A comprehensive combined experimental and computational framework for pre-clinical wear simulation of total knee replacements

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ABSTRACT

A more robust pre-clinical wear simulation framework is required in order to simulate wider and higher ranges of activities, observed in different patient populations such as younger more active patients. Such a framework will help to understand and address the reported higher failure rates for younger and more active patients (National_Joint_Registry, 2016). The current study has developed and validated a comprehensive combined experimental and computational framework for pre-clinical wear simulation of total knee replacements (TKR).

The input mechanical (elastic modulus and Poisson's ratio) and wear parameters of the moderately cross-linked ultra-high molecular weight polyethylene (UHMWPE) bearing material were independently measured from experimental studies under realistic test conditions, similar to the loading conditions found in the total knee replacements. The wear predictions from the computational wear simulation were validated against the direct experimental wear measurements for size 3 Sigma curved total knee replacements (DePuy, UK) in an independent experimental wear simulation study under three different daily activities; walking, deep squat, and stairs ascending kinematic conditions.

The measured compressive mechanical properties of the moderately cross-linked UHMWPE material were more than 20% lower than that reported in the literature under tensile test conditions. The pin-on-plate wear coefficient of moderately cross-linked UHMWPE was significantly dependant of the contact stress and the degree of cross-shear at the articulating surfaces.

The computational wear predictions for the TKR from the current framework were consistent and in a good agreement with the independent full TKR experimental wear simulation measurements, with 0.94 coefficient of determination of the framework. In addition, the comprehensive combined experimental and computational framework was able to explain the complex experimental wear trends from the three different daily activities investigated. Therefore, such a framework can be adopted as a pre-clinical simulation approach to optimise different designs, materials, as well as patient's specific total knee replacements for a range of activities.

1. Introduction

The number of younger and more active patients requiring total knee replacements (TKR) is increasing (National_Joint_Registry, 2016). The number of recorded TKR revisions in 2015 in the United Kingdom was 6104 (National_Joint_Registry, 2016). Unsurprisingly, the revision rate for young patients (under 60 years) was 10 times that for patients over 75 years, with more than 20% of the revisions attributed to implant wear (National_Joint_Registry, 2016). More advanced pre-clinical wear simulation methods are therefore needed to assess the wear performance of TKR under a wider range of physiological conditions, simulating the more demanding activities of younger and more active patients.

Pre-clinical pin-on-plate and pin-on-disk testers have been extensively used to screen the performance and explore the influence of parameters such as lubricant, sliding distance, contact stress, and cross-shear ratio on the wear of orthopaedic bearing materials (Barbour et al., 1995; Saikko, 2006, 2014; Abdelgaied et al., 2013b; Zhang et al., 2015; Brockett et al., 2016a). Although pre-clinical pin-on-plate and pin-on-disk studies are usually run under simplified test conditions and geometry configurations they provide significant insights into wear characteristics and wear mechanisms of the articulating as well as fixation interfaces of the bearing materials (Zhang et al., 2015; Brockett et al., 2016a). In addition, pre-clinical pin-on-plate and pin-on-disk studies provide the input parameters and validation required for reliable and accurate pre-clinical computational simulation studies (Fregly et al., 2005; Willing and Kim, 2009b; Abdelgaied et al., 2011, 2013a).

In an attempt to understand and address the higher failure rates

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reported for young patients, pre-clinical experimental testing methods which include a wider range of physiological conditions have been developed (Jennings et al., 2007; Nakamura et al., 2009; Schwiesau et al., 2013; r et al., 2014). In contrast to the pin-on-plate and pin-on-disk testers, experimental wear tests are run on the full size replacement and under complex and physiologically relevant test conditions (Galvin et al., 2009; Fisher et al., 2010; Brockett et al., 2012, 2016b; Jennings et al., 2012). Such in-vitro testing is an invaluable method for evaluating bearing materials and total knee replacement geometries. Experimental wear testing has however substantially associated cost and is time consuming, due to the large number of low frequency gait cycles that must be run (Knight et al., 2007).

Computational wear modelling has been extensively used for pre-clinical wear simulation in TKR (Barbour et al., 1995; Fregly et al., 2005; Abdelgaied et al., 2011, 2014; Brockett et al., 2013, 2016b), with the low cost and time as well as its appropriateness for parametric studies (Willing and Kim, 2009b; Abdelgaied et al., 2011). Based on wear factor, sliding distance, applied load, contact area, and contact stress, the simplified (Barbour et al., 1995; Maxian et al., 1996; Knight et al., 2007; Pal et al., 2008; Zhao et al., 2008) as well as modified (Willing and Kim, 2009b; Innocenti et al., 2014) versions of Archard's wear law (Archard and Hirst, 1956) have been adopted in many studies to predict wear in total joint replacements. The applicability of Archard's wear law to total joint replacements has been questioned (Galvin et al., 2009; Fisher et al., 2010; Liu et al., 2010; Abdelgaied et al., 2011; Innocenti et al., 2014). In addition, the majority of these wear models utilised a wear factor which was chosen from literature to match the experimental measurements. These models are therefore not independent of the experimental simulations, and hence are not validated. Wear factor based computational wear models have therefore shown a limited predictability when running other conditions than the ones they were adapted to simulate (Abdelgaied et al., 2011).

