5-7-2021

Field Improvised eXoskeleton (FIX) Final Project Report

Kelly Liu
Trinity University

Duncan Dang
Trinity University

Karla Peñaloza
Trinity University

Emi Mondragon
Trinity University

Field Improvised eXoskeleton (FIX)
Final Project Report

The FIX Team:

Kelly Liu

Duncan Dang

Karla Peñaloza

Emi Mondragon

Team Advisor: Dr. Emma Treadway

May 7th, 2021

Interoffice Memorandum

To: Dr. Lee Childers, Department of Defense (DOD) Prosthetist,
Project Sponsor
Dr. Emma Treadway, Team Advisor
Dr. Darin George, Senior Design Administrator

From: The Field Improvised eXoskeleton team (Kelly Liu, Duncan Dang, Karla Peñaloza, Emi Mondragon)

Subject: Final Project Report for the Field Improvised eXoskeleton (FIX)

Date: May 7th, 2021

CC: N/A

The FIX team presents this test report for the Field Improvised eXoskeleton senior design project. This test report describes the functional, non-functional, and interface requirements of our project while considering the constraints and codes and standards that apply. Each test will evaluate a design feature, address a project requirement or constraint, and define acceptance criteria. This report will show the results of our full prototype tests and explain the setup and outcome of each test.

Thank you for taking the time to read this report. Please contact our team liaison, Kelly Liu (kliu1@trinity.edu), if you have any questions or concerns. We hope that you will enjoy learning about our project's overall results.

1. Executive Summary/Abstract

The Field Improvised eXoskeleton (FIX) final project report serves to explain and evaluate the results of the testing performed during the Fall 2020 and Spring 2021 semesters to assess whether the FIX prototype meets the design requirements. A full prototype was built to treat a distal radius fracture on Soldiers in the field by testing the ability of an "injured" volunteer to perform a "buddy drag"and comparing between a standard SAM splint and a Modified Splint built by the team. Similarly, the prototype was split into two parts: a Modified Splint subsystem and an external task subsystem for the "buddy drag." The splint subsystem served the main purpose of improving upon the standard of care for splinting, which is a SAM splint. All subsystems were made of materials present in a Field Medic Pack or from materials that were considered easily accessible, such as straps and duct tape.

The general requirements for the prototype design were for the prototype to: stabilize the fracture site, be capable of performing the test adequately, be assembled quickly, minimize damage to the fracture, have clear fabrication instructions, stay within the given budget, be adjustable, apply an appropriate amount of pressure on the arm for the splint, prevent extra pain, and be comfortable. The fracture was proven to be stabilized using the first of two surrogate arms with an implanted fracture and hall effect sensor to measure maximum fracture displacement. All maximum fracture displacements of the Modified Splint subsystem of the prototype were less than the standard of care SAM splint, which made it an improvement of the standard of care. The "buddy drag" external subsystem of the prototype was proven to perform adequately by comparing a healthy "drag" to a "drag" using the external subsystem. The time taken to perform the "drag" was within 2 seconds of a healthy "drag" for a 10 yard distance for a small person's weight and was tested up to a weight nearly 50 pounds more than the average weight of a soldier. The fabrication time for the entire prototype is 9 min and 10 seconds, which was considered a reasonable amount of time for a Combat Medic to spend assembling the prototype in the field. The prototype was proven to minimally damage the fracture site using the second surrogate arm that experienced a simulated strap tug similar to the "buddy drag" performed. Similarly to before, the maximum fracture displacement was less than the standard of care in this case. The fabrication instructions were proven to be clear after a volunteer not on the FIX team read over the instructions and provided feedback that was resolved by the FIX team. The prototype cost less than half of the given budget, so it stayed within budget. The prototype was proven to be adjustable through the use of straps and the application of the splints on different volunteers and members of the FIX team with different arm sizes. The splint pressure was tested using pressure sensors and a capillary refill test that compared the pressure applied by the standard of care SAM splint and the prototype Modified Splint. In this case, all pressure tests proved that the Modified Splint compressed the arm more than the SAM splint without restricting the blood flow of the arm, which would prevent further damage to the fracture. There was no extra pain applied during the "buddy drag" because a volunteer filled out a comfort questionnaire regarding their discomfort and answered that he did not experience any pain during the test after resolving a complaint about the strap rubbing by adding a more realistic outer garb to his arm. Lastly, the volunteers answered comfort questionnaires for the splint and external system regarding how comfortable they felt. The volunteers said their comfort ranged from completely comfortable to slightly less comfortable, but none of them were answered in the uncomfortable range. Overall, the full prototype met all requirements and was considered successful while a work-in-progress external system for the ammo carry done by the team was not considered in the final prototype due to time constraints.

