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Four decades of finite element analysis of orthopaedic devices: Where are we now and what are the opportunities?

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ABSTRACT

Finite element has been used for more than four decades to study and evaluate the mechanical behaviour total joint replacements. In Huiskes seminal paper "Failed innovation in total hip replacement: diagnosis and proposals for a cure", finite element modelling was one of the potential cures to avoid poorly performing designs reaching the market place. The size and sophistication of models has increased significantly since that paper and a range of techniques are available from predicting the initial mechanical environment through to advanced adaptive simulations including bone adaptation, tissue differentiation, damage accumulation and wear. However, are we any closer to FE becoming an effective screening tool for new devices? This review contains a critical analysis of currently available finite element modelling techniques including (i) development of the basic model, the application of appropriate material properties, loading and boundary conditions, (ii) describing the initial mechanical environment of the bone–implant system, (iii) capturing the time dependent behaviour in adaptive simulations, (iv) the design and implementation of computer based experiments and (v) determining suitable performance metrics.

The development of the underlying tools and techniques appears to have plateaued and further advances appear to be limited either by a lack of data to populate the models or the need to better understand the fundamentals of the mechanical and biological processes. There has been progress in the design of computer based experiments. Historically, FE has been used in a similar way to in vitro tests, by running only a limited set of analyses, typically of a single bone segment or joint under idealised conditions. The power of finite element is the ability to run multiple simulations and explore the performance of a device under a variety of conditions. There has been increasing usage of design of experiments, probabilistic techniques and more recently population based modelling to account for patient and surgical variability. In order to have effective screening methods, we need to continue to develop these approaches to examine the behaviour and performance of total joint replacements and benchmark them for devices with known clinical performance.

Finite element will increasingly be used in the design, development and pre-clinical testing of total joint replacements. However, simulations must include holistic, closely corroborated, multi-domain analyses which account for real world variability.

1. Introduction

Finite element (FE) analysis has been used in orthopaedic biomechanics for more than forty years. According to Huiskes and Chao (1983), FE was first used in orthopaedic biomechanics in 1972 (Brekelmans et al., 1972), not long after the introduction of hip and knee replacements. In the review of the first decade of FE usage, there were still significant questions about the mechanics of the bone-implant system and how design influenced performance. Although early designs such as the Charnley hip replacement and the Total Condylar knee replacement performed well, there were many designs that had inferior performance and survivorship rates of less than 90% at five years were common (Knutson et al., 1986). Even though the numbers of joints replaced in the 1970s were relatively low, it was clear that the procedure was effective at alleviating pain and restoring function. After four decades of FE in total joint replacement, the clinical landscape has changed dramatically. An estimated 1 million hip replacements and a similar number of knee replacements are performed annually (Health at a Glance, 2011) and the numbers of surgeries continues to grow (Kurtz et al., 2007). Revision rates for hip and knee arthroplasty typically vary between 5% and 10% at 10 years (Australian Orthopaedic Association, 2013; National Joint Registry for England and Wales, 2013). Although the percentage of failures has

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decreased, the absolute numbers of failed joints has increased significantly.

The main reasons for failure include aseptic loosening, wear/lysis, pain, periprosthetic fracture, dislocation (hips) and instability (knees) (Australian Orthopaedic Association, 2013; National Joint Registry for England and Wales, 2013). Failure leading to revision is a complex mechanical and biological process (Huiskes, 1993) and is usually due to a combination of implant design, patient and surgical factors. In one of his most insightful papers Huiskes (1993) defined various *failure scenarios* for orthopaedic devices, including accumulation of damage, particulate reaction, failed bonding, stress shielding, stress bypass and destructive wear. These scenarios act in the short to mid-term (up to 5 years) or long term (10 years). Short to mid-term failure is due to the inability to achieve the required mechanical environment, either through poor implant design or due to surgical error leading to inadequate fixation, abnormal loading, peri prosthetic fractures, dislocation or instability. Longer term failures are thought to be more dependent on patient-related factors and the implant design (Katz et al., 2012) and are likely to be a result of debris-induced osteolysis (from implant wear) and damage accumulation of the prosthetic components.

FE has been used across the full spectrum of orthopaedic devices and there have been a number of thorough reviews (Huiskes and Chao, 1983; Huiskes, 1993; Huiskes and Hollister, 1993; Prendergast, 1997; Viceconti et al., 2009; Laz and Browne, 2010; Erdemir et al., 2012; Pankaj, 2013; Taylor et al., 2013; Carr and Goswami, 2009; Prendergast, 2001). The main focus of this review will be hip and knee replacement, as these have been studied the most, but the issues raised are applicable to the simulation of all orthopaedic devices. FE models have grown in both size and sophistication and techniques exist to assess the initial post-op mechanical environment (Taylor et al., 2012; Zivkovic et al., 2010; Chong et al., 2010; Pettersen et al., 2009; Reggiani et al., 2008; Udofia et al., 2007; Spears et al., 2001; Keaveny and Bartel, 1993; Halloran et al., 2005; Halloran et al., 2005; Baldwin et al., 2008; Fitzpatrick et al., 2011; Godest et al., 2002; Taylor and Barrett 2003; Perillo-Marcone and Taylor 2007; Chang et al., 2001) through to the simulation of time dependent processes including bone remodelling induced stress shielding (Huiskes et al., 1987; Perez et al., 2010; Behrens et al., 2009; Gillies et al., 2007; Taylor et al., 2004; McNamara et al., 1997; Weinans et al., 1994; Rietbergen et al., 1993; Gupta et al., 2006), tissue adaptation (Prendergast et al., 1997; Lacroix and Prendergast, 2002; Andreykiv et al., 2005; Simmons et al., 2001), wear (Strickland et al., 2011; Strickland and Taylor 2009; Knight et al., 2007; Fregly et al., 2005; Bevill et al., 2005; Teoh et al., 2002; Brown et al., 2002; Maxian et al., 1996; Pal et al., 2008), damage accumulation of the cement mantle (Coultrup et al., 2010; Janssen et al., 2009; Lennon et al., 2007; Jeffers et al., 2007; Janssen et al., 2006; Grasa et al., 2005; Stolk et al., 2002; Stolk et al., 2002; Verdonschot and Huiskes 1992), debonding of the stem-cement interface (Caruana et al., 2009; Perez et al., 2005; Verdonschot and Huiskes, 1996, 1997, 1998), the cement–bone-interface (Waanders et al., 2011; Pérez and Palacios 2010) and osseointegration (Tarala et al., 2011; Moreo et al., 2007; Fernandes et al., 2002). Implicit FE analysis is most commonly used, however in the past decade there has been increasing application of the explicit formulation (Halloran et al., 2005; Fitzpatrick et al., 2011; Godest et al., 2002; Perillo-Marcone and Taylor 2007; Knight et al., 2007; Baldwin et al., 2009; Fitzpatrick et al., 2010). For quasistatic analyses, the implicit formulation is recommended, however for dynamic analyses; problems involving large sliding contacts or very large models (tens to hundreds of millions of elements) the explicit formulation is recommended.

