

The effect of bone ingrowth depth on the tensile and shear strength of the implant–bone e-beam produced interface

M. Tarala · D. Waanders · J. E. Biemond ·
G. Hannink · D. Janssen · P. Buma ·
N. Verdonschot

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Abstract New technologies, such as selective electron beam melting, allow to create complex interface structures to enhance bone ingrowth in cementless implants. The efficacy of such structures can be tested in animal experiments. Although animal studies provide insight into the biological response of new structures, it remains unclear how ingrowth depth is related to interface strength. Theoretically, there could be a threshold of ingrowth, above which the interface strength does not further increase. To test the relationship between depth and strength we performed a finite element study on micro models with simulated uncoated and hydroxyapatite (HA) coated surfaces. We examined whether complete ingrowth is necessary to obtain a maximal interface strength. An increase in bone ingrowth depth did not always enhance the bone–implant interface strength. For the uncoated specimens a plateau was reached at 1,500 μm of ingrowth depth. For the specimens with a simulated HA coating, a bone ingrowth depth of 500 μm already yielded a substantial interface strength, and deeper ingrowth did not enhance the interface strength considerably. These findings may assist in optimizing interface morphology (its depth) and in judging the effect of bone ingrowth depth on interface strength.

1 Introduction

The success of cementless total hip arthroplasty (THA) relies on bone ingrowth into the metal structure. A good interface strength between metal and bone promotes long term stability of the implant. Surface characteristics of the metal structure, such as porosity, pore size and shape have a considerable effect on cell migration, adhesion and bone formation [1–3].

High implant porosity provides more space for bone ingrowth and bone interlocking, which improves the strength of the implant–bone bond. Shear strength and the percentage of implant–bone contact of porous implants compared to rough ones was reported to be significantly increased [4]. Another study, which compared bone–implant contact in three different groups of nickel–titanium bone graft substitutes, reported the greatest implant–bone contact in the group with the highest porosity [5].

There also appears to be an optimal pore size for bone ingrowth. An early study by Hulbert et al. [6] showed that pores below 100 μm may prohibit mineralization of bone tissue, and pores below 75 μm were reported to allow only fibrous tissue formation. In contrast, a study by Itala et al. [7] showed no threshold value for new bone ingrowth in pore sizes ranging from 50 to 125 μm under non-load-bearing conditions. A review study on implant fixation by bone ingrowth indicated the optimum pore size for bone ingrowth in the range of 100–400 μm [8]. However, several studies showed that also larger pores allow ingrowth to occur [2, 9]. One can conclude that, due to the wide variety of analyzed materials and pore shapes, the optimum range might be different for each particular structure and the site of application, requiring in vivo testing of each combination.

Several studies have shown that bone ingrowth and its strength can be enhanced by applying an additional surface

M. Tarala (✉) · D. Waanders · J. E. Biemond · G. Hannink ·
D. Janssen · P. Buma · N. Verdonschot
Orthopaedic Research Laboratory, Radboud University
Nijmegen Medical Centre, P.O. Box 9101, 6500 HB Nijmegen,
The Netherlands
e-mail: M.Tarala@orthop.umcn.nl

N. Verdonschot
Laboratory for Biomechanical Engineering,
University of Twente, Enschede, The Netherlands

coating to improve surface bioactivity and osteoconductivity [10]. Coating materials such as calcium phosphate (CaP) and hydroxyapatite (HA) can improve the area of bone ingrowth, the bone-to-implant contact fraction [11, 12] and the implant–bone interface strength [13]. It has recently been shown in a rabbit study that laser-treated implants with an HA coating achieved higher removal torque values than uncoated specimens [14].

Using new technologies, complex 3-dimensional shapes can be produced in which pore size and shape, and level of porosity of the interface structures can be easily varied. An example is the electron beam melting (EBM) technique. This technique allows to create structures of any desired shape, based on 3D computer-guided design [15]. The principle of this technology is the selective melting of powder layers by an electron beam under vacuum. The structures built with this technique are composed of Ti alloy (TiAlV).