2. Introduction

One of the United States Army's most significant research gaps relates to the treatment of wounded Soldiers on the battlefield, who cannot receive immediate assistance via air support. Specific to this project, one of the most common injuries incurred by a Soldier in the field is a distal radius fracture. The Field Improvised eXoskeleton (FIX) team has been tasked with designing and testing a prototype that can be fabricated quickly and easily on the battlefield by a Combat Medic. The prototype's overall goal is to stabilize a distal radius fracture while simultaneously allowing the Soldier to continue to perform one or more of the following tasks: performing a "buddy drag," carrying ammunition, or shooting a firearm. Beyond those goals, this project also requires the prototype to be an improvement upon the splint used as the current standard of care for treating a fracture, have a fabrication time under 15 minutes, create simple, understandable fabrication instructions, be physically adjustable to an individual Soldier's arm, and be comfortable without aggravating the Soldier's injury. The results of our external system design for the "buddy drag" and the splint subsystem are shown in Figures 1 (a) and (b). The external subsystem was created to fulfill the task capability requirement and tested on a surrogate arm to ensure damage was minimized for a requirement. A neckbrace was added to a standard SAM splint as a design change because it can be found in the Medic Pack and was likely to prevent more pain, apply needed adjustable pressure, and stabilize the fracture to fulfill requirements. Fabrication instructions and fabrication time was found for each system to fulfill requirements. Lastly, comfort questionnaires were given for the external system and SAM splint to ensure the external system and splint subsystem were comfortable for the user.

(a)

(b)

Figure 1. (a) "WBBS" Buddy drag external subsystem and (b) splint modification subsystem

One of the primary constraints requires the prototype to be constructed with materials commonly available in Combat Medic packs or carried by the Soldiers themselves in the field. Another constraint is that the cost of this prototype is limited to the $1200 budget provided by Trinity University, which was met since the team spent less than half of the budget. Lastly, resources available at Trinity University that are involved in building and testing may be affected by COVID-19 depending on if work can be continued on campus, but access was only affected minimally with restricted building hours. The design must follow codes 6 and 8 from the IEEE Code of Ethics to maintain technical competence for treating distal radius fractures and to create a design that does not discriminate against the user and is applicable to all users.The splints with the neckbrace and the standard SAM splint had the same adjustability, which fulfilled the constraint. The design must also follow the standards ASTM F3323 - 20 and ASTM F1555 - 94(2015) to adhere to facilitating common communication between related parties and including the characteristics that a typical extremity splint should possess. Similarly, since the only change is an added neck brace to the SAM splint, this constraint should still be met. Overall, our design met all design and requirements listed.

3. Overview of the Final Design

Our final design consists of the Waist/Biceps Belt Subsystem (WBBS) designed for the buddy drag and a splint modification subsystem, which uses the SAM splint with a cut neck brace that enhances the protection for the injury. The two subsystems will be elaborated in the following sections. Section 3.3 includes the design for the Carry Ammunition subsystem; although this subsystem was not included in our final prototype and was not a requirement for the project, the development and testing behind this subsystem was important to include.

3.1. Modified Splint

The Modification on the SAM splint, otherwise known as Modified Splint, combines long pieces of the SAM splint to clamp the arm in a "clam shell", which stops at the base of the finger that allows finger mobility, padding for comfort and reduction of external wounds, and adding Coban wrap for stabilization. These materials can be found in the Medic Pack as per our material constraint and were cheap to fit into our budget constraint. Compared to the idea that was mentioned in the Preliminary Design Report, we opted to use the Coban instead of the straps. The Coban is applied evenly on the splint that allows for consistent compression throughout the arm (according to Stakeholder Jon Wilson). The Coban provided more adjustability for compression or decompression needs and was a good replacement for straps because the straps took longer to put on a volunteer during the fabrication time test in our initial testing.

The Modified Splint includes the ACE Cervical Collar (typically used for stabilizing neck injuries), which was an added feature used to potentially reduce further injury compared to a standard SAM splint. This modification is simple to fabricate, provides better stabilization for the injury, and allows compression that is reasonably equal to the SAM splint alone (as demonstrated in the tests that our team conducted in the following Evaluation section). It is also easily removable to check for skin infection if the fracture is open (according to Stakeholder Maj. Sarah Pierre). Figure 2 shows our modification SAM splint design. The Modified Splint Fabrication Instruction can be found in Appendix 6.3 for a better understanding of how the splint can be made.

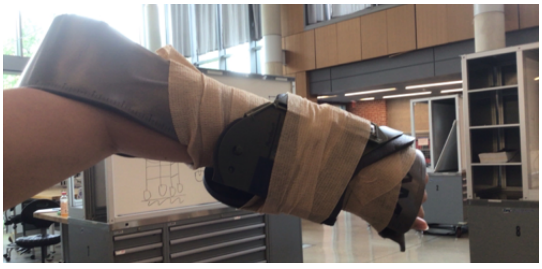


Figure 2. The SAM splint modification with the ACE Cervical Collar (neck brace)

3.2. Waist/Biceps Belt System (WBBS)

The Waist/Biceps Belt System (WBBS) is focused primarily on creating an effective "buddy drag" for the fulfillment of the "buddy drag" task given as one of the project requirements. The initial design sketch for the WBBS is shown in Figure 3 and was used to demonstrate the concept of redirecting force of the buddy being dragged to the bicep at a more natural angle than pulling with one healthy arm. With this subsystem, the pulling load would ideally be minimal at the fractured wrist.