The type of motion at the articulating surfaces in TKR has also been shown to have a significant effect on the wear rate of polyethylene bearings (Wang et al., 1998; Wang, 2001; Kang et al., 2008a, 2008b; Abdelgaied et al., 2013b). The cross-shear parameter was developed to describe the significant effect the multidirectional motion had on polyethylene wear, compared to unidirectional motion (Bragdon et al., 1996; Wang, 2001). The reported wear parameters under multidirectional motions were up to ten times more than that under unidirectional motion, depending on the degree of cross-shear at the articulating surfaces (Wang, 2001; Kang et al., 2008b; Abdelgaied et al., 2013b). However, the simplified Archard's wear law, and therefore the simplified Archard's wear law based models, does not account for these cross-shear effects.

The input mechanical properties of the total knee replacement bearing materials, such as elastic modulus and Poisson's ratio, significantly contribute to the predictability of computational models. They should ideally be determined from independent experimental studies, under similar test conditions to the clinical and experimental conditions, to provide reliability and validity to the computational models. In most cases, the reported values in the literature for the elastic modulus and Poisson's ratio of the bearing materials have been measured under tensile test conditions, in contrast to the compressive operating conditions of the total knee replacements (Bei et al., 2004; Bevill et al., 2005; Fregly et al., 2005; Jourdan, 2006; Zhao et al., 2006, 2008; de Jongh et al., 2008; Pal et al., 2008; Carr and Goswami, 2009; Jourdan and Samida, 2009; Kang et al., 2009; Willing and Kim, 2009a, 2009b; Innocenti et al., 2014).

In addition, clinical, experimental, and computational studies have reported increased polyethylene wear rate under high contact stress conditions (Griffin et al., 1998; Foran et al., 2004; Amin et al., 2006; Kang et al., 2008a, 2009; O'brien et al., 2015). In most cases, the input wear parameters to the computational models have been experimentally measured under average contact stresses to simulate standard activities. These wear studies are not therefore applicable for more adverse conditions, including higher levels of activities and severe loading conditions.

The aim of the current study was to develop and experimentally validate a new fully independent framework for pre-clinical wear simulation in total knee replacements. The input mechanical and wear parameters of the bearing materials were determined from independent experimental studies of material and wear properties under wider and more realistic test conditions. Our hypothesis was that the new fully independent framework would be a more reliable computational prediction of the wear of the polyethylene in TKR and provide a better agreement with the full TKR experimental simulation measurements of TKR wear.

2. Materials and methods

This study developed combined experimental and computational simulation methods to develop and validate a fully independent framework for pre-clinical wear simulation in TKR. In this approach, the experimental mechanical, pin-on-plate, and knee simulation studies provided the inputs as well as the validation to the computational wear model. The pre-clinical wear simulation framework proposed in the current study is summarised in Fig. 1.

2.1. Wear model

Based on the modification of Archard's law where wear volume (W) is proportional to the contact area (A) and sliding distance (S) (Liu et al., 2010), the wear volume was defined as:

$$W = A \times S \times C \tag{1}$$

where C is a non-dimensional wear coefficient.

Clinical and experimental wear studies have shown that wear is dependant on the cross-shear ratio (CS) and the contact stress (P) at the articulating surfaces (Wang, 2001; Foran et al., 2004; Kang et al., 2008b; Abdelgaied et al., 2013b; O'brien et al., 2015). The non-dimensional wear coefficient was therefore defined as a function of CS and a non-dimensional contact stress (P/E), where E is the elastic modulus of the polyethylene baring material:

$$C = \text{fun}(CS, \frac{P}{E}) \tag{2}$$

The linear wear depth (δ) can also be derived from Eq. (1) as:

$$\delta = S \times C \left(\text{fun}(CS, \frac{P}{E})\right) \tag{3}$$

Based on the unified theory of wear and frictional work by Wang (2001), the cross-shear ratio was defined as the frictional work component perpendicular to the principal molecular orientation (PMO) direction ($E_{cross-shear}$), divided by the total frictional work (E_{total}), thus:

$$CS = \frac{E_{cross-shear}}{E_{total}} \tag{4}$$

The non-dimensional wear coefficient (C), a function of CS and non-

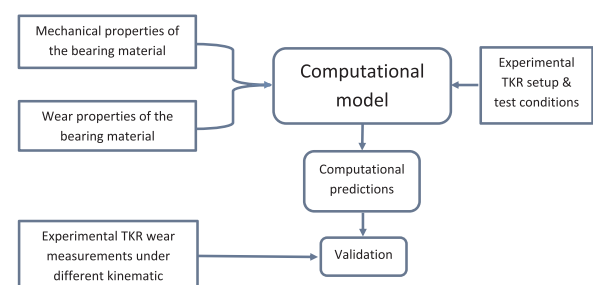**Fig. 1.** Combined experimental and computational framework for pre-clinical simulation of total knee replacements.