Historically, there have been two reasons for performing FE analyses on orthopaedic devices: (i) to gain a fundamental understanding of the behaviour of the bone–implant system or of a specific device and (ii) to assist the design and pre-clinical testing of new implants and to compare their performance with existing designs. Although at first appearance, these two reasons are similar, the level of confidence placed on the results is quite different. In the first case, FE is used to understand how a failure process initiates or progresses and the information gained tends to be qualitative rather than quantitative in nature. In essence these analyses are attempting to identify first order effects of design or of patient and surgical parameters on performance. Today, we are faced with a greater challenge, of having to try and assess whether subtle changes in design can lead to improvements as compared to already successful implants (Viceconti et al., 2009; Taylor et al., 2013). In addition, there is the question of whether the indications for existing implants can be extended to different patient populations, particularly younger more active individuals. There is also a need to demonstrate that new designs are robust to patient and surgical variability. These are more difficult problems to analyse, as the differences are likely to be smaller and are exploring second order effects. A third application is emerging, as a decision support tool for planning of orthopaedic surgery. The use of computer assisted surgery and customised patient instrumentation is growing and FE has the potential to further enhance the planning process by providing additional information about function and the potential risk of failure on a patient by patient basis.

FE analysis is improving our understanding of the mechanical behaviour of orthopaedic devices, and has tremendous potential to provide additional information about the individual patient to guide the decision making process of orthopaedic surgeons. In the aerospace and automotive fields, FE is truly a predictive tool and is used extensively in the design and development process. In 1993, Huiskes (1993) compared the available pre-clinical and clinical test methods and rated FE analyses as being indicative, rather than predictive. It is debatable whether in the following 20 years we have made any progress in shifting FE towards being an effective tool for screening implant designs and evaluating changes in surgical process. One aspect of finite element modelling close to Huiskes heart was its applicability vis-à-vis experimental models, and he always resisted the tendency of some investigators to see experimental models as inherently superior to computational models (Huiskes, 1995). Indeed, when his finite element models were critiqued for being too idealised and not like the 'imperfect' reality, his reply was to say that the surgeon should try to do a better job and get the implanted joint more like his idealised model – this was the necessary defence of clever engineers in the early days. Now, however, improved computational technologies can address the complexity that Huiskes had to skirt around, and in this review will take a critical look at the currently available FE modelling techniques and the way that they are applied.

2. Critical analysis of currently available FE modelling techniques

FE simulations are models, an abstraction of a real world problem aimed at answering a specific question, often by simulating a particular mode of failure. To answer the question, how detailed does a model need to be? More importantly, are the current modelling techniques sufficient to address the question being asked? To address this we not only need to clearly define the question, but also need to define the required sensitivity of the model. That is, should it only capture first order effects (differences greater than 10%–20%) or should it be able to discern second order effects (differences less than 5%). No single model will be able of answering every question, but there is a need to recognise whether the modelling approach is capable of discriminating between first and higher order effects. To achieve this for orthopaedic devices, there is a need to critically assess the way that (i) representative model(s) are developed and appropriate loading

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and boundary conditions are applied; (ii) the initial mechanical environment of the bone-implant system is represented; (iii) in the case of adaptive/time based simulations, the ability to replicate the time dependent behaviour and (iv) how studies are designed and the way that results are analysed.

2.1. Development of a representative model, with appropriate loading and boundary conditions

The fundamental building block of any FE analysis is the model of the intact or implanted bone segment or joint, with the assigned material properties and the associated loading and boundary conditions. Assumptions made at this level have consequences on the subsequent results, regardless of the complexity of the simulation. Since its first use in the 1970s (Brekelmans et al., 1972) there has been considerable improvement in the fidelity of FE models; however, it is important to understand what is the state-of-the-art and the limitations of current simulations. In terms of the model geometry and mesh, we have moved from idealised two dimensional models (Huiskes 1990; Vasu et al., 1982, 1986) to anatomical based, subject specific three dimensional models, the latter being the norm now in the majority of cases. The continuing increase in computing power has meant that the number of finite elements in a model has grown from a few 100's in the 1980s to 100,000's today. Although this means that the models are better able to compute accurate stress and strain fields, it does not necessarily mean they are better or more valid to address a particular problem or research question.

Mapping bone properties from CT scans using either custom written and commercially available software is now routine. There is still debate as to the most appropriate equations to represent the density to modulus relationship (Helgason et al., 2008) and there is growing evidence that this relationship may be subject specific (Eberle et al., 2013). However, there are still instances where simplified representations of the bone properties are implemented, e.g. FE simulations of the pelvis where only two materials are used to represent the cortical and cancellous bone (Zivkovic et al., 2010; Udofia et al., 2007). Models using idealised material properties may capture gross differences, but are unlikely to capture subtle variations and localised effects. Bone is routinely assumed to be isotropic and linear elastic, except for some instances which have implemented anisotropy (Taylor et al., 2002; Hazrati Marangalou et al., 2013) and post-yield behaviour (Taylor et al., 1995; Kelly et al., 2013; Helgason et al., 2008; Janssen et al., 2010; Ong et al., 2008). These assumptions of linear and isotropic material behaviour are, in part, due to the limited information that can be extracted from clinical grade CT scans. For many problems, these may be acceptable assumptions, however, they will not be so in all cases and rationale for using them need to clearly established on a study by study basis. At present, there are no reliable methods for deriving soft tissues properties from imaging data and researchers rely on literature derived data or fitting the mechanical response of the model to experimental data (Baldwin et al., 2009).

