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1 **Influence of soft tissue in the assessment of the primary fixation of acetabular cup**
2 **implants using impact analyses**
3

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

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35

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37

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44

45 Abstract

46

47 *Background*

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

54 *Methods*

55 To do so, different implants were inserted in three bovine bone samples. For each sample, different
56 stability conditions were obtained by changing the cavity diameter. For each configuration, the
57 acetabular cup implant was impacted 25 times with 10 and 30 mm of soft tissues positioned
58 underneath the sample. The averaged indicator I_m was determined based on the amplitude of the
59 signal for each configuration and each soft tissue thickness. The pull-out force was measured using
60 a pull-out test.

61 *Findings*

62 The results show that the resonance frequency of the system increases when the value of the soft
63 tissue thickness decreases. Moreover, an ANOVA analysis shows that there was no significant effect
64 of the value of soft tissue thickness on the values of the indicator I_m ($F=9.45$; p -value=0.64).

65 *Interpretation*

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

69

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

72

73

74 **Introduction**

75 Press-fit surgical procedures are widely used in clinical practice to insert cementless
76 acetabular cup (AC) implant into pelvic bone tissue (2,3). The aseptic loosening resulting from the
77 partial or total absence of osseointegration remains one of the major causes of surgical failure (4–6)
78 and depends on the primary stability of the AC implant. The AC implant primary fixation is an
79 important determinant of the surgical success and it depends in turns on many factors such as the
80 patient bone quality, the implant properties (e.g. surface treatment, implant geometry) and the
81 surgical protocol. The choice of the implant size, the shape and diameter of the cavity reamed into
82 bone tissue as well as the number and magnitude of the impacts used to insert the AC implant are
83 important parameters determining the surgical outcome. The surgeons should find a compromise
84 between a sufficient AC implant fixation in order to avoid micromotions at the bone implant interface
85 (7), which may lead to fibrous tissue formation, and an excessive pre-stressed state of bone tissue
86 (8) around the AC implant, which may lead to bone tissue necrosis. Moreover, while inserting the
87 AC implant into bone tissue, the energy of the impacts should be sufficient high to eventually obtain
88 a good primary stability but should not be too important to avoid acetabulum bone fracture (9). In
89 case of insufficient initial stability during surgery, the surgeon may cement and/or screw the implant
90 to help to osseointegration.

91
92 Despite the importance of the AC implant primary fixation, it remains difficult to be assessed
93 quantitatively in the operating room. Various biomechanical tests such as pull-out tests (3,10–15)
94 have been employed *in vitro* to evaluate the AC implant stability but such procedure cannot be used
95 during the surgery. Vibrational techniques have been used to estimate the implant primary stability
96 (16–20) but such an approach has not led so far to the development of a standardized method that
97 can be employed intraoperatively. Classical medical imaging techniques such as magnetic resonance
98 imaging or X-Ray microcomputed tomography are limited to provide quantitative information
99 related to the stability of the AC implant because of diffraction phenomena around titanium.
100 Moreover, such imaging techniques are still difficult to be used routinely during the surgery (21).

101 Orthopedic surgeons usually employ an empirical approach based on their experience and
102 proprioception to estimate the AC implant primary stability, for instance by listening to the noise
103 produced by the impact between the hammer and the ancillary (22) in order to adapt their strategy
104 and to obtain an appropriate implant stability while avoiding per operative bone fractures (23).

105 A method has been developed by our group in order to obtain quantitative information on the
106 AC insertion and fixation based on the analysis of the time variation of the force imposed to the
107 ancillary supporting the AC implant during its impactation into bone tissue (24). This approach uses

108 an instrumented hammer in order to record the time dependence of the force during a given impact.
109 An indicator, referred hereafter as impact momentum, has been defined and tested with reproducible
110 mass fall (25). A correlation between the AC primary stability and the impact momentum was
111 evidenced (26) and the approach was extended in order to account for the use of an instrumented
112 hammer (1). All the aforementioned studies were realized with bovine bone specimens fixed in a
113 clamp in order to work under reproducible conditions as far as practicable. The same approach was
114 then validated in cadavers, in a situation closer to that of the operating room (27). Moreover, finite
115 element models have been used in order to understand the dynamic biomechanical phenomena
116 occurring during the impacts (8).