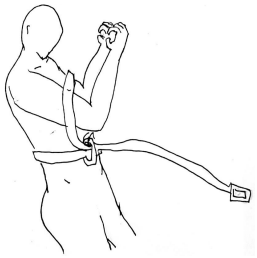


Figure 3. Initial sketch of the Waist/Bicep Belt System (WBBS)

The WBBS attaches straps to the waist and biceps of the Soldier and allows the Soldier to pull the buddy without aggravating the distal radius fracture. The only required materials for this design are straps and carabiners that can attach to a sturdy belt that comes with the Soldier's uniform. Since medics have access to straps and carabiners, and the materials were cheap, this assumption stays within the constraints of this project. Furthermore, this design does not interfere with equipment that the Soldier would likely already be wearing, such as a backpack. Specifically, our design does not attach to a Soldier's torso or back because that area is typically already occupied because a Soldier wears a protective vest over the torso and a backpack full of gear on the back. The majority of the load from pulling the fellow Soldier is transferred to the waist, while the biceps also help with adjusting the height of the Soldier off the ground. Pulling the "buddy" higher into the air prevents the "buddy" from receiving damage to the upper body and head when navigating through uneven terrain with obstacles. The WBBS Fabrication Instruction can be found in Appendix 6.4 for a better description of how the subsystem was made. Figure 4 shows our final design of the WBBS.

Figure 4. Final design of the Waist/Bicep Belt System (WBBS)

3.3. Carry Ammo Subsystem

While the team's WBBS design satisfies the requirement to enable one of the tasks, the team also attempted to design a carry ammunition subsystem with multiple versions and tested it on a volunteer. Figure A-10 in Appendix 6.7 shows our carry ammo subsystem put on a volunteer, who is about to perform the serpentine run in a 75-yard course. After testing the first two initial designs, we found that there was not enough time to complete the carry ammunition external system because other revisions would have been necessary to pass all given tests. While we are only able to present a nearly complete design, we would need a design revision and another iteration of testing to combine it with the WBBS to become a full prototype.

4. Design Evaluation

The Design Evaluation section highlights a description of two surrogate arms made for testing, design constraints, and the design requirements for the project. The Surrogate Arms section described the use of two different surrogate arms used in testing and why the arms were used. The design constraints for the prototype were: material limitations, budget, medic kit medical device authorization, COVID-19, and time limitation. These constraints were based on a prescribed material list given by the

project sponsor, a budget provided by the university, how COVID-19 affected the work environment, and the project timeline. The design requirements for this project included: a stabilized fracture, task capability, fabrication time, minimized damage, fabrication instructions, budget, and prevention of extra pain. These requirements were given to the team as a means of ensuring the design would be helpful to and would not hinder a Soldier with a distal radius fracture in the field. In addition, the prototype was designed to be capable of being reproduced by a Field Medic quickly, while using cheap materials within budget. The way in which each design was tested was also an important aspect of design evaluation for the WBBS and Modified Splint.

The test of the WBBS was done in two major testing events, which were the Fabrication Instructions and the Active Buddy Drag, and the entire test structure can be seen in Figure 5. The Fabrication Instructions included the tests for Clarity of Instructions and Minimum Assembly Time and was conducted by allowing a volunteer to recreate the WBBs with written instructions. For the Active Buddy Drag testing event, a dummy or sled was pulled to simulate dragging a human being. The tests included in the Active Buddy Drag event were the Minimum Times for Buddy Drag, a Comfort Questionnaire, and the Maximum Weight Dragged. While these three tests were being taken each run, there were two different kinds of objects that were being dragged. The Dummy Drag Round Tests involved a MMA dummy that weighed 140.5 pounds while the Sled Round Tests involved pulling a sled with varying number of circular weights on top to reach the 250 pound minimum weight assumed to be the average weight of a Soldier in the field with gear. Lastly, there were three different ways the user could drag the buddy. The Healthy drag was performed in a standard way using both arms. The Prototype drag used the WBBS and simulated an “injured” Soldier using the WBBS while the No Prototype drag involved using one arm to pull the dummy across the ground. Note: the reason that the sled round tests only involved the Prototype drag is because the primary purpose of the Sled Round Tests was to reach the 250 pound minimum that the WBBS should have been able to sustain rather than to compare different types of drags.

The test of the Splint Modification was done in four major testing events, which were the Fabrication Instructions, Compression- Applied Pressure, Comfort Questionnaire and Surrogate Arms. Similarly, the entire test setup can be seen in Figure 6. The Fabrication Instructions were identical to the WBBS test event with the Clarity of Instructions and Minimum Assembly Time being included in this test event. The tests involving the Compression- Applied Pressure were the Splint Compression, Range of Motion, and Capillary Refill Test. The Comfort Questionnaire was a separate test to assess the comfort of the splint. Lastly, the Surrogate Arms testing event involved the Bump Test, Twist Test, and WBBS Strap Tug, which involved measuring fracture displacement with a hall effect sensor. All test events except for the Fabrication Instructions involved applying either the Modified Splint or the SAM splint to the arm.

