Inducible Displacement of a Knee Implant

a finite element study and validation of a loose and fixed tibial component

Master Thesis

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Inducible Displacement of a Knee Implant
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Abstract

Introduction. Aseptic loosening is indicated as the main cause of knee implant failure. Despite all currently used techniques, it remains challenging to diagnose an aseptic loose knee implant. A promising technique to reveal aseptic loose related implant motions is inducible displacement (ID). ID measurements are used to detect implant motion relative to the bone. To diagnose a loose implant via ID, motion thresholds are required. Such thresholds are dependent on a number of subject specific factors including bone material, loading conditions, used implant and interface contact properties between implant and bone. Such thresholds do still not exist. As a first step towards subject specific motion thresholds, a finite element (FE) model can be used to investigate the factors affecting ID.

Objective. To set-up and to validate a finite element model that can be used to simulate inducible displacements of a tibial component of a knee implant.

Method. As a basis for the finite element modelling, a previously performed experimentally study was used. This study provides data and material to build two finite element models. One model represents an aseptic loose (i.e., silicone layer between implant and bone) tibial component and a model represents a fixed (i.e., cemented) tibial component. FE-models were based on quantitative computed tomography (QCT) scans of the cadaveric tibiae. The experiments were simulated on the FE-models and the ID compared to the experimentally determined ID. Inducible displacements were expressed in terms of rotations and translations. Sensitivity analyses were performed in order to investigate the effects of assumptions during the modelling process on ID. The following assumptions were analyzed: bone material properties, load application points, interface contact properties, silicone layer stiffness and cement material properties.

Results. Loose implant; translations due to top implant loads were found in good agreement to the experimental translations. FE determined rotations were considerably higher. Rotations and translations due to side implant loads were considerably less in the FE-model. Fixed implant: No clear agreement was found after comparing experimentally and FE determined displacements in the cemented implant model. A sensitivity analysis reveals that the implementation of interface interaction properties led to a considerable reduction of the error between experimentally and FE determined ID. A sensitivity analysis reveals also that experimental loading conditions were not correctly applied leading to a considerable increase of implant rotations. Effects of variations of bone material properties on ID are found negligible.

Conclusion. Two FE-models were build. A model representing a loose implant and a model representing a fixed implant. This study shows that: i) The implementation of interface interaction properties contributes to a considerable improvement of realistic FE determined ID. ii) Experimental data used to validate FE-simulations should be sufficiently accurate to analyze a cemented implant and be suitable to implement in a FE-model. iii) Bone material properties have a small influence on ID and might be implemented in a simplified way. Further research is required to optimize the validation of the FE-models.
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1 Introduction

1.1 Total knee replacement

Osteoarthritis is the commonest cause of loss of mobility among older adults, and its incidence has increased markedly over last years (Robertsson et al. 2010). The aging population and the prevalence of risk factors, particularly obesity are responsible for the marked increase (Suri et al. 2012). Total knee replacement (TKR) is the commonest surgical treatment for osteoarthritis and considered as a successful procedure as it restores the knee function and reliefs pain. Survival rates of TKR after 10 to 15 years are documented to be greater than 90% (Hossain et al. 2010; Mabry et al. 2007). In the U.S., TKR counts for 8.7% (n=700,100) of all surgical procedures and numbers of performed TKR have increased with an annual average of 4.9% during last years (Kathryn et al. 2014). The demand for TKR is expected to grow by more than 600% over the period 2005 to 2030 (Kurtz et al. 2007). That indicates the need for economic resources, technical capacity and improved knee implant longevity.

1.2 Knee implant loosening

A survival rate of 90% after 10 to 15 years implies a failure rate of 10% within 10 to 15 years. In numbers, that means 20,000 TKR are failing in the U.S. (American Joint Replacement Registry 2013) and 2,000 in the Netherlands each year (Landelijke Registratie Orthopedische Implantaten 2013). As a result of increasing primary TKR, an increase of revision TKR is reported by several orthopaedic registries (Rothwell et al. 2013; Bae et al. 2013).

A wide variety of causes have been indicated that lead to revision surgery including implant loosening, knee instability, infection, periprosthetic fracture, stiffness and knee pain, malalignment and polyethylene wear (Dalury et al. 2013; Deehan et al. 2006; Bader et al. 2006). A recently performed study based on worldwide arthroplasty registries shows that aseptic loosening is the most common cause of TKR revision, as it is responsible for 30% of the revision surgeries (Sadoghi et al. 2013). In general the tibial component loosens 2-3 times more frequently than the femoral component (Bozic et al. 2010).

Aseptic loosening results from the loss of fixation between the cement and bone in cemented fixation, and between metal and bone in cementless fixation. Without bony support, the implant can become loose and migrate. There are several theories about the cause of aseptic loosening:

1. Access of wear debris (polyethylene-, cement- or metal particles) to the bone-implant or bone-cement interface. This debris might lead to osteolysis and bone resorption followed by implant loosening.
2. Stress shielding because of differences between elastic moduli of implant and adjacent bone. This phenomenon causes bone resorption leading to inadequate bone support. (for a detailed description of stress shielding phenomenon see: (ABR 2015))
3. The formation of a soft tissue layer at the bone-cement interface or bone-implant interface. If sufficient initial stability is not guaranteed, micromotions
are allowed and osseointegration is prevented leading to the development of a fibrous tissue instead of bone formation (Sloten van der et al. 1998).

Aseptic loosening is considered as a process which underlying mechanism is still yet not fully understood (Sundfeldt et al. 2006). However, micromotion of the implant, is indicated as a strong indicator of aseptic loosening (Goodman 1994; Kärrholm et al. 1994; Ryd 1992; Ryd 1986).

1.3 Diagnosis of loosening

Clinically, it is challenging to diagnose aseptic loosening. X-ray imaging is commonly used to investigate implant loosening as it is clinically easily accessible. Roentgen images are used to reveal locations of no or minimal contact between implant and adjacent bone (radiolucent zones). A disadvantage of this technique is the sensitivity for subjective assessment by the surgeon (Ewald 1989). Moreover, the detection of small radiolucent lines is difficult (Ecker et al. 1987). Sensitivity and specificity to detect a loose knee implant by using X-ray are found to be 83% and 72% respectively (Marx et al. 2005).

Radiostereometric analysis (RSA) is a technique showing sufficient accuracy to detect micromotions associated with aseptic loosening (Selvik 1989; Grewal et al. 1992; Kärrholm et al. 1994; Ryd & Albrektsson 1995; Pijls et al. 2012). During an RSA investigation, the displacement between bone markers and the implant is measured in a 3-dimensional configuration. More details of this technique are provided by J. Kärrholm et al. (Kärrholm et al. 2006). The accuracy of RSA is reported in ranges between 0.05 mm and 0.5 mm for translations and between 0.15° and 1.15° for rotations (95% CI.) (Kaptein et al. 2004). The technique is considered being the gold standard in quantifying displacement or movements of orthopaedic implants in vivo (Kaptein et al. 2007).

Several imaging modalities have been developed including bone scintigraphy, PET-CT, FDG-PET to diagnose a loose implant. However it was found by Van der Aart et al. that the diagnostic performance of imaging techniques depends on the extent of implant loosening (Aart et al. 2014). Subtle implant motions are difficult to identify.

Despite all available techniques to identify a loose implant, revision surgery reveals that in 20 – 30 % of an expected loose implant, the implant is still fixed (Weissmann 2006). This means unnecessary performed surgery with associated costs and patient burden. Therefore, it is necessary to improve the techniques used to diagnose a loose implant pre-operatively.

1.4 Inducible displacement

Implant loosening is associated with motion of the implant (Wilson et al. 2010). Inducible displacement is method used to reveal implant motions. These implant motions can be distinguished in migration, i.e. gradual implant motion over time and inducible displacement. In the latter, implant position and orientation relative to the bone are measured during two different loading conditions of the implant. The difference of implant position between the two measurements is called inducible displacement (Ryd 1986); (Toksvig-larsen et al. 1998). However, measuring inducible displacements does not guarantee that an implant is loose. Even a clinically fixed implant shows inducible displacements due to elastic deformation of bone. It is assumed that if
micromotions above a certain value are measured, osseointegration has not occurred or is no longer present in an uncemented implant. And in the case of a cemented implant, no cement penetration in the bone (microlocking) has occurred or is no longer present.

To diagnose a loose implant, motion thresholds need to be determined. In the literature, several threshold values are mentioned. Engh et al. investigated implant fixation 1 to 8 years postoperatively (Engh et al. 1992). They related a maximum of 40 \( \mu \)m relative motion to a still osseointegrated implant whereas micromotion less than 40 \( \mu \)m was indicated as a result of elastic deformation of the bone tissue. Micromotions should ideally be smaller than 50 \( \mu \)m to obtain bone formation whereas fibrous tissue formation is known to occur where micromotions are greater than 150 \( \mu \)m (Pillar et al. 1986). Using a canine model, Jasty et al. demonstrated that 20 \( \mu \)m of cyclic motion allowed osseointegration, but at 40 \( \mu \)m the implants were surrounded by a fibrous cartilage or fibrous tissue in some areas (Jasty et al. 1997). Despite these investigations, no clear univocal threshold values exist which are clinically applicable.

Moreover, loosening thresholds are affected by several factors including loading conditions (i.e. externally applied load), implant geometry, bone quality and interface properties, i.e. layer between bone and implant (Taylor et al. 2012; Ploeg van der et al. 2012; Volz et al. 1987; Lee et al. 1991; Kraemer et al. 1995; Miller et al. 2014). All aforementioned factors need to be considered in order to determine subject specific inducible displacement thresholds. In other words, a loosening threshold should be considered as a function of a number of influencing factors.

\[
\text{Loosening threshold} = f(a, b, c, d, \ldots) \tag{1.1}
\]

with \( a, b, c \) and \( d \) are influencing factors. Approaching implant loosening from this point of view might lead to a more sensitive and specific diagnosis of implant loosening. A first step in this direction is to investigate the effects of these factors on inducible displacement. Doing this via an experimental or clinical approach by collecting data from different patients and knee implants is both expensive and time-consuming. Alternative methods make use of computational simulations. Finite element modelling (FEM) is such a tool that can be used to investigate mechanical behavior of a knee implant and to obtain more insight in the factors affecting implant loosening.