Compared with other engineering disciplines, our knowledge of the loading conditions acting on orthopaedic devices is poor. The intact and implanted femur has been investigated the most and is a good exemplar for the range of loading and boundary conditions that have been implemented. Various studies have examined the influence of muscle forces in an attempt to arrive at a physiological stress/strain distribution and in addition to the joint contact force researchers have applied just the abductors (Stolk et al., 2001; Tensi et al., 1989), the abductors plus one or two other muscles (Taylor et al., 1996) or models containing representations of all the major muscles which cross the hip and knee joint (Taylor et al., 2002; Duda et al., 1998; Polgar et al., 2003). There are some similarities in the predicted stress distributions in the proximal femur above the lesser trochanter. However, the stress distribution in the diaphyseal and distal femur appears to be sensitive to the chosen muscle forces and boundary conditions (Speirs et al., 2007). So, which set of muscle and boundary conditions best predicts the in vivo stress/strain field? The simple answer is that we do not know. To date, there has been no in vivo studies to measure the full field stress–strain distribution, due to obvious difficulties in obtaining data. At lower level, we do not even know how the femur deforms during normal activities of daily living. What do we know? The joint contact forces have been measured in a small number of hip replacement patients (Bergmann et al., 1993, 1995, 2001) and there has been a single study where the strains have been measured on the lateral aspect of the femur of two patients for a limited range of activities (Aamodt et al., 1997). This data is insufficient to establish the stress/strain distribution within the femur for single legged stance, let alone dynamic activities of daily living. Further computational studies will not bring us any closer to the answer, as the level of sophistication of the models is beyond the point that they can be verified with current in vivo measurement techniques. The only solution to this problem lies in the development and application of new imaging modalities, for example the use weight bearing MRI to try and measure the deformation of the unloaded and loaded femur, from which strains and then stresses can be calculated.

If we are unable to conduct satisfactory corroborations of our predictions of the displacement/stress/strain distribution within the intact femur, or any other bone segment or joint for that matter, how can we be expected to reliably assess the performance of a total hip replacement? We need to accept that the absolute results generated by FE studies may not be representative of the in vivo conditions and that any simulation are idealisations of in vivo. We are only able to perform comparative analyses and so need to compare results to the intact bone segment (bone stresses and strains), established performance metrics (e.g. yield strain/stresses for implant materials and bone, micromotion thresholds for bone ingrowth) or relative to a device with known clinical performance (for output metrics related the device such as micromotion, cement stresses, etc.). Then the choice of either a simplified load case, as proposed by Heller et al. (2005), or applying multiple muscle forces from muscular skeletal models (van der Ploeg et al., 2012) will depend on the problem and the objectives of the study. Simplified load cases have been shown to successfully differentiate performance (Stolk et al., 2001). The simplified approach is easy to implement and allows for comparison between studies. The majority of studies only explore a limited set of loading conditions, typically only applying the peak forces associated the stance phase of gait. As implementing different loading and boundary conditions is relatively simple and cheap, in comparison with the effort required to generate a model, perhaps we should be exploring a diverse range of load cases, including gait, stair ascent/descent and rising from a chair, as well as stimulating complete activity cycles (Taylor et al., 2012; van der Ploeg et al., 2011) to increase the sensitivity of our analyses.

2.2. Simulation of the initial mechanical environment of the bone–implant construct

The success or failure of cemented or cementless total joint replacement is largely dependent on the nature of the initial mechanical environment and therefore the ability to simulate the early, post-operative period is important. A high proportion of all FE studies only examine representations of the early post-operative mechanical environment and these predictions also act as the basis for time based, adaptive simulations and errors made in the first iteration will propagate through these time based solutions.

Some of the early FE studies of cemented hip stems (Huiskes, 1990; Crowninshield et al., 1980; Prendergast et al., 1989) assumed idealised cement mantle geometry, no interdigitation of the cement

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into cancellous bone and elastic properties for the cement and these assumptions are still routinely used today (Taddei et al., 2010; Galloway et al., 2013; Pal et al., 2009; Ramos et al., 2013). One of the main challenges is that the mechanical behaviour of the cement (Whitehouse and Evans, 2010) and of the stem-cement and cement-bone interfaces are still poorly understood, largely due to a lack of experimental data. Studies typically apply a generic modulus (reported to vary from 1.5 to 4.1 GPa (Lewis, 1997)) from the literature. An underlying, and often unstated, assumption is that the cement mantle is stress-free prior to loading, but experimental studies have shown that the thermal and volumetric shrinkage during the cure process results in initial stresses in the range of 1–5 MPa (Lennon and Prendergast, 2002; Li et al., 2004; Ramos et al., 2012) and possibly as high as 10 MPa (Roques et al., 2004). These are of a similar order of magnitude to the stresses generated by loading. Analytical algorithms have been developed to describe the temperature evolution during the cure process (Baliga et al., 1992; Borzacchiello et al., 1998; Gilbert, 2006). However, to date only a few studies have simulated the curing process in order to establish the initial stress state (Jeffers et al., 2007; Lennon and Prendergast 2002; Nuno and Avanzolini 2002; Briscoe and New 2010; Perez et al., 2009). Bone cement is a visco-elastic material (Verdonschot and Huiskes 1994; Jeffers et al., 2005) and this will lead to stress relaxation in the first few hours or days, further altering the initial stress state. Only a few studies have incorporated the viscoelastic properties, either ignoring (Pérez and Palacios, 2010; Lu and McKellop, 1997; Verdonschot and Huiskes, 1997; Stolk et al., 2004) or including the initial stress state (Jeffers et al., 2007). To date, insufficient work has been performed to clarify whether assuming a stress free cement mantle is an acceptable assumption.

