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Non-invasive vibrometry-based diagnostic detection of acetabular cup loosening in total hip replacement (THR)

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ABSTRACT

Total hip replacement is aimed at relieving pain and restoring function. Currently, imaging techniques are primarily used as a clinical diagnosis and follow-up method. However, these are unreliable for detecting early loosening, and this has led to the proposal of novel techniques such as vibrometry. The present study had two aims, namely, the validation of the outcomes of a previous work related to loosening detection, and the provision of a more realistic anatomical representation of the clinical scenario. The acetabular cup loosening conditions (secure, and 1 and 2 mm spherical loosening) considered were simulated using Sawbones composite bones. The excitation signal was introduced in the femoral lateral condyle region using a frequency range of 100–1500 Hz. Both the 1 and 2 mm spherical loosening conditions were successfully distinguished from the secure condition, with a favourable frequency range of 500–1500 Hz. The results of this study represent a key advance on previous research into vibrometric detection of acetabular loosening using geometrically realistic model, and demonstrate the clinical potential of this technique.

1. Introduction

Total hip replacement (THR) is aimed at relieving pain and restoring function. The procedure has come a long way since it was introduced by Charnley in the early 1960 s, and was nominated as the operation of the century [1]. The high success rate of THR has contributed to the rapid increase in its use, with well over one million operations performed annually worldwide [2]. However, approximately about 4%–10% of all the involved implants are expected to fail in their first decade [3,4], mostly due to aseptic loosening, which has been identified as the primary THR failure factor since 1979 [5]. Currently, imaging techniques are the primary diagnostic and follow-up method used clinically. These have, however, been shown to be unreliable for early loosening detection [6–8], especially of the acetabular cup [9]. The situation has led to the proposal of novel techniques such as vibrometry.

Vibration analysis is a mechanical non-destructive testing technique that is widely used in the inspection of composite materials and assessment of structural integrity, and has been successfully extended to the field of biomechanics [9,10]. Vibrometry predominantly involves the measurement of the response to low-frequency excitation, as reflected from the target surface or structure [11]. Long bone property assessment, fracture healing monitoring, osseointegration, and stability monitoring are some of the applications of vibration analysis in biomechanics [9]. However, the most widespread use was initially in the field of dentistry, following the pioneering works of Meredith et al. [12,13]. Since then, many research groups have used vibration analysis to detect prosthetic loosening through different measurement and excitation techniques [14].

Despite acetabular cups having a higher revision rate compared to femoral components, according to various national registries [15–19], the majority of published work on the use of vibrometry for the diagnosis of loosening [7,20–26] are femoral stem-related. Others have explored the detection of acetabular cup loosening [6,9,23] and were able to distinguish it from the stable condition, but did not define the detected level of loosening. Moreover, while the findings of a preliminary study [27] using Sawbones blocks substantiated the validity of the vibrometry approach, the complex geometry of the hemi-pelvis was not taken into consideration. The present study thus had two aims: i) to validate the outcomes of a previous study [27] related to the detection of loosening, and ii) to provide a more realistic anatomical representation of the clinical

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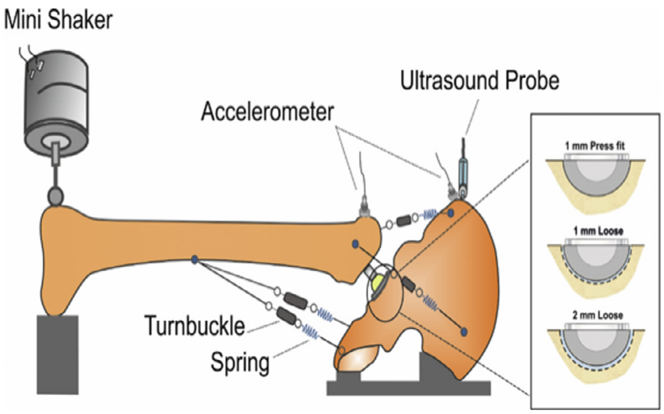

Fig. 1. Simulation setup of loosened acetabular cup using a femur and hemi-pelvis composite bone system.

scenario through the development of an acetabular cup loosening model using a composite Sawbones femur and hemi-pelvis bones.

2. Materials and methods

The loosening conditions of the acetabular cup were simulated using a composite femoral and hemi-pelvis bones (Femur 3406, Hemi-pelvis 3405, Sawbones Europe AB, Malmö, Sweden), a 44-mm stem (Exeter™ V40™, 28 mm standard head, Stryker Orthopaedics, USA), and a 56-mm cup (Trident® Hemispherical Cup, Stryker Orthopaedics, USA). The composite femur articulated with the hemi-pelvis that accommodated the loosened acetabular cup. The simulated conditions were 1 mm press-fit (secure condition), 1 mm spherical loosening, and 2 mm spherical loosening (Fig. 1).