1.5 Finite element modeling

FEM is a powerful numerical method to analyze a wide range of problems and is found to be a valuable tool in the development of orthopedic implants (Roberts & Pallister 2012). FE-models can provide insight in implant behavior as it provides detailed information regarding stresses, strains, displacements and reaction forces at arbitrary points within the model. Such detailed information is not available in either in-vitro or in-vivo experiments. Moreover, model parameters such as material properties, boundary conditions and design features, can relatively easily be changed to get insight in the effects of the variations with relative low effort and costs.

FEM is extensively employed to study the mechanical behavior of implant and bone e.g. (Viceconti et al. 2001; Giori et al. 1995; Mann et al. 2014). Finite element models are based on a number of assumptions and simplifications of the reality. There-
before, a prerequisite for the reliability of a FE models is, that they are independently validated by experimental measurements (Stolk et al. 2002; Viceconti et al. 2001).

A validated FE-model can be used to investigate the effects of model parameters on inducible displacements. Such information can subsequently be used for the development of subject specific loosening thresholds.

1.6 Objective

The objective of this study is to set-up and to validate a finite element model that can be used to simulate inducible displacements of a tibial component of a knee implant.

Validation of the FE-models will be supported by sensitivity analyses which are performed to investigate the sensitivity of the FE-simulations for variations in assumptions made during the modelling process. Contact surfaces between bone and implant are assumed to be fully tied. Implant load application points are assumed for several load cases since exact locations were not known. Soft tissue layer properties were assumed as linear elastic. Bone material properties are based on certain selected formulations in the literature whereas, there are many different formulations available in the literature. Cement properties were not known and are assumed based on values provided in the literature.
2 Materials and Method

The FE-models were based on data and materials of an previously performed experimental study. Details about the experimental measurements are minutely described by J. Zibulski (Zibulski 2014), and only briefly reported here.

2.1 Experiment

Eight cadaveric tibiae, four left and four right, of similar size were obtained from the Anatomy Department of the Leiden University Medical Center (LUMC). These tibiae were prepared for implantation.

The used implant was the NexGen® Legacy posterior stabilized (LPS) Flex Fixed (Zimmer Inc, Warsaw USA) (Fig. 1). This implant was developed as a fixed bearing mechanism for total knee replacement. It is designed to accommodate deep flexion for patients, up to 155 degrees of flexion (Zimmer 2014).

All eight bones were used to analyze an aseptic loose implant. In this case a two millimeter thick silicone layer was placed between the bone-implant surface (Fig. 2). The silicone material was provided of non-linear material properties similar to human fibrous tissue. The silicone was composed of 90% Dragon Skin Pro-FX and 10% Dragon Skin 20.

Two of the eight bones were used to analyze a fixed implant by cementing the implants to the bone. For that, a Hi-fatigue® bone cement (Zimmer Inc, Warsaw USA) was utilized.

For the finite element analyses, one aseptic loose implant and one fixed implant were modelled (see section 2.2.2).

Several loading configurations were analyzed. The implant was loaded from the top as well as around its outer surface. Top loads were applied vertically at three different locations on the implant: center, left and right (Fig. 5). These top loads were exerted via the head surface of a M12 hex bolt (Fig. 4). Load magnitude was set to 800 N, corresponding to an average human being standing on one leg.

Implant side loading, in the transverse plane, was realized by exerting a load at 7 different positions (1-, 3-, 4-, 7-, 9-, 11- and 12-o’clock) on the outer surface of the im-
plant (Fig. 5). A load magnitude of 0 N - 200 N was exerted in 4 equally divided steps representing a range of physical activity.

To ensure standardized loading for all bones, they were fixated in a standard manner. Each bone was placed in a polyvinylchloride (PVC) holder and fixated by epoxy. This holder was placed in an adapter during testing (Fig. 3).

To detect displacement of the implant and the bone, optical markers were fixated to the implant and the bone. At least three markers are required to fully describe a rigid body motion in space. Three markers were connected to the bone via a plastic holder. On top of the implant, a load platform with a height 45 mm was mounted. The load platform contains three markers to measure implant motions (Fig. 3). These markers are positioned 24.7 mm above the implant surface.

An optical measurement device Optotrak Certus (Northern Digital Inc., Waterloo, Canada) was used to detect positions with a resolution of 0.01 mm and an accuracy of 0.1 mm. Marker positions were measured prior to each loading case and during each applied load. The positions of all six markers was registered with a frequency of 100 Hz for 3 seconds. The resulting values were XYZ-coordinates in space.

Fig. 3 - Experimental setup with mounted tibia and tibial implant. Markers are fixated to the implant and the bone in order to detect inducible displacements.

Fig. 4 - Implant top loading during experimental testing. A M12 hex bolt was used to exert the load via a load-platform on top of the implant. Adapted from: “predicting loosening in total knee arthroplasty” by J. Zibulski. 2014

Fig. 5 - Loading setups. Top loading lateral, medial and at center (800N) (left). Side loading at 7 different positions at outer surface of the implant (200N) (right).
2.2 Finite Element Models

2.2.1 Image acquisition

The cadaveric bones used in the experimental study were imaged using Quantitative Computed Tomography (QCT) scanning including two tibiae with an cemented implant and six tibiae with a cavity for a 2 mm silicone layer. The bones were scanned together with the PVC-holder and epoxy in which they were fixated (Fig. 6). A Toshiba Aquilion™ One 320-detector row CT (Toshiba Medical Systems, Tokyo, Japan) was used to acquire CT-data of the bones. The specimens were positioned with the tibial plateau parallel to the scan plane (Fig. 7). All specimens were scanned separately one after another in one session. A CT-scanning protocol was used containing parameter values used for high resolution QCT-scanning. The following CT acquisition parameters were used: Scanner power 250 mAs and 120 kVp, in-plane pixel size of 0.351 x 0.351 mm², slice increment 0.25 mm and slice thickness of 0.5 mm (Appendix A)

A QCT scanning phantom (QCT-Bone Mineral™ phantom; Image Analysis, Inc., Columbia, Kentucky, Serial No. 4225) was scanned together with the bones. Calibration phantoms are often used during CT-imaging for FE-purposes in order to determine CT-scan specific conversion equations to map Hounsfield units (HU) to bone mineral density (BMD) (Dragomir-daescu et al. 2015; Ploeg van der et al. 2012; Cann 1988). The Image Analysis (IA) calibration phantom consists of three embedded rods (20 mm in diameter) with different concentrations of calcium hydroxyapatite (CaHA) embedded in a water-equivalent polymer housing, with dimensions of 300 mm × 152 mm × 32 mm. These rods represent the specified concentrations of 50.0, 100.0 and 200.0 mgHA/cc with an accuracy of +/-0.5% (Fig. 8). This phantom was designed for QCT studies of trabecular regions of bones (Smith et al. 2011).

Phantoms need to be placed as close as possible to the specimen to minimize errors introduced by variations within the scan-field (Lotz et al. 1990). Therefore specimens were placed directly on top of the phantom during scanning (Fig. 9).

Beam hardening and scattering are effects that occur if metallic implants are scanned, leading to dark and bright streaks on the CT-images. Such effects might lead to disruption of the HU and subsequently to inaccurate BMD-values (Boas et al. 2012). One of the tibiae, used in this study contained a cemented implant. The effects of these
artefacts in the used CT-images were found to be minimal in the bony regions of interest within the scans. For more details of these effects on the scans, see Appendix B.

2.2.2 Specimen for FE-modelling

In this study, two models were built. 1) A model representing a tibia with a “loose” implant that was surrounded by a 2 mm thick silicone layer. 2) A model representing a tibia with a “fixed” (i.e., cemented) implant. To determine which of the eight scanned tibiae should be used for FE-modelling, the following procedure was followed. For the “loose” implant model, six tibiae were available. All had an implant cavity for a 2 mm thick silicone layer. Based on the experimental measurements, the specimen was selected showing displacements most near to the average measured displacements of the other specimens. This tibia was labeled as 1950R.

For the “fixed” implant model, two cemented implant specimens were available. The CT-images of both specimens were used to determine which of the two seems to be the most representative for a cemented implantation. As there were no worth mentioning differences visible, the contralateral tibia of 1950R was chosen. This specimen was labeled as 1950L.

Hereafter, these two models are indicated as the loose implant model and the fixed implant model.

2.2.3 Model geometries

The QCT-images were segmented such that only the bone tissue, the PVC holder and the epoxy material were included. Mimics 14.0 (Materialise, Leuven, Belgium) was used to perform the segmentation. Region growing was used for initial segmentation. Each slice was edited manually to exclude soft tissue (i.e. the delaminated periosteum) and to ensure that the fully bony region was included (Fig. 10a). Cement was segmented by using a threshold value of 1021 HU.

The geometry of the implant was provided by the LUMC’s department of Orthopaedics (NexGen® LPS Flex Fixed, Zimmer Inc, Warsaw USA) (Fig. 10b). After creating a 3D-geometry of the bone, the implant geometry was positioned relative to the bone by making use of the editing tool in 3-MaticSTL 5.1 (Materialise, Leuven, Bel-
gium). The right implant position was determined in the cemented case by creating a proper fit to the scanned implant contours in the CT-scan. Contact between surfaces of implant and cement was subsequently manually created in Mimics by adapting the cement mask (i.e. designation for segmented section within CT-images). In the case of the loose implant, the implant was positioned with a 2 mm offset from the bone surface to allow for modelling a silicone layer between implant and bone. This layer was modelled as follows; The 3D-geometry of the bone and implant were imported in Mimics and transformed into masks. Subsequently, a new mask was created manually between implant and bone representing the silicone layer geometry (Fig. 10c).

The platform, used for top loading and implant marker fixation, was reconstructed by manually measuring the platform geometry and subsequently a 3D-model was created in Inventor 2014 (Autodesk, Inc.) (Fig. 10d). This 3D-model, including implant marker locations, was imported as a stl-file in 3-MaticSTL and positioned on top of the implant at the same location as it was fixated in the experimental setup.

