DEVELOPING A Y-SHAPED CUTTING DEVICE TOWARD EXPERIMENTALLY DETERMINING CUTTING PROPERTIES OF BLOOD CLOTS

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ABSTRACT

This material characterization research focuses on venous thrombi, blood clots that form in veins. Each year in the United States, 300,000 – 600,000 people experience venous thromboembolisms, with 62% of cases experiencing long term complications or death within a month of diagnosis. This subset of the patient population could benefit from improved treatment. Current mechanical thrombectomy procedures have a complete removal success rate of 48%, so there is significant room for improvement. In order to inform improvements in mechanical thrombectomy procedures and medical device designs we are studying the cutting properties of blood clots using Y-Shaped Cutting (YSC). In past studies, YSC has been used to test the material properties of rubber, silicone, and other soft materials. Utilizing a sample geometry in the shape of a "Y", YSC takes advantage of preloading the split ends of the sample to keep them from touching the edges of a razor blade which cuts down the center of the "Y". This technique minimizes frictional effects of the blade as it cuts through sample material, leading to accurate measurements of pure cutting energy. In this project, a YSC test setup was specifically designed towards measuring the cutting energy of blood clots. This has required modifications from past YSC setups to account for the unique testing challenges that blood clots present as a material.

INTRODUCTION

Venous Thrombi

This research focuses on venous thrombi, blood clots that form in veins. While clotting is essential to the proper healing of any skin abrasion, trouble begins when unwanted blood clots form and travel within veins far beneath the skin. Two of the most threatening venous blood clot conditions are deep vein thrombosis (DVT) and pulmonary embolisms. DVT involves a thrombus, meaning a clot, forming and blocking the flow of a vein far beneath the surface of the skin, commonly in the legs and torso. A pulmonary embolism occurs when a thrombus breaks away from its origin point in a vein and travels to the lungs, blocking oxygen in a potentially deadly event. Each year in the United States, 300,000 – 600,000 people experience venous thromboembolisms, the survival and impact on this population is shown in Figure 1.

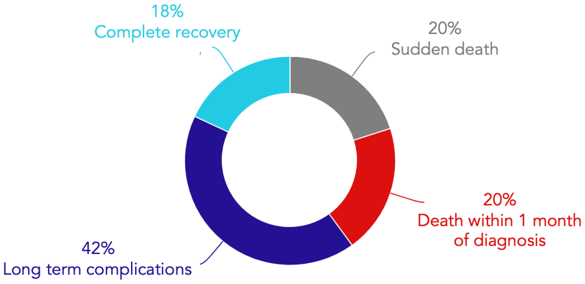


Figure 1. The impact of venous thromboembolisms on patients in the United States [1].

Mechanical Thrombectomies

We focused on mechanical treatments of venous blood clots. A mechanical thrombectomy involves physically removing the blood clot from a patient's vein. This treatment is useful for rapid clot removal in emergencies and when clot busting medications are not adequate. Current mechanical venous thrombectomy devices have a complete removal success rate of 48%, which leaves considerable room for improvement [2]. Improving the quality of such a procedure could be beneficial to the 20% of patients who die within one month of diagnosis and the 42% who experience long term complications from venous thromboembolisms.

Blood Clot Composition

One reason why mechanical venous thrombectomies have a success rate comparable to a coin flip is that blood clot material properties are complex and have not yet been fully characterized. In order to properly approach a blood clot for removal or design a new medical device for mechanical thrombectomies, clot material properties must be anticipated. A blood clot's irregular structure is composed primarily of red blood cells, collagen, fibrin, and platelets. On top of their already complex configuration, the composition of clots changes as they age, see Figure 2. This means clot material characterization requires complete analysis of many different clot ages and compositions.

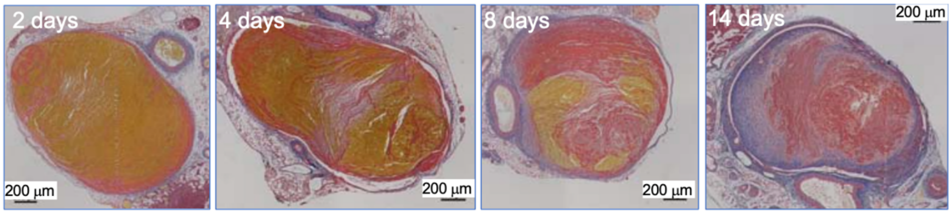


Figure 2. Blood clot cross section images by Dr. Andrea Obi. Shows the aging of a blood clot in 21 days, stain colors represent: Yellow: red blood cells, Red: fibrin, and Blue: collagen.