The geometry of the cement mantle and the description of the cement-bone interface are also simplified and idealised. These assumptions were originally made out of necessity, but with improvements both in model generation techniques and computing power, these assumptions should also be challenged. For simplicity the majority of FE studies assume that the stem is centrally located and the cement mantle has a uniform thickness, usually offset from the implant surface. The reality is that stems often sit eccentrically and the cement mantle has a variable thickness (Scheerlinck et al., 2006, 2010; Krause et al., 2012). These factors combine to give a complex and variable cement mantle geometry. This variability is likely to yield different stress patterns to idealised models, not forgetting that there will be patient-to-patient variability as well. The cement mantle is also made up of two distinct layers, one of pure bone cement and the other a composite layer of cement and cancellous bone. At the macro-scale this is difficult to model and as a consequence only a few studies have considered it as a composite layer (Shi et al., 2013). The majority of studies also assume that the bone-cement interface is rigidly bonded. MicroCT based FE models (Waanders et al., 2011) are leading to a greater understanding of the mechanics of the bone cement interface, both in terms of the load transfer across the bone-cement composite layer, but also in terms of the stiffness of the bone-cement interface. Cohesive zone elements offer the potential to implement information learnt from microscale FE models at the macroscale (Waanders et al., 2011) to better capture this behaviour.

In order to assess cementless devices, models need to replicate the mechanics of the bone-implant interface. Bone ingrowth/ongrowth will occur if the micromotions are less than 40–50 μm and fibrous tissue formation will occur if the micromotions are in excess of 150 μm (Pilliar et al., 1986). FE has been extensively to analysis the primary stability of femoral stems (Tensi et al., 1989; Rohlmann et al., 1988; Keaveny and Bartel, 1993; Viceconti et al., 2000; Pancanti et al., 2003; Reggiani et al., 2007; Abdul-Kadir et al., 2008; Park et al., 2009; Bah et al., 2011; Tarala et al., 2011), acetabular cups (Udofia et al., 2007; Spears et al., 2001; Janssen et al., 2010; Ong et al., 2008; Ries et al., 1997; Spears et al., 1999, 2000; Ong et al., 2006; Bellini et al., 2007; Amirouche et al., 2008; Hothi et al., 2011, 2012) and the tibial component of knee replacement (Taylor et al., 2012; Chong et al., 2010; Kelly et al., 2013; Taylor et al., 1998) since Rohlmann et al., 1988 first explored primary stability. A number of assumptions have become accepted and routinely implemented. Cementless components rely, in part, on an interference fit to achieve the necessary level of primary stability, and our knowledge of how the interference fit is developed through the interactions between the bone and the implant is poorly understood. The majority of studies of the implant proximal femur (Reggiani et al., 2008; Keaveny and Bartel, 1993; Pancanti et al., 2003; Bah et al., 2011) and proximal tibial (Taylor et al., 2012; Chong et al., 2010) assume no interference at the bone implant interface. If an interference fit is simulated, how much should be included and how to simulate it? Clinical practice is to under-ream the femur by up to 0.5 mm and the acetabulum by up to 2 mm (Ramamurti et al., 1997). Only a few studies of the implanted proximal femur have implemented an interference fit (Abdul-Kadir et al., 2008; Shultz et al., 2006) and have reported that high levels of interference are difficult to achieve. Low levels of interference of between 50 and 100 μm significantly reduced micromotion(Abdul-Kadir et al., 2008; Ramamurti et al., 1997). However, larger interferences have been shown to induce high hoop stresses in the surrounding cancellous bone (Ramamurti et al., 1997) and in the femoral cortex (Abdul-Kadir et al., 2008). In comparison, larger interferences of up to 2 mm are routinely implemented in models of cementless acetabular cups (Zivkovic et al., 2010; Udofia et al., 2007; Ong et al., 2008; Bellini et al., 2007). The simplest way of implementing the interference is by uniformly offsetting the surface of the implant (Zivkovic et al., 2010; Udofia et al., 2007; Janssen et al., 2010) or by thermal expansion (Janssen et al., 2010; Bellini et al., 2007). However, studies that have attempted to simulate the insertion process (Spears et al., 1999; Ong et al., 2006; Hothi et al., 2011, 2012) have shown that the acetabular cups rarely completely seat into the bone, leading to a polar gap behind the prosthesis. Larger gaps are seen with higher levels of interference and coefficients of friction and these may compromise the primary stability.

The material behaviour of the cancellous and cortical bone will influence the predicted micromotions. Most studies assume that the supporting bone is linear elastic (Chong et al., 2010; Reggiani et al., 2008; Pancanti et al., 2003; Abdul-Kadir et al., 2008; Bah et al., 2011), despite some studies reporting stresses that approach or exceed the yield stress (Taylor et al., 1995; Kelly et al., 2013; Rohlmann et al., 1988; Ong et al., 2006; Hothi et al., 2011; Rothstock et al., 2010). In addition, the viscoelastic properties will lead to stress relaxation, particularly if an interference fit is simulated. Shultz et al. (2006) reported that due to the viscoelastic response of cortical bone, the bone-implant contact pressures after 24 h are similar for interferences of 0.1 and 0.5 mm, suggesting that increasing the interference more than 0.1 mm is of little benefit.

Typically the bone cavity is assumed to be geometrically similar to that of the implant and that there are no defects or gaps. This assumption may be suitable for comparing different implant geometries, but is unlikely to capture the variation due to differences of surface coatings or cavity preparation techniques. The reality of the bone preparation technique is that broaching and reaming are both difficult to control, and this coupled with deformation of the bone during preparation leads to irregular shaped bone cavities. For example, the reamed cavity of the acetabulum tends to be elliptical rather than the desired spherical shape. The contact area has been reported to be as low as 68% and 42% in the metaphyseal and diaphyseal regions for cementless femoral stems using conventional preparation methods (Park et al., 2008). Tarala et al. (2011) considered the influence of the irregular surface geometry and noted that it

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was important to include this in the simulations. Viceconti et al. (2006) and Park et al. (2009) performed monte carlo based simulations and showed that gaps at the interface had a significant effect and assuming uniform contact underestimated predicted micromotions.

It is clear that, many years after Huiskes' early writings on this subject (Huiskes, 1988), we still only have a rudimentary understanding of how the interference at the bone interface develops and how implant surface coatings, bone preparation technique and surgical variation influence primary stability. Many of the advances in modern cementless joint replacement are related to the application of new/novel surface coatings. At present, these can only be accounted for by varying the coefficient of friction, but is this sufficient to account for these changes? For contact based simulations, we have control over a number of parameters, including surface separation forces and the potential to use more sophisticated algorithms/methods (e.g. cohesive zone elements) rather than simply changing the coefficient of friction in an attempt to alter the interface mechanics. There is a need for further experimenttal studies to characterise this behaviour which can be used to augment our simulations of primary stability.

