Real time monitoring of screw insertion using acoustic emission can predict screw stripping in human cancellous bone.

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Word count article = 3520

Word count abstract = 250

Abstract

Background: To develop experience, orthopedic surgeons train their own proprioception to detect torque during screw insertion. This experience is acquired over time and when implanting conventional/non-locked screws in osteopenic cancellous bone the experienced surgeon still strips between 38-45%. Technology needs to be investigated to reduce stripping rates. Acoustic-Emission technology has the ability to detect stress wave energy transmitted through a screw during insertion into synthetic bone. Our hypothesis is Acoustic-Emission waves can be detected through standard orthopedic screwdrivers while advancing screws through purchase and overtightening in cancellous human bone with different bone mineral densities replicating the clinical state.

Methods: 77 non-locking 4mm and 6.5mm diameter cancellous bone screws were inserted through to stripping into the lateral condylar area of 6 pairs of embalmed distal femurs. Specimens had varying degrees of bone mineral density determined by quantitative CT. Acoustic-Emission energy and axial force were detected for each test.

Results: The tests showed a significant high correlation between bone mineral density and Acoustic-Emission energy with R=0.74. A linear regression model with the mean stripping load as the dependent variable and mean Acoustic-Emission energy, bone mineral densities and screw size as the independent variables resulted in r^2=0.94.

Interpretation: This experiment succeeded in testing real time Acoustic-Emission monitoring of screw purchase and overtightening in human bone. Acoustic-Emission energy and axial compressive force have positive high correlation to bone mineral density. The purpose is to develop a known technology and apply it to improve the bone-metal construct strength by reducing human error of screw overtightening.

1. Introduction

In orthopaedic surgery the screw, simply explained a device that converts torque into compressive force, is widely employed in nearly all constructs used for fracture fixation. A screw under load creates tension within the screw and compression between the threads and the head. The ability for any screw to transform the torque applied into tension in the screw and compression between the threads and the screw head is dependent on the material that screw is purchased in. When fixing fractures in osteopenic or osteoporotic cancellous bone, screw purchase and its ability to apply compressive force without destroying the purchase material (stripping) is completely dependent on the surgeon's own experience [Maguire1995]. In order to develop experience, orthopaedic surgeons train their own proprioception to detect both the appropriate torque and the compressive force being applied to the screw during insertion. This experience is acquired over time with a learning curve and can be at the expense of construct stability. When implanting screws in cancellous bone the experienced surgeon is still far from perfect. In a study testing the need for bone filler in augmenting of screw fixation, a group of experienced trauma surgeons inserted 225 screws into 37 ankle fracture patients over the age of 50. Of these 225 screws, 86 screws (38%) stripped during the procedures [Andreassen2004]. This was further examined by Stoesz et al when they tested 10 orthopaedic surgeons in the tightening of 240 screws in synthetic bone and 109 (45.4%) were stripped. During the stripping process 90% of the time the surgeon did not notice that the screw was stripped [Stoesz2014]. When a screw is stripped, the pull-out strength of that screw decreases by 80% [Collinge2006] consequently decreasing the overall construct strength. This can lead to construct failure with increased morbidity to the patient. Torque monitoring has not been an ideal method in detecting screw purchase particularly because of the wide variation of bone mineral density in the older patient population [Tsuji2013]. In addition, Tsuji et al. showed that the stopping torque is similar to the stripping torque, which gives screw purchase a 'plateau' characteristic. Torque resistance stops increasing, requiring the surgeon to decide when to stop turning based on the torque response. In fragile bone this difference in torque response is difficult to feel and even in experienced hands overtightening occurs too often.

Alternative detection technology needs to be investigated. Acoustic Emission (AE) monitoring is a well-established Non-Destructive Testing (NDT) technique. Energy is released when deformation and damage grow within a material, this energy propagates as ultrasonic waves and is detectable using piezoelectric transducers (Figure 1). This technology, because of advances in computing, has been studied at an increased frequency in orthopaedic surgery. The reason is that AE monitoring has the ability to detect crack formation in bone at such an early point that a catastrophic material failure can be avoided [Kapur2016, Rashid2012]. A screw stripping in bone during fracture surgery is a type of

catastrophic material failure. In a previous study from this group, it was shown that AE waves were readily detected in synthetic bone during screw purchase, and a pattern was detected prior to screw stripping [Pullin2017; Fig 1].

