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EVALUATION AND DEVELOPMENT
OF TOURNIQUET TEST METHODS

A Thesis
Presented to
the Graduate School of
Clemson University

In Partial Fulfillment
of the Requirements for the Degree
Master of Science
Bioengineering

by
Catherine Virginia Pitts
May 2024

Accepted by:
Dr. John DesJardins, Committee Chair
Dr. David Neyens
Dr. Joseph Singapogu

ABSTRACT

Since the beginning of the 21st century the general perspective on tourniquets has changed to a more positive outlook on their life saving abilities. The US has seen a greater number of mass casualty events, and conflicts across the globe have led to an increased use of tourniquets. The increased demand has also led to faulty counterfeit tourniquets and improvised tourniquets that do not properly occlude blood flow or cause significant nerve damage to the injured limb.

ASTM started designing a tourniquet testing standard with experts in the tourniquet community to cut down on the dangers of tourniquet use. As part of the standard, the committee commissioned a tourniquet test fixture to be created, in multiple physiological sizes. The aim of this study was to evaluate tourniquet testing methods and the ASTM tourniquet test fixture. The test fixture needs to provide accurate and reproducible results, in addition to being durable enough to withstand extreme testing conditions and repeated tests.

The test fixture was analyzed by calibration methods, tourniquet application, and tension testing. The calibration methods were found to be difficult to run without failure and were difficult to reproduce. Several tourniquets that are currently on the market were used for tourniquet testing to measure if the test fixtures produced the expected results.

Also noted during testing was the wear and tear done on the fixture during the limited testing that occurred compared to what would be expected of the device if it was made a part of the standard.

Conclusions of this study are that the fixture is not able to be reproducibly calibrated to give accurate results from the fixture. Tourniquet testing does produce mostly expected results, but the design of the fixtures presents significant issues such as buckling and not returning to the original shape. Tension data showed that the large fixture does not produce what is expected from the theoretical data but the small fixture has much more similarity because of the size. ASTM is moving forward with designing a new test fixture that can hopefully eliminate some limitations of the current design.

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CHAPTER ONE

INTRODUCTION

Tourniquets are a life-saving medical device that are used to stop bleeding in traumatic situations. The main goal of tourniquet application is “occlusion pressure”, which is stopping blood flow through the vasculature by compressing with a pressure application¹. They are most often applied by people with emergency medicine training, such as soldiers, firefighters, and other emergency response personnel. Tourniquets often at a minimum consist of a strap and tightening system such as: windlass, ratcheting, pneumatic, or a stretch and wrap technique.

In 2010, a Department of Defense group met to determine tourniquet requirements and testing protocols. This meeting led to the eventual development of an ASTM tourniquet committee, in charge of creating a standard for tourniquet testing. The goal of this standard was to create a testing protocol that gave customers and manufacturers reassurance that their products can create proper occlusion pressure without causing nerve damage or other dangerous side effects. Experts in the tourniquet committee came up with a list of requirements for a tourniquet test fixture, and in 2019 a test fixture was commissioned with Sydor. Clemson University was sent the test fixture in 2022 to evaluate for accuracy and reproducibility as part of the ASTM test standard.

This body of work summarizes the results of the evaluation including the background of tourniquet testing, calibration testing for the fixtures, tourniquet baseline operation data, tension testing, and data analysis. Calibration and tourniquet operation data was collected following the Standard Operating Procedure (SOP) outlined by Sydor.

Supplemental data for the leak test and response test was collected for data analysis. Commonly used tourniquets were applied to the tourniquet test fixture as part of the tourniquet baseline operation tests also outlined in the SOP. Finally, tension testing was done using a set up built by Clemson to correlate the pressure change of the system with the diameter change experienced when a known amount of tension is applied to the system.

CHAPTER TWO

LITERATURE REVIEW AND BACKGROUND

Tourniquets historically have been used in a variety of situations where inhibiting blood flow is necessary such as blood draws, emergency extremity bleeds, and during limb surgery. The primary goal of a tourniquet is “occlusion pressure”, which is defined as when blood cannot flow through the vasculature due to compression from pressure application¹. Throughout history tourniquet use is heavily debated between being helpful or harmful for patients experiencing trauma. This literature review will focus specifically on a tourniquet’s use in an emergency bleeding situations.

A Brief History of Tourniquets

The earliest known use of a tourniquet was in 1674, where a surgeon named Morel used a rod and a band to constrict blood flow during an amputation from a battle wound^{2,4}. The tourniquet constricted blood flow efficiently enough for the surgeon to suture quickly to avoid excessive bleeding². Many other known instances of early tourniquet use also involved surgeons using several tight bands around the limb to minimize blood flow during amputation. Two famous tourniquets of the 17th and 18th centuries both included screw compressor systems that are similar to modern tourniquets².

World War I brought a focus on the drawbacks of tourniquet use during war. Soldiers who had tourniquets applied would not receive medical care for hours and this often led to catastrophic deaths⁴. Surgeons from this period highly discouraged the use of tourniquets because of intense pain, infection risk, and the potential for limb loss^{2,4}.

However, the use of tourniquets was also refined with the increased use and doctors began to emphasize the importance of a pad on the artery to distribute pressure off the veins in addition to a band around the limb, and a way to tighten the band³. Increased use of tourniquets also brought about many amputations for injuries that would not have been necessary, as tourniquets were often applied too often for injuries too minor⁵.

World War II brought another opportunity for tourniquet refinement once again but saw mostly the same results as WWI. Soldiers often misused tourniquets and left them hidden below blankets and clothing, allowed them to stay on soldiers for too long, and applied them to wounds unnecessarily⁴. It was not until the Korean and Vietnam Wars that surgeons began to see the correct usage of tourniquets and the number of lives saved by tourniquets outnumbered damages caused by them^{2,4}.

The 21st century was the first time that data was collected real-time on tourniquet use with the development of the Joint Theater Trauma System (JTTS) during 2004 and 2005. This data showed that tourniquet usage provided better survival rates which led to an increase in commercially available tourniquets in 2005 and 2006⁴. When commercially available tourniquets became available, training on these devices also increased both for military use as well as civilian use. This time period was also the first time that military operators began to collect data on tourniquet use, instead of surgeons who saw the aftermath of the tourniquet usage⁵, which may have helped lead users to a more positive outlook of tourniquets.

Principle of Operation

Since tourniquets were first used, the principle design has been incredibly similar. Overall, the key components to a tourniquet are a band that wraps around the limb to apply pressure and a way to further tighten the tourniquet, such as a rod or strap. The original circumference of the strap decreases with the additional tension in the strap which applies pressure to limb. The goal of this tension is to apply pressure to compress the arteries and veins to reach occlusion pressure, which is when blood flow through the vessels stops¹.

Windlass Tourniquets

Windlass tourniquets are what is commonly thought of when a layperson thinks of a tourniquet and are one of the oldest tourniquet designs⁶. They are composed of a strap that wraps around the injured limb, and a rod, referred to as a “windlass” in this situation, that is twisted with the strap to create the necessary tension to apply pressure. The windlass gives the user a mechanical advantage to create additional tension in the strap by increasing the moment arm of the applied torque, therefore making it easier to twist the trap and increase tension⁶. Many commonly accepted tourniquets in the marketplace currently include a windlass feature as the tightening mechanism, such as the CAT or Combat Action Tourniquet (Composite Resources, Rock Hill, South Carolina).

Ratcheting Tourniquets

Ratcheting tourniquets are composed of a strap with a ladder-like ratcheting function. These tourniquets use a tightening function that was modeled after snowboarding boots⁷, where tightening occurs by teeth of the locking system

interlocking with the teeth of the ladder attached to the strap. These tourniquets often have the fastest application times due to the ease of use, and also are easily applied with one hand. They do however possess many potential issues in the field such as the ratcheting strap becoming clogged depending on the environment⁸.

Pneumatic Tourniquets

Pneumatic tourniquets were originally designed to occlude blood vessels during surgery to allow for a bloodless operating site⁹. While typically not used in the emergency situations that this paper is focused on, it is included in this review due to its use in the calibration procedures of the ASTM tourniquet test fixture. A typical pneumatic tourniquet is the standard blood pressure cuff used universally in hospitals and other clinical settings, designed to be used for several minutes of arterial occlusion¹⁰. These cuffs consist of a bladder that can be inflated using a small hand pump that is attached¹¹. For the calibration procedure, the ASTM test fixture uses the TPT2 (Tactical Pneumatic Tourniquet 2", AlphaPointe, Richmond Hill, NY), a pneumatic tourniquet designed for tactical situations. The design is very similar to a blood pressure cuff but has a much smaller width and tubing and a hand pump that can be switched out with 3-way valves and more tubing to accommodate for the calibration procedures.

Other Tourniquets

Another common tourniquet design is the stretch and wrap tourniquet. These tourniquets come in a variety of widths and can consist of an elastic material to make the tightening process easier. These tourniquets are designed to be wrapped around the limb multiple times, with each wrap increasing pressure¹³. Tourniquet research is increasing in

interest again, as recent military and mass casualty incidents have changed the outlook on tourniquet risks versus benefits, so several novel tourniquets are being brought onto market with little research into their safety and efficacy.

Tourniquet Testing In a Laboratory Setting

Testing on Human Participants

Tourniquet testing in a laboratory space is a relatively new concept, as the perspective on their effectiveness has changed since the beginning of the 21st century. In a study done in 2000, the authors designed 7 tourniquets based on a compiled customer requirements survey⁷. These 7 tourniquets were then tested in a lab by 15 Navy SEAL corpsmen based on the application time on both the lower and upper extremities and then whether occlusion was obtained. This data showed that the most successful and preferred tourniquets were the pneumatic tourniquet and the ratcheting tourniquet⁷. Windlass tourniquets were not used in this study, as new potential options for the military were being explored.

In a another study done by Drake University, 16 participants had tourniquets applied to upper and lower limbs in order to measure arterial occlusion pressures and tourniquet completion pressures¹⁰. The two tourniquets used in this study were the CAT (Combat Application Tourniquet; Composite Resources, Rock Hill, South Carolina), and the Stretch, Wrap, and Tuck Tourniquet (SWAT-T; TEMS Solutions, Abingdon, Virginia), in addition to a standard blood pressure cuff. This study showed that occlusion pressures with each tourniquet were much higher than originally predicted. The SWAT-T had much lower and safer occlusion pressures than the CAT, and many CAT applications

lost occlusion within 1 minute of application, most likely due to muscle relaxation¹⁰. This study also found that pre-windlass twisting pressure of the CAT band did not have a relationship with the number of twists needed to reach occlusion.

In a second study done by Drake University, 4 tourniquet styles were tested on 16 volunteers with a blood pressure cuff around their limb segments¹⁴. The same gas pressure sensor system (Vernier Gas Pressure Sensor, Vernier LabPro interface and Logger Lite software; Vernier Software and Technology, www.vernier.com) that is used in the ASTM system was used to measure important pressures for the tourniquets. Blood pressure cuffs were hooked up to the system and then applied to the volunteer and tourniquets were applied on top of the cuffs in order to measure pressures. Results showed all 4 tourniquets were capable of reaching occlusion pressure on both the forearm and calf. While the widest tourniquet did have the lowest occlusion pressures, there was variability in the occlusion pressures reached with the other 3 tourniquets that were the same width¹⁴.

Simulated Tourniquet Testing

There are a few tourniquet testing options currently on the market. Two testers mentioned by ASTM during the initiation of this project were the HapMed Instrumented Trainer (CHI Systems, Plymouth Meeting, PA) and the SynDaver Synthetic Human Surgical Model (SynDaver, Tampa, FL)¹⁷. The HapMed Trainer was designed to teach first responders what it feels like to achieve the correct torque when applying a tourniquet to a patient. While this model is relatively low cost and does not use a synthetic blood replacement, it only comes in one size and cannot be calibrated for testing, meaning it

can not be used as part of the ASTM standard¹⁷. The SynDaver Model is currently used by the Department of Defense for testing and has an arm and a leg for testing in addition to adjustable blood pressure with the ability to reach occlusion pressures. The SynDaver Model is cost-prohibitive for the ASTM standard, with initial prices being ~\$60,000 and having significant annual costs to ensure the model remains functional¹⁷. Although having both an arm and a leg for testing it also still does not have the size range required for the ASTM tourniquet testing device.

In 2023, an open-source tourniquet tester was released by Western University. This novel 3D printed tourniquet tester presents a low cost method for ensuring that tourniquets are safe and effective for use¹⁸. All assembly instructions and calibration procedures are published. The calibration procedure for the load cell in the test fixture consists of a force reading and a pressure reading using known weights. Using the force measurement, the test fixture then converts that into pressure using $\text{Pressure} = \text{Force} / \text{Surface Area}$ ¹⁸. The open-source tourniquet tester also includes instructions for validating the calibration procedure with a blood pressure cuff.

