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ABSTRACT

The success of cementless hip arthroplasty depends on the primary stability of the femoral stem (FS). It remains difficult to assess the optimal number of impacts to guarantee the FS stability while avoiding bone fracture. The aim of this study is to validate a method using a hammer instrumented with a force sensor to monitor the insertion of the FS in bovine femoral samples. Cementless FS of different sizes were impacted into five bovine femur samples, leading to 99 configurations. Three methods were used to quantify the insertion endpoint of the FS: the impact hammer, video motion tracking and the surgeon proprioception. For each configuration, the number of impacts performed by the surgeon until he felt a correct insertion was noted N_{surg}. The insertion depth E was measured through video motion tracking, and the impact number N_{vid} corresponding to the end of the insertion was estimated. Two indicators, noted I and D, were determined from the analysis of the time variation of the force, and the impact number N_d corresponding to a threshold reached in D variation was estimated. The pullout force of the FS was significantly correlated with I (R^2=0.81). The values of N_{surg}, N_{vid} and N_d were similar for all configurations. The results validate the use of the impact hammer to assess the primary stability of the FS and the moment when the surgeon should stop the impaction procedure for an optimal insertion, which could lead to the development of a decision support system.

1. INTRODUCTION

Cementless hip arthroplasty aims at replacing defective hip joints. The femoral stem (FS) primary stability is an important factor of surgical success. Nevertheless, it remains difficult for the surgeon to assess the optimal number of impacts to guarantee the FS stability while avoiding bone fracture.

A few quantitative methods aiming at assessing the insertion of the FS into the host bone have been reported in the literature. One of them consists in using vibrational analysis to follow the FS insertion[1–3]. Such approach has been validated in vitro and in vivo [4] but it remains difficult to implement because of the device is in contact with bone tissue. Another diagnostic method based on acoustic analysis has been developed to monitor the FS insertion by studying the resulting sound produced by the hammer blows on the ancillary during the implant insertion process (5,6). This method has the advantage to be non-contact based but it is influenced by the environmental noise and the operational variability. Further, a study was performed to evaluate modal features as potential fixation predictors to assess cementless implant fixation [7], [8]. An *in vitro* study has been made on artificial bone but more work is needed to validate the method in a situation closer the operative room [9].

Another diagnostic method based on the analysis of the variation of the force applied between an instrumented hammer and the ancillary during impacts was developed by our group [10–12]. This method was first validated *in vitro* [13], [14] and on anatomical subjects for the acetabular cup implant (ACI) primary stability estimation [15]. More recently, the same technique using an instrumented hammer was applied to follow the FS insertion in bone mimicking phantoms [16] and with anatomical subjects [17].

The aim of the present study is to validate this method to FS insertion in bovine femoral samples. The signal processing technique aims at quantifying the insertion endpoint of the FS using three methods: i) the instrumented hammer, ii) video motion tracking and iii) the surgeon proprioception. To do so, the instrumented hammer was used to insert different sizes of FS in five bovine femurs. A system using optical markers was used to follow the FS insertion with video motion tracking (VMT) and the results were compared to the FS insertion endpoint estimated by the surgeon using his proprioception.

2. MATERIALS AND METHODS

2.1 Implants and specimens

Cementless femoral stems made of titanium alloy (TiAl6Al4V) and coated by hydroxyapatite (CERAFIT R-MIS, Ceraver, Roissy, France) and their corresponding rasps were used. Seven sizes were tested, from size 7 to 13. Five bovine femurs were collected and were prepared similarly to [16]. A home-made ancillary was screwed into the FS so as to obtain a rigid bilateral fixation between the two parts.

2.2 Experimental set-up and insertion protocol

The femoral stem was inserted in the femur with a 1.3 kg hammer equipped with a dynamic piezoelectric force sensor (208C05, PCB Piezoelectronics, Depew, New York, USA) screwed in the center of the impacting face as in [16], [17]. The variation of the force *s(t)* applied to the ancillary was recorded by the force sensor. Video tracking was carried out to follow the insertion of the FS into the femoral shaft during the impaction procedure. The relative displacement of the FS compared to the bone was calculated with the software Tracker (Cabrillo College, Aptos, CA, USA). A schematic representation of the experimental set-up is shown in Fig. 1.

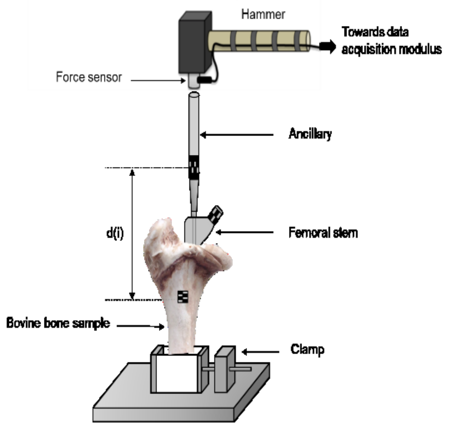

Figure 1 : Schematic representation of the experimental set-up.