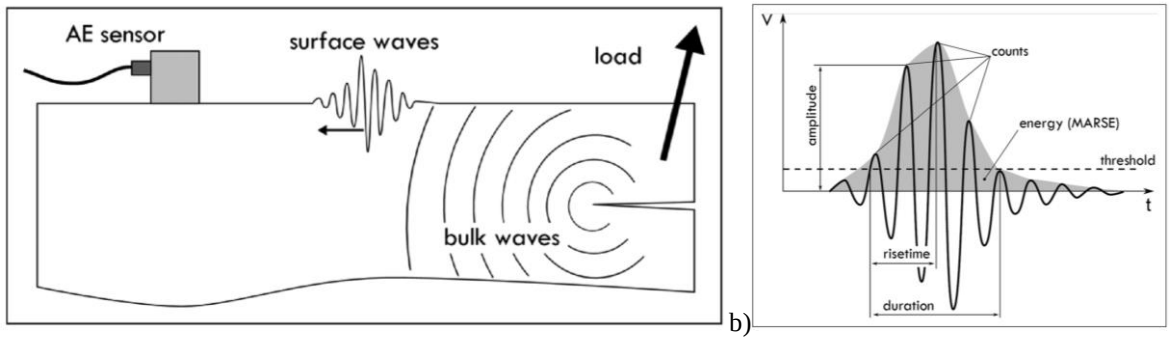

Figure 1: a) Working principle of AE, a crack is formed in the material generating energy waves that are detected on the surface by the AE sensor. b) Typical parameters for an AE event [pullin2017]

The aim of the current study is to detect AE waves in previously validated formalin fixed cadaver femurs [Wright2018]. There is currently no commonly used method to assist surgeons in the prevention of non-locking cancellous screw overtightening other than the surgeons own experience. As shown above there is a large amount of surgeon related error. New technology, like AE monitoring, needs to be investigated to help reduce the rate of stripping. The surface waves that are detected can indicate non-destructive micro-cracking that can be a warning before catastrophic material failure or screw stripping. The ultimate aim is to gain further ground in the development of a real-time AE monitoring system, capable of detecting screw purchase and decrease the occurrence of overtightening. The hypothesis is that AE waves can be detected through a standard orthopaedic screwdriver while advancing screws through purchase and into overtightening in cancellous human bone. The secondary hypothesis is that there is a positive relationship between the AE energy captured through the screws and the bone mineral density of the distal femurs. This will help validate the technique by showing that detected AE energy waves are able to delineate and differentiate between varying degrees of osteopenic bone.

2. Methods

Two different sets of tests were performed on the lateral condyles of distal human femurs. Six pairs of whole femurs without visible, radiological or historically significant bone pathology were harvested from human cadavers donated for post mortem research purposes at the Division of Anatomy, University of Oslo, Norway. Four pairs of female femurs and two pairs of male femurs

were used. The six pairs had a mean age of 82 (68–89) years. Each cadaver had been prepared in 5.6% formalin embalming solution and preserved in 40% ethanol according to a standardized routine procedure. Quantitative computed tomography (QCT) was used to assess bone mineral parameters as calcium density and calcium mass for all femurs in a Siemens SOMATOM Definition Edge (Siemens Healthcare GmbH, Erlangen, Germany) with parameters for a bone scan (100 mA, 120 kV, 1mm slice). Bone mineral content measurements were made in cross sectional slices perpendicular to the longitudinal axis in the metaphyseal center level of the condyles. Syngo.via imaging software (Siemens Healthcare GmbH, Erlangen, Germany) was used to draw a region of interest (ROI) around the condylar cross-sectional area (Figure 2). The ROI included the axial slice orientated to include both condyles proximal to the trochlear groove. The ROI also excluded the thin cortical wall in order to measure a more accurate density calculation of the predominantly cancellous bone. The bone mineral parameters that were used are QCT density and mass. Density was thus expressed as the mean number of Hounsfield Units (HU) within the ROI. Bone mass was calculated as the mathematical product of density and area cm^2 within the ROI and reflected radiological mineral mass [Lagravère2006]. The tests were performed on the lateral condyles because they contain cancellous bone that is the most osteopenic in nature compared to the rest of the femur.