History of ASTM Standards

The American Society for Testing and Materials was formed in 1898, by Charles B. Dudley, Ph.D. who worked for the Pennsylvania Railroads¹⁹. In 2001, the name changed to ASTM International, and they have continued their mission to develop and deliver voluntary consensus standards. There are over 12,000 standards today that are used to improve quality, enhance safety, strengthen market access, as well as improve

consumer's confidence in the quality of products they purchase¹⁹. Over 30,000 technical experts from 140 different countries help to develop these standards.

In 2010, a tourniquet group met through the U.S. Department of Defense with the goal of coming to a consensus on tourniquet requirements and testing protocols. During this time there were many counterfeit tourniquets on the market which was also a focus of the group. Prior to this meeting, standards that were already set by the Army for tourniquets were that they must be adequate for upper and lower extremity application, it must have a windlass, and a one-handed application was recommended method was recommended²⁰. FDA approval was discussed in this meeting, with FDA representatives stating that tourniquets were classified as Class I devices and therefore did not need clearance from the FDA. The group discussed re-classifying tourniquets to a Class II device which would require additional testing to ensure safety and efficacy. It was thought that additional testing would potentially help discourage tourniquet manufacturers who were not fully invested in their devices due to the cost²⁰. Overall this meeting pointed out gaps in regulations and protocols for tourniquets that were limiting their ability to be beneficial.

Testing policies for tourniquets were also discussed, and it was decided that the ISR test model would be used as a baseline. Incurred Sample Reanalysis or ISR, is a tool used to validate a test method where repeated measurements from a sample set are taken in separate sets on different days in order to ensure that the data is reproducible²¹.

This led to the development of an ASTM test standard for non-pneumatic limb tourniquets in 2016 in order to help fill the regulatory gaps. The standard aims to create a

way to give confidence to a tourniquet's performance or at least give manufacturers a baseline to test their tourniquets¹⁷. Ideally, the creation of this standard will help to limit situations where tourniquets fail during use and the sale of counterfeit tourniquets that are not well constructed. The committee worked on a creation of a test fixture in order to create a test procedure as part of the standard, as current fixtures on the market lacked the ability to test tourniquets on children and proper sizing to ensure tourniquets will function on upper and lower limbs. The proposed test fixture from the committee needed to meet the requirements below:

1. "Must not leak any fluid medium
2. Must return to its original shape when the tourniquet is removed
3. Must be capable of measuring occlusion pressures from 200 mmHg to ~500 mmHg
4. Must be capable of being calibrated to ensure accurate test results
5. Must be capable of accepting/testing tourniquets covered in simulated blood or tourniquets at temperatures between -51°C (-60°F) and 71°C (160°F)
6. Must be independent of strap width
7. Must be capable of being fabricated in two extreme sizes for simulation limb circumferences of 6.125 in to 27.75 in, respectively"¹⁷

A vendor was selected for the project and the resulting tourniquet test fixture consisted of two large aluminum cylinders with a rubber around the frame, creating a closed air system within the rubber bladder¹⁷. The funding of this device came from the

Irregular Warfare Technical Support Division (IWTSD), and Clemson University received the fixture in October of 2022 to test. The tourniquet test standard and test fixture are still in development as of 2024.

CHAPTER THREE

MATERIALS AND METHODS

Materials from ASTM

ASTM sent the kit created by Sydor for the tourniquet standard testing in October of 2022. This kit included a large test fixture and cover, a small test fixture and cover, 2 Vernier Pressure Sensor 400s , and a LabQuest Mini (Vernier Gas Pressure Sensor, Vernier LabPro interface and Logger Lite software; Vernier Software and Technology, www.vernier.com). For calibration materials, the kits also included a TPT2 pneumatic tourniquet and additional clamps (Figure 3.2). In December of 2023, ASTM sent over another 2 kits for testing. This package included double what the first package had for a total of 3 large devices (22.86 cm diameter) and 3 small devices (5.41 cm diameter) in addition to their sensors and calibration materials.



Figure 3.1. Large Test Fixture and Small Test Fixture with Nylon Sleeve



Figure 3.2. TPT2 Calibration Tourniquet with 3-Way Valve Attached

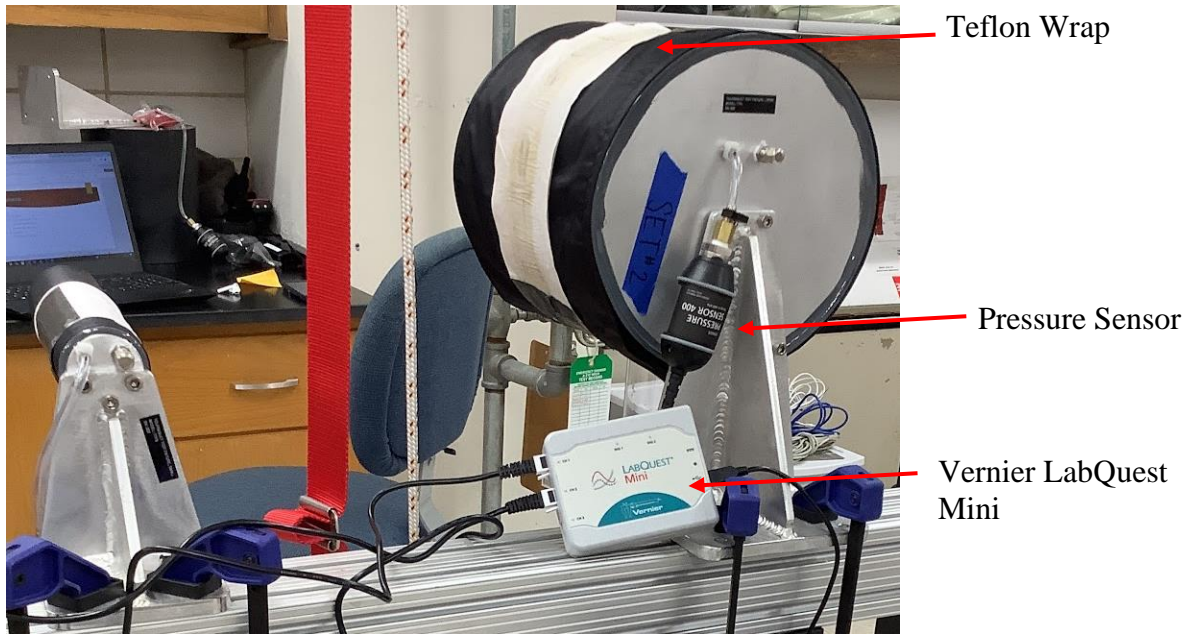


Figure 3.3 ASTM Materials in Testing Configuration

Testing Set Up

A large test fixture and small test fixture were clamped onto a beam supported by a metal frame, as shown in Figure 3.4. This allowed for tourniquet application, calibration testing, and easy access to the valves at the back of the device. The frame also supported the 2 pulley system that was used to perform tension testing.

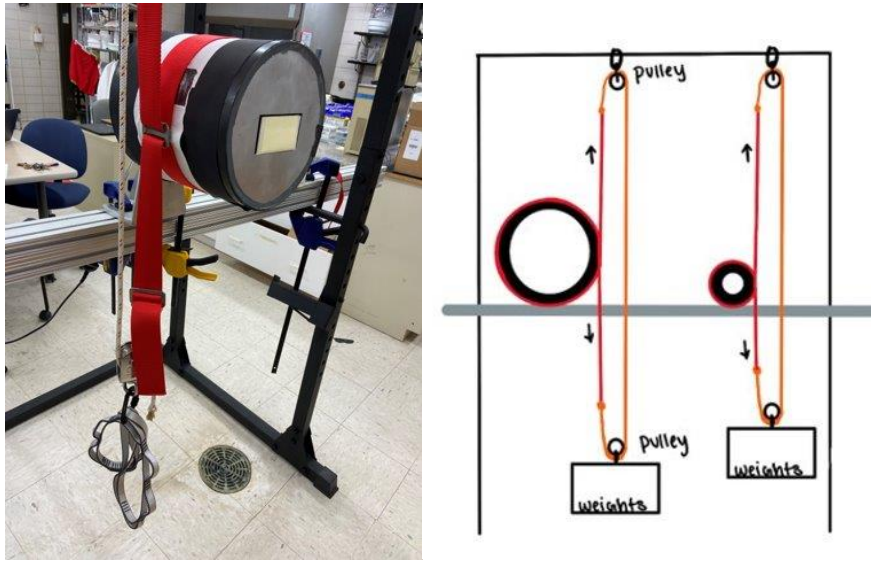


Figure 3.4. Testing Set Up and Diagram of Tensioning System

A Teflon sleeve was added to the test fixture on top of the provided nylon cover to reduce friction forces around the device. For tension testing, 3 sizes of webbing were used to mimic a tourniquet on the fixture: 1 inch, 1.5 inch, and 2 inch. A customized roller as shown in Figure 3.5 was also used to reduce friction from the webbing during testing.



Figure 3.5. Customized Roller to Reduce Friction in Webbing

A total of 11 commonly used tourniquets were used to test the system. These tourniquets are summarized in Table 3.1. A wide variety of ratcheting, windlass, and wrap tourniquets were tested on both sizes of the tourniquet test fixture, to ensure that the test fixture could accurately test tourniquets that are already commonly used.

Table 3.1. Tourniquets Used in Testing

Tourniquet Name	Manufacturer and Location	Tightening System	Width	Link
TMT	Safeguard US Operating LLC Harrisburg, NC	Windlass	2.5 inch	https://safeguardmedical.com/products/haemorrhage-control/tmt-tourniquet/
SOFT-T	TacMed Solutions Anderson, SC	Windlass	2 inch	https://tacmedsolutions.com/products/softtourniquet?variant=40626596544711
CAT	North American Rescue	Windlass	1.5 inch	https://www.narescue.com/combat-application-tourniquet-ca-t.html
RMT-XL	M2-corp	Ratcheting	3 inch	https://m2inc.biz/products/xl-3-e2-80-b3-wide-ratcheting-medical-tourniquet-rmt-60-long
RMT-T	M2-corp	Ratcheting	1.5 inch	https://m2inc.biz/products/ratcheting-medical-tourniquet-rmt-tactical
RMT-P	M2-corp	Ratcheting	1.5 inch	https://m2inc.biz/products/ratcheting-medical-tourniquet-rmt-less-than-120lbs-55kg
X8T	RCR Medical McKinney, TX	Ratcheting	1.5 inch	https://www.x8ttourniquet.com/
X-Force	S.T.A.T. MEDICAL DEVICES LLC Adelphia, NJ	Ratcheting	1 inch	https://www.xforcetq.com/
RATS	Rapid Medical	Stretch and Wrap	.25 inch	https://www.rapidtq.com/products/r-a-t-s-tourniquet
Response TK	H&H Medical Clear Brook, VA	Windlass	1.5 inch	https://www.911emergencysupply.org/Response_TK_Windlass_Tourniquet/p3525242_16807704.aspx
Rapid Stop	AERO Healthcare USA Cottage, NY	Ratcheting	1.5 inch	https://www.911emergencysupply.org/details/p3525242_20854519.aspx

Calibration Testing

Calibration procedures for the fixtures were provided by Sydor in their Standard Operating Procedure (SOP). Procedures were performed several times to ensure accuracy and repeatability within the procedures. All Sydor procedures began by equaling the pressure within the test fixture by using the Schrader valve in the back of the device. The Vernier software was then prepped for data collection by changing the units to mmHg.

Leak Testing Procedure

- “1. Using the Schrader valve on the test device, equalize to atmospheric pressure by holding in the middle needle for 5 seconds.
2. Start the vernier software. Change the units to read mmHg by clicking on “Experiment”, scrolling down and clicking on “Change Units” and then clicking on a channel. mmHg should be the first option on the list. This should be done for whichever test device you are calibrating.
3. Click on the “Collect” button to start collecting data.
4. Click on the “Scale” button.
5. After about 30 seconds, click on the “Stop” button and get an approximate average reading. Remember, Channel 1 is for the large test device and Channel 2 is for the small test device.
6. Add 200mmHg to the approximate average pressure to determine a calculated pressure. In the example shown in Figure 3, the approximate average pressure is 758.3mmHg, so the calculated pressure would be approximately 958mmHg.