Cutting Shows Promise To Study

Our work focused on characterizing a single property of blood clots: the energy it takes purely to cut them. As seen in Figure 3, cutting has an advantage over tearing in fracture because cutting has a smaller area of deformation surrounding the crack tip. Cutting has great potential in medical procedures because it is more controlled and precise. Indeed, the advantages of cutting have already been realized in many medical procedures involving blades sharp enough to optimize cutting over tearing.

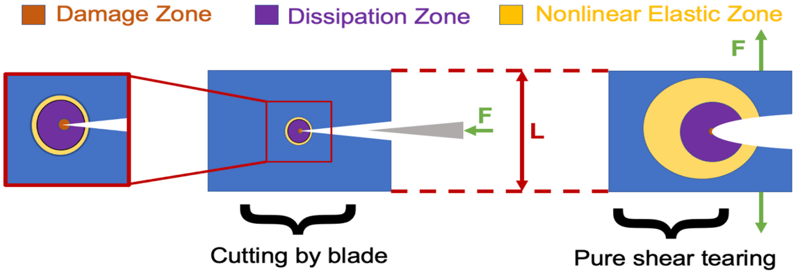


Figure 3. Adapted from Hutchins 2021, the difference between cutting and tearing

Y-Shaped Cutting Test Setup

To characterize the cutting energy of blood clots, we have chosen a test procedure called Y-shaped cutting (YSC). Developed in the 1970's by Lake and Yeoh to measure the cutting properties of rubber tires, YSC has since been used on silicone and other soft materials. The material testing setup, illustrated in Figure 4, utilizes a Y-shaped sample geometry that mitigates the effects of friction from the blade cutting into the sample by reducing contact between the sides of the blades and the sample. As the test is conducted, the force required to cut the material and the rate at which it is cut are measured. Equation 1 shows how measured and experimentally determined values are used to calculate the energy needed to fracture the subject material. To capture the pure cutting energy of the material, the cutting contribution to the total fracture energy must be dominant. In order to minimize the tearing contribution to the fracture energy, the leg angle of the sample will be minimized. This causes the tearing contribution term in Equation 1 to become much smaller than the cutting contribution term as the leg angle approaches zero. Therefore, one of the goals using this setup in our research is to minimize the sample leg angle to capture the cutting contribution while still enjoying the advantages of reduced blade friction between the sample.

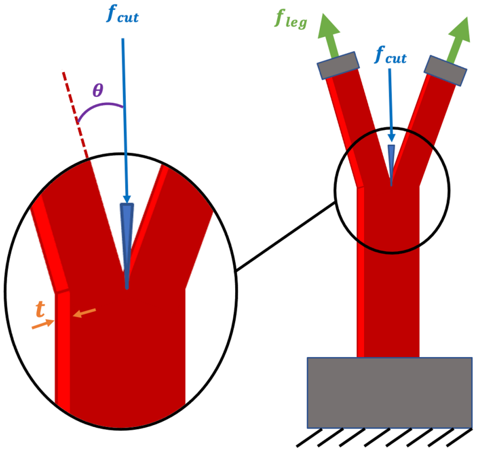


Figure 4. Y-Shaped Cutting configuration. f_{cut} is the cutting force measured by the blade, f_{leg} is the preload on each sample leg, t is the sample thickness, and Θ is the leg angle.

Load on the sample legs

Average pre-stretch of the sample legs

Cutting force

$$G_{fracture} = \frac{2 f_{leg} \bar{\lambda}}{t} (1 - \cos \theta) + \frac{2 f_{cut} \bar{\lambda}}{t}$$

Fracture Energy

Leg angle

Sample thickness

Equation 1. RHS: Fracture energy. LHS: the tearing energy contribution (first term) is determined by the load on the sample legs and leg angle, the cutting contribution (second term) is determined by the cutting force.