2.3. Time dependent/adaptive modelling techniques

Adaptive modelling techniques were pioneered by Huiskes and co-workers to simulate the degradation and/or failure of the prosthetic components (damage accumulation of bone cement, debonding of the cement-implant interface) and of biological processes (bone adaptation, tissue differentiation and osseointegration). The basic concept of all of these techniques are similar: based on the initial conditions, a parameter of interest is calculated and then this is used to adapt the FE model by modifying the geometry and/or the material properties in an iterative computational process. A new analysis is performed, the parameter of interest recalculated and this iterative process continues until either the solution converges, a pre-determined period of time elapses, or gross failure of the bone-implant construct occurs. The success of these techniques is dependent on the fundamental understanding of the underlying physical or biological processes, as well as having the necessary information to first build and then verify the models. In verifying the models, there is the additional challenge of not only quantifying what has occurred but when it occurred.

Bone adaptation and remodelling: Bone remodelling simulations have been performed extensively, primarily to assess stress shielding around the femoral component of hip arthroplasty (Perez et al., 2010; Taylor et al., 2004; Weinans et al., 1994; Gupta et al., 2006; Huiskes et al., 1992; Weinans et al., 1992, 1993; Stulpner et al., 1997; Folgado et al., 2009; Pal and Gupta 2011; Shim et al., 2012). Since the publication of the first bone remodelling simulations around implants by Huiskes and co-workers (Huiskes, 1988), there have only been incremental developments, for example accounting for overload induced bone loss (Behrens et al., 2009; Scannell and Prendergast, 2009). These tools are still phenomenological descriptions of bone remodelling and different stimuli have been shown to result in similar predictions of adaptation (Schmitz et al., 2004). These simulations are difficult to validate, particularly in humans, due to the ethical problems of collecting pre-operative CT and post-operative DEXA images. As a consequence, there has only been limited corroboration between FE predictions from single, representative models and clinical measures of bone adaptation (Lerch et al., 2012; Herrera et al., 2009; Turner et al., 2005; Kerner et al., 1999). Huiskes's early work on bone remodelling later resulted in many papers looking more fundamentally at remodelling at the tissue level as a self-organizational process with Huiskes (1997) being a paper describing his thinking when moving from the subject of remodelling around implants to an algorithm to describe bone remodelling at the tissue level. This subject of tissue level remodelling was, of course, later taken up by others to simulate remodelling around implants.

Tissue differentiation and osseointegration: Developed by Prendergast and Huiskes (Prendergast et al., 1997) and tested against an animal experiment performed by Soballe, simulations implement an algorithm that predicts the differentiation of granulation tissue to fibrous tissue, fibrocartilage or bone depending on the mechanical environment. Although used extensively in the analysis of fracture healing (Lacroix and Prendergast, 2002; Andreykiv et al., 2007; Isaksson et al., 2006), it has had limited application in the prediction of tissue differentiation around implants (Andreykiv et al., 2005; Puthumanapully and Browne, 2011; Gray et al., 2010). Various other approaches have also been implemented (Prendergast et al., 1997; Claes and Heigele, 1999; Carter et al., 1988), but the methodology is limited by the data required to populate the algorithms, often coming from disparate sources in the literature (Isaksson et al., 2006). Studies (Andreykiv et al., 2005; Puthumanapully and Browne, 2011; Gray et al., 2010) assume that the implant is surrounded by a layer of low modulus granulation tissue, whereas, in reality the implant is in direct contact with the supporting bone.

Damage accumulation of bone cement: This technique was pioneered by Verdonschot and Huiskes (1992) and is based on implementing continuum damage mechanics to predict the fatigue failure of the cement mantle. The technique has been mainly used to assess the performance of the femoral component of hip replacement (Lennon et al., 2007; Jeffers et al., 2007; Grasa et al., 2005; Stolk et al., 2002; Verdonschot and Huiskes, 1992; Stolk et al., 2004; Verdonschot et al., 1998; Stolk et al., 2003) but also acetabular components (Coultrup et al., 2010; Janssen et al., 2006). There has been limited verification work which has shown that the technique can predict realistic damage patterns (Jeffers et al., 2007; Stolk et al., 2003) and can differentiate between designs (Stolk et al., 2003). However, exploiting this technique has been limited by the lack of experimental data to populate the models. In addition to the elastic properties, a detailed knowledge of the fatigue properties is required. Experimental fatigue testing is expensive and limited data exists on commercially available cements. Most experimental data is derived from uniaxial tests (Lewis, 2003), yet bone cement is subject to a complex three dimensional stress state (Murphy and Prendergast, 2003). To date the life laws are assumed to be linear, although it is not clear if this is true for PMMA. The fatigue tests are typically carried at stress levels above those experienced by the cement mantle and it is unclear whether the fatigue life laws extrapolate well to low stress states. It is not clear whether Young's modulus degrades, through microcrazing prior to failure. Due to volumetric shrinkage, there is porosity present in the cement mantle, but this has only received limited attention to date (Coultrup et al., 2010; Jeffers et al., 2005; Janssen et al., 2005).

Debonding of the stem-cement or bone-cement interface: Again the technique was pioneered by Verdonschot and co-workers (Caruana et al., 2009; Verdonschot and Huiskes, 1997) and was originally based on a sequential release of the interface based on a predefined, static failure criteria. More recent studies have implemented a non-linear, fracture mechanics approach to simulate the failure process (Perez et al., 2005; Pérez and Palacios, 2010). Although an interesting and potentially useful methodology, its widespread application is again limited by the lack of experimental data, particularly the fatigue behaviour of the bone–cement interface.