The 1 mm press-fit condition included a computer numerical control machined cup cavity of diameter 55 mm and depth 28.5 mm. A Stryker cup of diameter 56 mm was inserted through repeated impacting by a soft mallet until it was fully seated, in accordance with the existing literature [28–30]. The two spherical loosening conditions with gaps of 1 and 2 mm were simulated using machined hemispherical cavities of diameters 58 and 60 mm respectively, including a 5 mm wide channel of depth 3 mm in the lower cavity surface, used to control the silicone thickness. The loosening gaps were filled with a silicone layer (EVO-STIK, Bostik Limited, England) in accordance with previous practise [10,21,31] to replicate the soft fibrous interface between the surfaces of the cup and bone. The silicone thickness was controlled using two 56-mm Nylon 66 domes (RS Ltd. Northants, UK) with different extended stem lengths of 4 and 5 mm, respectively. The domes were fixed inside the cup cavity channel (length 3 mm) for 24 h to cure the silicone (Fig. 2).

The Exeter stem was cemented into the fourth-generation femur composite bone, in accordance with the manufacture's recommended surgical protocol. The femur was subsequently attached to the pelvis with springs to replicate the attachment muscles, as previously adopted by Rieger et al. [9]. Two springs with a spring constant of 2.26 N/mm, were respectively used to simulate the adductor magnus and adductor longus, while the gluteus medius muscle was simulated by two springs with a spring constant of 4.17 N/mm.

Two test mediums were used in this study. One set of tests was conducted in water to simulate the soft tissue surrounding the femur and pelvis, while the second set was conducted in air using a foam support (Fig. 3). The water medium was used in replication of the work of Rowlands et al. [32] to investigate its effect on the ultrasound readings. In the case of the air medium, two accelerometers were used together with the ultrasound probe to determine the optimal response measurement location.

2.1. Excitation signal

The excitation signal was introduced at the femoral lateral condyle with a frequency range of 100–1500 Hz in increments of 25 Hz and a constant amplitude of 4 V (peak-to-peak) using a mini-shaker (V201, Ling Dynamic Systems Ltd, UK). That was driven through a function generator (TG230, Thurlby Thandar Ltd, UK) via a power amplifier (PA25E, LDS Ltd, UK). The excitation method, input signal characteristics, and frequency range were adopted from previous works [20–23,32], which highlighted the suitability of detecting implant loosening using a frequency sweep range below 1500 Hz.

2.2. Measurement and analysis

The measurement instruments used for the two test mediums were different. In the case of the water medium, only the ultrasound probe was used, and it was positioned facing the anterior superior iliac spine (Fig. 3b). In the case of the air medium (foam support) test, two accelerometers (Model 353B18, PCB Piezotronics Inc, Depew, NY, USA) and an ultrasound probe (Mini Dopplex 500 4 MHz, Huntleigh Technology PLC, Cardiff, UK) were used (Fig. 3a). The ultrasound probe and one accelerometer were coupled at the iliac crest, whereas the second accelerometer was located at the greater trochanter of the femur. Two accelerometers were attached to the surface of the Sawbones by screws using threaded steel inserts (PEM® Inserts, UK) for additional stability. The ultrasound probe was positioned on the Sawbones and supported using a laboratory stand, and an ultrasound gel (Aquasonic 100, Doppler size 60 g, Huntleigh Technology PLC, UK) was employed between the probe and Sawbones surfaces for the air medium only.

Three composite hemi-pelvises and one femoral Sawbones were used to obtain ten sample readings for each simulated condition (1 mm press fit, 1 mm spherical loosening, and 2 mm spherical loosening). The hemi-pelvis was Velcro-coupled (VELCRO® Brand Heavy Duty, Polyamide) with the foam support material (Neoprene Foam, durometer value 15A–20 A). The Sawbones femur medial epicondyle was also foam-supported rather than clamped [21,22] or counterbalanced by weights [32]. After each reading, the system was disassembled and reassembled based on the marks on the composite bone and the holding table.

The characteristics used to diagnose THR loosening by vibrometry are mainly dependent on the frequency analysis of the targeted system based on the magnitudes of the primary frequency and related harmonics. This was completed with the aid of the spectrum analysis tool in the LabVIEW sound and vibration package (Signal Express, Suite version 11, National Instruments). The harmonic ratio was used to better illustrate the relationship between the harmonics and the fundamental frequency over the entire driving frequency range. At each response to the driving signal frequency, the magnitude of the resultant harmonic was divided by the main fundamental frequency of the response. The obtained harmonic ratios were numbered based on the number of harmonics used.

2.3. Statistics

The data normality was tested using the Shapiro–Wilk test. Based on the results of these tests, a non-parametric analysis was adopted for comparisons at each excitation frequency. A Kruskal–Wallis test was performed among the three simulation conditions (1 mm press-fit, 1 and 2 mm spherical loosening); in cases of significance, this was followed by Mann–Whitney U-tests. All statistical analyses were conducted using SPSS (IBM SPSS Statistics 20.0, IBM Corporation, Armonk, NY, USA), with the significance level defined as $p < 0.05$.

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