EVALUATING VIBRATIONAL AND STRUCTURAL STABILITY OF OSSEOINTEGRATED FEMORAL PROSTHESES: FINITE ELEMENT APPROACH

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Abstract. Bone anchored femoral implants offer clear advantages over standard socket-type prosthetics. By connecting directly to the bone, they improve stability and allow better movement for people with lower-limb amputations. This study has been carried out in two stages to carefully examine how the implant's fit, the bone's structure, and vibrations are all connected. In the first stage, which this paper covers, a straightforward computer model of the femur was used. It included a cylindrical bone shape and a titanium alloy implant the authors had already tested and confirmed. The simulations were run in ANSYS Workbench using standard static loading first, followed by vibration analysis that accounted for internal stress. Two main types of loading were applied: small displacements (0.001 mm, 0.05 mm, and 0.1 mm) and pressure (1.65 MPa, 16.5 MPa, and 160 MPa). Each case was tested with the sides of the implant either left free or held fixed. 20 vibration frequencies were analysed. The results showed that when the implant was pushed in by displacement and the sides were free, the system became more flexible and frequencies dropped. Pressure loading, on the other hand, caused the structure to stiffen and frequencies to increase. The second part of the study, which will be published separately, involves real tests on femur bone models where light impacts are used to check how the system responds. Preliminary results already show similar patterns to what the simulations predicted. This study results provide details about how the implant and bone respond to applied forces across the implant surfaces and where stresses concentrate and how small movements of vertical motion on the implant corresponds to stresses that accumulate at the interface. It is hoped that this information can be used to guide future efforts to improve implant design, make surgeries more predictable, and enhance the overall comfort and stability of bone anchored prosthetic limbs.

Keywords: osseointegrated femoral implant, vibrations, stability, FEA.

Introduction

The emerging osseointegrated femoral implants have become an unprecedented alternative to conventional socket based prostheses, providing for better mobility and comfort to the amputees of lower limbs. The direct structural and functional shape including that permitted by load bearing implant located in bone is eliminating common problems such as the pressure ulcers, mismatch and the rapid decrease in range of motion with socket suspension systems [1]. While these advancements have improved the mechanical reliability of such implants, the long term reliability is still a challenging problem.

It is dynamic behaviour such as structural stability and vibrational response in the bone–implant system which is a critical factor influencing implant performance. Femoral implants are subject to complex loading patterns during day to day activities such as walking, running and stair ascent. These loads may cause resonance if their frequency coincides with the frequency or frequency ranges of the implant's natural frequencies, and such effects may include patient discomfort, increased bending for micromotion, and loosening over time [2; 3]. Therefore, it is necessary to understand the modal properties of the implant–femur system (natural frequencies and mode shapes) in order to reduce these risks and improve the implant design.

Evaluation of the vibrational characteristics of a bone–implant system by modal analysis, especially in conjunction with the Finite Element Analysis (FEA) has become an accepted technique. Simulation of stress distribution and frequency response under different anatomical and loading configurations is provided by FEA, which would be more difficult to obtain from physical experimentation alone. It has been shown that modal analysis could detect changes in fixation of the implant as well as in the quality of osseointegration [4-6]. Mohamed et al. presented a section of vibration of transfemoral implant using 3D finite element models, showing that the natural frequency response was dependent on the insertion depth [7]. Various other important findings have also been highlighted by further vibrational studies [8; 9].

The first phase of this research programme is to carry out computational analysis using the finite element analysis (FEA) to conduct a systematic study of the vibrational mechanics of bone-anchored femoral implants through the use of a model system. Running this first phase, utilizing simpler cylindrical bone models and implant geometries that have been previously validated [10], how various insertion induced prestress conditions change the modal response is assessed. Incremental axial displacements as well as externally applied pressures were then simulated in detail using the FEA parameters; and then, pre-stressed modal analyses were performed to assess the impact of geometric boundary constraints and mechanical loading of the implant.

Published separately, in the subsequent second phase of this research programme, real human femur bone is then used to perform a rigorous experimental validation. Vibrational response is quantified in controlled laboratory experiments to assess numerical predictions in a direct comparison and empirical validation.

This will help explain how prestress, vibration, and structural stability correlate. These results will aid in better understanding of how implants function and how decisions can be made better by doctors and implant designs can be better made by designers. Both the computer simulations and lab tests have direct use in turning osseointegrated implants into better performing, lasting implants for patients.

