IN VITRO MECHANICAL STUDIES OF IMPLANTABLE TRUSS TECHNOLOGY FOR TOTAL KNEE ARTHROPLASTY DESIGNS

An Undergraduate Research Scholars Thesis

by

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ABSTRACT

In Vitro Mechanical Studies of Implantable Truss Technology for Total Knee Arthroplasty Designs

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Total Knee Arthroplasty (TKA) is a common treatment for patients with severe knee pain due to osteoarthritis, a condition characterized by the loss of articular cartilage or injury. Most patients that opt to proceed with a TKA procedure report effective pain mitigation; however, approximately 30% do not realize sufficient pain relief following the procedure. This post-operative pain is typically associated with fixation, integration, and mechanical complications that can lead to a loss of bone mass. In cases where the procedure is successful, a revision procedure may still be required as the lifespan of the device is limited to 10-20 years when problems with fixation culminate in total failure of the device. The proposed research will evaluate a TKA device that incorporates unique geometrical and mechanical properties that address the problems associated with initial and long-term fixation, as well as component wear. Consequently, this technology is expected to enhance the quality of life of the patient, as well as potentially eliminate the need for revision procedures.

DEDICATION

We dedicate this research to our parents. Without their continued support this opportunity would not have been possible.

ACKNOWLEDGEMENTS

We would like to thank Dr. Michael Moreno for his tremendous support. His teachings have been paramount to the production of this thesis and our improvements as students and professionals. This material is based upon work supported by the National Science Foundation (NSF) under Grant No. 7449783 Phase I & II.

NOMENCLATURE

AP	Anterior-Posterior
ASTM	American Society for Testing and Materials
FDA	Food and Drug Administration
IACS	International Association of Classification Societies
NSF	National Science Foundation
OA	Osteoarthritis
S/N	Stress/Failure (i.e. S/N curve)
TKA	Total Knee Arthroplasty
UHMWPE	Ultra-High Molecular Weight Polyethylene
UR	Unified Requirement

CHAPTER I

INTRODUCTION

Osteoarthritis (OA) is the second most common diagnosis made in older adults seeking medical care [1] and the leading cause of disability at older age [2]. OA causes significant damage to the articulating surfaces of the knee, as shown in **Figure 1**.

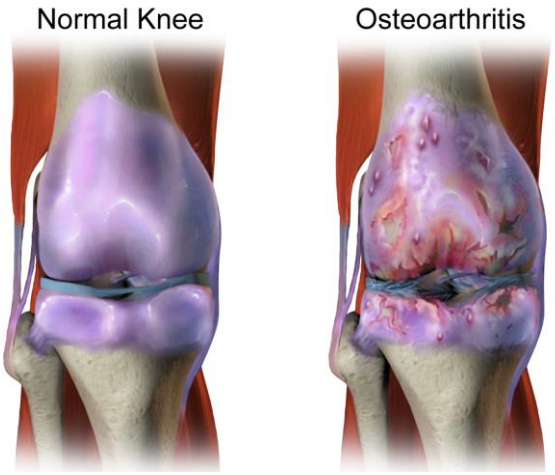


Figure 1: *A rendered image comparing a normal knee to a knee suffering from osteoarthritis. The damaged articular cartilage can be seen on the femoral and tibial components as well as on the meniscus. Attribution: By BruceBlaus (Own work) [CC BY-SA 4.0 (http://creativecommons.org/licenses/by-sa/4.0)], via Wikimedia Commons*

For individuals who suffer from severe knee osteoarthritis, Total Knee Arthroplasty (TKA) is a treatment option to improve function and alleviate pain [3, 4]. The incidence of TKA procedures in the United States has increased from 378,000 per year in 2003 to 700,000 per year in 2012 [13]. TKA incidence is expected to continue rising over the next decade as life expectancy increases and prevalence of osteoarthritis increases among younger age groups [5]. Most patients who

receive TKA procedures experience pain-relief afterward [5, 6], however, up to 30% of patients continue experiencing significant pain. This pain typically results from stress shielding, which is a loss of bone density in the anterior femur and proximal tibia, as depicted in **Figure 2** [7-12].

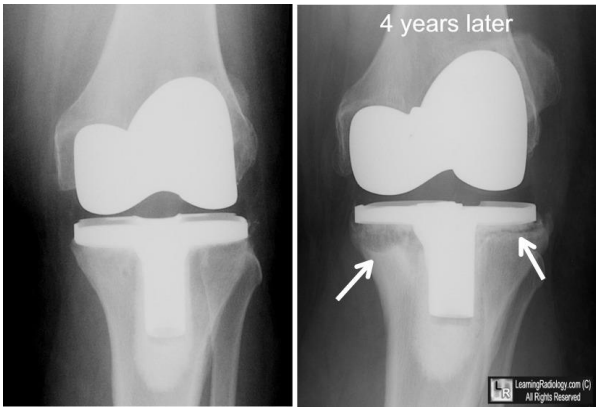


Figure 2: *A radiographic image depicting the development of aseptic loosening in a current stemmed TKA. The white arrows indicate areas of decrease bone density, which result from stress shielding. Published with permission from LearningRadiology.com*

The pain that is associated with TKA procedures can also be a result of damage to the bone and bone loss caused by the implantation of the tibial tray. Typically, current TKA fixation requires replacement or revision after 10-20 years. Revision TKA procedures can become complex for a litany of reasons depending on the purpose of the revision and extent of native tissue damage. In all cases, the initial bone geometry of the tibia must be modified and additional native bone removed to accommodate a new device. As a result, during the revision procedures autologous bone grafts may be necessary to compensate for the bone loss and damage. While some patients show significantly improved stability after TKA in the coronal and sagittal planes with an acceptable range of motion, most are far from normal [6-8]. This is often a consequence of incomplete restoration of a normal knee situation [2].

A number of current devices on the market use cemented TKA techniques to adhere the implant to bone. These methods of non-biological fixation are susceptible to long term cracking and eventual loosening of the implant due to a reduction in the amount of cancellous bone interlock. During implantation, the bone cement flows around the cancellous bone as it polymerizes, over time the cancellous resorbs leaving cavities which decrease the area of contact between the bone and cement. Other common devices that are on the market employ cementless TKA techniques through the use of porous coatings. From as early as the 1940s, porous coatings have been theorized as the potential solution to non-biologic fixation. In 1968, JS Hirschhorn and JT Reynolds reached a major milestone with the first implant specific fabrication of a porous metal [14]. Experiment investigation has continued unremittingly ever since. Notably, this technique has been proven successful in femoral TKA components and femoral stems for hip replacement, which receive continual compressive forces to squeeze the bone and implant together. However, limited success has been seen with the tibial TKA component. This is primarily because the bone does not have time to grow into the micro pores in the porous coating to establish a firm fixation. In order to address this problem, the company, 4WEB, has developed a device which establishes a firm initial fixation in the bone. The 4WEB device uses an innovative structural design which facilitates direct incorporation between the implant and bone. This design allows for the bone to grow throughout the device's webbed structure, similar to that of a truss, becoming fully incorporated in the implant. This improved biomechanical attachment between the implant and the bone may protect against lifting of the tibial tray and the adverse development of soft connective tissue and the implant, which contributes to loosening of the implant. **Figure 3** below gives a comparison between the osseointegration exhibited in cemented fixation and porous coating methods.

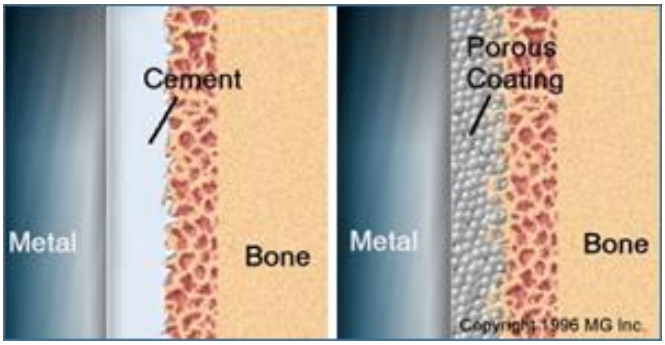


Figure 3: *Image depicting the osseointegration differences between cemented fixation (left) and porous coating methods (right).*

Our group will evaluate the performance of a novel TKA system that will employ innovative manufacturing processes and structural engineering principles to improve the bone/implant interface in TKA procedures to facilitate bone ingrowth. The proposed research plan is to evaluate the device through *in vitro* mechanical testing as outlined in the Food and Drug Administration (FDA) guidance document for TKR implants. Of particular concern for the FDA is the porous coating decoupling from the substrate of the truss network and thus disengaging the device with the surrounding bone tissue. Secondly, the decoupling of the Ultra High Molecular Weight Polyethylene (UHMWPE) tibial insert from the tibial tray is of general concern for all TKR devices. In order to characterize the TKA prototype, and evaluate the hypothesis that the novel implant interface will lead to increased knee stability, the following objectives will be explored:

Objective 1: Mechanical and Metallurgical Evaluation of Porous Surface Method Utilized on Truss Network

Objective 2: Performance Analysis of Tibial Bearing/Baseplate Interlocking Mechanism

CHAPTER II

METHODS

The purpose of Objective 1 is to quantify the porous surface characteristics of the novel TKA device designed by 4WEB. The device is manufactured with a porous surface by applying a titanium plasma spray to an additive-manufactured, fused-titanium base structure. Shear and fatigue protocols will be performed in accordance with ASTM F1044 and ASTM F1160. Together, these tests will evaluate the mechanical response of the surface modification to uniaxial shear stress (i.e. shear strength) and the effects of the surface modification on the fatigue resistance of the base material (i.e. fatigue properties).

