RESEARCH ARTICLE

Replacement of Destructive Pull-out Test with Modal Analysis in Primary Fixation Stability Assessment of Spinal Pedicle Screw

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Abstract

Background: Pedicle screw fixation devices are the predominant stabilization systems adopted for a wide variety of spinal defects. Accordingly, both pedicle screw design and bone quality are known as the main parameters affecting the fixation strength as measured by the pull-out force and insertion torque. The pull-out test method, which is recommended by the standards of the American Society for Testing and Materials (ASTM), is destructive. A non-destructive test method was proposed to evaluate the mechanical stability of the pedicle screw using modal analysis. Natural frequency (ω_n) extracted from the modal analysis was then correlated with peak pull-out force (PPF) and peak insertion torque (PIT).

Methods: Cylindrical pedicle screws with a conical core were inserted into two different polyurethane (PU) foams with densities of 0.16 and 0.32 g/cm3. The PIT and PPF were measured according to the well-established ASTM-F543 standard at three different insertion depths of 10, 20, and 30 mm. Modal analysis was carried out through recording time response of an accelerometer attached to the head of the screw impacted by a shock hammer. The effect of the insertion depth and foam density on the insertion torque, natural frequency, and pull-out force were quantified.

Results: The maximum values of ω_n, PIT, and PPT were obtained at 2,186 Hz, 123.75 N.cm, and 981.50 N, respectively, when the screw was inserted into the high-density foam at the depth of 30 mm. The minimum values were estimated at 332 Hz, 16 N.cm, and 127 N, respectively, within the low-density PU at the depth of 10 mm. The higher value of ωn was originated from higher bone screw stability and thus more fixation strength. According to the regression analysis outcomes, the natural frequency (ω_n) was linearly dependent on the PIT (ω_n=14 PIT) and also on the PPF (ω_n=1.7 PPF). Coefficients of variation as the results of the modal analysis were significantly less than those in conventional methods (i.e. pull-out and insertion torque).

Conclusion: The modal analysis was found to be a reliable, repeatable, and non-destructive method, which could be considered a prospective alternative to the destructive pull-out test that is limited to *the in-vitro* application only. The modal analysis could be applied to assess the stability of implantable screws, such as orthopedic and spinal screws.

Level of evidence: V

Keywords: Bone screw fixation, Insertion torque, Non-destructive modal analysis, Polyurethane foam, Primary stability, Pull-out strength

Introduction

Low back pain is one of the major health problems around the world. One of the leading causes of low back pain is considered to be the degeneration of the intervertebral discs (1-3). The treatment options for low back pain may vary depending on the severity of the case. Pedicle screw fixation is the standard method

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adopted for posterior stabilization in patients with a spinal fracture, spinal instability, or degenerative disc disease and it is widely used in correcting pathologic deformities (1, 4, 5).

Pedicle screws are used since the late 1950s and boosted after the screw-rod fixation system in 1988 (6, 7). Currently, spinal fixation with pedicle screws is one of the most frequently performed instrumentation procedures in thoracolumbar spine reconstruction (2). The prime advantage of this method is the immediate immobilization of the motion segment. In spite of all the technological progress over the last decades, the results of several studies have reported different types of failure for pedicle screws. The most common failures were screw bending, breakage, and loosening (8).

In order to minimize the risk of mechanical failure, a wide variety of pedicle screw designs, such as cylindrical, conical, expandable, self-tapping, self-drilling, asymmetric progressive, dual-core, and double thread screws, have been proposed and developed (4, 19-17). The efficacy of all designs is usually assessed based on two kinds of mechanical stabilities, namely primary and secondary. Primary stability is the immediate stability after the implantation of a screw into the bone and comes from mechanical engagement (18). In the spinal stabilization systems, the primary stability enhances the fusion process and is considered a prerequisite for achieving secondary stability and long-term fixation. Secondary stability is the stability of the screw after bone remodeling and healing, which depends on the primary stability and the rate of bone remodeling (19).