DESIGN EVOLUTION

This section outlines the initial design and implementation of the Y-cutting setup and its development.

The Dynamic Mechanical Analyzer (DMA)

This test was conducted on the RSA III DMA in our lab. The resolution of the force gauge is 2 µN, which has been suitable for past blood clot experiments conducted in the lab.

Initial Design

The initial YSC design, shown in Figure 5, was composed of two 3D printed covers for the platens of the DMA, a tensioning system, and a razor blade with a mount. The bottom cover was used as a surface to glue the sample to and the top cover had a dovetail slot to accommodate a razor blade mount. The razor blades used were manufactured by Blue Ridge Tools. The mount was also 3D printed and held the razor blade with a press fit and a fastener through the center hole of the blade.

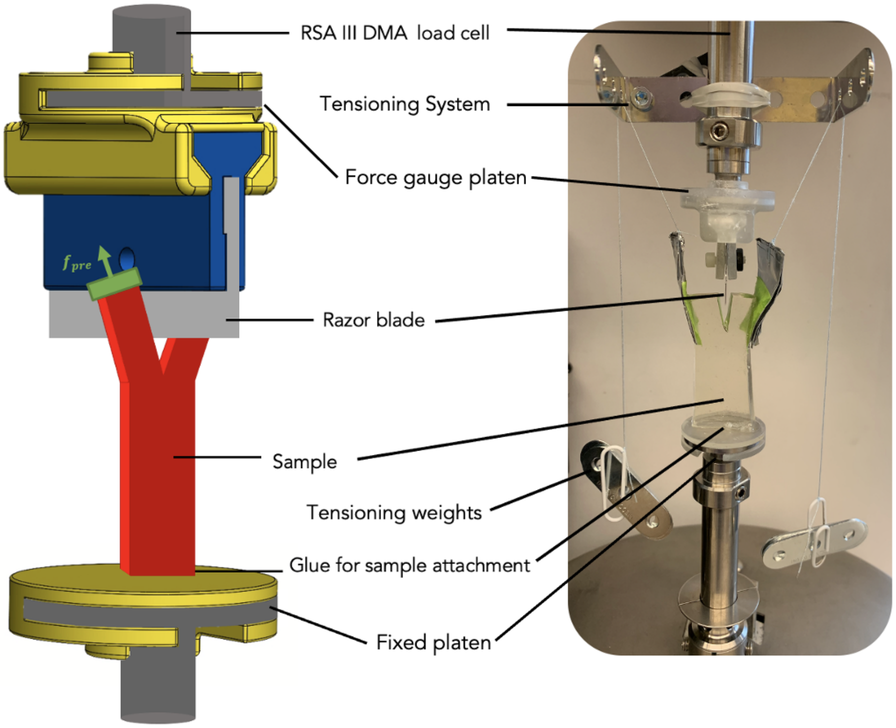


Figure 5. The initial design and general experimental setup.

Blade mounting

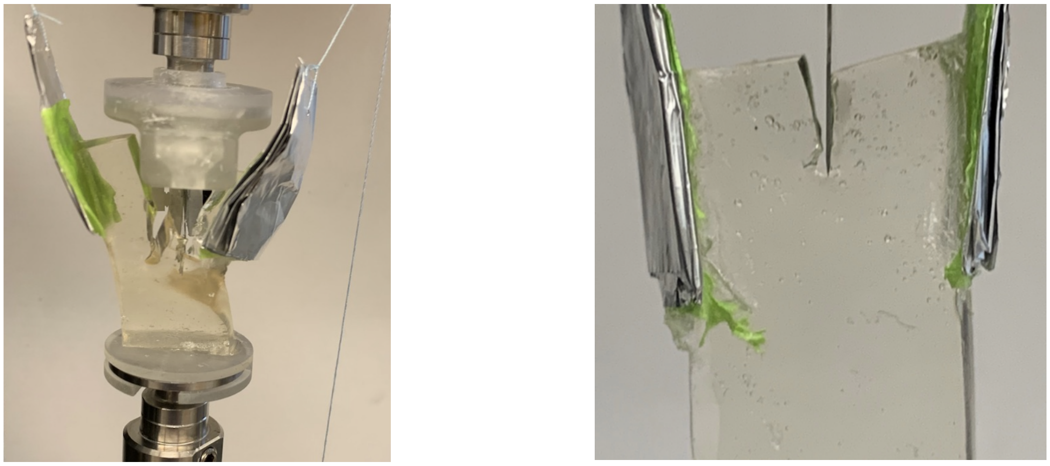
This design had plenty of failures to build off of. The most immediate was that the razor blade mount was too wide to fit into the small gap produced by the small leg angle. The consequence of this was that once the blade traveled 1 centimeter into the sample, the wide part of the blade mount would come in contact with the legs of the sample and begin crushing the sample. This crushing action is pictured in Figure 6 (a).

