

# 1 Homogenized finite element models can accurately predict screw 2 pull-out in continuum materials, but not in porous materials

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4

## 5 Abstract

6 **Background and Objective:** Bone screw fixation can be estimated with several test methods such as  
7 insertion torque, pull-out, push-in and bending tests. A basic understanding of the relationship between  
8 screw fixation and bone microstructure is still lacking. Computational models can help clarify this  
9 relationship. The objective of the paper is to evaluate homogenized finite element (hFE) models of bone  
10 screw pull-out.

11 **Methods:** Experimental pull-out tests were performed on three materials: two polyurethane (PU) foams  
12 having a porous microstructure, and a high density polyethylene (HDPE) which is a continuum material.  
13 Forty-five titanium pedicle screws were inserted to 10, 20, and 30 mm in equally sized blocks of all three  
14 materials ( $N = 5/\text{group}$ ). Pull-out characteristics *i.e.* stiffness ( $S$ ), yield force ( $F_y$ ), peak pull-out force ( $F_{ult}$ )  
15 and displacement at  $F_{ult}$  ( $d_{ult}$ ) were measured. hFE models were created replicating the experiments. The  
16 screw was modeled as a rigid body and 5 mm axial displacement was applied to the head of the screw.  
17 Simulations were performed evaluating two different conditions at the bone-screw interface; once in which  
18 the screw fitted the pilot hole exactly ("free-stressed") and once in which interface stresses resulting from  
19 the insertion process were taken into account ("pre-stressed").

20 **Results:** The simulations representing the pre-stressed condition in HDPE matched the experimental data  
21 well;  $S$ ,  $F_y$ , and  $F_{ult}$  differed less than 11%, 2% and 0.5% from the experimental data, respectively, whereas  
22  $d_{ult}$  differed less than 16%. The free-stressed simulations were less accurate, especially stiffness (158%  
23 higher than the pre-stressed condition) and  $d_{ult}$  (30% lower than pre-stressed condition) were affected. The  
24 simulations representing PU did not match the experiments well. For the 20 mm insertion depth,  $S$ ,  $F_y$  and

25  $F_{ult}$  differed by more than 104%, 89% and 66%, respectively from the experimental values. Agreement did  
26 not improve for 10 and 30 mm insertion depths.

27 **Conclusion:** We found that hFE models can accurately quantify screw pull-out in continuum materials such  
28 as HDPE, but not in materials with a porous structure, such as PU. Pre-stresses in the bone induced by the  
29 insertion process cannot be neglected and need to be included in the hFE simulations.

30 Keywords: Finite element method; Pull-out test; Simulation of screw insertion; Bone analog; Pre-stress  
31 modeling; Bone screw

32 Level of evidence: 5

33

## 34 **1. Introduction**

35 Bone screws are one of the most commonly used orthopedic implants worldwide. They are used for fixation  
36 of complicated bone fractures and for fixation of other implants under complex and cyclic loading [1]. In  
37 2-40% of patients, these screws dislocate and/or loosen with failure of the surrounding bone as the main  
38 reason [2].

39 Conventional *in-vitro* testing of the implant-bone structure using cadaveric bones is usually employed to  
40 evaluate mechanical fixation of screws [3, 4]. However, this approach is time-consuming, requires human  
41 specimens and is still not well standardized. Moreover, the complications listed above are difficult to predict  
42 and accommodate during implant design, leading to limitations in the robustness of each surgical solution  
43 [3]. Some studied screw pull-out *in-vitro* using both synthetic materials [5, 6] as well as human bone [7, 8].  
44 It has been suggested that thread “shape factor” *i.e.* the average product of pitch and thread depth, is an  
45 important factor and that, decreased thread pitch increases screw purchase strength in porous material [6].  
46 The concept of screw pull-out failure is based on the shear failure of an interface between the outer  
47 perimeter of the screw and the material in which it is placed. It is assumed that the shear failure of this  
48 interface will lead to pull-out in literature, and a thread shape factor is often computed to allow for different  
49 thread designs [5, 6, 9]. Novel screw designs are commonly evaluated via static and quasi-static loading  
50 according to ASTM F543 [10] using poly-urethane (PU) as bone analog material as specified in ASTM F  
51 1839 [11, 12]. It is worth to mention that the real *in-vivo* loosening of bone screws are affected by dynamic  
52 and cyclic loadings which is not implemented in ASTM F543. The PU foam as indicated in the ASTM  
53 standard has pore sizes ranging from 0.5 mm to 2.0 mm. Hence, whereas this standard ensures consistent  
54 and uniform material with properties similar to human cancellous bone, it does not necessarily ensure a  
55 proper representation of bone microstructure.

56 In contrast with experimental tests, computer simulations can provide a more efficient screening process  
57 for new design ideas or research questions and can provide cost savings as well as a reduced need for  
58 valuable tissue samples [13]. Several numerical models have been developed over the last few years aiming

59 to predict the deformation that occurs during a pull-out test of a bone screw. Due to the complex  
60 microstructure, different simplifying assumptions have been made, such as the use of a cylinder as  
61 simplified screw geometry [14], and perfect bonding between the screw and bone [15-18]. Finite element  
62 (FE) simulation of bone-screw interface has been carried out using either Micro FE [19] or homogenized  
63 FE (hFE) [20].

