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3-D finite element model of the impaction of a press-fitted femoral stem under various biomechanical environments

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Abstract

Background: Uncemented femoral stem insertion into the bone is achieved by applying successive impacts on an inserter tool called "ancillary". Impact analysis has shown to be a promising technique to monitor the implant insertion and to improve its primary stability.

Method: This study aims to provide a better understanding of the dynamic phenomena occurring between the hammer, the ancillary, the implant and the bone during femoral stem insertion, to validate the use of impact analyses for implant insertion monitoring. A dynamic 3-D finite element model of the femoral stem insertion *via* an impaction protocol is proposed. The influence of the trabecular bone Young's modulus (E_t), the interference fit (IF), the friction coefficient at the bone-implant interface (μ) and the impact velocity (v_0) on the implant insertion and on the impact force signal is evaluated.

Results: For all configurations, a decrease of the time difference between the two first peaks of the impact force signal is observed throughout the femoral stem insertion, up to a threshold value of 0.23 ms. The number of impacts required to reach this value depends on E_t , v_0 and IF and varies between 3 and 8 for the set of parameters considered herein. The bone-implant contact ratio reached after ten impacts varies between 60% and 98%, increases as a function of v_0 and decreases as a function of IF , μ and E_t .

Conclusion: This study confirms the potential of an impact analyses-based method to monitor implant insertion and to retrieve bone-implant contact properties.

Keyword: femoral stem, finite element analysis, dynamic modeling, impact analysis, friction coefficient, interference fit, Young's modulus, bone-implant contact

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1. Introduction

Total hip arthroplasty (THA) is one of the most frequent orthopaedic surgeries. More than 150 000 operations are performed in France yearly [1] and this number is expected to rise due to population's aging. Such surgery aims at replacing the dysfunctional joint to relieve pain and recover the loss of mobility due to degenerative joint disease (e.g. arthrosis) [2] or traumatic injury. Currently, the surgeons use both cemented and uncemented procedures. While the first technique is the oldest and uses cement to provide the initial fixation of the implant into the bone, uncemented procedures, which consist of inserting the implant directly in contact with the bone are developing fast. Cemented procedures are interesting for patients with poor bone quality, but allergic responses and shocks due to the detachment of cement particles are widely reported in the literature, which are the important reasons for revisions [3]. Interestingly, uncemented techniques foster bone remodeling at the bone-implant interface and increase the long-term success of the surgery when performed properly. The success of uncemented surgeries depends on the implant primary stability, achieved during the surgery [4]. In particular, the femoral stem is inserted into a slightly undersized bone cavity previously prepared by the surgeon, by applying successive impacts on the upper surface of an inserter tool called "ancillary", which is temporary fixed to the implant during the insertion. An important challenge for the surgeon is to adapt the impaction protocol to reach sufficient initial mechanical fixation, thanks to press-fit phenomena, while avoiding excessive stresses at the bone-implant interface [5]. Reaching this compromise is tricky since it depends on several parameters related to the patient, the implant or the surgical protocol. Currently, the surgeons relies on their proprioception to adapt the impaction procedure, which is subjective and may lead to failures due to aseptic loosening [6] or periprosthetic fractures [7]. A method allowing to assess implant stability would therefore be useful to improve the surgical procedure.

Among the different vibro-acoustic methods under development [8, 9, 10], impact analysis has shown to be a promising non-destructive and quantitative technique to estimate acetabular cup implant stability [11, 12, 13, 14] and monitor femoral stem insertion [15, 16, 17]. The method consists in analyzing the temporal variation of the impact force applied by the hammer on the ancillary during the implant insertion. In particular, a temporal indicator was derived from this force signal [15, 16, 17] to indicate the femoral stem insertion end-point, which is defined as the insertion step that maximizes initial fixation while avoiding periprosthetic fracture. This indicator, which corresponds to the time difference between the two first peaks of the impact force signal [15], was shown to be in agreement with the surgeon proprioception in previous *in vitro* [15] and

42 *ex vivo* studies on bovine femurs [16] and anatomical subjects [17]. However, several phenomena
43 should be clarified for an optimal application of this method in the clinic. First, the sensitivity
44 of the indicator to the bone-implant contact (BIC) ratio, which plays an important role on the
45 implant stability [18], could not be retrieved experimentally [15, 16, 17]. Second, the influence
46 of various biomechanical parameters (*i.e.* bone geometrical and material properties), along with
47 the influence of the surgical procedure (*i.e.* impact number and velocity, implant geometry and
48 material) on the impact force signals remains unclear. Due to the varying physical characteristics
49 of bone tissues and to the difficulty to measure the BIC ratio experimentally, the use of numerical
50 simulations is the most adapted approach to address these issues.

51 In the literature, many numerical studies focused on the femoral stem stability by considering
52 the evaluation of the contact pressure [19] or the estimation of the micromotions at the bone-
53 implant interface during daily activities such as stair climbing [18, 20] or walking [21, 22]. These
54 analyses give good insights on the influence of the implant design geometry [23, 24] and material
55 properties, the patient bone quality [25], the bone-implant contact ratio [18] or the bone cavity size
56 geometry [19] on the implant primary and/or secondary stability [26]. However, these studies did
57 not investigate the implant impaction process itself -which determines the success of uncemented
58 surgeries [5]-, since they were performed on the femoral stem already inserted into the bone cavity.
59 In this context, previous studies by our group investigated the biomechanical phenomena occurring
60 during the press-fit quasi-static insertion of both uncemented Acetabular Cup Implants (ACI)
61 [27, 28] and femoral stems [29]. The influence of the bone Young's modulus, of the bone-implant
62 friction coefficient and of the interference fit on both the implant insertion and the primary stability
63 was analyzed. While these studies [27, 28, 29] are relevant to understand the determinants of
64 implant stability, they do not provide information on the dynamic phenomena occurring during
65 the insertion and in particular, on the temporal variation of the impact force signal. Very few
66 dynamic simulations of uncemented implant insertion are proposed in the literature. Michel et
67 al. [30] developed a dynamic finite element model of the ACI impaction and validated the use
68 of impact analysis to predict the bone-implant contact area of an ACI. However, such study has
69 not yet been performed for the femoral stem. A uni-axial model of the femoral stem impaction
70 configuration was developed by Bishop et al. [31] including the hammer, the ancillary, the femoral
71 stem and the bone, modeled by discrete masses connected by linear elastic springs. However, this
72 model is not based on finite element modeling and two limiting points for its application may be
73 raised. First, the geometry of the bone-implant system was not studied, which prevents analysing

74 of the stress field at the bone-implant interface. Second, the bone-implant interface was modeled
75 by linear springs, which does not allow to quantify the bone-implant contact ratio, which plays an
76 crucial role on the primary and secondary stability. Interestingly, Monea et al. [32] investigated
77 the influence of femoral stem geometry and press-fit conditions on the evolution and distribution of
78 the bone-implant contact, stresses and strains during and after the hip stem insertion by means of
79 a dynamic analysis. Moreover, bone damage during impaction was studied. However, the impact
80 force features and their variation during impaction were not studied.