Adhesive/abrasive wear: Originally developed by Maxian and co-workers (Maxian et al., 1996, 1997) to assess the polyethylene wear of acetabular cups, the technique has been extended to assess intervertebral disk replacements (de Jongh et al., 2008), knee replacements (Strickland and Taylor, 2009; Knight et al., 2007; Pal et al., 2008; Willing and Kim, 2008; Zhao et al., 2008) and metal on metal hip replacements (Uddin and Zhang, 2013). The wear algorithms are based

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on Archard's law or a modified version of it, which states that wear is proportional to the contact pressure and the sliding distance. Typically the wear constant, *k*, is derived from pin-on-disk testing, but only limited data is available in the literature for different grades of polyethylene and sterilisation techniques. Tests are also performed under constant load, with simplified (linear, rectangular or elliptical) wear paths. FE predictions have been shown to improve when crossing motions, so called cross shear, is accounted for (Strickland and Taylor, 2009). Our understanding of the fundamentals of the wear process is still evolving and there is a need for further experimental based research, to better understand the contribution of contact pressure, sliding distance and cross shear to the wear process.

2.4. Design of computer based experiments

The outcome of a computational study is a much dependent on the way it is designed as it is on the techniques used. There is significant patient and surgery related variability that has the potential to influence the performance of orthopaedic devices. Morphometric and material property variations are known to exist between individuals and are influenced by a wide range of factors such as gender, ethnicity, age and underlying pathologies. In addition, there is significant variation in patient's body mass. The England and Wales National Joint Registry (National Joint Registry for England and Wales, 2013) reported that the average BMI of hip and knee replacement patients is 28.7 and 30.8, respectively. For the knee replacement patients, 56% had a BMI greater than 30 (obese) and 23% had a BMI greater than 35 (morbidly obese). There is clear evidence that the inclusion of inter-, and even intra-, patient variability can make significant differences to computational results (Radcliffe and Taylor, 2007; Pancanti et al., 2003). This, coupled with the significant variation in the placement and alignment of components and soft tissue balancing can mean that an implant is subjected to a diverse range of mechanical environments. The degree to which we chose to either account for this variation, or ignore it, will determine a study's ability to answer a specific research question or differentiate between prosthesis designs. The power of FE modelling, over in vitro and in vivo studies, is the ability to perform multiple analyses by altering the input parameters. Simple parameters to vary include the applied loading and boundary conditions and the assigned material properties and these can be performed without altering the model geometry or the finite element mesh. It is more difficult, but not impossible, to change implant geometry, implant orientation and the morphology of the bone segment or joint. Available designs of computer experiments include comparative, parametric, design of experiments and probabilistic analyses.

Comparative analyses: This study design has been used extensively and typically compare the performance of two or more designs or surgical scenarios in a single model of a bone or joint under idealised conditions. Comparative studies take no account of variation and only provides a very limited snapshot of the behaviour of the bone-implant construct.

Parametric analyses: Sensitivity of a FE model to a small number of input parameters is often explored using parametric analyses. Each parameter is swept over a pre-defined range, whilst keeping the other model parameters constant. Typically this approach has been used to explore the influence of modelling assumptions (Abdul-Kadir et al., 2008; Spears et al., 1999), surgical variability (Taylor and Barrett, 2003; Perillo-Marcone and Taylor, 2007; Martelli et al., 2012) and patient variability (Martelli et al., 2012). Parametric studies begin to assess the sensitivity of the bone–implant construct but the potential interaction between parameters is not accounted for. In addition, the probability that a particular level of a parameter will occur is not considered.

Reviewing the literature to date, a high proportion of all studies are comparative or parametric and therefore either partially or completely ignore the influence variability on the behaviour of the bone-implant system.

Design of experiments (*DoE*): This powerful tool has been used extensively in experimental mechanics and production engineering, but has been under-utilised in computational biomechanics. The method allows for large numbers of parameters (*P*) to be explored at a fixed number of levels (*N*). For full factorial designs (Clarke et al., 2011, 2012) the number of required analyses is P^N, but by implementing fractional factorial designs (e.g Taguchi method) the number of analyses can be substantially reduced whilst still extracting the required information (Shi et al., 2013; Ong et al., 2006; Amiri and Wilson, 2012; Bahraminasab et al., 2013, 2014). Through careful study design, it is possible to explore both design related and environmental, patient and surgery related variability. The advantage of DOE, particularly with fractional factorial designs, is the ability to sweep through multiple parameters efficiently and assess their relative contribution to the predicted behaviour. Like parametric studies, there is no probability associated with the fixed levels for each parameter but the interaction between parameters is accounted for.

Probabilistic analyses: The only approach capable of simultaneously exploring multiple design and environmental parameters (Ong et al., 2008) and assess the risk/probability of a particular outcome is by using probabilistic analyses. The variation of each parameter is now defined by a distribution, rather than by the fixed levels used in parametric and DOE studies. The most commonly used approach is the Monte Carlo analysis (Pal et al., 2008; Viceconti et al., 2006; Laz et al., 2006, 2007; Strickland et al., 2010; Dopico-Gonzalez et al., 2009, 2010; Prendergast et al., 2011; Galibarov et al., 2012), where the parameter space is randomly sampled. The Monte Carlo approach suffers from the curse of dimensionality, with the number of deterministic analyses needed increasing exponentially with the addition of more parameters. The number of analyses needed can be reduced through sampling methods (Dopico-Gonzalez et al., 2009), implementing reliability methods (Pal et al., 2008; Laz et al., 2006a,b) and the additional use of surrogate modellling (Bah et al., 2011) to minimise the computational cost. The challenge in developing and implementing probabilistic techniques is automating the simulation process, particularly when aiming to generate hundreds or thousands of models to explore the effects implant alignment or patient to patient variability. Automated pipelines to generate implanted bone segments have been developed using; CAD based boolean operations followed by automated meshing (Taylor et al., 2013; Dopico-Gonzalez et al., 2009, 2010); meshed based boolean operations (Galloway et al., 2013); or mesh morphing (Bah et al., 2009). Early attempts to account for patient variability either manually modelled a small cohort of subjects (Radcliffe and Taylor, 2007; Perillo-Marcone et al., 2004; Lengsfeld et al., 2005) or scaled either the size (Viceconti et al., 2006) and/or the material properties (Viceconti et al., 2006; Wong et al., 2005) of a single femur. An alternative approach to account for patient variability is the use of active shape and active appearance models, which are statistical representations of the morphology and material properties of the bone segment (Taylor et al., 2013; Bryan et al., 2010) or joint (Fitzpatrick et al., 2011). The advantage of active appearance models is that they can be used to generate 100s–1000s of synthetic instances based on a smaller training set of representative bones or joints. This has led to population-based finite element models of the implanted proximal femur (Bryan et al., 2012) and tibia (Galloway et al., 2013). Probabilistic study designs now allow for failure processes to be properly explored. In addition to expressing performance as a distribution, probabilistic

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analyses can elucidate the relative contribution of each parameter studied to the variation within that distribution.

