversion is, to take the patient-individual orientation of the femur in the transversal plane (femoral torsion/femoral anteversion) into account during the operation in order to increase the post-operative impingement.
free range of motion (ROM)\textsuperscript{2,3}. Femur First means to reverse the traditional workflow during THR to first implant the shaft and adjust the acetabular cup to it in order to account for the patient-individual bone anatomy to further increase the impingement-free ROM post-operatively\textsuperscript{4,5}. To ensure the most accurate implant positioning a computer assisted system (CAS) is used that guides the surgeon intra-operatively\textsuperscript{6}. In general it was hypothesized that the compliant implant orientation of CAS FF reduces the risk for impingement and dislocation and leads to an increased ROM postoperatively. A greater unrestricted ROM may also lead to an (i) increased gait performance for CAS FF patients postoperatively. Due to the compliant implant positioning CAS FF may also lead (ii) to favorable musculoskeletal loading conditions at the hip joint. In order to examine the gait performance GA was used for 60 patients that were randomly assigned to either CAS FF or free-hand conventional (CON) MIS THR group, a detailed study protocol was published prior to the start of this study\textsuperscript{5}. GA was conducted on three time-points, preoperatively, six month post-operative and twelve month post-operative. From this data highly patient-specific musculoskeletal models have been retrieved that are capable of computing the \textit{in vivo} biomechanics during gait and can be facilitated for quantitative comparisons\textsuperscript{7}. The target parameters were if the hip reaction force magnitude, symmetry and orientation with respect to cup are improved for CAS FF patient.

When comparing MIS with conventional surgery, the results of the computational study suggest that MIS is favorable compared to conventional surgical approaches from a biomechanical point of view, but this is only one half of the story. Visualization is of utmost importance for a safe THR procedure and only experienced surgeons, or surgeons supported by a computer-assisted system (CAS), may be able to translate the biomechanical benefit of MIS into a benefit for the patient. The computed changes in hip reaction force orientation (hrf angles) show that MIS approaches are less influential on hip biomechanics which is also supported by the changes in computed muscle force and activity. The gait analysis study adds a valuable perspective to this. After six month both groups performed very similar to a healthy normal which is according to Madsen et al. not the case for patients operated with conventional surgery\textsuperscript{8}. This indicates a faster recovery of patients when surgeons use MIS. However the literature is not consistent if MIS THR yields functional benefits for the patient, which shows that other important influences are canceled out or unknown\textsuperscript{9,10}. In this context computational models are advantageous, since it is possible only alter biomechanical parameters and neglect other influences. This study provides baseline evidence that MIS THR has the potential of being favorable compared to conventional surgery. The \textit{in silico} study shows that there is great potential in MIS THR, but the true challenge is to transfer this improved biomechanical outcome into an improved outcome for the patient\textsuperscript{11}. The gait analysis study shows that the use of a CAS and the accompanied improved accuracy might support surgeons in being able to transfer biomechanical benefit into a benefit for the patient\textsuperscript{12}, but an experienced surgeon is able to perform the surgery with sufficient accuracy without any influence on gait performance.

Computer-assisted Femur First THR (CAS FF) is believed to improve the post-operative outcome of THR. Based on the concept of combined anteversion/femur first it was hypothesized that such an optimized component positioning leads to an overall improvement of gait performance and to improved musculoskeletal loading conditions. The outcome of the gait analysis study and the musculoskeletal modeling study is compared to free-hand conventional MIS THR where surgeons do not follow the concept of femur first and they are not supported by a computer-assisted system.
While all gait parameters do improve over the follow-up period for all patients, there are no statistically significant differences between the groups (conventional MIS THR vs. CAS FF). An increase of gait performance due to an optimized range of motion (ROM) following the concept of 'combined anteversion/femur first' (CAS FF) was not observed. One of the possible reasons for this is that walking is not a critical motion during which impingement occurs. We investigated walking since it is one of the most-performed ADL in THR patients, followed by sitting down and getting up. Sitting down and getting up motions may result in impingement, that is why we investigated the biomechanics of such motions only in silico which, because it is from an ethical point of view not acceptable to test this in vivo. The follow-up point at six months post-operative may also be too long after surgery to measure an effect on gait performance parameters. We chose six month as a follow-up point because the clinical experience showed the patients are more willingly to come back and do not suffer from so-called 'study fatigue'.

