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A large scale finite element study of a cementless osseointegrated tibial tray

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A B S T R A C T

The aim of this study was to investigate the performance of a cementless osseointegrated tibial tray (P.F.C. ® Sigma®, Depuy® Inc, USA) in a general population using finite element (FE) analysis. Computational testing of total knee replacements (TKRs) typically only use a model of a single patient and assume the results can be extrapolated to the general population. In this study, two statistical models (SMs) were used; one of the shape and elastic modulus of the tibia, and one of the tibiofemoral joint loads over a gait cycle, to generate a population of FE models. A method was developed to automatically size, position and implant the tibial tray in each tibia, and 328 models were successfully implanted and analysed. The peak strain in the bone of the resected surface was examined and the percentage surface area of bone above yield strain (PSAY) was used to determine the risk of failure of a model. Using an arbitrary threshold of 10% PSAY, the models were divided into two groups ('higher risk' and 'lower risk') in order to explore factors that may influence potential failure. In this study, 17% of models were in the 'higher risk' group and it was found that these models had a lower elastic modulus (mean 275.7 MPa), a higher weight (mean 85.3 kg), and larger peak loads, of which the axial force was the most significant. This study showed the mean peak strain of the resected surface and PSAY were not significantly different between implant sizes.

1. Introduction

Due to the increasing number of total knee replacement (TKR) procedures, assessment of TKR performance in the general population is becoming more important. To evaluate the performance of a tibial tray, computational models are often used. Many studies only use a model of a single patient (Keja et al., 1994; Tissakht et al., 1995; Taylor et al., 1998; Hashemi and Shirazi-Adl, 2000; Barker et al., 2005; Perillo-Marcone and Taylor, 2007; Chong et al., 2010). A problem with such an approach is that population variability is not taken into account and the results cannot be applied to the general population.

Studies using multiple patients have investigated tibial tray performance. Perillo-Marcone et al. (2004) modelled four patients, ranking the models using percentage volume of bone at risk of failure. The rank order matched the measured implant migration from radiostereometric analysis. Wong et al. (2010) looked at the factors influencing the risk of subsidence, modelling four specimens in neutral and varus alignment. The volume of bone at risk of damage was significantly higher for varus alignment, despite the variation among specimens. Rawlinson et al. (2005) carried out experimental tests and finite element (FE) analyses on nine paired-tibiae to compare stemmed and un-stemmed tibial trays. From the FE analyses, it was seen that a stem reduced the stresses and strains in the bone beneath the tibial tray. However, due to the biological variability between specimens, the displacement between the bone and implant was highly variable and the effect of the stem inconclusive. Despite the use of multiple patient geometries, the loading was limited to a single magnitude for all specimens.

Larger scale studies have focussed on the hip; two studies of a hip resurfacing used 16 patient specific models to investigate varus–valgus alignment (Radcliffe and Taylor, 2007a) and cementing technique (Radcliffe and Taylor, 2007b). A statistical shape and intensity model (SSIM) of the femur (Bryan et al., 2010) has been used to analyse hip fracture risk (Bryan et al., 2009) and influence of head diameter of a hip resurfacing (Bryan et al., 2012). Using the

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SSIM, variability of both the femur geometry and elastic modulus was captured and a large numbers of "FE-ready" meshes representing a population were easily generated.

Inter-patient variability has been observed in clinical measurements of knee loads (Kutzner et al., 2010). However, in most studies variation of loading is not taken into account and a fixed magnitude static load is applied for all cases. Loads are often scaled by body weight (Perillo-Marcone et al., 2004; Rawlinson et al., 2005; Perillo-Marcone and Taylor, 2007) which does not represent the significant variation in the ratio of the load components (e.g. anterior–posterior to axial force) known to occur between subjects (Kutzner et al., 2010). To capture this inter-patient variability, a statistical model (SM) has been used to generate a population of load cycles (Galloway et al., 2012).

In this study, the inter-patient variability of both the bone and loading is considered to assess a cementless osseointegrated tibial tray (P.F.C. ® Sigma®, Depuy® Inc, USA) in a large population. The outcome of a TKR is dependent on many factors; pre-operative function, surgical technique, fixation type, implant design, and the physical, emotional and social health of the patient (Wylde et al., 2007). Cementless fixation is of interest as it is thought to provide long-term fixation for younger more active patients without the problems associated with cement degradation (Lombardi et al., 2007) and studies have reported good survivorship rates of around 95% after 10 years for cementless tibial trays (Hofmann et al., 2001; Oliver et al., 2005; Baker et al., 2007; Epinette and Manley, 2007). The objective of the present work is to develop a methodology for carrying out population based studies and to investigate factors which increase the failure risk of the tibial tray.