2.5. Criteria for assessing the performance of joint replacement

FE studies generate volumes of data (displacements, strains, stresses, etc.) and processing and interpreting this information is challenging, particularly as we move from the single representative model to probabilistic and population based analyses. In order to assess performance, we must first define reliable performance metrics. Martelli and co-workers (Martelli et al., 2011a,b, 2012) developed and implemented an approach to assess the mechanical performance of orthopaedic devices (Fig. 1), which first involves identifying the likely modes of failure that would lead to clinical failure and then identifying measureable and quantifiable parameters for each failure mode. Huiskes (1993) stated that failure is a matter of stress versus strength (Fig. 2). For engineering materials, strength is well defined, therefore quantifying the risk of failure (stress/strength) is straight forward. However, for biological materials and when simulating the complete bone-implant system, assessing the risk of failure is not so straight forward. Consider assessing the primary stability of cementless tibial trays, where failure to osseointegrate will lead fibrous tissue formation and potentially revision. This can be assessed by examining the micromotion at the bone implant interface, where micromotions less than 50 μm are known to lead to osseointegration and micromotions in excess of 150 μm will cause fibrous tissue formation. How can this data be used to develop a performance criteria? Simple criteria would be that the micromotion should not exceed 150 μm and the mean micromotions should be less than 50 μm. However, based on these criteria, three designs of clinically successful cementless tibial trays would 'fail' based on simulations of a single representative model and only one would pass based on predictions from a population based study (Table 1). Only when the criteria is set so that at least 40% of the bone–implant interface should experience micromotions less than 50 μm do all of these clinically successful designs 'pass'. This example highlights the need for further work, not only to clearly define performance metrics for a device, but to bench mark them against designs with known clinical performance, where possible using both positive and negative controls.

2.6. Validation and verification

It is important that wherever possible, the predictions from simulations are compared with in vitro testing to help verify the predictions; this is seen as the gold standard for assessing the predictive capabilities of models (Knight et al., 2007; Pal et al., 2008; Stolk et al., 2002; Maxian et al., 1997; Cristofolini et al., 1996; Viceconti et al., 2001; Reggiani et al., 2007; Gray et al., 2008). However, we must remember that we are comparing the results from one model to another (Huiskes and Chao, 1983) – from in silico to in vitro – and as a consequence we are only verifying some of the assumptions made in the modelling process, including the assigned material properties, material models and interface conditions; we only need to establish the model's potential to answer the research question posed. Other assumptions, particularly the loading and boundary conditions, remain constant in both and, as discussed earlier, may not be representative of the in vivo situation. Moreover, models are typically only verified for specific metrics, for example surface bone strains, and there will still be uncertainty associated with other metrics such as the underlying cancellous bone strains. Emerging experimental techniques may allow for greater levels of verification for micromotion (Gortchacow et al., 2011) and cancellous bone strains in the future (Gillard et al., 2013). There are major challenges to verify and validate predictions of probabilistic studies as there is the need to ensure that the models capture the distribution as well as the mean response. For population based studies the only approach may be to establish benchmarks for the behaviour of a number of devices with known clinical performance using both positive and negative controls. If FE models are to be trusted and accepted, there is a need to demonstrate that they are capable of predicting in vivo performance. To date, only a few studies have attempted to correlate their findings with clinical data (Lennon et al., 2007; Lerch et al., 2012; Herrera et al., 2009; Turner et al., 2005; Kerner et al., 1999; Perillo-Marcone et al., 2004). Historically, this has been limited by the availability of pre- and/or post-op CT scans, as these were not required as part of the routine

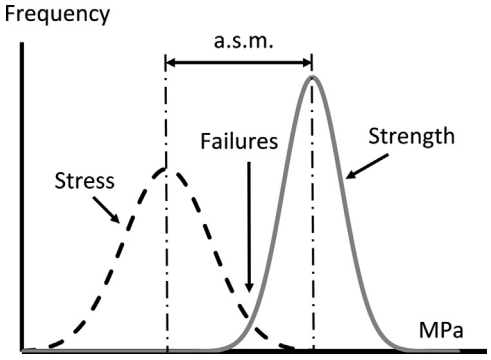

Fig. 2. Mechanical failure is a matter of stress versus strength, which are both distributed stochastically in a patient population. The average safety margin (a.s.m.) determines the number of failures. Adapted from Huiskes (1993).

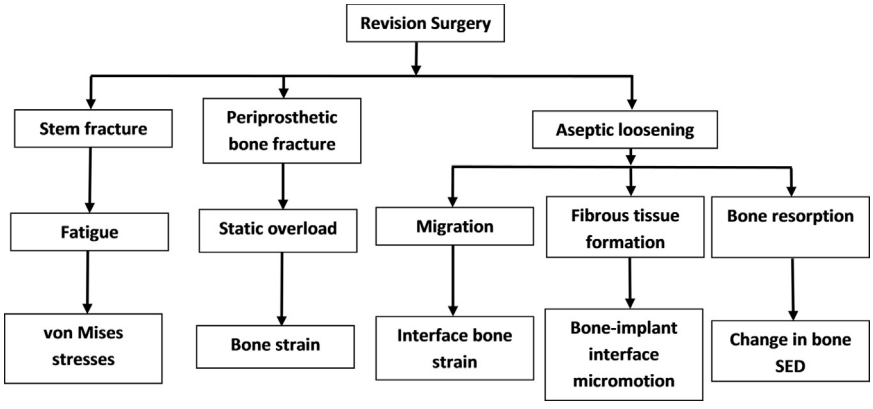

Fig. 1. A top down approach to identify the possible causes for revision of a cementless hip stem from the revision surgery, the observed failure modes, the physical mechanism associated with the failure mode and the measureable parameter associated to each failure mode (adapted from Martelli et al. (2011)).