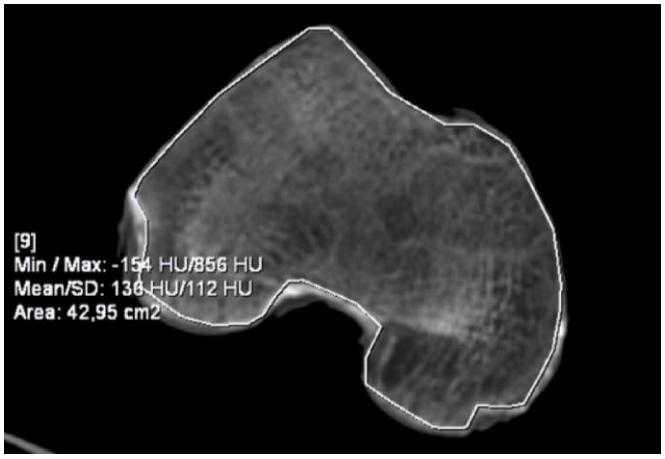

Figure 2: CT image of a cross sectional intercondylar axial slice of a left distal femur with the ROI drawn around excluding the thin cortical wall.

AE data was collected using a National Instruments PXIe-1071 (National Instruments, Austin, TX,USA), this instrument is designed for receiving input from a broad spectrum of measurements and test applications, and combining them in a specifically designed Laboratory Virtual Instrument Engineering Workbench (LabVIEW) (National Instruments, Austin, TX,USA). The data acquisition environment LabVIEW allows for the creation and combining of the different user interfaces for each measurement. AE waveforms generated by the screw to bone surface contact and cutting were converted to electrical signals using a Mistras Pico piezoelectric sensor (200-750 KHz lightweight mini, Physical Acoustics, NJ, USA) bonded with superglue to the screwdriver, as shown in Figure 3.

The signal was amplified using a Mistras 2/4/6 preamplifier with built in 20kHz to 1,200kHz analogue filter and external power source. Data was collected at a sample rate of 2MHz with 2ms worth of data being collected per hit and a timeout period of 3ms. A threshold of 0.1V (60dB) was used to trigger the recording of data, with a 400µs pre-trigger. As well as AE, the system collected the axial load through the screw using a doughnut load cell (LCMWD-1KN, OMEGA Engineering, Inc. CT, USA) which was positioned between the bone and the head of the screw seen in Figure 3. The load cell captures the axial force being applied by the user during turning and, because of its position, it also measures the axial force being generated between the screw head and the screw threads during and after each turn. When the screw begins to tighten the axial force generated by the screw threads does not dissipate between turns, because the material is holding it in a compressive force between the screw head and the load cell. When the axial force fails to increase during a turn, the material the screw was purchased in has failed. In the screw purchase process there has been shown to be an increase in axial force together with strain from torque and AE energy [pullin2017]. In the synthetic bone model, even with continued screwing past the point of stripping, the axial force dramatically decreased together with the strain caused by torque and AE energy. This gave a reliable subjective method for determining real-time stripping that could be correlated with our AE data. The advantage of the LabVIEW system, and the reason it was chosen, over a traditional AE system is its versatility. It is able to collect and analyse multiple data sources like the AE signals and force together with time and be used to produce multiple output options.