The first protocol for Objective 1 is a lap shear test that consists of parallel titanium plates, one of which has the aforementioned surface modification. The dimensions of the plates are 3.00” in length, 1.00” in width, and 0.44” in thickness. On the plate with the surface modification, the treatment area is limited to a 1.00” x 1.00” section. **Figure 4** below depicts the dimension with the shaded region denoting the area with the surface modification. For a more detailed depiction consult **Appendix 8**.

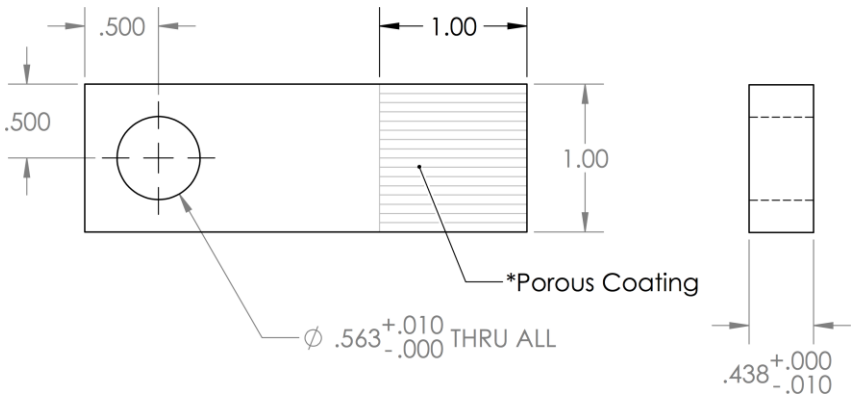


Figure 4: *Lap shear test parallel titanium plates with surface modification.*

The plates are epoxied together using ScotchWeld 2214 using the following procedure. While in storage, ScotchWeld 2214 is kept at 45°F (7.5°C), but is removed from storage and allowed to warm to room temperature before use. Both plates are degreased and cleaned to prevent loose particles from becoming embedded into the adhesive. A syringe is used to extract 12 mL of the ScotchWeld and evenly distributed on the untreated plate. The untreated plate is then placed face-up on the bottom of a specially designed bonding fixture to ensure proper alignment of the plates. The plate with the surface modification treatment is placed face down in the top slot of the bonding fixture. Anchor bolts on the bonding fixture are tightened to secure the plates. To complete the assembly, a clamp is attached to the adhesion area by applying a minimum of 20 psi to the samples. The completed assembly is placed into an oven at 350° F (176° C) for 15 minutes to allow the adhesive to cure. After the adhesive cures, the assembly is removed from the oven and allowed to cool to room temperature before handling. Afterwards, the clamp and anchor bolts are undone and the adhered sample is removed from the bonding fixture. The process is shown below in **Figure 5**.

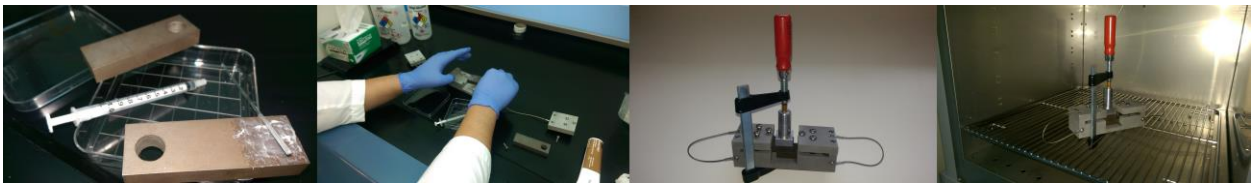


Figure 5: *Left to right: Adhesive applied to 1 sq. inch of specimen, placing specimens in bonding fixture, applying 20psi with clamp, entire assembly in oven*

This process is repeated with six (6) samples. If testing cannot be performed immediately, the adhered samples are stored in climate-controlled packaging to maintain uniform humidity and temperature conditions between the samples. This is in order to prevent environmental discrepancies from affecting the test results. Afterwards, the samples are attached to a loading frame using the lap shear loading grips. Load is applied to the sample at a constant cross-head rate of 0.1 in./min. The test continues until complete separation of the plates has been achieved. The maximum load applied and failure mode (adhesive or cohesive) are recorded on all six (6) samples. Lastly, the adhesive (or cohesive) strength is found by calculating the failing stress using Equation (1), where *S* denotes failing stress, *F* denotes maximum load to failure, and *A* denotes cross-sectional area.

$$S = F/A \tag{1}$$

The second protocol for Objective 1 includes two fatigue tests: a shear fatigue test and a rotating beam test. These tests are designed to examine the response of the coated material to shear fatigue and bending fatigue loading conditions. For the shear fatigue test, two cylindrical titanium components are used. Each cylinder is 1.00” in length and 0.75” in diameter. Consult **Appendix 1**

for a more detailed schematic. Similar to the lap shear plates, one face of one cylinder is modified to have the surface characterization properties under investigation while the other cylinder will not be modified. Prior to experimentation, the cylindrical components are prepared and adhered following the same procedures as the plates. Since the surface area is smaller than in the lap shear protocol, only 5.5 mL of epoxy is needed to adhere each sample. A bonding jig is used to hold the cylinders concentric with one another as shown in **Figure 6**.

Figure 6: *Shear fatigue sample in bonding jig during adhesion*

A clamp is secured on either end of the sample applying 20 psi while the assembly is placed into an oven at 149°C for 15 minutes to allow the ScotchWeld to cure. This process is repeated until six (6) samples are prepared. As with the lap shear samples, if testing cannot be conducted immediately, the samples are stored in climate-controlled packaging. Afterwards, the bonded samples are placed in the shear fatigue gripping assembly. The setup is examined to ensure the samples are uniaxial with the loading grips and not eccentric to the loading axis. When the machine is cycling at 40 Hz, load is applied to the system, maintaining an R ratio of 0.1; this corresponds to a minimum load of 250N and maximum load of 2500N. Testing is terminated when the sample

fails or when the sample is subjected to 10^7 cycles, whichever occurs first. The maximum load applied and failure mode (if relevant) are recorded after which the test is repeated on all six (6) samples. Lastly, the adhesive (or cohesive) strength is found by calculating the failing stress using Equation (1).

For the rotating beam fatigue test, two "dog-bone" titanium samples are utilized. The surface modification is applied all around and extends slightly beyond the reduced sections as can be seen in **Figure 7.** Consult **Appendix 10** for a detailed schematic.

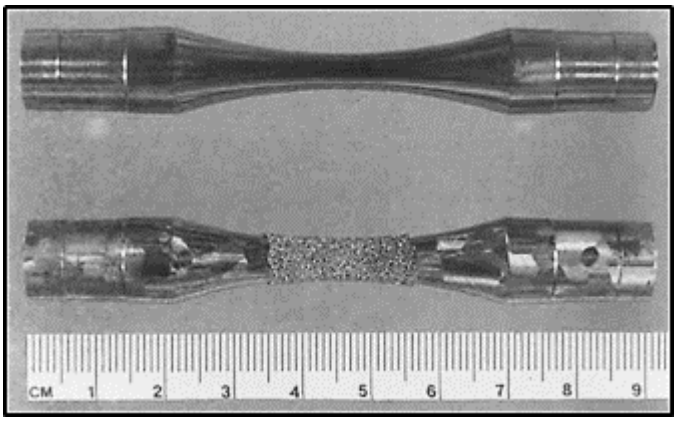


Figure 7: Untreated dogbone sample (top) and dogbone sample with surface modification (bottom).

Before the modified samples are tested, an untreated titanium dogbone is used to establish a baseline from which to assess the effect of the coating. The sample is mounted into an R.R. Moore machine (aka. rotating beam fatigue machine). A load of 50 lb. is applied once the machine is operating at 40 Hz. Testing is terminated only with sample failure or when the number of cycles exceeds 10^7, whichever occurs first. The remainder of the protocol proceeds using a modified stair-

step fatigue testing method as outlined in International Association of Classification Societies (IACS) Unified Requirement (UR) M53, Appendix IV *Guidance for evaluation of Fatigue Tests*. Once three (3) unmodified samples are run to establish a baseline, the procedure is repeated with six (6) modified titanium dog bones. Lastly, the applied stress is calculated using cycles to failure and recorded stress values to generate an S/N curve depicting endurance limit. This curve is compared with the baseline curve to establish the impact the surface modification has on the titanium.

The purpose of Objective 2 is to assess whether the interlocking mechanism of the device is able to withstand physiological loads without decoupling. In order to ensure that the device will not decouple after implantation, the strength of the attachment between the polymer insert and tibial tray is characterized. In order to verify that the system will not decouple after implantation, three shear tests are performed: static anterior-posterior shear testing, static medial-lateral shear testing, and static tensile pull-off testing. Each of the three tests uses a mechanical testing machine that applies shear traction to the polymer insert to the frontal, sagittal, and transverse plane, respectively. For both shear tests, the tibial interlocking mechanism is secured to an Instron breadboard in the configurations corresponding to the desired geometric loading (anterior-posterior or medial-lateral). **Figure 8** below shows the setup in the anterior-posterior (A-P) orientation with laser alignment device (**Appendix 9**) and indenter (**Appendix 7**) in foreground.