The standard test methods are recommended by the American Society for Testing and Materials (ASTM)-F1717 and ASTM-F543 (two parts) for spinal posterior fixation systems, mechanical assessment of metallic bone screw insertion torque, and pull-out strength tests (conventional methods), respectively (20, 21). The pull-out test is the most common test to evaluate the bone screw stability, and numerous researchers have reported the correlation of pull-out force with insertion torque (16, 22-24). However, such correlation was not reported by the findings of some other studies (4, 25, 26). Other approaches, such as cyclic fatigue, compression, and shear tests, have been also proposed for the evaluation of the mechanical performance of the bone screws (27-30).

The results of biomechanical studies have demonstrated the existence of a correlation between bone quality and bone screw strength (10, 22, 24, 31). Karami et al. evaluated the pedicle screws in spine cadavers and found out an improvement in the pull-out force by increasing the insertion depth up to 290% from the mid-body to the bi-cortical portion of the vertebra (29). The effects of bone analog density were also assessed on insertion torque and pull-out force, where growth rates of 180% in insertion torque and 301% of pull-out force were obtained by increasing foam density from 0.16 to 0.32 g/cm^3 (24).

Modal analysis has been introduced to examine the mechanical stability of dental implants (32-34). This method has been presented as a new assessment technique for both primary and secondary stabilities

measurements of dental implants (32, 35, 36). Modal analysis is a non-destructive method that has been used in several biomechanical studies (37-42). Leuridan et al. determined the mechanical properties of a bone replicating material with modal analysis (43). Implant fixation in an acetabular cup was also investigated using mode shapes (44). Moreover, Goessens et al. used acoustic modal analysis to determine the insertion response of 26 cementless hip prostheses and showed its potential *in vivo* application in the primary fixation stability assessment, while the conventional testing methods were not appropriate for real patient surgeries (45). Therefore, it is required to propose a non-destructive method with a good correlation with conventional tests. According to the modal analysis, any stimulated mechanical system vibrates on one or a combination of its natural frequencies. The cantilever beam system has a natural frequency that depends on the length, material property, mass, and boundary condition of the system (45, 46). An elastic or non-rigid boundary condition reduces the fixation and stability, and consequently, reduces the natural frequency (47). The screw-bone fixation strength can be quantified by measuring its natural frequency. While a high natural frequency is associated with a strong screw-bone attachment, a low frequency displays a loose screw-bone fixation. It means that the natural frequency can be used as a fixation strength assessment tool, similar to the insertion torque and pull-out strength tests (48-50).

This study aimed to firstly apply a modal analysis approach to determine the principal natural frequency of an inserted screw in a bone analog, secondly correlate that with the pull-out strength and the insertion torque, and thirdly evaluate how these correlations were affected by the block test density and screw insertion depth.

Materials and Methods
Pedicle screw specification
A commonly used pedicle screw (Fortex, X.spine cooperation, Cruiser Lane, USA) of titanium alloy was used in this study [Figure 1]. It had a length of 47 mm, an outer diameter of 6.5 mm, and a mass of 5.1 g. The tip of the screw was self-tap and the thread pitch was constant throughout the screw. The crest thickness in this study varied from the proximal to the distal portion, which allows the involvement of the screw with both the cortical and cancellous regions of the bone. In one-third of the screw proximal length, the screw threads were distributed cylindrically, whereas the central core distribution was conical. The core diameter gradually increased from 3.35 to 5.35 mm from distal to proximal regions. This generates a better grip in the bone-screw interface both in cortical and cancellous portions (9, 10).

Block test
Samples of 40*60*40 mm3 (12 samples per foam) were extracted from 40*180*130 mm3 cellular polyurethane (PU) blocks (Sawbones, Pacific Research Corporation, Vashon, Washington, USA) and used as biomechanical testing material [Figure 1]. During cutting the samples, a cold cutting technique was employed by a low-speed
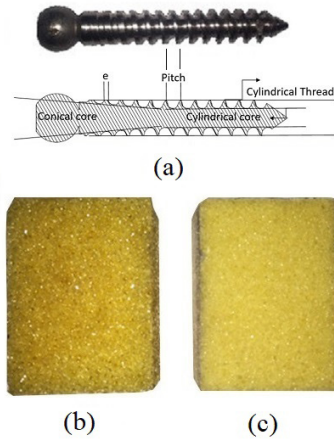
Figure 1. a) Real pedicle screw used in this study, b) Schematic pedicle screw and its different parts, c) typical low-density polyurethane samples (0.16 g/cm³), and d) typical high-density (0.32 g/cm³) polyurethane samples.