The efficacy of new surface structures can be tested in animal experiments. In such studies, the bone ingrowth depth into the metal structure [16, 17] or the interface shear strength at different time points is measured [18, 19]. Typically, both histology and mechanical tests are performed in this type of research, requiring a large number of animals. However, it is not known how much ingrowth is actually needed to provide an adequate interface strength, and how ingrowth depth and strength are related. The finite

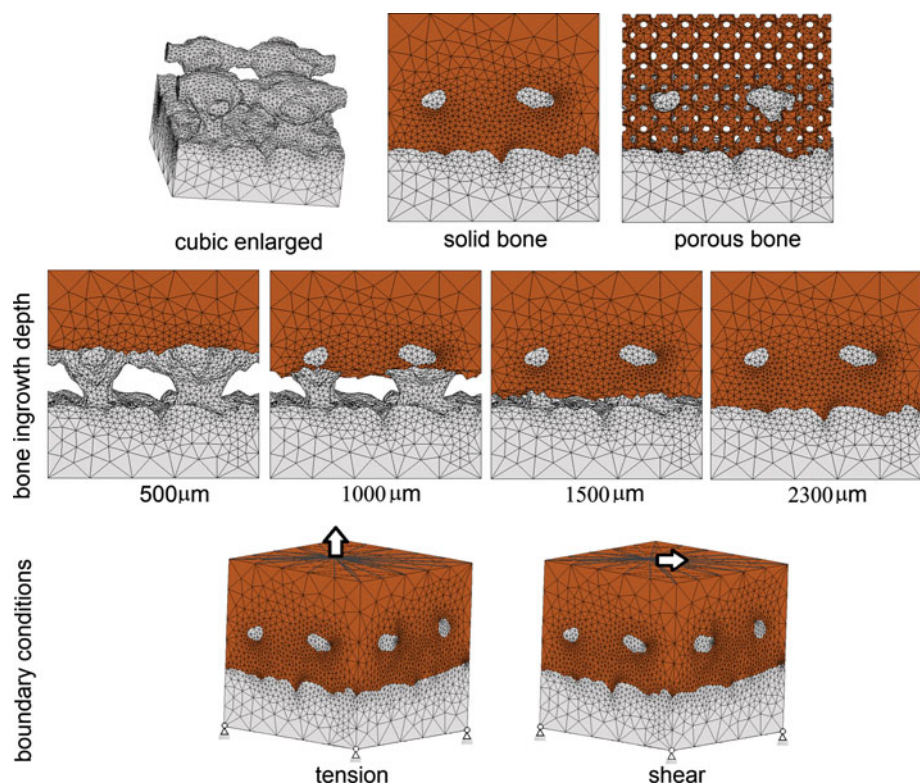
element method (FEM) is a valuable method to test such phenomena.

The present FEM study was designed to test the relationship between bone ingrowth depth and interface strength. We focused on the following research questions: (1) What is the relationship between interface strength and bone ingrowth depth for the uncoated and HA coated specimens? (2) Is a maximum ingrowth depth necessary to obtain an optimal interface strength? If not, which bone ingrowth depth can be considered sufficient? and (3) Does interface coating enhance the interface strength?

2 Materials and methods

The FEM models were based on micro CT data of a titanium cubic enlarged structure (73% porosity and a pore size of 1.25 mm) (Fig. 1), provided by the manufacturer (EUROCOATING Spa, Italy). In the previous animal experiment [17], this particular structure yielded the greatest bone ingrowth depth compared to other EBM-produced structures. The size of the current FEM models ($5 \times 5 \times 5$ mm) embraced four symmetric pieces of the cubic enlarged structure. The bone structure was modeled in two ways: by solidly filling the cavities in the surface structure (simulating complete ingrowth with cortical bone), and by completely filling the cavities with a porous

Fig. 1 FEM micro models of the bone–implant interface with bone tissue modeled solid and porous. Various bone ingrowth depths were modeled. In order to quantify bone–implants interface strength, the metal part of the model was fixed at the bottom, while the bone was displaced with an incremental displacement in the tension or shear direction, while monitoring the reaction force of the top bone nodes



bone structure (Fig. 1). The porous bone structure had a face-centered cubic (fcc) arrangement of the empty pores, with a pore size of 740 μm , resulting in 80% porosity of the bone structure [20]. The models were 3D meshed with four-noded tetrahedral elements using an FEM software package (MSC.Mentat 2007r1, MSC Software Corporation, Santa Ana, CA, USA). Mesh density (number of elements/model volume) of the metal structure was $\sim 780/\text{mm}^3$ and mesh density of the solid and porous bone structures ~ 815 and $\sim 8,750/\text{mm}^3$, respectively.