Two series of experiments were performed by a trained orthopedic surgeon. In the first series (similar to what was done previously in [16]) all FS were inserted in a cavity that was reamed with the size of the rasp corresponding to the FS, while in the second series which aimed at obtaining relatively unstable configurations, the size of the FS was smaller than the rasp size used to ream the cavity. Four bovine samples were considered for the first series, while only one bovine sample was used for the second series. All FS were inserted in a cavity created in each bovine bone with the smallest available rasp (size n=7). The impaction procedure was performed: the FS - ancillary system was impacted with the instrumented hammer until the surgeon considered that the FS was stable. Then, 12 additional impacts were carried out in order to assess whether the implant could be further inserted into the femoral shaft, and to determine the average value of the indicator *I* obtained for stable conditions of the FS. The aforementioned procedure was repeated four times with the same implant as far as i) the sample was not fractured and ii) the surgeons felt that it was possible to obtain a good FS stability. Then, the surgeon checked if the femur was fractured. If so, the tests were stopped for the sample. If not, a bigger size of rasp and the corresponding FS was used. Eventually, the implant was pulled out axially and the pullout force *F* was measured.

2.3 Signal processing and video motion tracking

A dedicated signal processing method was developed to analyze the force signal *s(t)* as illustrated in Fig. 2. Two specific indicators were employed. First, a specific indicator noted *D* and given in ms based on the time difference between the first and second local maxima of the force signal was calculated for each impact as follow :

$$D = f_2(s) - f_1(s) \quad (1)$$

The second indicator, noted *I* and given in kN, corresponds to the impact momentum, and was defined similarly to our previous works [16]:

$$I = \frac{1}{t_2 - t_1} \int_{f1(s)+t1}^{f2(s)+t2} s(t)dt \quad (2)$$

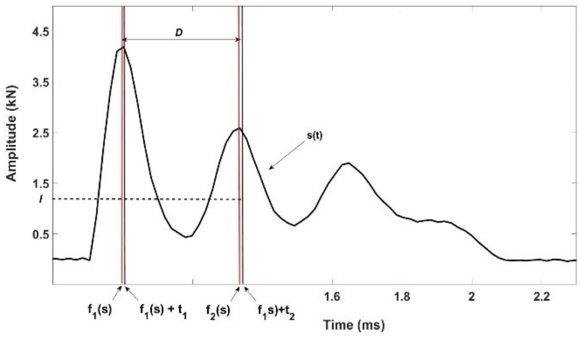

Figure 2 Illustration of a signal *s(t)* corresponding to the variation of the force

The third indicator, noted *E* and given in cm based on VMT was defined by the relative motion of the FS compared to the femoral bone in relation to the initial position following:

$$E(i) = d(0) - d(i) \quad (3)$$

2.4 Post processing and data analysis

Three different analyses were performed for each insertion procedure in order to estimate the required number of impacts to reach the insertion endpoint, corresponding to the end of the migration phase of the FS into the femur. The first method consists in following a parameter *Nd* defined as the number of the first impact for which the indicator *D* respects :

$$D(i) < D_{th} \quad (4)$$

where D_{th} is a threshold defined empirically to 0.47 ms.

The second method consists in defining a parameter N_{vid} defined as the lowest impact number for which the indicator *E* respects:

$$E\ (Nvid) \geq\ Em - \delta \times Esd \quad (5)$$

where E_m and E_{sd} are respectively the average and the standard deviation of the values of *E* for the last ten impacts and δ is a parameter empirically chosen equal to 7.

The third method is based on the surgeon proprioception as in clinic: when the surgeon felt that the insertion endpoint of the FS was reached, the parameter N_{surg} was noted. In order to determine the accuracy of the three methods presented in 2.4, it was necessary to quantify the difference obtained between the different parameters values N_d, N_{vid}, and N_{surg}. To do so, we defined three parameters as follow:

$$M_d = N_d - N_{surg} \quad (6)$$

$$M_{vid} = N_{vid} - N_{surg} \quad (7)$$

$$M_c = N_{vid} - N_d \quad (8)$$

3. RESULTS

A total of 99 configurations were tested. Tab. 1 shows an example of the number of impaction procedures considered for each bovine bone sample for the first series of experiments were stable configurations were considered.