7. Using a hand pump attached to the Schrader valve, inflate until the pressure reading is slightly higher than the calculated pressure. Do not exceed by more than 300mmHg over the initial pressure.
8. Click the “Collect” button again. It will reset back to 0. Let it run until the end which will be 900 seconds (15 minutes).
9. Get an average pressure for the first 30 seconds and the last 30 seconds of sampling. The two averages should be within 5mmHg if there is no leak. You will notice that during the first 3 minutes it will appear like it is leaking as shown in Figure 6. This is due to the relaxation of the hook-and-loop fabric. The last 12 minutes as shown in this example demonstrate there is not a leak in the system.
10. If the system does not level out as shown in Figure 6, check all the fittings to assure the tubing clamps are tight enough. If that does not work, use of a soapy mixture can help identify where the leak is. Ensure the electronic items are not subject to any moisture.
11. If the leak is in the bladder, replace the bladder.”²².

The leak test was performed 2 extra times on each fixture: once only pressurizing to 50 mmHg over atmospheric pressure, and then once at 100 mmHg over atmospheric pressure.

Response Testing Procedure

- “1. Using the Schrader valve on the test device, equalize to atmospheric pressure by holding in the middle needle for 5 seconds.
2. Start the vernier software. Change the units to read mmHg by clicking on “Experiment”, scrolling down and clicking on “Change Units” and then clicking on a

channel. mmHg should be the first option on the list. This should be done for whichever test device you are calibrating.

3. Insert a nipple into the end of the 3-way valve as shown in Figure 8 and then insert the nipple into the tubing going to the vernier pressure sensor from the test device that is not being calibrated.

4. Remove the pump from the pneumatic tourniquet and attach both the pump and the pneumatic tourniquet to the 3-way valve as shown in Figure 9. Ensure the valve is open on the pump and the 3-way valve is positioned as shown in the Figure 9.

5. Wrap the pneumatic tourniquet around the test device snugly.

6. Start collecting data with the vernier software.

7. Wait for 30 seconds and note the average internal pressure as reported by the test device.

8. Close the pump valve and begin pumping up the pneumatic tourniquet.

8.1 For the large test device, pump until the internal pressure indicated by the pneumatic tourniquet is 600 ± 30 mmHg.

Note: When getting close to the 600mmHg, slow down pumping so that there is not a spike in the graph. It should be a smooth transition when pumping is finished.

8.1.1 Note the time that the pumping was stopped. Wait for 5 minutes (300 seconds), and then release the pressure on the pump bulb.

8.1.2 Keep recording for another 30 seconds after the pressure has been released

8.1.3 Stop the software and save the file for future reference.

8.1.4 Determine the average interior pressure of the large test device for the first 30 seconds.

8.1.5 Determine the average interior pressure of the large test device and the pneumatic tourniquet for the last 30 seconds of the 5-minute run.

8.1.6 If the interior pressure of the pneumatic tourniquet during the last 30 seconds is still within 600 ± 30 mmHg, the test device output can be evaluated.

8.1.6.1 Subtract the average of the initial 30 seconds of the test device output from the average of the last 30 seconds of the test device output.

8.1.6.2 The result should be 33 ± 5 mmHg. If it is not, repeat the test two more times and average the results. If they are not in compliance, it is time to replace the bladder on the test device.

8.2 For the small test device, pump until the internal pressure indicated by the pneumatic tourniquet is 300 ± 5 mmHg.

Note: When getting close to the 300mmHg, slow down pumping so that there is not a spike in the graph. It should be a smooth transition when pumping is finished.

8.2.1 Note the time that the pumping was stopped. Wait for 5 minutes (300 seconds), and then release the pressure on the pump bulb.

8.2.2 Keep recording for another 30 seconds after the pressure has been released.

8.2.3 Stop the software and save the file for future reference.

8.2.4 Determine the average interior pressure of the small test device for the first 30 seconds.

8.2.5 Determine the average interior pressure of the small test device and the pneumatic tourniquet for the last 30 seconds of the 5-minute run.

8.2.6 If the interior pressure of the pneumatic tourniquet during the last 30 seconds is still within 300 ± 5 mmHg, the test device output can be evaluated.

8.2.6.1 Subtract the average of the initial 30 seconds of the test device output from the average of the last 30 seconds of the test device output.

8.2.6.2 The result should be 60 ± 5 mmHg. If it is not, repeat the test two more times and average the results. If they are not in compliance, it is time to replace the bladder on the test device”²².

The response test was also performed using Clemson’s tensioning system in place of the pneumatic tourniquet in order to provide tension around the fixture to investigate whether the test device could meet the requirements for holding pressure with a different tensioning system.

Tourniquet Testing Procedures

Standard Operating Procedure instructions for tourniquet testing on the fixture, as written by Sydor are below:

“1. Using the Schrader valve on the bladder, equalize to atmospheric pressure by holding in the middle needle for 5 seconds.

2. Start the vernier software. Change the units to read mmHg by clicking on

“Experiment”, scrolling down and clicking on “Change Units” and then clicking on a channel. mmHg should be the first option on the list. This should be done for whichever test device you are using.

3. Unless instructed otherwise, click on the “Collect” button to start collecting data.

4. Click on the “Scale” button.

5. After about 30 seconds, apply the tourniquet to the center of the test device.

Remember, Channel 1 is for the large test device and Channel 2 is for the small test device.

6. Following the manufacturer’s instructions, ensure that the tourniquet is snugly applied prior to tightening. Failure to apply the tourniquet tight enough may result in the inability to tighten the tourniquet to the appropriate pressure.

7. Following the manufacturer’s instructions, tighten the tourniquet until the interior test device pressure exceeds the required pressure. Ensure that the pressure noted is after the original spike at the pressure of interest location as shown in Figure 12.

7.1 For the large test device, tighten until the pressure of interest (after the spike) is at least 35mmHg above the average pressure during the initial 30 seconds. Note the time.

7.2 For the small test device, tighten until the pressure of interest (after the spike) is at least 50mmHg above the average pressure during the initial 30 seconds. Note the time.

8. Continue recording for 5 minutes.

9. Remove the tourniquet from the test device.

10. Stop recording.

11. Save the graph into a file.

12. Determine the average initial internal pressure of the test device by averaging the first 30 seconds of output.
13. Determine the initial pressure of interest by averaging the 30 seconds starting with the line denoting the pressure of interest as shown in Figure 12. This should be higher than the required pressure. If not, repeat the test.
14. Determine the final pressure by averaging the pressures between 4:30 minutes and 5:00 minutes from the line denoting the pressure of interest as shown in Figure 12.
15. The pressure drop between the values from step 13 and step 14 should be less than 5mmHg²².

This tourniquet test was repeated at least 5 times with each tourniquet on each test fixture. In addition to the SOP testing, the average pressure loss from each test was calculated to quantify the “relaxation” of the tourniquet on the system after application.

Tension Testing

Tension testing was not outlined in the SOP and was done to correlate the relationship between tension, diameter change, and pressure changes in the system. Pressure data was collected with the Vernier sensor, and pressure was equalized between each trial. Weights were added to the lower pulley of the system one at a time and given time to level out in between weights. There were two rounds of tension testing done for the final data collection. Each round consisted of 18 trials: 9 large fixture trials and 9 small fixture trials. The 9 trials for each fixture were composed of 3 trials with each of the 3 webbing sizes. For the first round of testing, diameter and pressure were recorded without any adjustments made to the system. For the second round of testing, starting

diameter for each trial was kept the same for each fixture. Theoretical pressure was calculated for each trial using a theoretical volume change calculation, assuming the cylinder most closely resembled two conical cylinders connected by a regular cylinder.

Analysis

Results were analyzed using Vernier Logger Lite software and Microsoft Excel. For the leak testing, pressure over time was graphed according to the SOP and then again according to the leak tests done at lower pressures. For these tests, pressure lost over the 15 minutes was the variable of interest to see if lower pressures caused less leakage from the system.

For the response tests, the procedure was performed 4 times over several months. During the process, we found that it was difficult to set up and perform the procedure so the main focus for this test was to determine if the results were reproducible. For the calibration testing, the SOP also gives expected results in terms of mmHg. Our research tried to translate that data into a change in diameter instead of mmHg, to make the results of the testing more reproducible.

The main purpose of the tourniquet test fixture is to ensure that the tourniquets reach occlusion pressure safely, so therefore as part of the evaluation of the fixture commonly used tourniquets were applied to the device and pressures were recorded. The purpose of this test was to confirm that the test fixture produced the expected results and was capable of withstanding multiple tourniquet applications.

Tension testing with the pulley and known weight system was done in order to quantify how tension and diameter changed correlated with pressure, as the resistance of

the rubber around the fixture was unknown. ANOVA tests were done on the slopes of the pressure vs diameter trials to quantify if there was a statistical difference in how the fixture reacts with the different tourniquet widths.

CHAPTER FOUR

DATA ANALYSIS AND RESULTS

Calibration Testing

Leak Test

The leak test was performed 4 times at the designated pressure of 200 mmHg. During the very first test, the nylon cover provided with the fixture came off and we continued to inflate to 200 mmHg. This caused a rupture in the rubber cement between the aluminum frame and the rubber bladder during the last minute of the 15 minute test. The second time this leak test was performed on a different large fixture, the nylon sleeve once again came off the fixture and the test was stopped to avoid another rupture.

After two unsuccessful leak tests, the third test did manage to get to 200 mmHg over atmospheric, however the bladder did not manage to maintain the designated pressure in the SOP. For the fourth test, a valve cover was added to the Schrader valve at the back of the device, and then the device did hold pressure better during the leak test but still did not meet SOP values.

In order to quantify the leak problems, more tests were performed on the fixtures at 50 mmHg and 100 mmHg over atmospheric to see if the same problems existed at these pressures. During these tests, there was a large jump between pressure lost between the lower pressures and the SOP stated 200 mmHg as shown in Table 4.1.

Table 4.1. Leak Test Pressures

Fixture	Test Pressure	Max Pressure	Min Pressure	Total Lost
Large	50 mmHg	45.53 mmHg	41.47	4.06
Large	100 mmHg	94.46	88.96	5.5
Large	200 mmHg	200.27	190.99	9.28

Small	50 mmHg	53.79 mmHg	52.82	0.97
Small	100 mmHg	113.00	111.46	1.54
Small	200 mmHg	207.10	195.25	11.85

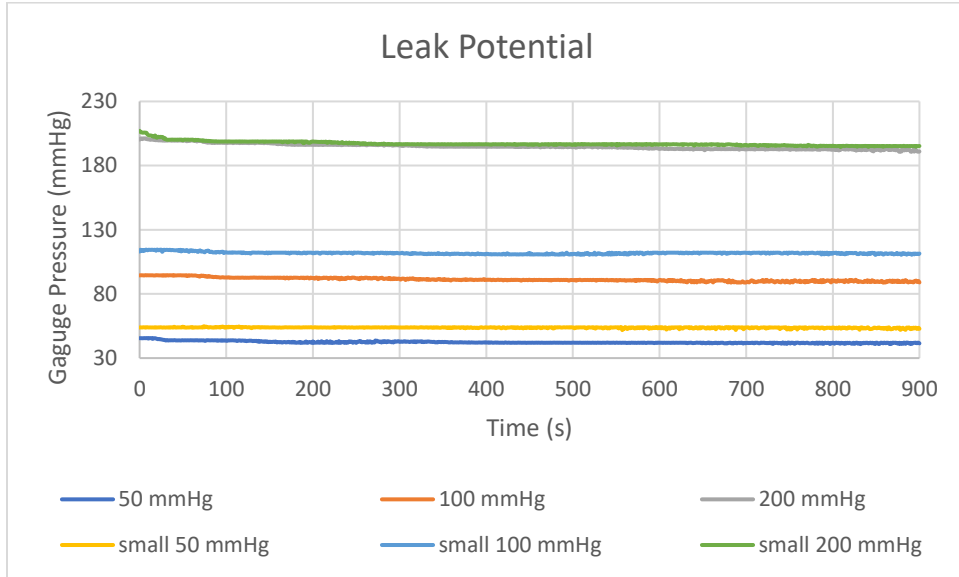


Figure 4.1. Leak Test Pressure

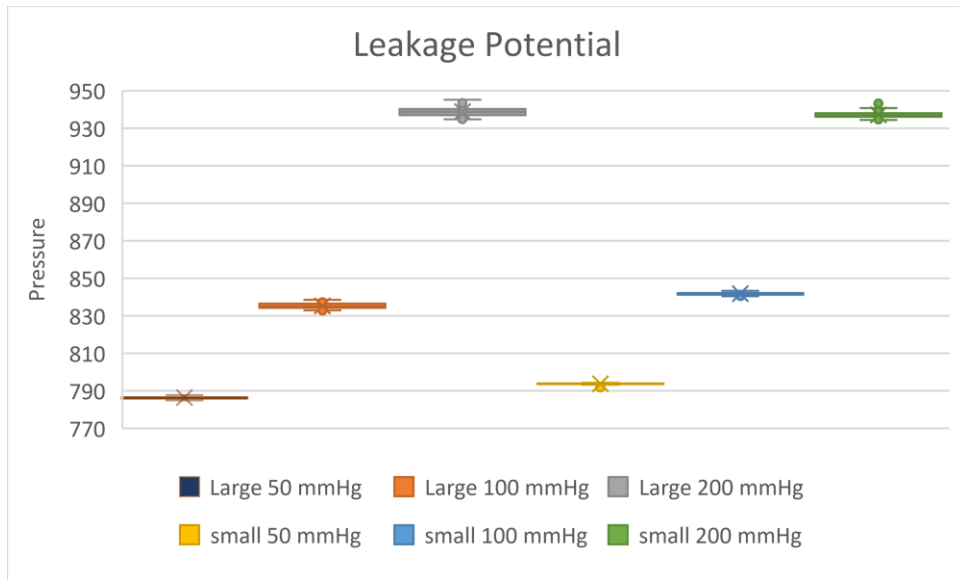


Figure 4.2. Potential for Leaks in the System

Response Test

None of the response tests performed on the fixtures were able to meet SOP standards for a calibration response. Of the TPT2 Pneumatic Tourniquets that were sent

to calibrate the test fixtures, 2/3 were broken, which meant they could not meet and maintain the required pressure to pass the calibration testing. This test was performed 6 times.