Statistical significant improved hrf angles after six month were observed for the CAS FF group. This shows that the concept of CAS FF does indeed lead to improved musculoskeletal loading conditions. Therefore the patients in the CAS FF group are subject to a lower propensity for dislocation and rim-loading at the artificial hip joint. The hrf after twelve month were practically similar to those of a healthy normal, which indicates a possible long term benefit for patients undergone CAS FF. This remains to be proven and is the focus for further research. Such computational models of human walking take two aspects into account, the motion and the anatomy. The combination of both give detailed insight into human biomechanics. Gait analysis alone may not be sensitive enough to capture such operation-dependent differences which obviously highly depend on the patient specific anatomy and especially implant position and orientation. Only analyzing medical images (anatomy) is meaningful if one wants to know if the implant position is satisfactory, but it cannot give any information about the load-case during locomotion, which means that a combination of anatomy and motion is needed. GA takes the anatomy into account to some extent, but not in the same fashion as musculoskeletal models do. Data such as this cannot determine how close the hrf can get to the rim and the edge of the cup. Additional Finite Element Analysis using may however help to determine rim-loading and how close the hrf can get to the rim before the implant is subject to increased wear rates.

There is baseline evidence that MIS THR is favorable to conventional surgery in terms of biomechanics, but the true challenge lies in translating this potential benefit into a benefit for the patient. There were no differences between the groups in terms of gait performance postoperatively. In the CAS FF group the hrf angles were statistical significant closer to optimum compared to the CON group. Therefore it is eligible able to accept the hypothesis that CAS FF leads to improved musculoskeletal loading conditions. Analytical laws derived from this data make the definition of a new implant safe-zone based on biomechanical parameters thinkable which is also a scope for future research.

Applications

Wear is function of use and not of time, meaning that patient specific motion pattern and the corresponding biomechanics play an important role in wear mechanisms. Estimating wear in vivo and in a patient-specific manner is however only possible with work intensive Finite Element
Analysis. Using the patient-specific data as retrieved during this study as an input Finite Element Analysis can be applied for the computation of individual wear rates. Computing wear is only possible using Finite Element Analysis which is based on the deformable body principle. Musculoskeletal models are rigid body models, therefore a computation of wear based on this data is not possible. However, the proposed methods in Chapter 5 define several biomechanical outcomes that are related to wear and they can be quantified using such rigid body models of human walking. A comparison between the computed wear rates by Finite Element Analysis and the parameters as defined in Chapter 5 might make a prediction of wear rates based on musculoskeletal models (rigid body models) possible. Such models are not too complex and are computational beneficial, which makes an application for operational planning thinkable.

From the recorded data during the gait analysis it is possible to compute the ‘typical’ gait pattern of THR patients based on dynamic time warping (dtw). Those analysis can be achieved for the raw motion data as well as the raw data from ground reaction forces. Using the data for all patients at all follow-up point (t0, t1, t2) it is possible to compute the ‘typical’ gait pattern for each time-point respectively. Not only can this data then be used for post-hoc analysis and the determination of ‘typical’ parameters such as ‘typical’ joint angles, ‘typical’ symmetry and ‘typical’ ground reaction forces, it also can be used as an input for musculoskeletal modeling. There are two different applications for this. First, to verify the post-hoc analysis, since logic dictates that the computations should deliver at least very similar results when using the ‘typical’ input data or performing dtw on the population data. Second, such data can be used for studies as presented in Chapter 3. A virtual operation could be performed on such a ‘typical’ model in order to find what muscles are mostly responsible for impaired walking or to find muscles that can be incised or should be avoided. Also influences of the implant position or anatomical features on the biomechanics can be investigated. Since data like that was lacking, it was only possible to use a parametrized motion such as a squat in Chapter 3. Similar investigation on complex motions such as gait become possible and may be of interest for the orthopedic community.