Recent studies

To understand how implants behave, are stable, and integrate with a bone over time, growth in femoral implant research has recently seen more use of experimental vibration testing in conjunction with the Finite Element Analysis (FEA). Together, these methods have become necessary for predicting how implants will function in the body, how to design them better and for better outcomes for patients.

Recently Mohamed [7] had developed and validated a one dimensional finite element model for characterising the bone implant interface dynamics in transfemoral prostheses. The complexity of bending responses he identified which were highly influenced by the implant–adapter configuration is suggestive of the requirement for customised design techniques to minimize stability loss and minimize the risk of mechanical failure.

In Poudrel [6], a three-dimensional FEA framework was utilised to investigate femoral stem vibrations during surgery insertion. Their findings showed how the biomechanical environment is so subtle that it could change the stability and the quality of initial fixation of their implant greatly, and with that strongly support intraoperative vibration monitoring, as a promising clinical strategy to optimize implant placement techniques and postoperative outcomes.

Among the many recent experiments that made a significant advancement for vibration based studies of cell-based structures, Leuridan [11] invented a novel instrumentation approach solely for experimental vibration analysis of stability of the cementless implant during the total hip arthroplasty. Indeed, rigorous in vitro tests of validation to ensure agreement with the clinical potential of vibration diagnostics to predict implant stability intraoperatively provided remarkable agreement.

Presas [12] also carried out a very interesting exploration of the resonance characteristics of bovine femurs and synthetics by means of combined experimental and numerical approaches. Resonance based diagnostic methods are shown as being effective to utilize to move away from invasive mechanical testing and animal models, in order to move away from more ethically sustainable, but less accurate, biomechanical research practices. Manral [13] also expanded on material focused analyses based on material selection and implant optimisation to include vibration based modal analyses. Just like the experimental data, their simulations predicted frequencies up to 8,480 Hz which had outstanding correlation. They also determined that titanium alloys, particularly Ti-6Al-4V, exhibited excellent vibrational stability, and a superior mechanical compatibility for orthopaedic applications.

In their work, Gainutdinovs et al [14] performed a comprehensive experimental study on vibration transmission properties of femoral prostheses anchored to bone under varying compressive axial loads. Their work showed that increased axial loading was associated with higher resonance frequencies as well as with decreased vibrational displacements within the bone–implant–prosthesis system. For instance, at low frequency range (40-80 Hz), the transmissibility decreased as the axial loads increased while there were less consistent trends at medium frequency range (200-270 Hz). This highlights the importance of the axial preload conditions in determining the vibrational transmissibility and their consequences for haptic feedback (osseoperception) on which the assessment of prosthetic stability is dependent and the optimization of their user experience.

Recently, Zhou [15] focused on the harmonic vibration analysis for detecting transfemoral implant loosening. The third harmonic of torsional vibrations were found to be more sensitive to interface conditions and as such are able to demonstrate harmonic analysis as a viable tool for early diagnostics and monitoring of implant integrity in clinical settings.

Taken collectively, these most recent investigations are consistent with an extremely high intrinsic worth to the mix of precise experimental vibration diagnostics with powerful finite element modelling. Posed as such, synergistic production such as that described has great promise in improving the accuracy of predictive orthopaedic solutions, decreasing the revision surgery rate, and supporting the development of patient specific orthopaedic solutions.

Methods of simulating bone–implant interfaces

It is necessary for biomechanical integration, implant stability and longevity that the interfaces between the bone and implants are simulated accurately.

Bonded vs frictional contact modelling

The primary goal of any bone–implant interface investigation is that of simulation to determine biomechanical integration, implant stability and longevity. Two key elements are used in these simulations: one - representation of the interface contact in terms of bonded and frictional conditions, and two - the representation of pre-stressed modal analysis (i.e. where realistic physiological loading states are used during the simulations).

On the other hand, friction contact modelling results in more realistic relative contact motion and stress redistribution across the interface with the friction coefficient that is associated with the physiological situation. For example, Castrillo and Carnicero [16] based on a submodelling procedure, suggested that the comparison of bonded and frictional contact assumptions on bonded and frictional subperiosteal implants reported significant differences between the predicted stress distributions from the selected interface model. Poudrel [6] systematically evaluated bonded and frictional interfaces and showed that frictional conditions more accurately simulated biomechanical environments in particular with cementless fixation scenarios.

