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Development and validation of an acoustic emission device to measure wear in total hip replacements *in-vitro* and *in-vivo*

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ABSTRACT

An increasing demand for total joint replacement surgeries has provided a great need for more effective diagnostic procedures for monitoring and identifying wear, loosening, and other failure modes in total joint replacement implants. Significant recent research attention has been focussed on the contributing factors to wear and audible squeaking of total hip replacement (THR) implants and in particular those with hard-on-hard bearing combinations. An acoustic emission (AE) monitoring prototype diagnostic device has been developed for the assessment of implant wear and stability in THR patients.

Implant vibrations have been recorded by AE monitoring during *in-vivo* patient testing from 90 patients with a range of age, implant type, and implant conditions. A number of these patients have gone on to have subsequent revision surgery and *in-vitro* testing of implant components previously tested *in-vivo* has been possible. The AE monitoring device has been able to detect a significant number of acoustic events, including audible squeaking, from both the *in-vivo* and *in-vitro* environments. This manuscript focusses on the data from five patients with ceramic-on-ceramic bearing interfaces for whom significant audible squeaking occurred and both *in-vivo* and *in-vitro* AE monitoring was undertaken.

Preliminary results from the *in-vitro* monitoring data show audible squeaking AEs have similar characteristics to *in-vivo* audible squeaking AEs and both have primary frequencies in the 1–4 kHz range. This study has indicated that the AE device shows promise as a potential diagnostic tool for assessing the condition of THR implants. In addition, the *in-vitro* technique was shown to be useful at providing further insight into the mechanisms of wear and acoustic emissions of THR implants. The study also provides important initial results for the assessment of the AE device as a diagnostic tool through the unique contribution of the testing and analysis of the same implant components in both *in-vivo* and *in-vitro* environments.

1. Introduction

Total hip replacement (THR) is a common surgical procedure for patients with degenerative joint disease and has a high success rate in returning patients to pain-free activities. The ageing population has seen the incidence of primary THR increase dramatically and the predictions for the next 20 years suggest over a threefold increase for patients over 65 years [1–3]. As a consequence, the number of patients requiring revision surgery will also rise proportionately due to failure of the THR implant. The most common cause of late failure of THR has been aseptic loosening secondary to particle debris from the articulating surfaces of the replacement [4–6]. The traditional bearing surface for THR has been high molecular weight polyethylene articulating with a metal femoral head which results in wear debris causing bone destruction (osteolysis) and prosthesis loosening [6], ultimately leading to prosthesis failure and the requirement for a revision procedure. A typical revision procedure for a loosened implant costs on average four times that of the initial procedure and consequently places a large burden on health expenditure.

To improve the outcome and survivorship of THR different bearing surfaces have been developed using either ceramic-on-ceramic (CoC) or metal-on-metal (MoM) articulations, both of which have a much lower co-efficient of friction and wear rate than metal-on-polyethylene (MoP), in an attempt to reduce polyethylene wear debris. However these bearing articulations have introduced the relatively new complication of audible 'squeaking' of the implant

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within the patient (*in-vivo*). These abnormal and irritating acoustic emissions from hard on hard articulations, although troublesome to the patient, have not been associated with significant wear or failure of the prosthesis to date. However, there remains controversy as to their underlying cause and the potential impact on the longevity of the prosthesis [7–9].

Research over the past 20 years has investigated acoustic emission (AE) monitoring to provide insight into both the status of the prosthesis and the detection of early wear and loosening, and more recently, the origin of audible squeaking. AE monitoring devices generally use passive ultrasonic receivers to record high frequency vibrations emitted by the prosthesis and correlate the recorded signal with clinical outcomes. The ultrasonic signals are typically characterised on frequency content or time domain signal characteristics (short-duration high amplitude events/long-duration, lower amplitude events). These AE signals can be correlated with events such as micro-scale brittle breakages of bone or bone cement, or vibrations due to wear and/or wear debris within the bearing surface. Previous laboratory (*in-vitro*) and *in-vivo* studies demonstrated the potential AE frequency range of interest varies significantly (up to 1 MHz *in-vitro*, but only up to 50 kHz for *in-vivo* tests on the skin surface) due to attenuation of vibrations through tissue [10,11]. These devices typically utilise a single sensor located near the greater trochanter to determine joint condition.

Previous *in-vivo* studies have measured AEs in THR patients using acoustic transducers attached to the skin. Two studies [12,13] found good indications that the AE technique could not only identify patients with confirmed loose implants but could also detect very early-stage loosening that X-ray inspections could not. These two studies however, did not attempt to correlate the AEs with any other common THR revision reasons. A more recent *in-vivo* study [14] found distinct correlations between high frequency AEs and the re-articulation of the femoral head and acetabular liner following component separation during normal gait.

