Honors Research Thesis

Screw Pull Out under Cyclic Fatigue Loading in Synthetic and Cadaveric Bone

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Abstract:

Fracture fixation devices, used to stabilize fractures internally to reduce the recovery time, are often held in place by screws. While the devices themselves are frequently tested for failure, the interface between the bone and the screw is usually not. Very few studies have been conducted on this interface failure which causes concern as to whether this mode of failure is accurately modeled by the composite bone models frequently used for testing. The integrity of the screw-bone junction is essential to the functional stability of the device as a whole. This project tested bone-screw interface fatigue in both synthetic and cadaveric bones. Cortical bone screws (3.5 mm diameter) were inserted bi-cortically in both human femurs and Sawbones® composite bones. Each screw was cyclically loaded between 200 and 1000 N at 7.0 Hz until failure or 200,000 cycles (chosen as the clinically appropriate load cycle for fracture healing applications). The distance the screw was pulled out over the course of the testing was recorded. A two sample t-test was performed to compare the pull out in cadaveric and composite bone. None of the screws pulled out of the bone. The screws inserted in cadaveric bone moved 0.094 ± 0.030 mm over the 200,000 cycles; the screw in the composite bone moved only 0.057 ± 0.026 mm. While statistically significant ($p<0.001$), this result is not clinically relevant as neither screw pulled out a clinically meaningful distance over the course of the testing.

Introduction:

There are on average six million bone fractures treated in the United States per year [1]. Many of these can be treated by internal fixation, various forms of which have been used for over 100 years [2]. Internal fracture fixation ranks as one of the greatest advances of the 20th century on a list by American Academy of Orthopaedic Surgeons [3]. This has been a heavily researched area. In a PubMed search of fracture fixation plates, 2397 articles were returned for the past five years [4]. One of the many reasons this advancement is beneficial is that it reduces the recovery time, allowing individuals to regain function sooner [3]. This not only allows patients to resume normal activities sooner, but also decreases complications due to prolonged inactivity. A fracture fixation plate acts as an internal splint which provides stability and alignment to the body during healing (Figure 1). To do so, it must bear a portion (or sometimes all) of the physiological stresses. Clinically, internal fixation devices fail in various ways: implant fatigue, screw breakage, screw pull-out. One of the most common modes of failure is through screw pullout from the bone after repeated weight bearing load. This results from repetitive fatigue loading of the screw-bone interface.

New types of devices must be tested to determine their clinical ability, creating the need for a consistent model for testing. Cadaver bone is preferred, but the availability is often limited or expensive and the bones being tested vary widely between different cadavers due to age, gender, weight, osteoporosis, etc. [5]. These differences result in differing mechanical behaviors which would skew test results making it difficult to determine the clinical value of the device being evaluated.

The generally accepted solution has been to test products on synthetic bone. One company that provides a large proportion of the synthetic bones used in this type of research is

Pacific Research Lab (PRL) which produces and sells biomechanical models called Sawbones®. PRL has provided more than 2000 products for over 30 years and are leaders in anatomy models for testing and medical education [6]. While using bones such as those produced by this company has facilitated testing of implant mechanical behavior by standardizing the mechanical properties of the bone, other aspects of the bone and failure modes have not been tested. There is a lack of cyclic fatigue testing in the literature and it remains an open issue. Many studies have been done to test the fatigue load of the bones themselves and shown that the Sawbones® Fourth-Generation Composites [Part #3403 – "Medium Composite Fourth Generation Left Femur", Pacific Research Lab, Vashon, WA] accurately model the cadaveric bone [7]. Sawbones® are made of a foam material with a plastic coating and are manufactured in a way to have the "physical strength properties similar to real bone" [6]. This physical strength has been tested, but other properties of the bone have not.

The aim of this study is to test the mode of failure that is less often tested: screw pull-out. To achieve internal fixation, a fracture fixation plate must be rigidly secured to the bone on both sides of the fracture. When the screws loosen, this stability and proper fracture alignment can be lost. Few studies have been done in the area of screw pullout. One, by Zdero, et. al, studied pull out force, shear stress, and energy [8]. They tested quasistatic screw pull-out behavior. The Zdero study tested straight pull out force [8], but did not evaluate the cyclic loading that occurs under physiologic loads with weight bearing. No study, to our knowledge, has been done to determine the effect of cyclic loading on the screw which is often more clinically relevant. The proposed study will evaluate the failure of screws in this cyclic nature.

