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Assessment of implant stability of cementless hip prostheses through the frequency response function of the stem–bone system

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ABSTRACT

Cementless joint prostheses require adequate initial press-fitting to achieve sufficient primary stability, which is necessary for bone ingrowth and implant success. A device was developed that measured intra-operatively the stability of a hip stem in the host bone. It included an excitatory piezoelectric system based on a ceramic multilayer bender, which delivered a controlled excitation in the range 1200–2000 Hz to the prosthesis. An accelerometer mounted on the host bone measured the transmitted vibration so as to identify the resonance frequency. Resonance frequency (and its associated shift) was measured immediately after implant press-fitting, and while a torque was applied to the implant. The proposed method was validated *in vitro* on 5 femurs covering a wide range of bone quality. Each bone was tested with different degrees of implant press-fitting. Implant stability estimated with the vibration method was compared against implant–bone micromotions that were measured simultaneously by a displacement transducer during this validation session. A strong correlation was found between the shift of the resonance frequency caused by load application, and implant stability. A quantitative threshold was identified that enabled consistently discriminating stable implants form quasi-stable ones: when the resonance frequency shifted less than 5 Hz during torque application, the residual micromotion after load removal was always less than 150 μm.

1. Introduction

Cementless hip implants are mechanically stabilized in the host bone during surgery by a press-fitting procedure. The primary mechanical stability achieved by these implants is critical for the long-term outcomes of the operation [1,2]. Various factors affect long-term stability and finally the outcome. It is commonly accepted that one of these is the achievement of a good level of osteointegration between bone tissue and stem surface. Osteointegration is possible if the relative stem/bone micromotion is below a certain threshold. In the literature, different thresholds can be found for relative micromotions that do not prevent osteointegration, from 30 to 150 μm [3,4]. Thus, the stability of this prosthesis type relies on the achievement of a good mechanical interlock between stem and bone. As the primary mechanical stability achieved by these implants is critical for the long-term outcomes of the operation [1,2,5], significant effort has been dedicated for the development of reliable methods for measuring the degree of implant stability *in vitro* [6,7], with numerical models [8]. Recently, a prototype telemetric prosthesis for measuring implant–bone micromotion has been presented [9].

To help the orthopaedic surgeon identify the optimal degree of implant–bone press-fitting, a device to address implant stability intra-operatively was explored in the latest years [10]. It was based on the direct measurement of micromotion caused by application of a torque. The device was thoroughly validated: it provided sufficiently accurate results, but its use in a clinical setting was quite complicated [11]. For this reason, alternative methods based on vibration analysis were explored.

The vibration analysis technique is largely used to monitor integrity of structures. In most cases, vibration-based methods can offer an effective and convenient non-destructive way to detect

Abbreviations: BL, biomechanical length of the femur; BW, body weight; CMB, ceramic multilayer bender (piezoelectric component used to excite the implant–bone system); CT, computed tomography; DEXA, dual energy X-ray absorptiometry; FE, finite element; FRF, frequency response function; HD, diameter of the head of the femur; LVDT, linear variable differential transformer (displacement transducer used to measure implant–bone micromotions).

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cracks in a target object by monitoring changes in the resonant frequencies, in the mode shapes or in the damping factors [12–15]. Vibration analysis has been successfully introduced in the field of biomechanics to investigate the mechanical properties of the bone [16,17]. Furthermore, a possible application to evaluate the extent of fixation of dental implants has been explored [18], also using simplified animal models (small insert in rat tibia) [19,20]. Validity of this method in the field of dentistry is still under debate [21].

Over twenty years ago, the potential of vibrations in diagnosing loose implants has been suggested [22], although that early study was probably not sufficiently sensitive to discriminate between the most critical cases in a clinical perspective. Recently, several studies have been published on the assessment of the stability of cementless hip implants by vibration analysis. The main findings could be listed as follows:

- The amplitude response at all frequencies (within a certain range) and the spectral analysis of particular waveforms could be successfully used to diagnose implant loosening [23]. Some interesting solutions that enabled *in vivo* monitoring loosening of hip prostheses have been designed that incorporated a telemetric device [24,25]. The ability of such telemetric devices in discriminating loose from stable implants based on a clinically relevant implant–bone micromotion threshold (see above) has not been demonstrated yet.
- The vibration testing method was 20% more sensitive with respect to radiographs and was demonstrated being able to correctly diagnose 13% more patients with total hip arthroplasty [26]. It must be noted that this was a limited trial, and patients were not randomly selected (elective THR revision candidates versus symptom-free THR patients presenting for routine follow-up).
- The implant–bone system should be excited with high frequencies (at least 1000 Hz or higher) being more sensitive to implant stability and indicative of interface failure [25,27], while at lower frequency the method was capable of detecting only grossly loose implants [28].
- The resonance frequency shift of the higher vibration modes of the implant–bone system seems to be the most sensitive parameter to detect the stability of the prosthesis in the femur [29,30].
- Clinical usefulness of vibrations to diagnose stability of a hip implant has been demonstrated [31,32]. So far this approach has been used for detecting when the maximum implant stability has been achieved by press-fitting, but absolute implant–bone micromotions were not estimated [30,33].