After performing the SOP stated calibration testing, a non-SOP response test was performed using the tension system. Weights (120 lbs) were used to create the required amount of tension and pressure, 33 ± 5 mmHg. This did meet the requirements of the test for the large fixture, however the small fixture was not able to meet the requirements.

Testing was then done to quantify what the SOP meant by “apply tourniquet snugly to the device”. The response test was done with a normal application of the pneumatic tourniquet to the device. Then the test was performed 2 more times, once with a diameter that was roughly 3 mm smaller than the original diameter and then once with a diameter that was roughly 3 mm larger than the original diameter. The results are shown in Figure 4.3, showing how the fit affected the max pressure.

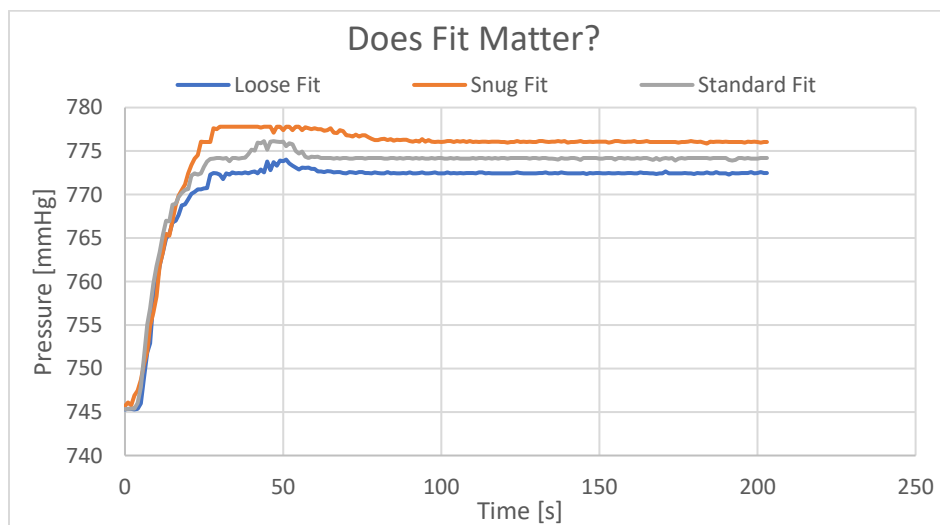


Figure 4.3. Does the fit of the tourniquet affect max pressure?

Tourniquet Test

For the tourniquet function tests, several different types of tourniquets were tested on the test fixtures to determine if they met the criteria (Table 3.1). The purpose of this testing was to see if current tourniquets on the market were able to produce the data that was expected of them on the ASTM test fixture. Results are shown in Figure 4.4 and Figure 4.6. Data was collected from resting pressure to pressure of interest and then collected for 200 seconds. Each data point shown the box and whisker graph is 1 second of data, so pressure points that were repeated more often make up the largest parts of the box and whisker graph. Ideally, the mean of the data should be around the pressure of interest, which is represented as a red line on the graphs.

The X in the middle of the box and whisker plot represents the average pressure of the tourniquet, while the top line represents the max pressure reached. The outlier points represent where the tourniquets max pressure during tightening, or the “spike” that occurs when tightening tourniquets was drastically higher than the average pressure after the tourniquet relaxes to its normal pressure. This is more obvious in windlass tourniquets that “settle” more after the windlass is secured than in ratcheting tourniquets where pressure is held better. Points below the box and whisker are representative of where the tourniquet settles to after the spike and before the resting pressure was reached. Tourniquets that do not reach the pressure of interest were tightened until the tourniquet physically could not be tightened anymore via their advertised method of tightening (windlass, ratcheting, etc.).