117
118 The radiofrequency (rf) signals corresponding to the variation of the force applied between the
119 hammer and the ancillary as a function of time were qualitatively different when the experiments
120 were carried out with a bone sample clamped on a rigid frame (1) and with cadavers (27), which
121 shows the influence of the environment (such as for example the presence of soft tissues) on the
122 measurements. Despite the aforementioned difference, the influence of the presence of soft tissues
123 on the results of the method remains unexplored because it is difficult to determine quantitatively
124 the thickness of soft tissues when working with cadavers. It is important to determine the influence
125 of soft tissues on the measurements since it could jeopardize future measurements that could be
126 carried out in the operating room to determine the AC implant stability when working with patients
127 with varying body mass index for instance.

128
129 The aim of this paper is to examine the effects of soft tissue thickness (STT) on the impact
130 momentum and estimate the influence of STT on the AC primary stability evaluation using impact
131 analyses. To do so, three bone samples were considered *in vitro* with several drilling and AC sizes
132 conditions and the value of STT was varied for all 48 different configurations considered.

133

134 **Methods**

135 1. Acetabular cup implant, bone samples and soft tissues

136 Three bovine femurs were prepared similarly to what was done in the protocol described in Michel
137 et al. (1). Briefly, each bone sample was embedded in a fast hardening resin (polymer SmoothCast
138 300, Smooth-On, Easton, PA, USA) for better handling and positioning, as shown in Fig. 1. All
139 bone samples were made of trabecular bone in the region of the AC implant insertion.

140 Two slices of turkey breast were cut in order to obtain a thickness of 10 mm of soft tissues
141 when one slice only was positioned underneath the sample and of 30 mm when both slices were
142 employed. As schematized in Fig. 1, two beams located around the bone sample allow a translation
143 along the vertical direction without friction (which was obtained through lubrication) of the bone
144 sample during the impacts, similarly as in the clinical situation.

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

150

151 2. Hammer impaction procedure

152 An impaction procedure corresponds to 25 successive impacts with the constraint that the
153 maximum amplitude of the force should be comprised between 2500 and 4500N, which corresponds
154 to a relatively weak impact compared to typical forces recorded during impacts employed to insert
155 the AC implant (typically around 15 kN (28)). For each impact, the ancillary was held manually and
156 impacted by the hammer ($m = 1.3$ kg). A dynamic piezoelectric force sensor (208C05, PCB
157 Piezotronics, Depew, New York, USA) with a measurement range up to 22 kN in compression was
158 screwed in the center of the hammer impacting face. A data acquisition module (NI 9234, National
159 Instruments, Austin, TX, USA) with a sampling frequency of 51.2 kHz and a resolution of 24 bits
160 was used to record the time variation of the force applied between the hammer and the ancillary for
161 each impact. The data were transferred to a computer and recorded using a LabVIEW interface
162 (National Instruments, Austin, TX, USA) for a duration of 10 ms.

163

164 3. Signal processing

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

$$169 \quad I = \frac{1}{A_0 \cdot (t_2 - t_1)} \int_{t_1}^{t_2} A(t) \cdot dt$$

170 where *A(t)* is the variation of the force applied between the hammer and the ancillary as a function
171 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
172 of the indicator *I* comprised in the interval [0;1]. The choice of the values t_1 , t_2 and A_0 will be
173 discussed in section 4. Matlab (The Mathworks, Natick, MA, USA) was used to analyze the data.

174

175 4. Tangential stability mechanical test

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

182

183 5. Experimental protocol

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

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

197 described in subsection 2.4 was carried out to determine the corresponding AC implant stability
198 noted F .

199 The procedure described above including i) the implant insertion, ii) the impaction procedure
200 (25 impacts) with the determination of the averaged values I_m of the indicator I for the two values of
201 STT and iii) the tangential stability test was then repeated three times with the same 52 mm diameter
202 implant, leading to a total number of four values for the pull-out force and of eight values for I_m .