Tensioning system

The tensioning system of the initial design was mounted to the top platen of the DMA holding the blade. In this configuration the anchor points of the tensioning pulleys moved along with the blade as it traveled downwards, this is referred to as a blade-fixed configuration for the remainder of this report. The blade-fixed configuration was visibly unstable, with the tensioning weights swinging as the blade traveled which caused disturbances in the measured cutting force. Additionally, the rigid design of the tensioning system did not allow for the adjustments needed to discover what the minimum leg angle could be in testing. This is important because determining the minimum leg angle is essential to maximizing the cutting energy contributions to total fracture energy. After initial testing of the original tensioning system, it was apparent that a new design was needed with increased stability and leg angle adjustment functionality.

Blade tracking and adjustment

The final failure of the initial setup was in the blade tracking, or lack thereof. The success of a YSC trial weighs heavily on the blade finding the exact point in the center of the Y-shaped sample to begin cutting. There was no infrastructure to adjust the aim of the blade so no corrections could be made once the setup was prepared. This design flaw often led to the blade touching the one of the sample legs as it traveled, causing the sample to deform undesirably as shown in Figure 6 (b). It was hard to predict whether the blade was centered as the test was running, because the scale of the crack is small enough to make visual distance estimations difficult. It became apparent in observing the test that a magnifying lens would be needed to accomplish any proper blade tracking and adjustment. One way we were able to work around this inflexibility in blade tracking and adjustment over the crack center was by setting up the sample without an initial crack and then lowering the blade on the uncut sample to make the initial indentation. The blade was then backed off and the test run with the centered indentation. This method prevented the blade from coming into contact with the legs of the sample but it also produced a slightly jagged initial fracture which occasionally led to unintentional tearing. An ideal test setup would be able to accept pre-cut samples that have had their initial cracks cut in a more controlled manner.

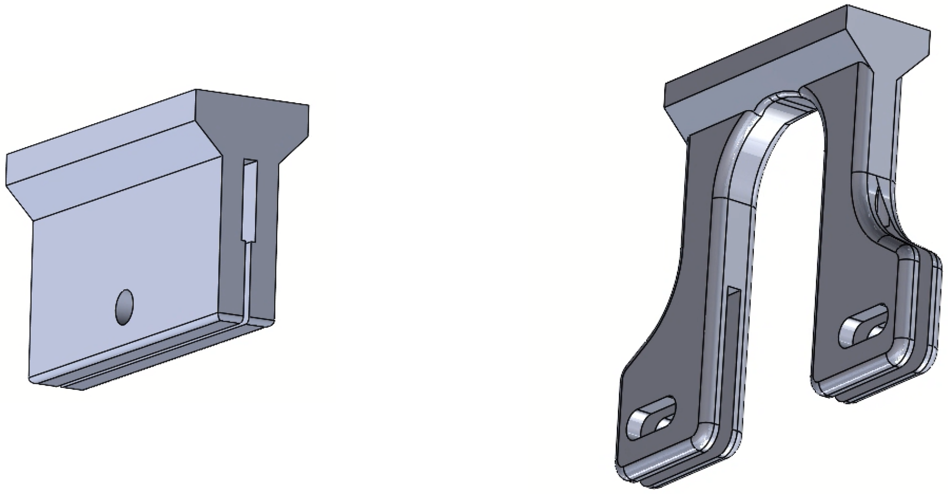


(a) (b)

Figure 6. Initial design failures. (a) Undesired Y-Shaped Crushing. (b) Poor blade tracking, the blade approached the sample from too far to the right, so the right hand leg of the sample is shown caught on the blade.