Fracture fixation plates only need to be in place for the length of time it takes for the fracture to heal sufficiently to bear the loads associated with normal activities. The question becomes how many cycles can the screw-implant interface withstand prior to failure? Is that enough to last until the fracture is healed and the plate can be removed (if clinically indicated)? Is that number the same in the composite bones used to test such devices as in cadaveric bone? If the screws fail before the fracture heals, this could result in further injury and pain for the patient. If composite bones are not accurately modeling this factor, modifications must be made when designing experiments to test new devices. This study will evaluate whether the synthetic and cadaveric bone behave the same under cyclic loading of screws.

The null hypothesis tested was that the fatigue endurance of the screws in the synthetic bone is equal to what it is in the cadaveric bone. The alternative hypothesis was that the synthetic and cadaveric bones are not equal in cyclic load screw pullout. Two groups of specimens were tested and the fatigue endurance of the screw-bone interface statistically compared by two sample t-test. A significance of $p = 0.05$ was used to test the hypothesis.

Methods:

Bicortical anterior-posterior holes were drilled 3 cm apart in both the composite and the cadaveric bones. These holes were tapped for 3.5 mm cortical bone screws which were inserted bicortically into the bone. Each test construct was loaded into a servohydraulic materials test frame [Bionix 858, MTS Corp, Eden Prairie, MN] with a custom-designed screw grip to assure axial alignment of the force and the screw. The custom screw grip can be seen in Figure 2. The screw slid into the grip and the bone was held in place by two metal bars as shown in Figure 3.

Axial, quasistatic pull-out force was collected under displacement control at 0.1 mm/sec. This was performed on 5 composite bones and 4 cadaveric bones. After these pull-out tests were performed, the cyclic loading tests were performed. A 20 N pre-load was applied followed by a tensile cyclic load of 200 to 1000 N applied at 7 Hz for 200,000 cycles. This approximates twelve weeks of post-fixation ambulatory activity, a clinically relevant time frame for having a fracture fixation device in place. This process was repeated on 17 cadaveric bones and 19 composite bones. After data was collected, a two sample t-test was performed to analyze comparisons between the two bone types.

Results:

The quasistatic pull-out force results are consistent with the results of Zdero's study in regards to the Fourth Generation Sawbones® (Table 1); there is no statistical difference between the cadaveric and composite bones in terms of this pull-out strength ($p > 0.05$). It should be noted that Zdero’s values, though not statistically different had higher pull-out forces for the composite bone whereas this study had higher values for the cadaveric bone.

Table 1: Straight Pull-Out Force in Composite and Cadaveric Bone

	Mean ± Standard Deviation
Cadaveric **n = 4**	4746 ± 553 N
Composite **n = 5**	3865 ± 571 N

The method of failure varied amongst the bones. The composite bones pulled out as expected where the screw pulled completely out of the bone with a sudden and complete loss of tensile resistance in the specimen. A representative load-displacement curve from this type of failure is shown in Figure 4. The cadaveric bones failed in two different ways. Half of the bones broke before the screw pulled out completely yielding a load-displacement curve similar to Figure 5. The second method of failure was by screw deformation. The screw head deformed to the point where it squeezed through the test fixture. This resulted in a load-displacement curve as shown in Figure 6.

The cyclic load data was collected continuously for 200,000 cycles. There were no construct failures in the fatigue tests. The displacements at initial peak load, at 100,000 cycles, and at 200,000 cycles were analyzed and used to compare failure in composite and cadaveric bone. The results are presented in Table 2 as the mean and standard deviation, in millimeters.