2. Methods

A SSIM of the complete tibia incorporating both geometry and elastic modulus variation was created using principal component analysis (PCA), following the method of Bryan et al. (2010) as detailed in the Appendix A. A set of 32 left computed tomography (CT) scans of mixed resolution and an unknown demographic were used to train the SSIM. The full tibia from each CT scan was semi-automatically segmented using Avizo (Visualization Sciences Group, Bordeaux, France) and a tetrahedral mesh of each was generated using Ansys ICEM CFD (Ansys Inc., PA, USA). The maximum element size for the proximal and distal regions was set to 1.5 mm and 5 mm, respectively. The baseline volume mesh, which consisted of 65,655 nodes and 337,205 tetrahedra, was then morphed to each training case in a two-step process, first through elastic registration of the surface mesh and then volumetric morphing of the tetrahedral mesh. Having established correspondence between each member of the training set, PCA was then performed to generate the SSIM. The SSIM was then used to generate a large population of tibia models, where each tibia model is described by a tetrahedral mesh and associated element material properties, based upon the smaller training population of tibia models. A population of 500 tibiae was generated by sampling the first 24 of 32 PC weights, which explained 95% variance, assuming each had a normal distribution with mean μ and standard deviation σ for each PC and truncated to $\pm 3\sigma$. The generated population was considered to be realistic in shape, size, and modulus distribution (see Appendix A).

To generate loading for each tibia, a SM of internal tibiofemoral joint loads for a single gait cycle (heel strike to heel strike) was generated following Galloway et al. (2012). The training data were taken from musculoskeletal models of 20 older healthy subjects (9 male, 11 female, age 55–79) (Worsley et al., 2011). The loads

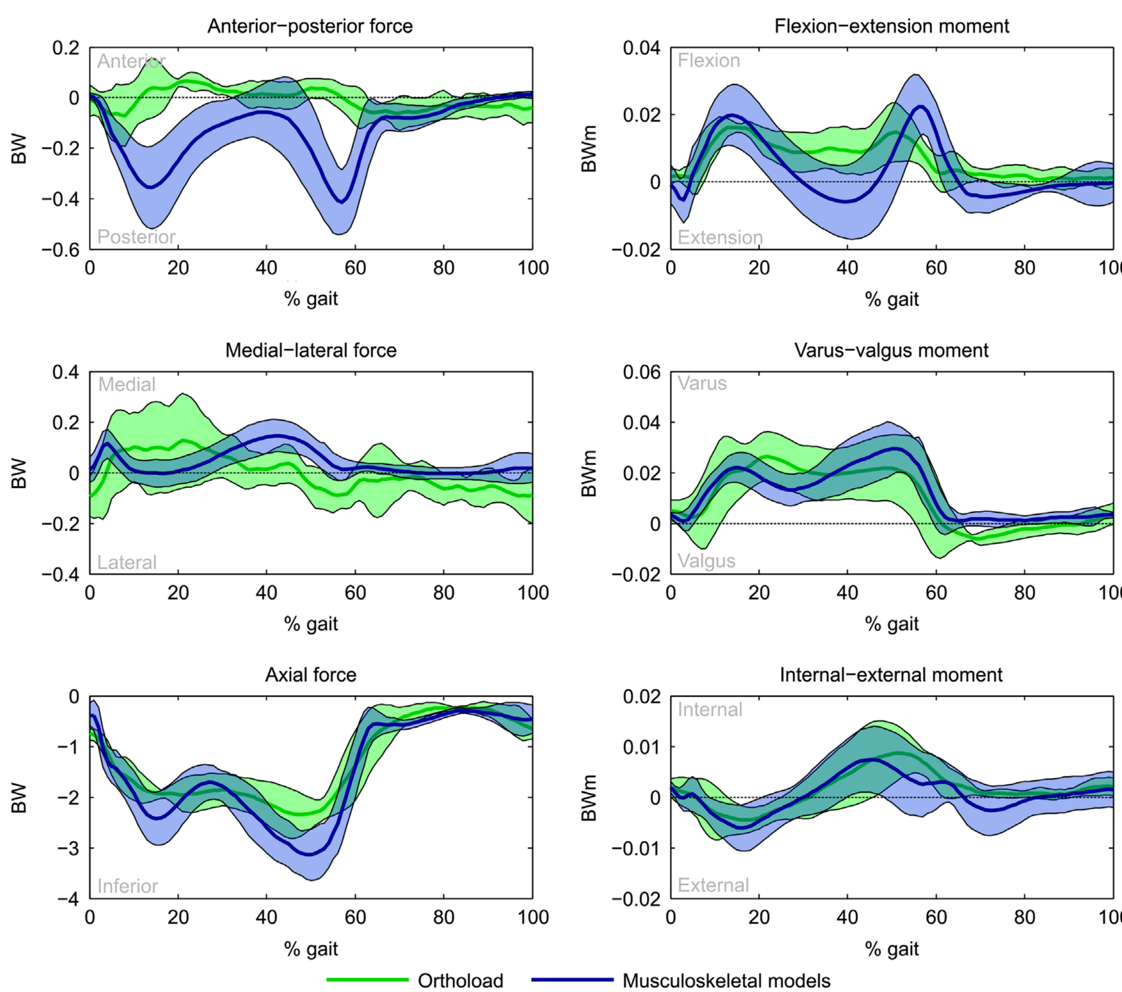

Fig. 1. Comparison of the internal joint reaction forces from Orthoload (light) and musculoskeletal models (dark). The A–P force, F–E and V–V moments of the musculoskeletal data have been scaled by 0.5. The heavy line represents the mean of each component and the shaded area is ± 1 standard deviation. The forces and moments act in the directions defined in Fig. 4.