81 The aim of this study is twofold. The first objective is to investigate the variation of the impact
82 force over time during femoral stem insertion in order to validate the use of impact analyses to
83 monitor femoral stem insertion. The second objective is to quantify the influence of varying
84 parameters such as the impact velocity, the bone Young's modulus, the friction coefficient at the
85 bone-implant interface and the interference fit on the implant stability, represented by the bone-
86 implant contact ratio. For that purpose, a three-dimensional finite element nonlinear dynamic
87 analysis of the insertion procedure using successive impacts is developed. The originality of the
88 study is to quantify the effects of various biomechanical parameters on the impact force signal and
89 on the implant stability in order to optimize the impaction protocol, using a realistic geometry of
90 the femoral stem. In particular, the variation of the indicator D , derived from the impact force
91 signal and developed in previous experimental studies [15, 16, 17] will be studied as a function of
92 i) the impact number, ii) the bone-implant contact ratio and iii) the biomechanical configuration.

93 2. Material and methods

94 2.1. Finite element model

95 A 3-D finite element model was used to simulate the insertion of the femoral stem into the
96 bone by successive hammer impacts similarly as in the experiments described in [15] and [10] and
97 schematized in Fig. 1a. Figure 1b shows the geometry of the problem, which consists in five
98 domains: the hammer Ω_h , the ancillary Ω_a , the implant Ω_i and the bone specimen composed of
99 two subdomains: the trabecular bone Ω_{tb} and the cortical bone Ω_{cb} . The ancillary was modeled
100 as a cylinder with the same shape and dimensions as in [29, 10] (outer radius of 16 mm, length of
101 180 mm) and it was bonded to the femoral stem. The choice of the implant geometry, the bone
102 cavity size and the interference fit were validated by two experienced surgeons. The FS geometry
103 was created from the STL file of a scan of the FS RMIS implant of size 9 (CERAFIT RMIS,
104 Ceraver, Roissy, France). The bone specimen was designed as a cylinder of 110 mm length and

105 20 mm radius, with an outer layer of 3.5 mm of thickness corresponding to the cortical bone, the
 106 inner cylinder representing the trabecular bone. The distal part of the femur was neglected in the
 107 model to represent the *in vitro* tests described in [15, 10]. A bone cavity was created in ANSYS
 108 workbench (v.20, ANSYS Inc., Canonsburg, PA, USA) by boolean subtraction of the rasp volume,
 109 similarly as in [29]. The rasp's geometry corresponds to the FS's one, undersized with a scale
 110 factor. The diameter difference between the rasp and the implant is called the interference fit IF .
 111 Eventually, the full geometry was reduced to a symmetric model following the plane of symmetry
 112 of the implant, corresponding to the (XZ) plane (see Fig. 1).

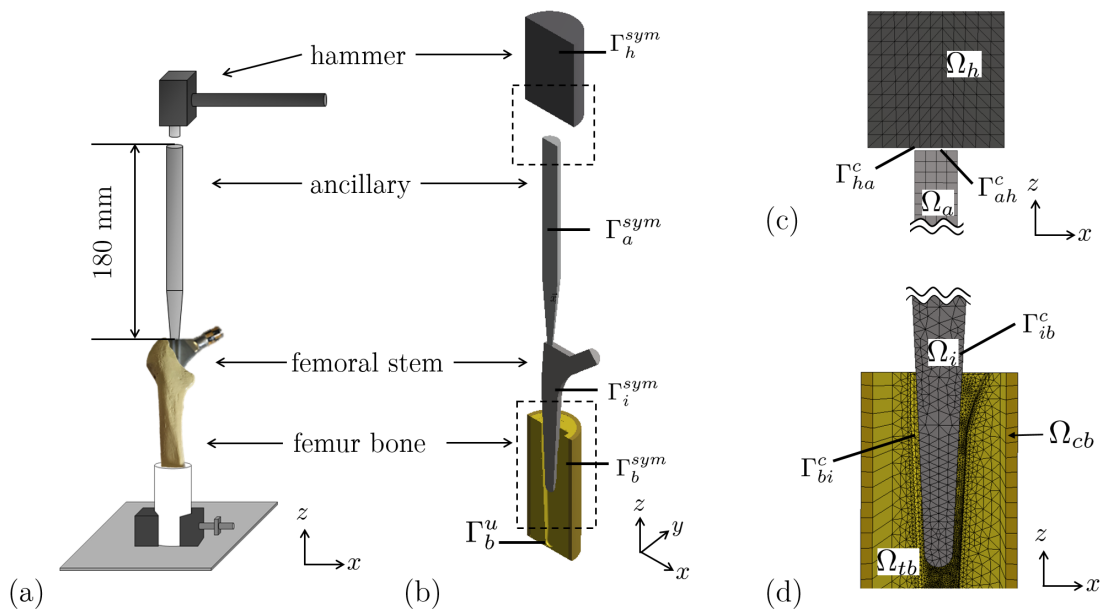


Figure 1: Representation of the experimental setup (a) and the geometry of the different domains for the simulation (b) with zooms on the meshes at the hammer-ancillary contact (c) and at the bone-stem contact (d). The hammer, the ancillary, the FS implant, the trabecular bone and the cortical bone are denoted by Ω_h , Ω_a , Ω_i , Ω_{tb} , Ω_{cb} , respectively.

113 In this work, all media were modeled as isotropic elastic materials, similarly as what was done in
 114 [30, 28, 29]. The material properties associated to each domain are given in Table 1 for the reference
 115 case. Each material was assumed to be homogeneous and had the same Poisson's ratio equal to
 116 0.3. The mesh was generated in ANSYS Workbench software (v.20, ANSYS Inc., Canonsburg, PA,
 117 USA) and consisted in 89381 tetrahedral elements. The mesh was refined around the bone implant
 118 contact. A convergence study on the bone and implant element size h_e and the time increment Δt
 119 was conducted for the reference case.

Parameter	Density (g/cm ³)	Young's modulus (GPa)
Hammer	8.3	210
Ancillary	7.85	200
Femoral stem	4.4	113
Cortical bone	1.64	18 [33, 34]
Trabecular bone	0.27	0.2 [28, 35]

Table 1: Material properties of the five subdomains taken from [33, 34, 35, 28]

120 *2.2. FS insertion simulation*

121 All simulations were performed using the ANSYS software (v.20, ANSYS Inc., Canonsburg,
122 PA, USA). To describe the dynamic behavior of the system during the insertion process, large
123 displacement hypothesis was assumed. Therefore, the initial configuration at $t = 0$ described by
124 the point coordinates \mathbf{X} was distinguished from a given configuration at a time t described by the
125 point coordinates $\mathbf{x} = \mathbf{x}(\mathbf{X}, t)$.

126 *2.2.1. Boundary, initial and contact conditions*

Different boundary conditions were defined for each subdomain, denoted Γ^{sym} for the symmetry
condition, Γ^c for the contact condition and Γ^u for the imposed displacement as indicated in Fig.
1. The bone distal surface, Γ_b^u , was fixed to represent the distal bone clamping of the experimental
configurations [15, 10]. No external forces were applied to the system. The symmetry condition
 Γ^{sym} in the (XZ) plane was applied to the whole system, according to the plane of symmetry of the
femoral stem. The symmetry boundary conditions read (except for the contact surfaces):

$$\mathbf{u} = \mathbf{0}, \quad \text{on } \Gamma_b, \quad (1)$$

$$\mathbf{u} \cdot \mathbf{e}_y = 0, \quad \text{in } \Gamma_\alpha^{sym}, \quad (2)$$

127 where $\mathbf{u}(\mathbf{X}, t) = \mathbf{x} - \mathbf{X}$ is the displacement vector and $\Gamma_\alpha^{sym} = (\Gamma_h^{sym} \cup \Gamma_a^{sym} \cup \Gamma_i^{sym} \cup \Gamma_{tb}^{sym} \cup \Gamma_{cb}^{sym})$.