cutting machine (BS-1018B, WMT CNC Industrial, China) to ensure no damage to the block structure. Blocks with two different densities, as specified in ASTM-F1839, were considered (51). The high-density PU had a density of 0.32 g/cm³ and an elastic modulus of 137 MPa with pore sizes between 0.5 mm and 1 mm. The density and elastic modulus of the low-density PU test block were 0.16 g/cm³ and 23 MPa, respectively. The pore dimensions in low-density PU varied from 0.5 to 2 mm.

Screw insertion

Based on the recommendation of ASTM-F543 (the standard test method for the medical bone screws), 24 pedicle screws were inserted (n=4 each group). The screws were implanted to a depth of 20 mm (n=4 each group), according to the standard. Furthermore, the insertion depths of 10 and 30 mm (n=4 each group)

were included to examine their effects on the dependent variables. The pilot hole preparation has remarkable effects on results (52, 53) and all drilling parameters are kept constant during tests. The pilot hole diameter for implantation was 5.5 mm and its depth was adjusted on-demand depending on insertion depth (21). Subsequently, the screw was tightened using a torque meter (LT Lutron, TQ-8800, Taiwan) up to the predefined insertion depth. The desired value of insertion depth was adjusted as the following: First, the pilot hole was drilled into the samples based on their insertion depth. Secondly, before insertion, the required length of the screw was marked on the screw threads. Finally, the rapid increase in insertion torque stated the on-demand depth (21). The peak insertion torque (PIT) was recorded for each sample. The block-screw structure for modal and pull-out tests was placed in a clamp to carry out modal analysis, followed by pull-out tests, as schematically shown in Figure 2. Four samples were used for each experimental condition.

Modal analysis

Before insertion, a small flat section was created on the head of each screw for the installation of a lightweight uni-directional accelerometer (code 4374, Bruel & Kjaer, Denmark) with a mass of 0.27 g. After the insertion, the accelerometer was mounted on the head of the screw in the direction of impact, with strong double-sided adhesion. Conventional modal analysis (accelerometer response of oscillation) was performed for each sample. The impulse recording device was calibrated to avoid excessive impact. The impact was exerted by a standard impact hammer (code 8202, Bruel & Kjaer, Denmark), and the response was recorded digitally. The recorded accelerometer response was then analyzed, and the damped natural frequency (ω_d) value was determined. According to equations 1-3, decaying oscillation amplitude (δ), the system's damp ratio (ζ), and the natural frequency (ω_n) were calculated, respectively (46). $A(x)$ and $A(x+T)$ are the amplitudes of two sequential periods at the accelerometer time response curve
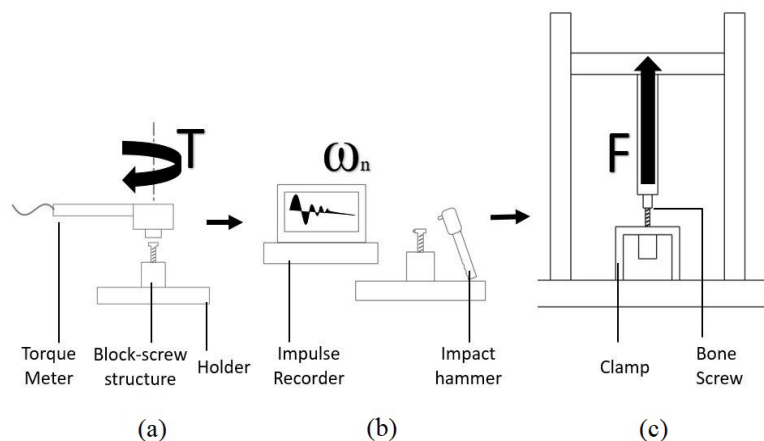

