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Contributions

Each author has materially participated in the research and the article preparation.

- The conception and design of the study: Guillaume Haiat and Antoine Tijou
- Acquisition and analysis of data: Romain Bosc and Antoine Tijou
- Interpretation of data: Romain Bosc, Charles-Henri Flouzat Lachaniette and Guillaume Haiat
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Abstract

Background

The acetabular cup implant primary stability is an important determinant for the long-term success of cementless hip surgery. However, it remains difficult to assess the implant fixation due to the complex nature of the bone-implant interface. A method based on the analysis of the impact produced by an instrumented hammer on the ancillary has been developed by our group (1). The aim of this study is to evaluate the influence of the soft tissue thickness on the acetabular cup implant primary fixation evaluation using impact analyses.

Methods

To do so, different implants were inserted in three bovine bone samples. For each sample, different stability conditions were obtained by changing the cavity diameter. For each configuration, the acetabular cup 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 soft tissue thickness. The pull-out force was measured using a pull-out test.

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=9.45; p-value=0.64).

Interpretation

This study shows that soft tissue thickness does not alter the prediction of the acetabular cup implant primary fixation obtained using the impact analysis approach, opening the path towards future clinical trials.

Keywords: Biomechanics; Acetabular cup implant; hip prosthesis; bone; impact; implant stability.

Introduction

Press-fit surgical procedures are widely used in clinical practice to insert cementless acetabular cup (AC) implant into pelvic bone tissue (2,3). The aseptic loosening resulting from the partial or total absence of osseointegration remains one of the major causes of surgical failure (4–6) 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 (7), which may lead to fibrous tissue formation, and an excessive pre-stressed state of bone tissue (8) around the AC implant, which may lead to 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 important to avoid acetabulum bone fracture (9). In case of insufficient initial stability during surgery, the surgeon may cement and/or screw the implant to help to osseointegration.

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 (3,10–15) 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 (16–20) 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 (21).

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 (22) in order to adapt their strategy and to obtain an appropriate implant stability while avoiding per operative bone fractures (23).

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 (24). This approach uses an instrumented hammer in order to record the time dependence of the force during a given impact. An indicator, referred hereafter as impact momentum, has been defined and tested with reproducible mass fall (25). A correlation between the AC primary stability and the impact momentum was evidenced (26) and the approach was extended in order to account for the use of an instrumented hammer (1). 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 (27). Moreover, finite element models have been used in order to understand the dynamic biomechanical phenomena occurring during the impacts (8).

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 on a rigid frame (1) and with cadavers (27), 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.

Methods

1. Acetabular cup implant, bone samples and soft tissues

Three bovine femurs were prepared similarly to what was done in the protocol described in Michel et al. (1). 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 schematized in Fig. 1, two beams located around the bone sample allow a translation along the vertical direction without friction (which was obtained through lubrication) of the bone sample during the impacts, similarly as in the clinical situation.

Two AC implants of diameter 52 and 54 mm (Pinnacle by Depuy, a Johnson & Johnson company, Warsaw, IN, USA) were employed. The AC implants were made of titanium alloy and coated with DUOFIX®, a combination of porous coating and highly amorphous hydroxyapatite. The AC cups were screwed to the dedicated ancillary and used similarly as in the operating room by an experienced surgeon.

2. Hammer impaction procedure

An impaction procedure corresponds to 25 successive impacts with the constraint that the maximum amplitude of the force should be comprised between 2500 and 4500N, which corresponds to a relatively weak impact compared to typical forces recorded during impacts employed to insert the AC implant (typically around 15 kN (28)). 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 for each impact. The data were transferred to a computer and recorded using a LabVIEW interface (National Instruments, Austin, TX, USA) for a duration of 10 ms.

3. Signal processing

A dedicated signal processing technique was developed in order to extract information from the *rf* signal corresponding to the time variation of the force applied between the hammer and the ancillary. Similarly as in the *in vitro* study of Michel el al. (1), a quantitative indicator *I* referred to as impact momentum was determined for each impact following:

$$I = \frac{1}{\mathrm{A0.(t2-t1)}} \int_{\mathrm{t1}}^{\mathrm{t2}} \mathrm{A(t).dt}$$

where A(t) is the variation of the force applied between the hammer and the ancillary as a function of time, t_1=0.31 ms and t_2=0.63 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, t_2 and A_0 will be discussed in section 4. Matlab (The Mathworks, Natick, MA, USA) was used to analyze the data.