To assess the relationship between interface strength and bone ingrowth depth we simulated different ingrowth depths. We used the models with maximal ingrowth depth (2.3 mm) to subsequently generate models with a reduced ingrowth depth. Thus, for both bone structures (solid and porous) five additional models were created (250; 500; 750; 1,000; and 1,500 μm ingrowth depth) by removing the elements below the levels of the corresponding ingrowth depths [21] (Fig. 1), which resulted in 12 unique FEM micro models in total. Both bone and metal were modeled isotropic, with a Young’s modulus of 6.8 GPa [22] and 105 GPa (provided by the manufacturer) for the bone and the metal structure, respectively. Poisson’s ratio was set to 0.3 for the metal and bone structures.

To measure interface strength under tension and shear, the models were loaded until failure. To simulate this process the bottom part of the model (metal) was fixed, while the bone was displaced with an incremental displacement in the tension or shear direction, while monitoring the reaction force of the top bone nodes (Fig. 1). The apparent stress in tension or shear was computed by dividing the corresponding reaction force by the cross-sectional area of the interface (Fig. 2). The interface strength was defined as the maximum applied load divided by the cross-sectional area of the metal–bone interface. We simulated damage to the bone and metal using a modified in-house failure algorithm [23]. Only static failure was allowed to occur [21]. A crack could occur perpendicular

to the principal stress direction when the stress of bone or metal exceeded their ultimate strength. The ultimate tensile bone strength was set to 47.5 MPa and was calculated from the equation proposed by Keyak et al. [24]. The ultimate tensile strength of the TiAlV alloy structure was set to 900 MPa. Cracks could occur in any of the principal directions (three per element). A crack occurrence was simulated by setting the Young’s modulus perpendicular to the principal stress direction to 0.1 MPa, while leaving the stiffness in the other directions intact. If multiple cracks would occur, the stiffness in multiple directions would be reduced to 0.1 MPa resulting in a very compliant element.

To test the effect of an interface coating on the magnitude of interface strength we simulated two different interface conditions: (1) uncoated, simulated as a frictional interface (friction coefficient 0.3 [25]), and (2) HA coated, modeled as a bonded interface. The bonded interface was simulated using the ‘glue’ option in MSC.MARC, while frictional contact between metal and bone was modeled using a double-sided node-to-surface coulomb contact algorithm [26].

To assess whether implant fixation enhances with increasing bone ingrowth depth, the results for models with reduced ingrowth depths were compared with the values obtained for the model with simulated full ingrowth.

3 Results

For the uncoated reconstructions, the interface strength increased with increasing ingrowth depth, but the relationship was not linear (Fig. 3). For these uncoated models 250 μm of ingrowth depth provided no tensile or shear strength at all, while only a slight strength occurred at 500 μm ingrowth depth. A close to maximal fixation strength for these models was obtained when the ingrowth depth reached 1,500 μm (94 and 99% of max for the tensile and shear strength, respectively).

Fig. 2 An apparent strength–displacement curve was used to define the specimens’ (implant plus bone) strength in tension and shear