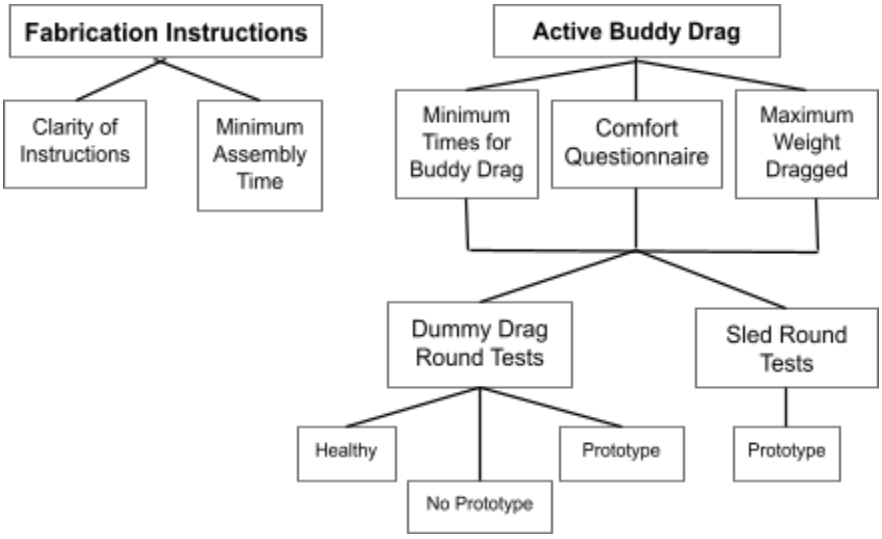


Figure 5. Test structure for WBBS testing along with defined sections

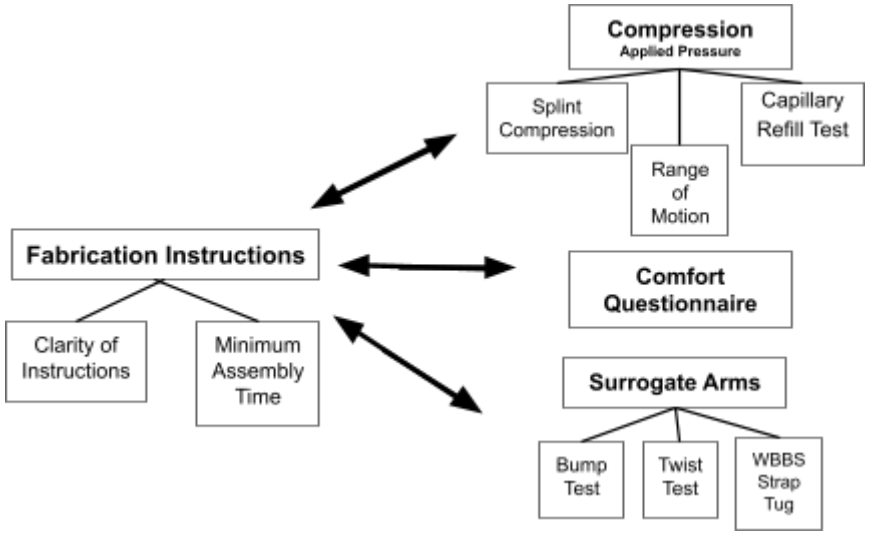


Figure 6. Test structure for Splint Modification testing along with defined sections

4.1. Surrogate Arms

Two surrogate arms were made and used for the purpose of more accurate results. The first surrogate arm was used in the first iteration of tests and the second iteration of the twist and bump test, as shown in section 4.3.1. The second arm was made for the purpose of having a more accurate representation of a pulling motion with the WBBS. The pictures that describe the process of building the surrogate arms can be found in Appendix 6.2. The process involves designing the 3D printed bones for the first surrogate arm (we used a premade arm skeleton for the second surrogate arm), calibrating the hall-effect sensor, and then putting everything together in the mold for pouring silicone.

As shown below in Figure 7, the first surrogate arm is straight compared to the second surrogate arm, shown below in Figure 8. During the first iteration of tests, the first arm was used in the WBBS Strap Tug test, which produced failing results. This was due to the straightened position of the arm putting more strain on the neck brace of the Modified Splint and, therefore, also the fracture site. The design of

the surrogate arm was not ideal because it did not imitate the shape of an arm when the “buddy drag” was being performed and created unnecessary force in an unwanted location because of this shape. For this reason, a second surrogate arm was made for the second iteration of the WBBS Strap Tug test. The testing apparatus with the second arm can be shown in Figure 10, in section 4.3.4.

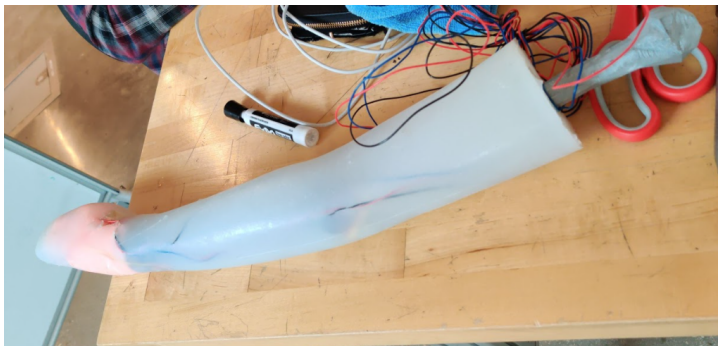


Figure 7. Image of first surrogate arm

Figure 8. Image of second surrogate arm made for the WBBS test

4.2. Design Constraints

4.2.1. Constraint: Material Limitations

The product must contain materials, which can be found in Appendix 6.1, that are commonly available in Field Medic Packs carried by the Field Medical Personnel or by the Soldiers themselves.