Table 2: Mean and Standard Deviation of Pull-Out Length in Cyclic Loading

	Entire Run	First 100,000 Cycles	Second 100,000 Cycles
Cadaveric n = 17	0.094 ± 0.030 mm	0.084 ± 0.030 mm	0.0099 ± 0.0040 mm
Sawbone n = 19	0.057 ± 0.026 mm	0.051 ± 0.027 mm	0.0065 ± 0.0043 mm

Results were compared using a two sample t-test between the cadaveric and the composite bones. The results were compared over the entire 200,000 cycles as well as the first 100,000 cycles and the last 100,000 cycles. These results are shown graphically in Figure 7. There was a statistically significant difference for each comparison – $p = 0.001$ over the first 100,000 cycles; $p = 0.021$ for the second 100,000 cycles; $p < 0.001$ for the entire 200,000 cycles. There was also a statistical difference between the first half and the second half in terms of amount displaced. The displacement consistently leveled off after some initial displacement. The rate of screw pull-out was not constant through the testing period. Initially, it displaced more rapidly and then the rate of displacement decreased as shown in Figure 8 which shows the cumulative amount of displacement from the beginning of the trial.

Discussion:

The p-value for the comparison of force in the straight pull-out test between cadaveric and composite bone was 0.054. This indicates that there is not statistical difference between the composite and cadaveric bone in terms of axial, quasistatic screw pull-out strength. In the Zdero study [7], there were mixed results on this comparison because they tested multiple Sawbones® types (i.e. Third Generation and Fourth Generation). For at least one Fourth Generation type, there was no statistical difference between the force of screw pull-out in composite and cadaveric bones.

The p-value for the comparison between composite and cadaveric bones in terms of cyclic screw failure was $p < 0.001$. This indicates a statistical difference in the displacement value between the two bone constructs.

The displacement at various cycle times was compared to the final displacement value. This was done to determine when most of the displacement was occurring. In the composite bone, the p-value when comparing displacement at 200,000 cycles with a mid-trial cycle was 0.027 at 10,000 cycles and 0.071 at 20,000 cycles. At 20,000 cycles, 73% of the displacement had occurred. This indicates that at some point between 10,000 and 20,000 cycles, the screw had displaced an amount not statistically different from the final displacement. The displacement transitioned from statistical significance to statistical insignificance meaning most of the displacement that occurs in a clinically-relevant time frame occurs within the first 20,000 cycles. In cadaveric bone, the p-value at 30,000 cycles was 0.034 and at 40,000 was 0.055 and accounted for 78% of the displacement. Similar to the composite bone, this indicates that for the cadaveric samples tested most of the screw displacement occurred between 30,000 and 40,000 cycles. It is an interesting discovery that the displacement was so much greater in the beginning than in the end and should be considered in the design of future fatigue testing of the screw-bone interface. The reason for this is not entirely known, but could be due to the hierarchical structure of bone.

Conclusion:

While there is a statistically significant difference between screw displacement in cadaveric and composite bones under cyclic loading, indicating that Sawbones® are not a statistically accurate representation of this property of bone, it is not believed that it is a clinically significant problem. The small displacements (0.1 mm) are not enough to cause loosening or failure in the clinical setting. This does raise concerns as to whether or not other properties of the bone-screw interface are accurately represented by the composite bone as it applies to a clinical setting.

Additional testing still needs to be conducted in several areas. Many veterinarian researchers use these human composite bones to test their new devices designed for use in animal surgery. The Sawbones® have not been validated for use as an animal model. This study also only evaluated one screw insertion type and screw size. We tested the screw size, 3.5 mm, most commonly used for fracture fixation but both smaller and larger screws are used in specific clinical applications. Larger and smaller diameter screws as well as unicortical insertion or insertion at various angles could be tested to determine if those have similar failure patterns to the screws used here.