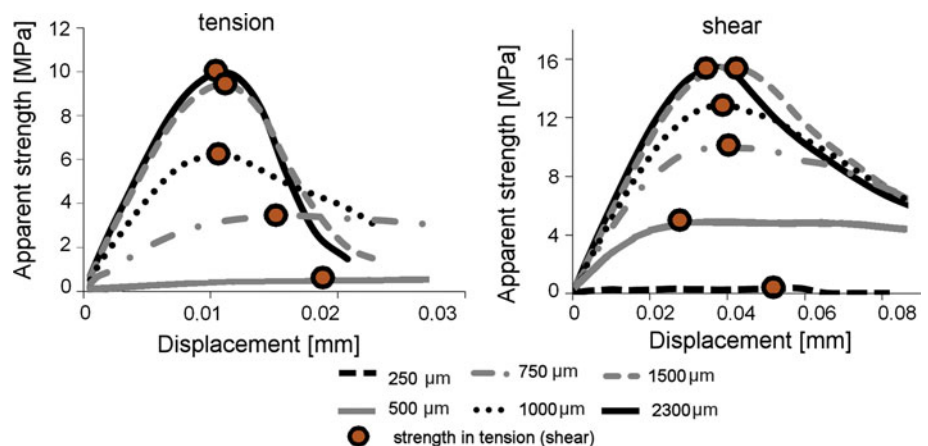
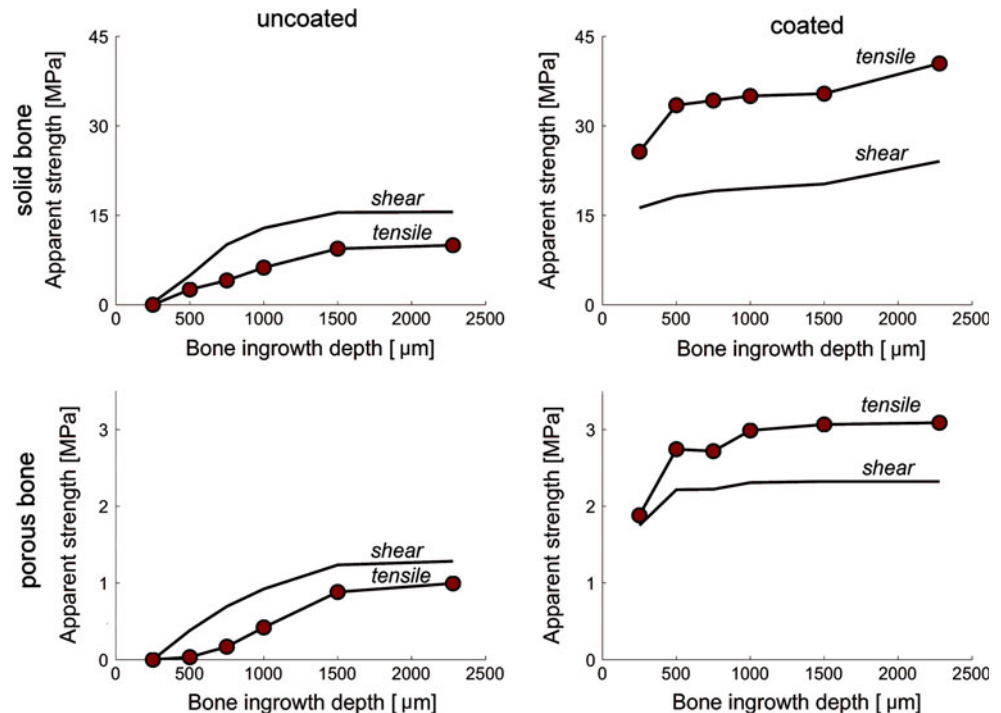


Fig. 3 For the uncoated specimens, the interface strength increased with increasing bone ingrowth depth. This relationship was considerably weaker for the HA coated specimens



For the HA coated models the interface strength at 250 μm ingrowth depth was already substantial (63 and 68% of max for the tensile and shear strength, respectively. Fig. 3). An ingrowth depth above 500 μm for these models provided interface strength values in shear and tension that were comparable with those in the fully ingrown case scenario (83 and 76% of max for the tensile and shear strength, respectively). The ultimate shear strength of models with a fully ingrown interface did not differ considerably between the models with a simulated HA coating and the uncoated ones. However, the tensile strength was considerably improved for the HA coated interfaces. There was a strong relationship between the tensile and shear strength of the metal–bone interface ($r^2 > 0.86$, Fig. 4), which depended on the surface treatment. The strength of the metal–bone interface in shear was about 1.25 times stronger than in tension for the uncoated specimens and approximately two times stronger in tension than in shear for the HA coated ones. The crack pattern appeared to depend on the surface treatment. Damage under tension occurred only to the bone, while some damage also occurred to the metal under shear in the lower part of the porous cubic enlarged structure, but only for the specimens with solid bone and a simulated HA coating. The models with a simulated coating under tension produced cracks above the metal–bone interface, while the other models produced cracks at the weakest point of the contact interface (Fig. 5). In all cases, more cracks were formed under shear than under tensile loading. For the uncoated models, the crack volume did not increase considerably with

ingrowth depth when loaded in tension, while in shear this was the case. For the coated models, the crack volume increased with ingrowth depth (both in shear and tension).