First Design Iteration: Redesigned Blade Mount

The most immediate issue of the sample being crushed by a blade mount that was too wide was solved by designing a mount that avoids all interference with the sample. In testing, a mount thickness in the plane of the blade of even 1mm interfered with the cutting process. Figure 7 shows the original blade mount in comparison to the new blade mount which is designed with an open section to have no thickness in the plane of the blade. The height of the mount in the cutting direction was also increased to avoid contact between the sample legs and the dovetail section of the mount. These improvements increased the functional cutting distance sixfold from .5 cm to 3 cm.



(a) (b)

Figure 6. Design improvements on the razor blade mounting component. (a) The initial blade mounting design with one central fastener hole. (b) The redesigned mount with an open space for cutting the sample and increased height between the bottom of the razor blade and the dovetail mounting section of the component. The blade is secured using two fastener holes for either side of the razor blade.

Second Design Iteration: Ground-Fixed Tensioning System

The tensioning system of the second design had pulley anchor points fixed to a stationary mount in an effort to improve stability. In this configuration the anchor points of the tensioning pulleys stayed fixed with respect to the ground as the blade traveled downwards, this is referred to as a ground-fixed configuration for the remainder of this report. Difficulty in finding attachment points on the DMA was sidestepped by creating a semi-stable mounting surface that fit around the DMA stage. The leg angle was adjustable by approximately 10º with this setup, although this feature was not tested in trials. The adjustibilty of the leg angle could certainly be improved.

(a) (b)

Figure 7. Design improvement of the tensioning system. (a) The original tensioning system.

TESTING AND RESULTS

Test Material

Gelatin hydrogel was used in place of clot material for all testing. This was a reasonable substitute for prototype testing because blood clots are considered hydrogels.

Expected Soft Material Cutting Behavior

Based on the results of past YSC studies on soft materials, expectations can be set for the results gathered in testing with the gelatin hydrogel. Figure 8 shows the expected cutting behavior for a soft material, which includes an indentation force, constant cutting force, and a relaxation period at once blade displacement had ended.

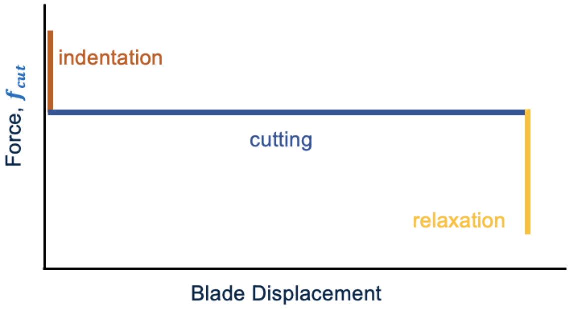


Figure 8. Expected soft material cutting behavior. Adapted from Zhang 2021.

General Testing And Preparation Procedure

Gelatin hydrogel was prepared in a sheet of uniform thickness, from which the testing samples were cut as rectangles. No uniform rectangular dimensions were used for samples in the initial testing described in this report, ideally samples would be uniformly cut or molded for future testing. To create a "Y" shape from the rectangular sample, it was glued to the bottom platen cover of the DMA and to the tensioning system and then the blade mounted to the DMA was manually lowered to make a cut in the sample. This method of producing the "Y" sample ensured that the opening crack in the “Y” was directly aligned with the blade. Once the setup was complete, the DMA would be used to conduct a single-ramp displacement sequence, taking force data on the blade as the top platen traveled. Video of each test was also recorded, this made it much simpler to connect anomalies in the results to specific mishaps in the experimental trial. To ensure that the cutting speed was appropriate for the gelatin hydrogel, cutting speed was increased until a steady cutting force region was observed, rather than a stick-slip region as shown in Figure 9. The optimal cutting speed for the gelatin hydrogel used was determined to be around .75 mm/second. For the particular data collection sequence used on the DMA, there is no relaxation period recorded in any of the tests because data collection was stopped immediately after the blade displacement stopped.