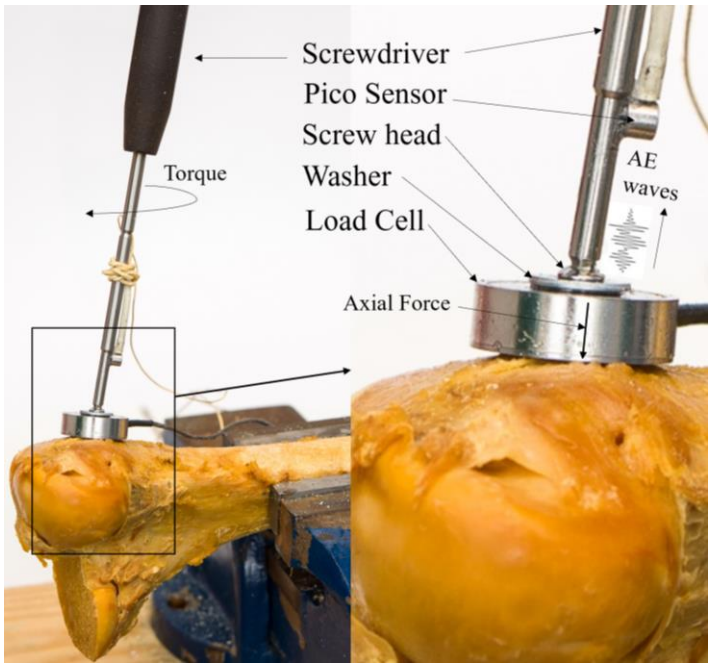

Figure 3 – Screwdriver delivers torque to the screw which creates an axial load captured by the load cell. The screwthread/bone interface also is producing AE waves that travel through the screw and the screwdriver, and are then captured by the PICO sensor bonded to the screwdriver.

Once collected, data was post processed using Python programming language. This involved extracting several parameters including amplitude, duration and absolute energy from each AE event (see Figure 1). The AE data can then be automatically split into data-pre-turn by finding the points where no AE data is seen for 0.2s, which indicates that the screwdriver is not turning. The data was then plotted in terms of load and cumulative energy per turn vs time, an example of which is shown in Figure 4. The load in Figure 4 (continuous line) is seen to drop in-between turns, this is a result of the force being applied by the screwdriver being removed, as well as some relaxation of the screw. As a result of this the point of stripping is not necessarily the point of maximum load, but instead the point where the load drops whilst AE data is being recorded (red line). In many cases this was the maximum load, however in others, such as Figure 4 where the stripping point has been labelled, it was not. When the point of stripping is identified the total AE energy produced prior to stripping can then be found.

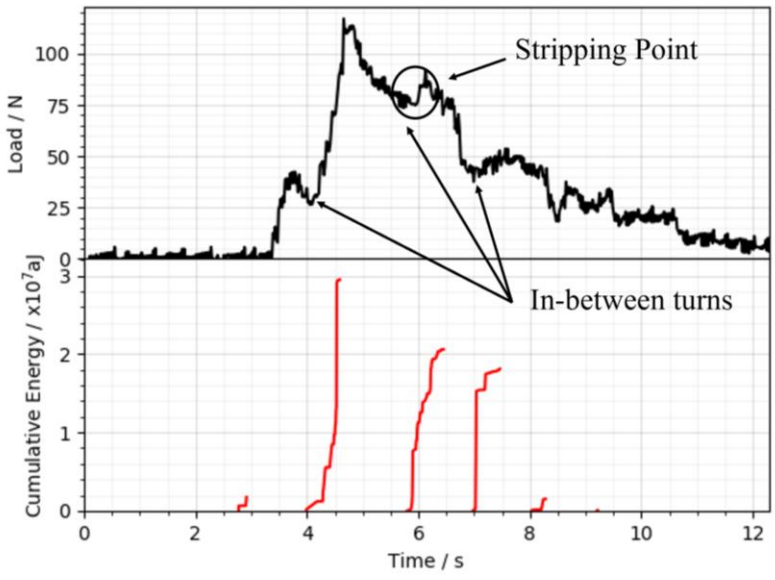

Figure 4 – Load vs Time over, and the same test Cumulative AE energy per turn vs Time under (Test 18_5) (see txt)

The first set of tests were performed on all of the right femurs at the lateral epicondyle. A standard large fragment set (Depuy Synthes Johnson & Johnson Medical West Chester, PA, USA) was used. Each hole was pre-drilled with a 3.2mm diameter drill bit and a 30mm long 6.5mm diameter partially threaded cancellous bone screw was inserted. The second set of tests were done on all of the left femurs at the lateral epicondyle. A standard small fragment set (Depuy Synthes Johnson & Johnson Medical West Chester, PA, USA) was used. Each hole was pre-drilled with a 2.5mm diameter drill

bit and a 30mm long 4.0mm diameter partially threaded cancellous bone screw was inserted, both tests as per manufacturer's instructions. Each cancellous screw from both the large and small fragment set was inserted, gained purchase and proceeded to stripping. 5 to 9 tests were performed on each femur in order to capture adequate AE signals. As seen in Figure 2 the trabecular architecture is heterogeneous and not uniform, so more samples were taken when a larger range of axial forces were obtained during tests.