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

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

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

216

217 6. Statistical analyses

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

222

223

224 **Results**

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

234 The results show that the rf signal exhibits i) a first maximum occurring just after the impact (around
235 $t=0.25$ ms), ii) a second maximum between 0.6 and 1 ms and iii) a third maximum between 3.0 and
236 5.5 ms. As shown in Fig. 3, the different rf signals around the first maxima (~ 0.25 ms) are
237 qualitatively similar for all data obtained. However, the rf signals are significantly different around
238 the second (0.6 - 1 ms) and the third maxima (3 - 5.5 ms). More specifically, the times of the second
239 and third maxima are shown to increase when the AC implant stability increases, which is consistent
240 with the results obtained in previous studies (1,25,26).

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

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

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

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

268

269 **Discussion**

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

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

286
287
288 Although the correlation between the indicator I and the AC implant fixation has been shown
289 not to depend on the STT, the rf signal itself depends on the STT, as shown in Fig. 3. In particular,
290 the time of second maximum (between 0.6 and 1.0 ms in Fig. 3) of the rf signal is more often lower
291 for 1 cm of STT compared to the results obtained with 3 cm of STT. The results are even more
292 significant when considering the third maximum of the rf signal (between 3 and 5.5 ms in Fig. 3)
293 because almost all configurations (except one) are concerned and because the time difference
294 between the third maxima obtained with STT values equal to 10 and 30 mm is higher compared to
295 the results obtained with the second maximum (see Fig. 3). The qualitative variation of the rf signals
296 obtained with different STT may be explained by the fact that adding soft tissue to the tested system
297 induces a decrease of its overall rigidity, thus resulting in a decrease of its resonance frequency. It
298 has been shown experimentally (27), analytically (25), and numerically (8), that the frequency of the
299 rf signal is determined by the rigidity of the system composed by the bone sample, the implant and
300 the ancillary. Therefore, an increase of rigidity (corresponding to a decrease of STT) induces an
301 increase of the resonance frequency and hence a decrease of the time of the different maxima of the
302 rf signal, which is more important for higher order maxima. Despite this dependence of the rf signal

303 to soft tissue thickness, the indicator I is shown to weakly depend on the soft tissue thickness, which
304 can be explained by the fact that the indicator is determined for relatively weak values of the time.

305
306
307 Different pull-out tests have been employed in the literature to assess the AC implant primary
308 stability (33). We have chosen a tangential stability test because of its simplicity and because it has
309 been already used in previous papers (5,34,35). In this study, the highest values of the pull-out force
310 were obtained for an interference fit equal to 1 mm, which is consistent with previous studies (5) and
311 with the recommendation of the implant manufacturer (8,36). A value of 1 mm for the interference
312 fit is known to provide an adequate primary stability conditions of the AC implant (5,36). The effects
313 of the interference fit on the AC insertion parameters have already been studied (8) and authors have
314 concluded that a compromise has to be found between a sufficiently high value of the interference
315 fit to ensure the AC stability and a sufficiently low value to avoid too important polar gaps and
316 heterogeneous distribution of stresses within bone tissue (37,38).

317
318
319 Several parameters were chosen empirically in this study. First, the range of the maximum
320 force (2500-4500 N) corresponding to the impacts used to determine the indicator, which is similar
321 to what was done in (1), was chosen to obtain a compromise between a sufficiently low energy in
322 order to avoid modifications of the implant insertion and/or of the bone-implant interface properties
323 and a sufficiently high energy to obtain accurate measurement of the second and third maximum and
324 to retrieve information on the bone-implant interface.

325 Second, the values of $t_1 = 0.31$ ms and $t_2 = 0.63$ ms were chosen approximately in the same range
326 compared to previous studies (24) because the rf signals obtained herein are qualitatively similar to
327 the ones obtained by Michel and al. (1). Note that the upper bound of the interval chosen in the
328 present study (0.63 ms) is slightly lower compared to what has been done previously (1) so that the
329 higher value of the time of the second maximum does not influence the results. However, the
330 difference of the value of the upper bound of the interval does not significantly modify the results.
331 Moreover, an optimization study was run to maximize the correlation coefficient between I and F .
332 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
333 not affect significantly the results (less than 3% difference for R^2 , data not shown).

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

336

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

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

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

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

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

358

359

360 **Conclusions**

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

368

369

370

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377

378 **Conflicts of interest : none.**

379

380

381

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498 Legends

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

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502 Figure 2: Experimental protocol employed in the present study.