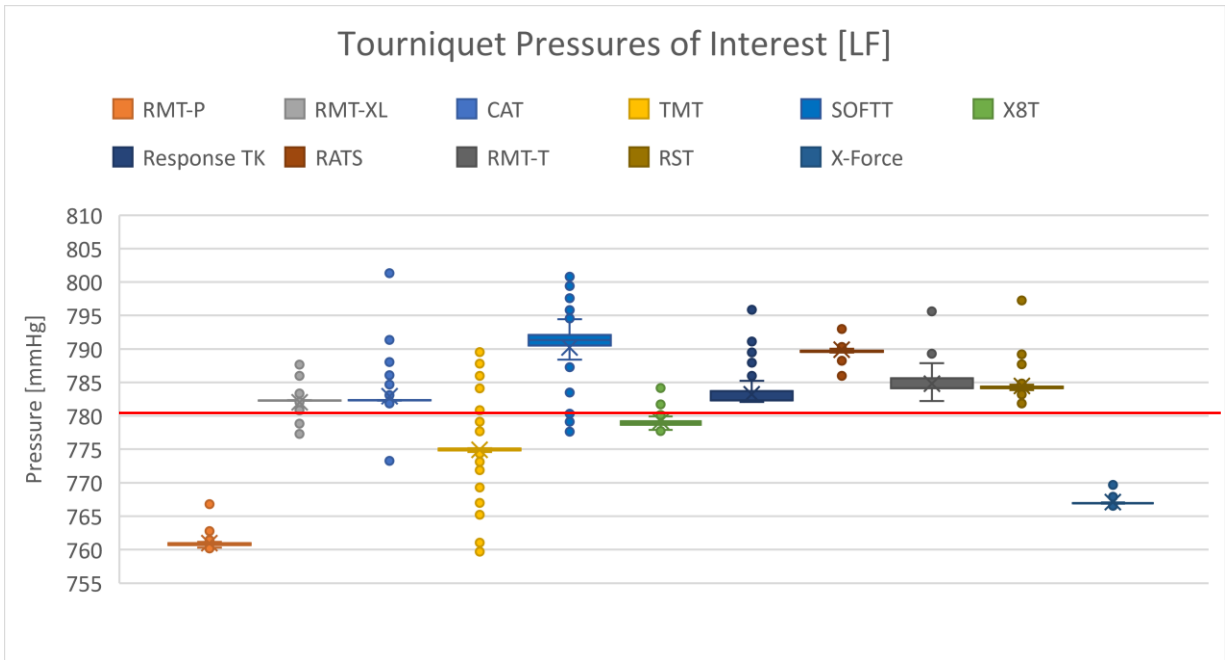


Figure 4.4. Large Fixture Tourniquet Operation Pressures

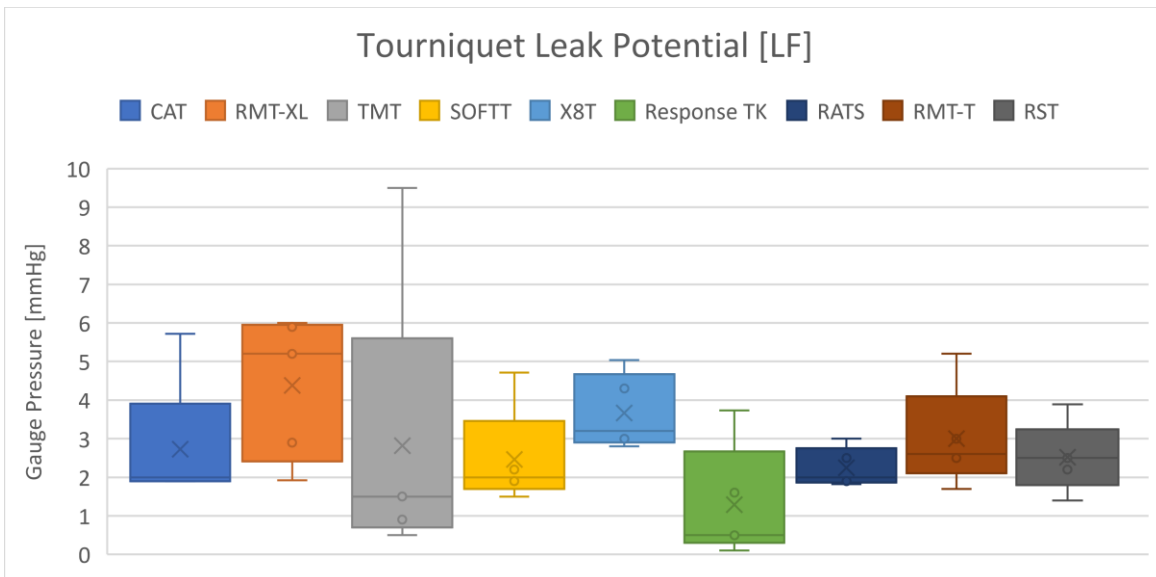


Figure 4.5 Large Fixture Tourniquet Avg Settle

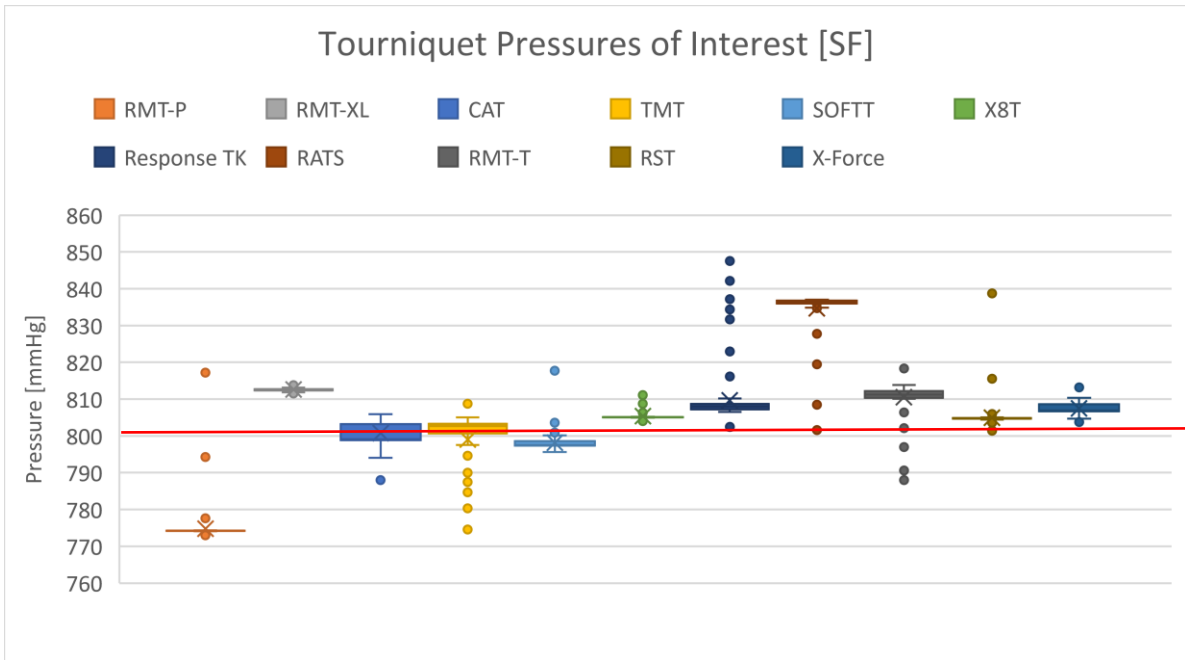


Figure 4.6. Small Fixture Tourniquet Baseline Pressures

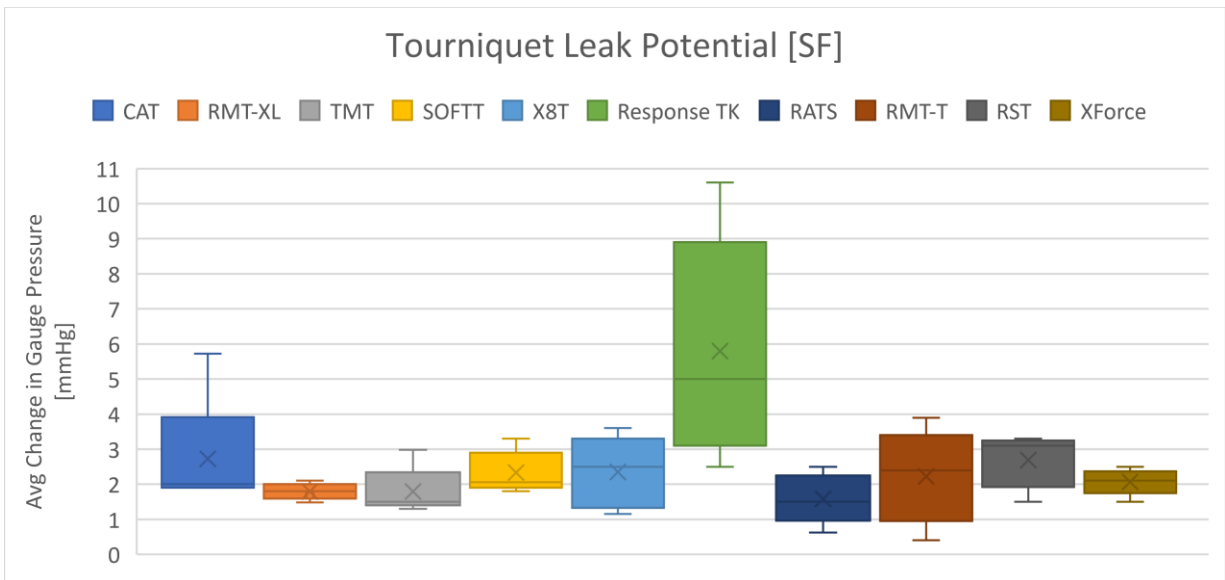


Figure 4.7 Small Fixture Tourniquet Avg Settle

The tourniquet test was performed 5 times with each tourniquet on each fixture if it could meet the pressure of interest. The average loss of each tourniquet test over the 5 minute period is represented in Figure 4.5 and 4.7. These results demonstrate that

tourniquets respond to application on both test fixtures differently but do still manage to pass. Pass in this situation is considered that the tourniquets can meet the pressure of interest and then remain within 5 mmHg over the ~4 minute duration of the test.

Tension Testing

In the first round of testing, known weights were used to simulate tourniquet tension around the test fixture to the “pressure of interest” indicated by the SOP. Max weights are shown in Table 4.2. Differing weights based on webbing size were used to avoid unnecessary wear and tear on the fixture based on observations from the first fixture that was used for testing.

Table 4.2. Known Weights Required to Meet POI

Fixture Type	Pressure of Interest	Webbing Size	Weight
Large	35 mmHg	1 in	110
		1.5 in	120
		2 in	140
Small	50 mmHg	1 in	60
		1.5 in	60
		2 in	60

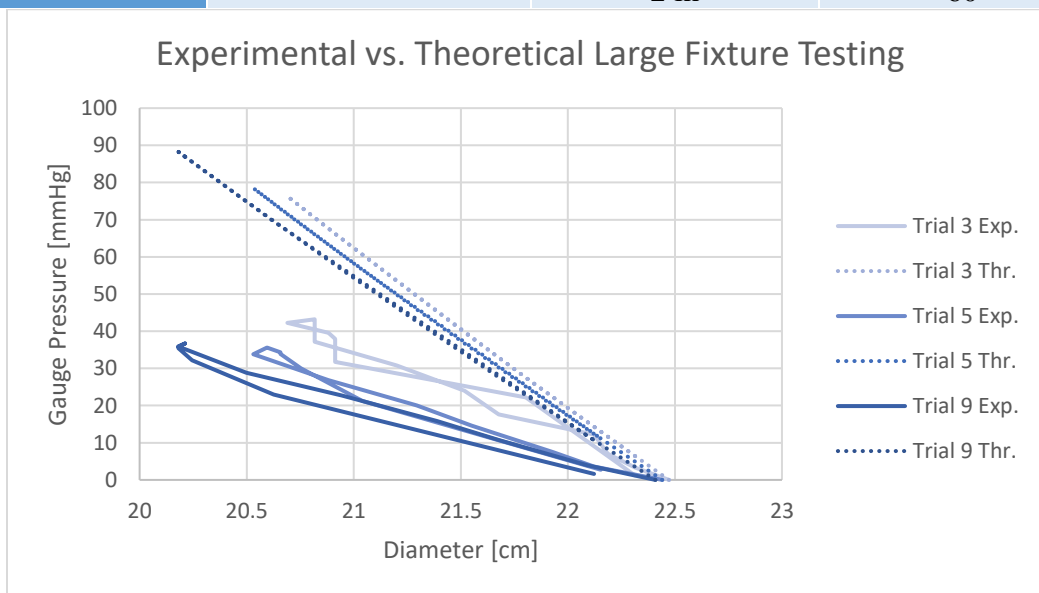


Figure 4.8. Experimental vs Theoretical Change in Pressure for Large Fixture

Table 4.3 Quantified Differences in Experimental and Theoretical Data

Trial #	Strap Width [in]	Exp/Thr	Max Pressure [mmHg]	Slope [mmHg/cm]
3	2	Exp	43.2	-23.42
3	2	Thr	76.29	-42.86
5	1.5	Exp	35.6	-19.33
5	1.5	Thr	78	-41.23
9	1	Exp	36.9	-16.28
9	1	Thr	88.26	-39.87

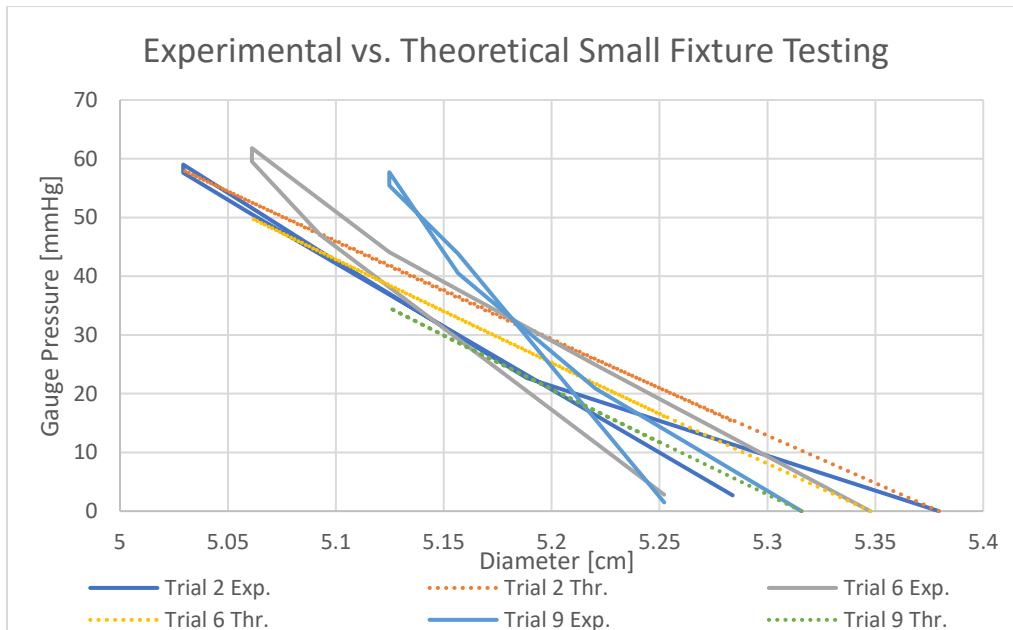


Figure 4.9. Experimental vs Theoretical Change in Pressure for Small Fixture

Round 1 of testing identified several problems with the test fixture. First, there was a large discrepancy in between theoretical data and experimental data, but only for the large fixture. Second, the test fixtures did not return to their original diameter even after releasing pressure of the tension system and letting the fixture rest without tension. Results from round 1 of testing are shown in Figures 4.8 and 4.9.

In round 2 of tension testing, diameter was kept the same for every trial. This meant inflating the fixture to the appropriate size for each test. Even when starting the

test with the same diameter, it did not equate to an equal starting pressure. Results from 1 trial of each webbing size are plotted in Figure 4.10 for the small fixture and 4.11 for the large fixture. From the experimental results K values were calculated from the slope of the data for each trial. The slope of the lines represents how fast the diameter change affects the pressure.