![Fig. 10](image)

**Fig. 10** – *a) CT-image in the transverse plane showing segmentation of bone (red) and cement (blue). b) 3D geometry of the implant. c) Cross-section in the sagittal plane of the bone (green) and implant (grey). Area between implant and bone was modelled as the silicone layer (orange). d) Manually measured and 3D-defined geometry of the load platform containing the marker implant positions (red).*

Unfortunately, it was not possible to import the full geometry of the loading platform (Fig. 10d) because the platform geometry partly fell out of the modelling range in the segmentation software. This was caused by the fact that during CT-scanning the modelling boundaries were determined tight around the bone specimen. Therefore, a smaller loading platform was modelled with a height of 8 mm instead of 45 mm. Also, the implant markers were repositioned at a distance of 5 mm above the implant instead of 24.7 mm (Fig. 11). To allow a fair comparison between the experimental outcome and FE-study outcome, the experimentally measured implant marker coordinates were corrected for this repositioning (Appendix D1).

The three markers connected to the bone were reconstructed as follows; Since, from the experimental data, the coordinates of these markers were known with respect
to the implant marker coordinates, all six marker coordinates were 3D-modelled being small spheres in *Inventor 2014*. This 3D-model was imported in 3-MaticSTL and positioned such that the spheres of the implant markers match with the implant marker positions on the loading platform. Thereafter, bone markers were connected to each other via a simple geometry, that on its turn was connected to the bone via modelling pins in the bone at the same locations as the screws in the experimental study (Fig. 12).

An overview of the defined geometries used for the FE-analyses is provided in Fig. 13.

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*Fig. 11 – Due to modelling limitations in the software, implant markers were repositioned at 5 mm above the implant surface (left) in contrast to 24.7 mm in the experimental setup (right).*

*Fig. 12 – In blue, the applied structure used to connect the bone markers (red) to the bone.*

*Fig. 13 – Overview of geometries included in the FE-models.*
2.2.4 Meshing

3D-dimensional FE-meshes of the model geometries were generated using 3-MaticSTL 5.1 (Materialise, Leuven, Belgium). To determine an appropriate mesh size, a mesh convergence analysis was performed. Three different uniform meshes with maximum element edge lengths of 5 mm (course mesh, 300,000 elements), 3.5 mm (medium quality mesh, 600,000 elements), 2.5 mm (semi-fine mesh, 1,200,000 elements) and 2 mm (fine mesh, 2,300,000 elements) were generated. A finer mesh could not be analysed since Mimics was not able to manage the data of such a fine mesh. The results of the fine mesh were used as a standard for the comparison of the results generated by the other meshes. Convergence – in terms of marker displacement - was found by increasing the number of elements. Since the semi-fine mesh differs less than 1% from the standard, and the medium quality mesh and coarse mesh less than 5%, a “smart” mesh was created. This mesh was generated by applying elements with a maximum element edge length of 1 - 2 mm in the bone, silicone layer and implant regions whereas in the remaining regions the maximum element edge length was set to 5 mm. In this way long computational times were avoided while preserving accuracy.

The used element type was the linear 4-node tetrahedrons (C3D4), mainly used to mesh irregular geometries and complex shapes (Zelle et al. 2011).

2.2.5 Material assignment

Assignment of material properties to the mesh was automated using the material assignment module in Mimics. Isotropic inhomogeneous material properties were assigned to the elements of the bone mesh. These properties were based on the linear relationship between HU and bone density. First, a linear regression analysis was performed to determine the relation between HU and CaHA concentrations within the phantom resulting in the linear relationship $\rho_{CaHA} = a \times HU + b$, where $a$ and $b$ are the calibration coefficients (Schileo et al. 2008; Gray et al. 2008). It was assumed that $\rho_{CaHA} = \rho_{ash}$ where $\rho_{ash}$ is the bone ash density that represents the bone mineral content (Schileo et al. 2008; Chen et al. 2010). For both finite element models, referred to as the “loose” and the “fixed” model, the following relations were determined:

$$\rho_{ash,\text{loose}} = 0.677 \times HU - 5.42$$

$$\rho_{ash,\text{fixed}} = 0.678 \times HU - 5.65$$

where $\rho_{ash}$ is calculated in [mg/cm$^3$].

The elastic modulus was determined based on a non-linear E-modulus - ash density relation found in the literature. Since it was found that the anatomic location of the bone has a considerable influence on the bone material properties, a relationship was selected that was defined for the proximal part of the tibia. (Morgan et al. 2003). The following relation was applied:

$$E = 15520 \times \rho_{ash}^{1.93}$$

Assigning this relation leads to a range of elastic moduli between 1 and 33 GPa in accordance to published finite element studies (Zelle et al. 2011; Cong et al. 2011;
Taylor et al. 1998). The poisson’s ratio was assumed as 0.4 based on previously performed research (Schileo et al. 2008; Stolk et al. 2002). The holes in the bone were represented in the models as low-stiffness elements (Tarala et al. 2011).

To allow for inhomogeneous material distribution, the mean HU number of each element was averaged from the values of the contained voxels. Elements were then grouped into 40 discrete material bins that approximate the continuous distribution (Fig. 14). Forty material bins was found to be a sufficient number (Dragomir-Daescu et al. 2011).

The silicone layer representing the soft tissue layer of the loose implant, was modelled as a non-linear material in the experimental study (Fig. 15). A pre-analysis showed that the strain values of the silicone layer in the finite element model did not exceed 0.1. Therefore, the silicone material was modelled with a E-modulus based on the linear part of the stress/strain curve, \( E = 0.188 \text{ N/mm}^2 \) (V. Waide et al. 2004). Possion’s ratio of 0.45 was assumed also been used for a silicone material in a similar study (Waide et al. 2004). The E-modulus for bone cement was assumed as 2.7 GPa and a poisson’s ratio of 0.4 based on previously performed finite element studies (Waide et al. 2004; Janssen et al. 2008).

The material properties of the implant were obtained from the manufacturer. An overview of all assigned materials is provided in Table 1.
2.2.6 Load & boundary conditions

For both FE-models, 9 different loading conditions were analyzed. Three load cases exerted on top of the implant and 6 loads cases exerted on the outer surface of the implant conformed performed experiments. Top loads (800N) were exerted at three locations (Pt1; center, Pt2; left, Pt3; right) on the implant via a load platform in which also three markers were fixated (Fig. 16). Implant side loading was applied at 6 different locations on the outer surface of the implant: 1 o’clock (P2), 3 o’clock (P3), 4 o’clock (P4), 7 o’clock (P5), 9 o’clock (P6), 11 o’clock (P7) (Fig. 17). A load magnitude of 200N was applied similar to the maximum applied load in the experimental study. Experimental results of side loading P1 were not available and therefore not analyzed in the FE-simulations.

The outer surface of the cylindrical holder was fully fixated similar as was done in the experimental study by the adapter, see Fig. 18 and section 2.1.

<table>
<thead>
<tr>
<th>Material</th>
<th>Elastic modulus [GPa]</th>
<th>Poisson’s ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant</td>
<td>Ti-6Al-4V</td>
<td>110</td>
</tr>
<tr>
<td>Bone</td>
<td>-</td>
<td>1 - 33</td>
</tr>
<tr>
<td>Cement</td>
<td>PMMA</td>
<td>2.7</td>
</tr>
<tr>
<td>Bone-holder</td>
<td>PVC</td>
<td>2.5</td>
</tr>
<tr>
<td>Epoxy</td>
<td>Epoxy</td>
<td>2.7</td>
</tr>
<tr>
<td>Loading platform</td>
<td>Steel</td>
<td>210</td>
</tr>
<tr>
<td>Bone marker holder</td>
<td>Steel</td>
<td>210</td>
</tr>
<tr>
<td>Silicone</td>
<td>-</td>
<td>0.19</td>
</tr>
</tbody>
</table>

Table 1 - Material properties of finite element components

Fig. 16 - Implant load positions on top of the implant at three different locations

Fig. 17 - Load positions at the outer surface of the implant at six different locations.
2.2.7 Interface modelling

For both FE-models, the interfaces between bone-silicone and silicone-implant (loose model) and between bone-cement and cement-implant (fixed model) were considered as fully tied. Several authors have assumed frictional contact at these interfaces, e.g. (Tarala et al. 2011; Chong et al. 2011; Stolk et al. 2002). It is likely that friction takes place at the silicone-implant and/or silicone-bone interface during loading moreover, during side loading, unbounding interfaces seems to be realistic. However, solving a FE-model containing frictional contact in Abaqus led to severe problems. No convergence was found during solving (See Appendix E). To investigate the effects of modelling tied interfaces compared to unbounding interface behavior, a sensitivity analysis was performed (See 2.4.1).

2.2.8 Finite element simulations

Simulations were performed in Abaqus v. 6.13 (Simulia, Providence, RI) by an implicit solver (Abaqus standard). The node coordinates representing the markers were captured before and after loading for each load case.

2.3 FE and Experimental comparison

Comparison between FEM and experimentally obtained results was done by comparing inducible displacements. Since three non-collinear markers were connected to both implant and bone, the rigid body motion of implant and bone could be calculated in 3D-space. Global coordinates of all six markers were available from the experimental study for both unloaded and loaded configurations. Marker coordinates in a global coordinate system were also extracted from the FE-models in an unloaded and loaded configuration. To allow for comparison between FE- and experimental obtained displacements the following procedure was used.

Global coordinates were transformed to a local coordinate system via the Matlab function “coordinate transformation” (Appendix D2) and expressed in an orthogonal XYZ-coordinate system. The implant markers midpoint was used as the local coordinate system origin. The implant markers could easily be used for an anatomical ori-
tation of the axes of the local coordinate system. The axes were aligned in such a manner that displacements along the X-axis can be described as medial and lateral, depending on a right or left tibial bone. The Y-axis was directed distally whereas the Z-axis can be used to describe anterior-posterior displacements (Fig. 19).

2.3.1 Implant and bone displacements
Rotation matrices and translation vectors were calculated for implant and bone displacements for each loading conditions by making use of the matlab function “move” based on an algorithm described by Söderkvist (Söderkvist & Wedin 1993) (Appendix D3). This function was made available by the Department of Orthopaedics of the LUMC. The displacements computed by this algorithm should be interpreted as a rotation around a basepoint equal to the origin and a translation \( d \) (Fig. 20).