4.2.1.1. Evaluation

This constraint did not need to be tested because the fulfillment behind the constraint of material limitations is proven with the prototype design. The specific materials included were straps, a SAM splint, scissors, a neck brace, medical Coban wrap, duct tape, and carabiners. All of these materials used to build the WBBS and Modified Splint can be found in materials commonly carried by Medics or Soldiers themselves. Therefore, our prototype satisfies this constraint.

4.2.2. Constraint: Budget

The cost of the prototype(s) development and evaluation is limited to the $1200 budget provided by Trinity University.

4.2.2.1. Evaluation

This constraint was satisfied since the FIX team did not use more than the $1200 budget provided for this project. A total of $649.12 remains in the budget, so the FIX team used less than half of the allotted budget for the project.

4.2.3. Constraint: Medic Kits Medical Device Authorization

The purchase of larger medic kits through North American Rescue requires a Medical Device Authorization. This kit encompasses most of the materials available in the medic kit, which includes the primary material used for this project.

4.2.3.1. Evaluation

Since the team decided to not purchase any kits from the North American Rescue that required a Medical Device Authorization, this constraint can be disregarded. The FIX team decided that buying materials individually would save money and prevent waste of materials that were not used in the project.

4.2.4. Constraint: COVID-19

The building and testing processes may have been affected by COVID-19 during Fall 2020 and Spring 2021 by limiting on-campus access to students. If work was able to be continued on campus throughout the two semesters, the team would have been able to access the machine and electronics shop for the completion of the prototype build and testing with the help of relevant staff members. If work could not be continued on campus due to COVID-19 restrictions, the team was going to contact relevant staff at the machine and electronics shop for assistance in completing the prototype build and testing with minor assistance from the team advisor.

4.2.4.1. Evaluation

The team was allowed to stay on campus for Fall 2020 and Spring 2021, but there were limited building hours. Progress was not affected by COVID-19 regarding access to on-campus resources and the limited building hours; therefore, this constraint did not affect the project in a major way.

4.2.5. Constraint: Time Limitation

The time allotted for the project is limited to the Fall 2020 and Spring 2021 school semesters.

4.2.5.1. Evaluation

This constraint was upheld since the project was completed within the allotted time. The FIX team was able to complete the project by designing, building, and testing a prototype that satisfied the Sponsor's specifications within the Fall 2020 and Spring 2021 school semesters.

4.3. Design Requirements

4.3.1. Requirement: Stabilized Fracture

For a distal radius fracture, the limb should be stabilized and movement should be minimized in a way that is comparable to a SAM splint.

4.3.1.1. Associated Tests

The associated tests with this requirement are:

- Splinting Maximum Fracture Displacement: This test determined if unintentional loads or different forearm movements affected the distal radius fracture site when the splint subsystem was applied to a surrogate arm. Comparisons between the standard of care SAM splint and the Modified Splint subsystem were made to prove that the new splint was an improvement of the standard of care.
    - Twist Test - A load that was up to 5 pounds was applied to the surrogate arm pinky and thumb to simulate a twisting motion of the wrist.
    - Bump Test - A load of up to 10 lbf was suddenly applied to the tips of the surrogate arm fingers to simulate a "bump" on a surface while wearing a splint.

Objectives:

The objectives associated with this test included:

1. Determining whether the splint subsystem would minimize any further damage to the fracture site.
2. Proving that the splint subsystem was an improvement to the current standard of care by showing that maximum fracture displacement, or damage, was reduced or equal to the standard of care's fracture displacement.

Feature(s) Evaluated:

This test evaluated:

1. Prevention of Fracture Movement: This test determined the efficacy of the splint by introducing unintentional loads onto the surrogate arm and measuring the resultant displacement of the fracture. Such loads included twisting and/or pulling on the hand and sudden forces or "bumps'' that may occur. A comparison between the standard of care and Modified Splint subsystem was made from these measurements.

Test Scope:

The test with only the splint subsystem was simulated at various unintentional loads that a Soldier might encounter in the field. These loads included bumping into the fingers at up to 10 lbf, accidentally bending or twisting the wrist up to 5 pounds of force. This environment will be tested on the surrogate arm by a testing apparatus that uses clamps and applies a compressive sudden force of a falling weight or adding loads to certain parts of the surrogate arm to create twisting or bending movements similar to a real arm. For more descriptive information, refer to Figure 9 and 10 of our set up.