2.1 Statistics

Spearman correlation was used as well as a linear regression model with robust standard errors (due to small sample size). Both were run in SPSS statistical software (IBM Corporation, New York, USA). The magnitude of the correlation coeffcients were interpreted according to the rule of thumb by Hinkle (negligible: 0.00–0.30; low: 0.30–0.50; moderate: 0.50–0.70; high: 0.70–0.90 and very high: 0.90–1.00) [Hinkle2003].

3. Results

A total of 77 test were completed, 41 on the six right femurs and 36 on the six left femurs. In each test the screw was tightened at a normal rate a doctor uses in the operating room by an experienced orthopaedic trauma surgeon and then continued through to stripping. Stripping was shown when the axial load began to decrease, because the bone material has failed and can no longer hold the compressive axial force between the screw head and the loadcell. The mean cumulative AE energy and mean stripping load for each bone were correlated to each other and to the bone mineral density. Each of the tests showed a high correlation coefficient and all were significant (See Table 1).

Table 1. Results of the Spearman correlation (R). BMD – Bone Mineral Density, AE – Acoustic Emission

Test	R	Significance
BMD v Stripping Load	0.867	$p < 0.01$
BMD v AE Energy	0.741	$p < 0.01$
AE Energy v Stripping Load	0.888	$p < 0.01$

A linear correlation was seen for the bone mineral densities and the mean AE energy and load, as shown in the figure 5 graphs.

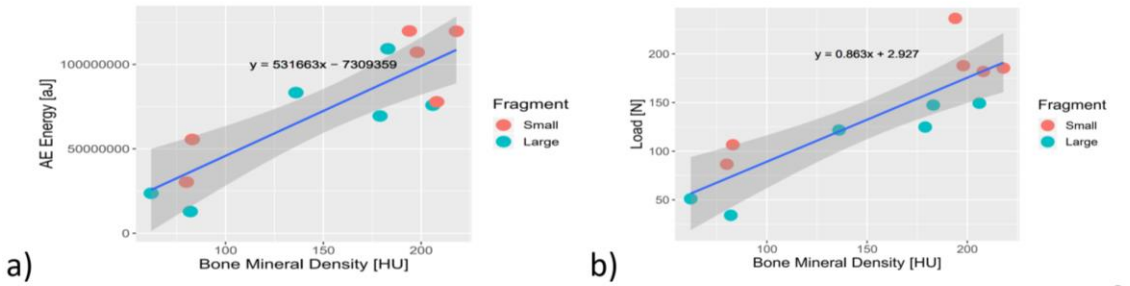

Figure 5 – Bone mineral density plotted against acoustic emission energy (a) and against load (b). The different fragment sizes are indicated with either a red (small) or green (large) dot. The corresponding linear model is included in the plot (blue line), with the dark grey representing the 95% confidential interval. Graph produced using R (R Core Team, 2019) and ggplot2 [wickham2016].

A linear regression model was investigated with the mean stripping load as the dependent variable and mean AE energy, bone mineral densities and fragment size as the independent variables. The parameters from the regression model using small fragment as an example, with corresponding significance levels are presented in Table 2. The AE energy mean value has been rescaled by a factor of 1 million, equivalent to giving the measurements in pico-J instead of atto-J. This was done to improve interpretability of the model. All variables have a significant effect on the measured stripping load. An increase in bone mineral density of 1 HU is expected to increase load by 0.385 N, provided all other variables are kept constant. Similarly, an increase in AE energy of 1 pJ is expected to increase load by 0.794 N. All of these results are in keeping with the correlation analysis indicating that there is a positive linear relationship between both load and BMD, as well as load and AE energy. Interaction effects of mean AE energy, mean BMD and fragment size were also examined, but none of these were found to have a significant effect on the model.

Table 2. Parameters from the linear regression model with robust standard errors. The model consisted of the stripping load as the dependent variable and AE energy, bone mineral density and fragment size as the independent variables. B is the unstandardized correlation coefficient and the rate of change per unit. a - Parameter omitted due to redundance, as it is the reference category for the fragment size variable.