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504 Figure 3: Averaged variations of the force as a function of time corresponding to the 25 impacts
505 realized during the impaction procedure for 6 different conditions of implant insertions. The black
506 (respectively grey) signals correspond to 10 mm (respectively 30 mm) of soft tissue thickness
507 (STT). The solid (respectively dotted and dashed) lines correspond to the implant stability equal to
508 31 N (respectively 63.4 N and 72.80 N). The two vertical lines indicate the time window
509 considered to compute the value of the indicator I_m .

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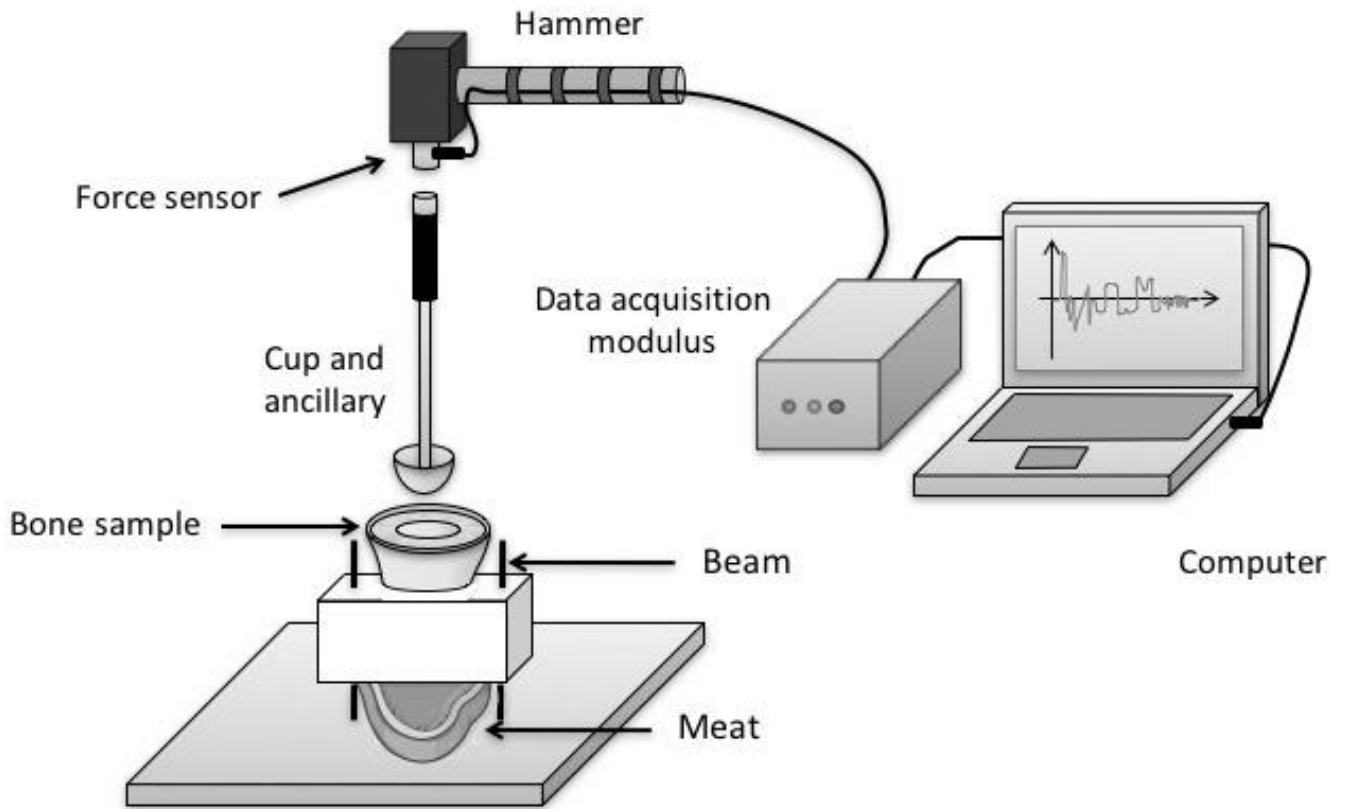
511 Figure 4: Variation of the tangential stability F as a function of the averaged value of the indicator
512 I_m for all data pooled from all bone samples and configurations. The circles (respectively the stars)
513 show the data corresponding to a value equal to 10 mm (respectively 30 mm) for the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