128 Frictional contact model using Coulomb's law [36] was assumed between the hammer and the
129 ancillary noted $(\Gamma_{ha}^c, \Gamma_{ah}^c)$ (see Fig. 1c) and between the trabecular bone and the FS implant noted
130 $(\Gamma_{bi}^c, \Gamma_{ib}^c)$ (see Fig. 1d), where:

$$f_s = |F_t| - \mu|F_n| \leq 0. \quad (3)$$

131 $|F_t|$ and $|F_n|$ are the absolute values of tangential and normal components of the interface traction
132 force vector, respectively; μ is the friction coefficient; and f_s is a slip criterion which is negative
133 ($f_s < 0$) when no sliding occurs (sticking) and null ($f_s = 0$) in case of sliding. Using ANSYS

134 software (v.20, ANSYS Inc., Canonsburg, PA, USA), the Augmented Lagrangian method was
 135 employed to solve the problem involving contact with friction. In particular, a friction coefficient
 136 of 0.1 was chosen between the hammer and the ancillary, similarly as in [30] and it was chosen
 137 equal to 0.3 for the reference case based on previous values used in the literature [37, 30, 28].

138 To simulate the impact of the hammer Ω_h on the ancillary Ω_i , an initial vertical velocity was
 139 imposed to Ω_h at $t = 0$. At $t = 0$, the bone and the implant were supposed to be at rest and
 140 already in contact along Γ^c . The initial conditions read:

$$\mathbf{u}_{(t=0)} = \mathbf{0}, \quad \text{in } \Omega_\alpha, \quad (4)$$

$$\dot{\mathbf{u}}_{(t=0)} = \mathbf{0}, \quad \text{in } (\Omega_a \cup \Omega_i \cup \Omega_{tb} \cup \Omega_{cb}), \quad (5)$$

$$\dot{\mathbf{u}}_{(t=0)} = (0, 0, -v_0), \quad \text{in } \Omega_h, \quad (6)$$

141 where $\dot{\mathbf{u}}(\mathbf{X}, t)$ is the velocity vector and $\Omega_\alpha = (\Omega_h \cup \Omega_a \cup \Omega_i \cup \Omega_{tb} \cup \Omega_{cb})$.

142 2.2.2. Impaction procedure and parametric study

143 Different simulations of the femoral stem insertion by impaction were performed using the
 144 numerical model described above. Before starting the impaction procedure, the implant was posi-
 145 tioned into the bone cavity to establish the contact between the bone and the implant by applying
 146 a quasi-static vertical force of 10N to the upper surface of the ancillary, similarly as what was done
 147 in [29]. This stage represents the manual positioning of the implant into the bone performed by
 148 the surgeons before the hammer impacts. The insertion procedure by impaction (denoted “implant
 149 impaction” in what follows), starts at the end of the implant positioning. It consisted in applying
 150 successive impacts of the hammer on the ancillary, with an initial vertical velocity equal to v_0
 151 for each new impact. The number of impacts was set equal to 10 for each simulation (except for
 152 $v_0 = 2$ m/s, which will be discussed in Section 4) in order to be able to compare the influence of
 153 the configuration on the implant insertion. The time duration between two successive impacts was
 154 adapted to each configuration so that the system was at rest at the beginning of each new impact,
 155 to ensure consistency of the initial condition across the configurations. Because of the dynamic
 156 behavior of the system, this time duration was larger at the beginning of the insertion than at the
 157 end.

158 A parametric study was carried out based on the experimental variations observed in [15, 16, 17]
 159 by repeating the protocol described above with different biomechanical configurations. To model

160 the variability of the patient and of the surgical procedure, different values of trabecular bone
 161 Young's modulus E_t , friction coefficient at the bone-implant interface μ , interference fit IF and
 162 impact velocity v_0 were considered, leading to a total of 17 simulations. The range of variation
 163 of each parameter is indicated in Table 2 and was defined according to both the experimental
 164 data taken from the literature and the feedbacks of two experienced orthopedic surgeons. In what
 165 follows the reference values of the aforementioned parameters will be denoted by E_t^* , IF^* , μ^* and
 166 v_0^* .

Parameter	Symbol	Range	Reference value
Trabecular bone Young's Modulus	E_t	[0.1-0.6] GPa [38, 39, 40]	0.2 GPa [35]
Interference fit	IF	[100-300] μm [41, 21, 42]	200 μm
Friction coefficient	μ	[0.2-0.5] [34, 37, 43]	0.3 [28]
Impact velocity	v_0	[0.5-2] m/s	1 m/s

Table 2: Parameters and range of variation for the parametric study. [38, 39, 40, 35, 41, 21, 42, 34, 37, 43, 28]

167 2.3. Insertion monitoring and signal processing

168 To analyze the femoral stem insertion, the positions of the hammer and of the ancillary, the
 169 implant vertical displacement U_I , as well as the BIC ratio were evaluated during the impaction
 170 procedure. The implant displacement U_I was defined by the variation of the position of the
 171 ancillary during each impact $\#i$. The BIC was defined by the ratio of the bone surface in contact
 172 with the femoral stem and with the total bone cavity surface. To investigate the impact method
 173 sensitivity, the time variation of the impact force F_I applied by the hammer on the upper surface
 174 of the ancillary was determined during each impact $\#i$ of the impact procedure. The same signal
 175 processing method as the one presented in [15, 16, 17] was employed in order to analyze the impact
 176 force signal $s(t)$ measured at the hammer lower surface. An indicator, noted D , was calculated
 177 for each impact $\#i$. The indicator D , given in milliseconds, corresponds to the interval between
 178 the times t_2 and t_1 of the second and the first local maxima of the signal $s(t)$ respectively (see
 179 [15, 17, 16] for more details).

180 3. Results

181 3.1. Analysis of the FS insertion: reference case

182 The variation of the positions of the hammer's impact surface and of the ancillary's upper
 183 surface during an impaction procedure composed of ten impacts is shown in Fig. 2 for the reference
 184 case ($E_t = E_t^*$, $IF = IF^*$, $\mu = \mu^*$ and $v_0 = v_0^*$). During each impact $\#i$, the hammer bounces

185 on the ancillary fixed to the femoral stem, which is illustrated by the local minima on the curve
 186 representing the hammer position (see Fig. 2). The femoral stem displacement U_I is higher at
 187 the beginning of the insertion procedure. The position of the ancillary varies by less than 0.25
 188 mm between each impact after the 6th, which indicates that from a macroscopic perspective, the
 189 femoral stem may be considered as almost fully inserted into the host bone.