Data such as the presented can also be used for implant design. Up to now, implant design is rather driven by experience than being driven by biomechanics. Topology optimization is a famous tool to optimize a design based on applied boundary conditions. It is often used to minimize the used material and to numerically drive designs. This method can also be used for implant design. When thinking of custom-made implants, a design process becomes thinkable that in-cooperates patient-specific anatomy and patient-specific boundary conditions as retrieved from patient-specific musculoskeletal models, ultimately resulting in a most adapted patient-specific implant. Using the emerging methods of additive manufacturing even a cost-effective process might be possible. Additionally an accurate implant positioning can be achieved by using computer-assisted surgery. If such a process is possible, if it is useful from a commercial point of view and if it is applicable from a medical point of view remains to be proven. It is however a fact that the data is there and that the first steps towards truly patient-specific implants can be made.
Strengths and Limitations

As with all scientific research, this study is also subject to several strengths and limitations which will briefly be discussed in the following sub-sections. Please find a detailed discussion of all sub-studies in the regarding chapter.

Strengths

One of the greatest strengths of the presented work is that the experimental data was collected during a prospective, randomized, double-blinded controlled trial (prct), which was also registered in the German Clinical Trials Register under the Main ID: DRKS00000739. This fact cancels out many possible biases that can be introduced due to patient-selection or during clinical examination and experiments if the study would not have been of a prct-nature.

Another strength of this work is that the biomechanical model used was highly patient-specific due to the non-linear scaling technique used. Scaling was achieved in two subsequent steps: (i) scaling according to anthropometric data (weight and height) and (ii) scaling according to static MoCap trial for defining joint axes. To the authors knowledge this is the highest level of detail to which musculoskeletal models have been adapted to during such a prospective randomized controlled trial.

The standard MoCap marker protocol has been extended to as much as 27 markers in total. This was done to ensure that on every body segment at least three markers are placed in order to fully kinematically constrain the motion. This ensures that the motion of every segment is always measured in all three directions in space, which is not the case when using the standard Plug-In Gait marker set.

The outcome of the rather large workflow verification study demonstrates the limits and capability of the system and the workflow. Three crucial influences that bias the results have been investigated (see Chapter , Figure 2 and Chapter 6, Table 2 and Figure 5). While the MoCap gait analysis sensitivity is comparable to such as found in the literature, no study (to the author knowledge) that uses biomechanical, musculoskeletal models has previously reported a possible deviation in terms of hip reaction forces. This makes the interpretation of the results much more valid, since it is known if a difference is simply measurement noise added by different systems or if it is a measurable difference between patient models.

The method of determining 'typical signals' via dynamic time warping (dtw) is superior to the widespread use of the arithmetic mean for the representation of joint reaction forces and additionally an integral measure of signal similarity. The greatest strength of dtw is that it connects every data point of a reference signal to every data point of a target signal and determines the typical signal by means of an optimization algorithm. While the arithmetic mean most certainly has its application, investigating strongly varying signals with it might bias the results signal (see Chapter 6 Figure 3). 'Typical signals' counter this limitation and are a better representation for strongly varying signals. Also asymmetry measures based on dtw are superior to traditional symmetry measures since, as mentioned before, they compare every time point to every time point rather than using fixed time values or only peak values for comparison. This makes user-based
decisions obsolete. DTW is also able to reflect to different aspects of asymmetry, the magnitude symmetry and the phase shift symmetry respectively, which is not possible by using traditional symmetry measures.

A previously validated and detailed biomechanical model of human walking has been used. Validation has again been achieved for this model using the gait data gathered during this study. Together with the verification experiments, not only a well-defined workflow has been used, but it can also be used for other studies with different research questions.

The video-based MoCap system is one of the most accurate solutions that can be used for gait analysis. Especially beneficial is that even if the experiments are finished, the examiner is still able to check the markers on the videos taken during the gait experiments. This reduces possible sources of errors in contrast to infra-red based system, where the analyst has to fully trust the equipment. The aforementioned verification study does support, that the system is at least as accurate as other motion capture methods.

