ISB 2013 BRAZIL
XXIV CONGRESS OF THE INTERNATIONAL SOCIETY OF BIOMECHANICS
XV BRAZILIAN CONGRESS OF BIOMECHANICS

MEASUREMENT OF THE VARIATIONS OF IMPACT DURATIONS TO MONITOR THE PRESS-FIT INSERTION OF THE ACETABULAR CUP IMPLANT

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SUMMARY
Cementless hip implants are stabilized mechanically in host bone during surgery using a press-fitting procedure. Primary mechanical stability of these implants is critical for the long-term outcome of the operation. A compromise must be found between excessive press fitting, causing intra operative fractures, and insufficient press fitting, leading to aseptic loosening of the implant. However, current techniques used for the assessment of primary stability remain empirical, and based on the surgeon's experience. The aim of the present study was to develop and validate a prototype device based on the measurement of impact duration during the *in vitro* press-fit insertion of an acetabular cup implant in bovine bone samples. A test bench was built to impose impacts with controlled and reproducible force amplitudes. The force induced by the impacts was measured using a piezoelectric sensor and a post processing technique enabled to determine the duration of each impact. In parallel, an optical camera mounted on the frame of the test bench was used to quantify the penetration of the acetabular cup implant in host bone. The results show similar trends of variations for impact duration and penetration as a function of impact number. Impact duration first decreases and reaches a stationary value after an average number of four impacts. The decrease of impact duration may be explained by the progressive increase of bone-implant contact stiffness during press-fitting. This feasibility study provides promising results for intra operative monitoring of the insertion of the acetabular cup implant.

INTRODUCTION
During total hip replacement (THR) surgery, a press-fitting procedure is used for the mechanical stabilization of cementless hip implants in host bone [1]. Primary mechanical stability and correct positioning of the cup in the acetabulum during surgery is still a practical issue [2]. In particular, the level of press-fitting during cup insertion is critical. Excessive press-fit of the cup can cause intra-operative fractures [3]. Conversely, if the surgeon does not insert properly the cup, risks of aseptic loosening of the prosthesis increase [4,5]. Currently, most orthopedic surgeons use empirical approaches based on their experience and on proprioception to adapt and optimize their surgical strategy. However, the use of such empirical approaches lacks accuracy [6]. The aim of the present study is to investigate the variations of impact duration in order to monitor the insertion of the acetabular cup (AC) implant.

METHODS
An AC implant (Ceraver, Roissy, France) was used in this study. The diameter of the implant (50 mm) corresponds to the average size used for hip arthroplasty. For the impaction, the cup is screwed to a threaded cup impactor. A collection of eleven cadaveric bovine femurs was obtained at the local butcher shop. Two bone samples were prepared from each femur, leading a total of 22 bone samples. To do so, two sections were realized in the distal and proximal parts of each femur using a handsaw in planes perpendicular to the bone axis (see Fig. 1(a)), in order to consider bone samples composed of trabecular bone (see Fig 1(b)). Then, the base of the diaphysis side of each sample was embedded using a fast hardening resin in a cube-shaped mould (see Fig. 1(c)) to ensure a rigid positioning of the samples in the clamp of the device. Following the technical guidelines provided by the implant manufacturer, a dedicated 50 mm diameter reamer was used to prepare the insertion cavity.

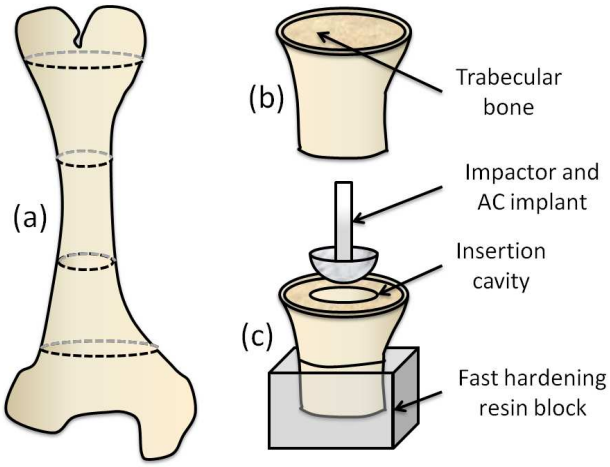

Figure 1: Preparation of bone samples.