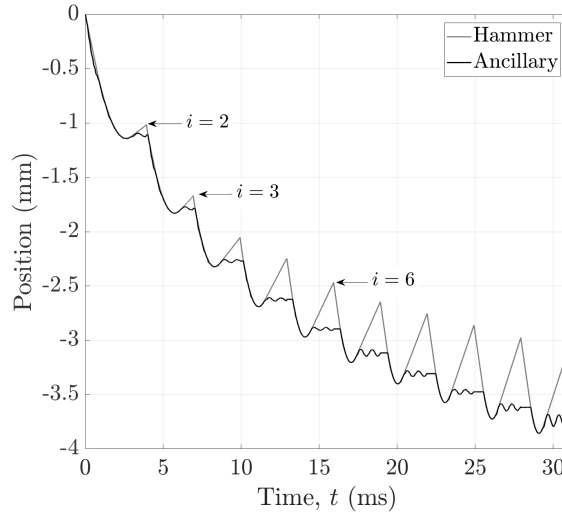


Figure 2: Positions of the hammer impact surface (grey line) and of the ancillary upper surface (black line) along the z -axis obtained during the impaction for the reference case. The origin ($z = 0$) of the ordinate axis corresponds to the position of the upper surface of the ancillary at the end of the contact positioning for the reference case.

190 Figure 3 shows the spatial variation of the Von Mises stresses in the peri-implant bone tissue
 191 after one, three, six and ten impacts realized during the insertion procedure for the reference case.
 192 As shown in Fig. 3, the stresses are concentrated around the contact region. First, stresses are
 193 localized around the bone-implant interface corresponding to the proximal curvature of the implant
 194 (indicated by the circles in Fig. 3 for impact #1) at the beginning of the insertion and then they
 195 extend to the distal region after several impacts.

196 The description of two impacts (#1 and #3) measured during the femoral stem insertion
 197 procedure is illustrated in Fig. 4 for the reference case. The variation of the force applied between
 198 the hammer and the ancillary as a function of time is shown in Fig. 4a for the impact #1
 199 (respectively in Fig. 4c for the impact #3). The variation of the position of the ancillary and the
 200 hammer during the impact #1 (respectively impact #3) is represented in Fig. 4c (respectively 4d).
 201 The first peak of the force signals $s(t)$ corresponds to the initial hammer blow on the ancillary.
 202 The following peaks represent the rebounds of the ancillary on the hammer. When the curves of
 203 the hammer and ancillary positions shown in Figs. 4b and 4d are superposed, $s(t)$ is shown to

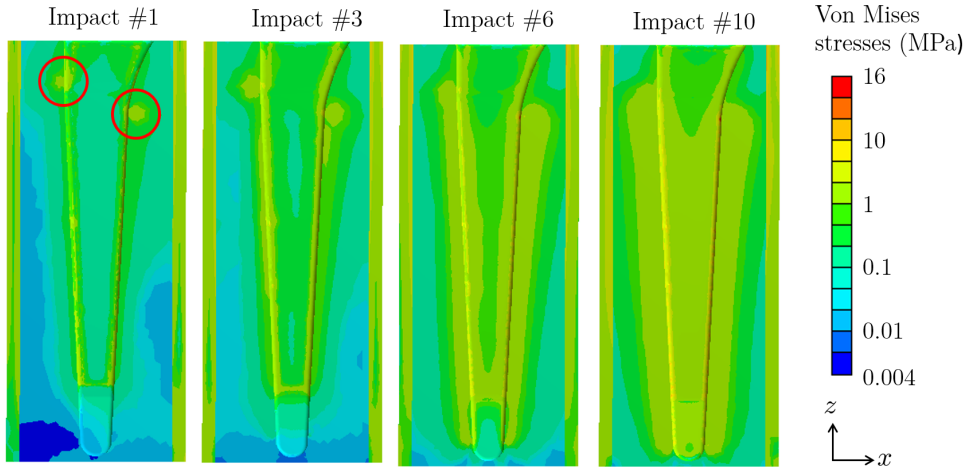


Figure 3: Von Mises stresses in the peri-implant femoral bone after one, three, six and ten impacts for the reference case. The circles indicate the bone area corresponding to the proximal curvature of the implant.

204 be strictly positive, which corresponds to a rebound of the hammer on the ancillary. The time
 205 difference between the initial hammer blow (peak #1) and the first rebound of the ancillary on
 206 the hammer (peak #2) varies throughout the impaction procedure. The time of the second peak
 207 is around 0.9 ms for the impact #1 (see Fig. 4a) and 0.5 ms for the impact #3 (see Fig. 4c).

208 Several examples of the signal $s(t)$ corresponding to the variation of the impact force as a
 209 function of time measured between the hammer and the ancillary are shown in Fig. 5 for different
 210 impacts # i during the insertion procedure for the reference case. The impact number # i is
 211 indicated above each second peak of the force signal $s(t)$. The value of the time difference described
 212 in Fig. 4 and defined as the indicator D [15, 16, 17] decreases during the implant impaction
 213 procedure. In particular, the variation of the indicator D as a function of the impact number # i
 214 is shown in Fig. 6 for the reference case, together with femoral stem displacement U_I (Fig. 6a)
 215 and the BIC ratio (Fig. 6b). The time difference D first decreases as a function of the impact
 216 number # i and then stays constant and equal to around 0.23 ms after seven impacts. The total
 217 implant displacement after 10 impacts is around 4 mm for the reference case (see Fig. 2). Note
 218 that the implant displacement is calculated from the beginning of the impaction procedure, once
 219 the implant is positioned inside the bone cavity. The implant displacement U_I is higher at the
 220 beginning of the impaction procedure than at the end. Even if the displacement still varies after
 221 the impact #10, the variation of U_I between the impacts #10 and #9 is about 0.25 mm, which is
 222 much smaller than its variation about 0.75 mm between the impacts #1 and #2 (see Fig. 2 and
 223 6). Similarly, 80% of the BIC ratio is reached after the four first impacts. The BIC ratio only

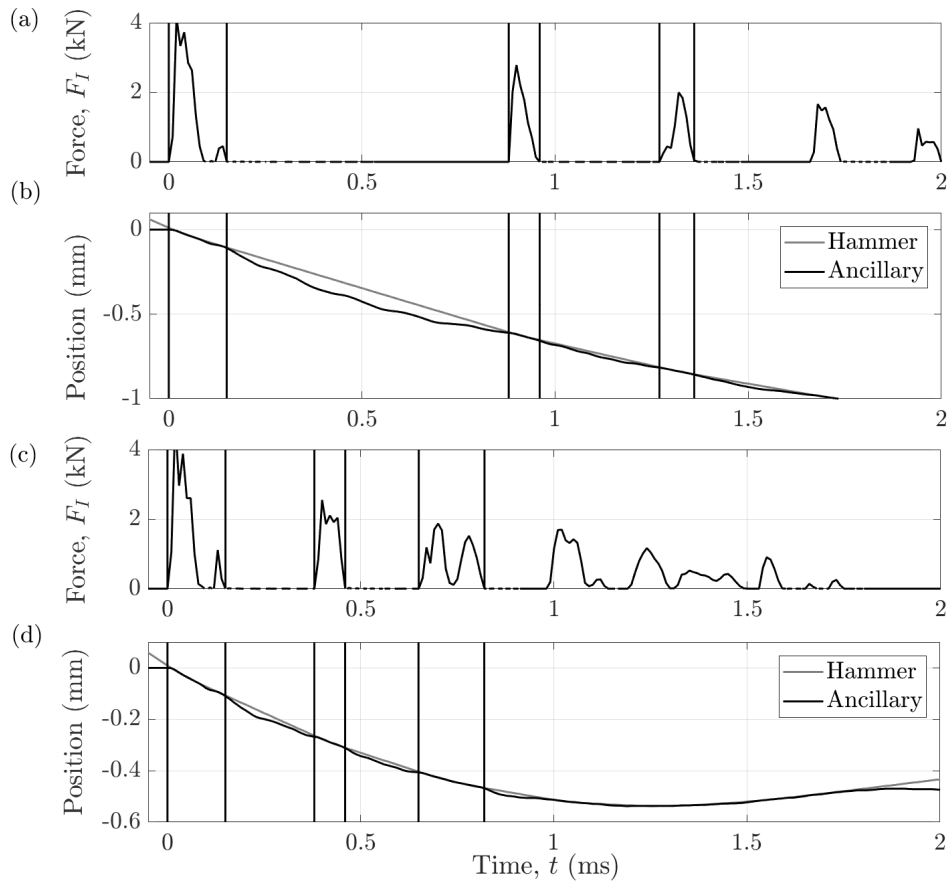


Figure 4: Description of the impact realized during femoral stem insertion for the reference case. a) (respectively c): force measured at the hammer lower surface and b) (respectively d) positions of the hammer and of the ancillary along the z -axis during the impact #1 (respectively impact #3).