Figure 8: *Interlock shear test setup in the A-P orientation (back), laser alignment device (front left), and indenter (front right). Consult* ***Appendices 2,3,4,5,6,7,9*** *and* ***11*** *for further technical schematics of all fixtures.*

The indenter is aligned to ensure the force is in the center of the tibial tray. Load is applied to the sample at a constant rate of cross-head speed of 0.1 in./min. The test continues until complete separation of the polymer insert and tibial interlocking mechanism has been achieved. Afterwards, the maximum load is recorded. For the pull-off test, the sample is oriented orthogonally to the loading apparatus. Instead of an indenter, a pull-bar is secured in the center of the polymer insert. The load is applied in the vertical direction at a constant cross-head rate of 0.1 in./min. The test continues until complete separation of the polymer insert and tibial interlocking mechanism has been achieved. Maximum force for separation is recorded and compared to expected physiological loads.

CHAPTER III

RESULTS

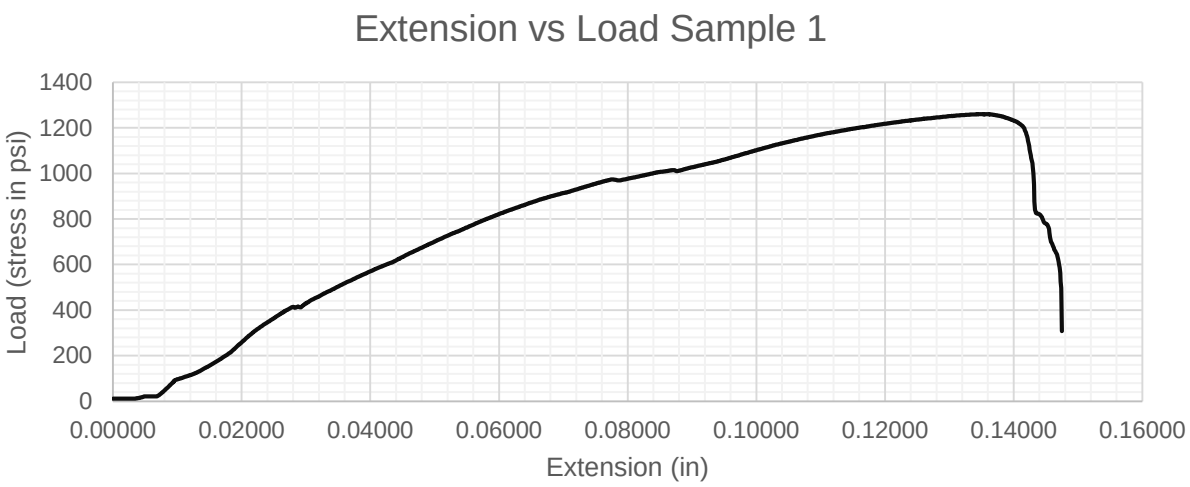
In order to validate the procedure protocols and infrastructure, pilot tests were carried out using samples from the same titanium alloy as the device. The results of the lap shear protocol are shown below:

Table 1. *Values at failure for each sample*

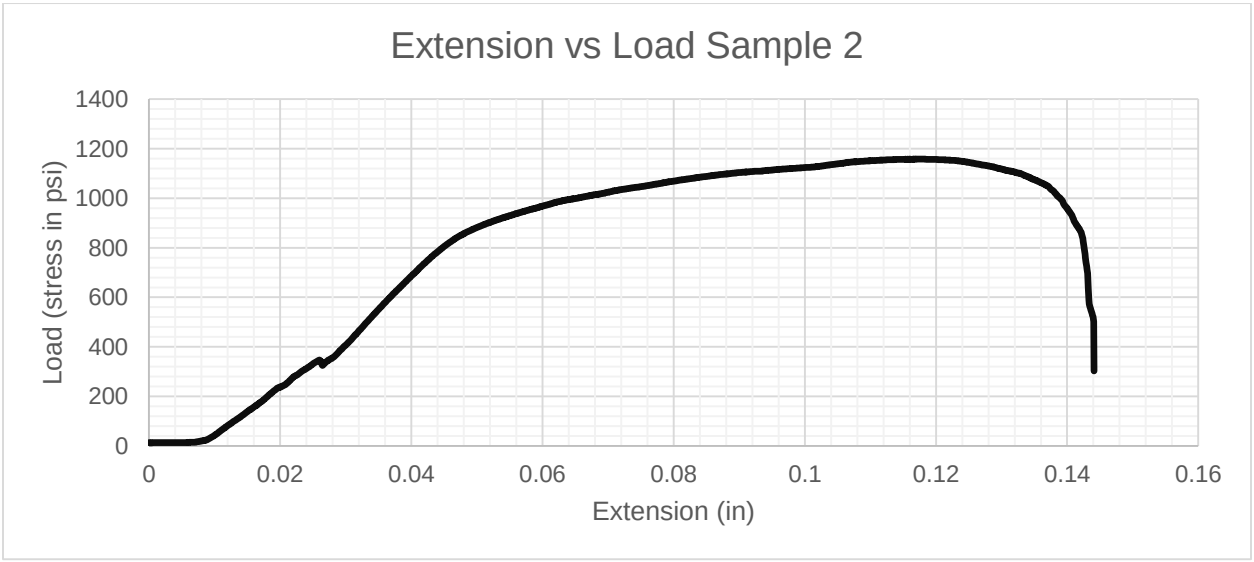
Sample	Load at Failure (lbf)	Area	Max Extension(in)	Mode of Failure
1	1259.8	$1.00in^2$	0.26354	Sample Fracture
2	1158.182	$1.00in^2$	0.14408	Sample Fracture

Table 2. *Meta-analysis of failure mode of all samples*

Max Failure Load (lbf)	Min Failure Load (lbf)	Mean Failure Load (lbf)
1259.8	1158.182	1208.991



***Graph 1**. Stress strain curve of sample 1*



***Graph 2.** Stress strain curve of sample 2*

Graph 1 and **Graph** 2 illustrate the extension versus load. In other words, how much force was applied compared to how far the apart the lap shear fixtures had been pulled. Using **Equation 1**, the failing

stress of Sample 1 was found to be 1259.8 psi and the failing stress of Sample 2 was found to be 1158.2 psi. In all cases, the failure mode was fracture of the sample and neither cohesive nor adhesive. **Figure 9** shows the fracture of the bolts holding the sample in place.

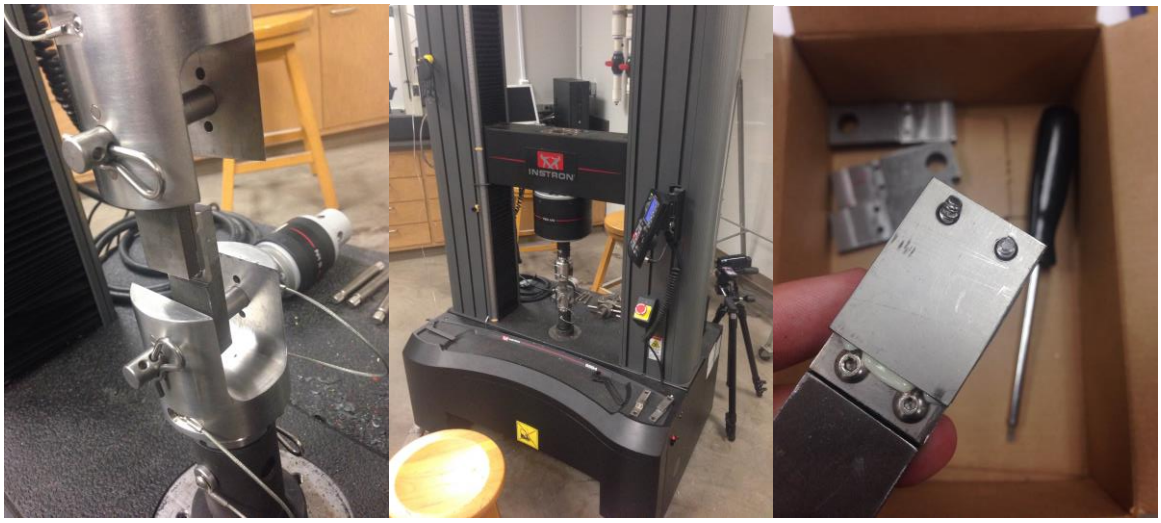
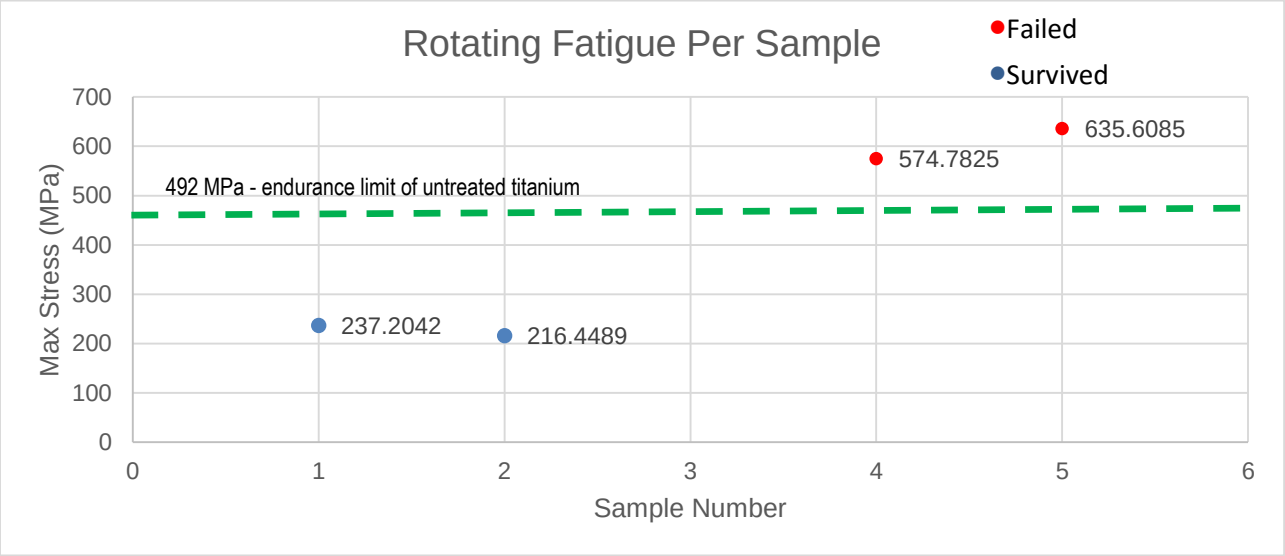