Today, Coulomb frictional contact formulations are most common due to their robust but computationally manageable approximation of clinical conditions. Dickinson [17] succeeded in applying Coulomb friction laws to investigate fatigue life in modular, pre-stressed orthopaedic implants, thus demonstrating the necessity of accurate friction dynamics at the interface. Moreover, Jayathilaka [10] has recently conducted strength and fatigue analyses for which even frictional contact modelling is indispensable for the accurate prediction of long term femoral implant stability and performance.

Pre-stressed modal analysis

In modal analysis of bone–implant systems it is essential to include pre-stress (generated by surgical insertion forces or physiological muscular loads). These results change the structural stiffness, the natural frequency spectrum, and the vibrational response, pre-stressing them significantly, which improves the results obtained in simulation in terms of closeness to the actual clinical conditions. As illustrated in the most recent studies by Einafshar [18] and Gao [19] neglecting pre stress significantly reduces the physiological relevance of numerical predictions, as one can obtain unreliable frequency estimates and implausible mechanical characterisation.

Together, these emerging application methods show that physical modelling has to be carefully balanced against computational speed. Each is an appropriate choice of contact conditions and careful application of a prestressed modal analysis to the creation of useful and clinically relevant predictions of how the bone and implant will interact.

Known effects of geometry on implant vibration/stability

Orthopaedic and dental implant geometry has a large impact on the vibrational characteristics and mechanical stability that have a direct impact on osseointegration and long clinical performance. With geometric changes, resonant frequencies, mode shapes and stiffness parameters are inherently sensitive to structural geometry and therefore numerous experimental and numerical studies have been reported.

Increasing the implant length is seen to affect the vibrational characteristics of the novel femoral implant design during simulated osseointegration, as reported by Lu [20]. Likewise, Zanetti [8] performed comparative modal analyses of dental implants of different cross-sectional geometry and discovered large stability differences especially on the third vibrational mode resulting from apparently minor geometric differences.

Xu [21] also demonstrated that geometric variations are sensitive to implant stability through the development of a sub resonant diagnostic device designed to measure angular stiffness. Based on their research, they were able to establish a direct correlation in terms of rotational stability that depended on the neck geometry modification in the implant design, and the clinical relevance of precise geometric optimisation in the implant design was emphasised.

As noted by Swami and Vijayaraghavan [22], as well as Lachmann [23], geometrical factors such as the insertion depth, thread morphology and diameter have consistently been shown to significantly affect resonance frequency responses. During primary fixation, which is of great importance for long term osseointegration, these geometric considerations are particularly critical since up to even the slightest micromotion can lead to severe problems.

Meredith's [24] earlier work later reinforced the role of the implant taper geometry and surface roughness on resonance frequency, primary stability and clinical integration outcome. Specifically, Jayathilaka [10] recently focused on the determinants of geometric nature in the mechanical performance and stress distribution of femoral implants and buttressed these numerous roles of implant geometry in overall structural stability through discrete finite element simulation.

Collectively, these studies highlight that the design of the implant must be considered carefully and optimised because it strongly determines vibrational characteristics, mechanical performance and inevitably the clinical outcome.

Methodology

Model and geometry design

Using a controlled mechanical model as the vitality principle, bone-anchored femoral implants were studied systematically in terms of vibrational behaviour with a simplified cylindrical finite element model. The cylindrical representation of cortical femoral diaphysis is an idealized geometry that can be implemented consistently as an analogue of cortical femoral diaphysis and is controllable of geometric parameters, meshing, and interface conditions.