224 increases from 10% for the six last impacts.

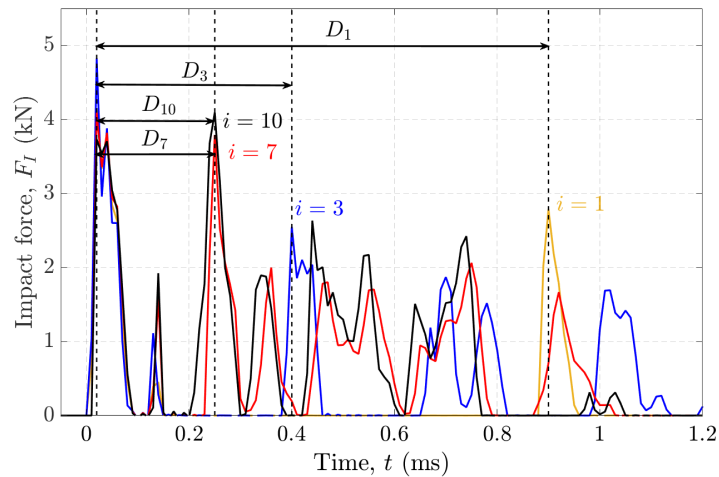


Figure 5: Illustration of signals $s(t)$ corresponding to the variation of the force as a function of time measured during different impacts # i applied to the ancillary to insert the femoral stem into the bone for the reference case.

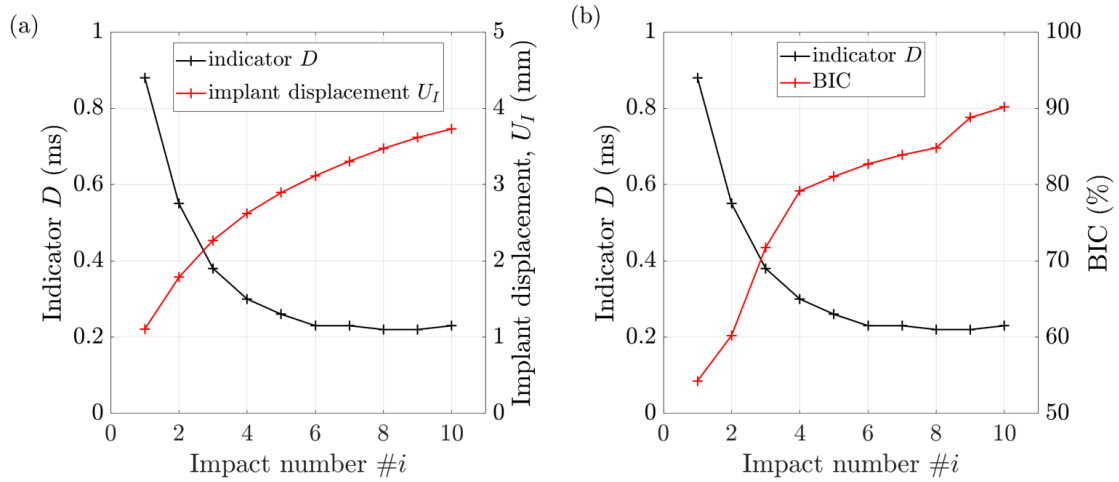


Figure 6: Variation of the indicator D , the implant displacement U_I (a) and the BIC ratio (b) as a function of the impact number $\#i$ during the femoral stem insertion procedure for the reference case.

225 3.2. Influence of the environment on the FS insertion: a parametric study

226 Figure 7 shows the influence of the trabecular bone Young's modulus E_t , the friction coefficient
 227 μ , the impact velocity v_0 and the interference fit IF on the BIC ratio as a function of the impact
 228 number $\#i$. The values of the BIC ratio always increase during the femoral stem insertion procedure
 229 for all values of E_t (a), μ (b), v_0 (c) and IF (d). Except for the case $E_t = 600$ MPa (see Fig. 7,
 230 which will be discussed in Section 4), the increase of the BIC ratio is higher at the beginning of the
 231 impaction procedure and the BIC asymptotically reaches a threshold value during the impaction
 232 procedure. The number of impacts necessary to obtain the threshold depends on the configuration
 233 and is smaller for the lowest values of E_t , μ and IF and for the highest values of v_0 .

234 Overall, for any impact number $\#i$, the BIC ratio increases when E_t , μ , IF decrease and when
 235 the impact velocity v_0 increases (see Fig. 7). The BIC ratio reached at the end of insertion ($i = 10$)
 236 varies between 74% and 97% according to the value of E_t , between 81% and 96% according to
 237 the value of μ , between 60% and 98% according to the value of v_0 and between 81% and 91%
 238 according to the value of the interference fit IF . A difference of BIC ratio of 40% is obtained after
 239 the tenth impact for the two extreme values of impact velocities considered herein: $v_0 = 0.5$ m/s
 240 and $v_0 = 1$ m/s (Fig. 7c). In particular, the BIC ratio corresponding to $v_0 = 0.5$ m/s does not
 241 significantly increase after the 7th impact, which may be explained by insufficient tangential forces
 242 at the bone-implant interface produced by an impact with $v_0 = 0.5$ m/s compared to the normal
 243 forces. For $v_0 = 0.5$ m/s, it may be hypothesized that continuing the impaction procedure with
 244 such velocity would not lead to an increase of the BIC ratio.