Figure 2. Schematic test setup used for a) insertion torque, b) modal analysis method with an accelerometer, and c) pull-out test.
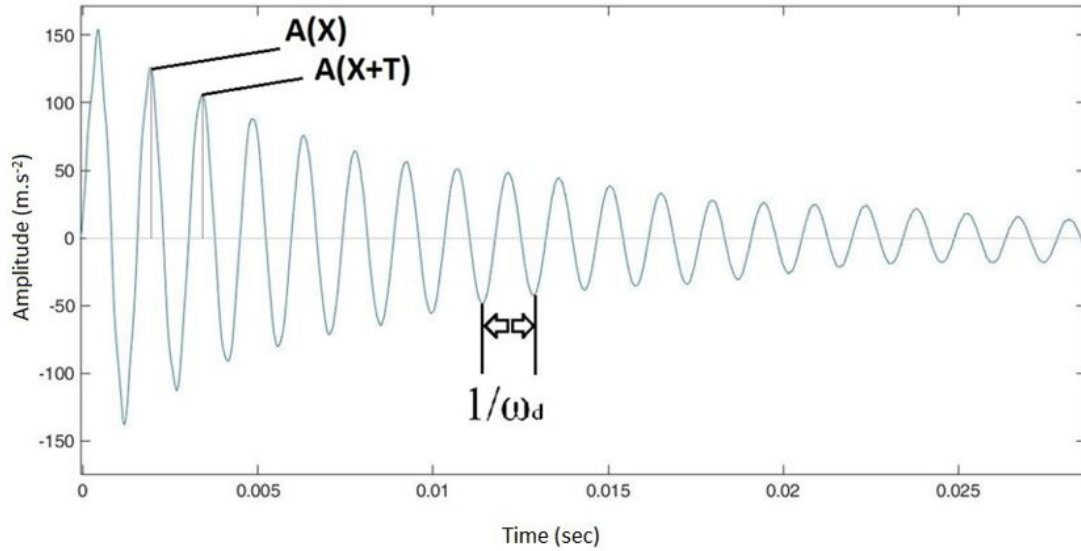
Figure 3. Typical time response of the accelerometer modal test for insertion depth of 30 mm in higher density

[Figure 3]. Equation 4 represents the decay behavior of the accelerometer time response. The inverse product of

$$\delta = \ln(\frac{A(x)}{A(x+T)}) \quad (1)$$

$$\zeta = \frac{\delta}{\sqrt{4\pi^2 + \delta^2}} \quad (2)$$

$$\omega_n = \frac{\omega_d}{\sqrt{1 - \zeta^2}} \quad (3)$$

$$a(t) = -Ce^{-\zeta\omega_n t} \quad (4)$$

natural frequency by damped ratio indicates decay time (46). The modal testing for each sample was repeated four times. The mean and standard deviation values were extracted from modal analysis and reported for different test samples [Table 1]. All calculations, figures, and charts were generated using Microsoft Excel 2003 (Microsoft Corp., Redmond, WA, USA).

Pull-out
A unidirectional testing apparatus (DTM 25KN, Zwick-Roell, Germany) was used to perform a pull-out test according to ASTM-F543 (21). After the pedicle screw insertion within the PU block, the orientation of the bone screw and tensile hook were set in the coaxial direction and the load cell was set to zero. Displacement

Table 1. Mean and standard deviation Datasets obtained according to equation 1 to 3 for each group of interest. Damped natural frequency (ω_d) measured from the time response of accelerometer and then Logarithmic decrement (δ) calculated from equation 1. Damping ratio (ζ) and natural frequency (ω_n) then calculated from equation 2 and 3, respectively. Decay time (1/ $\zeta\omega_n$) was calculated to show the decaying trend of equation 4.

