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Monitoring the bone degradation-induced loosening of osseointegrated percutaneous implant using vibration analysis

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Abstract. Osseointegrated implants attach prosthetic devices directly to the skeletal system with a stable connection, allowing amputees to control prostheses with good proprioception. However, periprosthetic cortical thinning can occur if the remaining bone is stress shielded after implantation, resulting in aseptic implant loosening, and requiring revision surgery. It is therefore important to quantitatively monitor the degree of bone loss and probability of loosening to provide evidence for doctors to plan treatment. This computational study investigates the vibration behavior of a bone-implant construct by monitoring its transient response over varying degrees of bone degradation. The thickness of distal bone is progressively reduced through a revolving material removal to simulate cortical thinning due to stress shielding. First, bonded contact is adopted to represent the case of the fully osseointegrated implant under bone resorption, leading to a linear vibrational response. Next, frictional contact with 0.05 mm over-fit offset is adopted to include the non-linear contact behavior when loosening is induced by cortical thinning. The torsional mode shape of the bone-implant construct is identified through cross-spectrum analysis. The results suggest that the change in the natural frequency of the first torsional mode provides the most sensitive indicator of cortical thinning and implant loosening. The findings underpin the potential of vibration analysis in the monitoring of bone degradation-induced implant looseness.

Introduction

Osseointegration (OI) prostheses provide an alternative treatment to conventional socket prostheses for amputees. Instead of using a prosthetic socket to attach artificial limbs, it achieves bone anchorage of the limbs through percutaneous implants that are press-fit into the intramedullary cavity of residual bone [1-4], thereby improving the comfort level and functionality of the prosthetic system, such as providing better control of the prosthetic device with proprioception (Osseoperception), reducing skin irritation, and avoiding pressure sores [5-7]. Despite these benefits, failed implantation can make patients suffer and make revision surgery even more difficult. Repair surgery is normally more complicated and invasive, which can bring a higher possibility of requiring another replacement surgery [7].

Bone resorption due to a stress-shielding phenomenon can cause long-term implant failures [8]. After implantation, the implant will take most of the load because the Young's modulus of titanium alloy is significantly higher than that of bone, resulting in stress shielding of the bone. According to Wolff's Law, the bone will adaptively change its geometry and mineral density based on the altered load field [9-12]. This bone degradation can lead to a reduction of effective contact area and contact stiffness; consequently, the micromovement between the bone and implant will increase. A micromotion that is higher than 150 μm [13-15] may lead to fibrous tissue interposition at the porous coat of implants rather than bone ingrowth, which could further lead to mechanical instability and eventually looseness.

A two-stage surgical protocol and rehabilitation plan can help patients gain implant stability gradually [16]. In the first stage, the implant will be hammered into the bone remnant and the wound is closed using a stump pressure bandage. Initial stability could be immediately acquired after the installation [3, 17]. In the second stage, the adapter of the external prosthesis will be connected to the Implant through a cutaneous stoma. After that, the patients need to perform load-bearing exercise progressively [3], which is designed to stimulate bone mineralization and prevent rapid load increase that might cause large micromotion at the bone-implant contact [2]. A secondary stability will be acquired as new bone grows into the micropore of the titanium oxide layer of implants during rehabilitation [4, 5].

Strict monitoring of implant stability can provide evidence for doctors to plan treatment, avoiding unsuccessful implantation. It is proposed that effective monitoring technology should be noninvasive, not hinder implant integration, permit personalized monitoring, and monitor conditions over the patients' everyday life [18]. The vibrometric approach is suitable for satisfying these targets. For example, acceleration sensors could be mounted at the extracorporeal part of the distal end of implants, thus achieving noninvasive monitoring. The vibration can be excited by normal walking activities to accomplish continuous monitoring, and vibration data can be analyzed by incorporating a mobile computation module to provide a personalized experience.