2.3.2 Inducible displacement
The relative rotation and translation were calculated following the formulations provided by Yuan et al (Yuan et al. 1997);

\[
R_{\text{relative}} = R_{\text{bone}}^{-1} R_{\text{implant}}
\]
Implant and bone rotations were extracted from the rotation matrix using the
matlab function “rotxyz” obtained from the LUMC’s Department of Orthopaedics
(Appendix D4). It computes the Euler angles which fully describe the orientation of a
rigid body. Using Euler angles, the order of rotation is of crucial importance. The used
matlab function makes use of the following sequence: \( \alpha \); first rotation about the X-axis,
\( \beta \); second rotation about the Y-axis and \( \gamma \); third rotation about the Z-axis.

2.3.3 Displacement directions

Dependent of the load case, some rotations and translations are highly sensitive for
the applied load direction and the load application point. For example consider load
case P3 (Table 2), a small movement of the load application point in the Z-direction
could easily lead to a totally different displacement in the Z-direction and/or rotation
about the Y-axis. Since the load application points were not exactly known, rotations
and translations were only calculated in the dominant displacement directions in ac-
cordance to the induced displacement directions of the applied load. For the side load
cases P2, P4, P5 and P7, rotations and translations are provided in two directions. In
these cases the applied load induces displacements in two main directions leading to
two main rotations and translations.

An overview of load cases and corresponding calculated rotations and translations
is provided in Table 2.

2.3.4 FEM validation

The finite element models were used to predict the inducible displacements of the
experiments translations under the aforementioned load cases. Rotations and transla-
tions were calculated and compared to the experimental retrieved values. The root-
mean-square-error (RMSE) analysis was applied to determine an agreement between
experimental and numerical determined inducible displacements. The RMSE is defined
as the square root of the average of the squared errors between FE and experimental
determined inducible displacements.

\[
RMSE = \sqrt{\frac{\sum_{i=1}^{n}(u_{\text{experimental},i} - u_{fem,i})^2}{n}}
\]  

(2.6)
<table>
<thead>
<tr>
<th>Load case</th>
<th>Pt1 (topload, center)</th>
<th>Pt2 (topload, left)</th>
<th>Pt3 (topload right)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculated rotations</td>
<td>No dominant rotation</td>
<td>γ-rotation</td>
<td>γ-rotation</td>
</tr>
<tr>
<td>Calculated translations</td>
<td>Y-direction</td>
<td>Y-direction</td>
<td>Y-direction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Load case</th>
<th>P2 (side load)</th>
<th>P3 (side load)</th>
<th>P4 (side load)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculated rotations</td>
<td>α-rotation</td>
<td>γ-rotation</td>
<td>α-rotation</td>
</tr>
<tr>
<td>Calculated translations</td>
<td>X-direction</td>
<td>Z-direction</td>
<td>X-direction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Load case</th>
<th>P5 (side load)</th>
<th>P6 (side load)</th>
<th>P7 (side load)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculated rotations</td>
<td>α-rotation</td>
<td>γ-rotation</td>
<td>α-rotation</td>
</tr>
<tr>
<td>Calculated translations</td>
<td>X-direction</td>
<td>Z-direction</td>
<td>X-direction</td>
</tr>
</tbody>
</table>

Table 2 - Overview of calculated rotations and translations for each applied load
2.4 Sensitivity analyses

The FE-models were based on a number of assumptions and simplifications of the reality including bone material properties, load application points, interface modelling and cement material properties. Such assumptions and simplifications might lead to a certain error in comparison to the real situation. Sensitivity analyses are performed to obtain valuable information in order to assess to what extend these assumptions and simplifications affect the inducible displacements.

Results of the sensitivity analyses will also be used to explain the differences between experimental and FE-model obtained results.

2.4.1 Contact interface properties

For both FE-models, the interfaces between bone-silicone and silicone-implant (loose model) and between bone-cement and cement-implant (fixed model) were considered as fully tied. However, in reality, during loading, it is likely that to some extent the implant-silicone and/or silicone-bone interfaces will become loose (Hefzy & Singh 1997). To approximate such behavior, without modelling complicated interface interaction properties in Abaqus, the following approach was applied: First, loading cases P3, P6 and P5 were analyzed with tied interfaces since these load cases led to the largest inducible displacements. Subsequently, elements of the silicone layer that show displacements in the off bone direction were manually selected (i.e. elements in tension). These elements were provided of low stiffness properties (\( E = 0.01 \text{ N/mm}^2 \)) and the load cases were analyzed again (Fig. 21). Doing so, tension between implant and bone was avoided leaving only compression of the silicone layer.

To analyze the effects on inducible displacements in terms of rotations and translations, the RMSE was determined in order to assess the effects of fully tied and loose modelled contact surfaces.

2.4.2 Load application point

Load application points for the side load an top load cases were not exactly known and might be implemented with a deviation of a few millimeters. These points are briefly described in the experimental study. In order to assess the effects of the assumed applications points on the inducible displacements, position changes were made for top loads and side loads.

Load application point changes were applied and analyzed for side loads and a top load The latter was performed because it was expected that load application point changes in the X-direction will have a great effect on inducible rotations. Moreover, it was assumed that in the experimental study the load applications points were changing...
in the X-direction during loading as follows: Considering loading case Pt2 in the experimental study; during loading, the implant will rotate in positive direction about the Z-axis. The load was applied by a circular surface (M12 hex bolt) that is not able to rotate (Fig. 22). That results into a displacement of the load application point in the negative X-direction, to the edge of the load surface (Fig. 23). Effects of changing the load application point 10 mm in the negative X-direction on relative displacements were analyzed. Ten millimeter is half of head diameter of a M12 hex bolt.

Load application point changes were analyzed for three different side loading cases P3, P5 and P6. Loads application points were analyzed for a +5° and -5° rotation about the Y-axis (Fig. 24).

In order to determine the effects of load application point changes, the RMSE between numerical and experimental data was calculated for both, rotations and translations.
2.4.3 Bone material properties

An important assumptions is found to be the relation between bone density and elastic modulus of the bone (Schileo et al. 2008; Morgan et al. 2003). This relation is often formulated as follows: \( E = a^b \). Many relations between bone E-modulus and bone density are provided in the literature. More realistic results will be obtained if the anatomic site of the bone is considered (Helgason et al. 2008; Morgan et al. 2003). In the present study the proximal tibia is of interest. However, even large differences were found in relationships considering only the proximal tibia site (Helgason et al. 2008; Morgan et al. 2003). Values for \( a \) and \( b \) are found in a range of 10.83 – 22.23 and 1.7 – 2.16 respectively (Morgan et al. 2003).

To assess the effects of different elastic-density relationship on inducible displacements, two relationship were analyzed;

1. A relationship containing the minimum values for \( a \) and \( b \).

\[
E = 10.83 \times \rho_{\text{ash}}^{1.7}
\]

(2.7)

2. A relationship containing the maximum values for \( a \) and \( b \).

\[
E = 22.23 \times \rho_{\text{ash}}^{2.16}
\]

(2.8)

These two relationships are almost a doubling and halving of the assumed elastic-density relationship (Fig. 25).

Loading case P3 was selected as the loading condition leading to the largest displacements and therefore analyzed in this sensitivity analysis. In order to determine the effects of load application point changes on inducible displacements, the error between numerical and experimental results was calculated for both, rotations and translations.

Fig. 25 – Elastic – density relationships used for the sensitivity analysis containing minimum and maximum values for \( a \) and \( b \), based on Morgan et al. (Morgan et al. 2003)
2.4.4 Soft tissue material properties

The silicone material, used in the loose implant model, was assumed to be linearly elastic. The E-modulus was estimated as being 0.188 N/mm² (see 2.2.5). Since the silicone layer covers the whole implant surface and has a relatively low stiffness, it was expected that changes of the E-modulus would have a relatively great effect on inducible displacements. Inducible displacement were analyzed by doubling (E = 0.37 N/mm²) and halving (E = 0.095 N/mm²) the initially assumed E-modulus of the silicone layer. For this analysis, an implant top load (Pt2) was exerted on the implant. A top load was chosen since it was expected that the effects of interface properties on inducible displacement are the least for implant top loads. In order to determine the effects on inducible displacements, the error was determined between numerical and experimental results.

2.4.5 Cement material properties

The properties of the cement used for the implant fixation were not exactly known. A sensitivity analysis was performed to assess the effects of several cement elastic moduli. In the literature, E-moduli were found in a range between 2000 MPa and 3000 MPa. (Taylor et al. 1998; Janssen et al. 2008; Zelle et al. 2011; Waide et al. 2004).

Two analyses were performed by analyzing a cement with a E-modulus of 2000 MPa and 3000 MPa. For these analyses, the P3 load case was applied for aforementioned reasons. To determine the effects the errors were calculated between experimental and numerical determined inducible displacements.
3 Results

3.1 Results loose implant model

3.1.1 Top implant load cases

Considering the top loads Pt1, Pt2 and Pt3, induced implant translations based on the FE-analyses results are in good agreement with the experimentally based translations. Translations in the FE-model are found in the same direction as been measured in the experiment for all load cases. The FE-based translations are on average 4.4% larger (Fig. 26).

Rotations due to top loads are calculated for the P2 and P3 load case. The rotations were found in the same directions as in the experiments. The rotation magnitude in FE-study for both load cases is found about 5 times higher (Fig. 27).

A good correspondence was found between experimentally and numerically determined translations (RMSE = 0.05mm). The RMSE value with regard to rotations is relatively large (1.71°) in comparison to the maximum rotation of 2.36° (See Table 3).

<table>
<thead>
<tr>
<th>Top load cases</th>
<th>translations [mm] (RMSE)</th>
<th>rotations [°] (RMSE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pt1, Δy</td>
<td>1.08</td>
<td>-0.43</td>
</tr>
<tr>
<td>Pt2, Δy</td>
<td>1.11</td>
<td>2.36</td>
</tr>
<tr>
<td>Pt3, Δy</td>
<td>1.09</td>
<td>-1.95</td>
</tr>
</tbody>
</table>

Table 3 – Root mean square error (RSME) between experimental and numerical rotations and translation as a result of applied top implant loading.

