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Quantitative Monitoring of Osseointegrated Implant Stability Using Vibration Analysis

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Abstract. Reliable and quantitative assessments for the stability of the osseointegrated prostheses are desirable and advantageous in ensuring the success of the installation and long-term performance. However, the common evaluation techniques are qualitative, where their accuracy of which relies on the surgeon's experience. This computational study investigates the potential of using vibrational response to evaluate the stability of the osseointegrated implant using finite element simulation. This paper mainly focuses on the resonance frequency shift and mode shape changes associated with the degree of osseointegration which is simulated by varying bone-implant interface Young's modulus. The resonance frequency of the specific torsional modes increases 211% and 155% for low-frequency (0 to 1800Hz) and high-frequency (1800 to 5000Hz) ranges respectively, as the simulated osseointegration process. Moreover, the torsional mode change from the implant to the femur-implant system is clearly evidenced. The findings highlight the potential application of vibration analysis on the assessment of implant stability.

Introduction

Osseointegrated implant, of which intramedullary part inserting into the skeletal system directly, provides joint mobility and control of the prosthesis with the sensory feedback from the ground [1-3]. This surgical treatment is developed based on a biological phenomenon, which is known as "osseointegration". Osseointegration is a highly complex and dynamic process, which constructs a direct mechanical connection between bone and biocompatible material gradually [4-6]. This functional structure allows the load transmission through the bone-implant interface. The common material of the osseointegrated implant is a titanium alloy due to its great biocompatibility and high resistance to the repeated load and corrosion [3, 4, 7]. Even though the osseointegrated implant has been described as the preferred surgical treatment for the amputee, the success of the osseointegrated requires relative strict prerequisites such as sufficient primary (mechanical) stability to promote bone regeneration and remodeling [1, 8, 9]. Otherwise, the formation of fibrous tissue at the bone-implant interface will hinder the initial osseointegration [3, 10, 11]. After the accomplishment of primary stability, the osseointegration starts with bone tissue formation at the bone-implant interface. This mechanical structure requires adequate time for rehabilitation to be capable of the full weight of patient [2, 3, 12]. The integrity of this

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structure is also known as secondary stability and therefore, the secondary stability is highly related to the state of osseointegration.

The conventional methods used to assess the implant stability such as clinical X-ray, pull-out test and magnetic resonance imaging (MRI) are invasive and subjective where their accuracy is highly dependent on the surgeon's experience [1, 13-16]. Recently, there is a significant research interest in using non-invasive approaches to monitor implant stability. Vibration analysis is a non-destructive structural health monitoring technique, which was firstly used in evaluating bone fracture healing [17-19] and monitoring the total hip arthroplasty loosening [20-23]. The methodology of using the dynamic response of the bone-implant system to assess the stiffness at the bone-implant interface is widely recognized [1, 21, 24]. Recent researches have also shown that the stiffness change at the bone-implant interface was related to the state of osseointegration [20, 24, 25]. Shao. et. al.[1] conducted an experiment on an amputee during his rehabilitation process and their results illustrated a gradually increase in the resonance frequency until the implant is capable of full weight load bearing. Moreover, a previous experimental study on rabbit tibias, implants were installed into different size predrilled cavities to simulate secure-fit and loose-fit connection [26]. Their result demonstrated that the bone-implant system with the loose-fit connection had lower initial resonance frequency compared to those with the secure-fit condition. In addition, the study conducted by Carins et. al.[14, 27] exhibited higher resonance frequencies and that the associated mode shapes are more sensitive to the stiffness change at the bone-implant interface. Similar findings were also reported in [21, 22, 25, 28, 29].

The objective of this paper is to investigate the vibrational response on monitoring the degree of osseointegration at the bone-implant interface via finite element simulation. This vibrational-based approach is based on the detection of the shift in resonance frequency and mode shape change to assess the level of osseointegration.

Methodology

In the computational analysis, the bone model used in this project was based on an artificial femur model scanned by a structured light 3D scanner. The femur model consists of two parts: the cortical shell and spongy bone (see Fig. 1a). The material of femur-implant model was assumed to be homogeneous and isotropic [30, 31]. The material properties of the femur and implant system [32-34] are described in Table 1. The novel osseointegrated endoprosthesis implant model was developed based on the design concept proposed by Russ et al.[35]. As shown in Figure 1b, the novel implant model consists of two parts: Extramedullary (EM) strut and Intramedullary (IM) stem. The implant model was generated by using the Shell function in the SolidWorks. The contour of the EM strut and IM stem have certain tolerance with the outer surface of the cortical shell and medullary cavity for the application of femur-implant interface layer.