A lot of mechanical vibration characteristics have been investigated to monitor the structural integrity of implants non-destructively. The stability of the bone-implant constructs can be examined through tracking the frequency shift in dynamic response. Shao et al. [19] conducted in-vivo experiments with one transfemoral implant patient and found that the fundamental natural frequency (NF) of the trans-femoral implant system can reflect the boundary condition of implants. They found a reduction in the NF after the first load-bearing exercise and suggested it was due to the formation of load-induced micro-fractures at the interface. However, Shao et al. [19] restricted their frequency analysis to the fundamental NF. Cairns, Pearcy [20], on the other hand, extended the investigation to higher resonant frequencies by conducting modal experiments on a composite femur-implant model. They found larger percentage changes in the second and third bending response than the fundamental frequency. Due to different boundary conditions and experiment setups used between Shao et al. [19] and Cairns, Pearcy [20], their results cannot be directly compared. However, their findings are important contributions to the vibration-based method because they show that the resonance of a transfemoral-implant system is correlated to its stability as a reflection of the interface stiffness. The frequency shift methods are also applied for determining the mechanical properties of the Total Hip Arthroplasty (THA) interface for loosening assessment [21-23], whereas the identified frequency band for THA implants may not be applicable for transfemoral implants. The above studies only examined the bending response of implants. The works by Chiu et al. [24] and Ben et al. [25] expand the capability of the vibration method for bone healing assessment by employing a two-sensor strategy to extract both bending modes and torsional modes from vibration response. They have shown that the torsional modal frequencies are sensitive to stiffness recovery in the case of an internally fixed femur, indicating the potential of utilizing torsional responses for transfemoral implant monitoring.

Harmonic-related vibration characteristics have been utilized to monitor the loosening states of THA implants. It has been reported that the number of harmonic spikes will increase as the

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stiffness of implant systems decreases due to implant failure [26], which is symptomatic of increasing nonlinearity in the vibrational response. As a result, the energy distribution in harmonics and amplitude of spikes will be influenced. Georgiou [27] conducted an extracorporeal vibration test on 23 patients who undertook hip replacement surgeries. The results have shown that waveform distortion and resonant frequency of output acceleration signals can deliver a more accurate diagnosis of the stability of implants than radiographs. They detect loose states by evaluating the amplitude of the first and second harmonics, the number of harmonics and the number of resonant frequencies of output signals. More loosening states could be detected through Alshuhri's [28] improvements which compute harmonic ratios in the output signal.

Although these methods have proved effective, they may not be practical for the monitoring of bone degradation-induced transfemoral loosening. Many factors can influence the dynamic response of implants, such as implant type, input excitation, sensor location and boundary conditions. The identified frequency range or harmonics spikes that are sensitive for hip implants may not be suitable for transfemoral implants. Besides, the effect of bone degradation on dynamics responses has not been investigated so far, which highlights the innovative aspect of this paper since it is critical for the validity of long-term monitoring. The bone mineral density and shape of bone will change slowly if aseptic loosening is induced by bone resorption, and these changes can complicate the diagnosis of interface loosening. Hence, to develop a more suitable vibrometric approach for transfemoral implants, we first need to investigate the effect of bone degradation on dynamic responses and identify the vibrational characteristics that are most sensitive to the change of boundary condition.

This paper aims to computationally investigate the potential of monitoring bone degradation-induced transfemoral implant looseness using vibration signals. This paper studies the transient response of a bone-implant construct using cross-spectrum analysis and the results indicate that the first torsional mode is the most sensitive to cortical thinning-induced loosening.

Materials and Methods

This computational study investigates a simplified femur bone model to explore potential useful characteristics arising from loosening and cortical thinning. Muscles, hip joints, and ligaments are ignored in the analysis to simplify the dynamic response. The femur bone is assumed to be amputated 250 mm above the knee, representing a common case of resection level [29]. As shown in Fig. 1a, the femoral shaft is simplified to a hollow cylinder with 25 mm and 35 mm for inner and outer diameter separately. Additionally, cortical thinning due to stress thinning will be simulated in such a way that the distal shaft is gradually tapered by rotational material removal (see Fig. 1b). The percentage of removed bone volume and shaft volume is used to quantify the extent of bone loss.