Figure 9. *The left two photos are the setup using the Instron and the lap shear loading grips. The right-most picture is of the bolt failure that occurred as result of the testing.*

The results of the rotating beam fatigue test are below.

Table 3. *Results of the rotating beam fatigue protocol*

	Pre-Test Diameter Measurement (mm)	**After-Test Diameter Measurement (mm)**	**Stress at Initial Diameter**	**Stress at Fatigue Reduced Diameter**	**Failure?**
Sample 1	6.4533 mm	6.2367 mm	214.1029 MPa	237.2042 MPa	No
Sample 2	6.4533 mm	6.4300 mm	214.1029 MPa	216.4489 MPa	No
Sample 3	4.6867 mm	*Premature Fracture*	*N/A*	*N/A*	*N/A*
Sample 4	4.7233 mm	4.6433 mm	546.0476 MPa	574.7825 MPa	Yes
Sample 5	4.5200 mm	4.4900 mm	623.1326 MPa	635.6085 MPa	Yes



Graph 3*. The max stress that each sample was subjected to. No data collected for Sample 3. Blue dots indicate the sample ran for 10^7 cycles without failure. Red dots indicate the sample failed.*

In **Graph 3**, the green line indicates the expected failure load for titanium at 492 MPa. This number comes from material experiments that have been carried to quantitatively evaluate the endurance limit of titanium. We selected our numbers from the Titanium Information Group. Samples 1 and 2 ran for the entire protocol without failure. Sample 3 failed prematurely due to unrelated complications and no data was able to be collected. Samples 4 and 5 did fail before the threshold of 10^7 cycles. The green line indicates the endurance limit of untreated titanium. In other words, Samples 4 and 5 failed as expected and Samples 1 and 2 did not fail, as expected.

CHAPTER IV

CONCLUSION

Insufficient osseointegration continues one of the sources of TKA failure. Currently, 10% of TKA devices are expected to fail within 10 years of the initial operation; 20% of these devices are not expected to make it past 20 years. Revision procedures to replace failed TKA devices result in further damage to the native bone and there is additional bone loss caused by the implantation of a subsequent tibial tray. To address this problem, 4WEB Medical, Inc has proposed a two-prong solution which incorporates a novel truss system and porous surface to reliably anchor the tibial tray into the native bone tissue. As with any US Class II medical device innovation, 4WEB must pass this new device through the supervision of the FDA. One particular interest to the FDA is the porous surface modification, the investigation of which is encapsulated in Objective 1. From the results shown above, **Graph 1** and **Graph 2** show the load/extension of the pilot specimens that were evaluated. In these graphs, the maximum shear force of the lap shear samples was explored, shown in **Table 2**. These tests successfully validated the protocol and infrastructure, paving the way for the final lap shear specimens which are currently in the process of being manufactured.

Graph 3 depicts the stresses experiences in four specimens under oscillating compression and tension in a rotating beam fatigue machine. Specimens 1 and 2 were subjected to load lower than the endurance limit of the alloy and, as expected, did not fail. Specimens 4 and 5 were subjected to loads higher than the endurance limit threshold and, as expected, did fail. Specimen 3 unexpectedly fractured prematurely under unrelated circumstances and no data was collected. These testing protocols and resources have been confirmed via pilot testing to be in compliance

with the rigorous standards of both the FDA and the ASTM, in order to secure 510(k) approval. The 510(k) regulatory pathway demonstrates that the release a medical device is safe and effective to be used by patients and medical professionals.

In addition to the specific investigation regarding the porous surface modification, the FDA requires all TKA devices to undergo performance analysis of the tibial interlocking mechanism, as encapsulated in Objective 2. Towards this end, rigorous testing methodologies have been written and cross examined to be compliant to the highest standards of the FDA and ASTM. Moreover, several requisite components for these investigations have been manufactured as artifacts in the broad infrastructure needed for the interlock verification.

In conclusion, with these validation tests, rigorous methodology protocols, and preliminary infrastructure, we are able to confirm the path to 510(k) approval is on track. These steps will prove to be crucial in taking the innovation from the drawing table to the operating table.