Group		Damped Natural Frequency, ω_d (Hz)	Logarithmic decrement, δ	Natural Frequency, ω_n (Hz)	Damping ratio, ζ	Decay Time, 1/$\zeta\omega_n$(msec)
Density (g/cm³)	Insertion Depth (mm)					
	10	679(±26)	0.168(±0.016)	680(±30)	0.027(±0.003)	55(±3)
0.32	20	1101(±20)	0.129(±0.011)	1102(±23)	0.021(±0.002)	44(±3)
	30	2183(±22)	0.263(±0.104)	2186(±24)	0.029(±0.008)	17(±5)
	10	330(±41)	0.164(±0.013)	331(±43)	0.026(±0.002)	117(±17)
0.16	20	731(±21)	0.104(±0.009)	735(±23)	0.017(±0.001)	83(±8)
	30	1172(±25)	0.154(±0.019)	1174(±28)	0.023(±0.001)	38(±2)

was controlled at a rate of 5 mm/min for each sample. The sampling rate of 25 Hz was used to record load-displacement data, and data acquisition was continued until the screw was pulled out completely. The peak pull-out force (PPF) was extracted from the recorded data, highly similar to our previous study (21, 23).

Statistical analysis

In this study, PU density and insertion depth were the independent variables, while the ωn, ζ, PIT, and PPF were considered dependent parameters. The effects of high and low PU densities and three different insertion depths were determined on dependent variables. Linear regression analysis was used to relate the modal analysis, pull-out, and insertion torque tests. All the data for each test condition (i.e., ω_n, ζ, PIT, and PPF) were statistically analyzed using one-way ANOVA (Microsoft Excel 2003, Microsoft Corp., Remond, WA, USA). A confidence level of 95% ($P<0.05$) was considered to evaluate the statistical differences. Furthermore, a Tukey-Kramer honesty significant difference (HSD) post hoc test was used to determine significant differences among the results in each test group.

Results

The maximum of ωd, ζ, and ωn occurred in a high-density bone analog with an insertion depth of 30 mm [Table 1]. All groups experienced underdamped oscillation with a light decaying oscillation amplitude [Table 1]. The decaying time response of the oscillation (i.e., equation 4) for a typical accelerometer in the modal test is presented in Figure 3. In modal analysis, decay time represents the period of oscillation for an approximately constant damping ratio (46). The smallest bone screw insertion depth in the low-density PU showed the highest decay time value and the least natural frequency, which was significantly lower ($P<0.05$) than those in the high-density PU within the highest insertion depth

(i.e. 30 mm) [Figure 4]. Moreover, all subgroups were significantly different in terms of bone analog density and insertion depth according to the Tukey-Kramer honesty test ($P<0.05$).

The PPF [Figure 5.a] and PIT [Figure 5b] were demonstrated as response variables in regression analysis. The predictor variable was ωn, which was
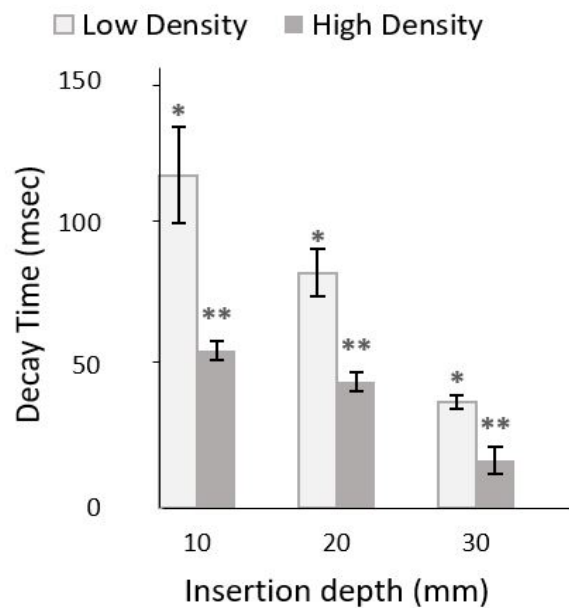
Figure 4. Decay time vs. three insertion depths in two different block test densities (low-density PU: 0.16 g/cm3 and high-density PU: 0.32 g/cm³)

