Original Research Article

Development of a Fully Actuated Realistic Finger Prosthesis for Proximal Phalanx Amputations

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Abstract

Introduction: Finger amputees today struggle with finger prosthetics in two ways. First, the lack of an inexpensive, customizable, and aesthetically subtle finger prosthetic in the market can cause embarrassment for the patient. Second, the lack of functional capabilities in cheaper finger prosthetics is an inconvenience for amputees with an active lifestyle who can't afford the more expensive, functional prosthetics. A 3D printable skeletal finger prosthetic was developed, with the intention of implementation underneath a realistic silicone sleeve. The design uses 'bridges' on the palmar surface and rubber bands providing an extension force to allow the user to flex the part with their adjacent finger. The objective of this study is to (1) test the fatigue limits and wear patterns of the proposed prototype, (2) investigate the strength of the design in relation to normal usage and (3) gather preliminary data on the usability and comfort of the design.

Materials and Methods: Three tests were performed to evaluate the design of the finger prosthetic skeleton. Firstly, a fatigue test of the PIP joint was performed, using a modified medial segment and an MTS Insight Electromechanical Testing System. Two samples were fabricated from Formlabs Tough TOTL03 resin and printed on Form 2 3D printer, using orthodontic bands for the extension mechanism. A clamp attachment and stage adapter were used to actuate the medial segment and hold the proximal segment stationary, respectively. The test was run for up to 1000 cycles of full flexion and full extension. Secondly, a three point bending test was performed to assess the strength of the bond of the device to a simulated residuum cap. 5 samples were fabricated using an Ultimaker 3 3D printer, using PLA as a material. Samples were bonded to hardened PMMA residuum caps by using uncured PMMA. Testing was performed with an MTS Sintech 10G/L with three point bending fixtures. Samples were loaded until failure. Finally, a preliminary qualitative assessment of the design was performed, where a non-amputee simulated use of the device by holding it under a finger and attempting various simple and gestures and tasks, such as picking up objects.

Results: The fatigue tests did not show significant wear of the band or joint, but did highlight an unexpected issue. Namely, the two samples tested failed before reaching the 1000 cycles because the screw holding the joint together came loose. The three point bending test gave an average force 282.66 N to induce failure, which was well above the literature values for forces exerted by fingers. The qualitative testing indicated that the finger bridges were comfortable and easy to use. In addition, a reasonable amount of dexterity is imparted, allowing the user to grasp various sized objects in both a full hand grip and between the fingertips. However, the range of motion of the device prevents the user from gripping small objects or making a fist.

Conclusions: The use of finger bridges in a prosthetic is a potentially useful design in creating a prosthetic that is both mechanically functional and realistic in appearance. Further study and design work is needed to assess the viability of the design.

KEY INDEXING TERMS: finger amputation, aesthetic prosthetics, articulation, biomechanics, human factors

INTRODUCTION

One in two hundred people have undergone amputation. Twenty-three percent of those causes are due to trauma to the upper limbs. Of the estimated two million of those living with limb loss, research shows that thirty to fifty percent prefer to either not or only periodically use prostheses, due to insufficiencies with aesthetics, movement, and sensitivity.[1] It is therefore necessary to design a prosthetic that can bridge this gap in functionality, that is able to restore some mechanical function while also serving as an aesthetically indistinguishable finger replacement. Dr. Greg Gion of Medical Art Prosthetics© has elected to provide a realistic silicone covering that will fit over the functional prosthetic skeleton designed by the team. In order to address the price of the finger prosthetic, Dr. Gion also requires a prosthetic that can be 3D printed on his Roland ARM 10 printer. Finally, Dr. Gion expressed interest in experimenting with foams to more accurately shape the finger, and desired some space to be left between the prosthetic and the sleeve.

Using a real pointer finger as a model, the prototype was formulated to have a diameter 10 mm smaller than the model finger to allow for the incorporation of shaping foams. For the purposes of actuation, two "bridges" were added underneath the distal and medial segments These are intended to function by extending underneath the adjacent finger to allow the patient to naturally and easily actuate the design. To ensure the prosthetic returns to its resting extended state, places for elastic bands to be fixed via set screws were made on either side of each joint. The designs were modeled in SolidWorks.

As is the case with any design where materials are being subjected to repeated cyclic stress, it is necessary to perform fatigue testing of the design. Fatigue is defined as the failure of a material due to stresses well below its yield strength, and can account for up to 90% of in-service part failure in the service industry. Fatigue is believed to be caused by the propagation of small cracks through a material during cyclic loading, but the precise cause remains unclear.[2] Fatigue testing is vital to determine the viability of the design, as it will give an estimate of part lifetime and durability. Typical fatigue tests simulate use in the real world by applying compression and then tension sequentially until failure. Fatigue propagates through several different mechanisms, but this design, which utilizes hinges of PLA or hard resin photopolymer rubbing against each other, is assumed to be most susceptible to fretting fatigue. Fretting fatigue occurs where cyclic loadings are associated with frictional sliding between parts.[3]

Additionally, it was necessary to gain insight into how well the prosthetic functioned for a patient. The team formulated an adaptor for the prosthetic to be affixed to a normal hand. Testing results were based on a subjective evaluation from a volunteer team member.