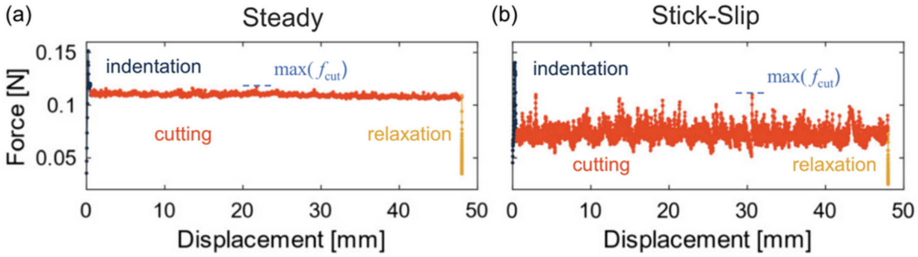


Figure 9. From Zhang 2021

Testing Of The Initial Design

Testing of the initial design illuminated many of the design flaws discussed in the Design Evolution section. Figure 9 shows data taken using the initial design setup. Instead of there being a region of zero force up until around 5mm, there is a region of friction due to the lack of blade adjustment, causing the flat of the blade to contact the side of the sample leg. Friction within the tensioning system also added to the region of friction shown in Figure 5 because the tensioning system was mounted to the top platen of the DMA, involving the force gauge. Blade indentation occurs and approximate steady state cutting begins between 5 mm and 6 mm in Figure 5.

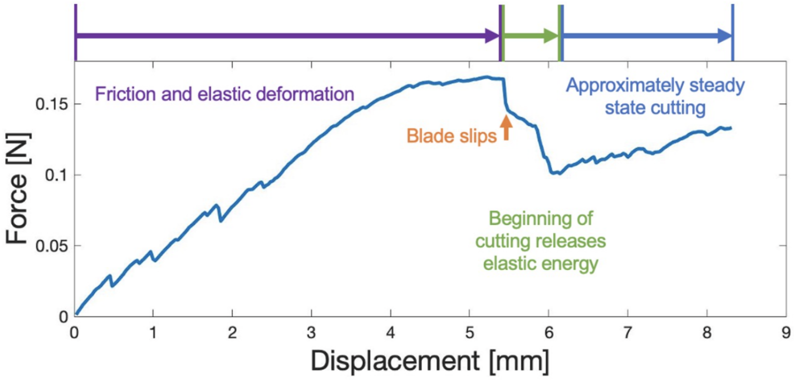
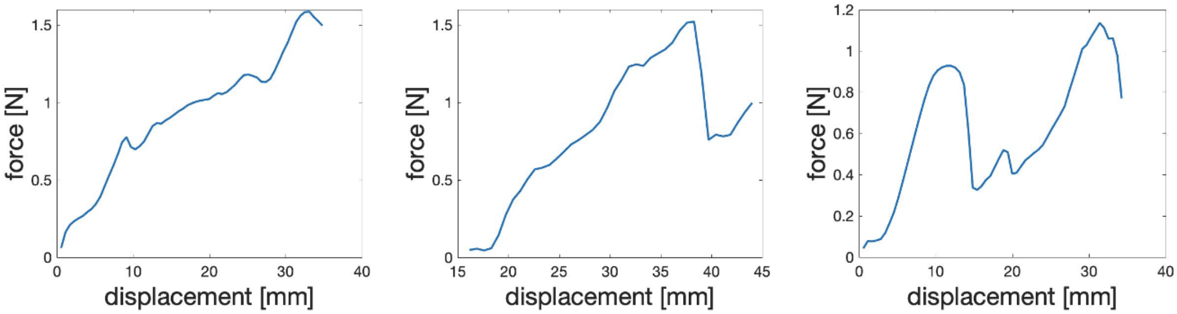


Figure 10.

Testing Of The First Design Iteration (Redesigned Blade Mount)

Inconsistent behavior in the tensioning system made it impossible to get consistent results. Figure 11 shows three tests with identical procedures and conditions which produced widely differing results. Using the video taken of the test procedures, it was possible to link the many inconsistencies in the tests to malfunctions in the tensioning system such as the tensioning weights swinging. Though results were inconsistent, the redesigned blade mount proved its worth as the new system did not visibly interfere with the sample as the old mount had done. The new mount allowed for testing to be conducted over a displacement range that was 4X larger than the displacement allowed by the initial design. An increased displacement range gives greater certainty to the approximate steady state cutting force because the cutting can occur over a greater distance and more data on the constant force is collected.