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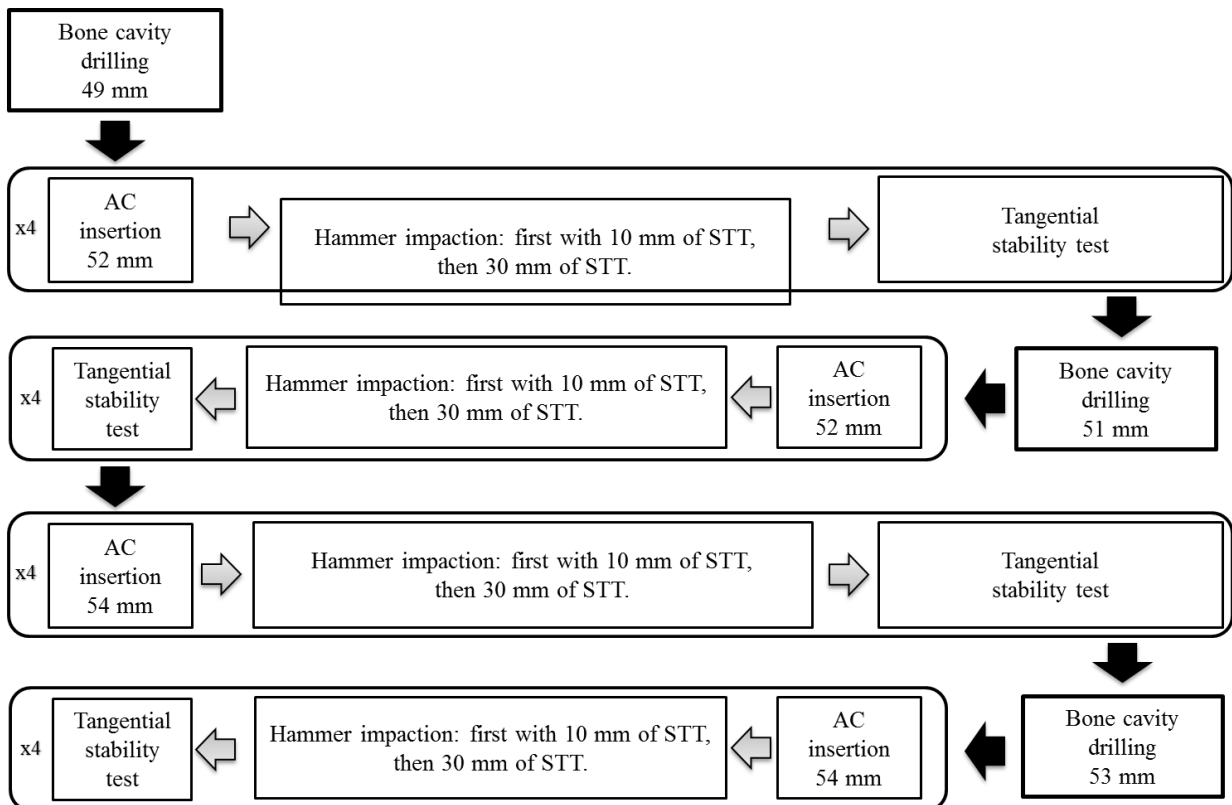
517 Figure 5: Representation of the average and of the standard deviation of the indicator I (black
518 segments) and of the pull-out force (grey segments) as a function of the soft tissue thickness (for
519 the indicator) and of the implant and cavity diameter