Acknowledgements:

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Figures:

Figure 1: Internal Fracture Fixation Plate [9]

Figure 2: Custom Designed Screw Grip

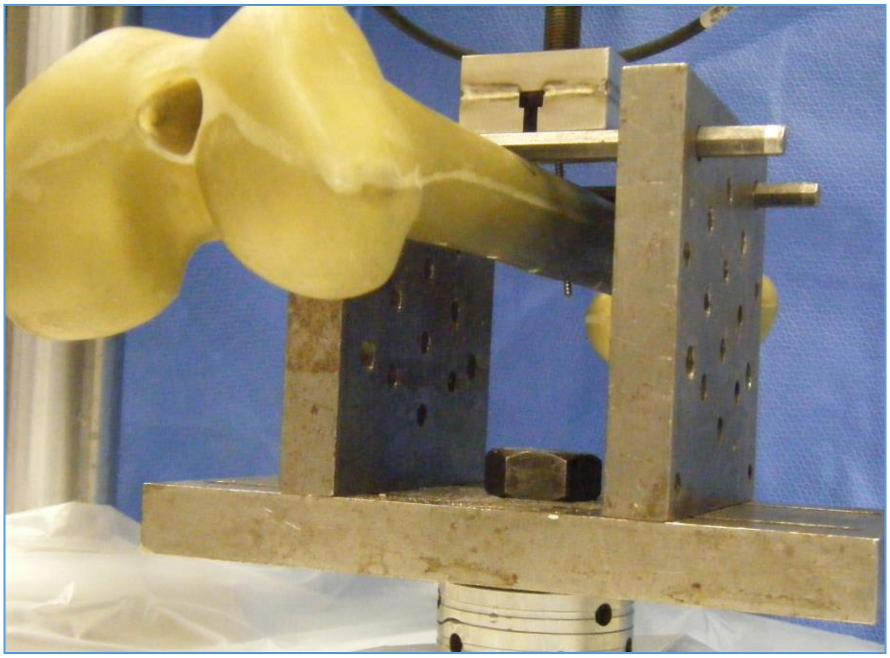

Figure 3: Testing Procedure Set-Up

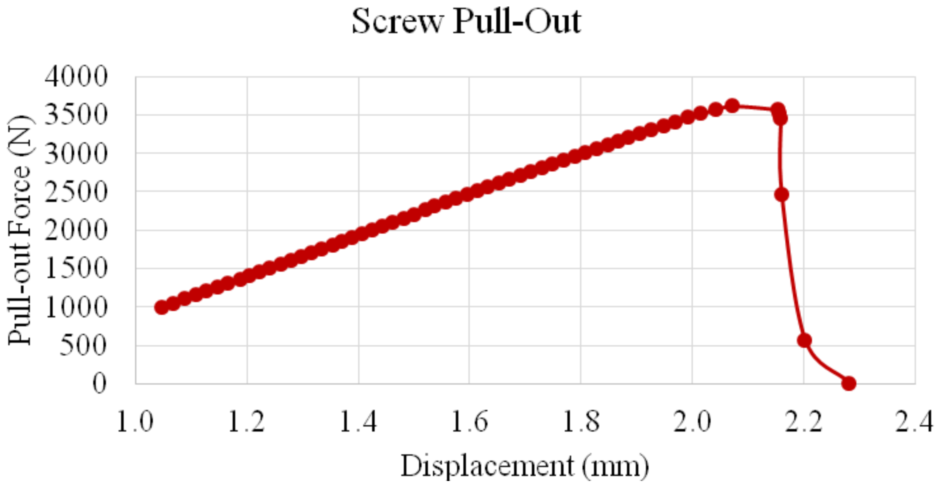

