Healing assessment of an internally fixated femur using vibration analysis

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KEYWORDS: Internal fixation; fractured femur; healing assessment; dynamic response; spectral analysis

ABSTRACT
The lack of a quantitative method to adequately assess fractured bone healing that has undergone fixation limits prognostic capabilities on patients’ optimal return to work. This paper addresses vibrational analysis - used to monitor the state of healing of a plate-screw fixated femur to supplement the current clinical radiographic assessment. This experimental study involves an osteotomized, composite femur specimen with modelling clay added to simulate the damping effect of overlying soft tissues. Epoxy adhesive was applied to the fractured region and allowed to cure to simulate the healing process. With the instrumentation described, the cross-spectrum and coherence were obtained and analyzed in the frequency domain over a period of time. The results suggest that it is crucial to analyze the cross-spectrum and proposed healing index to quantitatively assess the stages of healing. The results also show that the mass loading effect due to modelling clay did not influence the described healing assessment technique. The findings indicated a potential, non-intrusive technique to evaluate the healing of fractured femur by measuring the vibrational response.

1. Introduction
Internal fixations are a common treatment for a fractured femur to correct alignment, provide mechanical stability, allow weight bearing and prompt early use of the limb while the bone is healing. In comparison to external fixation, internal fixation has been associated with decreased issues such as pin tract sepsis and joint stiffness [1]. The plate-screw fixation healing efficiency involves reducing fracture gap such that bone contact developed at the fracture interface and immobilising the fracture site [2]. Internal fixation allows patients to return to normal function earlier than casts and splints allow, as well as reducing the incidence of non-union and mal-union. Figure 1 shows examples of the installed plate and screws internal fixation on a long bone.

Figure 1: Internal plate-screw fixation

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However, the difference in modulus between the plate and bone, as well as the induced compressive stress by over-tightened screws, disturbs the bone vascularity and bone resorption underneath the plate, thus compromising healing, strength and longevity [9]. Furthermore, the bone stress-shielding due to the stiff internal fixations adversely delays the bone healing. There has been a considerable amount of research on plate-screw fixation to improve fracture healing, and prevent stress-shielding and bone loss [3-7]. An essential part of the treatment is accurately determining healing progression and unification of the fixated fractured femur. The healing process of a fractured bone is complicated and delayed union, mal-union and non-union are common occurrences due to the delicate balance between the anabolic and catabolic phases of normal healing [8]. Prior to allowing the patient to return to previous function, the degree of healing is often assessed through clinical interpretation of images from X-rays or CT scans. These radiography techniques are known to be subjective and inconclusive [9]. Therefore, it is desirable to develop a novel, analytical technique to objectively and accurately determine the state of healing.

There are a variety of measurement techniques available, including ultrasound, direct static measurement and vibration measurement to measure stiffness in an internally fixed fractured bone [9-26]. Shah et al. [11] reported on clinical measurements on 11 patients for whom they assessed the change in stiffness of fractured tibial shaft as it healed. In their study the fractured tibial was placed in a cast and casts were removed during measurement and replaced afterwards. The stiffness of the fractured tibial was measured statically using a Goniometer and a load cell - and they measured significant changes in the stiffness of the tibial as it healed. The use of stiffness to assess the state of healing of 100 tibial fractures was also substantiated by Claes et al. [12]. Borchani et al. [13] reported the use of an instrumented fixation device to monitor bone healing by integrating measurement sensors within the internal fixation. Nemchand [14] investigated wireless telemetered instrumented intramedullary nail implants and reported sufficient sensitivity to monitor strain with callus growth of Young’s Modulus 0.2 MPa. However, their recent instrumentations have yet to produce a reliable set of significant data for potential clinical use.

The existing literature commonly reports strain readings used to determine the extent of healing [13-17]. However, others have reported that there is no correlation between strain and bone healing [16]. Talaia et al. study [15] used fiber Bragg gratings to assess the stiffness of callus formation of fractured bone by loading intact and plate femur to 600N, however, at this particular loading further damage to a fractured femur may result.