There were quantitative but no qualitative differences between the strength of models with solid bone and porous bone (Fig. 3). Strong correlations were found between two bone representations for the uncoated models ($r^2 = 0.99$, $r^2 = 0.94$), and moderate ones for the models with the HA coated interfaces ($r^2 = 0.87$, $r^2 = 0.54$). The apparent ultimate strength in shear and tension was mainly nine times smaller for the models with porous bone with respect to the solid bone models. A factor of 12 between the shear strengths of the solid and porous bone groups was present in the uncoated models. There were no differences in the localization of cracks between the two groups of models.

4 Discussion

The current study presents the first FEM approach to assess the theoretical effect of bone ingrowth depth on the strength of metal–bone porous structures. The study was designed to give an insight into the clinical findings on porous interface structures. We built FEM micro models with variations in bone ingrowth depth and interface treatment (uncoated and HA coated). Subsequently, we computed the bone–metal interface strength for each model with reduced ingrowth and compared the value with maximum interface strength obtained for the complete bone ingrown case.

Fig. 4 The metal–bone interface was approximately 1.25 times stronger in shear than in tension for the uncoated specimens and approximately two times stronger in tension than in shear for the HA coated specimens

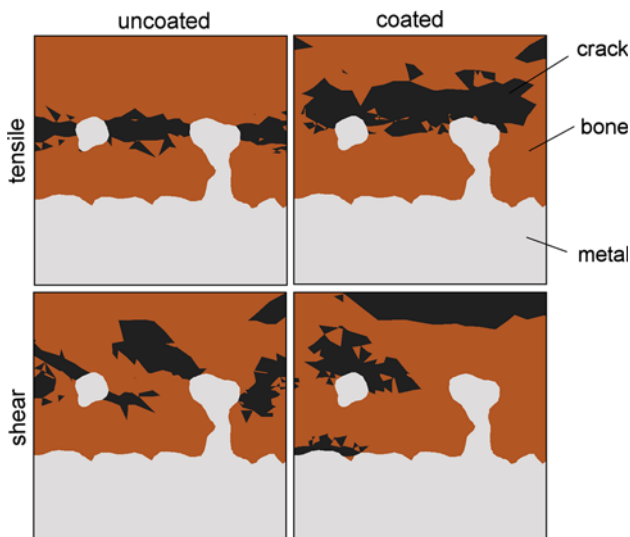
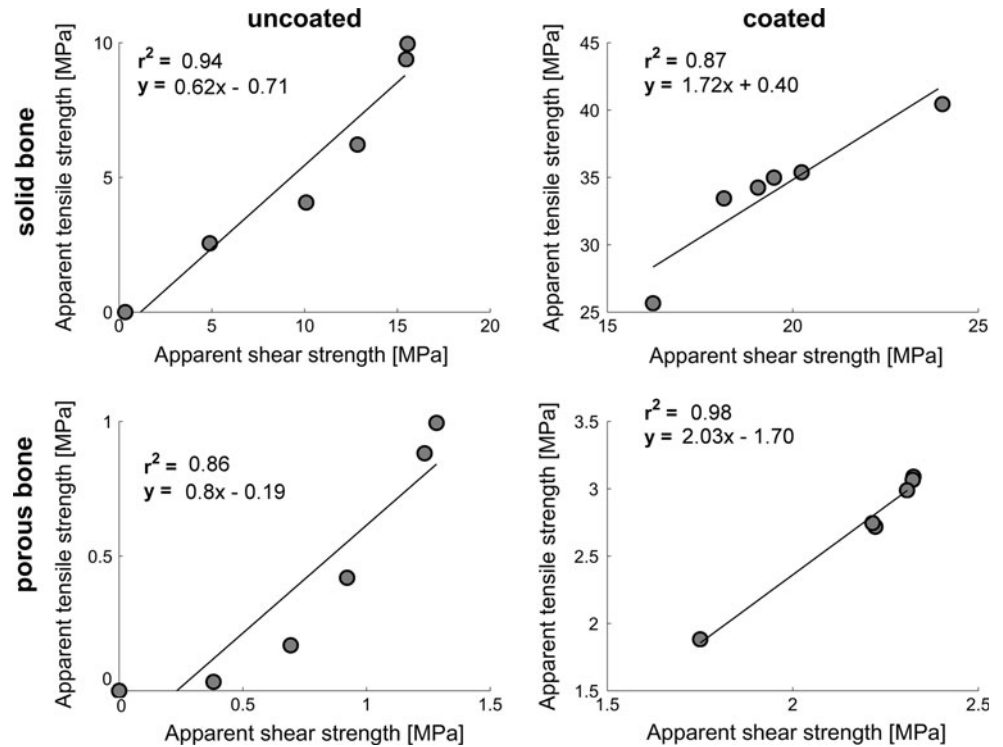