64 Different levels of complexity can be applied in FE modeling, *i.e.*, with respect to geometry, material  
65 properties and interface conditions. The bone anisotropy and microstructural variability between patients  
66 complicate the design of screw implants *i.e.* different screw designs may give different results in different  
67 subjects since each piece of trabecular bone is unique. Micro finite element ( $\mu$ FE) analysis has a high  
68 potential to resolve these phenomena, but still require proper implementation of the underlying non-linear  
69 effects and representation of the bone-screw interface [21]. Only a limited number of studies [21] have  
70 compared the results of numerical models with mechanical pull-out tests demonstrating a good agreement  
71 with either stiffness or strength [11]. Thus far, no data on primary stability of implants has been reported in  
72 terms of yield force and displacement at ultimate force, indicating a need for further development in this  
73 area.

74 hFE (also known as continuum FE) models offer an alternative with reasonable computational efforts even  
75 for entire bone-implant systems. While not explicitly resolving the complex geometry and mechanical  
76 behavior of the bone-screw interface, continuum models have been shown to be able to predict  
77 experimentally measured stiffness [4]. Nonlinear material behavior of the bone has been modeled as an  
78 elastoplastic material with multiple yield points [22].

79 Implants are usually inserted in the bone through a press-fit procedure where the drill hole is undersized  
80 with respect to the implant. The amount of undersizing is critical because too much undersizing will induce  
81 excessive press-fit leading to bone damage, which in turn will decrease primary stability and even lead to  
82 implant loosening [23-25]. No standardized technique exists to take these effects into account in finite  
83 element studies of pull-out process. Some have neglected these [11], while others have presented several  
84 modeling techniques to take the press-fit situation into account, *e.g.*, by incorporating a pre-stress

85 configuration [3, 13], through displacement of the interface boundaries [26], by reducing the bone material  
86 properties within at a specific boundary layer around the implant [27], by accounting for damage occurring  
87 at the bone-implant interface [28] and by changing the friction coefficients at the bone-screw interface [29,  
88 30].

89 This study aimed to quantify hFE pull-out characteristics *i.e.* stiffness (S), yield force ( $F_y$ ), peak pull-out  
90 force ( $F_{ult}$ ) and displacement at peak pull-out force ( $d_{ult}$ ) of screws in continuum materials as well as in  
91 porous materials and relate these to experimental tests. The tests included different bone analogs and screw  
92 insertion depths.

93

## 94 **2. Material and methods**

### 95 *2.1 Experiments*

#### 96 *2.1.1 Sample preparation*

97 Two different porous PU foams (Sawbones, Pacific Research Corporation, Vashon, Washington, USA) and  
98 a solid high density polyethylene (HDPE) sheet (Direct Plastics Ltd, Sheffield, UK) were cut into 4\*4\*6  
99 cm<sup>3</sup> blocks. The dimension of the blocks was chosen according to the dimension of the screws (section  
100 2.1.3). These polymers are recommended to use for mechanical testing according to ASTM F543 and  
101 ASTM F1717 [10, 31]. High density PU (HDPU) and low density PU (LDPU) can mimic cancellous and  
102 osteoporotic cancellous bone, respectively [32]. HDPE can replicate human vertebrae and strongly reduces  
103 interspecimen variability [33]. The mechanical properties of the three materials as provided by the  
104 manufacturers are summarized in Table 1.

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107

108 *Table 1. Material properties of the bone analog polymers used for both experimental and finite element*  
 109 *models. All Poisson's ratios for low density polyurethane (LDPU) and high density polyurethane (HDPU)*  
 110 *are considered 0.3 and no pore size was defined for homogenous high density polyethylene (HDPE)*  
 111 *materials.*

Bone analog	Density (Kg/m <sup>3</sup> )	Young's Modulus (MPa)	Pore size (mm)
LDPU	160	23	0.5-2
HDPU	320	137	0.5-1
HDPE	947	1000	

113

### 114 2.1.2 Pre-drilled hole

115 Fifteen HDPE blocks were pre-drilled to depths of 10, 20, and 30 mm (N=5/group); the 20 mm depth is  
 116 recommended in ASTM F543 [10]. Similarly, the two PU foams were cut into blocks (fifteen per foam)  
 117 and prepared for three insertion depths *i.e.* 10, 20 and 30 mm (N=5/group) to demonstrate potential effects  
 118 of insertion depth. The pilot hole size was considered 5.5 mm based on the recommendation of the  
 119 manufacturer. The pilot hole preparation has remarkable effects on results [34, 35] and all drilling  
 120 parameters kept constant during tests.

