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Influence of soft tissue in the assessment of the primary fixation of acetabular cup implants using impact analyses☆,☆☆

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ABSTRACT

Background: The acetabular cup (AC) implant primary stability is an important determinant for the success of cementless hip surgery but it remains difficult to assess the AC implant fixation in the clinic. A method based on the analysis of the impact produced by an instrumented hammer on the ancillary has been developed by our group (Michel et al., 2016a). However, the soft tissue thickness present around the acetabulum may affect the impact response, which may hamper the robustness of the method. The aim of this study is to evaluate the influence of the soft tissue thickness (STT) on the acetabular cup implant primary fixation evaluation using impact analyses.
Methods: To do so, different AC implants were inserted in five bovine bone samples. For each sample, different stability conditions were obtained by changing the cavity diameter. For each configuration, the AC implant was impacted 25 times with 10 and 30 mm of soft tissues positioned underneath the sample. The averaged indicator I_m was determined based on the amplitude of the signal for each configuration and each STT and the pull-out force was measured.
Findings: The results show that the resonance frequency of the system increases when the value of the soft tissue thickness decreases. Moreover, an ANOVA analysis shows that there was no significant effect of the value of soft tissue thickness on the values of the indicator I_m ($F = 2.33$; p-value = 0.13).
Interpretation: This study shows that soft tissue thickness does not appear to alter the prediction of the acetabular cup implant primary fixation obtained using the impact analysis approach, opening the path towards future clinical trials.

1. Introduction

Press-fit surgical procedures are widely used in clinical practice to insert cementless acetabular cup (AC) implant into pelvic bone tissue (Adler et al., 1992; Perona et al., 1992). The aseptic loosening resulting from the partial or total absence of osseointegration remains one of the major causes of surgical failure (Hamilton et al., 2007; Kwong et al., 1994; Wilson et al., 2016) and depends on the primary stability of the AC implant. The AC implant primary fixation is an important determinant of the surgical success and it depends in turns on many factors such as the patient bone quality, the implant properties (*e.g.* surface treatment, implant geometry) and the surgical protocol. The choice of the implant size, the shape and diameter of the cavity reamed into bone tissue as well as the number and magnitude of the impacts used to insert the AC implant are important parameters determining the surgical outcome. The surgeons should find a compromise between a sufficient AC implant fixation in order to avoid micromotions at the bone implant interface (Mathieu et al., 2014), which may lead to fibrous tissue formation, and an excessive pre-stressed state of bone tissue (Michel et al., 2017) around the AC implant, which may lead to

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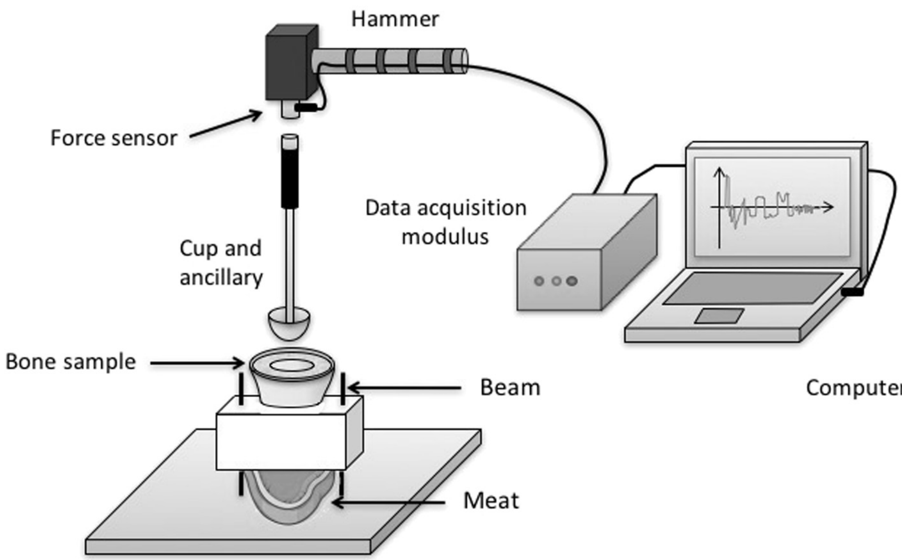

Fig. 1. Schematic representation of the experimental set-up used to determine the indicator *I*.

bone tissue necrosis. Moreover, while inserting the AC implant into bone tissue, the energy of the impacts should be sufficient high to eventually obtain a good primary stability but should not be too high to avoid acetabulum bone fracture (Pierce et al., 2015). In case of insufficient initial stability during surgery, the surgeon may cement and/or screw the implant.