Parameter	B	95% Confidence interval		p-value
		Lower	Upper	
Small Fragment [N]	32.895	21.512	44.278	<0.001
Large Fragment	0[a]			
BMD [HU]	0.385	0.212	0.558	<0.001
AE Energy [pJ]	0.794	0.386	1.203	<0.001

4. Discussion

In both the small and the large fragment screw group a clear positive high correlation was found between the stripping load, the bone mineral density and the AE energy. Screw threads that are overtightened or stripped cause a considerable amount of damage in bone, this was visibly shown in the previous study done by this group with synthetic bone [pullin2017]. The compressive and stripping force applied to the screw causes shear and crushing, affecting the area of trabecula around the screw threads. This overall bone breaking process releases high rate AE energy that was detected. Figure 5 shows that the bone mineral density is the material property that is directly correlated to the amount of AE energy captured and the amount of compressive force a screw is able to produce. This makes sense because the higher density means a larger amount of trabecular bone around the screw threads. This in turn translates to increased amounts of organic and mineral material components of bone being damaged between the threads. The damage of the material components of bone is essentially their covalent bonds which normally hold them together being broken, releasing energy, and hence an increase in AE energy. A denser trabecular environment also increases the resistance to failure, hence a higher load. Similar to previous synthetic bone tests, each test in the cancellous bone had an energy peak and brief plateau before a subsequent decrease (Figure 6). This is likened to the stopping and stripping torque. The stopping torque is the ideal torque applied to a screw thought to give the best construct stability. The stopping torque has been shown to be anywhere between 66% and 86% of the maximum or stripping torque [aziz2014]. In Figure 6 the plateau area of the AE energy signals (the blue dots and red dots) is the area where we find the stopping torque. Tankart et al found that there is no significant difference in the pull-out strength of a screw after it is tightened to just 50% of the stripping torque [tankart2013].

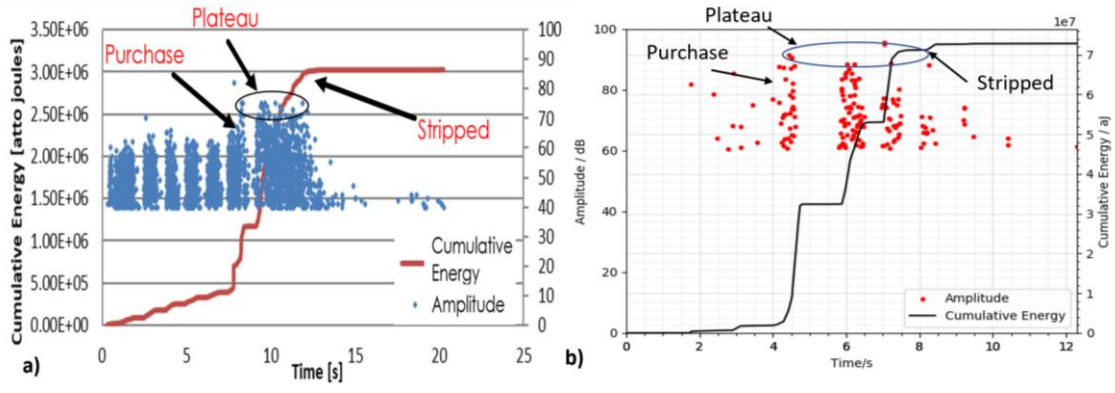

Figure 6 – Example of acoustic emission output of screw stripping showing the point of purchase, plateau and stripping. a) synthetic bone b) current cadaver bone.

The ranges of resistance generated at the stopping torque during screw purchase is the elastic energy accumulated from the trabecular bone before the shearing and crushing of permanent deformation. This elastic energy as well as the shearing and crushing are all producing AE signals. This is seen in both graphs in figure 6, after screw purchase the cumulative AE energy slope is almost vertical with each turn of the screwdriver, with a slight change in slope and then flatline. In this there can be a possible indicator of impending stripping. In the literature this is further confirmed by microCT imagery where it has been shown that there is little to no damage seen in the microarchitecture of trabecula when a screw is inserted up to 80% of the stripping torque [ryan2016].