### 121 2.1.3 Screw insertion

122 Titanium conical pedicle screws (Fortex, X.spine cooperation, Cruiser Lane, United States of America)  
 123 were used in this study. The core and thread profile was conical and cylindrical, respectively. The core  
 124 diameters were 3.35 mm and 5.35 mm at the tip and the head portion, respectively. The pitch was constant  
 125 throughout the screw length and crest thickness gradually increased from distal to the proximal part of the  
 126 screw (Fig. 1). The screws were inserted into the pre-drilled hole using a torque meter (LT Lutron, TQ-  
 127 8800, Japan).

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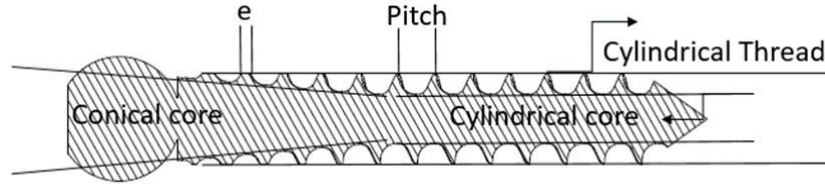


Figure 1. Different features of the pedicle screw used in this study. Crest thickness ( $e$ ) is the top thickness of a thread.

#### 2.1.4 Pull-out test

Pull-out test based on ASTM F543 standard was done using a unidirectional testing apparatus (DTM 25KN, Zwick-Roell, Germany). After placement of the pedicle screw within the HDPE and PU blocks, the orientation of the pedicle screw and tensile hook was set in the coaxial direction and the load cell was set to zero. Displacement control mode with a displacement rate of 5 mm/min was carried out for each sample. Load-displacement data were recorded at a rate of 25 Hz. The pull-out force over displacement was recorded for each test case and data acquisition was continued until the screw was pulled out completely.  $S$ ,  $F_y$ ,  $F_{ult}$  and  $d_{ult}$  were calculated for the five samples of the seven groups.  $S$  is the slope of linear elastic part of the force-displacement curve.  $F_y$  was determined as the intersection of a 0.2% offset line with the force-displacement curve [10].

## 2.2 Simulation

### 2.2.1 Geometry and mesh

Three-dimensional (3D) models of the HDPE and PU blocks and pedicle screw were created using Catia V5R21 and imported in Abaqus CAE 2017 (both software packages by Dassault Systèmes, Vélizy-Villacoublay, France). Boolean operation was used in order to assemble two parts and create the tapped hole in the 3D block model mimicking the experiments. The screw was finely meshed using 15522 4-node 3D bilinear rigid quadrilateral element. The mass of the screw was 5.1 grams. For the deformable 3D PU and HDPE blocks, 4-node linear tetrahedron element type were used. A radial seeding gradient was performed to obtain better mesh quality. Mesh distortion control was employed to avoid distortional errors.

152 The mesh of these blocks contained 121082 elements. The mesh convergence analysis was done for  
153 different seed sizes of 0.25, 0.5 and 1 mm.  $S$  and  $F_{ult}$  were evaluated rather than  $F_y$  and  $d_{ult}$  (Fig. 5). The  
154 reason that  $F_y$  was not included in the convergency analysis, was the high correlation of  $F_y$  to  $F_{ult}$ . Also,  $d_{ult}$   
155 was excluded because it was hardly affected by mesh size, hence, was not discernable in the convergency  
156 analysis. The analyses demonstrated that with a seed size of 0.5 mm convergency was reached; hence, a  
157 0.5 mm seed size around the pilot hole was chosen for all subsequent numerical analyses.

158

### 159 *2.2.2 Material properties*

160 The Dynamic Explicit approach was used in this study. An elastoplastic material model with yield strain  
161 equal to 10%, and 10% isotropic hardening [36, 37] was implemented for the HDPE blocks. Yield strains  
162 equal to 5%, and 5% isotropic softening were assigned to the LDPU and HDPU foams [38, 39]. Density  
163 and Young's modulus as provided by the manufacturer were assigned (Table 1). Poisson's ratio was set to  
164 0.3 for all blocks. Due to the notable differences between the elastic properties of the bone analogs and the  
165 screw, the latter was considered as a rigid body in all simulations.

### 166 *2.2.3 Interface modeling*

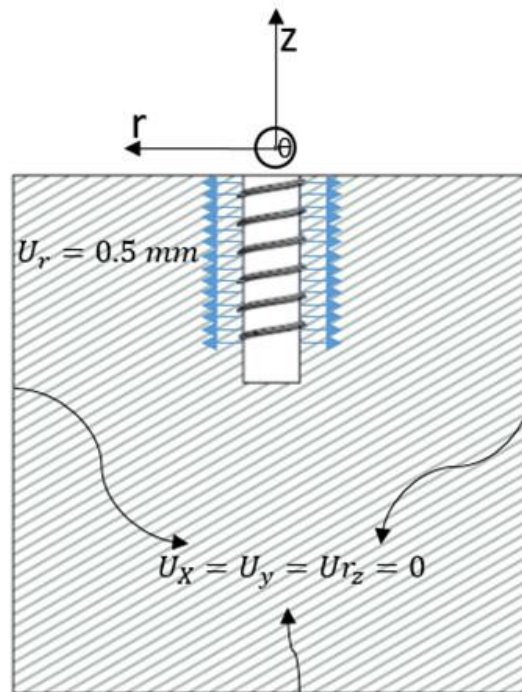
167 Surface on surface contact was defined in Abaqus dynamic explicit for the interface between the screw  
168 threads and the threaded hole in the bone analogs. Tangential friction contact of 0.6 [37] and hard normal  
169 contact were applied between the two bodies.