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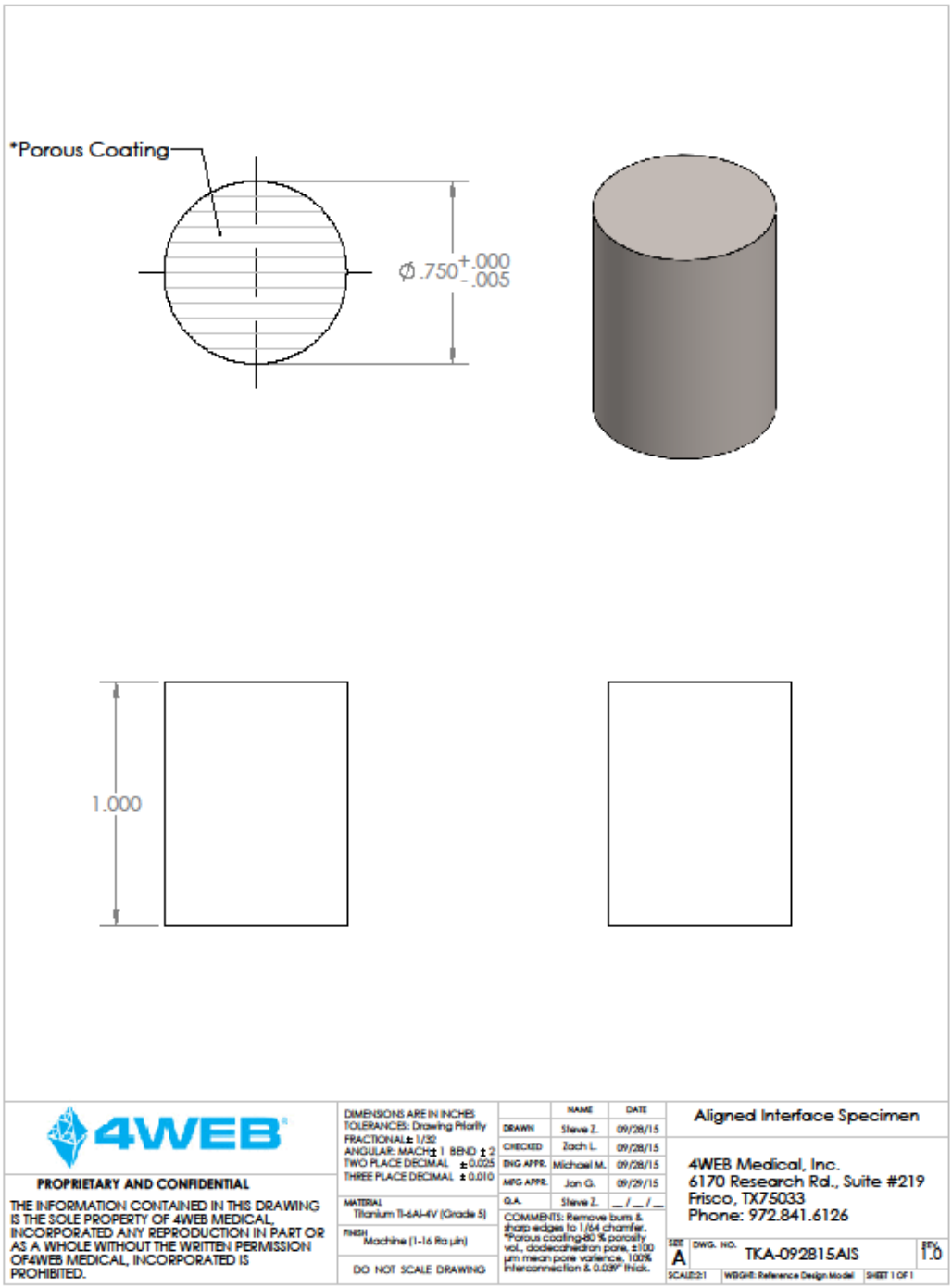
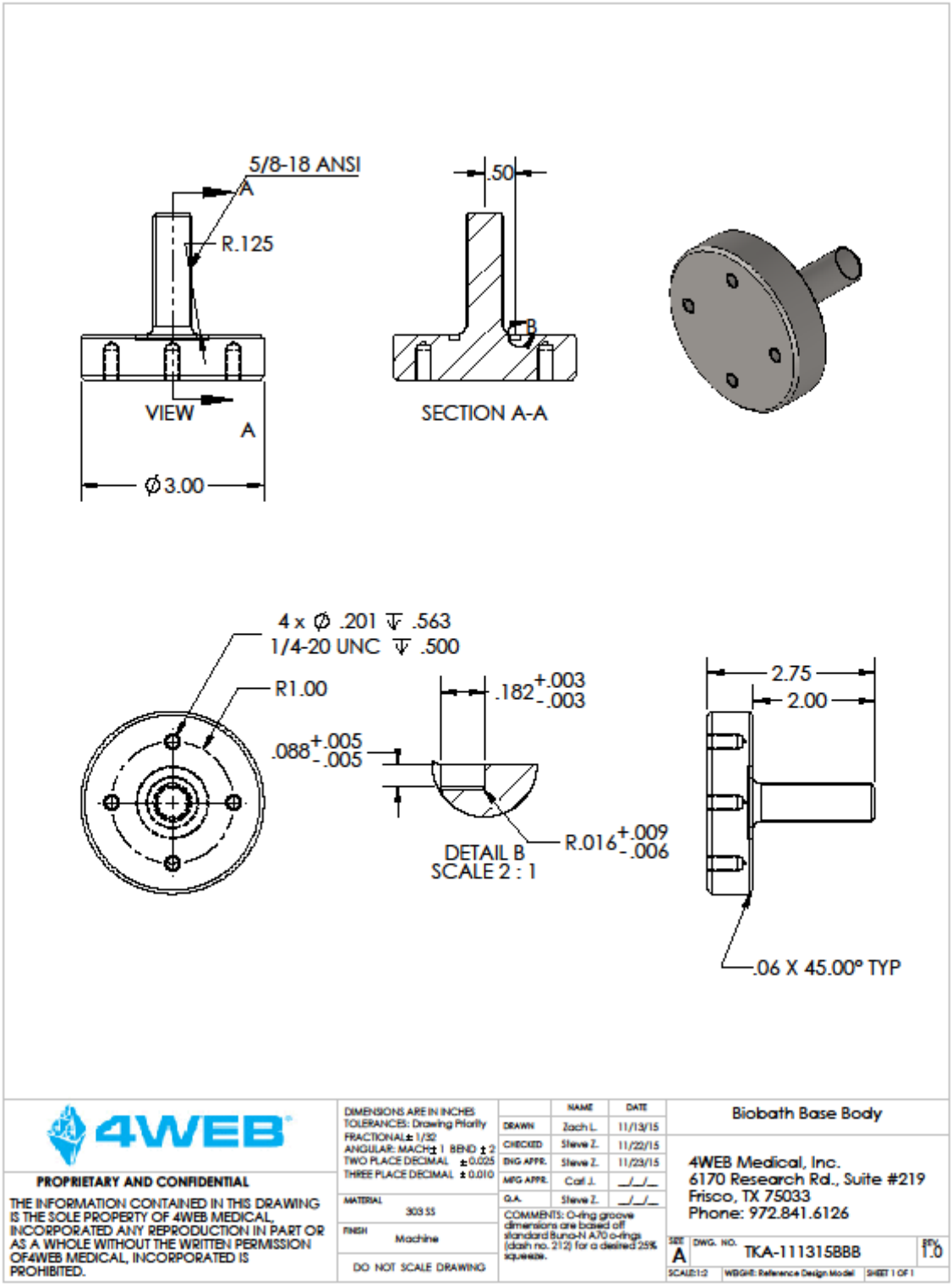
APPENDIX

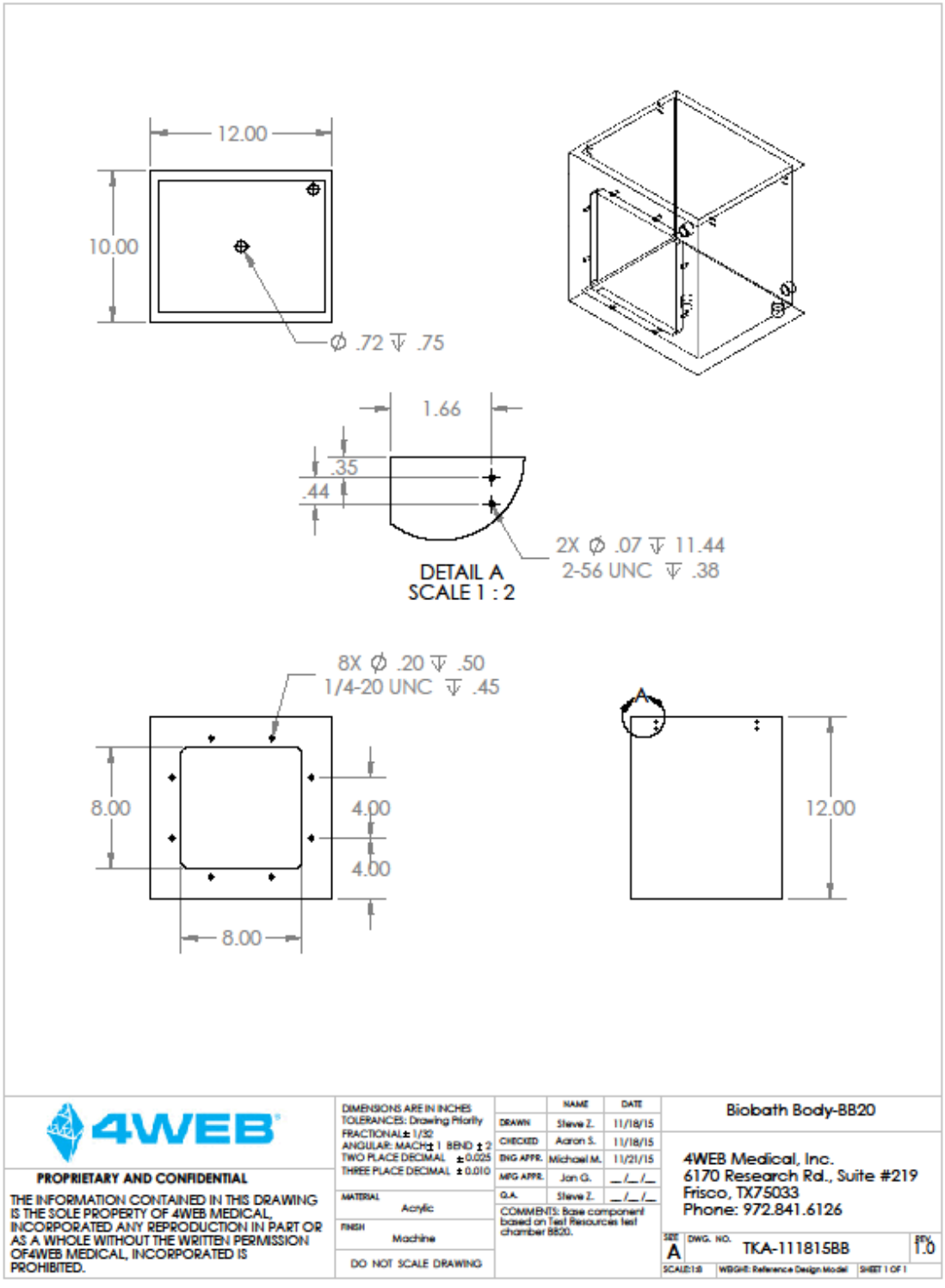
Appendix 1: Aligned Interface Specimen Technical Drawing