Bone sample is held on the experimental device by a clamp. A testing bench is used to impose impacts with controlled and reproducible force amplitude (around 2 kN, in agreement with ranges observed in the clinic [7]). The force

induced by the impacts on the head of the cup impactor is recorded using a piezoelectric sensor (PCB Piezotronics, Depew, NY, USA). The radiofrequency (*rf)* signal recording duration is equal to 10 ms (sampling frequency equal to 25.6 kHz) to cover the duration of the return to stationary values after the impact. The duration of each impact (referred as *I* hereafter) is derived from each recorded signal as the time interval during which one the amplitude of the *rf* signal is superior to a threshold value of 30 N. Changing the value of this threshold between 15 and 100 N does not modify significantly the results found herein. For each bone sample, the same insertion procedure was followed. First, the bone sample is maintained by the clamp on the testing bench. Second, the AC implant is screwed to the cup impactor and positioned in contact with the insertion cavity of the bone sample. Third, the cup impactor is manually hold while 10 successive impacts are applied for the insertion.

RESULTS AND DISCUSSION

The same general behavior of the function *I(n)* (*n* corresponds to impact number) is obtained for the 22 bone samples: *I(n)* first decreases and reaches a stationary value. Figure 2(a) represents the function *I(n)* for one particular bone sample. The variations of impact duration may be due to variations of the bone–implant interface properties in terms of rigidity. The initial decrease of impact duration can be explained by the insertion of the AC in the bone cavity, which induces an increase of the contact area of the bone–implant interface and thus of the contact rigidity. After *N* impacts, the contact duration is constant, which may be explained by the fact that the bone-implant interface properties do not vary significantly because the AC implant is completely inserted in the bone cavity.

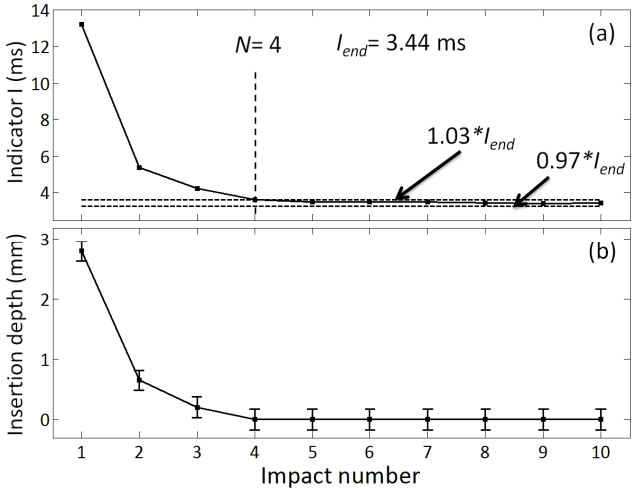

Figure 2: For one particular bone sample: (a) indicator *I* and (b) insertion depth as a function of impact number.

In order to confirm the trend of variation of *I(n)*, we defined a convergence speed *N*, corresponding to the value of *n* from which *I* lies in the range I_{end} +/-3%, where I_{end} refers to the average value of *I* for the three last impacts. Changing the range width coefficient between 2 and 4 % does not affect the results. Table 1 summarizes the mean, standard deviation, minimum and maximum values of *N* and I_{end}.

In order to verify the physical explanation given above, a simple optical system was used to monitor the displacement of the AC relatively to the bone sample after each impact. A camera was mounted on the frame of the device to monitor the insertion depth induced by each impact. Figure 2(b) shows the results obtained for the variation of the implant insertion depth as a function of impact number for one particular bone sample. The behavior obtained for the implant insertion depth is qualitatively similar to the behavior of the indicator *I* shown in Fig. 2(a), which constitutes a validation of the approach.

Table 1: Average, standard deviation, minimum and maximum values of *N* and I_{end}.

	Mean (SD)	**Range**
N	4.1 (1.7)	2-7
I_{end} **(ms)**	4.2 (0.7)	2.5-5.4

This study has several limitations. First, a testing bench was used to produce reproducible impacts under controlled conditions, while surgeons may adapt the impact energy according to their perception. Second, due to ethical points of view, the authors decided not to conduct a study using human bone specimens before having achieved the proof of concept of the device in the framework of the present feasibility study. Therefore, experiments using human bone tissue, *in vivo* animal experiments as well as clinical studies must be carried out in order to validate the method in more realistic situations. However, similar results should be achieved with higher (respectively lower) values of *N* when using bone samples with higher (respectively lower) bone mineral density. Third, the present experimental device allows to determine when the conditions of contact between the AC implant and bone tissue stop evolving as a function of the impact number *via* the measurement of impact duration. However, the relationship between impact duration and primary stability of the implant remains unknown and further work is required in this direction.

CONCLUSIONS

If used in a clinical situation, the present method could be promising because it could allow the surgeon to determine when to stop impacting the AC and when the bone-implant interface properties do not vary during further impaction, thus avoiding possible intra-operative bone fracture.

ACKNOWLEDGEMENTS

This work has been supported by French National Research Agency (ANR) through EMERGENCE program (project WaveImplant n°ANR-11-EMMA-039), by the Centre Francilien de l'Innovation and by OSEO through the Aima Laboratoire funding.

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