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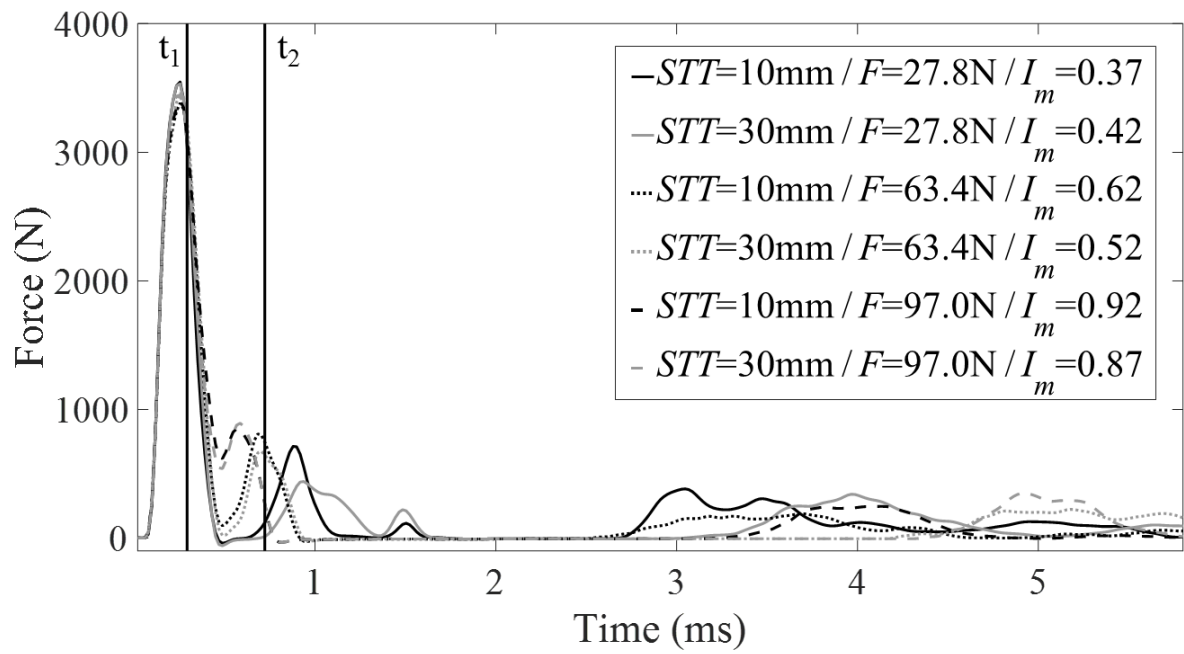