### 170 *2.2.4 Boundary conditions and loading protocols*

171 Simulations were performed evaluating two different conditions at the bone-screw interface. Once in which  
172 the screw fitted the pilot hole exactly without causing stress at the bone-screw interface ("free-stressed")  
173 and once in which interface stresses resulting from the insertion process were taken into account ("pre-  
174 stressed"). In the latter case, before starting the simulation of the pull-out process, the strains that develop  
175 due to the screw insertion process were quantified. Specifically, a radial displacement of 0.5 mm was



176 applied to the threaded part of block (Fig. 2). Two lateral and bottom faces were fixed in pre-straining step  
 177 in three directions *i.e.*  $U_x=U_y=U_{r_z}=0$ . The radial displacement equals the difference between the outer  
 178 diameter of the screw and the pilot hole. These 'pre-strains' were transferred to the screw-block model called  
 179 pre-stressed model in this study. In agreement with the pull-out experimental setup, the top surface of the  
 180 block was fixed in vertical directions except for a circular section in the center of the top surface of the  
 181 block replicating experimental setup test, (Fig. 3). All nodes on the screw were coupled to a reference point  
 182 placed on the head of the screw (Fig. 4). Quasi-static simulations were performed, where variable mass  
 183 scaling of  $10^{-6}$  was used to reduce the analysis time and it was ensured that kinematic energy remained  
 184 secure *i.e.* less than 5 % of the internal energy. The simulations were run on Microsoft windows (Intel ®  
 185 Xeon ® Gold 6152, 96 GB RAM) for an average time of 12 hours per sample. A 5-mm displacement was  
 186 applied to this point. The pull-out process was simulated by applying the displacement of the reference  
 187 point along the longitudinal directional of screw using a one-by-one tabular amplitude in Abaqus. Other  
 188 displacements and rotational components were set to zero.

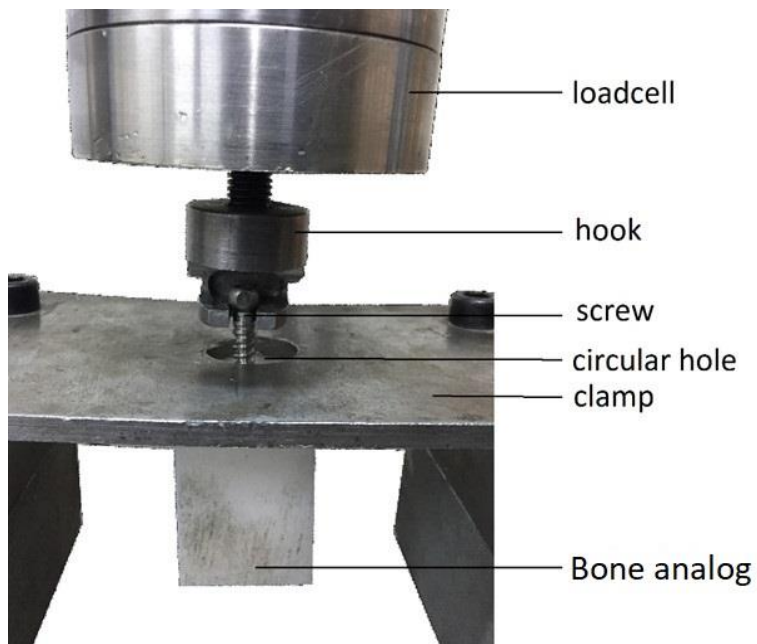


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Figure 2. Schematic boundary conditions of preconditioning step in FEM.

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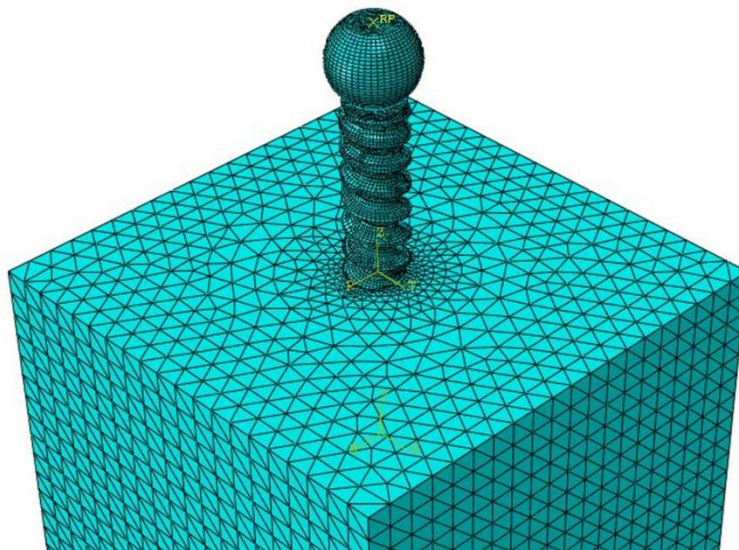