METHODS

Instrumentation

<u>Fatigue Test</u>

The fatigue testing was performed using an MTS Insight Electromechanical Testing System. A sampling frequency of 100 samples per second (100 Hz) was selected. A load cell of 250N was used and a 2kN Advantage Grip Clamp (fig. 1) was attached to the 250N load cell. A pin was used to stabilize the MTS base attachment (fig. 2) to the MTS machine. Figures 1 and 2 show a designed and fabricated adapter known as the MTS Stage adapter (fig. 3, 4), connected to the MTS base attachment using a M6x1 screw.

Figure 1. MTS clamp attachment used to hold a dowel pin inside the prototype.

Figure 2. MTS base attachment with a hole for the pin. The MTS Stage Adapter is attached to the hole using an M6x1 screw.

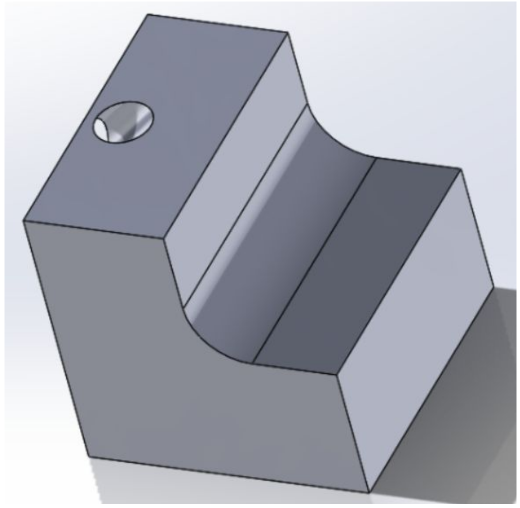

Figure 3. Solid view of MTS Stage adapter. The MTS Stage adaptor places the finger bridge in the line of action of the thumb grip attachment and stabilizes the prototype.

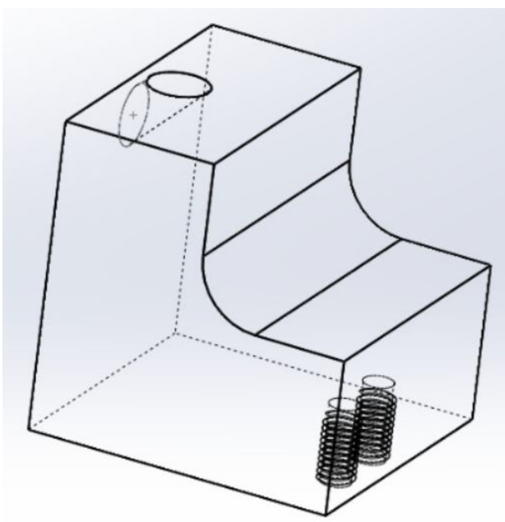

Figure 4. Hidden lines view of MTS Stage adapter. Shows the dimensions and cuts.

The MTS Stage adapter secured the proximal segment of the prototype at a 45° angle to the MTS apparatus' line of action, with the medial segments finger bridge placed directly along the line of action. For simplicity of testing, the distal segment of the prototype was excluded from testing, and only the proximal interphalangeal (PIP) joint was tested. A dowel was placed in a slot of the prototype and the advantage clamp compressed the ends of the dowels without touching the prototype (fig. 5). The actuating bridge was removed to ensure consistent testing without interference between the clamp and the bridge.

Figure 5. Image of the MTS setup with the clamps and MTS stage adapter with a dowel pin bending the PIP joint. Bridge is clipped.

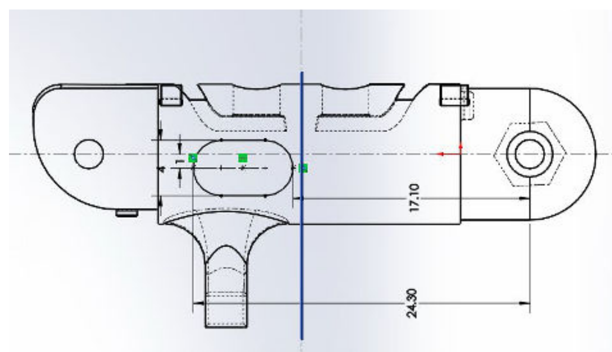

Figure 6. Image of the cross section of the medial segment of the prototype, showing the dowel pin slot used for MTS attachment.

Two samples of the prototype, with an altered medial segment (fig. 6), were printed using Formlabs Tough TOTL03 resin on a Form 2 3D printer. M2x10mm screws and nuts were used to hold the joints together. 2 lengths of ¼" heavy orthodontic rubber bands were attached to the dorsal slots, and held in place by M4x5mm set screws (fig. 7).