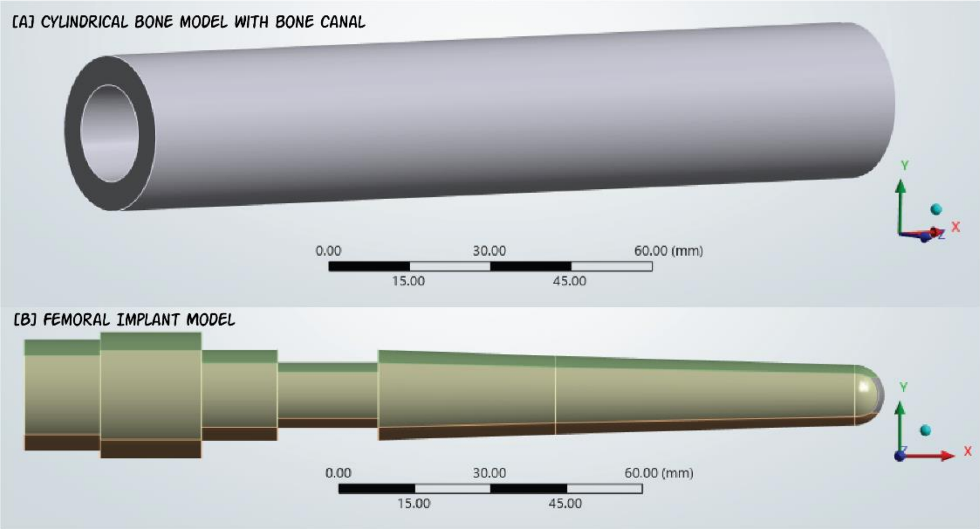

Fig. 1. **Finite element geometries used in the simulation study:** (A) Cylindrical femoral bone model with a central canal to accommodate the implant; (B) Ti-6Al-4V femoral implant model designed to achieve a press-fit within the bone canal

The model is composed of two key parts (Fig. 1), the femoral implant and a synthetic bone substitute. The design of both geometries was carefully designed according to previous experimental and numerical research performed by the authors [10]. The implant was made from biomedical titanium alloy (Ti-6Al-4V) where the stem was conically tapered and the proximal base was stepped cylindrical, ending with a smoothly rounded tip to reduce the stress concentration.

To keep the synthetic bone canal internal conical geometry precise match to clinical osseointegration scenario, the synthetic bone was designed with a conical internal geometry to provide a uniform and full length press fit contact. This removal of unrealistic gaps or overlaps of the bone–implant interface is a direct product of this design choice, the purpose of which was derived from surgical observations and prior morphometric analyses.

It uses structured hexahedral elements (Fig. 2), wherein the element refinement is enhanced in the contact region. The elements were oriented longitudinally along the axis of the bone to improve the accuracy in modal simulations. In order to ensure mesh quality, strict aspect ratio and skewness criteria were followed.

The implant (target) and bone (contact) were represented as undergoing a frictional interface using ANSYS augmented Lagrange contact formulation, where normal stiffness was updated dynamically each load sub step to provide accurate stress and frictional behaviour.

By means of its carefully designed geometric and contact model, this model is capable of performing accurate pre-stressed modal analyses under both displacement and pressure controlled loading conditions that match realistic physiological response characteristics needed for the purpose of reliable clinical implant assessment.

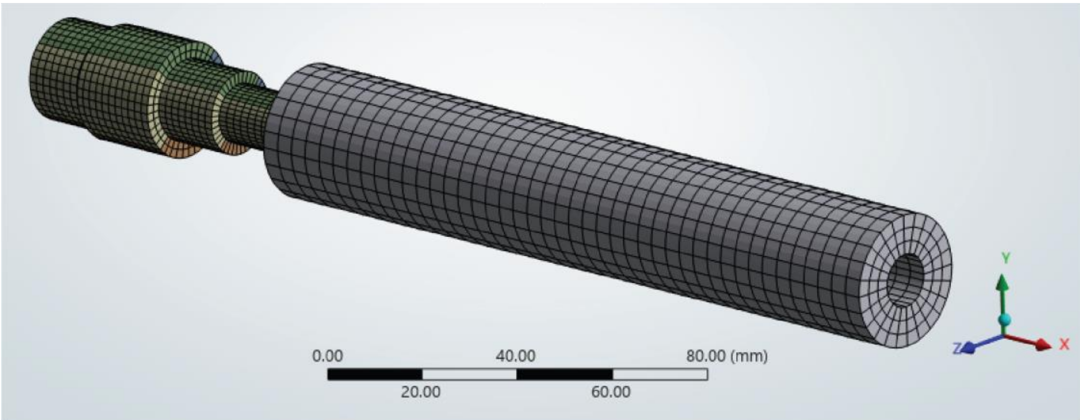

Fig. 2. **Hexahedral element mesh of the assembled bone–implant model, illustrating conformal contact between the Ti-6Al-4V implant and the internal canal of the cylindrical bone**

Material properties and boundary conditions

A solution was assigned with distinct material properties that would replicate the biomechanical interactions inside the bone–implant system. At these small deformation modal analyses, both the implant and bone materials were assumed to be homogeneous, isotropic and linearly elastic.