Fig. 5 Crack formation in the metal–bone interface in tension and in shear for uncoated and HA coated specimens. The cross-sectioned view is taken through the center of the specimen

The first question we wanted to answer concerned the relationship between bone ingrowth depth and bone–implant interface strength. Our results suggest a strong relationship for the uncoated specimens, for which bone interface strength enhanced with increasing bone ingrowth depth. However, when a bone ingrowth of 1,500 μm was achieved the interface strengths both in shear and tension were comparable to the ones obtained in the completely ingrown case. For the HA coated specimens, increasing

bone ingrowth depth did not considerably enhanced interface strength. Already at an ingrowth depth of 500 μm , an interface strength comparable to the complete ingrown case was reached.

The aforementioned findings allowed us to answer the second question. Under the modeling conditions as simulated in this study (equal ingrown depth throughout the model without consideration of partial bonding effects), complete ingrowth does not seem to be necessary to obtain optimal interface conditions. However, the bone ingrowth depth threshold value for HA coated and uncoated specimens differed considerably. While 500 μm of bone ingrowth depth appeared to be sufficient for the HA coated specimens, at least 1,500 μm was required for the uncoated ones.

Our third question concerned the effect of the HA coating on the interface strength in tension and shear. Furthermore, we were interested in the crack patterns that occur at the interface when uncoated and coated interfaces are modeled. Considering only mechanical effect of HA coating (and ignoring the biological potential of HA coatings), the results showed that in tension an HA coated interface is considerably stronger than the uncoated one, while the shear strength in models with complete ingrowth was not considerably improved by a coating treatment.

Although quadratic elements are better capable of capturing the bending behavior, the models in the present study were built of linear tetrahedrons. The reason for this choice is the current problem is clearly contact-driven, and

linear elements are more suitable for the node-to-surface contact algorithm adopted here for modeling frictional contact (MSC.Marc). Moreover, we balanced computational expense with model accuracy.

The size of the elements in our models was chosen to well model complex morphologies of the metal structure and assure relatively low computational time. Further refinement of elements would require massive computational power. In the same lines, we only meshed a representative section to make sure we could run the models, even though the specimens which we based our models on were larger. One could argue that our failure algorithm is mesh dependent, meaning that bigger elements have to absorb more energy to fail than the small ones. However, the mesh (element size and element distribution) was the same in each model, therefore the mesh dependence effect of failure algorithm was constant. Although we did not perform a convergence study to assess mesh dependencies for this particular bone–metal interfacial behavior we have performed extensive experimental verification studies in the past with similar meshes focusing on bone–cement interface micro-mechanics [21] and we therefore expect that the mesh density as used in this study is adequate for our purposes.

In a parametric study, we also analyzed the effect of the friction coefficient (uncoated models) by setting friction coefficient to 0.05, 0.3, and 1 and it turned out that the friction coefficient had relatively little effect on the interfacial strength. For a model with simulated full ingrowth, the interface shear strength was equal to 14.4, 16, and 17.2 MPa for $\mu = 0.05$, $\mu = 0.3$ and $\mu = 1$, respectively. The interface tensile strength was 10.2, 10.2, and 8.9 MPa for $\mu = 0.05$, $\mu = 0.3$ and $\mu = 1$, respectively. For the model with 1,000 μm bone ingrowth, the interface shear strength was 11.2, 13.2, and 15.3 MPa for $\mu = 0.05$, $\mu = 0.3$, and $\mu = 1$, respectively, while the tensile strength was equal to 5.8, 6.4, and 6.8 MPa for $\mu = 0.05$, $\mu = 0.3$ and $\mu = 1$, respectively. Interface strengths for models with $\mu = 1$ were much lower than models with bonded interfaces indicating that high friction cannot mechanically replace an actual bonding interfacial characteristic. In summary, the interface strength increased with friction coefficient, mainly noticeable in the shear direction. Unfortunately we do not have experimental data to validate the current choice of friction coefficient, although our results allow for a qualitative comparison of the effect of ingrowth depth on interface strength.