Figure 7. Image of prototype. Finger bridges can be seen extending laterally from the palmer side of the medial and distal segment. A rubber band is inserted on the dorsal side of the segments around the joints.

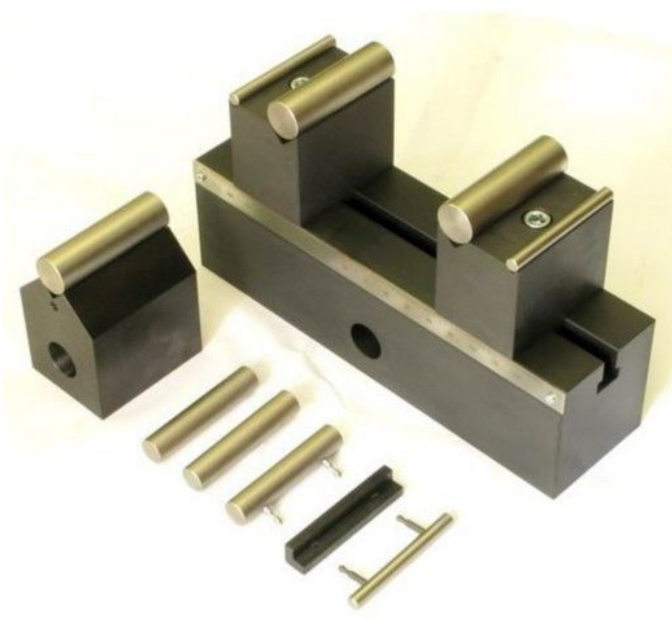

Figure 8. Image of three point bending fixtures similar to those used in the three point bending setup. The block to the left is the moving crosshead that applies a downward force, while the sample rests lengthwise on the part to the right.

<u>Three Point Bending Test</u>

A three point bending test was performed using an MTS Sintech 10G/L, with a 10-kip capacity and screw-driven load frame. Three point bending fixtures were used (fig. 8). 5 samples of the distal phalanx was printed in PLA on an Ultimaker 3 at a temperature of 215°C at a speed of 100% extrusion rate with a layer height of 0.1 mm. The layers were printed in the transverse plane. Prosthetics were assembled using the parts described in the fatigue section above. The samples were bonded to a PMMA block by painting wet (uncured) PMMA to the bottom and sides of the part.

<u>Qualitative Test</u>

Qualitative testing was performed using a fully assembled part printed using Formlabs Tough TOTL03 resin on a Form 2 3D printer. The prosthetic was assembled using the parts described in the fatigue testing section.

Procedures

<u>Fatigue Test</u>

The MTS machine was programmed using a TW Elite software program which set the crosshead of the tensile testing apparatus (which was zeroed when the PIP joint was under full flexion) to travel from 0 mm to 32mm (full extension). The crosshead travelled at a constant rate of 10 mm/s with no rest time at either extreme, resulting in a cycle time of ~8 seconds where the cycle is the crosshead moving up and down. The testing apparatus recorded the amount of force required to enact the flexion and extension of the joint at all points of the cycle. This test was run for 1000 cycles or until failure over a period of 3 hours. The relatively low value of 1000 cycles was chosen to reduce experiment time and provide preliminary data about the presence of fatigue and potential modes of failure not considered in the design process. Failure generically was defined as the point when the MTS stops extending the prosthetic.

The printing parameters were at a temperature of 215°C at a speed of 100% extrusion rate with a layer height of 0.1 mm. The layers were printed in the transverse plane.

The screws were tightened to provide the minimal possible amount of friction between the joints.

<u>Three Point Bending Test</u>

The part was placed in the apparatus as shown in figure 9, keeping the crosshead as close to the bonding interface as possible. The MTS crosshead moved at a speed of 6 mm/s until the force read zero. The apparatus was controlled and force/displacement data collected with TestWorks software. After breakage, the crosshead was moved up and pictures of the broken assembly was taken. This was repeated for all the samples.

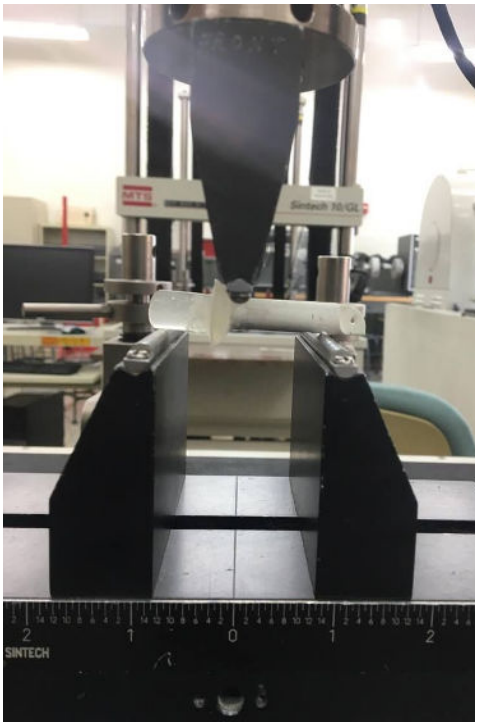

Figure 9. Image of three point bending setup. The piston tip was positioned as close to the interfacial bond as possible.