The bone mineral density used is the mean number of Hounsfield Units (HU) found on the axial slice of the mid-condylar area of each distal femur. This is a heterogeneous area of cancellous bone which gives a range of stripping loads and AE signals. Because the bone mineral density was a mean, it was decided to use the means for the stripping load and the means for the AE energy to compare like with like. Embalmed bone was used instead of fresh frozen bone and some might argue that this is a limitation to the study. A previous study from this group [Wright2018] showed that the bone mineral parameters and the biomechanical properties of embalmed bone continue to correlate and that the literature has not shown a clear difference between fresh frozen and embalmed bone during biomechanical testing. A limitation to the study is the possible error of choosing the stripping load, because of the axial force introduced through the screwdriver by the user. In addition to the load cell, a strain gauge could have been mounted to the screwdriver to also calculate a value for torque which in turn could have given a more accurate stripping endpoint. This is a limitation to the study. The justification for not using a strain gauge was that the previous study done by this group [pullin2017] showed that AE signal mirrors torque and that the logistics of including one in the experimental set up was not possible at the time.

Standard training methods are taught to trainee surgeons on how tight screws should be. The two finger tightness method is used the most. The two finger method is very vague and shown to be inadequate and inaccurate [acker2016]. When surgeons were shown a digital and graphical visualization of real time torque of screws being purchased into standardized osteoporotic synthetic bone, the incidence of stripping decreased from 40% to 15% [gustafson2016]. Torque metres and torque limited motorized drills and screwdrivers have had some success in the laboratory. They are dependent on knowing or calculating the bone mineral density of the bone first in order to calculate the stopping torque. Gilmer et al describe a dual motor drill that was very accurate in calculating bone mineral density during drilling and the energy of screw insertion, and correlating that to pull-out strength [gilmer2018]. The limitation of their system was the inability to calculate stripping torque and applying it to be used for stopping torque. Two other systems were successful in cortical bone. The mechatronic screwdriver and a “turn-of-the-nut method” of screw tightening, both could sense when the head of the screw makes contact with the bone and detect the rate of change in torque

[thomas2008, belkoff2014]. These systems work well in cortical bone, but not well in cancellous bone. Another real time torque system was able to calculate the stripping torque during screw insertion into an ovine vertebral specimen and set a threshold for stopping torque [reynolds2017]. The estimate in the system yielded good results from cancellous screws but only in ovine bone, which is not representative of the aged human population as replicated in this study. Orthopaedic surgeons gain experience by training their proprioceptive feedback of torque and axial compressive force as to when to stop tightening a screw. This has been shown to be riddled with human error by the large amount of stripped screws seen in osteopenic bone even with experienced surgeons [andreassen2004, stoesz2014]. This problem is further amplified when one takes into account the learning curve of a trainee surgeon. Torque-limiting screwdrivers have limitations primarily because of the varying degrees of torque required for varying bone mineral densities. A recent systematic review of screw stripping by Fletcher et al highlights the need for development of augmented screwdrivers that are capable of signalling when the ideal non-locking screw tightness occurs in any bone density situation [Fletcher2020]. The results obtained in the current article in testing human bone with different bone densities further advances the legitimacy in developing a device that uses AE monitoring to aid in screw fixation in osteopenic bone. The proposed device has the potential to improve construct stability in the operating room and assist in the developing of trainee orthopedic surgeons. The next stage will be developing an algorithm that enables a device to produce a stop or warning signal for the surgeon to recognize fast enough to halt advancement. As previously described the design and development of a device will need to address sterility and the ergonomics of on-board electronics [pullin2017].

5. Conclusion

This experiment succeeded in detecting AE surface waves during screw fixation and stripping through a normal orthopedic screwdriver in human cancellous bone. The AE energy recorded had a positive high correlation to bone mineral density and stripping force. AE energy showed a clear signal during screw purchase through to stripping proving to be a potential technology for the prevention of stripping.

6. Acknowledgements

Lydia Ragan from the Division of Anatomy, Institute of Basic Medical Sciences, University of Oslo, Norway and Department of Physiotherapy, Faculty of Health Sciences, OsloMet - Oslo Metropolitan University, Norway is acknowledged for her help in obtaining and preparing the cadaver bones used for this study. Øystein Horgmo master photographer, Photo- and videodepartment, Institute for Clinical medicine, Oslo University Hospital is acknowledged for taking professional pictures used in

the project. Gøril Meland, radiographer, Oslo University Hospital, for her assistance with densitometric measurements.

7. Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

8. Funding

The authors from Cardiff University were funded by the Medical Research Council as part of a Confidence in Concept scheme. Other author(s) received no financial support for the research, authorship and/or publication of this article.

This project was approved by the Norwegian Regional Ethical Committee (REK): 2017/1018/REK sør-øst C

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