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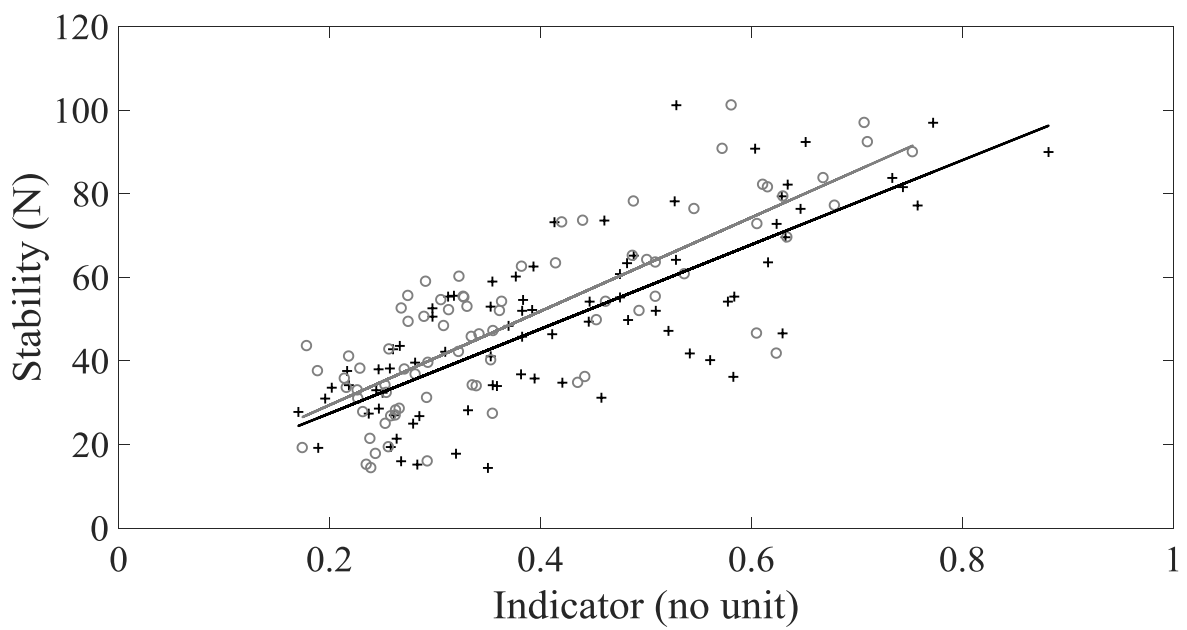
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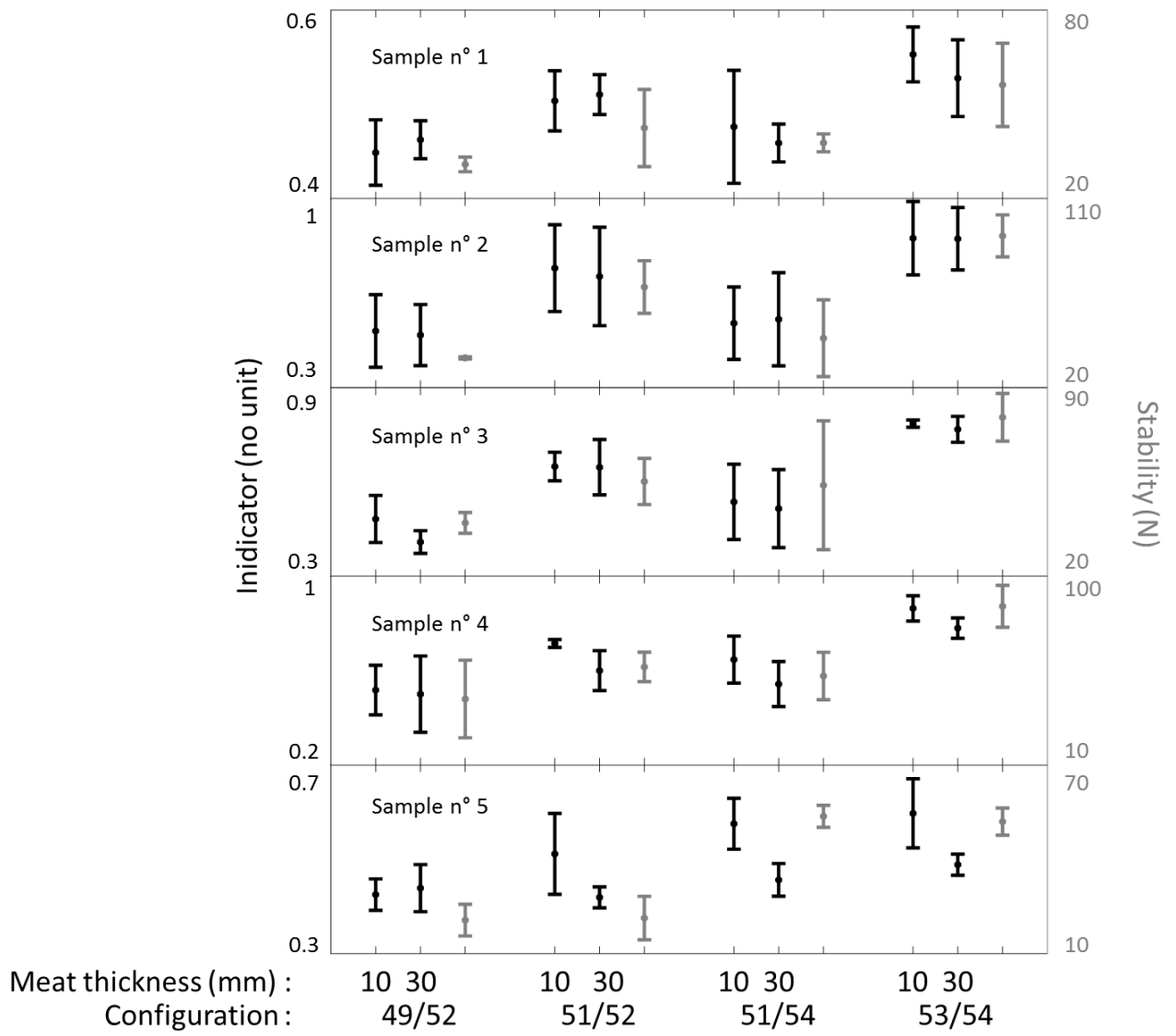
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