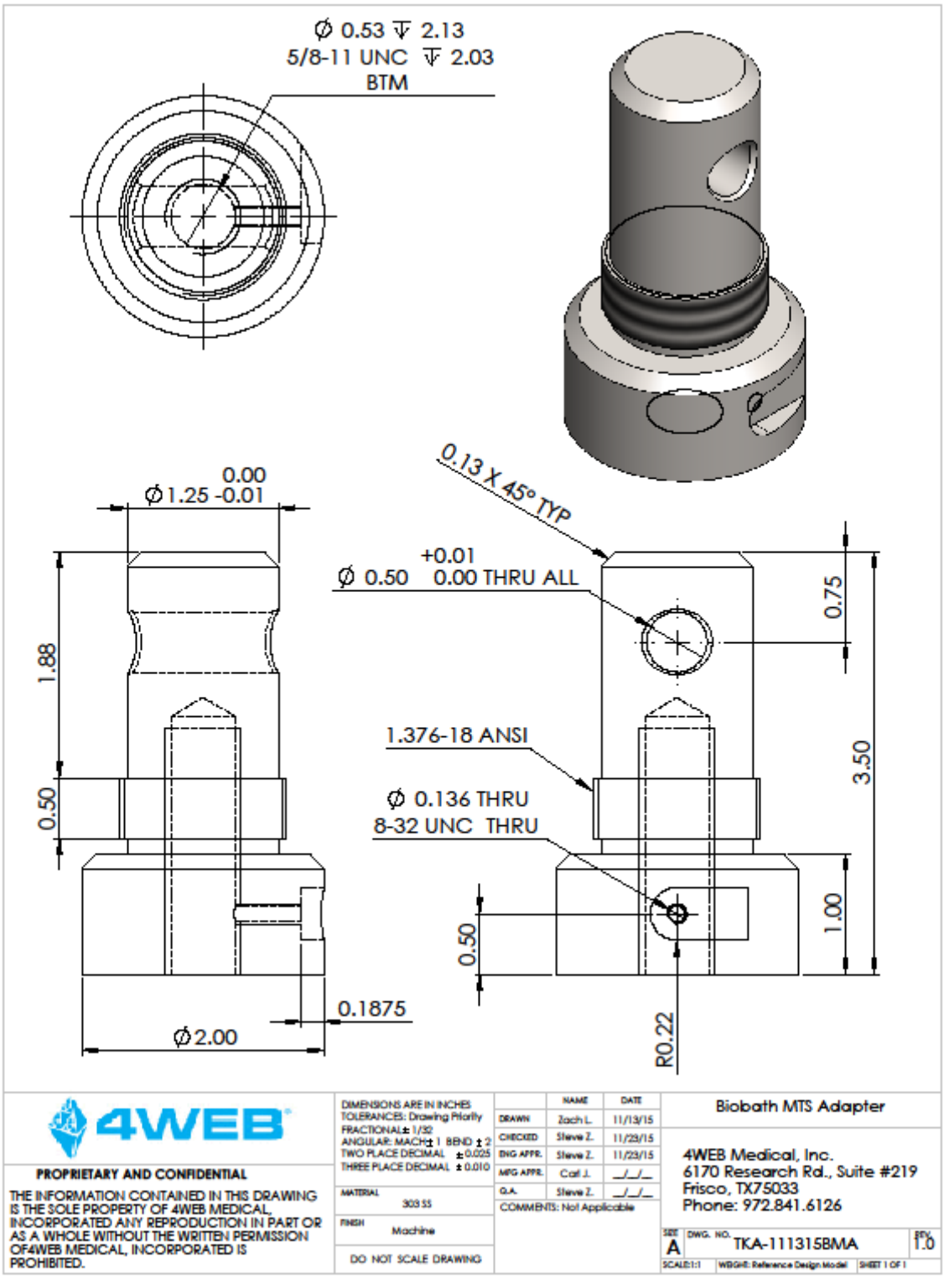
Appendix 2: Biobath Base Body Technical Drawing



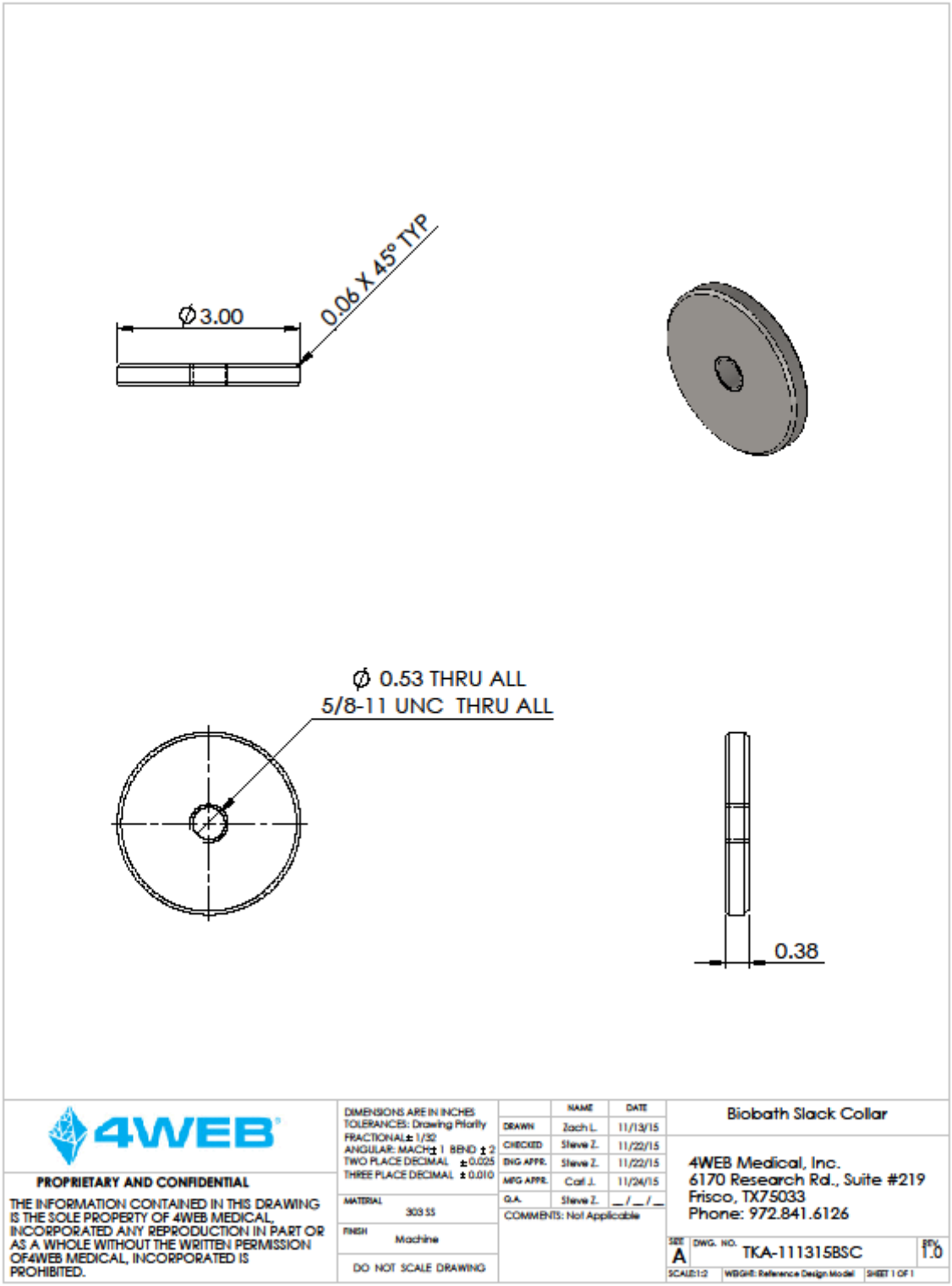
Appendix 3: Biobath Body Technical Drawing



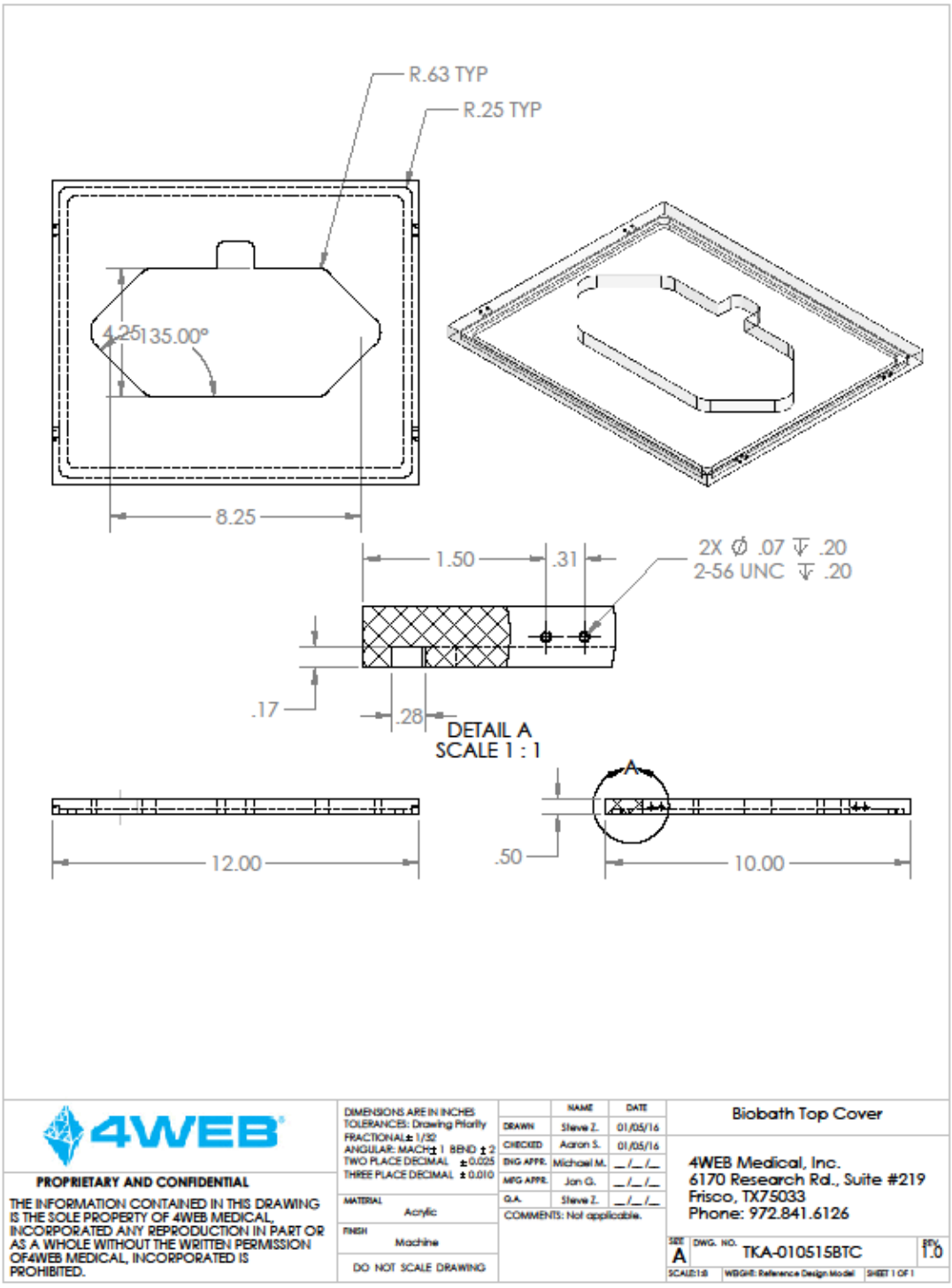
Appendix 4: Biobath MTS Adapter Technical Drawing