3.1.2 Side implant loading cases

Translations due to side loads in the FE-study were found in the same direction as in the experimental study (Fig. 28). FE-based translations were found on average 4.5 times lower compared to the experimental values with a minimal differences of 1.1 times (P7, Δx) and maximal 8.8 times (P2, Δx) (Fig. 28).

Rotations as a result of the side loadings were found in the same direction as in the experimental study. All numerically calculated rotations are found on average 2.9
times lower compared to the experimentally based rotations. Minimal difference 1.3 times (P2, Δγ) and maximum difference 8.6 times (P5, Δγ) (Fig. 29).

![translations [mm]](image)

<table>
<thead>
<tr>
<th></th>
<th>P2, Δx</th>
<th>P2, Δz</th>
<th>P3, Δx</th>
<th>P4, Δx</th>
<th>P4, Δz</th>
<th>P5, Δx</th>
<th>P5, Δz</th>
<th>P6, Δx</th>
<th>P6, Δz</th>
<th>P7, Δx</th>
<th>P7, Δz</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Experiment</strong></td>
<td>0.77</td>
<td>1.98</td>
<td>2.69</td>
<td>2.18</td>
<td>-1.89</td>
<td>-1.97</td>
<td>-2.10</td>
<td>-2.45</td>
<td>-0.75</td>
<td>2.35</td>
<td></td>
</tr>
<tr>
<td><strong>FEM</strong></td>
<td>0.09</td>
<td>1.01</td>
<td>0.33</td>
<td>0.28</td>
<td>-0.28</td>
<td>-0.55</td>
<td>-0.58</td>
<td>-0.96</td>
<td>-0.68</td>
<td>1.00</td>
<td></td>
</tr>
</tbody>
</table>

Fig. 28 - Relative implant translations for the load cases P2, P3, P4, P5, P6 and P7. Translations are plotted for the main displacement directions as described in Table 2.

![rotations [°]](image)

<table>
<thead>
<tr>
<th></th>
<th>P2, Δα</th>
<th>P2, Δγ</th>
<th>P3, Δγ</th>
<th>P4, Δα</th>
<th>P4, Δγ</th>
<th>P5, Δα</th>
<th>P5, Δγ</th>
<th>P6, Δα</th>
<th>P6, Δγ</th>
<th>P7, Δα</th>
<th>P7, Δγ</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Experiment</strong></td>
<td>-1.88</td>
<td>0.71</td>
<td>2.73</td>
<td>1.37</td>
<td>1.91</td>
<td>2.08</td>
<td>-2.03</td>
<td>-3.14</td>
<td>-2.87</td>
<td>-1.00</td>
<td></td>
</tr>
<tr>
<td><strong>FEM</strong></td>
<td>-1.19</td>
<td>0.57</td>
<td>0.85</td>
<td>0.55</td>
<td>0.72</td>
<td>0.95</td>
<td>-0.24</td>
<td>-0.56</td>
<td>-1.17</td>
<td>-0.20</td>
<td></td>
</tr>
</tbody>
</table>

RMSE values for both rotations and translations were large 1.44° and 1.46mm in comparison to the maximal rotation value (2.73°) and translation value (2.69mm) (Table 4).

<table>
<thead>
<tr>
<th>Side load cases</th>
<th>translations [mm] (RMSE)</th>
<th>rotations [°] (RMSE)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.46</td>
<td>1.44</td>
</tr>
</tbody>
</table>

Table 4 – Root mean square error (RMSE) between experimental and numerical based rotations and translation based on applied side implant load cases.
3.2 Results fixed implant model

3.2.1 Top implant load cases

In contrast to the experimentally measured implant translations, nearly no translations were calculated for the FE-model (Fig. 30). FE based rotations are found in the same directions as in the experimental study. FE-model based implant rotations were found to be lower for both analyzed load cases, 0.85 and 0.40 times for Pt2 and Pt3 respectively (Fig. 31). Implant rotations for Pt1, i.e. center load of the implant, were not plotted since such a load case does not induce implant rotations.

RMSE values for both rotations and translations were large 0.016° and 0.012 mm in comparison to the maximal rotation value (0.037°) and translation value (0.015 mm) (Table 5).

<table>
<thead>
<tr>
<th></th>
<th>translations [mm]</th>
<th>rotations [°]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(RMSE)</td>
<td>(RMSE)</td>
</tr>
<tr>
<td>Top load cases</td>
<td>0.012</td>
<td>0.016</td>
</tr>
</tbody>
</table>

Table 5 – Root mean square error (RSME) between experimental and numerical rotations and translation as a result of applied top implant loading.

3.2.2 Implant side loadings

Relative translations and rotations of the FE-model are mainly found in the same directions as the experimentally based values. Contradictory translation directions occur in the Z-direction of load case P4 and P7 (Fig. 32). Such contradictory results are also found with respect to implant rotations in load case P2, P4, P5 and P7 (Fig. 33). In general, the FE-model based translations are considerable lower whereas rotations are found higher.
RMSE values for both rotations and translations were large 0.018 mm and 0.011 mm in comparison to the maximal rotation value (0.034°) and translation value (0.027 mm) (Table 6).

Fig. 32 - Induced implant translations for the load cases P2, P3, P4, P5, P6 and P7. Translations are plotted for the main displacement directions as described in Table 2.

Fig. 33 - Induced implant rotations for the load cases P2, P3, P4, P5, P6 and P7. Rotations are plotted for the main displacement directions as described in Table 2.

RMSE values for both rotations and translations were large 0.018° and 0.011 mm in comparison to the maximal rotation value (0.034°) and translation value (0.027 mm) (Table 6).

<table>
<thead>
<tr>
<th>Side load cases</th>
<th>translations [mm] (RMSE)</th>
<th>rotations [°] (RMSE)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.011</td>
<td>0.018</td>
</tr>
</tbody>
</table>

Table 6 – Root mean square error (RMSE) between experimental and numerical based rotations and translation based on applied top implant load cases.
3.3 Sensitivity analysis

3.3.1 Interface modelling

Allowing for interface debonding led to a considerable increase of implant displacements in the case of a side load application. A considerable increase of both rotations (Fig. 34) and translations (Fig. 35) was calculated. The RMSE decreases from $1.92^\circ$ to $0.72^\circ$ and from 1.74 mm to 0.91 mm. (Table 7).

<table>
<thead>
<tr>
<th></th>
<th>Rotations [°] (RMSE)</th>
<th>Translations [mm] (RMSE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tied interfaces</td>
<td>1.92</td>
<td>1.74</td>
</tr>
<tr>
<td>Loose modelled interfaces</td>
<td>0.72</td>
<td>0.91</td>
</tr>
</tbody>
</table>

Table 7 - Root mean square error (RSME) between experimental and numerical based rotations and translation. RMSE values are presented in relation to assumed load application point loads and the displaced load application point loads.

3.3.2 Load application point

3.3.2.1 Top load application point changes

Changing the load application point 10 mm (half of the head diameter of a M12 hex bolt (2.4.2)) towards the implant center on top of the implant, led to a substantially decrease of relative implant rotations. Rotations decreased with $1.69^\circ$ and $1.57^\circ$ for load case Pt2 and Pt3, respectively (Fig. 36). The RMSE decreases considerably considering rotational values (Table 8). Effects on translations are found relatively small and remain similar to the experimental translations. These findings are in accordance to what was expected (see section 2.4.2).
3.3.2.2 Side load application point changes

The effects of load application points changes on side loading induced displacements were small for both rotations (Fig. 38) and translations (Fig. 39). These small effects are also indicted by the relative small differences of RMSE as presented in Table 9.

![Comparison of experimental and numerical obtained rotations and translations.](image)

<table>
<thead>
<tr>
<th></th>
<th>Rotations [°] (RMSE)</th>
<th>Translations [mm] (RMSE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assumed load application points</td>
<td>1.71</td>
<td>0.06</td>
</tr>
<tr>
<td>Displaced load application points (10mm)</td>
<td>0.14</td>
<td>0.07</td>
</tr>
</tbody>
</table>

*Table 8 – Root mean square error (RMSE) between experimental and numerical based rotations and translation. RMSE values are presented in relation to assumed load application point loads and the displaced load application point loads*
Fig. 38 - Comparison of experimental and numerical obtained rotations. FE-results are plotted for assumed load application points and displaced load application points on top of the implant.

Fig. 39 - Comparison of experimental and numerical obtained rotations. FE-results are plotted for assumed load application points and displaced load application points on top of the implant.

<table>
<thead>
<tr>
<th></th>
<th>Rotations [°] (RMSE)</th>
<th>Translations [mm] (RMSE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assumed load application points</td>
<td>2.71</td>
<td>2.00</td>
</tr>
<tr>
<td>Displaced load application points -5°</td>
<td>2.73</td>
<td>2.05</td>
</tr>
<tr>
<td>Displaced load application points +5°</td>
<td>2.75</td>
<td>2.04</td>
</tr>
</tbody>
</table>

Table 9 – Root mean square error (RMSE) between experimental and numerical based rotations and translation. RMSE values are presented in relation to assumed load application point loads and the displaced load application point loads
3.3.3 Elastic modulus of bone material

The effects of different elastic-density relationships on inducible displacements were found relatively low. Halving the bone E-moduli values results in an increase of relative rotations of $0.0005^\circ$ and an increase of $0.0002$ mm with regard to translations. Doubling the E-moduli led to a decrease of relative rotations of $0.0004^\circ$ and a decrease of $0.0002$ mm with regard to translations. Effects on the RMSE are small and do not lead to a better agreement between experiment and FE-analysis (Table 9).