There is interest in using dynamic vibrational analysis techniques for quantitative healing assessment [9, 18-26]. Cornelissen et al. [19] utilized vibrational measurements on a healing tibia, which revealed bending modes and frequency shifts during the healing process. Unfortunately, they were unable to track the frequency shift due errors which may have been caused by mode coupling. Sekiguchi et al. [20] investigated 41 in vivo cases of tibial fractures by inducing vibration to the tibia with a customized hammer at the medial malleolus and a piezoelectric receiver at the medial region of the tibial tuberosity. Their study reported that a completely healed long bone has higher frequency waveforms compared to a newly fractured bone. An in vivo study by Tower et al. [21] examined a vibrational response up to 400 Hz, of a fractured tibia with an external fixator and internal fixation which included intramedullary nails, unreamed and reamed nails, plates and inter-fragmentary fixation. The Tibial Stiffness Index, which is the ratio of the resonant frequency of the healing tibia and the intact tibia on the other leg, was then formulated to quantify the healing. Despite good correlation with the traditional methods, the authors did not recommend this method for clinical use due to a large error amount in the index. Chiu et al. [26] concluded that the vibrational response of the femur treated with a plate fixation is not significantly influenced by transverse or oblique fracture orientation. Nakatasuchi et al. [22] simulated the healing process by injecting epoxy adhesive into the fracture and observed a steady increase in bending mode frequency during healing. These studies suggest that the dynamic vibration response could possibly be used for quantitative healing assessment.

More recently, extensive works by Ong et al. [24, 25] reported the possibility to assess the healing of a fractured femur with external fixation. Ong et al. demonstrated that the state of healing of a femur could be quantified by using PVDF film sensing elements on the external fixation pin and an impulse excitation on the external fixation. Furthermore, the effect of mass loading from soft tissue on the healing assessment was also investigated and discussed in the Ong et al. study [25]. Tsuchikane [27] reported muscles were the most significant damper. The soft tissues, joints and fibula increase the ‘apparent’ weight and dampen tibial vibration, a recognized obstacle in analyzing vibrational response.
Zhang et al.\cite{28} demonstrated the dynamic response of a light-weight cantilever bar was severely dampened by the mass of an accelerometer. Previous studies using the dynamic response to account for stiffness changes as an indication of the state of healing relied on the definition of the frequency response function of the femur. Furthermore, these experiments require a knowledge of the input force measured with an instrumented impactor \cite{21, 24, 25, 29}.

The paper will present a methodical approach, investigating assessment of the state of healing by measuring the dynamic response of a plate-screw fixated femur. The sensor development method is demonstrated to mitigate the necessity for an instrumented impactor and to facilitate the transition to clinical use with minimal complexity. Additionally, this investigation also incorporates the mass loading effects of soft tissue, which is simulated by highly damped modelling clay around the fixated femur. The dynamic stiffness of the fractured femur treated with a plate-screw fixation was measured using a two-sensor arrangement. The change in the stiffness was used to define the state of healing of the plate-screw fixated femur. A sawbone, composite, bone test specimen was used and the healing was simulated by using long cure time epoxy adhesives applied to the fractured region. Chiu et al.\cite{26} serves a reference on the type of excitation that should be considered to distinguish the key responses of the construct as a function of healing. The findings demonstrate the ability to quantify the state of healing in the presence of the simulated soft tissues by defining the required spectral response that is associated with bone healing.

2. Experimental Methods

The experimental specimen is a composite femur fixated with plate-screw fixation, which was created from an AxSOS small fragment locking plate system from the Stryker\textsuperscript{®} Corporation, shown in Figure 2. The head of the femur was fastened with a vice rigidly attached to a heavy block concrete and securely gripped with a set of 3D printed vice clamps matched to the femur head geometry. Two B&K Type 4507 unidirectional accelerometers were attached to the other end of the composite femur head and orientated to measure the acceleration in the y-axis direction (perpendicular to the long bone). Modelling clay is chosen due to fundamentally and functionally represents soft tissue because of its high damping quality and it can be moulded with maximal contact (no slippage). Figure 3 shows a schematic of the experimental rig and the application of the input loading.

Previous works by Ong et al.\cite{24, 25} used an instrumented impact force hammer to acquire results in an orderly procedure. In this study, the input force is deliberately not recorded and the forcing location is not fixed. This test set-up allowed force variability during the experiment and facilitated the assessment of the robustness of the measurement technique proposed.