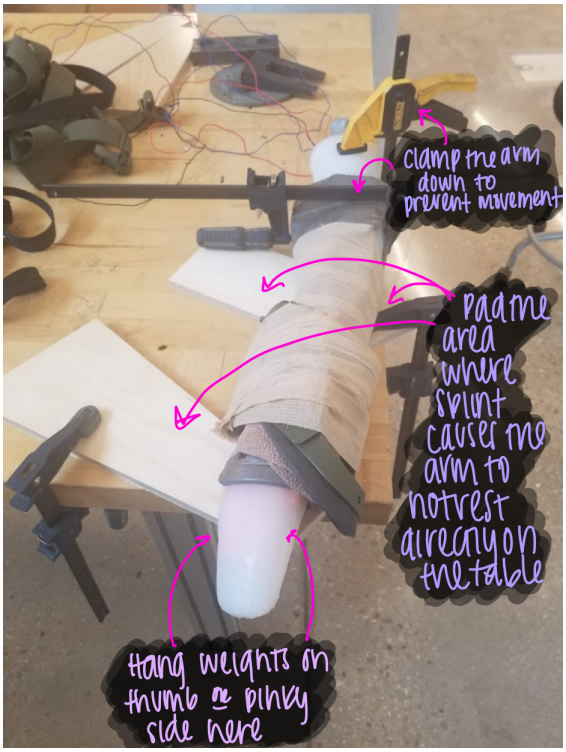


Figure 9. Twist Test Setup

Test Plan:

This test was conducted on a surrogate arm built by the FIX team, and the splint subsystem was applied to the surrogate arm. The surrogate arm distal radius fracture was made of 3D printed bones, as seen in Figures A-1, A-2, and A-3 in Section 6.2 of the Appendix, and covered in silicone in the shape of an arm mold. To measure the distance between the two pieces of bone at the fracture site, a hall effect sensor and magnet were attached to the printed bones at the fracture site. The sensor was calibrated to measure a displacement between 0.2 and 1 inch using an Arduino Uno, and changes in displacement are the measurements taken in the tests. Since the initial distance within the fracture site, measured in between the two bone pieces starts around 0.6 inches, there is a good margin of change that can occur between these points to measure to. A displacement change greater than 0.4 inches would indicate that the displacement is out of the range of the calibration curve, and the test would need to be redone.

There were several assumptions made in the test plan. Since the hall effect sensor had been calibrated and tested in ballistics gel prior to measurement, the FIX team assumed that the measurements were still accurate in the silicone of the surrogate arm and that a change in displacement of greater than 10% from that of the SAM splint is a failing result and required a redesign of the test setup or subsystem. If the FIX team's fracture displacement was within 10% greater than or less than the displacement of standard of care, the Modified Splint was considered an improvement or an equivalent replacement. In addition, the team assumed a surrogate arm was comparable to a real human arm and that the tests would adequately simulate human skeletal movement. The overall collected data included change in distance measurements for displacement within the distal radius fracture site using the hall effect sensors.

For the bump test, the team used a pulley system and fixed the surrogate arm inside of a circular tube under the pulley (Figure 10). The force is calculated based on the assumption that the gravitational potential energy of the falling weight is transferred into the work done on the surrogate arm (Eq. 1 -

Principal of work and energy). A weight would be dropped and hit the arm at the tip of the hand. The weight used was 1 lb (0.45kg) (m), dropped at a height of 4 inches (0.10m) (h), and we assumed that the distance the weight would travel after impact (into the silicone gel) to be 0.01 m (d). This assumption is based on the fact that we tried pushing the weight against the silicone hand reasonably around 10 lbf and it would deform about 1 cm (0.01 m) inwards. This would theoretically result in an average force of 10 lbf (44N) (F) to the hand during impact. This force value is an acceptable estimation but not perfect since the weight would not come to rest on the arm after impact.

$$W = mgh = Fd \Rightarrow F = \frac{mgh}{d} \quad (1)$$

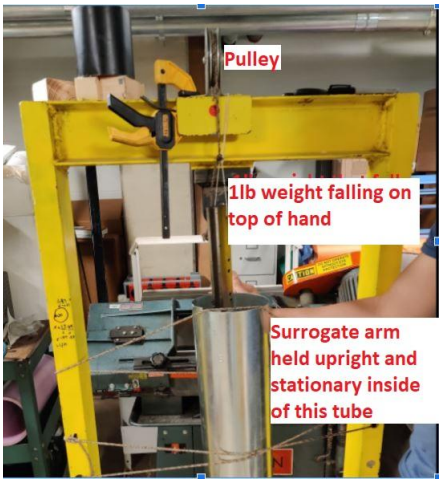


Figure 10. Bump Test Setup

Acceptance Criteria:

The splint subsystem would be considered a good replacement if the distal radius fracture site displacement change was less than +10% of the standard SAM splint. In other words, a failing result would be a value above 10% of the measured value of the maximum displacement for the SAM splint. If the fracture displacement change was less than standard SAM splint, the splint modification subsystem would be considered an improvement upon the SAM splint. A displacement above 10% of the SAM splint's displacement would be considered a failing result.