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Table 1
Comparison of four different criteria to assess the primary stability of three, clinically successful, cementless tibial trays (LCS Complete, PFC Sigma keeled and LCS Complete Duofix, all by DePuy Inc.) subjected to a full level gait cycle. Results are compared for a single representative model (SRM) (Taylor et al., 2012) and a population based study (PBS) (Galloway 2012). The four failure criteria are (i) the peak micromotions should not exceed 150 μ, (ii) mean micromotion should not exceed 50 μ, (iii) more than 75% of the interface should experience micromotions less than 50 μ and (iv) more than 40% of the contact area should experience micromotions less than 50 μ.

	Peak micromotion (μm) RF=PM/150 μm		Mean micromotion (μm) RF=MM/50 μm		% Area (A) < 50 μm (%) RF=A/A_1, where A_1=75%		% Area (A) < 50 μm (5) RF=A/A_2, where A_2=40%	
	SRM	PBS	SRM	PBS	SRM	PBS	SRM	PBS
LCS (Sorrells et al., 2004)	225 FAIL	797 FAIL	86 FAIL	95 FAIL	39 FAIL	42 FAIL	39 FAIL	42 PASS
PFC Sigma (Baker et al., 2007)	180 FAIL	612 FAIL	65 FAIL	56 FAIL	40 FAIL	58 FAIL	40 PASS	58 PASS
LCS Duofix (Holloway et al., 2010)	198 FAIL	639 FAIL	61 FAIL	46 PASS	46 FAIL	72 FAIL	46 PASS	72 PASS

surgical workflow. The growth of CT based navigation and patient customised instrumentation programs, there is the potential to access large volumes of pre-operative CT scans of patients that can be followed up. As failure rates are low, many patients need to be followed in order to identify and study the few that fail early. Since the vast majority will perform well, there is an opportunity to define what the safe working envelop is for joint replacements, which will be just as valuable information in the development of the next generation of joint replacements.

3. Discussion

Researchers and implant designers have a range of sophisticated modelling tools available to them, capable replicating a variety of mechanical and biological processes in order to assess the mechanical behaviour and performance of orthopaedic devices. However, our current ability to use these tools to their full potential is limited until at least three challenges are overcome:

i) Material properties: From defining simple Young's modulus and Poisson's ratio for isotropic materials through to time dependent viscoelastic and fatigue behaviour, finite elements simulations are limited by the lack of available experimental data. While defining the properties of biological materials is certainly still a problem, it also continues to be an issue for materials like bone cements and polyethylene. Complete material property data for all brands of bone cement and difference grades of polyethylene would be valuable to modellers. However, such data is expensive and time consuming to collect and there is little research value to be gained.
ii) Gaining a fundamental understanding of the behaviour of the system or physical processes: in some cases, we still do not have a sufficient understanding of the behaviour of the system, e.g. the loading of the skeletal elements, even of the femur where muscle loading has been extensively studied, or of the underlying mechanical or biological processes. In these cases, the sophistication of modelling tools have out-stripped our knowledge of the system; this is in marked contrast to the early days where the modelling tools provided were at their limits (see Huiskes, 1980)).
iii) Study design: FE studies tend to employ either comparative or parametric study designs, often based on a single representative bone or joint assuming optimal prosthetic placement subjected to benign loading conditions (peak forces associated with level dates for a 70 kg individual). These approaches are only able to capture a snapshot of implant behaviour, most likely around the mean response and not at the extremes where failure of modern joint replacements are likely to occur.

As a consequence, it appears the development of current modelling techniques has plateaued. As discussed earlier the ability of an FE model to answer a particular question or differentiate performance is dependent on its sensitivity. The currently available tools, when used as part of comparative or parametric study designs, may not be sensitive enough to answer the questions related to the improvement of performance of total hip and knee replacements. However, for other joint replacements such as ankle, elbow, shoulder and the small joints of the hand, where there is still potential for significant increases in performance, these tools may still be adequate.

This raises the question, how can we improve the sensitivity of the available modelling tools? From the development of the FE model, through replicating the initial mechanical environment and the use of adaptive simulation techniques, areas for improvement have been identified. There will always be value in improving the underlying modelling techniques but if these are implemented with simple study designs, will these incremental developments be any better at identifying the difference between a design that has a 5% failure rate at 10 years versus one that has a 3% failure rate? Is it more important to focus on developments of the underlying techniques or to focus on trying to account for patient and surgery related variability, where the high degree of variability may swamp incremental improvement in model predictions.

The major advance in finite element modelling has been the improvements in study design through the implementation of statistical methods, particularly probabilistic analyses. There are challenges in developing and implementing probabilistic analyses, particularly if patient variability and implant positioning are considered. However, simpler studies can be performed which can still yield useful information about the behaviour of the bone–implant construct. Finite element modelling is often seen as a quick and easy alternative to in vitro testing but the reality is that there is usually a significant time investment in developing a model. If this model is then just used once then it is not being used to its full potential. Parameters such as loading conditions, bone properties and interface conditions can all be varied without changing the geometry or mesh. For example, using a single representative model of an implanted proximal femur, a full factorial design of experiments can be used to explore variation of bone properties and body mass index at 3 levels each, using just 9 simulations. Now, rather than having a prediction at a single point, there is also some indication how the system will behave as a function of patient variability. In the next decade, there needs to be a move away from

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comparative and parametric studies to routine adoption of design of experiments and probabilistic analyses in order to maximise the potential of finite element simulations.

There are also opportunities that need to be exploited in the next decade, particularly related to bridging the in silico to in vivo gap. Computer assisted and robotic assisted surgery capture a wealth of information about the patients and the planned or final position of the prosthetic components. If motion analysis is performed on these patients and used to predict the joint contacts and muscle forces, then finite element models can be built and used to understand the behaviour of well-functioning implants as well as the early failures.

In the future, finite elements will continue to play an important role in understanding the behaviour of total joint replacements. Through improved study design and close corroboration with in vitro testing, we will increasingly rely on simulations in the development and preclinical testing of new devices. There are challenges to the use of finite elements as part of a decision support tool for planning orthopaedic surgery, but advances in model generation techniques and solution methodologies may lead to the emergence of this technology in the coming decade. Huiskes was the supereme advocate of applying mechanics in biology – taking the Newtonian angle – and he would have relished taking up these modelling challenges because, as he wrote himself "It doesn't help a soul if biomechanicians would transform themselves into biologists" (Huiskes, 1998).

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