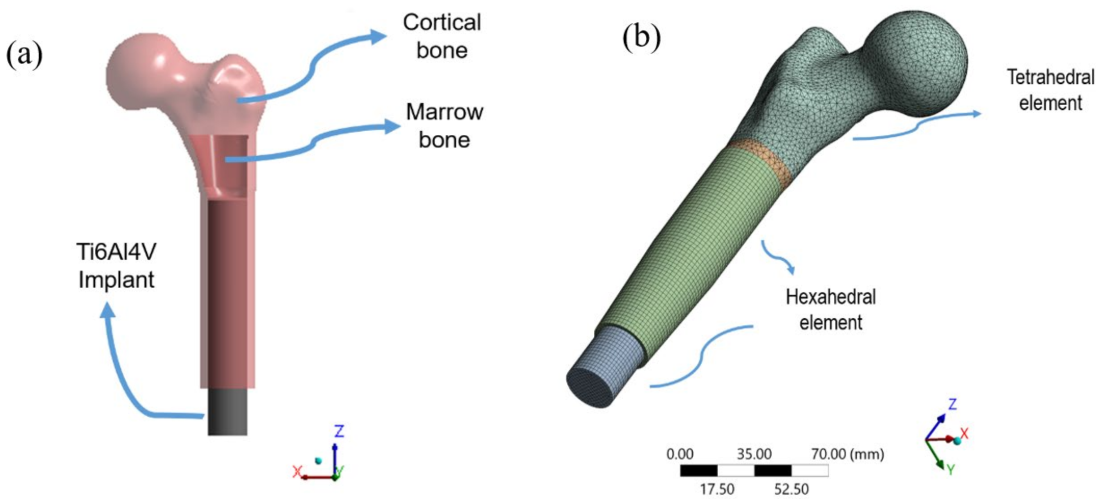

Figure 1:(a) The simplified femur with inserted implant and (b) The mesh of a bone-implant construct with a 15% bone loss amount.

The geometry of implants and designed intramedullary length differs across the different implants. For Integral-Leg-Prosthesis (ILP) implants, the length ranges from 132 mm to 180 mm, while for standard Osseointegrated-Prosthetic-Limb (OPL) implants, the insert length is 160 mm and a custom-made implant that is lower than the standard insert length can be designed for patients who have insufficient stumps length [29-31]. The Implant diameter varies from 14 to 25 mm [31]. In the present work, a cylindrical implant with a smaller insert length (120 mm) is employed because the actual effective contact region is smaller than the designed contact. The material of implants is titanium alloy due to its good biocompatibility and low rigidity compared with other alloys [32]. The material properties of bone and implant are listed in Table 1.

Table 1 Material properties of the bone and implant

Material	Young's modulus (GPa)	Poisson's Ratio
Cortical bone	17.6	0.3
Spongy bone	13	0.36
Titanium alloy	110	0.33

An appropriate contact model that can represent the implant boundary conditions is important for the accuracy of the finite element (FE) analysis. For the OPL and ILP implants, friction is the main mechanism for connecting bone and implants after the first surgery, whereas bonded contact is commonly used in many FE simulations [1, 8, 9, 16, 29]. There is no sliding and separation of the contact elements in bonded contact. Hence it is acceptable to use this contact condition when the implant can be assumed as fully osseointegrated. Depending on the assumptions and aim of the research, frictional contact can be more suitable than bonded contact. Weinans [33] compared the stress shielding effect of femoral hip prostheses using bonded and press-fit contact and suggested the press-fit stem would lead to a smaller amount of bone loss than fully bonded steam. His study shows that the press fit contact is more appropriate when prestressing effects are important in FE analysis. In this study, the change of bone geometry will influence the stress field of bone and subsequently alter the clamp pressure on the implant. To reflect the looseness resulting from the geometry change, the frictional contact condition is more appropriate than bonded contact.

Two cases with different contact conditions between bone and implant are investigated. First, bonded contact is employed to represent the case of a fully osseointegrated implant under bone resorption, which is designed to prevent the nonlinear effect originating from loose contact and only investigate the consequence of bone resorption. Next, over-fit contact with a 0.4 frictional coefficient was employed to explore the nonlinear behavior when cortical thinning is assumed to also lead to loosening at the bone-implant interface.

The value of interference fit is important to implant stability since lacking primary fixation will directly hinder the bone osteointegration process [12]. The actual value of performed interference fit is unknown because it is highly determined by surgeons' practical skills. It is believed that the actual value is typically lower than a 100 µm because an effective offset larger than this value could lead to femoral canal fracture, and it is suggested that a realistic range is from around 0.05 mm to 0.1 mm [34]. In the present work, an over-fit value of 0.05 mm for the implant diameter is assumed, along with a friction coefficient of 0.4, based on the value reported in [35].

ANSYS2021 Transient Structural (Ansys, Inc) was used to determine the transient response of bone implant structure. A global mesh size was determined to be 2.2 mm based on a mesh convergence check for the base frequency with a 5% convergence error. An example of the FE mesh is shown in Fig. 1b. In all cases, the proximal end of the femur is fixed [1, 36]. To excite all vibration modes, impact forces are applied on the distal end of the implant in x, y, and z directions, and at the same time, an axial torque is also applied at the distal end of implant. The time profiles of all excitation loads are the same, having a very short duration of 1.6e-4s to provide a wide and flat frequency excitation. Transient vibration responses are probed through accelerometers placed at two locations at the distal part of the implant, as shown in figure Fig. 2. Cross-spectrums between the signals probed from two accelerometers are further calculated for determining mode shapes and resonance frequencies.

