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Vibration-based fixation assessment of tibial knee implants: A combined in vitro and in silico feasibility study

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ABSTRACT

The preoperative diagnosis of loosening of cemented tibial knee implants is challenging. This feasibility study explored the basic potential of a vibration-based method as an alternative diagnostic technique to assess the fixation state of a cemented tibia implant and establish the method's sensitivity limits. A combined in vitro and in silico approach was pursued. Several loosening cases were simulated. The largest changes in the vibrational behavior were obtained in the frequency range above 1500 Hz. The vibrational behavior was described with two features; the frequency response function and the power spectral density band power. Using both features, all experimentally simulated loosening cases could clearly be distinguished from the fully cemented cases. By complementing the experimental work with an in silico study, it was shown that loosening of approximately 14% of the implant surface on the lateral and medial side was detectable with a vibration-based method. Proximal lateral and medial locations on the tibia or locations toward the edge of the implant surface measured in the longitudinal direction were the most sensitive measurement and excitation locations to assess implant fixation. These results contribute to the development of vibration-based methods as an alternative follow-up method to detect loosened tibia implants.

1. Introduction

Total knee replacement (TKR) is a surgical procedure to replace the weight-bearing surfaces of the knee joint with a prosthesis. Although literature shows high survival rates, approximately 5–10% of the prostheses still need to be replaced within 10–15 years [1]. Loosening of a component is one of the main indications for a revision.

The diagnosis of loosening of primary TKR's prior to possible revision surgery is a crucial but difficult one. In up to 75% of painful prostheses the cause remains unknown until the time of surgical intervention with microbiological culturing [2]. However, it is important to be able to differentiate aseptic loosening from e.g. infection because the treatment of these is radically different.

Currently, the routine investigation method used in the evaluation of TKR's consists of a combination of different techniques such as radiography and nuclear scanning tests. Radiography is used to evaluate prosthesis alignment, fixation, gross polyethylene wear, and quality of periprosthetic bone [3]. Although it is the classic evaluation method, it is also known as subjective, inconclusive and having a low sensitivity and specificity to assess loosening (e.g. for the tibial component, Sterner et al. [4] reported a sensitivity of 43% and a specificity of 86%, Marx et al. [5] reported a sensitivity of 83% and a specificity of 72%). Literature shows diverse results for the use of nuclear scanning tests (e.g. bone scintigraphy, digital subtraction arthrography, 18F-FDG-PET) to detect loosening of the tibial component [e.g. 4,6–12]. Very obvious loosened tibial prostheses are likely to be detected by these techniques, because of the osteoblastic proliferation giving rise to tracer uptake; but it is not straightforward to detect slightly loosened prostheses.

Vibration analysis might be an alternative technique for the detection of knee implant fixation. Vibration analysis, a non-destructive testing technique to inspect structural integrity [13,14], has been successfully used in biomechanics to determine bone mechanical properties [15,16] and to monitor fracture healing [17,18].

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It is also a promising method to assess the mechanical properties of implant-bone systems [19]. Vibrational techniques have shown their merit in the detection of loosening of total hip replacement systems e.g. using features such as harmonic distortion [20,21]. Besides the post-operative applications aiming to detect loosening of hip implants, vibration analysis is also used as a tool to aid the surgeon during surgery in determining the endpoint of insertion of cementless hip implants and to avoid peroperative fractures. It was shown that vibration or impact analysis allows for a reliable detection of the endpoint of insertion, both in vitro [22–28], ex vivo [29] and in an in vivo setting [30,31]. The assessment of the fixation of cemented knee implants by vibration analysis however, is currently a domain less explored.

This study presents a combined in vitro and in silico feasibility study to determine the potential of using vibrational information to assess the fixation of the tibial component of a TKR. The two main research questions posed in this study are: (1) can vibration based methods differentiate between loosened and fully cemented primary TKR implants in a simplified model and which vibrational features are adequate to capture this difference and (2) what are the sensitivity limits of such an approach? Answering these questions is an important first step toward the development of these methods as an alternative implant follow-up technique which may enable, in a further development stage, earlier and more accurate diagnosis of implant loosening in primary TKRs.

2. Methods

Several clinically relevant loosening cases were first replicated experimentally in a limited in vitro study. Different excitation and measurement locations and vibrational data features were proposed. Excitation and measurement locations expected to have more limited skin and fat tissue in vivo were selected to optimize accessibility in a post-operative setting. Furthermore, given the recent advances in instrumented implants for orthopedic applications (e.g. hip implant [32–34] or knee implant [35]), possibilities were likewise explored for the use of a vibration-based method under the assumption that an implant could be instrumented. These results were then complemented with a FE model, for which the experimental results were used as proof points, to further understand the sensitivities of the results to different parameters that were difficult to vary experimentally and to establish the detection limits of a vibration-based technique.