4. Tangential stability mechanical test

The AC implant fixation was assessed using a tangential stability mechanical test, similarly as in the previous studies of Michel et al. (1,26). The top end of the ancillary underwent a gradually increasing force (step of around 8 N.s-1) applied perpendicularly to its axis, with the bone sample rigidly clamped. The maximum value *F* of the force necessary to extract the AC implant from the bone sample was determined using a numerical dynamometer (DFX2- 050-NIST, AMETEK, Elancourt, FRANCE).

5. Experimental protocol

Figure 2 summarizes the experimental protocol carried out by a trained surgeon, which aims at investigating different configurations with various values of AC implant stability and to compare the results obtained with 10 mm and 30 mm of STT.

A 49 mm diameter cavity was initially drilled in each bone sample using the reamer recommended by the implant manufacturer. A 52 mm diameter implant was inserted into bone tissue, leading to an interference diameter fit equal to three millimeters. The AC implant was inserted into bone tissue by several impactions until the surgeon considered that the implant could not be further inserted without significantly damaging the surrounding bone tissue. The hammer impaction procedure described in subsection II.2 and corresponding to 25 impacts with relatively low energy was then carried out with one slice of soft tissue positioned under the bone sample (STT=10 mm) and then with two slices of soft tissue (STT= 30 mm). For each impact, the value of the indicator *I* was computed as described in section 2.3. For each value of STT, the average value of the indicator *I* obtained for the 25 impacts was determined and noted I_m. Then, the tangential stability test described in subsection 2.4 was carried out to determine the corresponding AC implant stability noted F.

The procedure described above including i) the implant insertion, ii) the impaction procedure (25 impacts) with the determination of the averaged values I_m of the indicator I for the two values of STT and iii) the tangential stability test was then repeated three times with the same 52 mm diameter implant, leading to a total number of four values for the pull-out force and of eight values for I_m.

The cavity was then enlarged from a diameter of 49 mm to a value of 51 mm using a dedicated reamer and the same procedure as the one described above was carried out with a 52 mm diameter implant to obtain an interference fit of 1 mm leading to another set of four values for the pull-out force and of eight values of I_m.

The same procedure was again reproduced without modifying the cavity using a 54 mm diameter AC implant. Eventually, a last round of experiments was realized using the same 54 mm diameter implant after having increased the size of the cavity up to a diameter of 53 mm using the dedicated burr.

The same protocol described above was carried out for the three bovine femoral bone samples, leading to a total number of 48 values of pull-out forces and 96 values of I_m which corresponds to three bone samples, three cavity diameters (49, 51 and 53 mm), two AC implant diameters and four measurements for each configurations (see Fig. 2). We verified that no fracture was present in the bone samples at all times.

6. Statistical analyses

The relationship between I_m and F was analyzed with linear regression analyses for each value of STT. An N-way analysis of variance and a multiple comparison test using the Tukey's Honestly Significant Difference method were performed to study the effect of the STT on the value of the averaged indicator I_m.

Results

Figure 3 shows different averaged rf signals corresponding to the force applied between the hammer and the ancillary measured after the AC implant insertion (*i.e.* during the impaction procedure) for a given bone sample under various conditions. The black (respectively grey) lines correspond to a STT equal to 10 mm (respectively 30 mm). The solid lines shows the results obtained for an AC implant diameter equal to 52 mm and to a cavity diameter equal to 49 mm, which corresponds to an implant pull-out force equal to 31 N. The dashed (respectively dotted) lines shows the results obtained for an AC implant diameter equal to 52 mm (respectively 54 mm**)** and to a cavity diameter equal to 51 mm, which correspond to an implant pull out force equal to 63.4 N (respectively 72.8 N).

The results show that the rf signal exhibits i) a first maximum occurring just after the impact (around t=0.25 ms), ii) a second maximum between 0.6 and 1 ms and iii) a third maximum between 3.0 and 5.5 ms. As shown in Fig. 3, the different rf signals around the first maxima (~0.25 ms) are qualitatively similar for all data obtained. However, the rf signals are significantly different around the second (0.6 - 1 ms) and the third maxima (3 - 5.5 ms). More specifically, the times of the second and third maxima are shown to increase when the AC implant stability increases, which is consistent with the results obtained in previous studies (1,25,26).

As shown in Fig 3, the time of the second maximum is slightly higher for configurations with STT equal to 30 mm compared to 10 mm. Similar results were obtained for most configurations (39 configurations out of 48). Figure 3 also shows that the time of the third maximum is always significantly higher for the results obtained with 30 mm of STT compared to the results obtained with 10 mm of STT. Similar results are obtained for almost all configurations (47 out of 48).