Figure 10. Images of the qualitative test showing the subject's hand actuating the prosthesis using their middle finger. Images A-C are, clockwise from top: grip of large object, grip of small object between fingers, and grip of small object in fist.

Qualitative Test

A preliminary qualitative test was performed, where a non-amputee team member placed the device under their pointer finger and actuated it with the middle finger (fig. 10). Simple tasks were performed, such as picking up objects of various sizes and experimenting with the device's actuation system. By attempting to simulate the use of the device by an amputee, a preliminary assessment of the design's viability was made.

Analytical Methods

Fatigue Test

The results of the fatigue test were assessed qualitatively and quantitatively. Qualitatively, signs of wear on the rubber band and the inner faces of the joint were assessed visually. Observations were made during testing to see deformation, range of motion, and any possible modes of failure. The primary focus of the visual inspection was of the inner faces of PIP joint of the prototype, where the two segments interacted. This inspection was meant to be taken as additional information, taking note of qualitative phenomena such as smoothing, thermal degradation, or visible wear particles. Quantitatively, the maximum tensile and compressive forces exerted by the MTS testing machine on the prototype during each cycle were compared. This force data was compiled into a scatter plot, and the trendline of this data was evaluated.

Three Point Bending Test

The results of the 3-point bend test was analyzed quantitatively and qualitatively. Pictures taken after the test documents the point of break. Quantitatively, a load vs. time line plot was created with the max force recorded.

Qualitative Test

Criteria evaluated included comfort, discreetness, dexterity, and range of motion (ROM). The user tested the device in various capabilities and wrote a subjective evaluation, which was analyzed by the team.

RESULTS

Fatigue Test

Sample	Cycles to Failure		Failure from screw Loosening Yes(Y)/No(N)
1	290.250	495.375	N
2	250.500		Y
3	465.875		N
4	485.750		Y

Table 1. Table showing the number of cycles to failure. Sample 1 has two separate values; the first value refers to the cycle at which the sample began to interfere with the testing apparatus itself and the second value refers to the cycle value at which an MTS limiter was activated and the interlock prevented any more data from being collected without the interlock being reset. True failure occurs in sample 2 and 4 from screw loosening.

Fatigue testing resulted in samples 2 and 4 failing before the intended 1000 cycles due to the joint screw coming loose, indicated by a sudden decrease in force amplitude. Force amplitude remained relatively constant until failure occurred. Samples 1 and 3 failed due to timeout in the MTS software. Full cycle data graphs can be found in figure A1 of the appendix.

Trial	Max Load (N)
1	247.1
2	385.2
3	267.7
4	238.4
5	272.7

Table 2. Results of three point bending test.

3-Point Bend Test

Static loading gave a mean force of 282.66 $\pm$ 59.20 N to induce failure. In 4 out of 5 cases, the part broke before the bond. Images of tested parts can be found in appendix figure A2. In general, the material of the finger was found to break before the interfacial bond. Results from testing can be found in table 2.

Qualitative Test

The user evaluated the bridges as reasonably easy and comfortable to use with little to no strain to reach or avoid the bridges. The user felt comfortable gripping large and small objects at the fingertips but could not create a fist to grip smaller diameter objects completely. The user commented the actuated motion was smooth and relatively biomimetic. When flexion force was removed and the device was allowed to extend from a flexed state, there was minimal recoil, but the user heard a slight clicking noise at the end of extension when the flanges stopped themselves.

DISCUSSION

Fatigue Test

Visual inspection of the rubber bands following the fatigue test revealed slight discoloration, indicating some wear may have occurred.

The force/time data showed that the amplitude of force in extension and flexion remained essentially constant until failure, indicating that the orthodontic bands have a good lifetime without much mechanical degradation. However, there was great variation in load ranges between samples, as shown in figure A1. **Figure A1b** (sample 2) had a load range from approximately -15 N to 15 N whereas samples 1,3 and 4 show load ranges from -5 N to 5 N of force. Most likely, sample 2 had an improper test setup. If the dowel and MTS weren't aligned carefully, the prosthetic would interfere with the movement of the MTS over time.

Visual inspection of joints did not show signs of wear or accumulation of debris. The failure of sample 2 and 4 from joint screw loosening was unexpected but reasonable as the part exerts a rotation on the screw each time it is actuated. This should be addressed in future design iterations by using a self-tightening screw or a different means of actuation.

3 Point Bending Test

Literature values for fingers in pressing give 52.58 N for males and 39.31 N for females. Pulling gives higher forces, with 70.84 N for males and 49.33 N for females[4]. The 282.66 N force to break the part in the three point bending test suggests that the forces required to break the piece are much higher than would be expected in normal usage of the part. This implies that the proximal segment of the prosthetic is strong enough to withstand normal usage.