In summary, as indicated in previous studies by several authors, vibration-based methods have been largely explored with the aim to evaluate the stability of a cementless stem by means of a simple, accurate and cost-effective technique. These methods seem to be sensitive and accurate enough to evaluate the interface micromotion, even if a validation of those findings is still challenging.

The aim of the present study was to assess if it is possible to quantitatively evaluate the implant–bone stability of a cementless prosthesis by using a device based on the vibration analysis technique. In particular, this work was devoted to overcome the limitations of a previous study [11] by validating the ability of a vibration-based method to quantitatively discriminate between stable and quasi-stable implants in human femurs. This is a necessary step after delivering proof-of-principle on synthetic femurs, and it represents the most critical decision for the surgeon during operation.

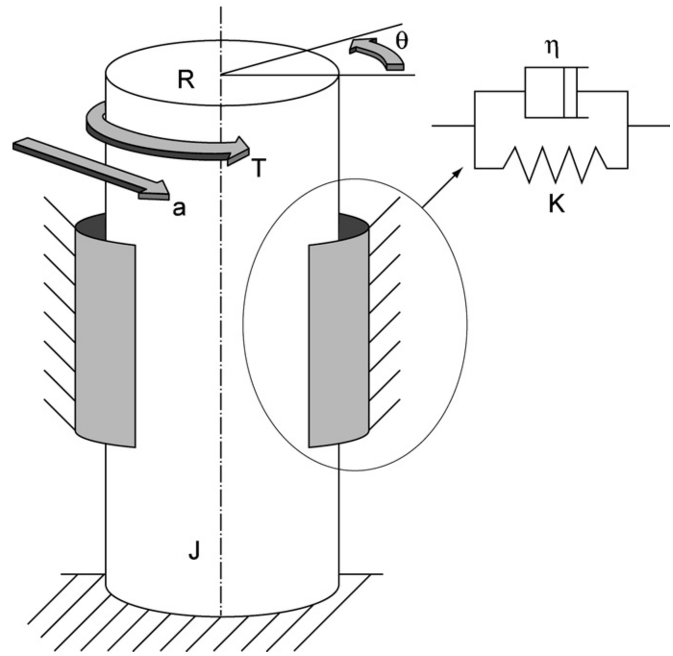

Fig. 1. Schematic of the simplified model of the stem–bone system used to illustrate the operating principle of the proposed device. The simplified model consists of a cylindrical shaft, representing the bone-prosthesis system, and a coupling that replicates the mechanical behaviour at the stem–femur interface. The interface between stem and bone was assumed to behave as a "spring–damper" complex, characterized by a coefficient of torsional viscosity (η), and a coefficient of torsional stiffness (K). The shaft is fully constrained at its distal extremity. The shaft is characterized by a polar moment of inertia (J). If a torque (T) is applied, its extremity rotates by an angle (θ). The associated tangential acceleration (a) can be measured by an accelerometer.

2. Simplified model of the system

A simplified model of the stem–bone system could help understanding the main issues related to the operating principle of the proposed device (Fig. 1). The simplified model consists of a cylinder, representing the bone-prosthesis system, and a coupling that replicates the mechanical behaviour at the stem–femur interface. As the bone during the test was clamped distally in a vice, in the simplified model a fixed joint is provided as constrained condition for the cylinder. Furthermore, the cylinder is characterized by a polar moment of inertia, J (Nms^2 rad^{-1}), with respect to the longitudinal axis of the femur, which remains constant (or nearly so). The interface between stem and bone was assumed to behave as a "spring-damper" complex, characterized by a coefficient of torsional viscosity, η (Nms rad^{-1}), and a coefficient of torsional stiffness, K (Nm rad^{-1}) (Fig. 1). If an external torsional excitation, T (Nm), is applied to the cylinder, the stem–bone system behaves as a second order system:

$$T = J\ddot{\theta} + \eta\dot{\theta} + k\theta \tag{1}$$

where θ is the torsional angular displacement. This torque is proportional to the inertial force generated by the excitation system.

The tangential acceleration measured by the accelerometer is:

$$a = R\ddot{\theta} \tag{2}$$

where R is the distance of the accelerometer from the longitudinal axis (Fig. 1).

The frequency response of the system:

$$G(j\omega) = \frac{a(j\omega)}{T(j\omega)} \tag{3}$$