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Ex vivo estimation of cementless acetabular cup stability using an impact hammer

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Obtaining primary stability of acetabular cup (AC) implants is one of the main objectives of press-fit procedures used for cementless hip arthroplasty. The aim of this study is to investigate whether the AC implant primary stability can be evaluated using the signals obtained with an impact hammer.

A hammer equipped with a force sensor was used to impact the AC implant in 20 bovine bone samples. For each sample, different stability conditions were obtained by changing the cavity diameter. For each configuration, the inserted AC implant was impacted four times with a maximum force comprised between 2500 and 4500 N. An indicator *I* was determined based on the partial impulse estimation and the pull-out force was measured.

The implant stability and the value of the indicator *I* reached a maximum value for an interference fit equal to 1 mm for 18 out of 20 samples. When pooling all samples and all configurations, the implant stability and *I* were significantly correlated ($R^2 = 0.83$).

The AC implant primary stability can be assessed through the analysis of the impact force signals obtained using an impact hammer. Based on these *ex vivo* results, a medical device could be developed to provide a decision support system to the orthopedic surgeons.

1. Introduction

Aseptic loosening remains one of the main cause of surgical failure for orthopaedic implants [1-3]. While several drawbacks have been associated with cemented implants [4-6], press-fit uncemented implants are increasingly used since this technique provide a good initial fixation [7-9] in healthy bone and constitute a reliable long term solution [10]. One of the most important objectives of press-fit surgical procedures employed to insert cementless acetabular cup (AC) implants is to obtain a good primary stability of the implant [11,12]. Micromotions at the bone implant interface should remain low after surgery to promote the osseointegration processes [13] and to prevent fibrous tissue formation at the implant interface, which may lead to the implant aseptic loosening [14]. However, the stress field amplitude in the periacetabular area should not exceed “some level” because it could lead to bone necrosis [15]. Therefore, obtaining a compromise in the AC implant primary stability is important for the long term implant surgical success.

Bone quality, implant properties and the surgeon’s technique (for example: reaming, implant choice, impact procedure…) are the most important parameters responsible for the AC implant primary stability. However, it remains difficult to quantify the AC implant stability per operatively because pull-out tests are destructive. The surgeons evaluate the implant stability empirically, for example by listening to the noise produced by the impact between the ancillary and the hammer [16] in order to adapt the number and amplitude of the impacts. A compromise must be found for the amplitude and the number of impacts in order to obtain an appropriate implant stability and to avoid per operative bone fractures [17].

Several destructive biomechanical stability tests such as pull-out [18], tangential [12,19], torsional [15,20] or edge loading tests [21,22] have been developed but remain restricted to *in vitro* studies. Medical imaging techniques such as MRI or X-ray cannot provide information on bone apposition around the implant because of diffraction phenomena caused by the presence of titanium [23,24].

Different approaches have been employed in the literature to evaluate both insertion and stability of orthopedic implants [16,25].

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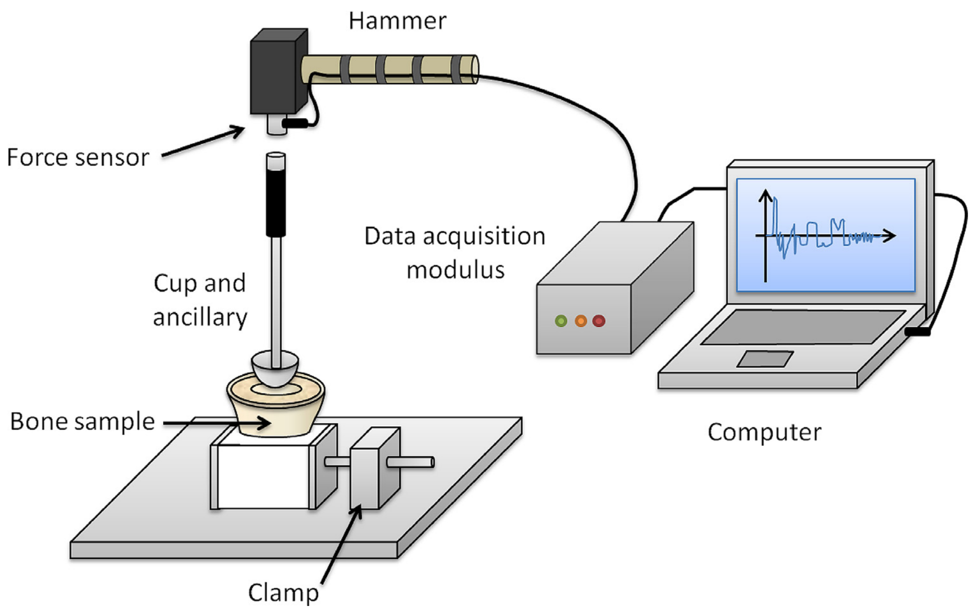

Fig. 1. Schematic representation of the experimental set-up used for impaction of the acetabular cup implant.