245 Figure 8 shows the variation of the indicator D as a function of the BIC ratio during the femoral

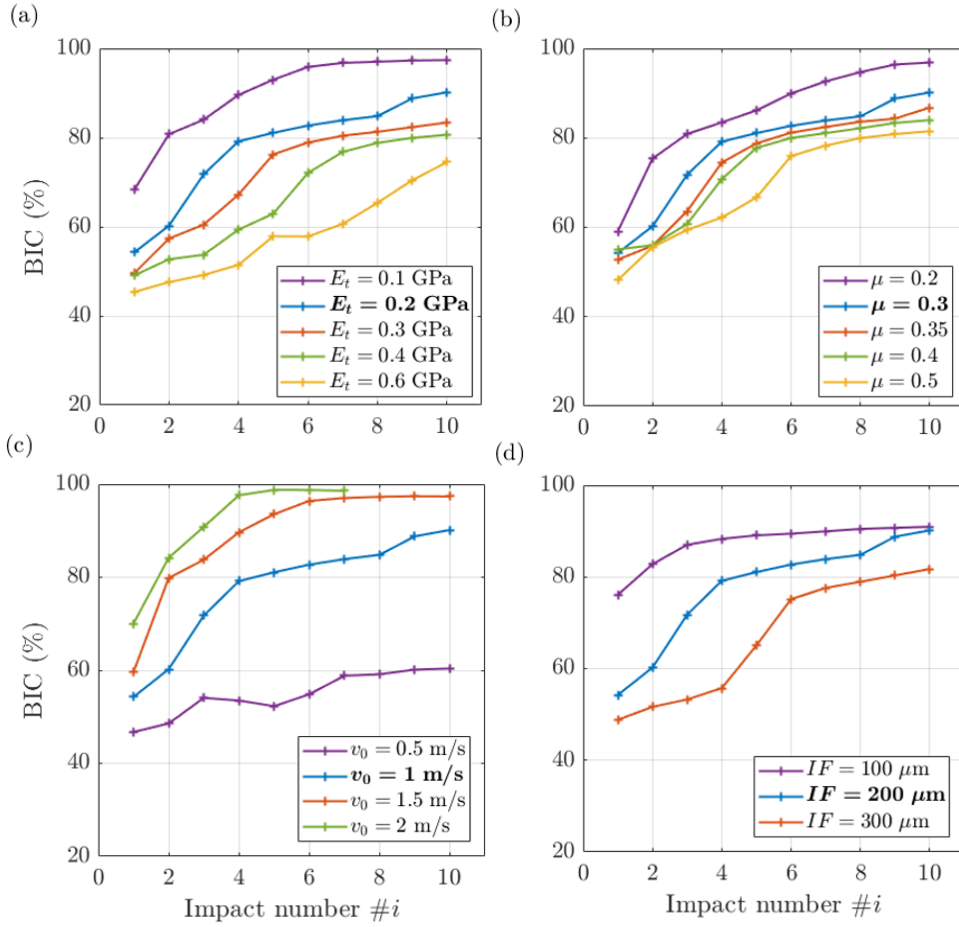


Figure 7: Variation of the BIC ratio as a function of the impact number $\#i$ during the femoral stem insertion procedure into the bone. The results are presented for different values of the trabecular bone Young's modulus (a), friction coefficient μ (b), impact velocity v_0 (c) and interference fit IF (d). When one parameter is investigated, the others are set to their reference values. The reference case is highlighted in bold in the legend.

246 stem insertion for different values of trabecular bone Young's modulus E_t (a), friction coefficient
 247 μ (b), impact velocity v_0 (c) and interference fit IF (d). For any value of E_t , IF , μ , and v_0 , the
 248 indicator D first decreases as a function of the BIC ratio and then remains constant at a value
 249 close to 0.23 ms. The value of the BIC ratio corresponding to the convergence of D varies from 60
 250 % to 95 % according to the configuration. This value is smaller for higher trabecular bone Young's
 251 modulus E_t (see Fig. 8a), higher friction coefficient μ (see Fig. 8b) and higher interference IF
 252 (see Fig. 8d) and for smaller impact velocity v_0 (see Fig. 8c).

253 4. Discussion

254 The aim of the present study is to provide more physical insights on the dynamic phenomena
 255 occurring during the femoral stem insertion of the impaction procedure under various biomechanical

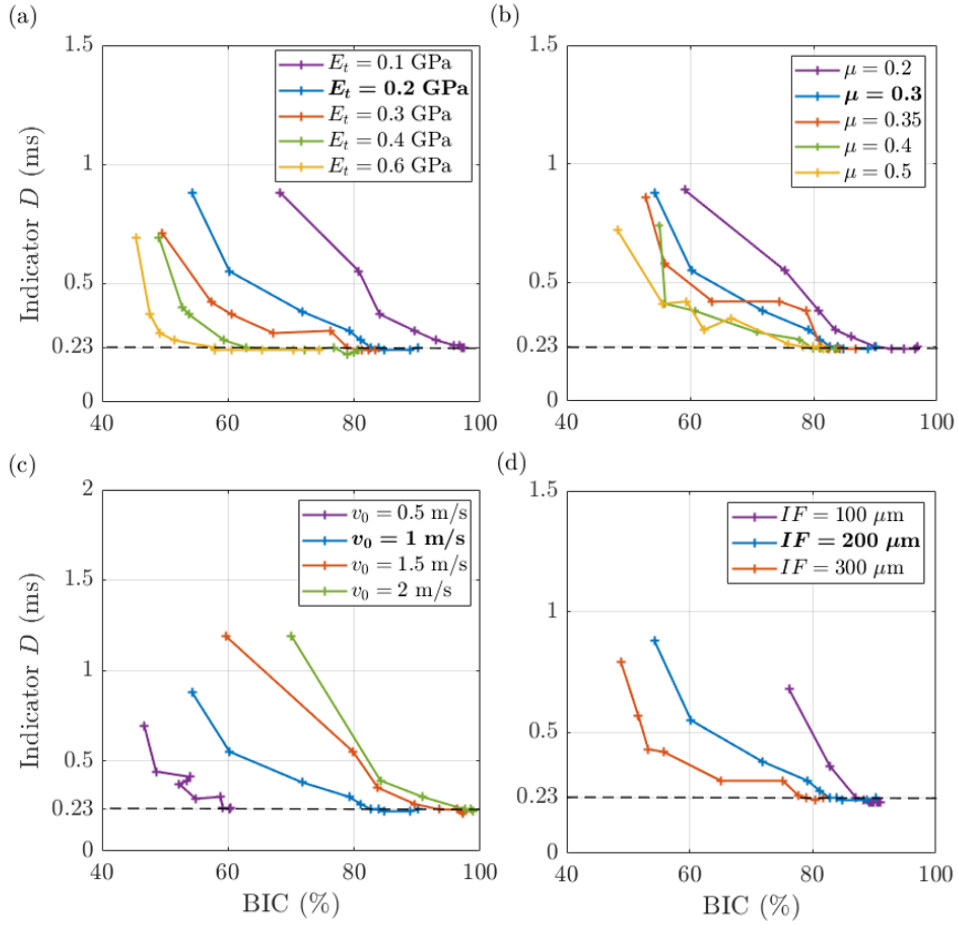


Figure 8: Variation of the indicator D as a function of the BIC ratio during the femoral stem insertion procedure into the bone. The results are presented for different values of the trabecular bone Young’s modulus E_t (a), friction coefficient μ (b), impact velocity v_0 (c) and interference fit IF (d). When one parameter is investigated, the others are set to their reference values. The reference case is highlighted in bold in the legend.

256 configurations. From the best of the author’s knowledge, this is the first work that analyzes the
 257 impact force during the femoral stem insertion using a 3D finite element model. In particular, the
 258 time indicator D [15, 17, 16], derived from the impact force signal is studied during the femoral
 259 stem insertion and its sensitivity to the biomechanical configuration is investigated. Moreover, the
 260 originality of the work is to analyze the influence of specific parameters on the impaction protocol
 261 and on the implant stability, such as the bone Young’s Modulus, the interference fit, the friction
 262 coefficient and the impact velocity, which had not all been studied so far [32, 31]. The findings of
 263 this study and the use of impact analysis to monitor implant insertion are of interest to improve
 264 not only the primary stability but also the long-term success of the implant, since it highly depends
 265 on the stability achieved during the impaction protocol [44].

