Medical Engineering and Physics 000 (2017) 1–10

Contents lists available at ScienceDirect

Medical Engineering and Physics

journal homepage: www.elsevier.com/locate/medengphy

A novel flexible capacitive load sensor for use in a mobile unicompartmental knee replacement bearing: An *in vitro* proof of concept study

M J A Mentink[a,*], B H Van Duren[a], D W Murray[a], H S Gill[b]

[a] Nuffield Dept. of Orthopaedics, Rheumatology & Musculoskeletal Sciences, University of Oxford, Botnar Research Centre, Oxford OX3 7LD, UK
[b] Department of Mechanical Engineering, University of Bath, Bath BA2 7AY, UK

ARTICLE INFO

Article history:
Received 17 March 2016
Revised 10 April 2017
Accepted 16 May 2017
Available online xxx

Keywords:
Tibiofemoral forces
Capacitive load sensor
In vitro
Load measurement
UHMWPE mechanical behaviour
Flexible sensor
Polyimide

ABSTRACT

Instrumented knee replacements can provide *in vivo* data quantifying physiological loads acting on the knee. To date instrumented mobile unicompartmental knee replacements (UKR) have not been realised. Ideally instrumentation would be embedded within the polyethylene bearing. This study investigated the feasibility of an embedded flexible capacitive load sensor. A novel flexible capacitive load sensor was developed which could be incorporated into standard manufacturing of compression moulded polyethylene bearings. Dynamic experiments were performed to determine the characteristics of the sensor on a uniaxial servo-hydraulic material testing machine. The instrumented bearing was measured at sinusoidal frequencies between 0.1 and 10 Hz, allowing for measurement of typical gait load magnitudes and frequencies. These correspond to frequencies of interest in physiological loading. The loads that were applied were a static load of 390 N, corresponding to an equivalent body weight load for UKR, and a dynamic load of ±293 N. The frequency transfer response of the sensor suggests a low pass filter response with a −3 dB frequency of 10 Hz. The proposed embedded capacitive load sensor was shown to be applicable for measuring *in vivo* loads within a polyethylene mobile UKR bearing.

1. Introduction

Mechanical loads experienced by human joints during functional activities play an important role in the initiation and progression of osteoarthritis (OA) resulting in joint degeneration [1,2]. The ability to measure the loads that occur within joints *in vivo* can give a valuable insight into the disease process. Measuring joint loads *in vivo* presents many challenges; both technologically and ethically.

Previous studies have attempted to estimate the mechanical forces and moments in the knee from external gait measurements [3], mechanical simulations (*in vitro* assessment) [4], computer simulations [5,6], and telemetered implants. However, these methods have shortcomings. Force calculations from external gait measurements are subject to a large number of assumptions. The accuracy of simulations is dependent on the data provided by measurements, for instance from telemetered implants [6]. Forces measured *in vivo* using those implants are reported to be lower than those calculated by models [7].

In recent decades, instrumented Total Knee Replacement (TKR) implants have been successfully used to measure joint loading. In TKR many of the important structures of the knee, such as the cruciate ligaments, are removed during surgery resulting in a significant change in the kinematics of the knee. Instrumented TKR implants may require additional bone volume to be removed in order to accommodate the added volume of the instrumentation [8–10]. In contrast during Unicompartmental Knee Replacement (UKR) most of the structures are left intact, particularly the cruciate ligaments, resulting in kinematics that more closely represent those of the normal knee [10–15].

Instrumentation of UKR potentially offers valuable data describing the loads experienced in the knee. To our knowledge an instrumented Unicompartmental Knee Replacement (UKR) has not been developed. With UKR it is important to retain as much bone as possible. Therefore, the electronics need to be fitted within the implant components without requiring the removal of additional knee structures.

In the Oxford mobile bearing UKR (Zimmer Biomet Ltd, Swindon, UK), the majority of the load is perpendicular to the tibial tray, owing to the bearing being mobile in the transverse and

* Corresponding author.
E-mail addresses: michielmentink@gmail.com, m.mentink@ucl.ac.uk (M.J.A. Mentink), b.h.vanduren@gmail.com (B.H. Van Duren), david.murray@ndorms.ox.ac.uk (D.W. Murray), r.gill@bath.ac.uk (H.S. Gill).

http://dx.doi.org/10.1016/j.medengphy.2017.05.002
1350-4533/

sagittal planes. Therefore, embedding a sensor within the bearing may offer the least intrusive method of measuring load. Strain gauges have been used to measure forces in TKR implants. However, previous work suggested that stress levels within an Oxford UKR bearing could rise as high as 5 MPa [16], which translates to 0.015 strain. Given that the fatigue life of typical Constantan strain gauges falls below 10^5 cycles for strains of ±0.002 [17], using strain gauges to measure UHMWPE deformation directly would result in an unacceptably short sensor life, compared to the 16 × 10^6 loading cycles typically experienced by a UKR [16].

Capacitive sensors suffer less from a limited life span as the material under load can more readily be chosen to be able to withstand load. Additionally, insertion of components with an elastic modulus that is dissimilar to UHMWPE may cause stress risers and promote damage of the bearing [16], whereas capacitive sensors can be designed to be more compliant, because sensor materials and electrode construction can be adjusted to closely match the mechanical properties of the host component. Polymer based capacitive sensors have previously been used to measure forces [18–25] but never to measure forces within joints and they have never been incorporated into industrial production process used in producing polyethylene bearings.