4.3.1.2. Tests Results

In Tables 1, 2, and 5, a negative value for maximum fracture displacement represents when the fracture was pushed closer together while a positive number referred to the fracture moving farther apart. A percent difference below 10% was considered passing, since a percent difference above 10% indicated that the fracture moved farther apart or closer together than the standard SAM splint did by a significant margin. More displacement corresponded to more pain and damage when defining a desirable and undesirable result for these measurements. Negative percent differences were acceptable because less displacement in the fracture site pieces was considered more ideal. All percent differences were calculated using Eq. 2.

$$Percent\ Difference = \frac{|Modified| - |SAM|}{|SAM|} * 100 \quad (2)$$

For the twist test results, the average maximum displacement was smaller for the Modified Splint compared to the SAM splint for all weights applied to both sides of the surrogate arm. The SAM

splint had an average maximum displacement on the pinky side of 0.095 in and -0.016 in on the thumb side when 5 pounds were attached. For the Modified Splint, the average maximum displacement on the pinky side when 5 pounds were attached was 0.0089 inches, where the fracture was pushed closer together.

Table 1. Fracture Displacement for the Twist Test

	SAM Splint (in)	Modified Splint (in)	Percent Difference (%)
1.5 pounds - Thumb side	-0.014	-0.011	-23.2
3 pounds - Thumb side	-0.026	-0.013	-51.4
5 pounds - Thumb side	-0.016	-0.0087	-46.5
1.5 pounds - Pinky side	0.023	-0.0071	-131.5
3 pounds - Pinky side	0.034	-0.0055	-116.3
5 pounds - Pinky side	0.095	-0.0089	-109.4

For the bump test results, the drop was measured for the SAM splint and the splint modification, shown in Table 2. The average maximum displacement of the Modified Splint was 3.5% less than the standard SAM splint displacement.

Table 2. Average Fracture Displacement for the Bump Test

	SAM Splint (in)	Modified Splint (in)	Percent Difference (%)
Average	0.042	0.040	-3.5

4.3.1.3. Evaluation

For the twist test, the SAM splint overall displayed slightly higher values of displacement that pushed the fracture apart when the weights were attached on the pinky side. This could be due to the location of the fracture site. The fracture is on the thumb side of the wrist and when the weights pulled down on the pinky side, the hand rotated to the left, which caused the fracture to spread apart instead of being pushed together. When comparing all of the tests, the Modified Splint resulted in a smaller displacement compared to the SAM splint, which means that the Modified Splint design was an improvement over the standard of care at preventing fracture movement when the same forces were applied.

For the bump test, the percent difference was a reliable result since the drops occurred at relatively the same position on the hand and were repeated three times for an average value in both cases. This shows that our modification resulted in better protection for the fracture compared to the SAM splint. Granted, the bump test apparatus is not perfectly designed so the weight did not stick to the hand after impact, and also our assumption that the distance traveled after impact by the weight could be incorrect. Regardless of the force applied, the data we gathered confirmed that the Modified Splint was better than the standard SAM splint in terms of minimizing displacement of the fracture in the bump test.

Overall, Tables 1 and 2 show that all of the trials successfully met our criteria of reducing fracture movement compared to the Standard SAM splint and can be deemed as successful. Both of these tests prove that this requirement was satisfied. The minimized fracture displacement seen in the surrogate

arm when the Modified Splint was applied compared to the SAM splint demonstrated that the limb can be stabilized and movement should be minimized in the field.

4.3.2. Requirement: Task Capability

The splint should allow the patient to perform one or more of the following tasks: shooting a firearm, carrying ammunition, and a "buddy drag".

4.3.2.1. Associated Tests

The associated test with this requirement is:

- Buddy Drag: A "buddy drag" was performed for this test at various weights to simulate a "buddy" being dragged across 10 yards. This test was used to confirm that the WBBS subsystem would not hurt the user and still allowed the user to simulate dragging a buddy.

Objectives:

The objectives associated with this test included:

1. Verifying that the WBBS subsystem did not significantly hinder the injured user's ability to accomplish a "buddy drag" that is 10 yards compared to a healthy user.
2. Ensuring that the subsystem is not painful or does not cause any discomfort to the user.

Feature(s) Evaluated:

This test evaluated two key features:

- Navigation time: The amount of time it takes to pull a buddy 10 yards. A comparison to a healthy person, a person with a SAM splint without the external system, and a person with a SAM splint with the external system can be made.
- Weight in pounds that can be dragged: The amount of weight that can be attached to the waist/belt/back dragging component and pulled successfully.

Test Scope:

This test assumed that the average weight of a Soldier in the field is approximately 250 pounds and consisted of a volunteer dragging weight that varied from around 140 pounds to 300 pounds across 10 yards to simulate a "buddy drag" in the field. This test compared the "buddy drag" where the volunteer performs a healthy scenario, a scenario with a SAM splint without the external WBBS system, and a scenario with a SAM splint with the external WBBS system. For this test, the splint subsystem was assumed to function similarly to a regular SAM splint and was not tested with the external subsystem.