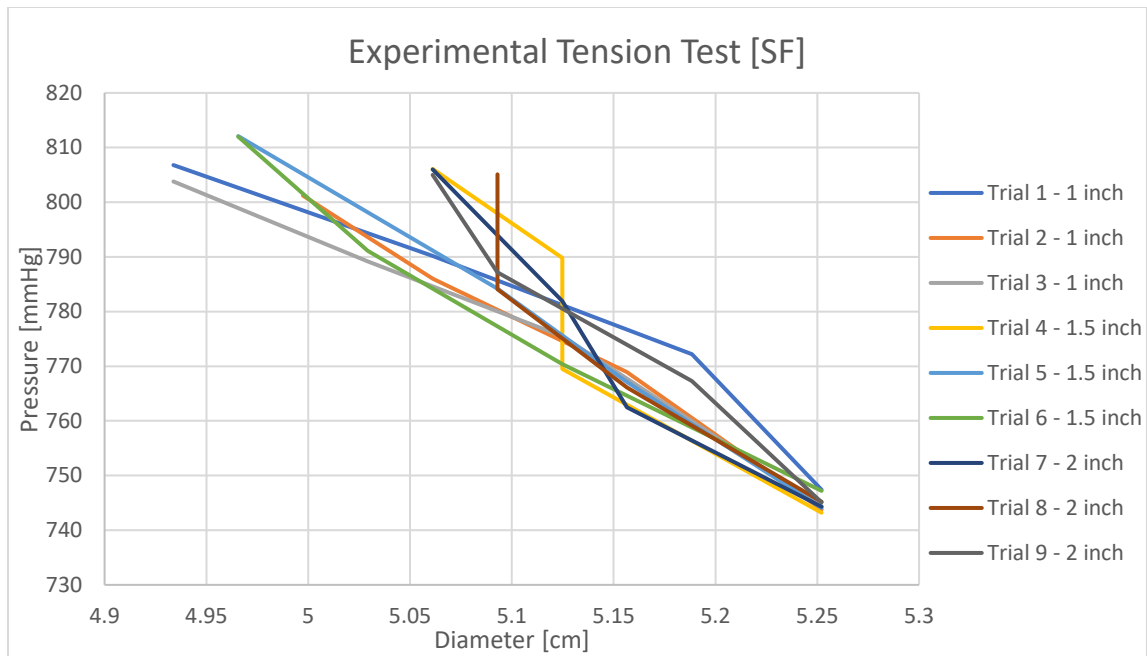


Figure 4.10. Experimental Pressure vs Diameter of Small Fixture

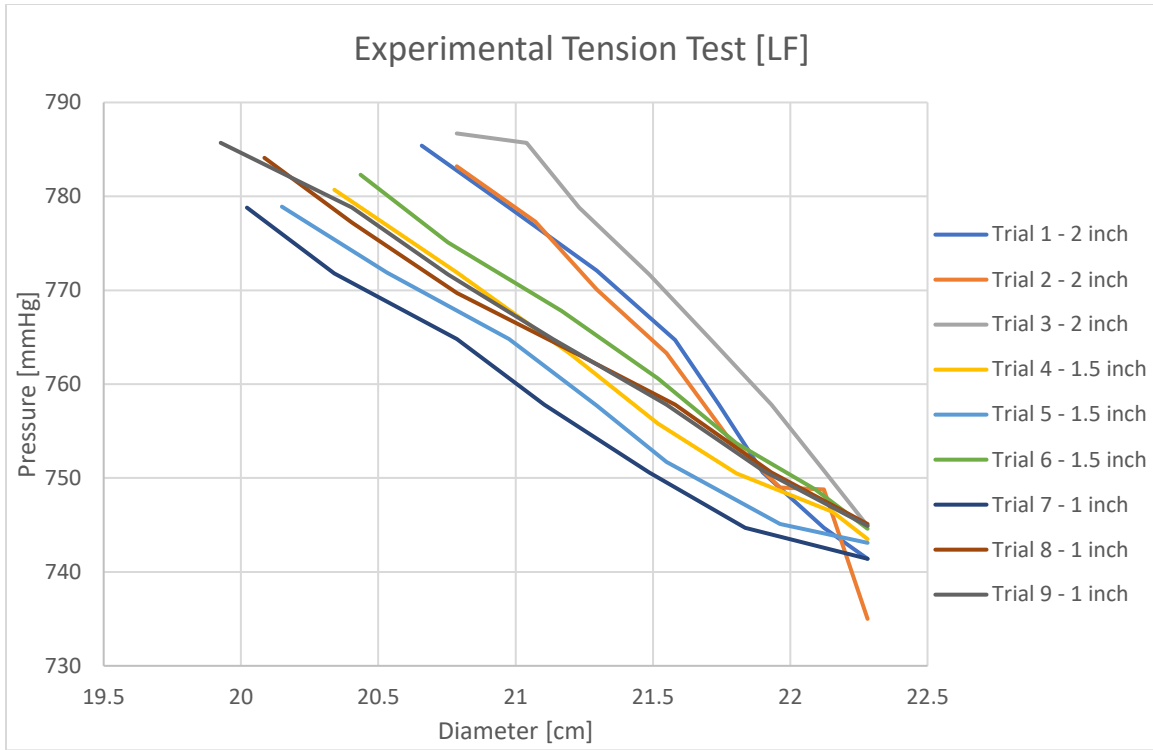


Figure 4.11. Experimental Pressure vs Diameter of Large Fixture

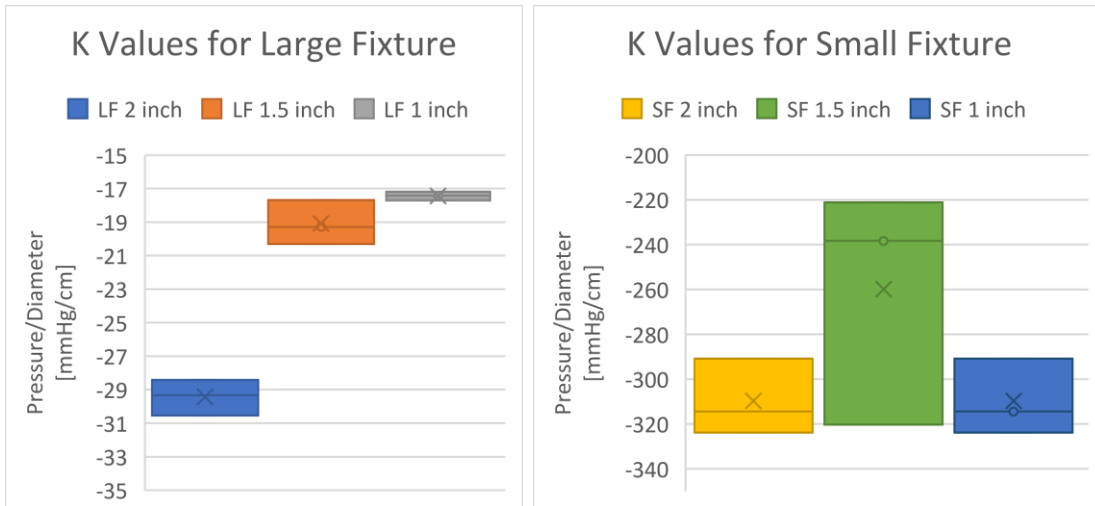


Figure 4.12 Experimental K Values of the Fixtures

Table 4.4 ANOVA Statistical Analysis for Large Fixture

Anova: Single Factor						
<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Between Groups	253.4958	2	126.7479	129.1604	1.17E-05	5.143253
Within Groups	5.887927	6	0.981321			
Total	259.3837	8				

Table 4.5 ANOVA Statistical Analysis for Small Fixture

ANOVA						
<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Between Groups	20471.54	2	10235.77	8.380663	0.018317	5.143253
Within Groups	7328.132	6	1221.355			
Total	27799.67	8				

CHAPTER SIX

DISCUSSION AND CONCLUSION

Calibration Testing

Leak Test

When the test fixture was tested at lower pressures for leaks, the system experienced less loss during the tests than with the SOP stated value. The pressure loss doubled every time the pressure in the system was doubled, which led to a pressure loss of values over what the SOP stated was “suitable” for loss during the test. Every other test in the SOP accounts for the differing sizes of the devices, apart from the leak test. The SOP states that pressure loss should be within 5 mmHg for both devices. However, the jump in pressure loss is much greater for the small device than with the large device as shown in Table 4.1. The rate of pressure loss is linear for the large fixture however the small fixture experiences a pressure loss of 8 times greater for the 200 mmHg test over the 100 mmHg test.

Another limitation of the test fixture design that the SOP did not address for leak testing the devices was the role of the nylon cover during testing. The first leak test that was performed, the nylon sleeve was taken off when it came undone because instructions did not state that the sleeve should always remain attached to the device in order to constrict the fixture during inflation. This eventually led to the first fixture rupturing. The second leak test performed on a different fixture with a new nylon sleeve experienced the same problem where the nylon cover Velcro did not stay closed during the inflation of the devices, although the second inflation was performed with a hand

pump to allow more control. The following tests were able to be performed with the nylon sleeve staying attached to the fixtures, however both of those tests still were not able to achieve the SOP stated pressure loss, despite no leaks being identified.

For the leak test, it mainly seems to be a limitation of the written SOP and could be fixed if the SOP was written with more detail and used an inflation pressure that was more closely related to the actual testing pressures the fixtures experience.

Response Test

Results for response testing were difficult to obtain and were not able to replicate what was expected of the devices during testing. The first problem that was encountered during response testing was the provided tubing and tubing clamp used to connect the TPT2 Pneumatic Tourniquet to the pressure sensors did not fit the valves. This caused audible leaking when the tourniquet was inflated, reflected in the readings on the pressure sensor. Several steps were taken to identify the leaking including using soapy water and inflating the tourniquet not on the device to find the leak.

Eventually, a new pneumatic tourniquet was set up and the second tourniquet had similar problems to the first. After connecting new tubing and clamps, the tourniquet still had a leaking problem. Using soapy water, a leak was found in the 3-way valve that was sent with the device to set it up as a calibration device.

The SOP instructions for the response test indicated the pneumatic tourniquet should be inflated to 600 mmHg so that the large tourniquet test fixture could reach 33 mmHg. During our testing however the pneumatic tourniquet was not able to tighten enough to reach 33mmHg, which has been a problem proved by other researchers¹². This

suggests that the pneumatic tourniquet may not be the best option for a calibration technique as setting up the calibration tourniquet is difficult without introducing leaks into the system, and the difficulty of reaching the intended pressure using the TPT2.

The fit test of the pneumatic tourniquet on the device did show that pressure increased with the tightening of the original fit before the tourniquet was used to add pressure. In order to calibrate the tourniquet, a testing set up where certain starting diameters are used to reach certain pressures would be more accurate than an average pressure of the inside of the pneumatic tourniquet. However according to previous literature, achieving “high initial strap tension” is important in order to minimize time spent tightening the tourniquet but should not affect end surface pressure that causes arterial occlusion¹⁴.

The failure of the response test to be accurate and reproducible was also a limitation of the written SOP. The pneumatic tourniquet proved to be an unreliable calibration technique and using the tensioning system did demonstrate that although the large fixture could hold the pressure, the pneumatic tourniquet couldn't apply enough tension to create that pressure. Equipment used in the calibration procedure such as the 3-way valves and tubing sent with the fixture were also a limitation, and also pointed to an air-based bladder system potentially being a problem for a tourniquet test fixture. A response method using known weights and a change in circumference that produces a set change in internal pressure would be a better measure of the test fixture's ability to respond appropriately to outer diameter changes.

Tourniquet Test

The focus of our research on the tourniquet test fixture was to see if it could give accurate and repeatable results. As part of this testing, 11 tourniquets were applied to both the large fixture and the small fixture. There were a few tourniquets that despite multiple tests were not able to achieve the pressures of interest determined to be adequate by the SOP. The RMT-P 1.5”, a tourniquet designed for pediatric use, was unable to achieve the pressure of interest for the large or small fixture because of its small ratcheting strap, even on the small fixture. However the RMT-T, which has the same width strap but a longer ratcheting strap was able to achieve the pressure of interest for both fixtures. Prior research has proven that the RMT-P can achieve occlusion pressures¹⁴, therefore this appears to be a limitation of the design of the device and not reflective of the RMT-P tourniquet itself.

Application of the tourniquet on the fixture did also affect the max pressure reached during testing. With several tourniquets, significant buckling happened with the rubber, creating extra wear and tear on the device, and decreasing the diameter even further. This buckling could be part of the reason that the experimental data and theoretical are so varied for the large tourniquet test fixture. This is not as prominent with the small test fixture because it is so small that the tourniquets experienced buckling during initial tightening on the fixture and not once the tourniquets were being tightened to the pressure of interest.

The tourniquet settle test that was done in addition to SOP guidelines discussed the average pressure of the 5 tourniquets applied to the fixture. This test showed that the

same tourniquet applied to the test fixtures 5 different times did not always have similar “relaxations”. Ideally, with a reproducible standard test fixture, it should have a similar response to each identical tourniquet applied in order to verify that the tourniquet can repeatedly reach safe occlusion pressures.

Tension Test

The tension test was not a part of the SOP, and was designed and performed in order to identify the relationship between tension in the system, circumferential changes, and internal pressure of the systems. The first round of tension testing done on the fixture pointed out the differences in the theoretical vs experimental data. For the large fixture there was a significant difference between experimental and theoretical however for the small fixture there was overlap between the two. As previously discussed, a major role in this difference could have been the buckling that the large fixture experienced during tightening. The theoretical calculations only accounted for two perfect conical cylinders connected by another cylinder and could not account for deformations that could’ve been experienced by the fixture.

The second round of testing was done keeping the initial starting diameter the same with every trial in order to identify if the differences in each webbing size came from the width of the webbing or if it was from the initial diameter differences. There were two problems encountered with this testing. The first was that although the test fixture was inflated/deflated according to getting the correct initial diameter, this did not produce the same starting “atmospheric” pressure. The second problem encountered was the difficulty getting the small fixture to the correct diameter. It was so small that any

minor inflations to get the fixture back to the initial diameter increased it by way more than necessary and using the Schrader valve to readjust let out too much air. These problems point out that the fixture does not meet the criteria of the test fixture returning to the original shape after the tourniquet is removed.

During the second round of testing results indicated that K values between each webbing strap were not as closely related as the theoretical data K values. An ANOVA test was done on each of the three slopes for each of the webbing sizes which showed there was a statistical difference in the slopes for the three different webbing sizes. Statistical significance in the three different webbing sizes means that the fixture is not functioning independently of strap width, one of the requirements from the ASTM committee. The theoretical data shows that even with the width of the strap increasing, the K values should not have statistically significant difference, proving a limitation of the device itself.

Wear and Tear

Throughout the testing of the fixture, several cracks and scratches were found in the rubber bladders. As previously stated, one large fixture developed a leak between the rubber bladder and aluminum frame during a routine leak test for calibration. Another significant problem experienced throughout testing was the large fixture experienced large deformation and often had to be re-inflated to achieve a true circular diameter again. The second set of fixtures was never tested beyond the limits set in the SOP, and the number of tests done on the fixtures was well below what would be expected of a manufacturer using the device repeatedly to validate safety and efficacy of their

tourniquets. The fixtures were also never subjected to any extreme conditions, such as cold or hot temperatures, or dirt and blood substitutes that would simulate the actual environment of use for the tourniquets. Testing with these simulated conditions is a requirement of the ASTM standard committee for the tourniquet test fixture, and it should be durable enough to withstand numerous tests in these conditions.

Limitations and Future Work

While tourniquets are single-use medical devices, the tourniquets used for testing the test fixture were used several times due to the number of tourniquets available for testing. These tourniquets however were not used to reach occlusion or completion pressures in most cases, as the tourniquet test fixture is only rated for a certain amount of pressure increase that was “representative” of occlusion pressure.

If research on the Sydor Tourniquet Test Fixture was continued, dedicated wear and tear testing should be done to verify if the test fixture can withstand conditions required by ASTM testing. After reviewing our research with members of the ASTM tourniquet committee, Clemson was asked to present a plan for a new test fixture that is designed to avoid potential flaws identified with the original tourniquet test fixture.