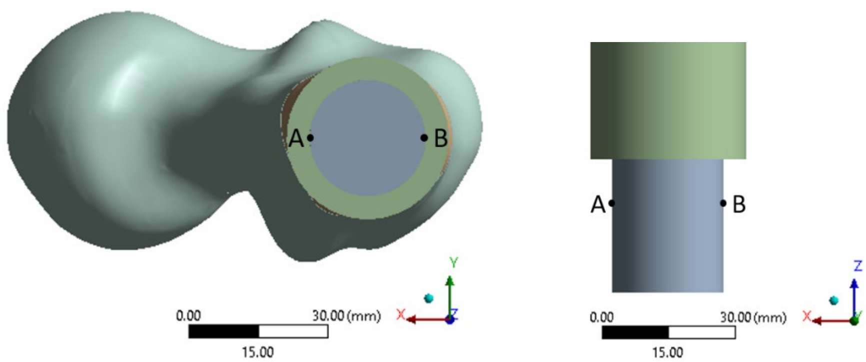

Figure 2. Location of the two accelerometers, shown as A and B, placed diametrically opposite each other, to facilitate the identification of torsional modes.

Results and discussion

The cross spectra of case 1 and 2 are plotted in Fig. 3 and Fig. 4 respectively. There are nine frequencies that can be identified from the frequency peaks in the amplitude of cross power spectral density (CPSD). The mode shape of the fifth frequency can be considered as torsional in that its corresponding phase angle in the Y-axis direction is 180 degrees, indicating that the two accelerometers are moving in the opposite direction.

The bonded contact condition excludes the possible non-linear effect that results from frictional contact. Fig 3 shows that the frequency of modes 1, 2, 5, and 6 increases as the amount of bone loss resulting from cortical thinning increases, while the seventh, eighth, and ninth frequencies decreases. The first torsional mode (Mode 5) is the most sensitive one to the amount of bone loss. This mode shifts from 2475 Hz to 2660 Hz (7.47% relative increment, 185Hz absolute increment) as the relative bone loss amount increased from 0% to 22.5%. Less absolute frequency changes are observed in mode 8 and mode 9 with 100Hz and 165Hz absolute frequency shifts, respectively.

Mode 6 is moderately affected by cortical thinning, with its frequency increasing from 2785 Hz to 2855Hz (70Hz difference).

In case 2, the friction stress at the contact will change with deformation during the impact test, leading to a nonlinear contact behavior. A nonlinear system can be difficult to predict because a small perturbation in the system may change the response significantly [37]. The vibration of rods with bilinear hysteresis boundary condition was explored by Balasubramanian et al. [38]. They found the resonant frequency of the rod decreases with the level of excitation due to the softening property of bilinear stiffness, suggesting that the frequency response of a nonlinear system was not invariant and can change with the level of excitation energy. By examining the shape of the amplitude spectra in Figure 4, no significant softening or hardening effect could be observed, even though the excitation level along the longitudinal axis in this study is much higher than the value (780N) [39] recorded during normal walking activities. The vibration response of the bone and implant construct with press-fit contact under 22.5% bone loss can be assumed as linear.

Compared with the results of case 1, the frequency of all modes in case 2 decreases due to decreasing stiffness attributable to contact loosening. The effect of bone loss amount on frequency shift in case 2 is similar to the effect in case 1. When bone loss amount increases, the first torsional mode (mode 5) still has the largest increment among all the modes. This mode shifts from 2395 Hz to 2575 Hz (7.52% relative increment, 180Hz absolute increment).