The aim of the current study was to investigate the feasibility of using a capacitive load sensor embedded in an existing design of a mobile bearing used in a UKR implant in order to measure loads acting on the knee. The minimum design specification for the sensor was that it should be able to measure static load equivalent to one body weight during one leg stance, which was defined as 780 N. The distribution of load between the condyles has been considered to have a 50/50 medial to lateral distribution [26–28], resulting in a static load of 390 N to be measured. Furthermore, the sensor should be able to measure a maximum expected frequency content of 4.2 Hz [29]; we therefore choose to use a conservative measurement frequency of 10 Hz. The sinusoidal load was set to be ±75% or ±293 N of the static load, to prevent lift-off of the actuator at minimum load during testing. The specification for physical dimensions required the sensor to fit within the existing Oxford UKR bearing, giving a size of 5 × 5 × 0.2 mm.

The construction of the UKR bearing with an embedded capacitive load sensor is detailed followed by *in vitro* tests to determine its electrical and mechanical characteristics.

2. Methods

2.1. Instrumented bearing design and construction

The Oxford UKR uses a fully conforming mobile bearing, resulting in the predominant load being in the proximal-distal orientation normal to the tibial plateau. Therefore a capacitive sensor was designed, consisting of parallel plates, placed within the centre of the bearing.

The capacitance of two parallel plates can be calculated using the equation (Eq. (1)):

$$C = \frac{\varepsilon_0 \times \ \varepsilon_r \times A}{d} \quad (1)$$

where: capacitance, ε_0 = permittivity of free space, 8.85e−12 F/m, ε_r = relative dielectric constant, A = overlapping area of two parallel electrodes (m^2), d = distance between electrodes (m).

When a load is applied to the sensor, the separation of the plates decreases, hence the capacitance increases. A sensor was developed which consisted of three copper layers (Figs. 1 and 2), of which the outer two layers were electrically connected, resulting in a doubling of capacitance with respect to Eq. (1), and providing shielding of the sensitive inner electrodes from electromagnetic interference by the common driven electrodes. The middle layer consisted of four electrodes (each with dimensions 2 × 2 mm) with an in-plane electrode separation of 0.5 mm. On the outer layers, there was a 5 × 5 mm common electrode. Together they formed four individually addressable capacitors. Polyimide (PI), a commonly used material for making flexible electronic circuits, was used for the dielectric layer. The total thickness of the sensor was 111 μm. The distance d between the electrodes was 44 µm, the area A of one electrode was 4E−6 m^2. The capacitive sensor was kept small, primarily to retain as much of the mechanical integrity of the UHMWPE as possible, and secondarily to remain within the bounds of the maximum capacitance that the chosen Capacitive to Digital converter (C2D, AD7746 v2.2.2 Analog Devices Inc, Norwood, MA, USA) could measure. The capacitance of each electrode was measured to be nominally 16 pF, including the measurement leads (Fig. 3). The flexible capacitive force sensor printed circuit board was designed using OrCAD 16.5 (Cadence Design Systems, San Jose, CA, USA). The sensors, designed by MM, were manufactured by Sunsoar Tech (Sunsoar Tech, Shenzhen, China), using standard Polyimide material 'SYE'. The C2D was used to send a signal to the common electrode and the electrode with the strongest load response was connected to the input of the C2D. This design was chosen because of its small size and potential for possible application in a future production instrumented knee replacement bearing.

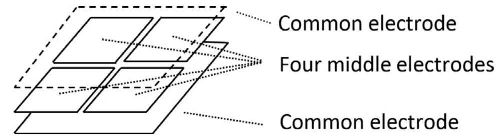

Fig. 1. Illustration showing the layout of the common and middle electrodes, made of a layer of solid copper foil.

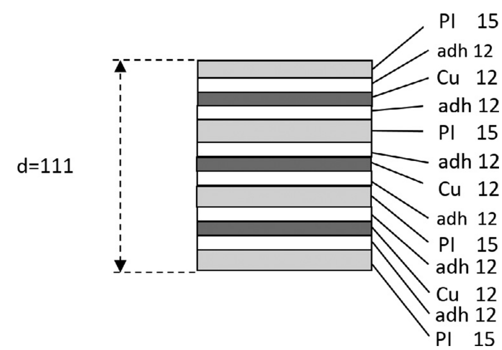

Fig. 2. Illustration showing the composition of the capacitive sensor layers, where PI = Polyimide, adh = adhesive, Cu = copper. For each layer, the thickness is given in micrometres (µm).

In order to be able to embed the sensor directly under the centre of the bearing concavity, the flexible sensor was shaped with limbs to position the electrodes in the middle of the bearing (Fig. 3a) during the moulding process. The sensor leads were folded in a harmonica-like manner so as to enable their release after the moulding process had been completed. The first step in the moulding process was to place a layer of half the required amount of UHMWPE powder in the bottom of the moulding tool for the UKR bearing. The sensor was then placed on top of this layer (Fig. 3b), and the remaining UHMWPE powder added. With the mould filled, the normal production temperature and pressure profiles were used to mould the bearing (Fig. 3c) [30]. Using a hot cutting tool, the UHMWPE covering the folded sensor lead was removed, and the lead was extended (Fig. 3d). After that, the shielded connecting leads were soldered to each sensor lead for measurement. Five instrumented left sided, large, size 6, Phase 3,