Qualitative Test

The qualitative test is preliminary since observations were not recorded with a fully assembled prototype; the full prototype will feature a foam filling and silicone sleeve provided by the client. In addition, the test subject was not an amputee and is hence unable to anticipate all potential issues a real amputee may encounter. In spite of these reservations, several important observations were made. Firstly, the finger bridges were both comfortable and easy to use, indicating that this aspect of the design is viable for continued research. Secondly, the device's operation is fairly quiet, but the sound of the part must be taken into account to ensure that the device is unnoticeable in all settings. The opinion of the tester was that the clicking sound would be inaudible in a busy setting with ambient noise, but would be noticeable in a very quiet setting. Thirdly, the device provides a reasonable degree of dexterity, allowing large objects to be picked up and gripped with ease, and small objects to be manipulated between the fingertips.

However, the device proved difficult to use with small objects, or when a fist was made. This will likely be alleviated with the addition of the outer portions of the prosthetic, however the range of motion of the prototype could be improved. The device only approximates the range of motion of a human finger, and when undergoing tasks which require great dexterity, a more biomimetic range of motion may be required. Thus, the range of motion of the prototype must be adjusted to more accurately mimic that of a real finger to prevent hindrance of the patients function.

Overall Observations

A final observation made by the team was the difficulty in assembling the device from the 3D printed pieces. Due to the dimensional variance inherent to the printing process, there were noticeable differences between parts in terms of joint tightness, which will cause problems in future use, but could be worked out by careful tuning of individual prosthetics. The process of attaching the rubber bands to the joints was time consuming and also led to variance, which could be improved.

The most important incoming step is to assess the function of this device when it has been fully assembled. Likely areas of improvement in future designs are an increase in the accuracy of the approximations of range of motion, a removal of the noises the device makes during actuation, and a transition to a more consistent manufacturing process.

Further tests are also needed to assess the quality and viability of the device. The joints of the device are relatively thin and have the potential to be weak points, so their strength must be assessed. A mechanical test simulating the device in use needs to be performed; this would involve fixing one end of a fully assembled prosthetic and applying static loads in several directions to the distal end until breakage occurs. The silicone sleeve may degrade under repeated flexion and extension, or may have an unrealistic appearance when flexed or extended; a fatigue and qualitative test should be run to assess this. Finally, the qualitative described in this report was very preliminary and cannot fully assess the quality of the device, as it was not performed by a future patient, and not performed on a finished device. In the future, a potential user (or users) of the device with a proximal index finger amputation should work with the team to better assess the functionality and discreteness of the device.

CONCLUSIONS

This study used fatigue testing, static loading, and a preliminary qualitative test to assess the viability of a finger prosthetic design aiming to bring together mechanical functionality and a realistic appearance. The results of this preliminary study indicate that the use of 'finger bridges' is a potentially viable method to provide finger amputees with a subtle, convenient, functionalized and aesthetically realistic prosthetic. However, further research and refinement of the design is needed. For example, the exact life cycle of the prosthetic, excluding failure by screw loosening, needs to be determined.