Figure 4 shows the results obtained when all data obtained from all bone samples and all configurations are pooled together. The circles (respectively the stars) show the data corresponding to a value of STT equal to 10 mm (respectively 30 mm). A significant correlation is obtained between the averaged values I_m of the indicator I and the tangential stability F for the configuration with 10 mm of STT (R^2=0.77, $p=2.6\ 10^{-16}$). The same result was obtained for STT values equal to 30 mm (R^2 = 0.78, $p= 4.3\ 10^{-17}$). Note that the two linear regression lines corresponding to the two values of STT are almost confounded.

The average and standard deviation values of the indicator I_m obtained for all samples and all configurations for a value of STT equal to 10 mm (respectively 30 mm) was equal to 0.482±0.186 (respectively 0.465±0.186). An ANOVA analysis shows that there was no significant effect of the value of STT on the values of the indicator I_m (F=9.45; p-value=0.64). This result is confirmed by the multiple comparison tests (F=0.22; p=0.64).

Figure 5 shows the different values of the indicator *I* (black segments) and of the pull-out force (grey segments) for each values of implant and cavity diameters. The averaged and standard deviation values of *I* are shown as a function of the STT (10 and 30 mm). The results shown in Fig. 5 correspond to average values obtained for 4 sets of experiments (see Fig. 2) with different AC implant insertion conditions, which may explain the relatively important reproducibility obtained. As shown in the Fig. 5, the results are not significantly different when comparing the two values of STT for each configuration. Moreover, the highest values of pull-out force and of the indicator *I* are obtained when the interference fit is equal to 1 mm, which correspond to an AC implant (respectively cavity) diameter equal to 52 mm (respectively 51 mm) and to an AC implant (respectively cavity) diameter equal to 54 mm (respectively 53 mm).

Discussion

The originality of the approach developed in this study is to provide in real time a way to estimate the AC implant primary fixation using an impact hammer in a non-invasive manner. Information provided by such impact hammer could be used in the future in a patient specific manner as a decision support system to determine whether the surgeons should modify the bone cavity, use screws or whether cementation is necessary. Moreover, the surgical protocol is not modified by the procedure.

In the literature, others techniques have been described to monitor the implants stability. Biomechanical techniques have been used to monitor dental implant primary stability (29,30) and bone integration (31) as well as the hip stem insertion endpoint (16) and primary stability (23,32). Vibrationnal technique have been tested to evaluate the AC implant primary stability (18). However, to the best of our knowledge, no accurate medical device can be used so far during surgery to assess the AC implant primary stability. Previous papers by our group have shown that the impact hammer could be employed with AC implant inserted in clamped bone samples (1) as well as in cadavers (27). The originality of the present study is to consider the effect of the STT on the indicator *I*. The results show that no significant effect of the STT on the indicator *I* has been obtained, which indicates that the measurements can be realized with any values of STT in the tested range (10-30 mm).

Although the correlation between the indicator *I* and the AC implant fixation has been shown not to depend on the STT, the rf signal itself depends on the STT, as shown in Fig. 3. In particular, the time of second maximum (between 0.6 and 1.0 ms in Fig. 3) of the rf signal is more often lower for 1 cm of STT compared to the results obtained with 3 cm of STT. The results are even more significant when considering the third maximum of the rf signal (between 3 and 5.5 ms in Fig. 3) because almost all configurations (except one) are concerned and because the time difference between the third maxima obtained with STT values equal to 10 and 30 mm is higher compared to the results obtained with the second maximum (see Fig. 3). The qualitative variation of the rf signals obtained with different STT may be explained by the fact that adding soft tissue to the tested system induces a decrease of its overall rigidity, thus resulting in a decrease of its resonance frequency. It has been shown experimentally (27), analytically (25), and numerically (8), that the frequency of the rf signal is determined by the rigidity of the system composed by the bone sample, the implant and the ancillary. Therefore, an increase of rigidity (corresponding to a decrease of STT) induces an increase of the resonance frequency and hence a decrease of the time of the different maxima of the rf signal, which is more important for higher order maxima. Despite this dependence of the rf signal to soft tissue thickness, the indicator *I* is shown to weakly depend on the soft tissue thickness, which can be explained by the fact that the indicator is determined for relatively weak values of the time.