Decay time was significantly different for two densities based on the ANOVA test, and the asterisks above each bar represent significant intra-group differences based on HSD.
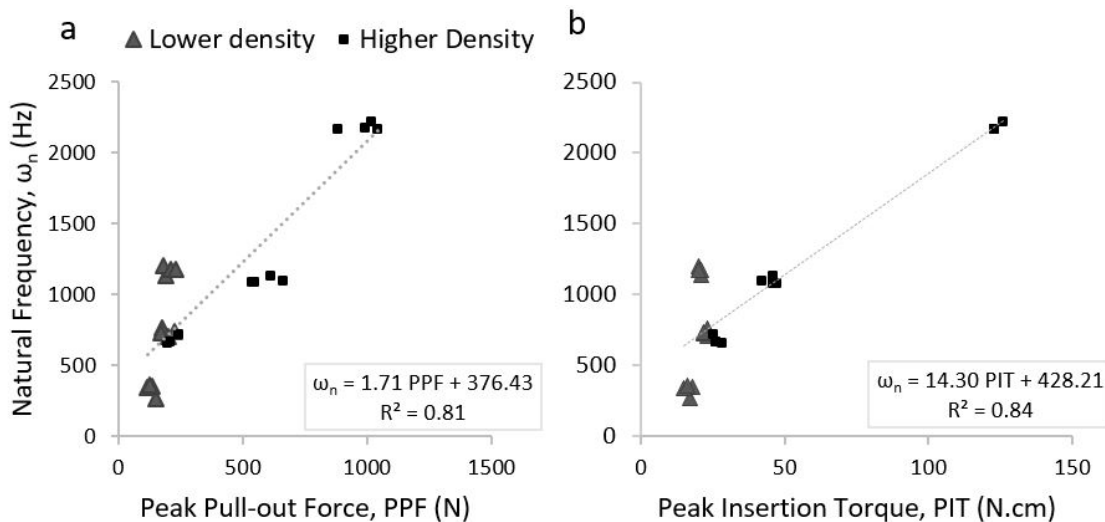
Figure 5. a) Natural frequency vs. Pull-out Force, and b) Natural frequency vs. Insertion Torque.
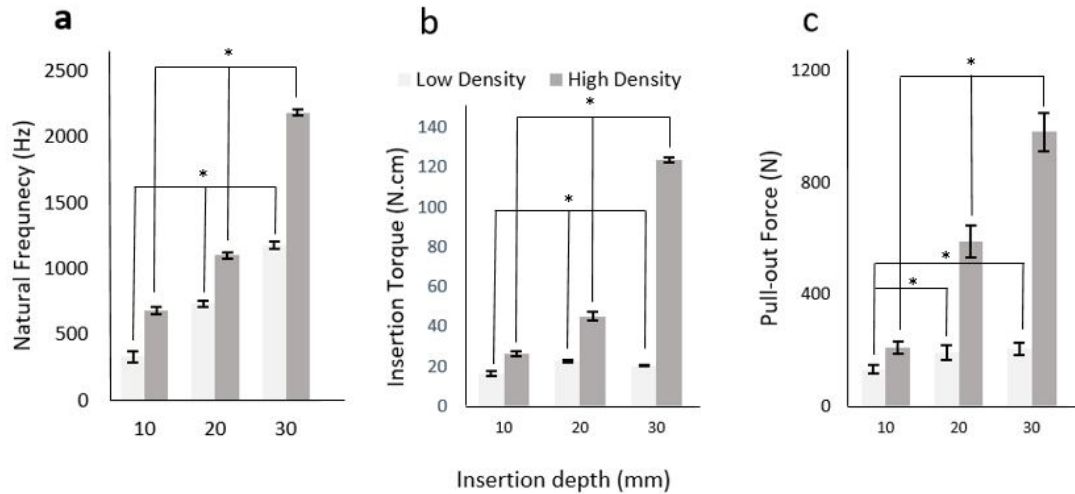
Figure 6. a) Natural frequency, b) Insertion torque, and c) Pull-out force vs. three different insertion depths in low (0.16 g/cm^3) and high-density (0.32 g/cm^3) bone analogs .

derived from the accelerometer response. A linear relationship among ωn, PPF (R^2=0.81, *P<0.001*), and PIT (R^2=0.84, *P<0.001*) was calculated at ω_n = 1.7 PPF and ωn = 14.3 PIT, respectively [Figure 5].