Conclusions

This evaluation of the ASTM tourniquet test fixtures identified limitations of the SOP for the fixtures as well as limitations of the functionality of the fixtures. The SOP created limitations for calibration testing of the fixture as well as not properly stating what a tourniquet had to achieve in order to “pass” on the fixture. Calibration testing of the fixture was not accurate or reproducible enough to be reliable for the tourniquet test

fixture due to the standards set by the SOP. The design of the test fixtures also failed evaluation based on the criteria set by ASTM. The test fixtures were not able to return to their original shape after each test. The fixtures were also not designed to withstand a physiological occlusion pressure of 200 mmHg – 500 mmHg, and were not capable of reaching that pressure range. Wear and tear on the fixture was also a significant limitation of the design, as there were several cracks in the fixtures after testing and the large fixtures did not return to their original shape after testing without re-inflation. In conclusion, ASTM has decided to design another test fixture to suit their needs for the tourniquet test standard.

APPENDICES

Appendix A

Sydor Non-Pneumatic Tourniquet Test Fixture Operations and Maintenance Manual



COMPLEX MEASUREMENTS
CRITICAL RESULTS

November 2022

Non-pneumatic Tourniquet Test Fixture Operations and Maintenance Manual

Task Number: CDRL A002

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Non-pneumatic Tourniquet Test Fixture

Operations and Maintenance Manual

UNPACKING

Packing List:

- 1 ea. Large Bladder
- 1 ea. Large Bladder Mount
- 1 ea. Large Bladder Fabric
- 1 ea. Small Bladder
- 1 ea. Small Bladder Mount
- 1 ea. Small Bladder Fabric
- 1 ea. LabQuest Mini
- 1 ea. LabQuest Mini USB cable
- 2 ea. Vernier Pressure Sensor 400
- 1 ea. TPT2 Tactical Pneumatic Tourniquet
- X ea. Tubing
- X ea. Tubing clips
- X ea. 3-way Diverters
- 7 ea. Mounting Screws

Assembly Procedures:

1. Attach the large bladder to the large bladder mount by use of 4 mounting screws. Tighten until snug.
2. Attach the small bladder to the small bladder mount by use of 3 mounting screws. Tighten until snug.
3. Affix the bladder mounts to a secure worktable with bolts or clamps. Ensure there is enough room between them to allow for single hand application of a tourniquet.
4. Attach the fabric cover to the bladders snugly with the hook-and-loop on the bottom.

5. If they are not attached, take a 2" section of the small diameter tubing and attach it to the end of the vernier pressure sensor 400 for the large bladder. Repeat for the small bladder.
6. If they are not attached, take a 12" section of large diameter tubing and insert it over the open end of the tubing that was previously attached to the pressure sensor. Ensure it overlaps by approximately 1". Apply tubing clamp and engage snugly. Repeat for other pressure sensor.
7. Attach open end of large diameter tubing to the nipple on the large test device. Apply tubing clamp and engage snugly. Repeat for small test device.
8. Plug the cable from the sensor attached to the large test device to channel 1 in the LabQuest Mini
9. Plug the cable from the sensor attached to the small test device to channel 2 in the LabQuest Mini.
10. Plug the USB cable to the LabQuest Mini and to the computer.
11. Download the latest Logger Lite software for the LabQuest Mini from [Logger Lite Updates - Vernier](https://www.vernier.com/downloads/logger-lite-updates/) (<https://www.vernier.com/downloads/logger-lite-updates/>). Choose either for Windows or Mac. For full product documentation, see www.vernier.com/manuals/lq-mini.

Sensor Calibration Procedure:

The sensor is calibrated prior to shipping. If you would like to perform your own calibration, follow the steps below. A one-point calibration at atmosphere is adequate for most applications.

To perform a one-point calibration:

1. Connect the Pressure Sensor 400 to the LabQuest Mini and launch the software.
2. Initiate the calibration procedure and make sure the one-point calibration option is checked. This should be the default option.
3. Enter the actual pressure as the known value for Reading 1.
4. When the voltage reading stabilizes, click Keep.
5. If you want to use the calibration for the current session only, click Done to complete the calibration process. To save the calibration onto the sensor, click the storage tab and save to the sensor.

Test Device Calibration Procedure:

Calibration of the test device consists of two different tests; the leak test and the response test. As the vernier software reports absolute pressure, guidance is provided to convert that to relative pressure.

Leak test:

1. Using the Schrader valve on the test device, equalize to atmospheric pressure by holding in the middle needle for 5 seconds.
2. Start the vernier software. Change the units to read mmHg by clicking on “Experiment”, scrolling down and clicking on “Change Units” and then clicking on a channel. mmHg should be the first option on the list. This should be done for whichever test device you are calibrating.

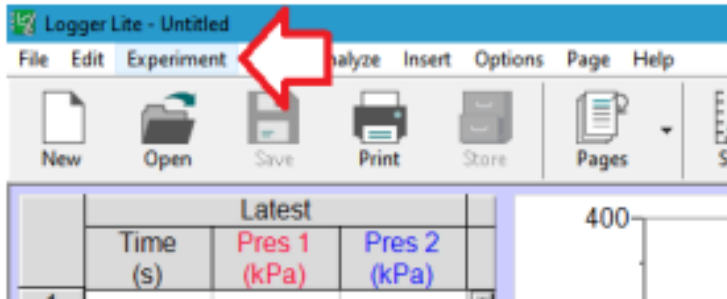


Figure 1. Location of “Experiment” button.

3. Click on the “Collect” button to start collecting data.



Figure 2. Location of “Collect” button.

4. Click on the “Scale” button.
5. After about 30 seconds, click on the “Stop” button and get an approximate average reading. Remember, Channel 1 is for the large test device and Channel 2 is for the small test device.

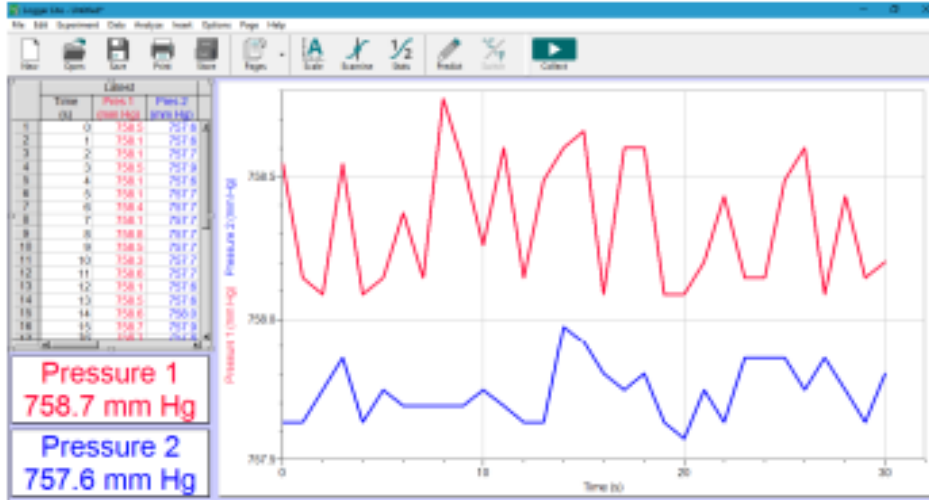


Figure 3. Example of output for 30 second run.

6. Add 200mmHg to the approximate average pressure to determine a calculated pressure. In the example shown in Figure 3, the approximate average pressure is 758.3mmHg, so the calculated pressure would be approximately 958mmHg.

7. Using a hand pump attached to the Schrader valve, inflate until the pressure reading is slightly higher than the calculated pressure. Do not exceed by more than 300mmHg over the initial pressure.

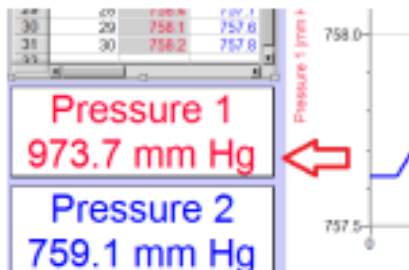


Figure 4. Example of approximate increase of 200mmHg.

8. Click the “Collect” button again. It will reset back to 0. Let it run until the end which will be 900 seconds (15 minutes).

9. Get an average pressure for the first 30 seconds and the last 30 seconds of sampling. The two averages should be within 5mmHg if there is no leak. You will notice that during the first 3 minutes it will appear like it is leaking as shown in Figure 6. This is due to the relaxation of the hook-and-loop fabric. The last 12 minutes as shown in this example demonstrate there is not a leak in the system.

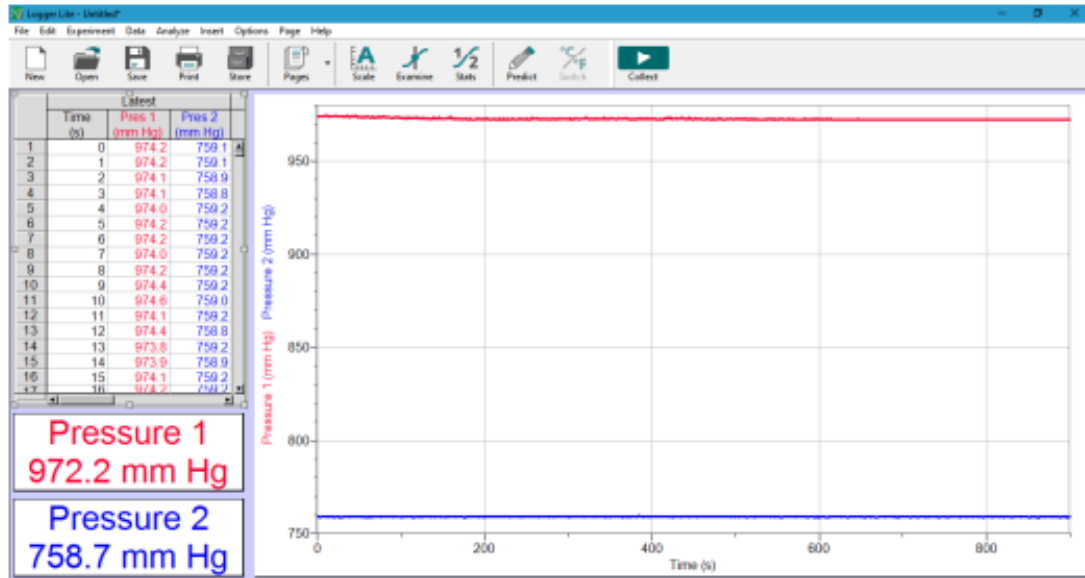


Figure 5. Example of output from 15 minute leak test.

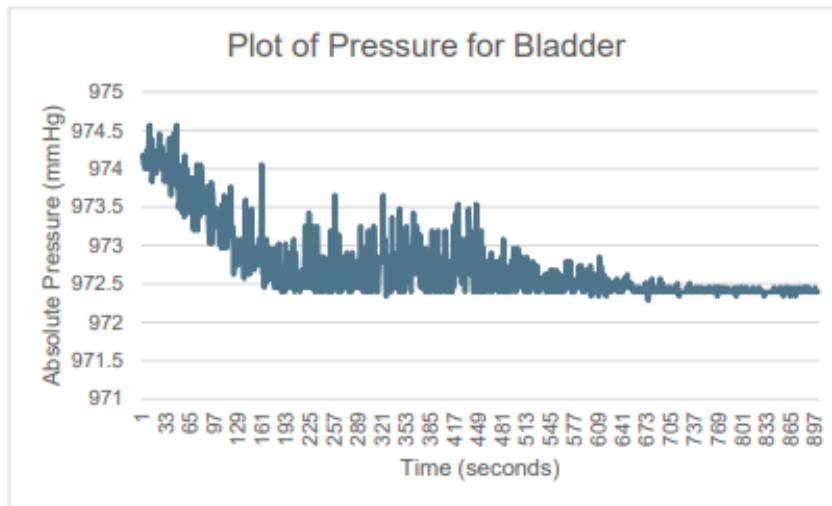


Figure 6. Zoomed in look at output from 15 minute test.

10. If the system doesn't level out as shown in Figure 6, check all the fittings to assure the tubing clamps are tight enough. If that doesn't work, use of a soapy mixture can help identify where the leak is. Ensure the electronic items are not subject to any moisture.

11. If the leak is in the bladder, replace the bladder.

Response Test:

1. Using the Schrader valve on the test device, equalize to atmospheric pressure by holding in the middle needle for 5 seconds.
2. Start the vernier software. Change the units to read mmHg by clicking on “Experiment”, scrolling down and clicking on “Change Units” and then clicking on a channel. mmHg should be the first option on the list. This should be done for whichever test device you are calibrating.