Different pull-out tests have been employed in the literature to assess the AC implant primary stability (33). We have chosen a tangential stability test because of its simplicity and because it has been already used in previous papers (5,34,35). In this study, the highest values of the pull-out force were obtained for an interference fit equal to 1 mm, which is consistent with previous studies (5) and with the recommendation of the implant manufacturer (8,36). A value of 1 mm for the interference fit is known to provide an adequate primary stability conditions of the AC implant (5,36). The effects of the interference fit on the AC insertion parameters have already been studied (8) and authors have concluded that a compromise has to be found between a sufficiently high value of the interference fit to ensure the AC stability and a sufficiently low value to avoid too important polar gaps and heterogeneous distribution of stresses within bone tissue (37,38).

Several parameters were chosen empirically in this study. First, the range of the maximum force (2500-4500 N) corresponding to the impacts used to determine the indicator, which is similar to what was done in (1), was chosen to obtain a compromise between a sufficiently low energy in order to avoid modifications of the implant insertion and/or of the bone-implant interface properties and a sufficiently high energy to obtain accurate measurement of the second and third maximum and to retrieve information on the bone-implant interface.

Second, the values of t_1 = 0.31 ms and t_2 = 0.63 ms were chosen approximately in the same range compared to previous studies (24) because the rf signals obtained herein are qualitatively similar to the ones obtained by Michel and al. (1). Note that the upper bound of the interval chosen in the present study (0.63 ms) is slightly lower compared to what has been done previously (1) so that the higher value of the time of the second maximum does not influence the results. However, the difference of the value of the upper bound of the interval does not significantly modify the results. Moreover, an optimization study was run to maximize the correlation coefficient between *I* and F. Changing the values of t_1 between 0.28 and 0.35 *ms* or the value of t_2 between 0.59 and 0.67 *ms* did not affect significantly the results (less than 3% difference for R^2, data not shown).

Third, the values of STT (10 and 30 mm) were selected because in our surgical experience, it could correspond approximately to the typical thickness of the soft tissues around the acetabulum.

This study has several limitations. First, the biomechanical properties of living human soft tissues may be different from the soft tissues used in our protocol. Turkey breast slices were chosen as a model of soft tissues because of their constant thickness and of their relative homogeneity in order to facilitate the interpretation of the data and the reproducibility of the results. It is therefore necessary to carry out future studies by an identical analysis on cadavers and then in real clinical situations.

Second, the biomechanical properties of human acetabular bone and of bovine femoral bone are also different, but of the same order of magnitude than bovine femoral bone (3,39). We considered bovine bone because of the large size of the epiphysis of the bovine femur which allows an easy and appropriate positioning of the AC implant (3,39).

Third, the value of the cavity diameter was not measured precisely for each impaction series. The cavities were realized manually, which also leads to imperfections in the shape of the cavity. Variations in the cavity diameter value may occur during the protocol run. However, such variations are also likely to occur in the clinical practice

Fourth, this study was performed only with one type of hammer. When using different hammer masses, impact signals could be different. Implant surface properties also has an impact on the AC implant stability (14,22,40). The effect of the AC surface properties and of the hammer mass on the variation of the implant stability and the indicator should be studied in further studies.

Fifth, we performed this study with a single trained operator. It is likely that the observed signals may vary with operator changes due to differences in hammer usage and striking forces. This is one of the important issues for clinical transfer that needs to be assessed in future studies.

Conclusions

This study shows that an impact hammer can be employed in order to estimate the AC primary fixation without needing to determine the thickness of soft tissue between 10 and 30 mm of STT. The same indicator *I* corresponding to the impact momentum can be used indifferently. These results, together with the previous results obtained in cadavers (27) show the feasibility of the development of a medical device dedicated to the estimation of the AC implant stability, which could be used as a decision support system in a patient specific manner by orthopedic surgeons. However, clinical trials are necessary to assess the performance of the approach in the operating room.

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Conflicts of interest : none.