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*Figure 3. Pull-out setup test. All the faces were free except the top one with a central hole.*



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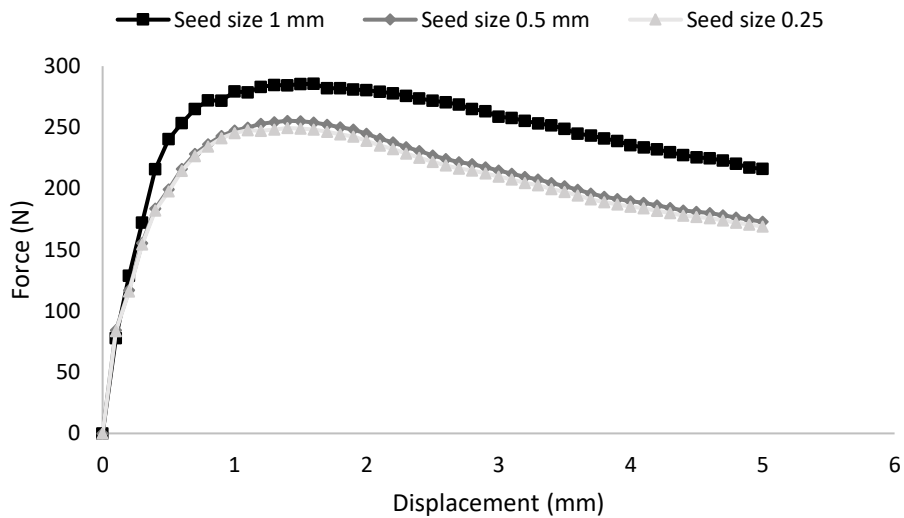
*Figure 4. The location of reference point and placement of the screw in the test block used to simulate the pull-out process.*

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202 *2.3 Criteria for validation and statistical analysis*

203 Validation of the FE results relative to the experimental measurements was performed for the parameters  
204  $S$ ,  $F_y$ ,  $F_{ult}$  and  $d_{ult}$ . Every single result was divided by the relevant average experimental result and was  
205 expressed as a percentage (Fig. 6). All the data for each test condition, *i.e.* polymer density and insertion  
206 depth were statistically analyzed using one-way ANOVA (Microsoft Excel 2003, Microsoft Corp.,  
207 Remond, WA, USA). A  $p$ -value of less than 0.05 was considered statistically significant. Furthermore, a  
208 Tukey-Kramer honesty significant difference (HSD) *post hoc* test was used to determine significant  
209 differences among the results in each test pair.



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211 *Figure 5. Force-displacement curves of 20 mm insertion depth in low density PU for different*  
212 *meshing seed sizes of 0.25, 0.5 and 1 mm.*

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218 **3. Results**

219 *3.1 Experimental results*

220 In all three bone analogs, increasing the insertion depth caused an increase in insertion torque (Table 2).  
 221 The maximum insertion torque was  $218 \pm 2.0$  N.cm for the 30 mm insertion depth in HDPE while the  
 222 minimum one was  $17 \pm 1.0$  N.cm for the 10 mm insertion depth in LDPU (Table 2).

223 *Table 2. The measured insertion torques for screws inserted into low density polyurethane (LDPU), high*  
 224 *density polyurethane (HDPU) and high density polyethylene (HDPE) to three insertion depths.*  
 225

Bone Analog	Group Density (kg/m <sup>3</sup> )	Insertion Depth (mm)	Insertion torque (N.cm)
LDPU	160	10	$17 \pm 1.0$
		20	$23 \pm 1.0$
		30	$22 \pm 1.5$
HDPU	320	10	$27 \pm 2.0$
		20	$45 \pm 2.0$
		30	$123 \pm 1.5$
HDPE	947	10	$89 \pm 3.0$
		20	$169 \pm 5.0$
		30	$218 \pm 2.0$

226  
 227 In all three materials the  $F_{ult}$  increased when increasing insertion depths (Table 3). The other pull-out  
 228 parameters also experienced an increase by increasing the insertion depth from 10 to 30 mm (Table 3). The  
 229 PU foam with high density had higher S,  $F_y$  and  $F_{ult}$  than the low density PU (Table 3). ANOVA test  
 230 indicated that all four parameters were significantly different between LDPU and HDPU ( $p < 0.01$ ) and  $F_{ult}$   
 231 in HDPE was higher than in both PU foams (Table 3).

232 In the HDPU foams with the standard 20 mm insertion depth, the mean S,  $F_y$  and  $F_{ult}$  were 375%, 228%  
 233 and 220% higher than those in the LDPU (Table 3). S,  $F_y$  and  $d_{ult}$  values in HDPE are higher than those in  
 234 PUs (Table 3) and all comparisons between PUs and PE experienced a significant difference ( $p < 0.01$ ).