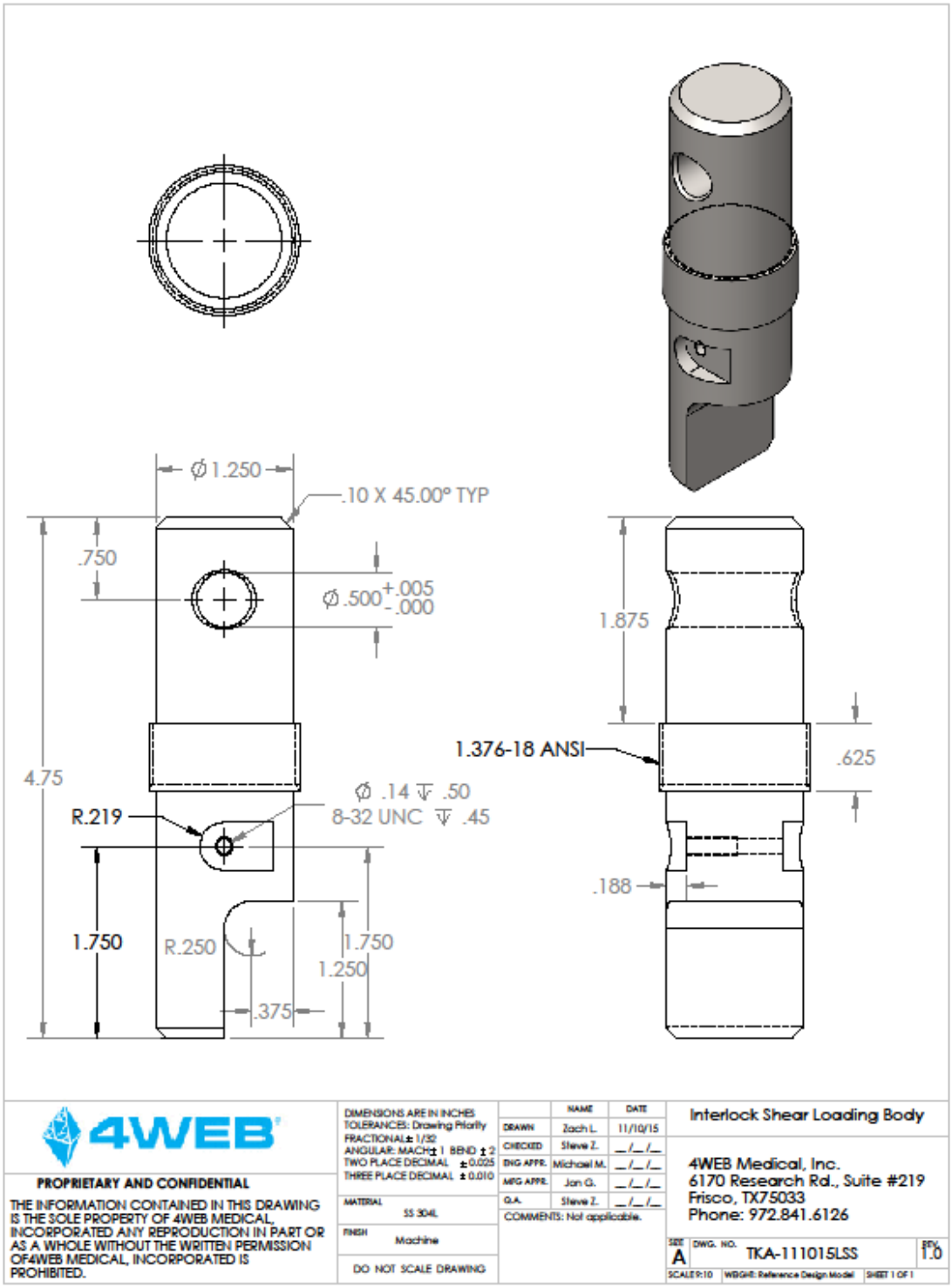
Appendix 5: Biobath Slack Collar Technical Drawing



Appendix 6: Biobath Top Cover Technical Drawing



Appendix 7: Interlock Shear Loading Body Technical Drawing



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DIMENSIONS ARE IN INCHES
TOLERANCES: Drawing Priority
FRACTIONAL ± 1/32
ANGULAR: MACH ± 1 BEND ± 2
TWO PLACE DECIMAL ± 0.025
THREE PLACE DECIMAL ± 0.010

MATERIAL: SS 304L
FINISH: Machine

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	Zach L.	11/10/15
CHECKED	Steve Z.	__/__/__
ENG APPR.	Michael M.	__/__/__
MFG APPR.	Jon G.	__/__/__
Q.A.	Steve Z.	__/__/__

COMMENTS: Not applicable.

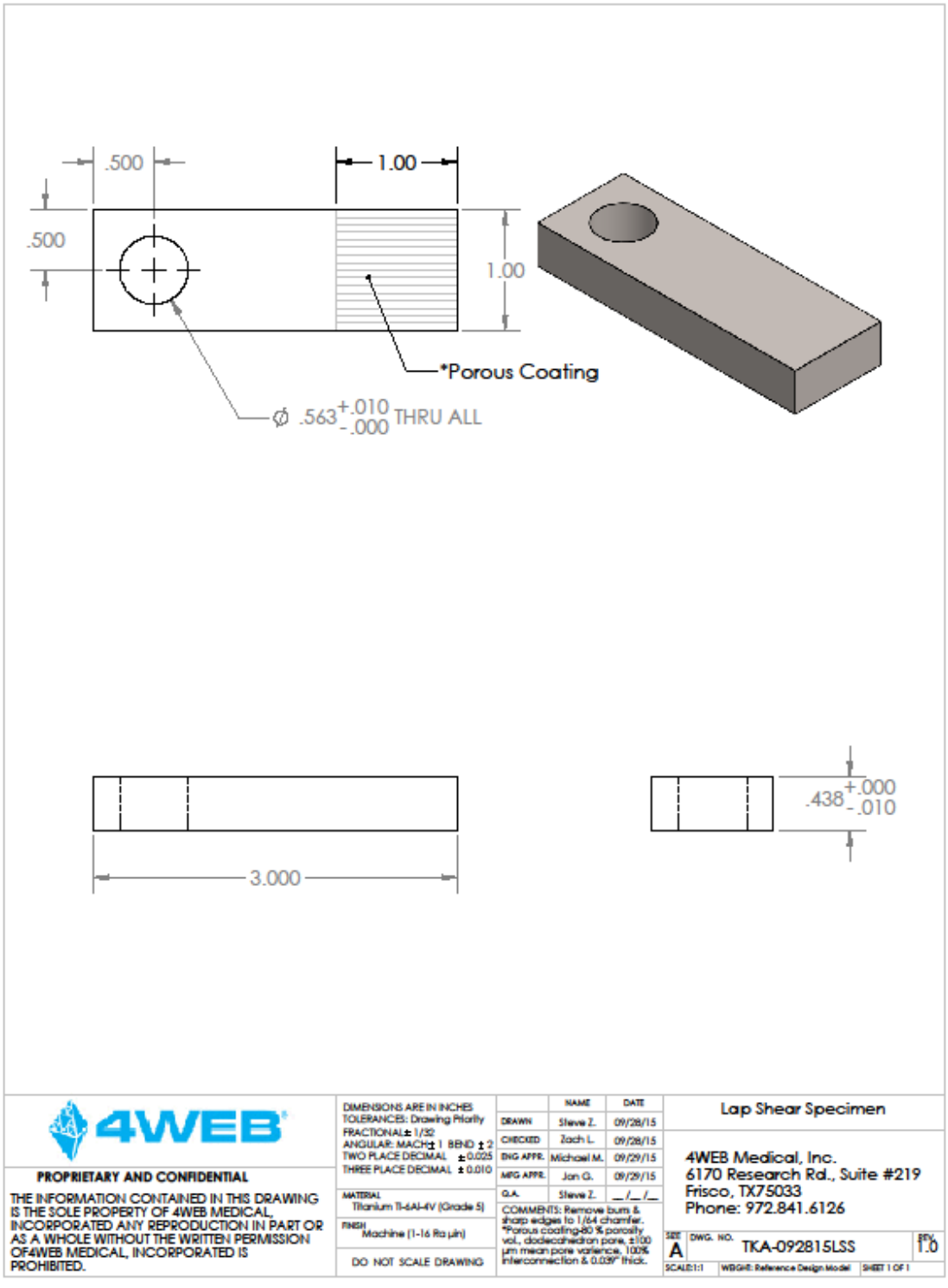
Interlock Shear Loading Body

4WEB Medical, Inc.
6170 Research Rd., Suite #219
Frisco, TX75033
Phone: 972.841.6126