The ωn, PIT, and PPF (considered dependent parameters in this study) for six groups of interest were measured [Figure 6]. The mean of PPF for 30 mm insertion depth was estimated at 981.7±70.3 N in high-density PU. Similarly, the ωn and PIT were estimated at 2186.07±24.45 Hz and 123.75±1.5 N.cm, respectively. All peaks were observed in high-density blocks with a 30-mm insertion depth [Figure 6]. For both PU densities, the one-way ANOVA test showed a statistically significant effect of insertion depth on the ωn, PIT, and PPF (*P<0.05*) [Figure 6]. The Tukey-Kramer honesty test revealed significant differences depending on insertion depth (*P<0.05*), except between 20 mm and 30 mm depths in the low-density PU for the PPF (*P=0.49*) [Figure 6c]. Significant differences were presented on each bar as an asterisk [Figure 6a].

Discussion

In this study, modal analysis was used to investigate the primary stability of the spinal pedicle screw fixation. Screw impacting (or tapping by impact hammer) in the modal analysis studied here determined the stability of the bone analog-screw interface and this stability was related to the screw loosing. If a single screw with a rigid boundary condition had been tested, then the bending and breakage mode would have been determined (54, 55). Furthermore, the correlations among modal frequencies, peak pull-out strength, and PIT (representative of primary stability) of a screw-block test structure were examined. Moreover, the effects of block test density and screw insertion depth (representative of the independent variable) on the natural frequencies, pull-out forces, and insertion torques were demonstrated using high- and low-density bone analogs and three different screw insertion depths.

The destructive pull-out test is the most common method adopted to evaluate the screw fixation strength (10, 16, 17, 23, 24, 31) and may give various results when used in human or animal bones because of the large variability in specimens. In this study, commercial polyurethane foams, rather than cadaveric bone samples, were used to minimize result variations (16, 51). The pore dimensions in the blocks varied at 0.5-2 mm, which was comparable with those in human cancellous bone either in the intact (0.5-1.0 mm) or osteoporotic (0.5-2.5 mm) forms (56). In addition, the foams elastic moduli (23 and 137 MPa) were similar to those in human osteoporotic and intact cancellous bones (~30 and ~110 MPa, respectively) (56). The purpose was to consider the test blocks resembling the porosity and properties of the healthy and osteoporotic cancellous bone. The insertion torque has been also assessed as a correlation measure between two test methods (3, 4, 26). However, the results of some studies have shown no correlation between the pull-out strength and insertion torque values (25). Due to the destructive nature of the pull-out test, it is impossible to use it during real patient surgeries; however, the proposed non-destructive modal analysis has a consistent correlation with pull-out force, which makes it a practical and possible substitution.

The ω_n, PPF, and PIT were higher in high-density PU and boosted with increasing insertion depth. The ωn increased by 77% by changing density from 0.16 to 0.32 g/cm^3. The PPF and PIT increased by 236% and 228%, respectively, as reported by Hashemi et al. , where the PPF and PIT changed by 180% and 301% by increasing the PU density from 0.16 to 0.32 g/cm^3 (24). In addition, similar to those reported by Kim et al. for bone analog density (10), in 0.24 g/cm^3 rigid PU, the PPF was quantified on average 3.5 times greater than in 0.08 g/cm^3 for different thread shapes and profiles. The PPF and the PIT increased by 366% and 371% for the higher density and 54% and 24% for the lower density, in case that the insertion depth increased from 10 to 30 mm, respectively. Likewise, for the PIT and PPT, the ωn improved by 221% in the high-

density and 253% in the low-density by changing the insertion depth from 10 to 30 mm.