Ti-6Al-4V was selected in preference for its high level of biocompatibility, optimum stiffness, and fatigue resistance in the literature for orthopaedic implants that it is widely recognised for. Previous experimental literature values of cortical bone material properties (Table 1) were used to assign a cortical bone set of material properties to the synthetic bone component.

Table 1

Material properties used during FEA simulations

Material	Density	Young's Modulus	Poisson's Ratio
Femur	2400 kg·m^{-3}	17600 MPa	0.330
Ti-6Al-4V	4405 kg·m^{-3}	107000 MPa	0.323

As in experimental boundary conditions, the distal end of the cylindrical bone model was fully constrained in all translational degrees of freedom. On A, structural response and internal stress distribution during loading and modal analysis were not constrained due to no rotational constraints (Fig. 3 - A).

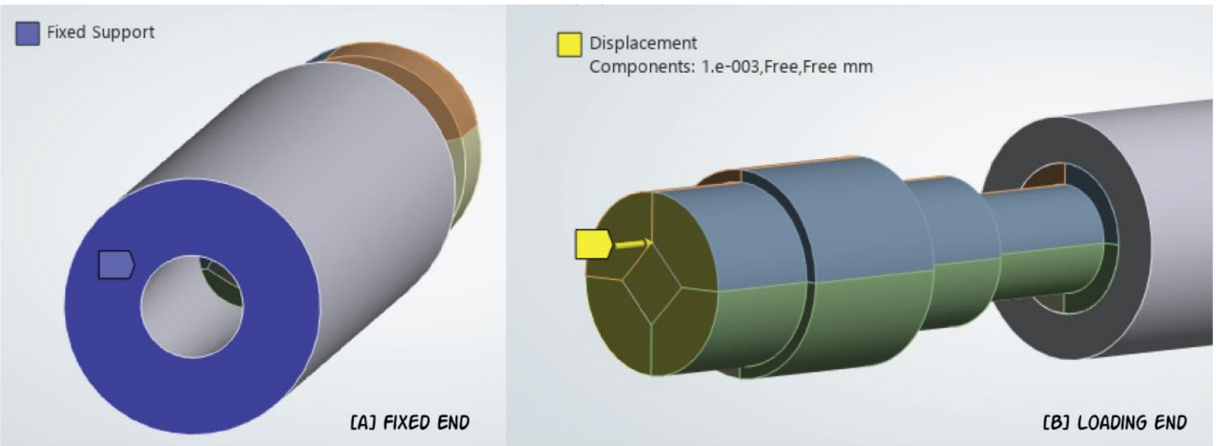

Fig. 3. **Boundary conditions for the static structural analysis:** (A) The distal end of the bone is fully constrained to simulate fixation; (B) A ramped displacement/pressure is applied to the proximal end of the implant to simulate press-fit insertion

In order to apply two distinct loading scenarios to the proximal end (external face) of the implant (Fig. 3 - B), a structured protocol is subsequently described to interchangeably test the implant under displacement-controlled and pressure-controlled modes. Magnitudes of incremental loading were designed so that each loading type included reasonable physiological and supra-physiological conditions. Frictional contact conditions in accordance with relative micromotion of the bone to implant surfaces following osseointegration were applied to reflect post osseointegration mechanical environments, and large deflection effects were enabled in order to accurately capture geometrically nonlinear interactions.

Simulation workflow and modal extraction

The finite element analysis (FEA) was systematically conducted in two stages where a static prestressing analysis, followed by pre-stressed modal extraction was performed with ANSYS Workbench analysing the pre-stressed mode shapes. Two loading strategies were developed to produce prestress conditions in the proximal (external) end of the implant.

- Displacement-Controlled Protocol: The displacement-controlled protocol consisted of axial displacements of 0.001 mm, 0.05 mm, and 0.1 mm, applied "ramped" (0-1s). Two lateral boundary conditions were considered: one was free displacement in Y and Z directions (compliant lateral boundary condition) and the second was zero displacement in Y and Z (pure axial boundary condition).
- Pressure-Controlled Protocol: Axial pressure of 1.65 MPa, 16.5 MPa, and 160 MPa, used as a representative of different realistic press-fit conditions, was uniformly applied once to the proximal implant face.

A post-static analysis stress field was then transferred into a modal analysis system in ANSYS Workbench to obtain modal characteristics with the structure under prestress. Prestress state was taken as the final load step of each static analysis with consistent "Force Bonded" contact settings. Twenty undamped frequencies and the associated 20 mode shapes were included in modal extraction.