Figure 4: Screw Pull-Out in Straight Pull-Out Test of Composite Bone

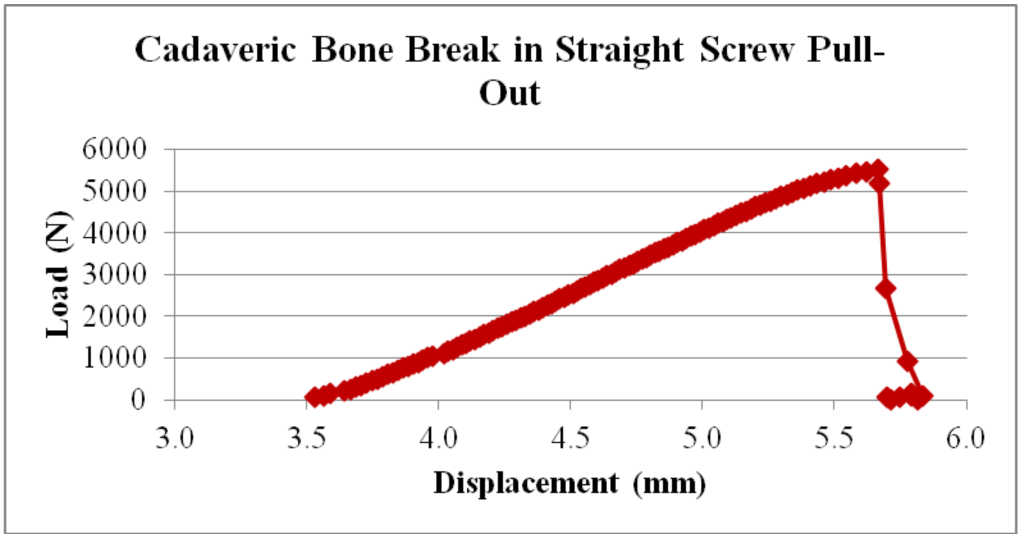

Figure 5: Screw Pull-Out due to Bone Break in Straight Pull-Out Test of Cadaveric Bone

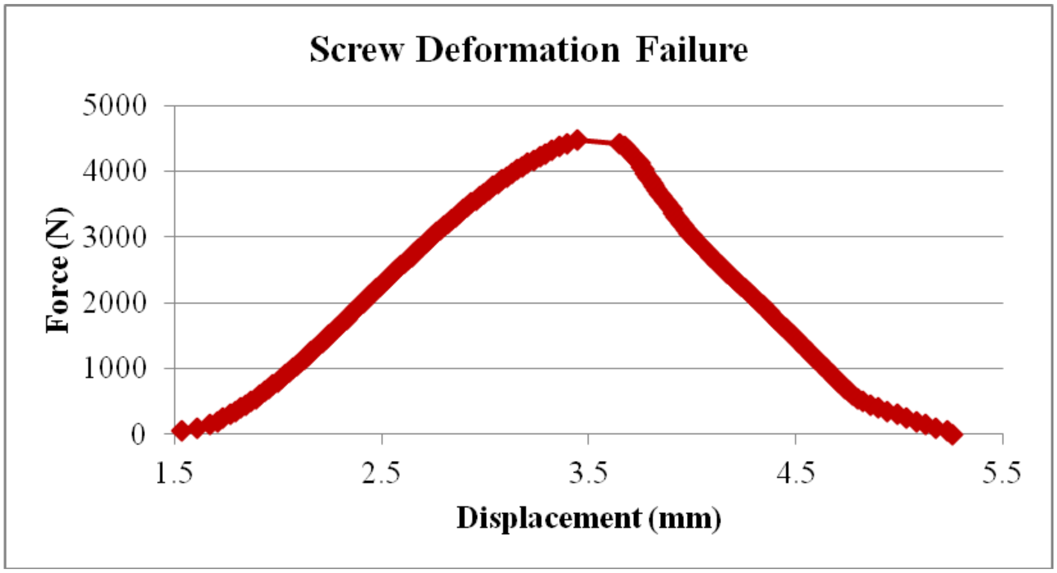

Figure 6: Screw Pull-Out from Screw Deformation in Straight Pull-Out Test of Cadaveric Bone