Table 1: Material properties of the femur and implant system.

Material	Young's modulus[MPa]	Poisson's Ratio
Cortical shell	17600	0.3
Spongy bone	13000	0.36
Titanium alloy	113800	0.342

A thin layer, which used to simulate the osseointegration, was applied to the femur-implant interface, as illustrated in Fig 2. The layer thickness at EM strut and IM stem surfaces were set to

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0.985mm and 0.5mm, respectively. The surfaces of the femur-implant interface layer were bonded with both implant and femur model.

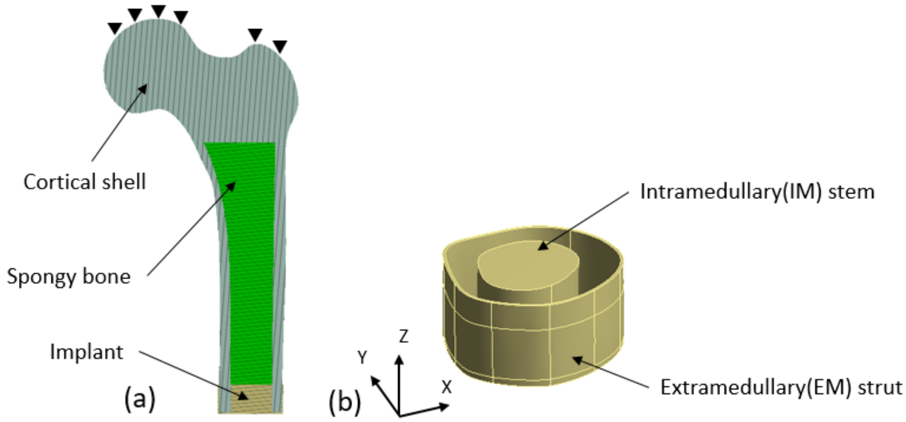


Fig. 1: (a) Cross-section of the computational femur model and (b) Implant.

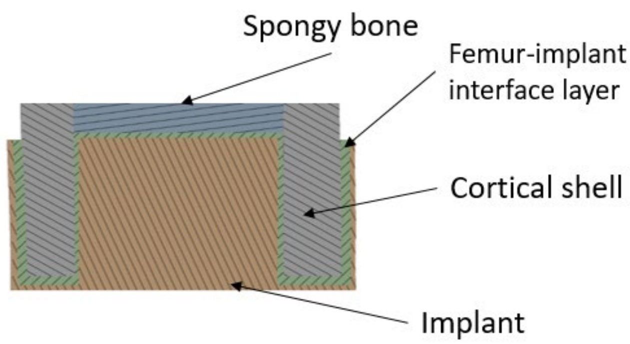


Fig. 2: Cross-section of the femur-implant interface.

ANSYS 19.0 Modal analysis was performed to determine the dynamic response of the femur-implant model. The femur model was fixed at the proximal end to simulate constraints from muscle and pelvis, as illustrated in Fig. 1a. The type of element was set to "Quadratic Tetrahedrons" to avoid stress singularity at sharp corners. The global mesh size was set to 5mm, which was optimized by a mesh convergence test with 5% convergence error for the maximum von Misses stress on the femur. In addition, the mesh around the interface was further refined with a localized body sizing of 1.5mm. The modal analysis mainly focused on the frequency range of 0 to 5000Hz as mentioned in [14, 27].

This computational analysis aims to investigate the resonance frequency shift and mode shape change under various conditions of primary and secondary stability. Hence, as illustrated in Table 2, Young's modulus (E) of femur-implant interface layer was varied from 0.001% to 100% that of the cortical shell (E_c) were investigated to simulate the process from 0% osseointegration to fully osseointegrated implant as mentioned in [36]. The method of employing the variation in E, is similar to the application of adhesive at the femur-implant interface to simulate the process of osseointegration in several experiments mentioned in [17, 37-39].