Equation 5 reveals that the ωn is proportional to the square root of the stiffness coefficient to the system mass ratio, where the moment of inertia (I), constant value (1.8752), cross-sectional area of the screw (A), and length of the screw (L) are constant for every comparison (46). It can be shown that this is almost equivalent to the elastic modulus to the system density ratio. Screw properties, except the insertion depth, were constant during the tests; therefore, this variation could be mostly attributed to changes in density and elastic modulus of the test block. Theoretically, this ratio can be calculated using equation 6 (46).

$$\omega_n = 1.875^2 \sqrt{\frac{EI}{\rho AL^4}} \qquad (5)$$

$$\frac{\omega_{n1}}{\omega_{n2}} \propto \frac{\sqrt{\frac{E_1}{\rho_1}}}{\sqrt{\frac{E_2}{\rho_2}}} \qquad (6)$$

where, E1, E2, ρ1, and ρ2 are the moduli of elasticity and PU foam densities, respectively. For high and low densities, the theoretical frequency ratio was approximated by equation 6 to be √3, regardless of the insertion depth. Experimentally, for the 10, 20, and 30 mm insertion depths, this ratio was calculated at 2.078±0.294, 1.5±0.055, and 1.863±0.064, respectively. The deviation from the theoretical values was mainly due to different insertion depths used in the experiment, which was excluded in the theoretical ratio of √3. Additionally, the mechanical vibration of an inserted screw in a porous medium could be simplified as a vibrating rigid rod, embedded within a relatively soft and elastic bed. A softer bed led to a lower natural frequency and vice versa; meaning that as the modulus of elasticity to density ratio increased, the natural frequency rose. Moreover, the system would be more stable and rigid by increasing the natural frequency. This can be observed in equation 4, where the higher natural frequency resulted in the rapid decay time even when the damping coefficient was highly small.

Modal analysis is a well-known and practiced experimental method to measure the natural frequency of a structural system (38). Furthermore, modal analysis is a non-destructive method, indicating that it can be repeated many times without causing any damage to the structure and performed during an actual screw planting. The modal analysis methods using Periotest and Osstell tests have been implemented considerably in inserting the dental implants (32, 33, 35). However, these methods have not been used to measure the initial stability of the orthopedic and spinal screws during surgery.

According to the results, using an accelerometer and obtaining the natural frequency from recorded time response was a non-destructive approach to determine the initial stability of the spinal pedicle screws, which also had a significant relationship with the PPF and PIT. The overall fitting lines represented the relationship between the ωn, PPF, and PIT, and these graphs had the potential to have different fitting lines for low- and high-density PUs [figures 5a and 5b]. Nakashima et al. used fitted lines in linear regression analysis and showed the correlation of the implant stability quotient (ISQ; measured by Osstell device) with both pull-out force and insertion torque (57). In the study conducted by Nakashima et al., the calculated R-squared value for the linear relationship between ISQ and pull-out force was estimated at 0.34, while it was equal to 0.81 in the present work, predicting a more linear relationship between the ωn and the PPF [Figure 5.a]. Similarly, the R-squared values for the linear relationship between ISQ and the insertion torque were calculated at 0.34 in the study performed by Nakashima et al. and 0.84 in the present study [Figure 5.b] (57). The proposed modal analysis in this study was repeatable since the standard deviation for ωn was close to zero in every single sample group for modal analysis.

There were a few limitations in the current study. First, high- and low-density PU foams, rather than cadaveric samples, were used to reduce the effects of local pore size and intra-variability among the samples. Second, some parameters could influence the results of modal analysis, such as the screw length out of the test block, the thread shape and mass of the screw, the clamping force, and the loading rate. This study aimed to investigate the effects of insertion depth and bone analog density on insertion torque, natural frequency, and pull-out strength by comparing them, regardless of the measured absolute values. Third, key factors, such as screw design, were not considered in this study, and a single screw design was used since the different bone screw designs would give various results and a solid comparison could be more difficult.

Modal analysis was found to be a reliable, non-destructive, and accurate method in predicting the bone screw primary fixation stability with excellent repeatability. Modal frequency can be considered a prospective alternative to the pull-out force, which is not considered to quantify in real surgeries. Furthermore, the insertion torque test is only a one-time primary stability assessment method and cannot be repeated on a single sample. The proposed approach has the potential to be applied for the fixation stability assessment of implantable screws, such as orthopedic and spinal pedicle screws, in different bone analog densities with different insertion depths.

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NEW SCREW STABILITY EVALUATION APPROACH

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