235 *Table 3. Stiffness ( $s$ ), yield force ( $F_y$ ), peak pull-out force ( $F_{ult}$ ) and displacement at peak pull-out force ( $d_{ult}$ ) obtained from FE and measured*  
 236 *experimentally. The FE analyses were performed twice, one as a free-stressed and one as a pre-stressed for three different insertion depths in a low*  
 237 *and high density of polyurethane foam and high density polyethylene.*

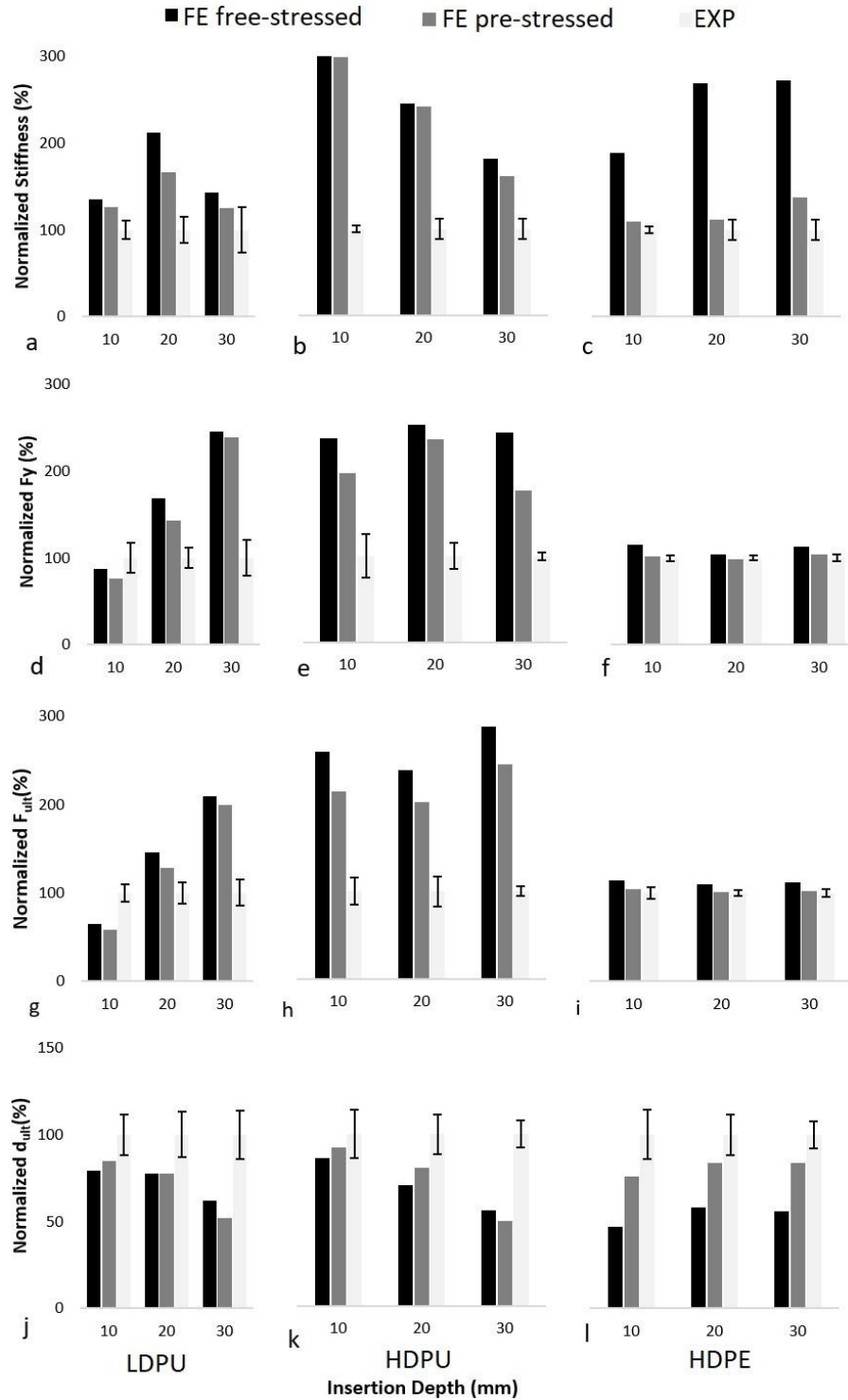
Group		Free-stressed FE				Pre-stressed FE				Experiment				
Bone Analog	Density (kg/m <sup>3</sup> )	Insertion depth (mm)	Stiffness (N/mm)	Yield force (N)	Pull-out force (N)	Displacement at PPF (mm)	Stiffness (N/mm)	Yield force (N)	Pull-out force (N)	Displacement at PPF (mm)	Stiffness (N/mm)	Yield force (N)	Pull-out force (N)	Displacement at PPF (mm)
<b>LDPU</b>	<b>160</b>	10	105	79	85	1.4	98	69	76	1.5	77.7 ± 8.3	90.1 ± 15.1	130.8 ± 13.3	1.77 ± 0.21
		20	182	237	252	1.6	143	201	223	1.6	85.8 ± 12.6	140.6 ± 16.0	173 ± 20.4	2.07 ± 0.65
		30	315	403	422	1.9	276	391	402	1.6	220.4 ± 56.9	164 ± 34.7	201 ± 29.6	3.06 ± 0.43
<b>HDPU</b>	<b>320</b>	10	410	379	506	1.4	401	315	418	1.5	134 ± 14.0	159.8 ± 40.6	195 ± 30.3	1.62 ± 0.23
		20	1002	1169	1323	1.4	988	1090	1120	1.6	408.2 ± 17.9	461.2 ± 70.6	554 ± 93.6	2.00 ± 0.13
		30	1576	2112	2710	1.9	1395	1524	2305	1.7	867.2 ± 74.7	865.6 ± 40.4	938.8 ± 54.2	3.44 ± 0.27
<b>HDPE</b>	<b>947</b>	10	1592	1813	1927	1.3	921	1602	1759	2.1	845 ± 34.5	1581 ± 5.0	1682 ± 106.0	2.76 ± 0.11
		20	5051	4921	5249	1.8	2086	4659	4824	2.6	1876 ± 215.0	4733 ± 120.7	4799 ± 174.0	3.10 ± 0.08
		30	6040	6918	7841	1.8	3042	6348	7122	2.7	2221 ± 255.0	6112 ± 222.0	7001 ± 301.0	3.23 ± 0.23