2.1. In vitro study

2.1.1. Sample preparation

Five left fourth-generation composite tibias (Sawbones Model 3401, Sawbones, Vashon Island, WA, USA) with cellular rigid polyurethane foam were used in combination with a cemented tibial knee implant (Genesis II, Smith & Nephew, Memphis, TN, USA). The replicate bone models were prepared by the same experienced surgeon following standard procedure while using manufacturer provided instruments. Cementation was performed using Refobacin Bone Cement R (Biomet, Warsaw, IN, USA). Four different fixation cases were replicated experimentally; two samples were prepared to have an optimal, fully cemented fixation between bone and implant, one sample was prepared to simulate peripheral loosening between cement and implant (49.4% of the implant surface was loose) and two samples were prepared to simulate loosening on the medial (31.8% of the implant surface was loose), respectively lateral (32.1% of the implant surface was loose) side between cement and implant (Fig. 1). Medial and lateral loosening has frequently been reported in clinical practice [36]. Loosening was realized experimentally by interposing a thin plastic film (thickness of approx. 40 µm, Esselte, Espoo, Finland), smeared with beeswax on both sides, between cement and implant at the areas where cement–implant interlock was to be prevented. The film was removed after the cement was fully cured. This approach mimics a situation of a local complete debonding without fibrous tissue formation. The percentage of loosened surface area was determined using Photoshop CC2014 (Adobe Systems, Mountain View, CA, USA) based on pictures taken of the tibia surface either before insertion with the plastic film in place, or after removal of the implant if an undamaged surface was obtained. All cases felt mechanically stable after preparation.

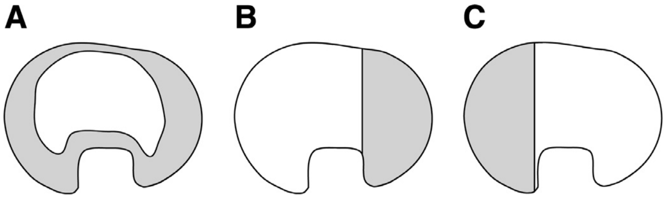

Fig. 1. Illustration of the cement–implant area that was loosened during experimental testing for (A) the peripheral loosening case, (B) the medial loosening case and (C) the lateral loosening case. The loosened areas are marked in gray, the fixed regions are in white.

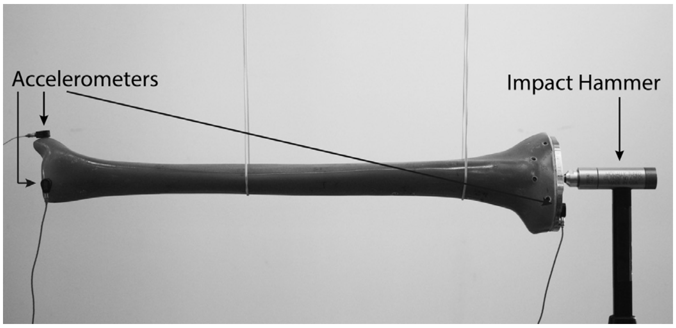

Fig. 2. The test setup for the experimental modal analysis is depicted. Three accelerometers were mounted on the test sample in three orthogonal directions during modal testing. The hammer was roved around to excite the structure at 48 impact locations. The test sample was mounted in free–free conditions.

2.1.2. Vibration analysis

Three sets of vibrational data were collected. Firstly, experimental modal analyses were carried out on four unprepared composite tibia samples and on the two fully cemented implant–tibia samples (*modal analysis set*). Each sample was mounted horizontally using soft elastic straps in order to simulate free–free boundary conditions (Fig. 2) [37]. Three unidirectional lightweight accelerometers (PCB A352A24, PCB Piezotronics, Depew, NY, USA, weight 0.8 g) were attached to the specimen using beeswax in three orthogonal directions. The sample was excited using a modal impaction hammer instrumented with a force cell (PCB 086C03). Impaction was performed in the direction normal to the specimen surface at 48 locations (roving hammer testing). Excitation locations were evenly distributed across the sample. Five measurements were averaged for each location. These input–output measurements resulted in a measurement set of 144 Frequency Response Functions (FRFs) per test sample. Mode shapes and resonance frequencies were extracted using the Polymax algorithm available in the modal analysis software package (LMS Test Lab, Siemens PLM Software, Leuven, Belgium) in a range of 50–4500 Hz, encompassing the first 12 flexible mode shapes. The frequency range was determined during pilot testing and was based on the force autopower spectrum to assure sufficient mechanical energy was injected into the system in the band of interest. The experimental modal results obtained for the unprepared composite tibia samples were used to update the cortical analog material properties of the composite tibia FE model

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