ACKNOWLEDGEMENTS

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Appendix

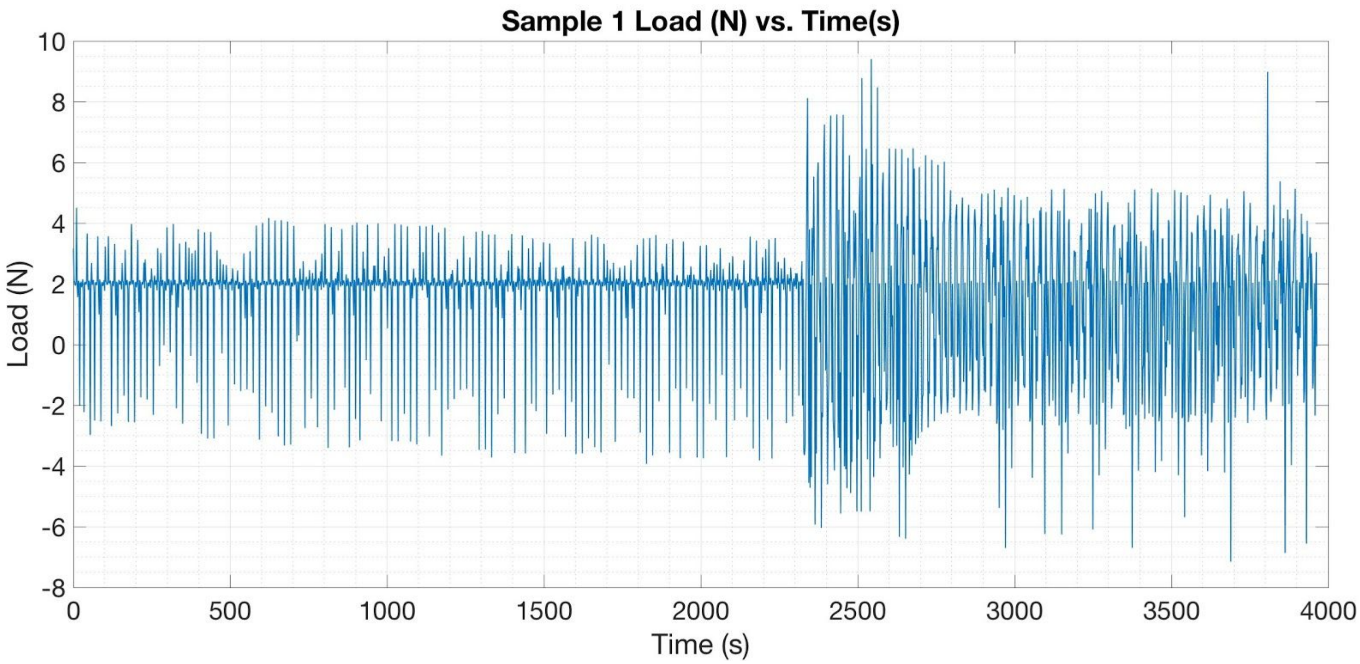

Figure A1a

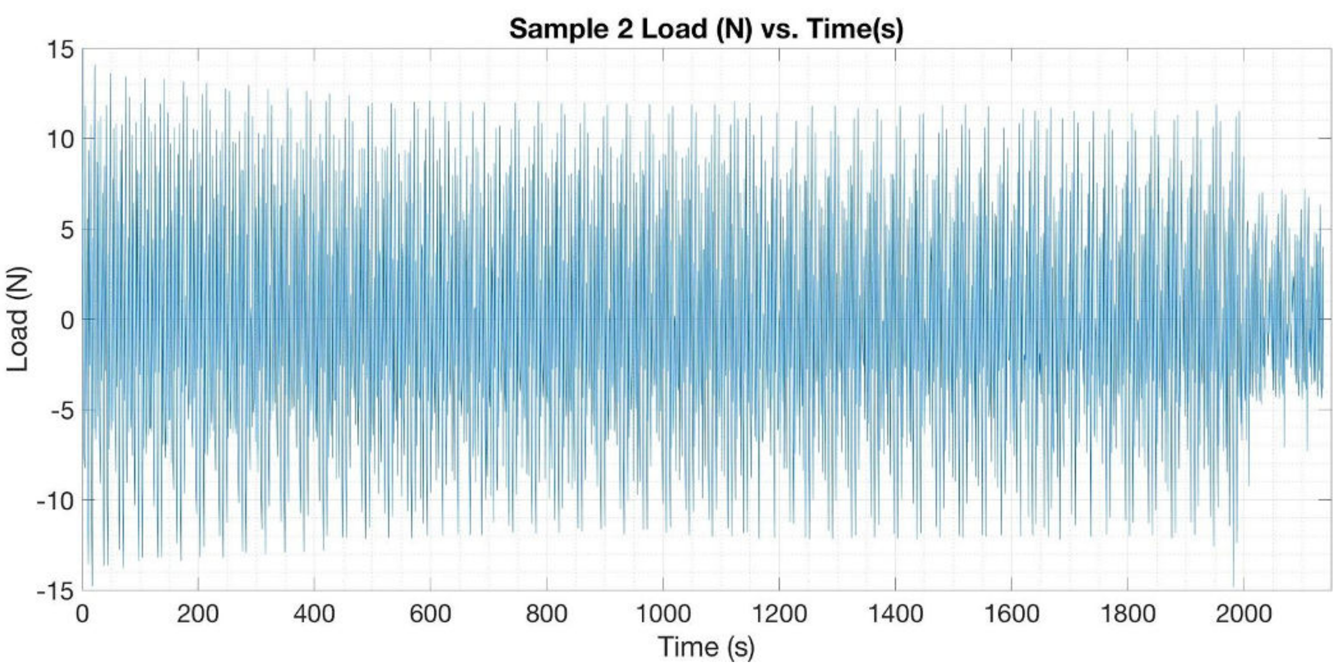

Figure A1b

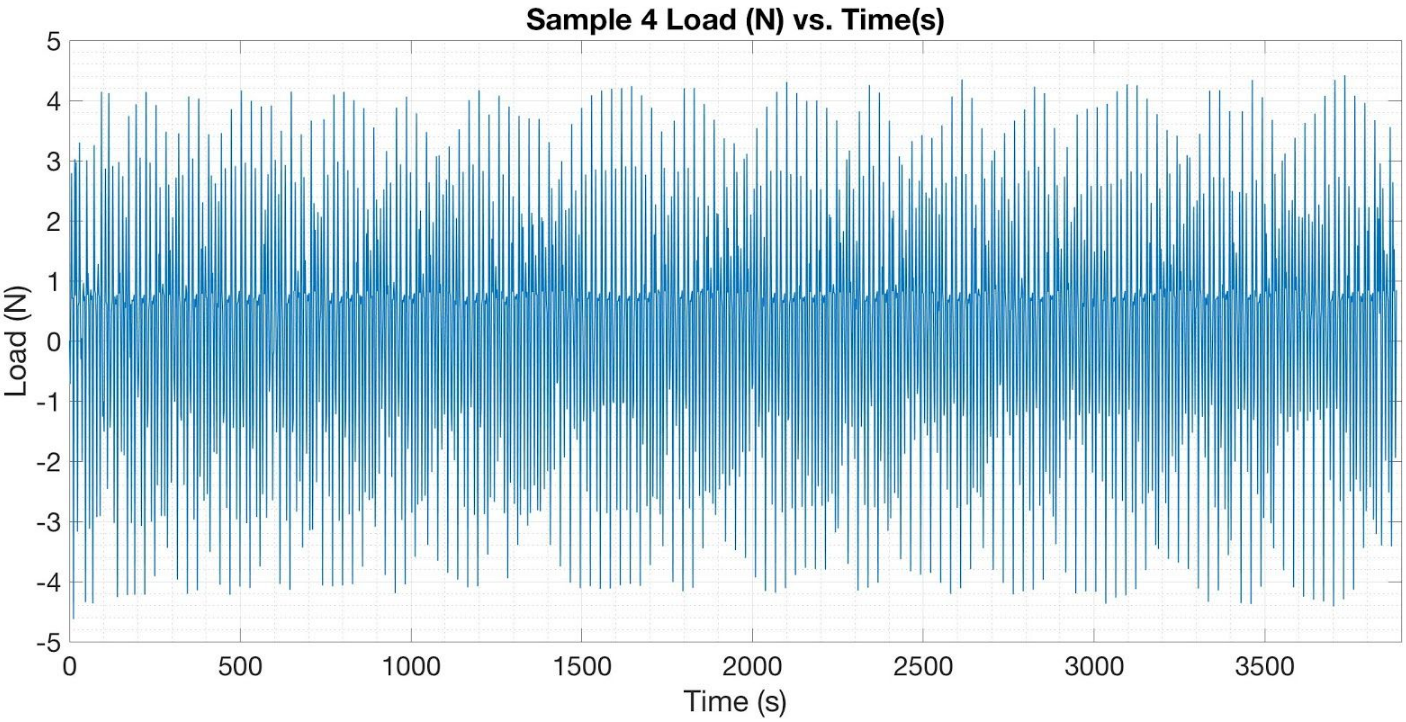

Figure A1c

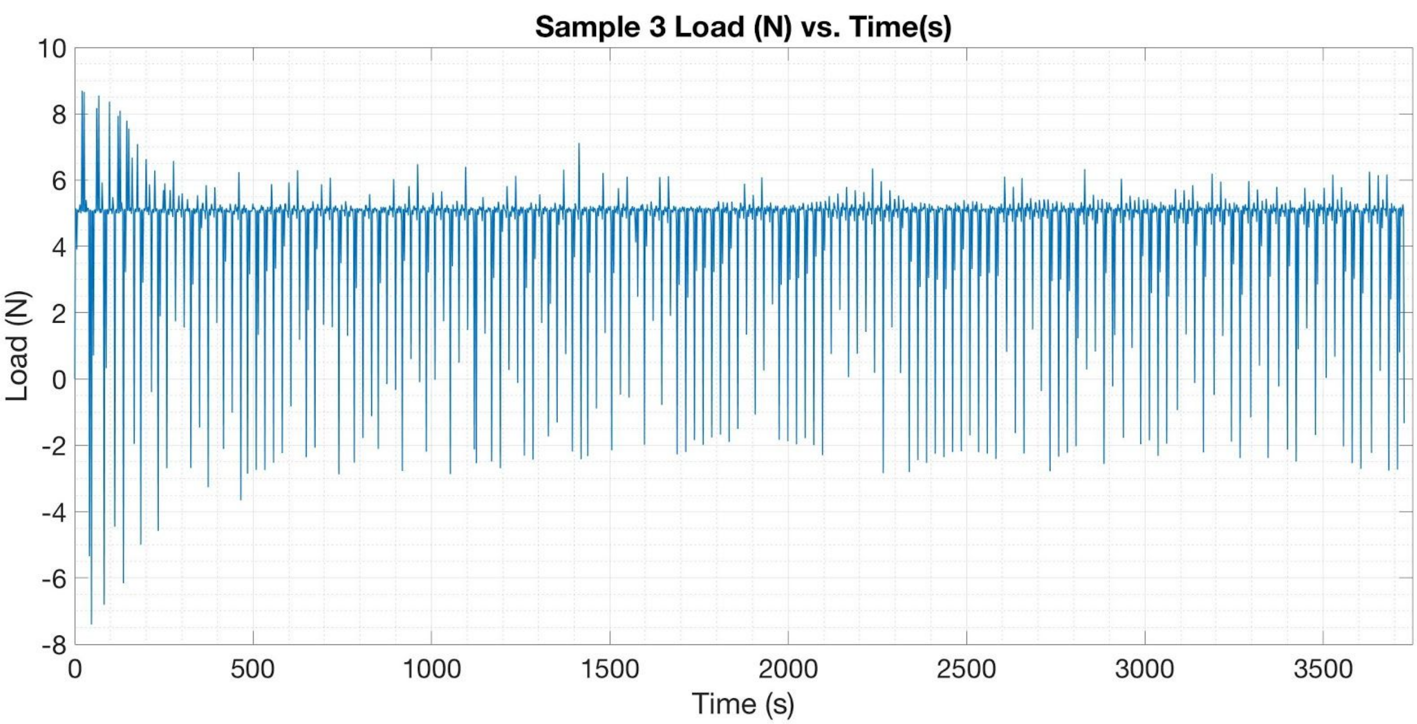