The models presented in the current study represent theoretical cases of ingrowth depth variations, and their possible effect on the interface strength under tensile and shear loads. The models were not based on actual ingrown surfaces retrieved from our previous animal study [17], as it was not possible to discern the interdigitated bone tissue

on micro CT scans. Hence, representation of partial bonding or differentiation of bony properties were not included in the model leading to the fact that the results of this study should be considered at a qualitative basis. Unfortunately, no mechanical tests were performed in the animal study, which would have enabled us to verify the strength values predicted by our models. However, it is worth mentioning that the values of tensile strength simulated in the present study for the HA coated specimen with porous bone (1.8–2.1 MPa) were in the same range as those reported in a previous study on a plasma-sprayed HA coating–titanium implant [27] (0.66–1.12 MPa) given the fact that both studies differed in exact geometry, bone properties and bonding characteristics.

Additional limitations to the current FEM models further impede a direct comparison with mechanical tests performed with specimens retrieved from animal experiments. In our FEM models the degradation and delamination in time of the interface coating was not modeled physically, thus, its degradation and delamination in time could not be simulated. In addition, the effect of bone maturation on its strength in time was neglected, while a previous study [27] reported three different mechanisms of bone–implant interface failure, in the localization of failure (bone or coating) strongly depended on time. As neither the HA coating nor bone maturation was simulated physically, we were unable to reproduce failure patterns corresponding to that study. However, failure modes similar to the ones predicted by our FEM models have been shown in physical experiments. A previous study reported the fracture line close to the implant surface for the smooth cylinders, while at a distance of 1–2 mm from the implant surface for the implants with axial groves [28]. Bone was represented in our models either as a solid or a porous structure. Both representations do not capture the “true” ingrowth morphology, but interestingly, the models with solid and porous bone showed a similar relationship between bone ingrowth depth and interface strength. This may suggest that interface failure does not qualitatively depend on the method in which bone structure is simulated but that the increase in strength is more driven by the morphology of the porous structure of the metal surface. However, whether this hypothesis is true can only be assessed by studying various metal–bone interfaces in animal experiments. To avoid CT image artifacts of the metal components, high resolution images of sequential histological sections of retrieved specimens from animal experiments are required for model creation.

Evidently, the results presented here are valid only for one particular surface structure. However, this methodology offers evaluation of the mechanical response of novel surface structures, without needing to perform a large scale animal experiment. Hence, this approach may be very

suitable particularly in the design phase of new interface structures, requiring only the creation and analysis of FEM models of the particular structure.

Despite its limitations the findings of the present study can aid in judging the theoretical efficacy of bone ingrowth reported in animal studies. For instance, an in-house animal experiment with goats [17] reported ingrowth depth values into uncoated cubic enlarged structure of $850 \pm 223 \mu\text{m}$ and $1,258 \pm 414 \mu\text{m}$ at 2 and 6 weeks postoperatively, respectively. Based on the current results, the ingrowth depth at 2 weeks postoperatively may not be sufficient to guarantee a maximal interface strength for the uncoated specimens. However, for the HA coated structures it would already ensure good stability. Bone ingrowth depth reported at 6 weeks postoperatively would be already optimal for both the HA coated and uncoated cubic enlarged interface structures. However, as explained above one needs to be careful when interpreting the results obtained in the current study since it is difficult to judge which interface strength is sufficient *in vivo*. All the comparisons we make are with respect to the cases with complete bone ingrowth. It is well possible that a stable interface condition does not require maximal strength, and already a percentage of the maximum possible strength is sufficient. Alternatively, it may be possible that the maximal strength may not be sufficient to fixate an implant adequately. As a result, in the present study we are only able to state whether the values measured with the deficient ingrowth models are different or not from the case with complete ingrowth.

Our FEM study tested the theoretical relationship between bone ingrowth depth and interface strength. The results suggest that an increase in bone ingrowth depth does not always enhance bone–implant interface strength. Therefore, the maximum ingrowth depth is not always necessary. Our simulations with approximated interface conditions showed that the threshold of bone ingrowth assuring optimal interface strength is likely to be lower for the HA coated specimens thanks to the better bone attachment strength to HA coating. The findings of the present study may assist in optimizing the shape and depth of implant's interface and judging the efficacy of bone ingrowth depth (as measured in animal studies) on interface strength. Further development of this simulation is warranted so that it can be used to pre-clinically assess the effect of metal surface morphology on the bone–metal interface under multi-axial loading conditions.

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