Results and discussion

Under displacement-controlled loading, Table 2 summarises the modal analysis results in terms of both boundary conditions (i.e. Y and Z components as zero and free). Axial displacements of 0.001 mm, 0.05 mm, and 0.1 mm reported first two frequencies of bending, torsional, and longitudinal vibration modes.

Both boundary conditions give clear consistent trends in the modal frequencies. For 0% axial displacement under the "0" condition (where lateral, Y and Z displacements are constrained), bending modes have frequencies from 1128.7 Hz to 2899.3 Hz. This slight downward trend in deformation with an increasing interface stiffness indicates a softening of the contact interface stiffness that may be due to contact interface micro motion or local sliding.

Table 2

Modal frequencies (Hz) under displacement (mm) controlled loading

Deformation	**Y and Z components "0"**			**Y and Z components "Free"**		
Displacement in X	0.001	0.05	0.1	0.001	0.05	0.1
Bending	1128.7	1123.5	1121.7	266.54	264.08	261.56
	2917.6	2902.1	2899.3	1411.1	1402.8	1400
Torsional	3218.3	3218.3	3218.4	1905.2	1904.3	1904.3
	7601.9	7590.1	7588.9	4682.5	4682.3	4682.6
Longitudinal	6549.5	6550.4	6551.5	6538.6	6539.5	6540.6
	12043	11998	11995	12037	11991	11988

The frequencies of torsional modes under the same condition only change very little (from 7588.9 Hz to 3218.3 Hz) which indicates torsional modes are less sensitive to small axial displacement. The longitudinal frequencies exhibit similar stability between 6549.5 Hz and 11,995 Hz.

However, in the case of "Free" boundary condition (lateral movement allowed) bending frequencies are considerably lower in the range of 266.54 to 1400 Hz. In addition, they decrease slightly with increasing displacement. Torsional frequencies have marginal reductions, indicating that to reduce natural stiffness and resonant behaviour, it is less prone to resonate when transverse freedom is allowed. Longitudinal frequencies respectively have much less dramatic reductions.

Finally, these results confirm that, in addition to magnitude of displacement, displacement-induced softening is very much sensitive to boundary constraints in vibrational response, with lateral freedom enhancing this effect.

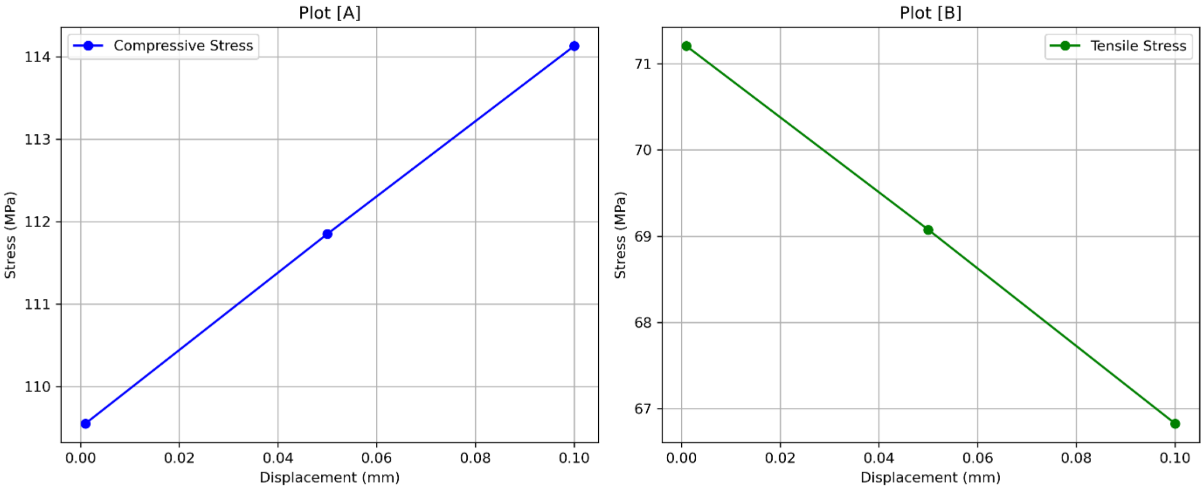

Fig. 4. **Compressive stress Plot [A] and tensile stress Plot [B] variations with respect to displacement**

Fig. 4 shows the plots of compressive and tensile stresses in the bone structure as a function of implant displacement along the longitudinal axis. In the left graph, compressive stress progresses to an approximate 114 MPa at 0.1 mm of displacement. The rise in the compressive load indicates that the bone canal is subject to inward deformation in order to receive the conically tapered implant, thereby exhibiting the aspect of press fit seen in clinic. An increase in the compressive stress with the increase in the insertion depth (i.e. increase of the number of threads) validates the mechanical engagement between the implant and bone, corresponding to a tightening interface under insertion.