Figure A1d

Figure A1. Force vs. time data from fatigue test for all samples. Samples A1b and A1d failed from screw loosening whereas the samples A1a and A1c failed from an set up in the MTS program. Notice how A1a and A1c stopped at approximately the same point.

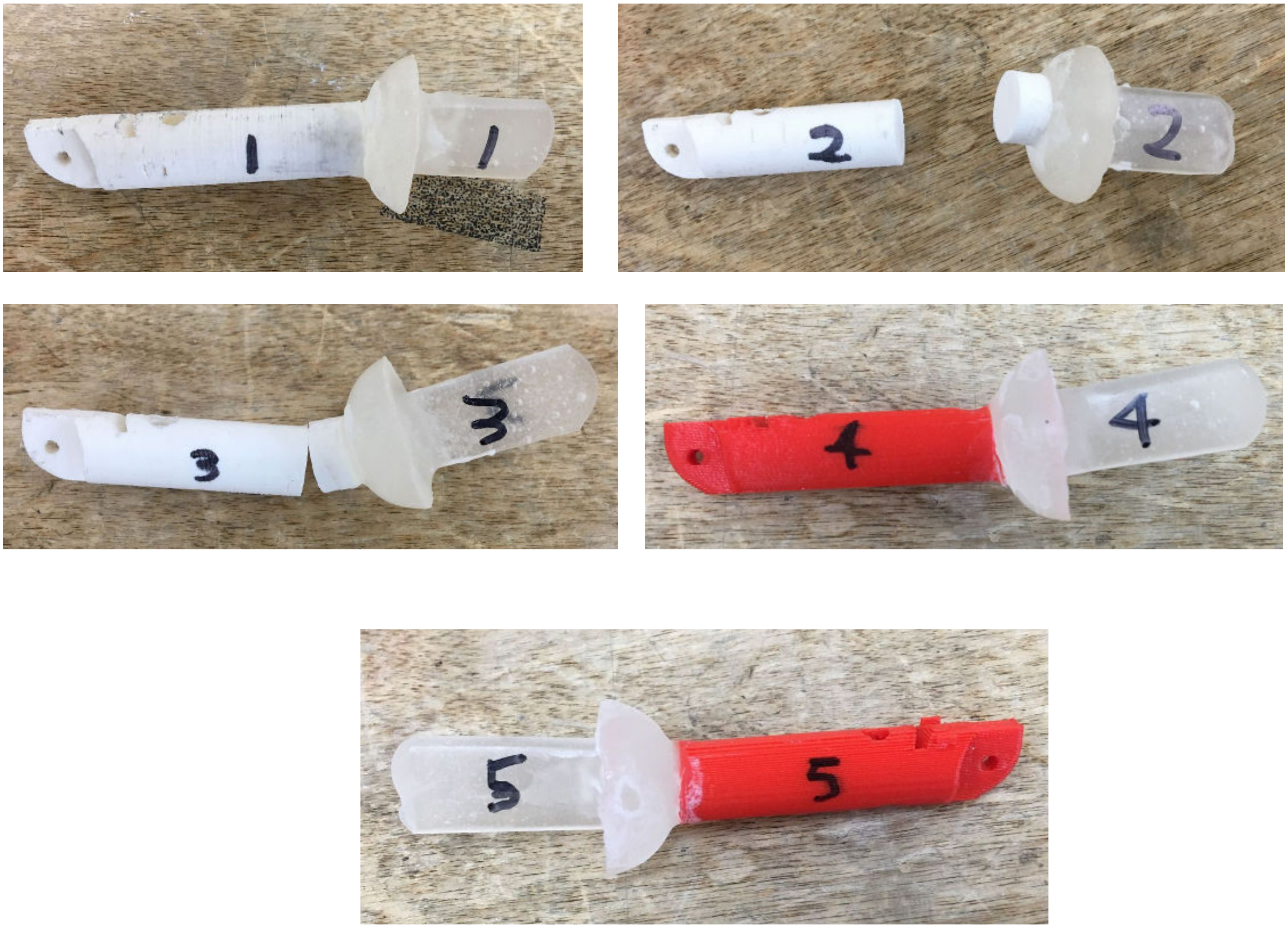

Figure A2. Images of three point bending samples after testing. Sample 1 failed at the interfacial bond. Sample 2, 3, and 5 failed within the bulk of the part. Sample 4 had cracks both at the bond and within the part.