![Rotations and translations comparison](image)

**Fig. 40** – Comparison of experimental and numerical obtained rotations. FE-results are plotted for the calculated bone E-moduli, doubled and halved E-moduli values

<table>
<thead>
<tr>
<th></th>
<th>Rotations $[^\circ]$ (error)</th>
<th>Translations [mm] (error)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculated bone E-moduli</td>
<td>1.89</td>
<td>2.35</td>
</tr>
<tr>
<td>Halved E-moduli</td>
<td>1.88</td>
<td>2.34</td>
</tr>
<tr>
<td>Doubled E-moduli</td>
<td>1.87</td>
<td>2.34</td>
</tr>
</tbody>
</table>

*Table 10 – Root mean square error (RSME) between experimental and numerical based rotations and translation. RMSE is presented between experiment and: the calculated bone E-moduli, halved E-moduli values and doubled E-moduli values*
3.3.4 Elastic modulus of silicone material

Doubling and halving the E-modulus of the silicone layer results into nearly a halving and doubling of inducible displacement. An E-modulus of 0.37 MPa (doubled) led to a rotational decrease of 1.04° and a translational decrease of 1.06 mm (Fig. 42, Fig. 43). A applied E-modulus of 0.095 MPa (halved) results into a rotational increase of 2.11° and a translational increase of 1.17 mm. Changing the silicone E-modulus has also a great effect on the RMSE. The rotational error changes with more than a factor 4 between doubling and halving the E-modulus whereas the translational error changes with more than a factor 2 between doubling and halving the E-modulus (Table 11).

|                               | Rotations [°] | Translations [mm] |
|                               | (error)       | (error)           |
| Assumed silicone E-modulus     | 1.88          | 0.07              |
| Halved E-modulus              | 4.00          | 1.23              |
| Doubled E-modulus             | 0.85          | 0.50              |

Table 11 – Root mean square error (RSME) between experimental and numerical based rotations and translation. RMSE is presented between experiment and: the assumed silicone E-modulus value, the halved E-modulus value and the doubled E-modulus value.

Fig. 42 – Comparison of experimental and numerical obtained rotations. FE-results are plotted for the assumed silicone layer E-modulus and for doubled and halved E-moduli values.

Fig. 43 – Comparison of experimental and numerical obtained translations. FE-results are plotted for the assumed silicone layer E-modulus and for doubled and halved E-moduli values.
3.3.5 Elastic modulus of cement

Miniscule effects on relative implant displacement are found by varying the E-modulus of the cement. A high E-modulus value (3000 MPa) led to a decrease of relative rotations (0.0001°) and translations (0.0001 mm). Analyzing a low E-modulus value (2000 MPa) led to no relevant relative displacements differences.

![Comparison of experimental and numerical obtained rotations. FE-results are plotted for the assumed cement E-modulus of 2700 MPa, for a cement E-modulus of 2000 MPa and for a cement E-modulus of 3000 MPa.](image1)

![Comparison of experimental and numerical obtained rotations. FE-results are plotted for the assumed cement E-modulus of 2700 MPa, for a cement E-modulus of 2000 MPa and for a cement E-modulus of 3000 MPa.](image2)

<table>
<thead>
<tr>
<th></th>
<th>rotations [°] (error)</th>
<th>translations [mm] (error)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assumed cement E-modulus, E = 2700MPa</td>
<td>0.0311</td>
<td>0.0265</td>
</tr>
<tr>
<td>E = 2000MPa</td>
<td>0.0310</td>
<td>0.0265</td>
</tr>
<tr>
<td>E = 3000MPa</td>
<td>0.0311</td>
<td>0.0266</td>
</tr>
</tbody>
</table>

Table 12 – Root mean square error (RSME) between experimental and numerical based rotations and translation. RMSE is presented between experiment and: the assumed cement E-modulus value, a cement E-modulus of 2000MPa and a cement E-modulus of 3000MPa.
4 Discussion

The objective of this study was to set-up and to validate a finite element model that can be used to simulate inducible displacements of a tibial component of a knee implant. Two FE-models were build based on experimental material and data that was created during a previously performed study (Zibulski 2014). One FE-model had a silicone layer between implant and bone to allow inducible displacements whereas the implant in the second FE-model was fully cemented into the bone to represent a fixed implant. In order to validate the FE-models, inducible displacements were calculated based on markers connected to the bone and the implant and compared to experimental based inducible displacements.

4.1 Loose implant model

All translation- and rotation directions of the FE-model were in the same directions as been measured in the experiment for all applied load cases. Displacement directions were also found in accordance to what was expected regarding the directions of the applied loads.

Translations induced by top implant loads were found to be in good agreement to the experimental results (RMSE = 0.05 mm). Inducible rotation differences due to top implant loads are relatively large (RMSE = 1.71⁰). A plausible explanation for this error is that load cases Pt2 and Pt3 were implemented incorrectly. As described in section 2.4.2, it was suggested that the load application points for load cases Pt2 and Pt3 (lateral and medial implant top loads) should be located more to the center of the implant similar to what may have occurred during experimental testing. Load application more centrally reduces the moment and thereby implant rotations. This suggestion seems to be correct since the RMSE with regard to the rotations decreased considerably (RMSE = 0.14⁰). To avoid the phenomenon of changing load application points during experimental loading, loads should ideally be exerted by a sphere as described by (Gray et al. 2008; Completo et al. 2007).

The side implant loads led to relatively large errors after comparing numerical and experimental determined inducible displacements. Both, numerical determined rotations and translations were considerably less resulting in a RMSE of 1.44⁰ and 1.46 mm. These differences can be explained by an essential modelling simplification. Interface interaction properties were not specified and interfaces between silicone and bone and between silicone and implant were simply fully tied. Tied interfaces results into stiffer implant behavior and less inducible displacement.

Several FE-studies in which implanted tibiae were analyzed demonstrate the use of frictional contact (e.g. Chong et al. 2010; Chong et al. 2011; Taylor et al. 2012; Viceconti et al. 2001). Also in the present study, an attempt was done to implement interface contact properties like frictional contact and debonding interface behavior. However, it was found that the inclusion of frictional contact led to convergence problems during solving. A solution was found unto 4.1% of the total load was applied, even with load increments of 1·10⁻⁵. Therefore, frictional behavior was not implemented in the FE-models. To get more insight in the convergence problem, a simplified model was designed (see Appendix E). Solving this simplified FE-problem led to similar
convergence problems as occur in the tibiae FE-models. No convergence was found and a solution was provided until 45% of the total load was applied.

The complexity of modelling frictional contact and soft tissue is also mentioned in previously performed research. No convergence was found during the analysis of a FE-model in which a soft tissue was modelled between implant and bone including frictional contact. (Viceconti et al. 2001). A study performed by Giori et al. related the convergence problems to the inclusion of a soft material (Giori et al. 1995).

An important question is what the effects on inducible displacements are if interfaces are modelled tied or with frictional contact properties. To come up with a estimation of the effects, the implanted tibia was analyzed with frictional properties at the interfaces and with tied interfaces. Frictional properties were implemented making use of a Coulomb friction model with a friction coefficient of 0.2µ (Janssen et al. 2008; Completo et al. 2008; Viceconti et al. 2001). Since the inclusion of frictional contact properties provides a solution until 4.1% of the total load (33.5 N), this load magnitude was exerted at load position Pt2 (top load at the left side). Displacements of the tied interface model were calculated 30% less compared to the displacements occurring in the friction model. The relatively large influence of friction was also confirmed by other authors (Bernakiewicz & Viceconti 2002; Viceconti et al. 2000). However, the found differences are only valid for small load magnitudes (33.5 N). More insight in the effects of frictional contact can be obtained if the total load is applied. Therefore, additional research is required to determine representative friction coefficients as well as a method to implement frictional behavior in the present FE-models.

If frictional contact is not set in Abaqus v. 6.13, it is impossible to define debonding interface behavior. Therefore, interfaces were fully tied. A sensitivity analysis, based on a trick to allow for debonding surfaces (see 2.4.1), indicates that this simplification introduces a large error for both translations and rotations in the case of side loading. RMSE are 1.92° and 1.74 mm. Allowing for debonding surfaces reduces the RMSE to respectively 0.72° and 0.91 mm. These errors occur especially if side loads are exerted on the implant. Implant side loads induce implant displacements away from the bone surface at some parts of the connected surfaces. The effects of debonding behavior in the case of applied top loads are thought to be small since top implant loads mainly induce displacements towards the bone surface. Despite the RMSE reduction, still an error remains for rotations (0.72°) and translations (0.91°). Including frictional contact properties might lead to a further reduction of the error.

A sensitivity analysis demonstrates that the silicone layer material properties have a considerable effect on inducible displacements. Doubling and halving the silicone layer stiffness leads, respectively, to almost a halving and doubling of inducible displacements. This is likely since the layer is considerably much less stiff compared to the bone and implant materials. One should be aware that the presence of a soft tissue layer on the whole implant-bone surface is a very unlikely situation (Haddad et al. 1987). It has usually been described only in the final stage of implant loosening. Further research is required to address the effects of soft tissue thickness and location on inducible displacements.

The effects of varying the bone stiffness on inducible displacements are negligible. Halving or doubling the bone stiffness results into, respectively, a decrease and increase
of inducible displacements in an order of magnitude of $10^{-3}$ millimeters. Implant displacements used as threshold values to distinguish a loose- or fixed implant are indicated to be in an order of magnitude of $10^{-1}$ millimeters (Pillar et al. 1986; Ryd, L. Carlsson, et al. 1993). That makes an accurate determination of bone material properties irrelevant in the assessment of inducible displacements of a loose implant. Many FE-studies demonstrate the use of a QCT-scanning procedure in order to determine accurate E-moduli for the bony regions e.g. (Ploeg van der et al. 2012; Viceconti et al. 2001; Tarala et al. 2011). However, one should be aware that the distance between bone markers and the implant is an important factor. The greater this distance, the larger the effects of bone deformations on inducible displacements are. Effects on inducible displacements were estimated 0.3 mm if bone markers are some centimeters away from the implant (Ryd, Lars Carlsson, et al. 1993). However, in the presented FE-models, the distance is only a few millimeters. That makes an accurate determination of bone material properties superfluous. In such cases probably, simply assigning homogeneous material properties to the cortical and trabecular bone regions will be sufficient as been presented in other studies (Completo et al. 2007; Completo et al. 2008).