Limitations

A major limitation of this work is that the number of participants is rather low. A greater number of participants during the experimental prct would increase the statistical power. Speaking of this kind of study, highly accurate MoCap gait analysis in combination with highly patient-specific musculoskeletal models, this work included (to the authors knowledge) the greatest number of participants which were also selected prospective and randomized. Still, the statistical validity would of course be increased when including more patients. A desirable statistical power is 80%, this study has a power of 77%. A sample size of 70 patients would have increased the power to 82%, however since this study was embedded into a greater clinical trial, it was not possible to further increase the patient number since this would have led to a not-acceptable delay.

The biomechanical, musculoskeletal models are of a purely mechanical nature and cancel out physiological effects on, for example, motion pattern. It is a fact that the psychological state does influence the gait pattern. Therefore there is a risk that a patient simply 'had a bad day' while conducting experiments in the gait lab. By also evaluating subjective and clinical outcome scores we tried to avoid such effects. The subjective scores showed no statistical difference and we were not able to include psychological effects.

Only walking as a motion has been evaluated, which is a non-critical motion in terms of impingement and rim-loading. Such critical hip-joint loading is more likely to occur during squat motions. However, since it is unethical to ask patients to perform a motion that might result in increased wear of their implant system, such investigations are better carried out using a computational approach then on real-life humans, such as presented in chapter 3.

It is a known fact that the during MoCap gait analysis the results are subject to so-called soft-tissue-artifacts (STA). The markers for conducting a MoCap gait analysis are placed on bony and anatomical landmarks. This becomes challenging for several body segments (thigh, pelvis) when patients are subject to a high BMI and a relative motion between the bone and the soft-tissue surrounding it becomes indeed very likely. STA due to a high BMI were countered by using more than three markers on body segments that are subject to great soft tissue movement (pelvis, thigh). The musculoskeletal model approximates the position of the bones over time according to
marker data. Since the markers are placed on the skin of the subject they may deviate from the position of the bones. Subsequently the STA influence the biomechanical simulation and therefore the results. By applying as many as 27 markers on the patients during walking and due to the definition of the joint axis based on the static trial prior to the actual gait experiments, the influence of STA is kept to a minimum. An effect of STA on the results can however not be excluded completely.

We did not include the effect of the patients physical activity (PA) in particular as a co-variate. Measuring PA on an individual level is very challenging. Patients tend to deceive the measuring equipment, and since ethics dictate that the patient must be informed about what data will be collected, a truly blinded test is not possible\(^1\). Patients that are more active even after rehabilitation may recover faster than others that are not as active. The effect of individual PA was included by asking the subjects to walk 'the way they normally do'.

The particular type of muscle trauma that the patients were subject to during the operation was not included. Such muscle trauma may influence the results of the hip reaction forces. Estimating muscle trauma after an operation is very challenging and nearly impossible, since it highly depends on patient-specific factors (anatomy, BMI) and factors that influence the operation (op time, experience of surgeon). Such investigations were not included in this protocol.

It cannot be estimated how critical the hrf orientation in terms of rim-loading is. Detailed analysis of how close the hrf can get to the edge of the acetabular cup can only be done using Finite Element Analysis computations that use patient-specific input data. There are some study that use the metal-ion count for an estimation of wear in the artificial implant system, but this parameter is not analyzed in this study since it was not a Metal on Metal (MoM) System\(^29\).

Conclusions

1. Minimally-invasive surgery (MIS) is from a biomechanical point of view favorable compared to conventional surgical approaches.

2. THR in general leads to an improved gait performance post-operative. The benefits of the combined implant position during computer-assisted Femur First (CAS FF) THR may improve the post-operative walking ability for the patients.

3. CAS FF does lead to a favorable musculoskeletal load case on the hip six month and twelve month after THR.

4. The fact that there were no statistical differences in terms of gait but in terms of musculoskeletal load case indicates that musculoskeletal models (as a combination of patient-specific anatomy and patient-specific motion pattern) are able to provide a more complete picture of patients or populations in terms of biomechanics. Only such computational models can provide knowledge about the in vivo load-case on great patient collectives.
References


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