The signals from the accelerometers were acquired and processed by a 2-channel B&K Photon+. The applied forcing is conducted without an instrumented forcing device which has been used in previous works\cite{24, 29}. The 2-sensor system measures the dynamic vibrational responses of the fixated femur as it heals with a statistical evaluation to validate the acquired data.

Figure 2: Close up view of the plate-screw fixation.

Figure 3: Experiment test setup indicating saw blade cut, modelling clay, two accelerometers and strike point.
A saw blade was used to perform a mid-shaft osteotomy of the composite femur and a plate-screw fixation was then installed. Prior to the experiment, tape was placed over the fracture site to form a mold to ensure uniform filling of adhesive epoxy, which is consistent with previous work on simulating healing across fracture site\(^{[30]}\). It should be noted that the use of epoxy is not an exact representation for healing since the solidified epoxy is not equivalent to the bone Young’s Modulus. However, the curing process is similar to an extent to fundamentally demonstrate the concept does indeed captures the changes in material properties and bone stiffness. A two-part, 30 minutes cure time adhesive epoxy was used to simulate the healing process. Prior to the epoxy filling, modelling clay was partially added to the femur then immediately around the femur once the fracture site was filled with epoxy, as shown in Figure 3. The mass of the modelling clay used was approximately 1kg. The final mass of the composite femur, plate-screw fixation and modelling clay is shown in Table 1.

| Sawbone composite femur | 512 g |
| Sawbone composite femur + plate-screw fixation | 598 g |
| Sawbone composite femur + plate-screw fixation + modelling clay | 1398 g |

Mixing the two-part epoxy initiates a chemical reaction. The epoxy cures while the test specimen is being prepared, with insertion of plate-screw fixation and modelling clay application surrounding the specimen. The initial recording of time \( t = 0 \) second denotes the first set of experimental results collected immediately after the experimental preparation and epoxy was applied to the fracture site. The experiments were conducted at regular intervals as the epoxy cured – simulating ‘healing’, in the osteotomized region of the femur. In order to span the entire curing process, data was recorded until 180 minutes at 2-minutes intervals for the first 100 minutes and 5-minute intervals for the remaining 80 minutes. The frequency bandwidth of 10 kHz with a frequency resolution of 1.56Hz and the spectra were averaged over 10 samples to obtain a good signal-to-noise ratio. The spectra were observed to stabilize after an average of 7 samples. The measurement at each healing stage took approximately 30 seconds to perform, which was considered not significant compared to the epoxy curing time. The cross-spectrum between the two accelerometers, coherence function and phase were recorded in the frequency domain. In spectral analysis, the relation between the measured two signals is shown in the coherence function. A high coherence value indicates the data acquired are associated with the changes in the stiffness resulting from the simulated healing of the fixated femur. On completion of the experiment, the test specimen was re-used and the test procedure repeated. A total of three experiments were conducted.

3. Results

a. **Mass loading effect on healed plate-screw fixated femur**

The magnitude and phase of the cross-spectrum and coherence function of the plate-screw fixated femur with and without the modelling clay are shown in Figure 4. The coherence function aids to identify the frequencies where coherent modes associated with the changes in the stiffness resulting from the simulated healing of the fixated femur. The response below 100 Hz is associated with the global response of the construct without the modelling clay mass effect, refer to Figure 4. However, at higher frequencies, the modelling clay mass contribution is significantly evident. The initial out-of-phase modes of the construct with and without mass loadings were observed at approximately 195 Hz and 300 Hz, respectively. The initial in-phase mode with and without mass loadings were measured at approximately 105 Hz and 160 Hz, respectively. These modes are associated with the fixated femur as indicated by its significant coherence values. Furthermore, the effect of the modelling clay dampens the magnitudes of the cross-spectral as shown in Figure 4. The modelling clay is seen to damp out the higher modes and this damping effect concurs with previous findings\(^{[28]}\).
Figure 4: Coherence, cross-spectra and phase with and without damping mass of the fully healed plate-screw fixation.

b. Healing assessment of the fixated femur with mass loading

Figure 5 shows the magnitude and phase of the cross-spectrum and the corresponding various stages of healing. The key observation and characteristic of the results are as follows:

At frequencies below 200 Hz, it is observed that frequency peaks at 16 Hz; 67 Hz and 109 Hz are not sensitive to the state of healing. The response in the vicinity of 179 Hz, however, was affected by the state of healing. The frequency associated with the peak response at this frequency was noted to increase as healing progressed that corresponded to the increased stiffness due to the simulated healing. It was also noted that at frequencies below 200 Hz, the dynamic responses of the fully healed specimens were identical.