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239        *3.2 Finite element results*

240    In the simulations of the PU foams and HDPE, both the free-stressed and pre-stressed FE models  
241    demonstrated that  $F_{ult}$  increased when increasing insertion depth (Table 3). In PUs the increase in  $F_{ult}$   
242    resembled the experimental results, yet, only in a qualitative sense; the absolute values did not match,  
243    neither in the free-stressed nor in the pre-stressed conditions (Fig. 6.g and h). More specifically, the results  
244    of the free-stressed models of 20 mm insertion depth were, on average, 128%, 110%, and 92% higher for  
245    experimental  $S$ ,  $F_y$  (Fig. 6.a, b, d and e) and  $F_{ult}$  (Fig. 6.g and h), respectively. Likewise, the results of the  
246    pre-stressed model were 104%, 89% and 66% higher for experimental  $S$ ,  $F_y$  (Fig. 6.a, b, d and e) and  $F_{ult}$   
247    (Fig. 6.g and h), respectively.

248    In the simulations of the HDPE blocks, the results of the pre-stressed model closely matched the  
249    experimental findings; specifically, the findings for  $S$ ,  $F_y$  (Fig. 6.c and f) and  $F_{ult}$  (Fig. 6.i) were 11%, 2%,  
250    and 0.5% higher than the experimentally measured data, while  $d_{ult}$  (Fig. 6.l) was 16% lower in 20 mm  
251    insertion depth. In contrast, the results of the free-stressed model in 20 mm insertion depth deviated much  
252    more, especially for  $S$  and  $d_{ult}$  which were overestimated by 169% and underestimated by 42%, respectively  
253    (Fig. 6.c and l). Similarly, the predictions of FE pre-stressed models in 10 and 30 mm insertion depths  
254    reveals 9% and 5% difference between FE and experiments for  $S$  and  $F_{ult}$ , respectively while, these  
255    percentages are 88% and 15% difference for the free-stressed models (Fig. 6.c and i).



256

257 *Figure 6. A comparison between the experimentally measured data (the average set to 100%) and the data*  
 258 *as determined from the finite element analyses of the free-stressed and pre-stressed interface conditions for*  
 259 *a, b and c) stiffness (S), d, e and f) yield force ( $F_y$ ), g, h and i) peak pull-out force ( $F_{ult}$ ) and j, k and l)*  
 260 *displacement at peak pull-out force ( $d_{ult}$ ) for the a, d, g and j) low-density polyurethane (LDPU), b, e, h and*  
 261 *k) high-density polyurethane (HDPU) and c, f, i and l) high-density polyethylene (HDPE), respectively. For*  
 262 *each insertion depth, the average experimental data was set to 100%.*

#### 263 4. Discussion

264 Several studies have experimentally quantified the pull-out characteristics of bone screws using synthetic  
265 bone [5, 40, 41], animal samples [42-44] and human cadavers [7, 8, 19]. Furthermore, various studies have  
266 numerically evaluated  $S$  [19, 21, 45, 46] and  $F_{ult}$  using a variety of assumptions among which bonded  
267 interfaces, smoothed screw geometry [13] and linear material properties. In this study hFE was used to  
268 mimic experimental pull-out test in a LDPU and HDPU foam as well as in HDPE which can be considered  
269 a continuum material. In order to simulate the mechanical consequences of the insertion process, two  
270 labelled modeling approaches *i.e.* "free-stressed" and "pre-stressed" were compared.