266

267 *4.1. Influence of the parameters on the implant insertion and stability*

268 The maximum value of the BIC ratio achieved during femoral stem insertion as well as the
269 number of hammer impacts necessary to reach this value, were shown to strongly depend on the
270 value of E_t , which is related to the patient's bone tissue quality and on IF , μ and v_0 , which are
271 related to the surgical configuration (see Fig. 7). This observation confirms the importance to
272 adapt the surgical procedure to maximize the implant stability [5, 31, 28]. The BIC ratio first
273 increases with the impact number and then stays constant. A similar behavior was observed in
274 [29] where the quasi-static insertion force is representative of the cumulative impacts in the study
275 herein. The number of impacts necessary to reach the maximal BIC value is higher when the
276 bone-implant system stiffness is higher, that is for higher values of E_t , μ and IF . Considering a
277 high value of $E_t = 600$ MPa, the BIC ratio still increases after the 10th impact, which indicates
278 that the implant can not be fully inserted and the primary stability could not be optimized. The
279 non-linear evolution of the bone-implant contact ratio during the insertion procedure as well as
280 the influence of the friction coefficient on the BIC ratio are in agreement with the results found in
281 the study of Monea et al. [32]. However, the values of the maximal BIC ratio are higher in the
282 present study than in [32], which may be due to differences of implant geometries or of interference
283 fit values and which does not allow a quantitative comparison of the results.

284 The present parametric study reveals that for low initial velocity of the hammer ($v_0 = 0.5$ m/s),
285 applying additional impacts with the same intensity does not lead to an increase of the BIC ratio,
286 even for relatively low BIC ratio values (around 60%). This result confirms the importance of
287 considering the impact force, which is related to the initial velocity of the hammer v_0 , to maximize
288 implant stability [45, 31, 46].

289 Contrarily to the case of the ACI where the stress field was concentrated around the equatorial
290 rim [27, 28, 30], more regular distributions of the stress field at the peri-implant bone zone were
291 obtained (see Fig. 3), which may be explained by the large contact surfaces between the femoral
292 stem and the bone. Note that the level of Von Mises stresses computed by the present model is
293 consistent with the results obtained by Monea et al. [32], comprised between [1-20] MPa.

294 These results on the influence of the various parameters on the bone-implant contact are difficult
295 to validate experimentally, because i) it is not possible to measure the bone-implant contact ratio
296 during the implant insertion and ii) it is difficult to vary each parameter independently. Although
297 imaging techniques could be used, the presence of artefacts around the implant would prevent from
298 a quantitative measurement at the bone-implant interface. Moreover, it is difficult to control the

299 geometry and the size of the bone cavity as precisely as in a numerical model.

300 Overall, some recommendations may be provided to the surgeons to improve bone-implant
301 contact, based on the influence of the trabecular bone Young’s modulus, the friction coefficient,
302 the interference and the impact velocity on the implant insertion (see Fig. 7). First, the surgeon
303 should adapt the number of impacts depending on the bone quality: the lower is the bone Young’s
304 modulus, the lower is the number of impacts required to reach a given bone-implant contact.
305 Second, the choice of a lower press-fit conditions (*i.e.* IF values) and a lower friction coefficient
306 (*i.e.* μ values) allows to reach higher bone-implant contact for a given number of impact. Third,
307 the impact velocity should be high enough to reach a sufficient bone-implant contact. Based on
308 the findings for the reference case (see Fig. 7c) the impact velocity should be higher than 0.5 m/s.
309 In addition, the higher is the velocity, the lower is the number of impacts necessary to reach a
310 given bone-implant contact value.

311

312 4.2. Impact force analysis

313 The time signal of the impact force measured between the hammer and the ancillary, which
314 is illustrated in Fig. 4 for different impacts in the reference case, is qualitatively similar to the
315 experimental signals obtained in previous *in vitro* [15, 10] and *ex vivo* studies [17, 16]. In these
316 experimental studies, the signal was measured by a piezoelectric force sensor fixed on the hammer’s
317 impact surface. The numerical model allows to precisely compare the impact force signal and
318 in particular, the time and duration of the peaks with the positions of the ancillary and the
319 hammer, which is more difficult experimentally. The analysis of the impact confirms that the peaks
320 following the initial hammer impact correspond to the successive rebounds of the ancillary on the
321 hammer (see Fig. 4). For any value of trabecular bone Young’s modulus E_t , friction coefficient
322 μ , interference fit IF and impact velocity v_0 in the ranges considered herein, it was verified that
323 the impact force signal was always made up of several successive peaks (data not shown). In the
324 literature, other numerical and experimental studies, mostly focused on the acetabular cup implant
325 [47, 30] found that the ancillary, which is fixed to the uncemented implants, “rebounds” on the
326 hammer during the insertion procedure, which is coherent with the temporal variation of the force
327 signal observed with the present numerical model (see Fig. 2). Michel et al. [30] studied the AC
328 implant insertion by means of a 2D axi-symmetric model. While a similar behavior of the impact
329 force signal was obtained in the present study, the bone-implant contact evolution could not be
330 compared because of the difference of geometry.

331 The time duration between the impact and the first rebound, named indicator D , first, de-
 332 creases as a function of the impact number and then, reaches a threshold and stays constant (see
 333 Fig. 6). This behavior was also observed experimentally in previous studies with bone mimicking
 334 samples [15, 10] bovine bone sample [16] and anatomical subjects [17], a situation closed to the
 335 operating room, allowing for the definition of an insertion end-point criterion based on the con-
 336 vergence of the indicator. However, these studies did not investigate the variation of the indicator
 337 as a function of the bone-implant contact, as it is not possible to measure such quantity during
 338 the insertion. In previous numerical works on press-fitted implants, Michel et al. [30] and Bishop
 339 et al. [48, 31] also showed that the time variation of the impact force signal provides information
 340 on the implant stability for the acetabular cup implant and the femoral stem, respectively. How-
 341 ever, the difference of the configuration (implant geometry, bone anatomy) with Michel et al. [30]
 342 and Bishop et al. [48, 31] does not allow to compare the different studies quantitatively. In the
 343 present study, the insertion end-point criterion based on the convergence of the indicator D was
 344 shown to be in good agreement with the surgeon proprioception and the implant insertion depth.
 345 The present parametric study proves that the indicator D converges to 0.23 ms for any value of
 346 E_t , μ , IF and v_0 (see Figure 8). However, for several configurations, the BIC ratio continues
 347 to increase after D reaches this threshold of 0.23 ms. The number of impacts needed for D to
 348 converge towards its threshold (0.23 ms) is lower when the bone-implant system rigidity is higher
 349 (*i.e* higher trabecular bone Young's modulus E_t , friction coefficient μ and interference fit IF). In
 350 addition, the BIC ratio corresponding to the convergence of D is lower when considering a higher
 351 bone-implant system rigidity. This result reveals that the indicator D is not directly correlated to
 352 the BIC ratio but rather to the global stiffness of the bone-implant system. Therefore, the pull-out
 353 force, which was shown to increase as a function of the bone-implant rigidity [29], could also be
 354 used (in addition to the BIC ratio) to evaluate the sensitivity of the indicator D to the femoral
 355 stem stability. It is worth noting that the implant displacement produced from the last impacts of
 356 the impaction procedure, for which the indicator D stays constant, is smaller than 0.25 mm (see
 357 Fig. 6 for the reference case), which is too low to be measurable in the clinic and may be neglected.