For the frequencies above 200 Hz, where the effect of mass loading was noted to be significant, the three tests conducted show that the state of healing is reflected by the frequency response measured. The increasing magnitude of the cross-spectra and the corresponding value of the coherence attest healing progression.

These observations show that a careful inspection of the cross-spectra, along with the coherence function, is required to properly define the state of healing of this fixated femur. However, relying on the changes in the frequency response alone is not sufficient. Both the effects of the healing on the natural modes of the fixated femur and the effects of the healing on the overall mass loading of the fixated femur have to be accounted for.
Figure 5: Coherence, cross-spectra and phase functions of three experimental investigations.

(a) Test #1
(b) Test #2
(c) Test #3
c. Healing Index for quantitative evaluation

The cross-spectrum for the three tests were processed by using the normalized healing index, as defined by Equation 1. The frequency bandwidth of interest is between 0 Hz and 600 Hz. The healing index is normalized to the cross-spectrum obtained from the first experiment conducted (i.e. time zero, see Figure 6). The gradient of the healing index defined by Equation (2) is also included in these results. These results show the behavior of the healing index and provide means to analyze and deduce the state of healing of the fractured femur.

\[
HI(t) = \frac{1}{\text{Initial Healing Index}} \int_{0}^{600} |\text{CS}(f, t = i) - \text{CS}(f, t = 0)| \, df
\]

Equation 1

\[
\text{where, Initial Healing Index} = \int_{0}^{600} \text{CS}(f, t = 0) \, df
\]

\[
HI_t(t) = \frac{d}{dt}(HI(t))
\]

Equation 2

The healing index and the time-derivative of the normalized healing index (HI_t) served to identify stages of healing, as calculated by Equation 2. Whilst the healing index curve can be seen to asymptote as healing progresses, a definitive statement on the state of healing is best made in conjunction with the cross-spectrum and the rate of the change of the healing index simultaneously, to identify and evaluate the healing process.

The evolution of the cross-spectra with respect to the healing of the femur is presented in Figures 6(a) – (c). The cross-spectrum PSDs measured during the experiment are presented in this intensity plot. Figures 6 show the application of the proposed healing index to the sets of experimental results. This indicated that the healed femur healing index is at least 80% relatively higher than the fracture fixated femur even with the presence of mass loading. Furthermore, the healing index curve shows the progression of healing and asymptotes with increasing time, which is a significant improvement compared to previous work by Ong et al. [25]. The robustness of the manner in which the state of healing is determined is evident in Figure 6. The measurement technique did not require a knowledge of the input stimulus. The variability of the strike point will lead to experimental error. This is shown in the healing index curves in Figure 6. However, with the curve fitted to the healing index and its associated gradient, when considered along with the cross-spectral lead gives a definitive statement on the state of healing.
4. Conclusion

This paper reports the assessment of healing progression of a simulated fractured femur treated with plate-screw fixation using dynamic vibrational responses. The 2-sensor deployment methodology was presented in this study to mitigate the common use of an instrumented impactor for healing assessments using vibrational analysis. The effect of the modelling clay as a simulated soft tissue influenced the dynamic response of the fixated femur. However, this mass loading effect is minimal on the proposed healing assessment technique. The findings emphasized the necessity for the proposed healing index, the rate of change of the healing index and the associated cross-spectrum to be concurrently analyzed to evaluate the state of healing. This study demonstrated a non-intrusive method by utilizing vibrational analysis to assess bone healing as a quantitative approach - which allows further insight to potentially predict and prevent common construct failures. Future works are currently being investigated on healing assessment for clinical use.

Acknowledgement

This project is funded by the US Navy Office of Naval Research (N00014-16-1-2882). The support provided is gratefully acknowledged.

References