### 4.2 Fixed implant model

Inducible displacements of the fixed implant model were found considerable less compared to the results of the loose modelled implant. Rotations and translations were found in an order of magnitude of $10^{-2}$ deg. and $10^{-3}$ mm whereas rotations and translations in the loose model are found in an order of magnitude of $10^{-1}$ deg. and $10^{-1}$ mm. The comparison of experimental and numerical determined displacements directions reveals contrary displacement directions for several load cases. Remarkable was that even several experimental determined displacement directions were in the opposite direction of the applied load directions (e.g. $\Delta Z$ in load case P7, and $\Delta \alpha$ and $\Delta \gamma$ in load case P2). These discrepancies could be explained by considering the accuracy of the 3D-measurement system used in the experimental measurements. The used measurement system was the optical measurement device Optotrack Certus (Northern Digital Inc., Waterloo, Canada) with an accuracy of 0.1 mm and a resolution of 0.01 mm (NDI Measurement Sciences 2016). The measured inducible displacements are found two orders of magnitude below the accuracy of the measurement device. That implies that inducible displacements based on this measurement device are unreliable. Experimental measurements suitable to validate a FE-model should be a factor 10 more accurate in comparison to the measured values (Viceconti et al. 2000);

Considering the results of the fixed implant from clinical point of view, motion threshold values to diagnose a fixed implant are believed to be <200 µm. (Burke et al. 1991; Pillar et al. 1986). Both, experimental and FEM determined displacements are found one order of magnitude less than this threshold value. Therefore, it can be concluded that the FE-model is valid to simulate a “fixed” implant.

### 4.3 Limitations

There are several limitation in the present study. No contact properties were implemented in the FE-models. However, it was demonstrated that inducible displacements are sensitive for contact properties in particularly if side loads are applied. Top loading of the implant mainly leads to compression that mainly will not lead to
debonding surfaces. Therefore modelling friction or debonding surfaces behavior seems to be of less interest if top loads are analyzed.

A limitation of the loose interface modeling approach, as described in section 2.4.1, was the following; elements that show displacements away from the bone surface were manually selected which is an inaccurate manner of selecting the elements. A more accurate approach would be if all elements were selected that show a positive strain value, since a positive value represents tension. The selection of the elements should be done in a computational way. However, the applied method gives a good indication of the model sensitivity to tied or untied surfaces.

Another limitation is that the silicone and cement layer were manually modelled. That implies for the silicone layer that an exact fit of the interfaces between implant-silicone and bone-silicone was created. However, it was found that the silicone layer used in the experimental study did not exactly fit into the bone cavity. Some compression force was needed to place the implant and silicone layer into the tibia. This compression force introduces stresses at the interfaces. Such stresses are hardly to detect and therefore not included in the FE-models. With regard to the cement layer, no cement penetration regions were modelled. A study performed by Janssen et al. showed that these regions have a considerable influence on implant behavior (Janssen et al. 2008).

Another limitation in this study was that load application points were not exactly known. The effects of assumed load application points on inducible displacements are small if implant side loads are applied. However, if implant top loads are analyzed, the load application point strongly affects inducible displacements as reported in section 3.3.2.

5 Conclusion and future research

Two FE-models were build, a model to present an aseptic loose implant and a model to present a fixed implant. The validation of a FE-model shows that large errors occur if interface interaction properties are neglected and if load application points are not implemented accurately. A sensitivity analysis shows that the inclusion of interface interactions properties and accurate load application points will contribute to a considerable reduction of the error. An accurate determination of bone material properties is superfluous if inducible displacements are analyzed with bone markers located close to the implant surface. To validate inducible displacements of a FE-model containing a cemented implant by using experimental data, a sufficiently accurate measurement device is required to capture the relatively small inducible displacements.

To obtain improved validation results of the present FE-models, an optimization step is required. In this step contact properties need to be implemented that at least allow for debonding surfaces. Also the effects of frictional contact need to be implemented in order to investigate the effects of frictional contact on inducible displacements. Moreover load application points should be implemented that represent accurately the experimentally applied load application points.
6 References


Dalury, D.F. et al., 2013. Why are total knee arthroplasties being revised? The Journal of arthroplasty, 28(8 Suppl), pp.120–1.


Wilson, D. a J. et al., 2010. Inducible displacement of a trabecular metal tibial monoblock component. *The


Appendix A

Quantitative computed tomography (QCT) scans were made at the Radiology department of the LUMC on May 5, 2015. Eight tibiae, including two implanted tibiae, were obtained from the anatomic department of the LUMC. A dry-bone-specific image kernel (FC81) was applied to acquire high resolution images. Details of the utilized protocol are shown below.
Appendix B

Introduction
The QCT-scanned tibiae specimens consist not only of bony material. The distally parts of the tibiae were potted in and PVC-holder and fixated by epoxy. Also, two of the included specimen had a cemented implant. High density materials like PVC and metals to some extent will affect the Hounsfield units (HU) in the CT-images (Boas et al. 2012). Since, density and E-modulus are calculated based on the HU, it is important to investigate the effects of the PVC, epoxy and implant material on the HU.

Method
The QCT-scans of the implanted tibia and the tibia without implant including the calibration phantom were divided in several scan-regions (Fig. 46). The regions 2 in both scans included bony material, epoxy and the PVC holder. The regions 3 included only bony material. Region 4 includes the implant stem together with the proximal part of the tibia whereas region 5 includes only the implant in the CT-scan of the implanted tibia. Within each scan-region the average HU were measured in the phantom-regions of known densities (50, 100, 200 mgHA/cm$^3$).

Results
Results for the regions of interest are plotted in Fig. 47 and Fig. 48. A average differences of about 20% was found between the regions 2 and 3 in both scans. Nearly no differences were measured between the regions 3 and 4 in the CT-scan of the implanted tibia (Fig. 48). HU differences in region 5 (only implant material) are on average -136% compared to region 3 (only bony material).

Discussion / conclusion
High density materials have a considerable influence on HU. However, the effects of high density materials is mainly interesting in the regions including bone material like region 2, 3 and 4. Region 3 and 4 are the main important regions since these regions mainly have an effect on inducible displacements. Differences in measured HU
between these regions are small. Therefore, relations between HU and density were based on measurements in regions 3.

**Fig. 47** - Measured HU in the known density-regions of the phantom for the several scan-regions of the tibia without implant.

**Fig. 48** - Measured HU in the known density-regions of the phantom for the several scan-regions of the tibia with implant.
Appendix D

Appendix D1

%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%
%%%%% This function allows a certain displacement %%%%%
%%%%% of the global implant markers coordinates in the %%%%%
%%%%% Y-direction (perpendicular to the plane between %%%%%
%%%%% the marker points)                                     %%%%%
%%%%% 29-9-2015                                               %%%%%
%%%%% G. van Wolfswinkel                                      %%%%%
%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%%

function [m4g_ul_c, m5g_ul_c, m6g_ul_c, ...
    m4g_lo_c, m5g_lo_c, m6g_lo_c] = ImplantMarkerCorrection(...
    m4g_ul, m5g_ul, m6g_ul, ...
    m4g_lo, m5g_lo, m6g_lo, ImpMaDisp);

% TRANSFORMATION OF UNLOADED MARKERS
% Definition of orthogonal local coordinate system
% X-axis pointing from marker 5 to marker 6
ex_ul = m6g_ul - m5g_ul;
ex_ul = ex_ul./norm(ex_ul)';
% Y-axis perpendicular to the plane of marker 4,5 and 6
ey_ul = (cross((m4g_ul - m5g_ul),(m6g_ul - m5g_ul))./
    norm(cross((m4g_ul - m5g_ul),(m6g_ul - m5g_ul))));
% Z-axis perpendicular to the X- and Y-axis
ez_ul = cross(ex_ul,ey_ul);
E_local_ul = [ex_ul, ey_ul, ez_ul];
% Coordinate system origin
origin_implant_ul = m5g_ul;
% Transformation of global into local coordinates
m4l_ul = (inv(E_local_ul)*(m4g_ul - origin_implant_ul))';
m5l_ul = (inv(E_local_ul)*(m5g_ul - origin_implant_ul))';
m6l_ul = (inv(E_local_ul)*(m6g_ul - origin_implant_ul))';
% displacement of the local coordinates in the Y-direction
m4l_ul_disp = m4l_ul + ImpMaDisp*[0,1,0];
m5l_ul_disp = m5l_ul + ImpMaDisp*[0,1,0];
m6l_ul_disp = m6l_ul + ImpMaDisp*[0,1,0];
% transformation of the local coordinates into global coordinates
m4g_ul_c = (E_local_ul*m4l_ul_disp'+origin_implant_ul);
m5g_ul_c = (E_local_ul*m5l_ul_disp'+origin_implant_ul);
m6g_ul_c = (E_local_ul*m6l_ul_disp'+origin_implant_ul);

% TRANSFORMATION OF LOADED MARKERS
% Definition of orthogonal local coordinate system
% X-axis pointing from marker 5 to marker 6
ex_lo = m6g_lo - m5g_lo;
ex_lo = ex_lo./norm(ex_lo)';
% Y-axis perpendicular to the Y-axis in the plane of marker 4,5 and 6
ey_lo = (cross((m4g_lo - m5g_lo),(m6g_lo - m5g_lo))./
    norm(cross((m4g_lo - m5g_lo),(m6g_lo - m5g_lo))));
% Z-axis perpendicular to the X- and Y-axis
ez_lo = cross(ex_lo,ey_lo);
E_local_lo = [ex_lo, ey_lo, ez_lo];
% Coordinate system origin
origin_implant_lo = m5g_lo;
% Transformation of global into local coordinates
m4l_lo = (inv(E_local_lo)*(m4g_lo-originImplant_lo))';
m5l_lo = (inv(E_local_lo)*(m5g_lo-originImplant_lo))';
m6l_lo = (inv(E_local_lo)*(m6g_lo-originImplant_lo))';

% displacement of the local coordinates in the Y-direction
m4l_lo_disp = m4l_lo + ImpMaDisp*[0,1,0];
m5l_lo_disp = m5l_lo + ImpMaDisp*[0,1,0];
m6l_lo_disp = m6l_lo + ImpMaDisp*[0,1,0];