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Legends

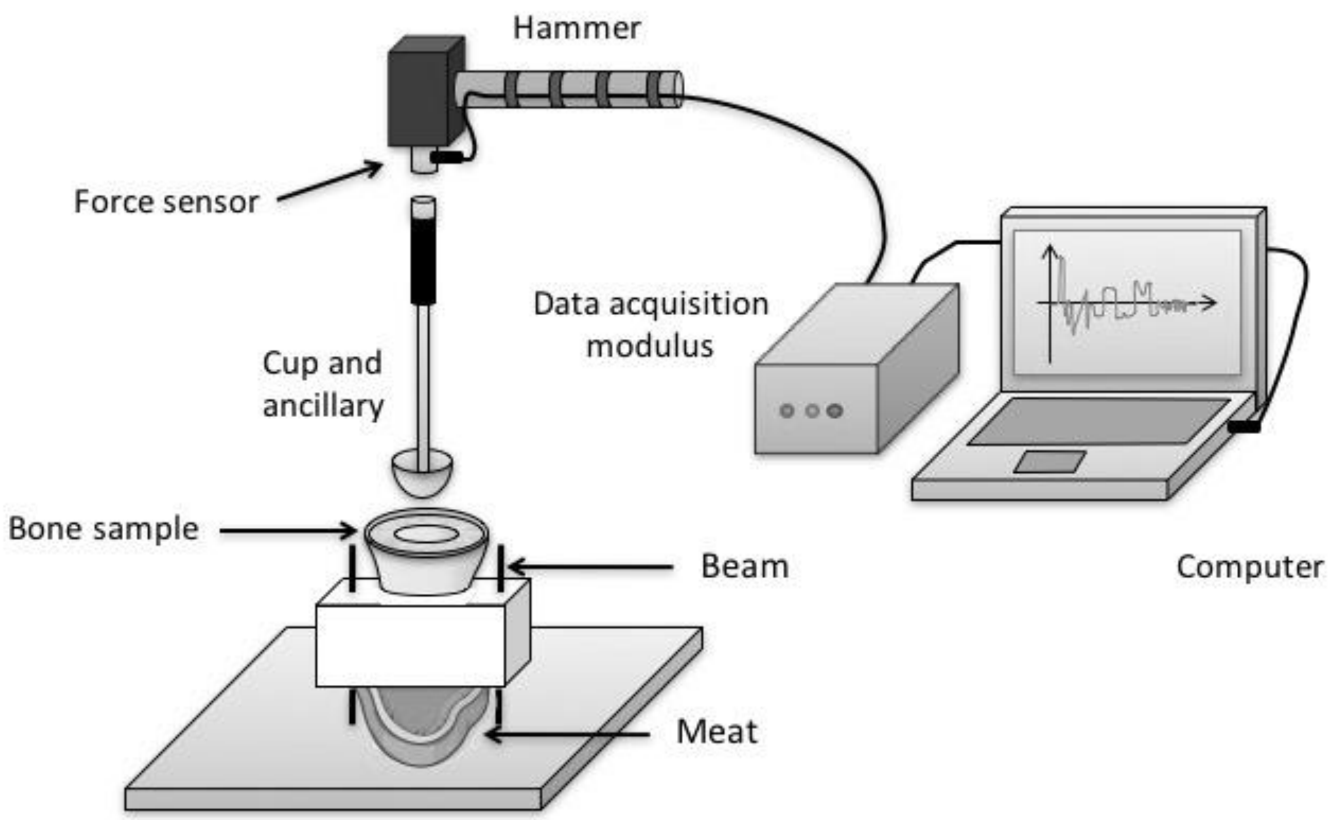
Figure 1: Schematic representation of the experimental set-up.

Figure 2: Experimental protocol employed in the present study.

Figure 3: Averaged variations of the force as a function of time corresponding to the 25 impacts realized during the impaction procedure for 6 different conditions of implant insertions. The black (respectively grey) signals correspond to 10 mm (respectively 30 mm) of soft tissue thickness (STT). The solid (respectively dotted and dashed) lines correspond to the implant stability equal to 31 N (respectively 63.4 N and 72.80 N). The two vertical lines indicate the time window considered to compute the value of the indicator I_m.

Figure 4: Variation of the tangential stability F as a function of the averaged value of the indicator I_m for all data pooled from all bone samples and configurations. The circles (respectively the stars) show the data corresponding to a value equal to 10 mm (respectively 30 mm) for the soft tissue thickness. The black (respectively grey) line corresponds to the linear regression analysis obtained for a value equal to 10 mm (respectively 30 mm) for the soft tissue thickness.