(a) (b) (c)

Figure 11.

Testing Of The Second Design Iteration (Ground-Fixed Tensioning System)

The experimental results using the ground-fixed tensioning system were much more consistent but also revealed a flaw in the redesigned tensioning system. The advantage of the ground-fixed tensioning system was that it did not exert any force on the blade force gauge, since it did not come in contact with the force gauge platen. The weights used for tensioning in the ground-fixed tensioning system did not move with respect to the ground so they did not swing around as the blade-fixed weights had a tendency to do. The flaw in the ground-fixed tensioning system was not realized until the results required interpreting. Figure 12 shows a typical result using the ground-fixed tensioning setup, in the figure it appears that a steady cutting force is reached between 15 mm and 20 mm. After about 20 mm the force begins to increase, this is because the angle between the legs is actually changing as the blade travels. The angle of the legs is decided by the location of the tip of the blade and the two points where the tensioning system for each leg is anchored. In the case of the blade-fixed tensioning system, all of these deciding points move with respect to the blade, so the angle they make remains constant because their own relative distances do not change. In the ground-fixed system, the tip of the blade moves with respect to the anchor points of the tensioning system so the leg angle changes as the blade travels. In these trials, the decreasing leg angle led to an increase in force due to a combination of tearing force from the previously wider angle being traded for cutting force to maintain constant displacement and friction between the blade and the material. To produce valid results, the leg angle must remain constant so we will need to return to the blade-fixed tensioning system. Stabilizing the blade-fixed system will be a priority in order to obtain similarly consistent results. While the ground-fixed system will not be adequate in regular testing, it may be useful in confirming the minimum cutting angle allowed by the setup and sample dimensions. Since the change in tearing contribution can be quantified using Equation 1, the remaining unknown in the force measurement is blade friction. While a certain amount of blade friction between the side of the blade and the sample leg can be caught by observing the contact between the two, using the ground-fixed tensioning system allows the effect to be quantified for different angles, saving time and increasing the precision of optimal angle calculations when a new setup is used or sample dimensions are changed.

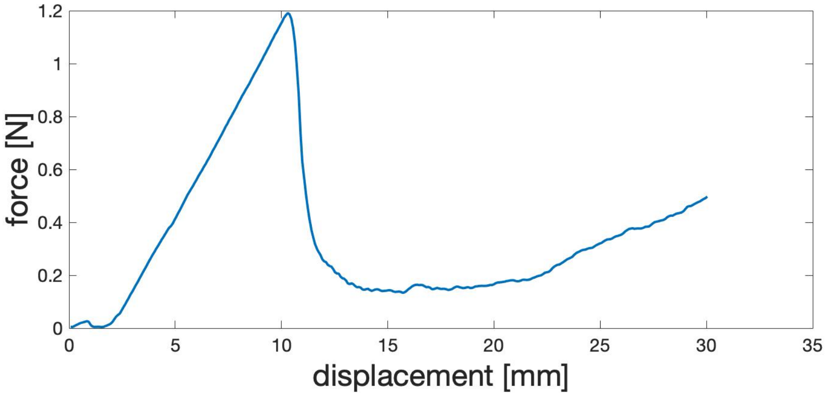


Figure 12.

FUTURE DIRECTIONS

This work will continue with the ultimate goal of characterizing the cutting energy of blood clots.

Upcoming Design Improvements

The tensioning system will need to be returned to a blade-fixed design, with instabilities combated by frictionless pulleys and other techniques. A blade tracking and adjustment system that utilizes magnified views of the sample crack propagation will also be in the works. The magnified view used for blade tracking will be used for video recordings of each trial, improving the quality of the recordings which have been taken at 0X magnification thus far.

Blood Clot Testing

Potential work with Dr. Albert Shi's lab using whole blood clot samples produced in vitro and tested using the finalized setup will yield a cutting energy for blood clots. This cutting energy will be made available to inform future designs of mechanical thrombectomy devices.

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