Table 2: Young's modulus of the layer (E) relative to that of cortical shell.

Percentage[%*Ec*]	0.001	0.0025	0.005	0.0075	0.01	0.05	0.1	0.5	1	10	100
***E* [MPa]**	0.176	0.44	0.88	1.32	1.76	8.8	17.6	88	176	1760	17600

Result

The deformation in y-axis direction along z-axis was shown in Fig. 3. This deformation shows the presence of the torsional mode. The results demonstrated in Fig 3a and 3c, where the implant is not osseoinegrated with the femur, shows only the implant responding (*TI*). When the implant is fully osseointegrated, the torsion response of the entire femur-implant system (denoted as *TS*) is recorded (see Fig 3b and 3d).

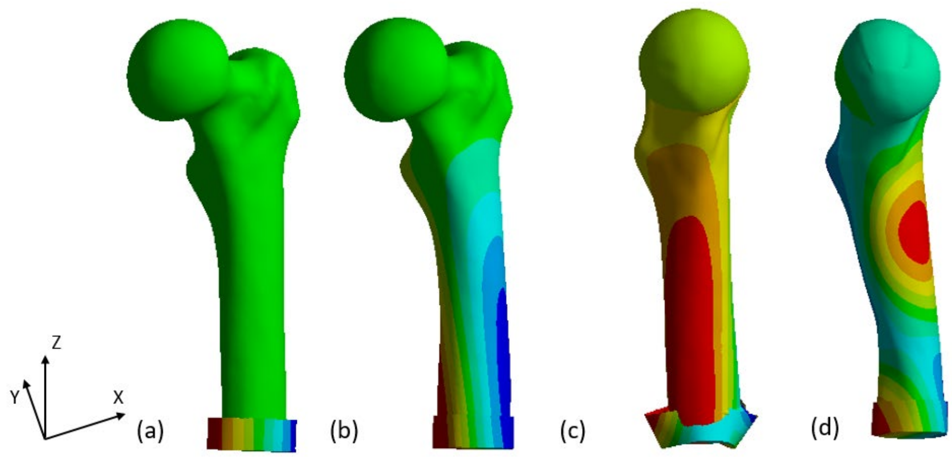
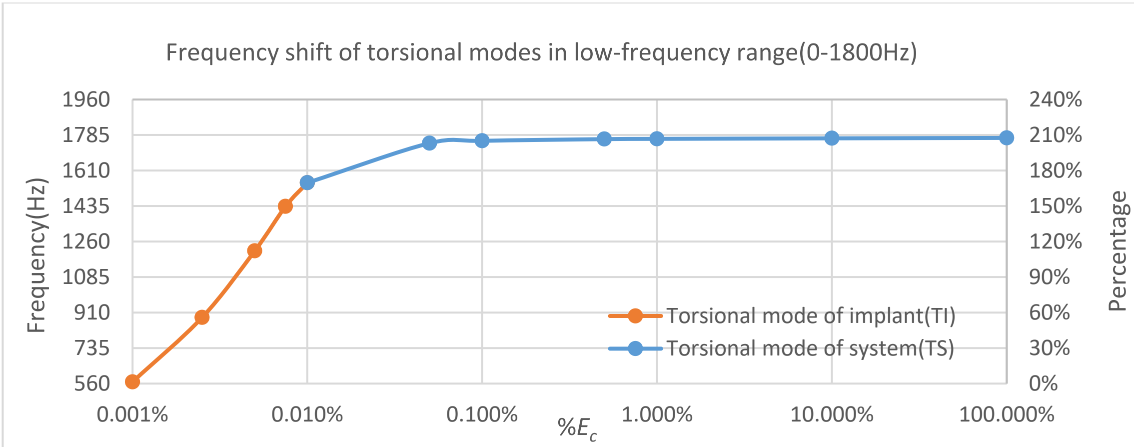