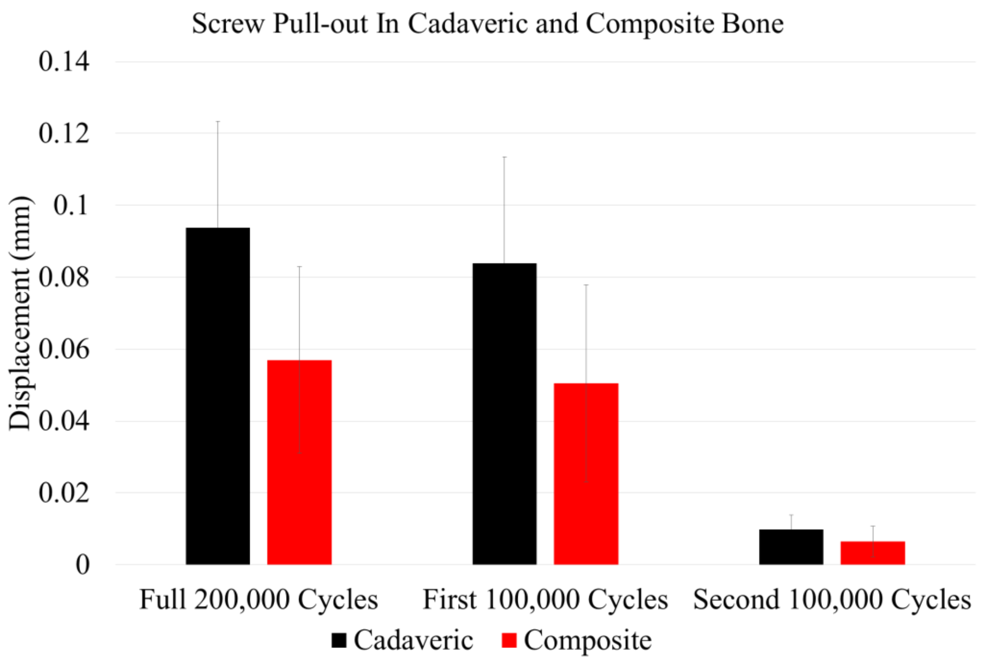

Figure 7: Screw Pull-out in Cadaveric and Composite Bone. Screw pull-out distance is shown as mean ± standard deviation. $p < 0.05$ in all cases comparing cadaveric and composite within the same time frame.

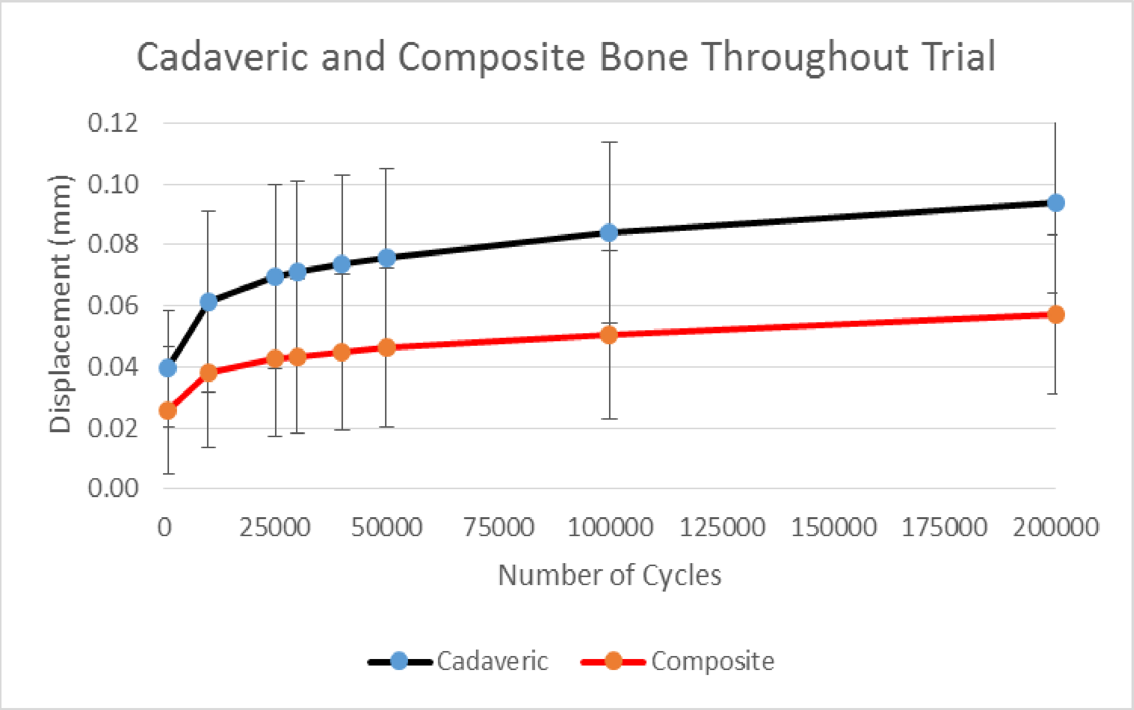

Figure 8: Displacement over Entire Course of Cycle Time

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