There have been a considerable number of *in-vitro* studies of THR components with many attempting to find the source of implant squeaking. One such study [15] found the eigenfrequencies of assembled femoral components were good predictors of squeaking frequencies and that higher axial loads caused an increase in these squeaking frequencies. Another *in-vitro* study [16] found that squeaking correlates well with increases in bearing interface friction. Furthermore, an investigation using finite element analysis (FEA) and an *in-vitro* hip simulator [17] found that modal frequencies from the FEA and *in-vitro* AE frequency content were consistent with each other. The investigation also found that when soft tissues were included in the FEA analysis the observed frequencies lowered to be a closer match to squeaking frequencies recorded *in-vivo*. Additionally, a critical review of AE testing research in orthopaedics [18] found well-conducted *in-vitro* studies that validate the use of AEs for early detection of aseptic loosening in femoral components of THA [19–21].

Recent research has developed an AE monitoring prototype diagnostic device for the assessment of implant wear and stability in THR patients [22]. The prototype utilises four passive ultrasonic sensors placed against the skin surface of the hip region. Multiple sensors provide additional information regarding location of vibration sources (*i.e.* bearing surface versus other implant components) and can help lead to clinical diagnosis. The device can be applied to all implant types and bearing surfaces and could potentially also be adapted for use on other joints of the body, such as the knee. This manuscript describes the development and validation of a novel AE monitoring device for wear measurement of *in-vivo* hip replacement implants through data gathered from both *in-vivo* and *in-vitro* environments. The findings presented here focus primarily around five patients with CoC THR implants which underwent *in-vivo* AE monitoring and then went on to have revision surgery, allowing the retrieval of their implant components and subsequent *in-vitro* implant testing and AE monitoring. The opportunity to directly compare AEs of the same implant components during both *in-vivo* and *in-vitro* testing is part of the unique contribution of this study.

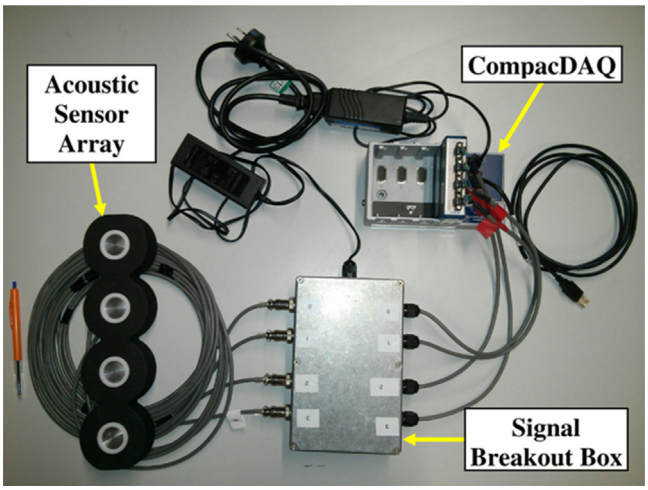

Fig. 1. Image of data acquisition hardware which consists of four ultrasonic sensors arranged in an array, signal breakout box for external power input, and National Instruments CompacDAQ (A ball-point pen of length 140 mm has been included at the left of the image for scale).

2. Methods

2.1. Acoustic emission detection device

The prototype device was developed to undertake *in-vivo* AE monitoring on a cohort of THR patients to investigate the unique acoustic emission characteristics of THR implants under dynamic patient motion. Any AEs generated by the implants were detected using four passive ultrasonic receivers, each with a resonant frequency of 32.8 kHz. The signals from the ultrasonic sensors were amplified by a circuit mounted within each sensor housing in order to prevent additional noise adding to the low voltage signal during transmission to the data acquisition (DAQ) system. A National Instruments CompacDAQ and NI-9222 analog module were used, in conjunction with LabVIEW software, to provide simultaneous recording of each channel and store signal data continuously at 100 kHz. The 100 kHz sampling rate provides a maximum practical frequency of 50 kHz by the Nyquist theorem, which is well above the range of human hearing and well beyond the typical frequencies observed during prior *in-vivo* and *in-vitro* implant testing [11]. Fig. 1 shows the AE monitoring equipment with the array of four sensors connected to the signal breakout box and then to the CompacDAQ which interfaces with a computer.

2.2. In-vivo *data collection*

Following local human ethics approval (New Zealand Upper South A regional ethics committee URA/10/11/075), a cohort of consenting THR patients were recruited for *in-vivo* monitoring with a range of age, implant type, and implant conditions. The recruitment criteria included patients scheduled for revision surgery with identified implant problems, such as audible squeaking. For AE evaluation of each implant, the four sensors were arranged in a flexible array and placed against the skin surface of the patient from the iliac crest to the upper-femur. The positioning of the sensors relative to the *in-situ* implant are shown in Fig. 2. Note that, while the photograph in Fig. 2 shows the sensor array on the outside of the clothing, this is only to demonstrate the position on the patient.