Figure 5: Representation of the average and of the standard deviation of the indicator I (black segments) and of the pull-out force (grey segments) as a function of the soft tissue thickness (for the indicator) and of the implant and cavity diameter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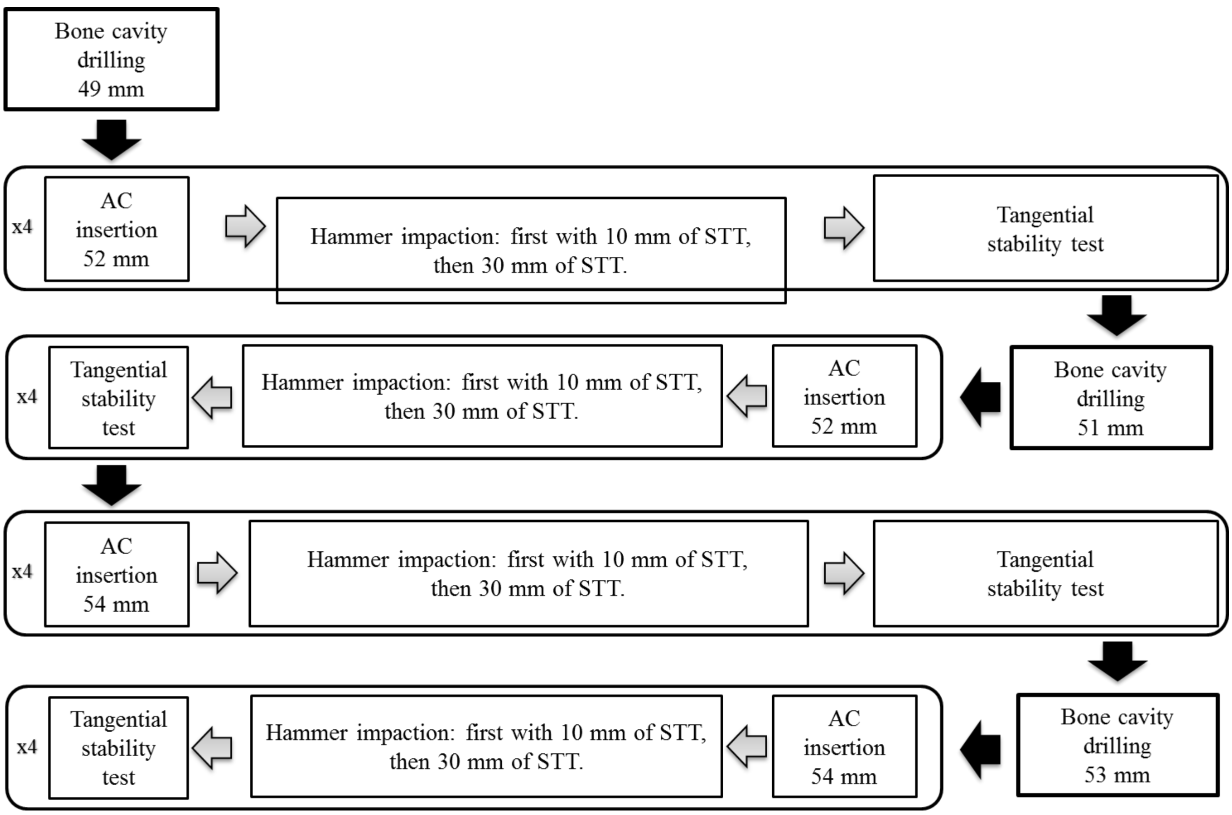
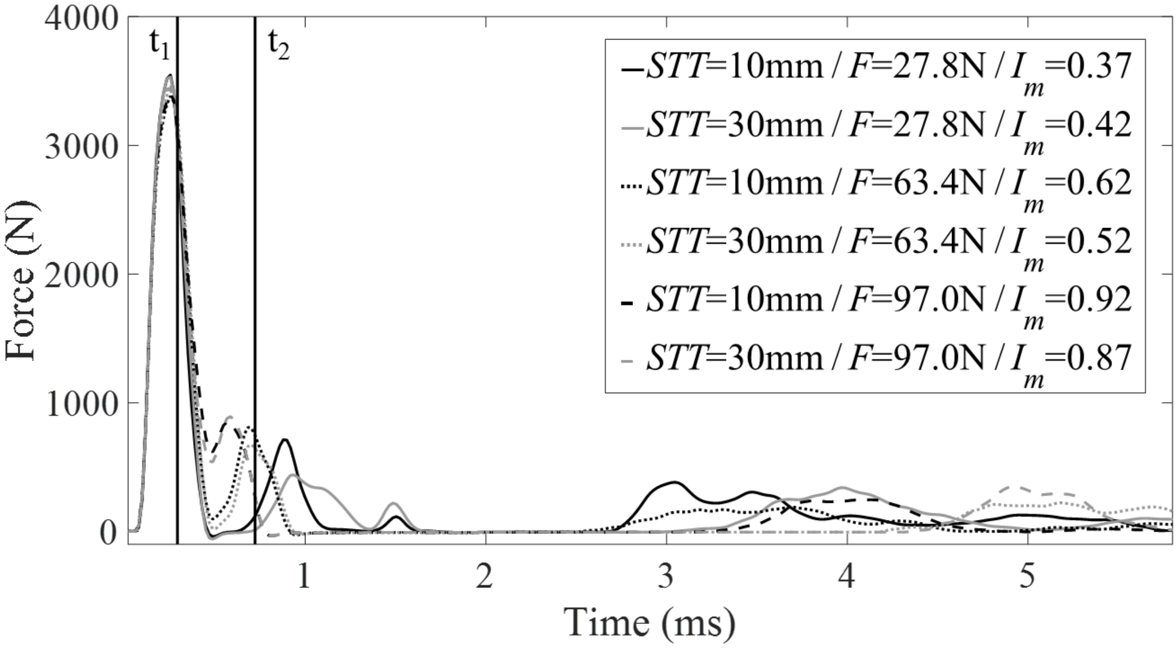
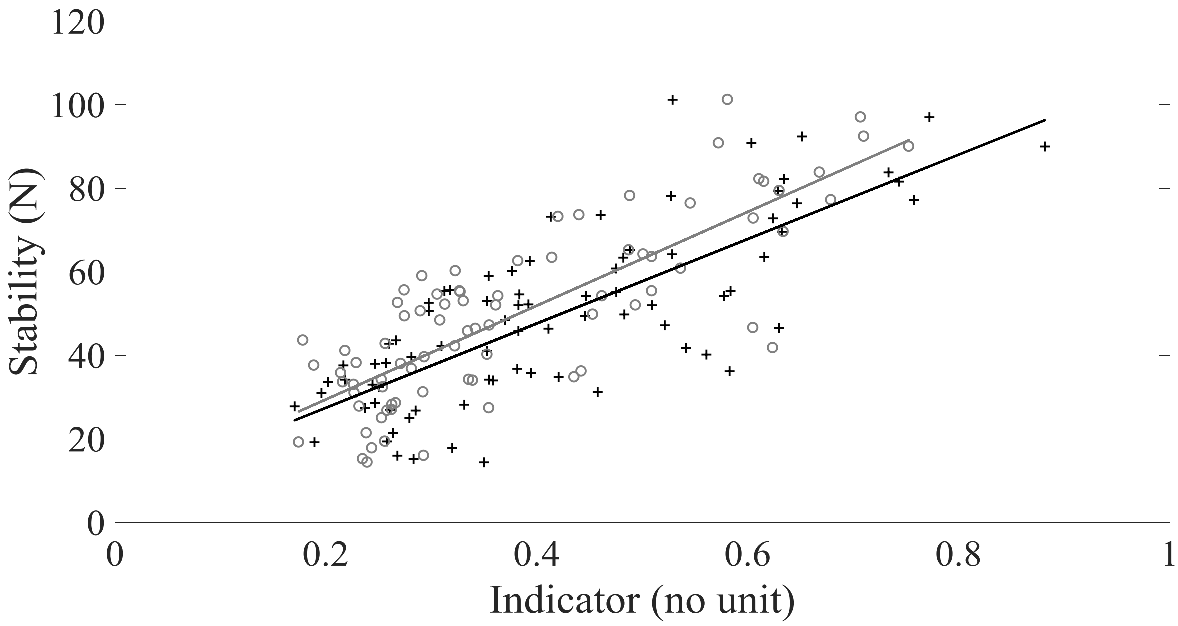
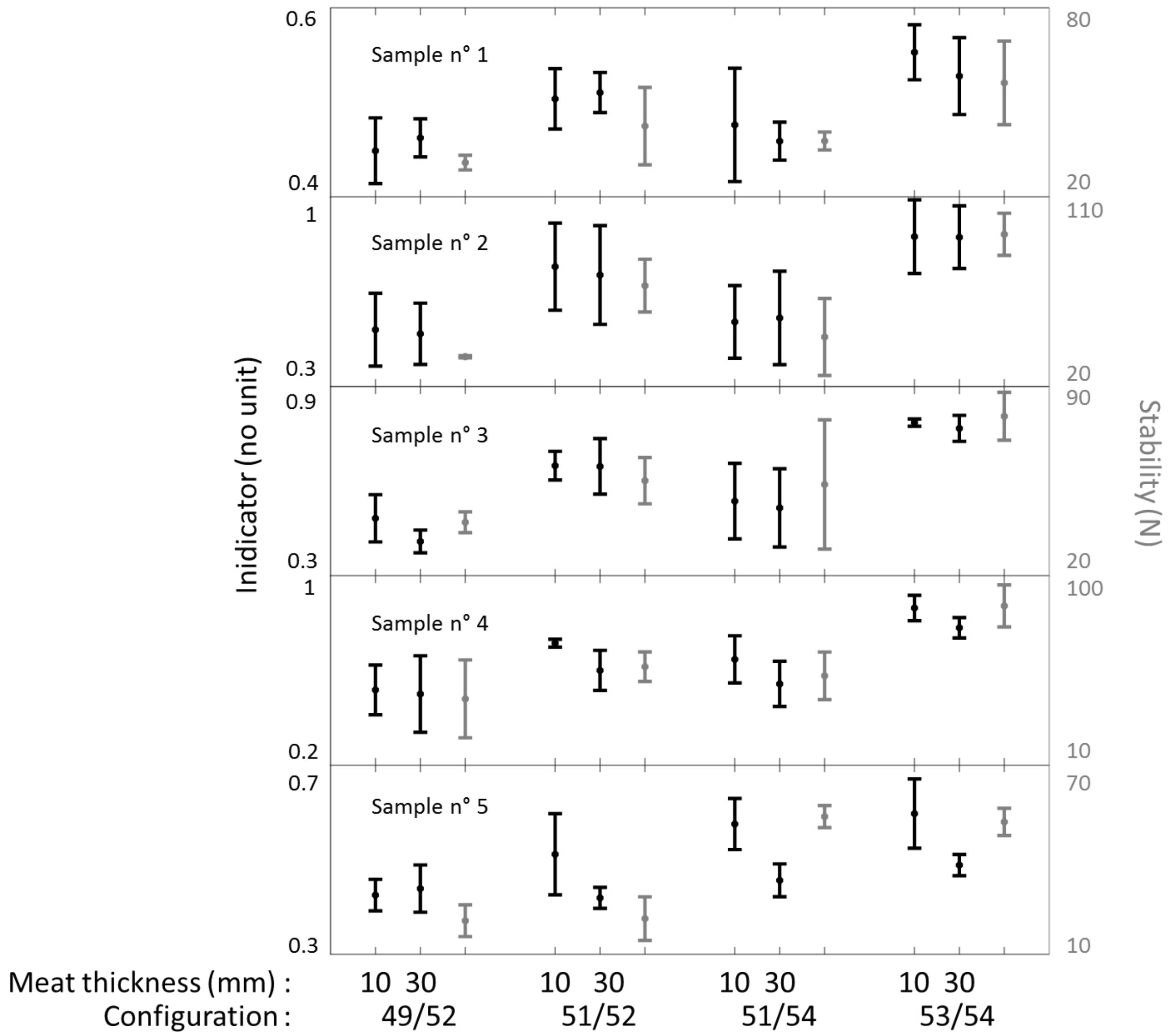
Force sensor
Cup and
ancillary
Data acquisition
modulus
Bone sample
Beam
Computer
Meat