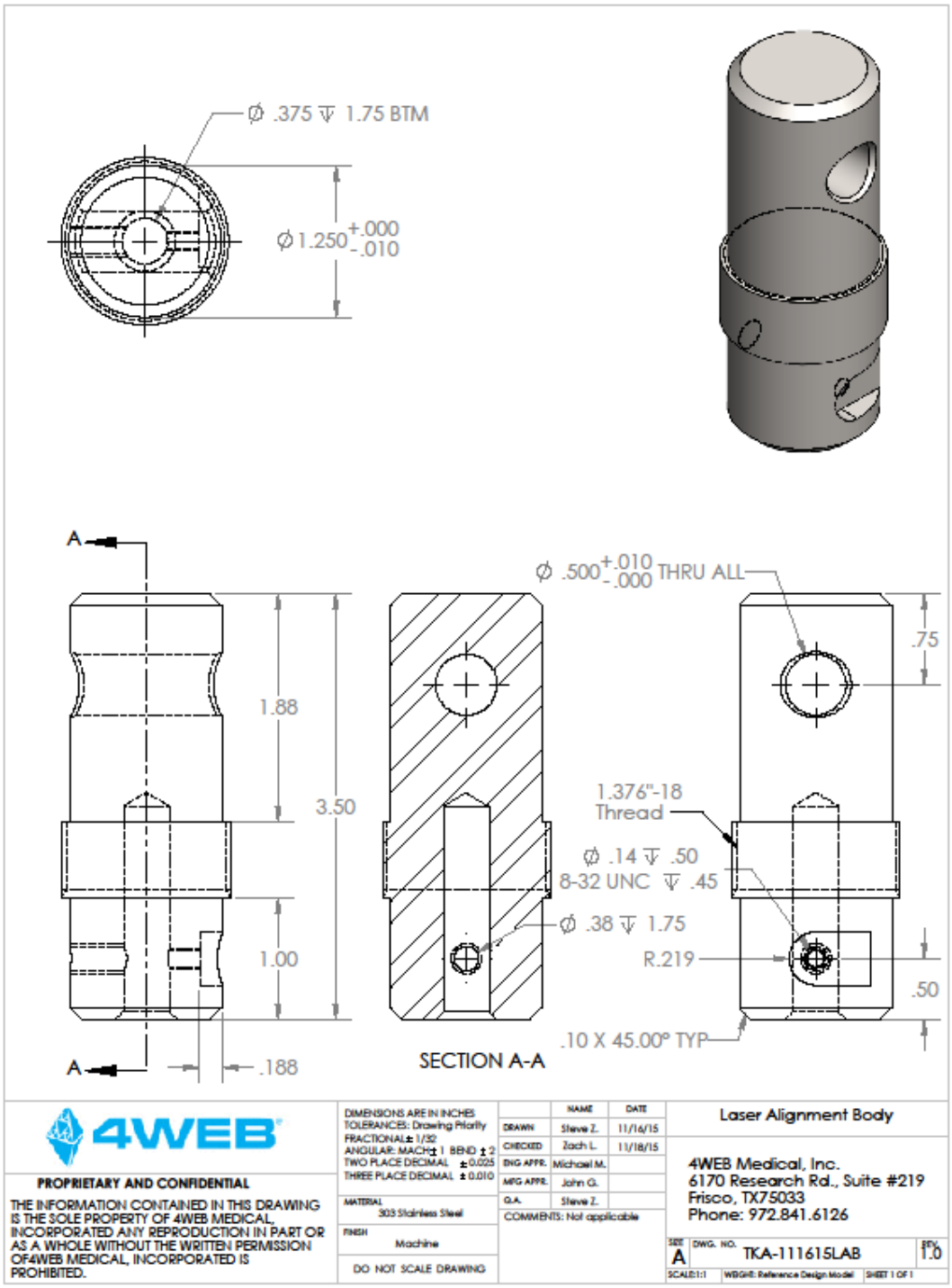
SIZE A | DWG. NO. TKA-111015LSS | REV 1.0

SCALE:9:10 | WEIGHT: Reference Design Model | SHEET 1 OF 1

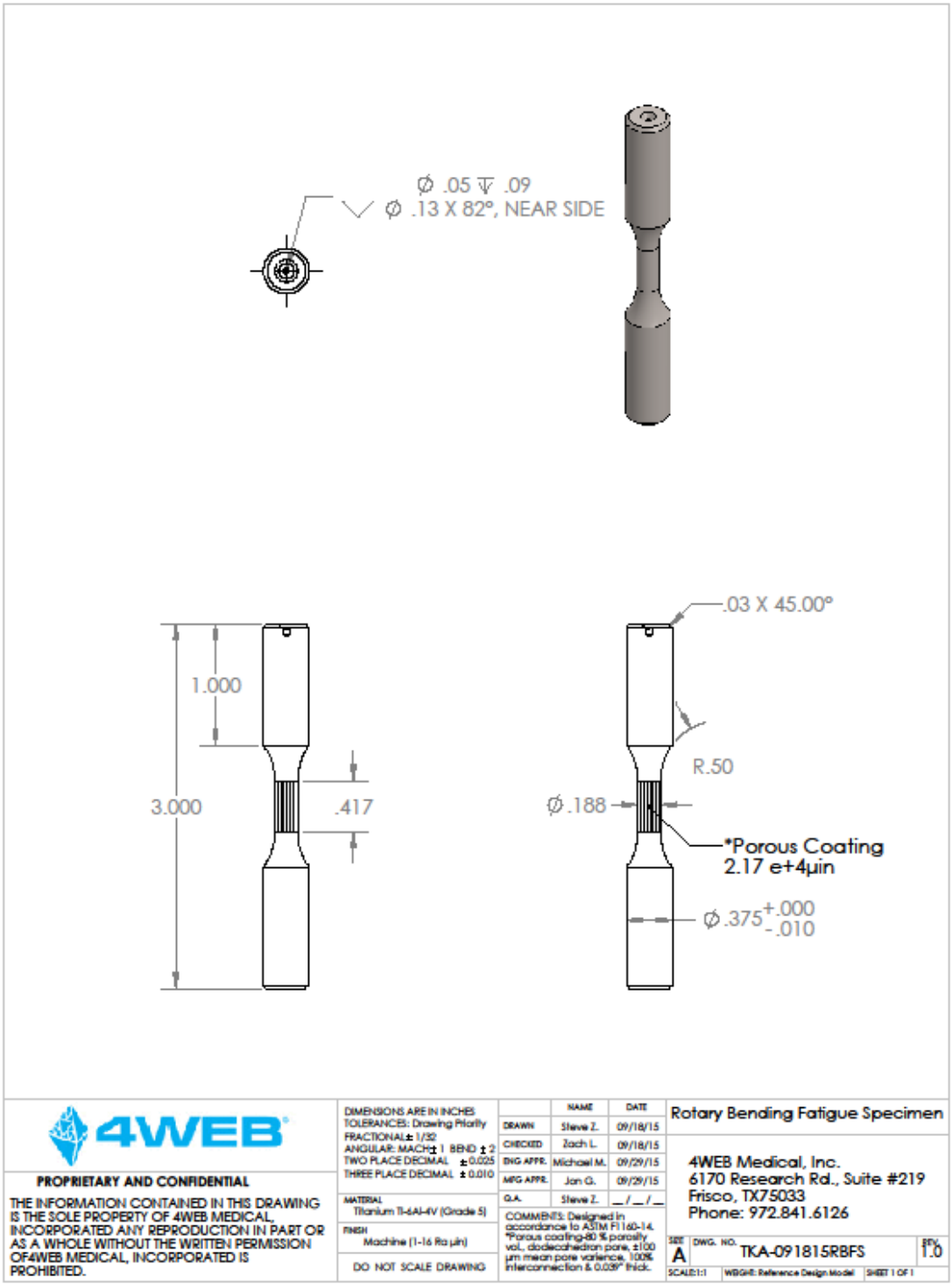
Appendix 8: Lap Shear Specimen Technical Drawing



Appendix 9: Laser Alignment Body Technical Drawing



Appendix 10: Rotary Bending Fatigue Specimen Technical Drawing



Appendix 11: Test Resources MTS Adapter Technical Drawing