% transformation of the local coordinates into global coordinates
m4g_lo_c = (E_local_lo*m4l_lo_disp+originImplant_lo);
m5g_lo_c = (E_local_lo*m5l_lo_disp+originImplant_lo);
m6g_lo_c = (E_local_lo*m6l_lo_disp+originImplant_lo);
end
Appendix D2

\[
\text{This function transforms marker coordinates from a global coordinate system into a user defined local coordinate system.}
\]

\[
\text{Input:}
\]
- Global coordinates of marker points
- The local coordinate system origin

\[
\text{Output:}
\]
- The marker coordinates expressed in the Local anatomical based coordinate system

\[
\text{function } \begin{bmatrix} m_{1l\_ul}, m_{2l\_ul}, m_{3l\_ul}, m_{4l\_ul}, m_{5l\_ul}, m_{6l\_ul}, m_{1l\_lo}, m_{2l\_lo}, m_{3l\_lo}, m_{4l\_lo}, m_{5l\_lo}, m_{6l\_lo} \end{bmatrix} = \text{coordinate transformation} \begin{bmatrix} m_{1g\_ul}, m_{2g\_ul}, m_{3g\_ul}, m_{4g\_ul\_c}, m_{5g\_ul\_c}, m_{6g\_ul\_c}, m_{1g\_lo}, m_{2g\_lo}, m_{3g\_lo}, m_{4g\_lo\_c}, m_{5g\_lo\_c}, m_{6g\_lo\_c}, \text{origin}\_\text{implant} \end{bmatrix};
\]

\[
\text{X-axis points from marker 5 to marker 6}
\]
- \(e_x = m_{6g\_ul\_c} - m_{5g\_ul\_c}\);
- \(e_x = e_x / \|e_x\|'\);

\[
\text{Y-axis perpendicular to } e_z \text{ and } e_y
\]
- \(e_y = (\text{cross}(m_{4g\_ul\_c} - m_{5g\_ul\_c}, m_{6g\_ul\_c} - m_{5g\_ul\_c}) / \|\text{cross}(m_{4g\_ul\_c} - m_{5g\_ul\_c}, m_{6g\_ul\_c} - m_{5g\_ul\_c})\|)\);

\[
\text{The Z-axis perpendicular to x and y}
\]
- \(e_z = \text{cross}(e_x, e_y)\);

\[
E_{\_local} = [e_x, e_y, e_z];
\]

\[
m_{1l\_ul} = (\text{inv}(E_{\_local}) \cdot (m_{1g\_ul} - \text{origin}\_\text{implant}))';
m_{2l\_ul} = (\text{inv}(E_{\_local}) \cdot (m_{2g\_ul} - \text{origin}\_\text{implant}))';
m_{3l\_ul} = (\text{inv}(E_{\_local}) \cdot (m_{3g\_ul} - \text{origin}\_\text{implant}))';
m_{4l\_ul} = (\text{inv}(E_{\_local}) \cdot (m_{4g\_ul\_c} - \text{origin}\_\text{implant}))';
m_{5l\_ul} = (\text{inv}(E_{\_local}) \cdot (m_{5g\_ul\_c} - \text{origin}\_\text{implant}))';
m_{6l\_ul} = (\text{inv}(E_{\_local}) \cdot (m_{6g\_ul\_c} - \text{origin}\_\text{implant}))';
m_{1l\_lo} = (\text{inv}(E_{\_local}) \cdot (m_{1g\_lo} - \text{origin}\_\text{implant}))';
m_{2l\_lo} = (\text{inv}(E_{\_local}) \cdot (m_{2g\_lo} - \text{origin}\_\text{implant}))';
m_{3l\_lo} = (\text{inv}(E_{\_local}) \cdot (m_{3g\_lo} - \text{origin}\_\text{implant}))';
m_{4l\_lo} = (\text{inv}(E_{\_local}) \cdot (m_{4g\_lo\_c} - \text{origin}\_\text{implant}))';
m_{5l\_lo} = (\text{inv}(E_{\_local}) \cdot (m_{5g\_lo\_c} - \text{origin}\_\text{implant}))';
m_{6l\_lo} = (\text{inv}(E_{\_local}) \cdot (m_{6g\_lo\_c} - \text{origin}\_\text{implant}))';
\]

end
Appendix D3

```matlab
function [R,d,cond_abs] = move(x,y)
% 7-14-1993
% Functie voor het bepalen van de rotatiematrix M en
% de translatievector d voor een stelsel punten volgens de
% methode van Soderkvist blz. A-5
% x = matrix met meetpunten van een voorwerp op tijdstip 0
% y = matrix met meetpunten van hetzelfde voorwerp op tijdstip 1
% R = rotatiematrix
% d = translatievector

% bepaling van hulpvariabelen
[dummyx,sizecolx] = size(x);
dummyy,sizecoly] = size(y);
e = ones(1,sizecolx);
f = ones(1,sizecoly);

% bepaling van gemiddelde waarden van x en y
% x en y worden getransponeerd om de gemiddelde waarden van de
% afzonderlijke coordinaten te kunnen bepalen
xmean = mean(x')';
ymean = mean(y')';

% aanpassen van gemiddelde waarden aan afmetingen van matrices x en y
Xmean = xmean*e;
Ymean = ymean*f;

A = x - Xmean;
B = y - Ymean;

F = B*A';
% singuliere waarden decompositie van F
[U,S,V] = svd(F);

% bepaling van rotatiematrix M
R = U*V';
% de determinant van de rotatiematrix wordt 1 gemaakt
correctie = [1 1 -1];
if round(det(R)) == -1
    R = U*diag(correctie)*V';
end

% bepaling van de verplaatsing van de punten
d = ymean - R*xmean;

cond_abs = inv(sqrt(S(2,2)^2 + S(3,3)^2));
```

49
Appendix D4

```matlab
function [x,y,z] = rotxyz(R)
% programma voor het berekenen van de rotaties x, y en z resp. rond de x-, y- en de z-as uit de gegeven matrix R

y1 = asin(R(1,3));
sz = -R(1,2)/cos(y1);
cz = R(1,1)/cos(y1);
z1 = atan2(sz,cz);
sx = -R(2,3)/cos(y1);
cx = R(3,3)/cos(y1);
x1 = atan2(sx,cx);
if y1>=0
    y2 = pi - y1;
else
    y2 = -pi - y1;
end
sz = -R(1,2)/cos(y2);
cz = R(1,1)/cos(y2);
z2 = atan2(sz,cz);
sx = -R(2,3)/cos(y2);
cx = R(3,3)/cos(y2);
x2 = atan2(sx,cx);
if ((abs(y1)+abs(z1)+abs(x1)) <= (abs(y2)+abs(z2)+abs(x2)))
    y=y1*180/pi;
    z=z1*180/pi;
    x=x1*180/pi;
else
    y=y2*180/pi;
    z=z2*180/pi;
    x=x2*180/pi;
end
```
Appendix E

Interface properties are often implemented in FE-studies in which mechanical implant behavior is analyzed. Previous studies considered the bone interface frictionless to represent no bony ingrowth or tied to represent either complete bone ingrowth or a cemented implant (Hashemi & Shirazi-Adl 2000). If friction is modelled, the Coulomb’s frictional model is mainly employed. The coulombs frictional model allows for sliding if tangential stresses exceed the friction stresses and for bonding if tangential stresses are below friction stresses.

The for this study used FEM package, Abaqus v. 6.13, provides the possibility to implement Coulomb friction properties. FE-problems containing friction behavior require a non-linear solving approach. Non-linear FE-problems are computational intensive, and often time consuming.

Implementation of frictional behavior in the FE-models of this study leads to convergence problems during solving. A solution was provided until 4.1% of the applied, thereafter, to solutions diverged even if small load increments of $1 \times 10^{-5}$ were applied. To get more insight in these problems and to save computational times, a simplified model was constructed.

Simplified model

The model consists of three disks located on top of each other with a diameter 40 mm and a thickness of 10mm. The outermost disks present a hard material like bone and implant. The disk in the middle was provided of material properties similar to the silicone layer. Bottom side of the bottom disk was fully constrained and an equally distributed pressure was exerted on top of the top disk (Fig. 49).

Between the disks, frictional contact was modelled according to the Coulombs friction model with a friction coefficient of 0.2. This coefficient was also used in a study to model friction between a silicone like material and a hard material (Viceconti et al. 2001).

In order to solve a this non-linear problem, the implicit solver of Abaqus v. 6.13 was used. A standard time step op 0.1 was applied whereas the minimum allowable time step was defined as $1 \times 10^{-5}$.

Solving this simplified problem led to a similar result as was obtained by solving the implanted tibiae. No convergence was found and the analysis stops after solving the application of 45% of the total load (Fig. 50).

Decreasing the load magnitude has a considerable influence on the solution. If half of the load is exerted, the implicit solver provides a solution until 90% of the total exerted load. A similar effect is found if the E-modulus of the silicone material is halved or if the friction coefficient is doubled. However, the application of values representative for the implanted tibiae problems were found insolvable.

The analysis of a soft tissue layer at the bone-implant or bone-cement interface is sparingly investigated by FE-modeling. A study performed by Giorgi et al. demonstrates the use of a 2D-model to analyze a soft tissue layer between bone and cement at the tibia plateau (Giori et al. 1995). However, no frictional contact was modelled and interfaces were modelled as fully tied. A 3D-FE-model containing both, a soft tis-
sue layer between bone and implant was modelled by Waide et al. to investigate the effects of a soft tissue layer on implant micromotions. Also in this study, no interface properties were defined and interfaces were assumed as fully tied (Waide et al. 2004); (Stolk et al. 2002).

The complexity of modelling soft tissue layers is also mentioned by Georgi et al (Giori et al. 1995) who stated that if a soft tissue layer is modelled in a FE-analysis with a E-modulus less than 0.81 MPa, a solution could easily diverge due to excessive element distortion.

**Fig. 49 - Simplified geometry used to investigate frictional contact. Outermost disks represent a hard material whereas the center disk is provided of a silicone material. Frictional properties are assigned at both disk interfaces.**

**Fig. 50 - Visualization of the loaded simplified model. Solution was found until 45% of the applied load. (Unscaled visualization)**