271 We demonstrated that the FE models can replicate well the pull-out characteristics in the PE material, but  
272 that results for the porous PU foams were far off. Hence, whereas the material properties of PU as used in  
273 this study describe well the mechanical characteristics at the apparent level, they do not represent the  
274 mechanical characteristics of the PU material in close vicinity to the screw. This can be explained by the  
275 microstructure of the PU and HDPE which differ strongly. The PU foams used in this study consisted of at  
276 least 0.5 mm pores which can be assumed as a porous model while the HDPE did not include any pores at  
277 this length scale and can be considered as continuum material. The improved FE pull-out predictions as  
278 seen in PE are not a consequence of increased material properties such as density, because the results for  
279 the HDPU foams are worse than those for the LDPU foams (Table 3). We hypothesize that in order to  
280 replicate the pull-out characteristics in foams a more accurate description of the porous nature of the  
281 material in vicinity of the screw needs to be taken into account, which can be achieved using so-called  
282 micro-finite element analyses.

283 We found that the radial displacements applied in the pre-stressed models could mimic the insertion process  
284 in HDPE. These displacements improved the pull-out characteristics slightly in PU, though in absolute  
285 numbers the findings were still far off from the experimentally measured data; this disagreement seems to  
286 be dominated by the continuum approach in the hFE models, which neglects the microstructure of the  
287 materials.



288 In the FE simulations, all pull-out characteristics except  $d_{ult}$  were found to be lower in the pre-stressed  
289 model than in the free-stressed one (Fig. 6.a to i). During screw insertion, the threads induce damage to the  
290 materials. The damage has not been modeled directly in this study, but the induced stresses in the region of  
291 block-screw interface called pre-stresses were considered. Pre-stresses weaken the material especially in  
292 the region of interface [27, 37]. In the FE screw pull-out simulations, material adjacent to the block-screw  
293 interface experienced yielding which have already yielded in insertion step.

294 For the standard insertion depth, the  $d_{ult}$  was on average  $2.07 \pm 0.65$  and  $2.00 \pm 0.13$  mm for LDPU and  
295 HDPU, respectively. The  $d_{ult}$  for HDPE was on average  $3.10 \pm 0.08$  mm, *i.e.* 55% and 50% higher than in  
296 LDPU and HDPU, respectively (Fig. 6.j, k and l). These differences are 36% and 41% for LDPU and HDPU  
297 in 10 mm insertion depth and 7% and 5% in 30 mm insertion depth in comparison with HDPE, respectively.  
298 This difference can be explained by the damage properties of the materials. The higher the fracture  
299 toughness, the more the material will deform before rupture. Indeed, the fracture toughness of PU is 47  
300  $J/m^2$ , which is much less than the fracture toughness of HDPE which is 4660  $J/m^2$  [47].

301 An explicit solver has been used in this study. Due to the limited convergence, implicit solvers cannot  
302 handle the excessive element distortion resulting from the implementation press-fit especially in  $\mu$ FE  
303 models [37]. The high deformation related to the implantation press-fit can best be captured by explicit  
304 solvers, as they provide the option of element deletion and distortion controlling for highly distorted  
305 elements. The explicit hFEM has been able to simulate the implant insertion in isotropic trabecular bone  
306 while neglecting the effect of bone geometry and volume fraction [40].

307 In our experimental mechanical tests of the standard 20 mm insertion depth in PU foams, the  $S$ ,  $F_y$  and  $F_{ult}$   
308 were 375%, 228% and 220% higher in the high density case as compared to the low density case; this is  
309 related to the better grip [32, 33]. Moreover, these pull-out characteristics experienced an increase of 183%,  
310 82% and 53% in LDPU and 547%, 441%, and 381% in HDPU, respectively by increasing the insertion  
311 depth from 10 to 30 mm which is in agreement with the study of Vargese *et.al* [48].

312 There are a few limitations of the current study. First, the insertion process has not been simulated directly  
313 but the induced stresses were considered as “pre-stresses” modeled due to calculation cost savings. The

314 concept to measure pre-stresses is still remaining inaccurate as Meyer *et. al* proposed in their study to  
315 measure pre-stresses directly by splitting the screw-block into two pieces [49]. Our implementation of  
316 applying radial displacement led to the development of pre-stresses adjacent to the threads and equal to the  
317 yield stresses of the materials. Second, the post-yield behavior of the PU foams and HDPE has been  
318 modelled as a linear softening and linear hardening, respectively. This modeling approach may present a  
319 simplification of the physical reality, especially for large strains. For the purpose of this paper this approach  
320 is justified because the aim of our study was not to determine the rupture point of the material. And third,  
321  $\mu$ FE could be implemented for PU foams but currently the ability of solvers to provide nonlinear contact  
322 deformation is limited.

323

## 324 **5. Conclusion**

325 We conclude that the hFE models replicated the pull-out characteristics well in a continuum material, *i.e.*  
326 HDPE, but not in porous materials, *i.e.*, LDPU and HDPU. Furthermore, the implementation of radial  
327 displacements to the bone analog improved the prediction of all pull-out characteristics. These radial  
328 displacements developed pre-stresses in the model simulating the effects of the insertion process.

329

330

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333 *Harry van Lenthe: Conceptualization, Supervision, Writing- Reviewing and Editing,*

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336

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