On the contrary, the right graph depicts the decreasing tensile stress as the displacement increases. Thus, at the bone level, this is the behaviour indicative of a mechanism of stress redistribution: as compressive zones grow around the contact interface, tensile zones (developed at a distance or on the outer cortical wall) relax.

This stress evolution is very dependent on the conical geometry of the implant. As the canal is filled additionally to the lead point, there is increased bone resistance to the expanding diameter of the implant. The outward reactionary force can occur if the bone material does not readily deform and if the inclined faces of the implant are used. In these circumstances, this mechanical response is consistent with a self-expelling action and emphasises the need to achieve good canal preparation and frictional engagement at surgery.

Table 3

Modal frequencies (Hz) under pressure (MPa) controlled loading

Pressure	1.65	16.5	160
Bending	183.57	183.57	183.1
	950.88	950.94	963.54
Torsional	1905.1	1905.1	1891.1
	4683.8	4683.8	4697.1
Longitudinal	2542.2	2542.3	2565.9
	9939.5	9939.9	10061

By ramping the axial pressure loading and subsequently quickly removing it (Table 3), the frequency response of all three principal modes is found to experience dynamic effects. With this in mind, the method of this pressure protocol aims to duplicate the impact testing to be used in Phase II of this research, in which transient loads are applied to the exposed end of the implant post integration.

As the pressure increases, bending modes showed negligible variation (183.57Hz to 183.1Hz). This is simply because the effect of the applied axial pressure (though ramped), is able to generate very little energy in the bending strain in the system. The impact impacts longitudinally in which case the flexural rigidity of the construct is not importantly changed.

Nevertheless, torsional frequencies exhibited a negligible reduction in the highest loading level (from 1905.1 to 1891.1 Hz), possibly caused by micro-rotational compliance as a result of high-pressure engagement. As the implant is compressed into the canal and unloaded quickly, interfacial shear stresses may get redistributed unevenly, temporarily, decreasing the torsional constraint torque afforded by frictional contact.

Longitudinal frequencies instead were slightly increased (9939.5 Hz to 10061 Hz) with pressure, possibly indicating increased axial stiffness of the bone–implant system with greater initial contact pressure. Improved load transfer and surface conformity during compression will contribute to less compliant interface and less independent vibrational response in an axial direction.

Conclusions

An analysis of the influence on vibrational behaviour of a bone–implant system of displacement and pressure induced prestressing was performed using a simplified finite element model, for which the results were then systematically evaluated. Consequently, modal characteristics were obtained through carefully controlled boundary and loading conditions to evaluate how axial loading protocols affect the frequency response across bending, torsional, and longitudinal modes. At the same time, the results show clear trends in displacement control, small shifts in pressure-driven cases, and the strong effect of implant confinement, interface mechanics and structural stiffness on the performance.

This work provides numerical insights which have directly informed the design and boundary logic for the forthcoming experimental validation phase of this research. Initial results from that phase already suggest modal shifts consistent with interface evolution, suggesting that the formulated simulation framework in this article is relevant. On the topic of bright future, additional simulation efforts will take place incorporating localized crack models and the fracture propagation pathways to study their effect on vibrational stability and diagnostic capability. It is anticipated that such work provides a critical bridge between computationally predicted designs and designs for clinical translation with respect to hybrid prosthetic implant osseointegrated fixation.

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Author contributions

Conceptualization, K.J., V.J. and O.G.; methodology, K.J. and V.J.; software, K.J.; validation, K.J. and V.J; formal analysis, K.J and V.J..; investigation, K.J.; data curation, K.J., and V.J..; writing – original draft preparation, K.J.; writing – review and editing, K.J., V.J., and O.G.; visualization, K.J.; project administration, V.J.; funding acquisition, K.J. All authors have read and agreed to the published version of the manuscript.

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