A device measuring the torsional rigidity of the hip stem implant [26,27] has been developed but remains difficult to be applied *in vivo* because of its reproducibility [28]. Vibrational approaches have been employed to assess the femoral stem implant loosening and its insertion endpoint [17,29-31] and more recently for the AC implant stability [32]. However, the aforementioned techniques remain difficult to be used in the operative room (OR). To the best of our knowledge, no device has been developed to estimate the AC implant stability non invasively in the OR.

Recently, our group has developed a method aiming at retrieving quantitative information on the AC stability from the analysis of the time variation of the force imposed to the AC implant during its impaction into bone tissue [33]. Bone abrasion due to the repetition of different implant insertions has been shown to influence the signals [34]. Moreover, a signal processing technique was developed and led to information correlated with the pull-out force obtained using mechanical testing. However, the aforementioned studies were performed using impacts produced with a dedicated device consisting in successive mass drops, leading to reproducible impacts properties, which prevents future potential use of the technique in the OR.

The aim of the present study is to investigate whether the AC primary stability can be related to the signal produced during non reproducible impaction procedure similar to the ones realized in the OR. To do so, a hammer was equipped with a force sensor to record the signal produced during the impacts and an indicator based on partial impulse estimation was compared with the tangential force necessary to pull the AC implant out of the bone cavity. Twenty bone samples were tested *ex vivo* with different drilling conditions.

2. Material and methods

2.1. Acetabular cup implant and bone specimen

Twenty bovine femurs were collected from the local butcher shop and kept frozen before the experiments. The bone samples were prepared similarly as in [34]. Briefly, the proximal epiphysis was cut and embedded in a fast hardening resin (polymer SmoothCast 300, Smooth-On, Easton, PA, USA) and maintained by a clamp to ensure its correct positioning (see Fig. 1). All bone samples were made of trabecular bone in the region of AC implant insertion. An AC implant of diameter 51 mm (Ceraver, Roissy, France) made of titanium alloy (TiAl6V4), with an external surface textured and roughened to promote bone osseointegration was used. It was screwed to the dedicated ancillary and used similarly as under clinical conditions. The AC implant manufacturer suggests 50 mm to be the optimum reaming diameter to secure press-fit insertion for this given AC implant.

2.2. Experimental set-up for impaction

A schematic representation of the experimental set-up is shown in Fig. 1. For each impact, the ancillary was held manually and impacted by the hammer ($m = 1.3$ kg). A dynamic piezoelectric force sensor (208C05, PCB Piezotronics, Depew, New York, USA) with a measurement range up to 22 kN in compression was screwed in the center of the hammer impacting face. A data acquisition module (NI 9234, National Instruments, Austin, TX, USA) with a sampling frequency of 51.2 kHz and a resolution of 24 bits was used to record the time variation of the force applied between the hammer and the ancillary. The data were transferred to a computer and recorded using a labview interface (National Instruments, Austin, TX, USA) for a duration of 2.5 ms.

2.3. Signal processing

For each impact, the variation of the force applied between the hammer and the ancillary was measured by the aforementioned device. A dedicated signal processing technique was developed in order to extract information from the radiofrequency (*rf*) signal. The beginning of the impact ($t = 0$) was determined by the time when the signal first exceeded a threshold of 30 N. Similarly as in [34], a quantitative indicator I referred as partial impulse was determined by:

$$I = \frac{1}{A_0} = \frac{1}{A_0 \cdot (t_2 - t_1)} \int_{t_1}^{t_2} A(t).dt \quad (1)$$

where $A(t)$ corresponds to the variation of the force as a function of time t, t_1=0.27 ms *and* t_2=0.82 ms. A_0 was arbitrarily set equal to 1200 N in order to obtain values of the indicator I comprised in the interval [0;1]. The choice of the values t_1 and t_2 will be discussed in the discussion section. Matlab (The Mathworks, Natick, MA, USA) was used to analyze the data.

2.4. Tangential stability mechanical tests

The AC implant stability was assessed with tangential stability mechanical testing, similarly as in [12,19,34]. As shown in Fig. 2, the