Implant size	Sample n°1	Sample n°2	Sample n°3	Sample n°4	Total
7	4	4	4	4	16
8	3	4	3	4	14
9	4	4	4	4	16
10	4	4	X	4	12
11	1	X	X	4	5
12	X	X	X	4	4
13	X	X	X	4	4
Total	16	16	11	28	71

Table 1 Number of configurations set up considered in the first series of experiments

Figure 3 shows the variation of the two parameters D and E as a function of the impact number i obtained for the configuration sample#4, implant size 9 and test #3. The horizontal back dashed line represents a threshold penetration for indicator E and the horizontal gray dashed line represents the threshold D_{th} = 0.47 ms. The vertical dashed lines represent the different parameters values, N_d, N_{vid}, and N_{surg} corresponding to three values of insertion endpoint obtained for each insertion procedure using the instrumented hammer, the video motion tracking and the surgeon proprioception, respectively.

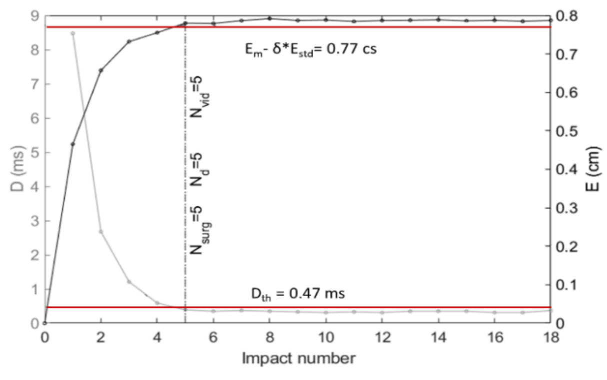

Figure 3 Variation of D (gray line) and E (black line) as a function of the impact number for sample#4, implant size 9 and test #3

Figure 4 represents the distribution of the values of M_d, M_{vid} and M_c, corresponding to the difference between the different methods developed for the estimation of the FS insertion The average and standard deviation values of M_d, M_{vid}, and M_c obtained for the 99

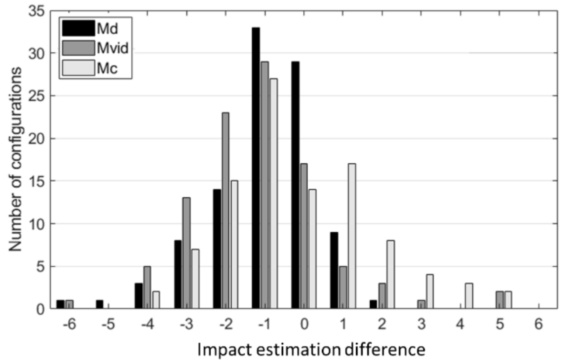

Figure 3 Distribution of the values obtained for M_d, M_{vid}, and M_c

show that the three indicators are in the same range of variation.

Finally, a significant correlation is obtained between I_m and F and the determination coefficient R^2 is equal to 0.81. The error bars correspond to the standard deviation I_{sd} obtained for each configuration.

4. DISCUSSION

The decrease of D as a function of the number of impacts can be explained to the increase of the bone-implant contact ratio during the insertion of the FS, resulting in an increase of the stiffness of the bone-implant system that may in turn explain the increase of its resonance frequency. Note that other authors also found a similar evolution of the resonance frequency during the insertion, with a comparable approach, using force signal tracking.

Figure 4 shows a good agreement between the three methods developed to assess the number of impacts required to reach the FS insertion endpoint. Again, these results are consistent with the previous in vitro results [16]. However, there remain some discrepancies between the methods. The average value of M_c, equal to −0.19, shows a good agreement between the results obtained with VMT (N_{vid}) and the instrumented hammer (N_d). However, the average values of M_{vid} (−1.17) and M_c (−0.98) indicate that the surgeon evaluation of the insertion endpoint is assessed in average one impact after the results obtained with VMT and the instrumented hammer. Several factors can explain these differences. First, the surgeon proprioception is mainly qualitative and depends on the surgeon's tactile feelings, hearing and vision. Second, errors may occur using VMT due to i) changes of angular position, ii) possible macroscopic 3D movements and plastic bone deformation, iii) errors based of the image processing, such as the precision of markers tracking, which can be observed in the fluctuation of E indicator even after reaching stability (Fig. 3).

This study presents several limitations. First, the biomechanical properties of the pelvic bone and of bovine femoral bone are different. Second, the multiple use of the bovine specimen is not representative of clinical situations and could lead to changes of bone properties. Third, our study only focused on one type of FS (CERAFIT R-MIS) and ancillary and further studies should be performed to evaluate the method for implants manufactured by others.

5. CONCLUSION

This study is the first *ex vivo* validation of the use of an instrumented hammer to assess the insertion endpoint of the FS as well as its primary stability. The results are in agreement with a previous in vitro study. The time variation analysis of the force applied by the hammer on the ancillary during the impacts allows the assessment of the number of impacts required for obtaining a satisfactory press-fit condition into the host femoral bone. Further work will focus on the adaptation of this method to clinical conditions, in order to develop a medical device that could help the surgeons estimating the FS stability, with minimal changes of the surgical protocol. The reader is referred to [18] for further details on the present study.

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