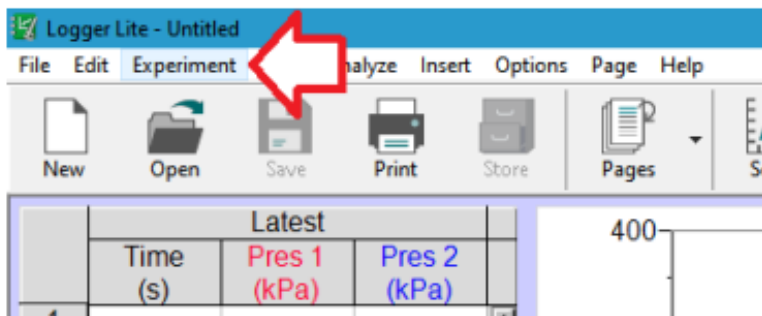


Figure 7. Location of “Experiment” button.

3. Insert a nipple into the end of the 3-way valve as shown in Figure 8 and then insert the nipple into the tubing going to the vernier pressure sensor from the test device that isn’t being calibrated.



Figure 8. Photo of 3-way valve and plastic nipple.

4. Remove the pump from the pneumatic tourniquet and attach both the pump and the pneumatic tourniquet to the 3-way valve as shown in Figure 9. Ensure the valve is open on the pump and the 3-way valve is positioned as shown in the Figure 9.

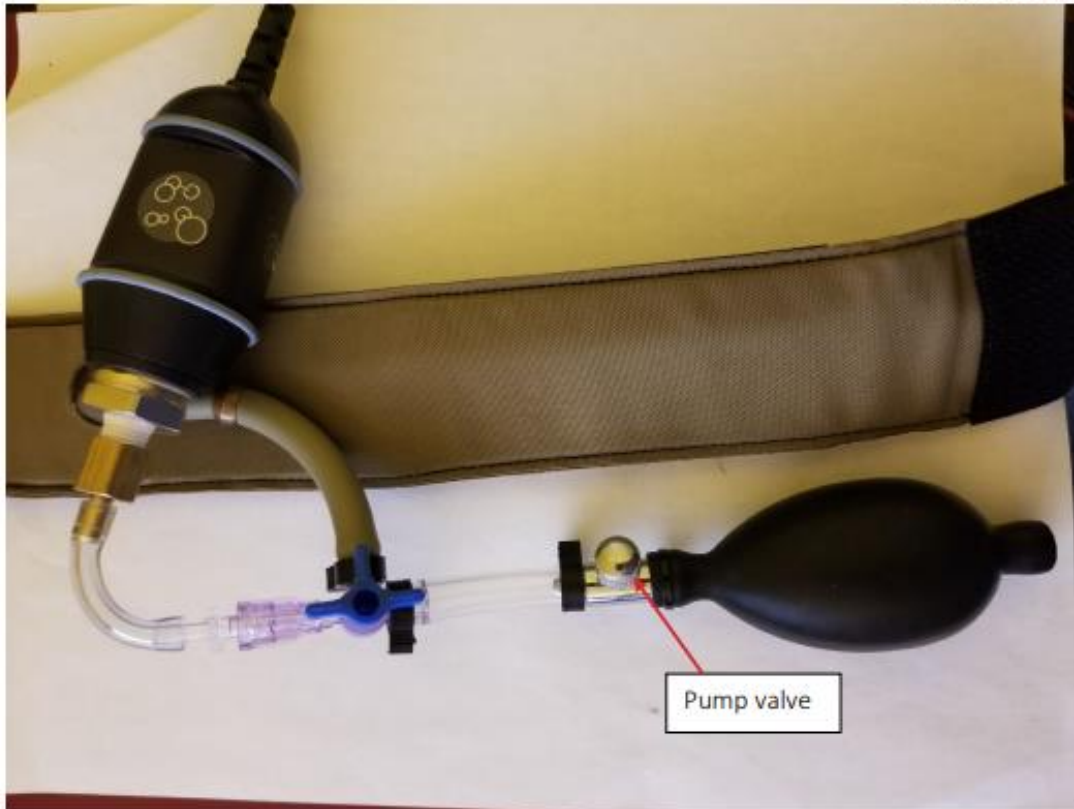


Figure 9. Photo of pneumatic tourniquet, pressure sensor, 3-way valve, and nipple.

5. Wrap the pneumatic tourniquet around the test device snugly.
6. Start collecting data with the vernier software.
7. Wait for 30 seconds and note the average internal pressure as reported by the test device.
8. Close the pump valve and begin pumping up the pneumatic tourniquet.
- 8.1 For the large test device, pump until the internal pressure indicated by the pneumatic tourniquet is 600 ± 30 mmHg.

Note: When getting close to the 600 mmHg, slow down pumping so that there isn't a spike in the graph. It should be a smooth transition when pumping is finished.

8.1.1 Note the time that the pumping was stopped. Wait for 5 minutes (300 seconds), and then release the pressure on the pump bulb.

8.1.2 Keep recording for another 30 seconds after the pressure has been released.

8.1.3 Stop the software and save the file for future reference.

8.1.4 Determine the average interior pressure of the large test device for the first 30 seconds.

8.1.5 Determine the average interior pressure of the large test device and the pneumatic tourniquet for the last 30 seconds of the 5-minute run.

8.1.6 If the interior pressure of the pneumatic tourniquet during the last 30 seconds is still within 600 ± 30 mmHg, the test device output can be evaluated.

8.1.6.1 Subtract the average of the initial 30 seconds of the test device output from the average of the last 30 seconds of the test device output.

8.1.6.2 The result should be 33 ± 5 mmHg. If it isn't, repeat the test two more times and average the results. If they are not in compliance, it is time to replace the bladder on the test device.

8.2 For the small test device, pump until the internal pressure indicated by the pneumatic tourniquet is 300 ± 5 mmHg.

Note: When getting close to the 300mmHg, slow down pumping so that there isn't a spike in the graph. It should be a smooth transition when pumping is finished.

8.2.1 Note the time that the pumping was stopped. Wait for 5 minutes (300 seconds), and then release the pressure on the pump bulb.

8.2.2 Keep recording for another 30 seconds after the pressure has been released.

8.2.3 Stop the software and save the file for future reference.

8.2.4 Determine the average interior pressure of the small test device for the first 30 seconds.

8.2.5 Determine the average interior pressure of the small test device and the pneumatic tourniquet for the last 30 seconds of the 5-minute run.

8.2.6 If the interior pressure of the pneumatic tourniquet during the last 30 seconds is still within 300 ± 5 mmHg, the test device output can be evaluated.

8.2.6.1 Subtract the average of the initial 30 seconds of the test device output from the average of the last 30 seconds of the test device output.

8.2.6.2 The result should be 60 ± 5 mmHg. If it isn't, repeat the test two more times and average the results. If they are not in compliance, it is time to replace the bladder on the test device.

Operations:

1. Using the Schrader valve on the bladder, equalize to atmospheric pressure by holding in the middle needle for 5 seconds.
2. Start the vernier software. Change the units to read mmHg by clicking on “Experiment”, scrolling down and clicking on “Change Units” and then clicking on a channel. mmHg should be the first option on the list. This should be done for whichever test device you are using.

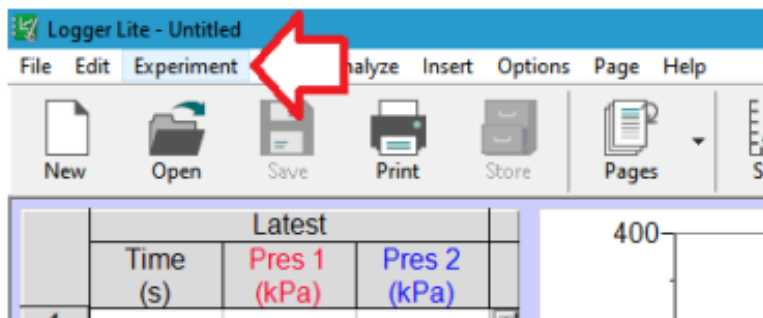


Figure 10. Location of the “Experiment” button.

3. Unless instructed otherwise, click on the “Collect” button to start collecting data.

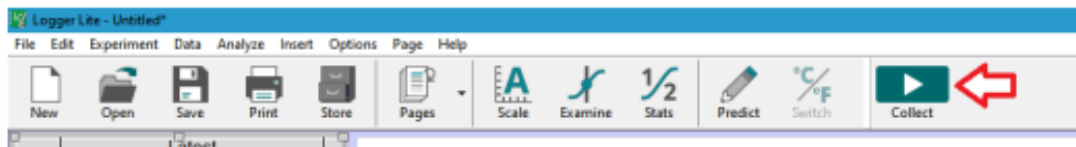


Figure 11. Location of the “Collect” button.

4. Click on the “Scale” button.
5. After about 30 seconds, apply the tourniquet to the center of the test device. Remember, Channel 1 is for the large test device and Channel 2 is for the small test device.
6. Following the manufacturers instructions, ensure that the tourniquet is snugly applied prior to tightening. Failure to apply the tourniquet tight enough may result in the inability to tighten the tourniquet to the appropriate pressure.
7. Following the manufacturers instructions, tighten the tourniquet until the interior test device pressure exceeds the required pressure. Ensure that the pressure noted is after the original spike at the pressure of interest location as shown in Figure 12.
 - 7.1 For the large test device, tighten until the pressure of interest (after the spike) is at least 35mmHg above the average pressure during the initial 30 seconds. Note the time.
 - 7.2 For the small test device, tighten until the pressure of interest (after the spike) is at least 50mmHg above the average pressure during the initial 30 seconds. Note the time.

8. Continue recording for 5 minutes.
9. Remove the tourniquet from the test device.
10. Stop recording.

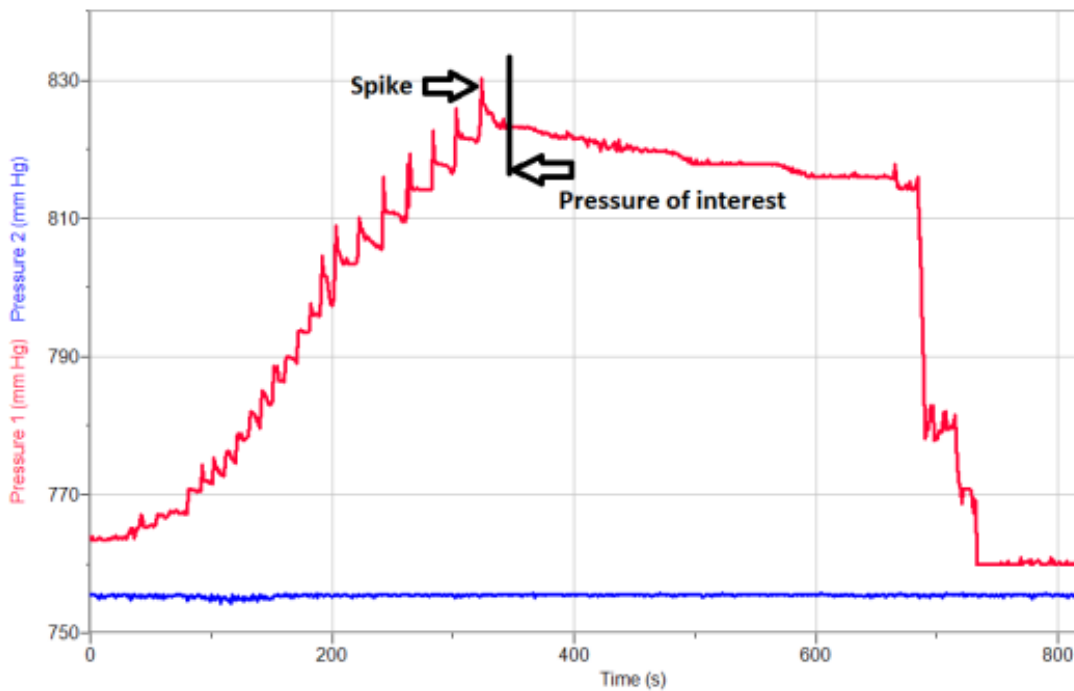


Figure 12. Example output showing spike and pressure of interest starting point.

11. Save the graph into a file.
12. Determine the average initial internal pressure of the test device by averaging the first 30 seconds of output.
13. Determine the initial pressure of interest by averaging the 30 seconds starting with the line denoting the pressure of interest as shown in Figure 12. This should be higher than the required pressure. If not, repeat the test.
14. Determine the final pressure by averaging the pressures between 4:30 minutes and 5:00 minutes from the line denoting the pressure of interest as shown in Figure 12.
15. The pressure drop between the values from step 13 and step 14 should be less than 5mmHg.

Maintenance:

There is not much maintenance on the equipment as it is rather straightforward. If the nylon covering gets damaged or dirty, replace it. They can be washed in the gentle cycle if necessary.

If the test devices don't calibrate, replace the bladder portion.

Extra parts can be obtained from the same distributor as where the test device was originally obtained.

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