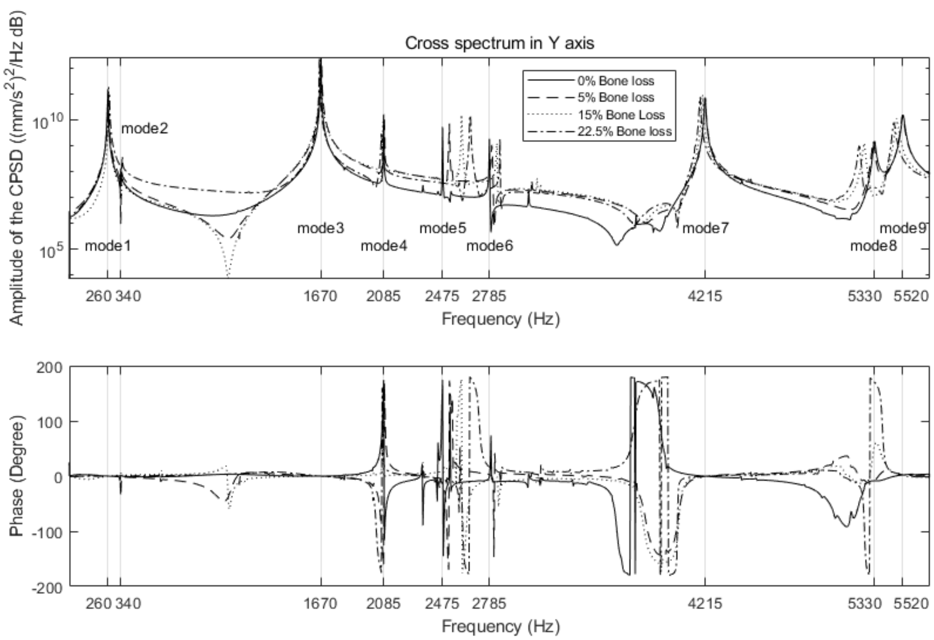

Figure 3. Cross-spectrum of case 1 with bonded contact condition

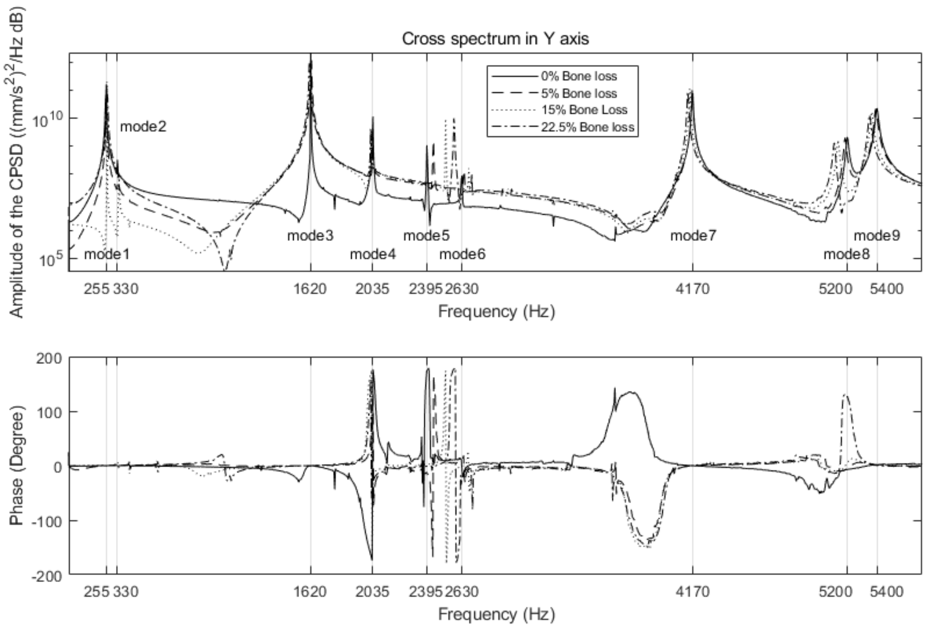

Figure 4. Cross-spectrum of case 2 with frictional contact condition.

In both cases (with and without contact loosening), the first 2 fundamental vibration modes are bending modes and no significant frequency shifts can be identified in these modes, indicating that they are not sensitive indicators of bone loss. Compared with mode 5 and mode 6, the high-frequency modes (mode 7, 8, 9) are significant but less affected by bone degradation. Even though the higher frequency modes are found to be generally more sensitive than fundamentals frequencies, such a phenomenon may not be observed in human limbs because the existence of muscles and tissues can damp out high frequencies.

The configuration of two-extracorporeal sensors placed 180° apart relative to the bone-implant axis (cf. Fig. 2) aims to deliver a non-invasive and continuous implant monitoring. The effectiveness of this setup is demonstrated in this paper. The torsional mode (fifth mode) can be successfully identified through cross-spectral analysis of transient responses collected by these two sensors. The results of this computational study show that when cortical thinning happens, the bone-implant construct can have a special pattern of modal shifts. The frequency of some of the vibration modes increases as bone loss amount increases. Bone resorptions can change both modal stiffness and modal mass of bone. When the modal mass decreases faster than the modal stiffness, the natural frequency of the bone-implant construct can increase. The result in this paper also indicates that the first torsional mode is the most sensitive to bone loss-induced loosening. These findings suggest that a suitable loosening index could be established using the modal information. An experimental program to verify the present simulation results is currently under way.

Conclusion

This computational study investigates vibration responses of a bone-implant construct under progressive bone degradation using a two-sensor setup. The results suggest that cortical thinning can influence the dynamic response of the implant in a unique pattern. And the changes in the frequency of the first torsional mode can provide a sensitive indicator, which increases by 7.52% as the bone loss amount increases by 22.2% regarding the press-fit contact, indicating the potential for non-destructive monitoring of bone degradation induced implant loosening using a vibration method.

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