Despite the importance of the AC implant primary fixation, it remains difficult to be assessed quantitatively in the operating room. Various biomechanical tests such as pull-out tests (Adler et al., 1992; Baleani et al., 2001; Clarke et al., 1991; Curtis et al., 1992; Markel et al., 2011; Saleh et al., 2008; Zietz et al., 2009) have been employed *in vitro* to evaluate the AC implant stability but such procedure cannot be used during the surgery. Vibrational techniques have been used to estimate the implant primary stability (Henys et al., 2015; Henys and Capek, 2016; Pastrav et al., 2008; Rowlands et al., 2008; Varini et al., 2008) but such an approach has not led so far to the development of a standardized method that can be employed intraoperatively. Classical medical imaging techniques such as magnetic resonance imaging or X-Ray microcomputed tomography are limited to provide quantitative information related to the stability of the AC implant because of diffraction phenomena around titanium. Moreover, such imaging techniques are still difficult to be used routinely during the surgery (Smith et al., 2011).

Orthopedic surgeons usually employ an empirical approach based on their experience and proprioception to estimate the AC implant primary stability, for instance by listening to the noise produced by the impact between the hammer and the ancillary (Sakai et al., 2011) in order to adapt their strategy and to obtain an appropriate implant stability while avoiding per operative bone fractures (Pastrav et al., 2009). When the AC implant is completely inserted into the host bone, the sound emitted by the impaction has been described as deeper (Sakai et al., 2011) than during the insertion phase. However, this method is not objective and there is no widely recognized standard to evaluate the implant stability.

A method has been developed by our group in order to obtain quantitative information on the AC insertion and fixation based on the analysis of the time variation of the force imposed to the ancillary supporting the AC implant during its impaction into bone tissue (Mathieu et al., 2013). This approach uses an instrumented hammer in order to record the time dependence of the force during a given impact. An indicator denoted *I*, referred hereafter as impact momentum, has been defined and tested with reproducible mass fall (Michel et al., 2014). A correlation between the AC primary stability and the impact momentum was evidenced (Michel et al., 2015) and the approach was extended in order to account for the use of an instrumented hammer (Michel et al., 2016). All the aforementioned studies were realized with bovine bone specimens fixed in a clamp in order to work under reproducible conditions as far as practicable. The same approach was then validated in cadavers, in a situation closer to that of the operating room (Michel et al., 2016). Moreover, finite element models have been used in order to understand the dynamic biomechanical phenomena occurring during the impacts (Michel et al., 2017).

The radiofrequency (rf) signals corresponding to the variation of the force applied between the hammer and the ancillary as a function of time were qualitatively different when the experiments were carried out with a bone sample clamped in a rigid frame (Michel et al., 2016) and with cadavers (Michel et al., 2016), which shows the influence of the environment (such as for example the presence of soft tissues) on the measurements. Despite the aforementioned difference, the influence of the presence of soft tissues on the results of the method remains unexplored because it is difficult to determine quantitatively the thickness of soft tissues when working with cadavers. It is important to determine the influence of soft tissues on the measurements since it could jeopardize future measurements that could be carried out in the operating room to determine the AC implant stability when working with patients with varying body mass index for instance.

The aim of this paper is to examine the effects of soft tissue thickness (STT) on the impact momentum and estimate the influence of STT on the AC primary stability evaluation using impact analyses. To do so, three bone samples were considered *in vitro* with several drilling and AC sizes conditions and the value of STT was varied for all 48 different configurations considered.

2. Methods

2.1. Acetabular cup implant, bone samples and soft tissues

Five bovine femurs were prepared similarly to what was done in the protocol described in Michel et al. (2016). Briefly, each bone sample was embedded in a fast hardening resin (polymer SmoothCast 300, Smooth-On, Easton, PA, USA) for better handling and positioning, as shown in Fig. 1. All bone samples were made of trabecular bone in the region of the AC implant insertion.

Two slices of turkey breast were cut in order to obtain a thickness of 10 mm of soft tissues when one slice only was positioned underneath the sample and of 30 mm when both slices were employed. As