358 Although the variation of the indicator D as a function of the impact number is in good
 359 qualitative agreement with previous experimental studies, the value of the convergence threshold
 360 slightly differs. It was shown herein that the indicator D converges to 0.23 ms for any value of
 361 E_t , μ , IF and v_0 . However, experimental results showed that the indicator D reached a threshold
 362 comprised between 0.4 and 0.6 ms according to the type of the bone (femur mimicking phantoms

363 [15], bovine femur bone [16] or human bone [17]). Multiple factors can explain this difference. First,
364 the material properties considered in the model are not fully representative to the real materials.
365 In particular, while bone tissue behaves as a viscoelastic material [49, 50], only elastic materials
366 are considered in the present model, which does not account for dissipation mechanisms. Note
367 that this assumption has already been made in previous similar modeling approaches [30, 28].
368 Second, the boundary conditions at the distal femur do not exactly reproduce the clamping nor
369 the anatomical conditions considered in the experimental configurations, which is likely to modify
370 the resonance of the bone-implant system and therefore the time duration between the rebound
371 of the ancillary on the hammer. Eventually, a cylinder represents the femoral bone, which differs
372 from a real femur anatomy especially in the proximal part and may also influence the stiffness of
373 the bone-implant system, and thus, the number of impacts necessary to insert the implant and the
374 corresponding value of the time indicator.

375 Overall, this study confirms that impact analysis is a promising non-invasive method to monitor
376 implant insertion (see Fig. 6 and 8), which supports the previous experimental findings [15, 17, 16]
377 and open the path towards a clinical study. However, this numerical study rises a limitation
378 concerning the sensitivity of the indicator D derived from the impact force signal, which no longer
379 varies for small changes of BIC ratio at the end of insertion. Therefore, the method could be coupled
380 with other monitoring methods studied in the literature such as vibration analysis [29, 10, 51] or
381 acoustic methods [8].

382

383 *4.3. Limitations and perspectives*

384 The finite element model developed in this study presents several limitations in addition to
385 the ones mentioned above. First, the geometrical configuration differs between the experimental
386 and numerical approaches. The thickness of the cortical bone was modeled as a uniform layer of
387 3.5 mm whereas it is actually non-uniform. Nonetheless, since the femoral stem is only in contact
388 with trabecular bone in the model herein, the uniform cortical bone thickness is not expected to
389 significantly influence the results. Moreover, an “ideal” bone cavity is modeled, whereas it was
390 shown that the cavity reaming may vary between surgeons [52]. The cavity reaming as well as the
391 impact direction may influence the femoral stem insertion into the bone [53]. In particular, the
392 femoral stem implant is perfectly aligned to the bone cavity at the beginning of insertion and the
393 impact force is purely vertical. However, the horizontal displacements along the x -direction are
394 allowed in our model. Eventually, it would also be relevant to consider other implant geometries,

395 since it is expected to influence the evolution of the bone-implant contact ratio as a function of the
396 impact number. Nonetheless, the stem type used in this study is largely employed for uncemented
397 surgeries, due to the cervico diaphyseal angle of 132° and the medial curvature adapted to different
398 morphologies [54], which confirms the relevance of the results obtained herein for most uncemented
399 procedures.

400 Second, bone tissue is known to exhibit viscoelastic, anisotropic [55] and heterogeneous [33]
401 properties. However, homogeneous, isotropic and elastic materials were assumed for all configu-
402 rations considered throughout this study because it allows to change only one parameter (Bone
403 Young's Modulus) rather than an important number if a more realistic assumption was made.
404 Heterogeneous and patient specific bone properties could be taken into account using CT scans to
405 recover the bone anatomy along with the spatial distribution of the bone density [56, 57, 58, 59].
406 The anisotropy [60, 55] of the trabecular bone could also be investigated, together with its vis-
407 coelastic behavior, which is out of the scope of the present work. The aim of the present study
408 was to investigate the influence of several parameters which are difficult to determine and control
409 experimentally on the phenomena occurring during femoral stem insertion. For that purpose, we
410 assumed a simplified material model for the parametric study, where only the global stiffness of the
411 bone was considered via the Young's modulus and neglecting the anisotropic bone properties [60],
412 to simplify the comparison between the different configurations. Overall, the comparison between
413 the different configurations should not be affected by this assumption, which was made consistently
414 for all of them.

415 Third, plastic deformations [61], as well as bone damage [48, 62] and bone compaction [53, 63]
416 are likely to occur in the peri-implant bone tissue during its insertion, which may affect the bone
417 cavity geometry and the bone stiffness. Because of the important stress field generated when
418 inserting the implant, significant fluid circulation in the bone porosities may occur [64], which
419 could also affect the acoustical response of the bone-implant system. These phenomena, which
420 could be modeled through bone damage modeling or coupling with computational fluid dynamics,
421 were not taken into account in the present work as it was assumed that they affect less the impact
422 force signal than the range of parameters chosen in the parametric study. Moreover, the value of
423 the Von Mises stresses in the peri-implant bone (see Fig. 3) at the end of insertion remains inferior
424 to the tensile and compression yield stresses of the bone reported in the literature [65, 39, 66].

425 In future works, it will be relevant to go deeper into the development of patient specific models.
426 Towards this goal, neural networks (*e.g.* siamese networks) could help taking into account even

427 more parameters related to both the patient and the surgical procedures than the ones studied
428 in the present work. Such analysis could provide more insights on their influence on the implant
429 insertion and stability. In addition, data fusion techniques could allow combining information from
430 various available sources including for instance: the force sensor, medical imaging and the surgeon
431 proprioception. This last point could provide a more comprehensive understanding of the influence
432 of the biomechanical environment on the implant stability and the impact analysis. Thereby,
433 artificial intelligence could help not only, to predict primary stability but also secondary stability.
434 Because of the wide variations observed in the clinic among patients and surgical protocols, these
435 techniques are of great interest to improve patient outcomes and to progress towards the use of
436 per-operative impact-based methods to optimize the implant insertion procedure.

437 **5. Conclusion**

438 In the present study, a 3-D finite element model of the femoral stem impaction into the bone
439 is proposed to provide more physical insights on the dynamic phenomena occurring during unce-
440 mented implant insertion. The femoral stem insertion is studied in terms of implant displacement,
441 bone-implant contact ratio and impact force for various values of bone properties, interference fit,
442 bone-implant-contact friction coefficient and impact velocity. The results emphasize the necessity
443 to adapt the number and velocity of the impacts depending on the biomechanical configuration to
444 reach a satisfying BIC ratio. The impact force is shown to vary during the impaction procedure.
445 A time indicator D is derived from the impact force signal based on previous experimental stud-
446 ies. This indicator corresponds to the time difference between the initial hammer impact and the
447 rebound of the ancillary on the hammer. The indicator D decreases with the impact number and
448 converges to a threshold value of 0.23 ms, independently of the biomechanical configuration. Based
449 on the results of this study, this indicator could be used experimentally to retrieve a macroscopic
450 bone-implant stiffness. Since this indicator allows real-time monitoring based on the temporal vari-
451 ation of the impact force only, this approach could be employed during the impaction procedure
452 to guide the surgeon to optimize implant insertion.

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459 **7. Declaration of Conflicting Interests**

460 The authors declare that they have no financial or non-financial interests that are directly or
461 indirectly related to the work submitted for publication.

462

463 **8. Data availability**

464 The data may be available upon reasonable request.

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