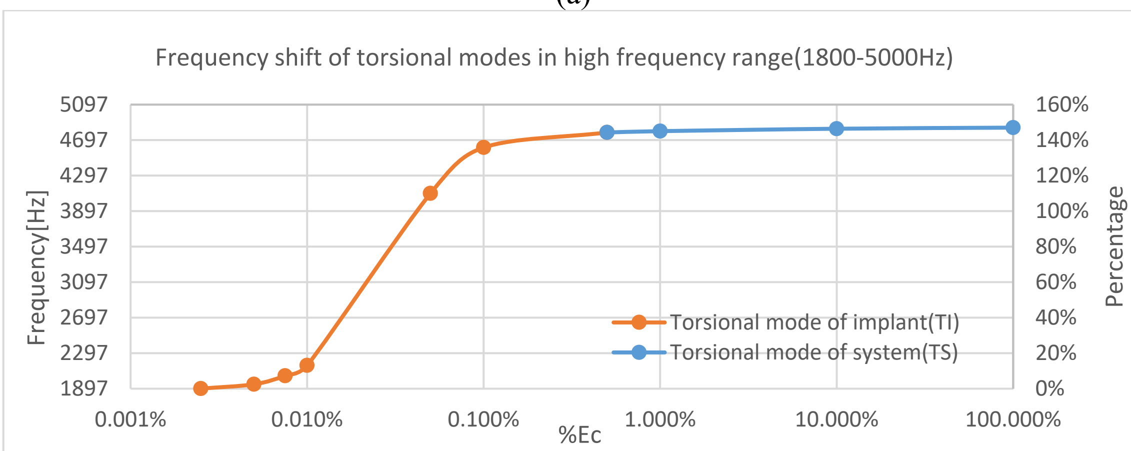
Fig. 3: Low-frequency torsional mode of: (a) implant (TI) with 0.001%Ec; (b) femur-implant system (TS) with 100%Ec and high-frequency: (c) TI with 0.0025%Ec; (d) TS with 100%Ec.

Figure 4 demonstrated the variation of the resonance frequency with the simulated osseointegration (*SO*) process in both low-frequency (0 to 1800Hz) and high-frequency (1800 to 5000Hz) ranges. The percentage on the plot indicated that the resonance frequency gradually increased relative to the first torsional frequency, along the *SO* process.

In the early stage of *SO* process, the change of resonance frequency could be easily identified in both frequency ranges. The resonance frequency of the specific torsional modes increases 211% and 155% for low- and high-frequency ranges respectively, as the *SO* process. As illustrated in Fig. 3a, there is a significant increase in the resonance frequency of *TI* from 568.45Hz to 1433.2Hz, as *E* increased to 0.01% E_c. Similar smooth variation in resonance frequency was identified in the high-frequency range. This result was in accordance with [1, 22, 28], suggesting that the frequency shift of the system increases along the mode shape complexity increasing. The change of frequency indicated a clear correlation between the *E* and resonance frequency in the early stage of *SO* and the result agrees with the findings in Cairns et. al. study [14].



(a)



(b)

Fig. 4: Frequency shift of torsional modes in frequency range: (a) 0-1800Hz; (b) 1800-5000Hz.

Moreover, the mode located at 568.45Hz was observed to initially vibrate as implant torsional mode *TI* and then migrated to system torsional mode *TS* at 1770.6Hz, with the process of *SO*. The transformation, from the significant vibration at implant to torsional mode of the femur-implant system, was apparent in high-frequency range as well. However, beyond 1% E_c, the frequency shift caused by the change of E was negligible for both low- and high-frequency ranges after the mode shape change.

Even though the sensitivity of this method was constrained in the relative small E value, this variation in frequency and mode shape were significant, suggesting that monitoring the resonance frequency and mode shape change could aid in early detection of insufficient stability, thereby decreases the likelihood of failure in osseointegration.

Conclusion

This paper reveals the preliminary concept that monitoring the primary and secondary stability of the femur treated with novel implant design could be evaluated with the dynamic response of vibration. The finite element investigation has demonstrated that the resonance frequency increased gradually along the *SO* process. The result has also demonstrated the significant shift in resonance frequency, 211% and 155% for low- and high-frequency ranges respectively, indicating the potential of vibration analysis on the quantitative evaluation of the implant stability at the early stage of osseointegration. Furthermore, the identification of mode shape change enhanced the evaluation of stimulated osseointegration process. Future work is currently in progress to investigate this vibrational analysis method on various length of residual femur.

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Conflict of Interest
The author declares that there is no conflict of interest regarding the publication of this paper.

Ethical approval
This article does not contain any studies with human participants or animals performed by any of the authors.

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