Bone cavity
drilling
49 mm
x4
AC
insertion
52 mm
Hammer impaction: first with 10 mm of STT,
then 30 mm of STT.
Tangential
stability test
Bone cavity
drilling
51 mm
AC
insertion
52 mm
Hammer impaction: first with 10 mm of STT,
then 30 mm of STT.
Tangential
stability
test
x4
x4
AC
insertion
54 mm
Hammer impaction: first with 10 mm of STT,
then 30 mm of STT.
Tangential
stability test
Bone cavity
drilling
53 mm
AC
insertion
54 mm
Hammer impaction: first with 10 mm of STT,
then 30 mm of STT.
Tangential
stability
test
x4


4000
3000
2000
1000
0
Force (N)
1
2
3
4
5
Time (ms)
t1
t2
STT=10mm / F=27.8N / Im=0.37
STT=30mm / F=27.8N / Im=0.42
STT=10mm / F=63.4N / Im=0.62
STT=30mm / F=63.4N / Im=0.52
STT=10mm / F=97.0N / Im=0.92
STT=30mm / F=97.0N / Im=0.87


120
100
80
60
40
20
0
Stability (N)
0
0.2
0.4
0.6
0.8
1
Indicator (no unit)


Sample n° 1
Sample n° 2
Sample n° 3
Sample n° 4
Sample n° 5
0.6
0.4
1
0.3
0.9
0.3
1
0.2
0.7
0.3
80
20
110
20
90
20
100
10
70
10
Inidicator (no unit)
Stability (N)
Meat thickness (mm) :
10 30
10 30
10 30
10 30
Configuration :
49/52
51/52
51/54
53/54

534