Test Plan:

In all three scenarios, the "buddy drag" was performed across the same 10 yards. The volunteer also wore the standard of care SAM splint while conducting the "buddy drag." With a scale in the Makerspace, a human-like dummy was filled with sand and weighed to ensure that it was adequate to simulate a "buddy." A stopwatch was used to time the volunteer while they dragged the buddy in the three different scenarios. The first test situation, which can be denoted as "Healthy", was a healthy scenario where the volunteer was able to drag the buddy with both hands normally. The second test situation, which is denoted as "No Prototype", was an "injured" scenario where the volunteer dragged

the buddy without the help of the external system, while the arm was splinted with a standard SAM splint. The third test scenario, which is denoted as “Prototype”, was another “injured” situation, but the volunteer used the WBBS to perform the “buddy drag”, while the arm was splinting with a standard SAM splint. It is important to note that the Institutional Review Board (IRB) decided that this test did not constitute any research and therefore did not require any IRB approval.

Acceptance Criteria:

The WBBS buddy drag was considered successful if the time to drag a buddy in the fully “injured” scenario did not exceed 15 seconds past the time taken for the “healthy” scenario. The system would be redesigned if the user was unable to maneuver quickly enough to meet the time constraint.

Tests Results:

During the Active Buddy Drag testing events, there were 6 rounds of testing conducted. The Dummy Drag rounds included the user wearing a backpack that had a weight of 17.5 pounds in Round 1 and 38.8 pounds in Round 2 and involved dragging a 140.5 pound dummy that was used as a replacement for a human being. All weights listed for their corresponding test are in Table 4. The dummy was the weight and size of a small human being rather than equivalent to an average Soldier, which could be a limitation to the test conducted. An MMA dummy made of fabric that is stitched together was filled with sand to add weight. These first two rounds tested three relevant scenarios for comparison, which were the Healthy, No Prototype, and Prototype scenarios. The purpose of these selections were to test a “healthy” or normal “buddy drag” compared to an injured buddy drag and an injured buddy drag improved by the external subsystem we fabricated. In Table 3, the minimum time it took the volunteer to perform an injured buddy drag with or without the prototype in the Round 1 tests were similar. The Healthy buddy drag had a minimum time of 5 seconds. In Round 2, there was a clearer difference between the Prototype and No Prototype tests. The No Prototype test took one second longer than the test run with the WBBS.

The Sled Round tests used a sled that weighed 27.25 pounds with added 45 pound circular powerlifting weights that incremented upward in weight. The Sled Round 2 test used 3 extra 45 pound circular weights and 45 pounds was added in each round with 6 circular weights being added in the sixth round. These rounds only tested the WBBS with a SAM splint on the volunteer. The amount of time for the Sled Round 1 tests was 1 second longer than the Dummy Drag Round 2 test of the “buddy drag” using the dummy.

Table 3: Minimum times (sec) for pulling a dummy with a backpack and pulling a sled

	Injured with Prototype	**Injured without Prototype**	**Healthy**
Dummy Drag Round 1 Tests Times (sec)	6	6	5
Dummy Drag Round 2 Tests Times (sec)	5	7	4
Sled Round 1 Test Times (sec)	6	-	-
Sled Round 2 Test Times (sec)	6	-	-
Sled Round 3 Test Times (sec)	7	-	-
Sled Round 4 Test Times (sec)	7	-	-

Table 4: Weight in pounds of objects used in each round of testing

	Backpack (lbs)	Dummy (lbs)	Dragging Sled (lbs)	Extra Weight (lbs)	Total Weight (lbs)
Dummy Drag Round 1 Test	17.5	140.5	0	0	140.5
Dummy Drag Round 2 Test	38.8	140.5	0	0	140.5
Sled Round 1 Test	38.8	0	27.25	135	162.25
Sled Round 2 Test	38.8	0	27.25	180	207.25
Sled Round 3 Test	38.8	0	27.25	225	252.25
Sled Round 4 Test	38.8	0	27.25	270	297.25

4.3.2.2. Evaluation

The timed results in the Dummy Drag Round 1 consisted of similar times across the three scenarios, which implies that the WBBS enabled our volunteer to perform almost as well as in the healthy scenario. As mentioned above, No Prototype test in Round 2 took one second longer than the test run with the WBBS, which suggests that the WBBS made the "buddy drag" more easy for the volunteer when more weight was added to the backpack.

Since the sled and circular weights were heavier than the dummy, the time results for the Sled Round tests, which were longer than the Dummy Drag Round tests in Table 3, are reasonable. There was not much of a difference in the times recorded for the injured buddy drag with the WBBS in the Sled Round 1 and 2 tests. The last two rounds of testing took longer than the Round 1 and 2 tests, which are consistent with dragging the sled becoming more difficult as weight increased. Since all times were under 10 seconds and had a range of 3 seconds, the "buddy drag" did not take a significant amount of time to perform. The slowest time occurred during the No Prototype test of the Dummy Drag Round testing, which implied that this would be the most difficult to accomplish and the kind of drag that would put the "buddy" in the most danger. The Prototype test was slower than the Healthy test but faster than the No Prototype test, except for the tests in Round 1. This discrepancy could be due to the fact that the backpack did not affect the user as much during the first round of testing. Since the Prototype test was mostly faster than the No Prototype test, the external system would produce a more effective buddy drag than the produced without the external system for a soldier with a distal radius fracture.

Overall, the "buddy drag" test on the WBBS was considered successful since the time and weight acceptance criteria were reached. This requirement can therefore be considered met because this test proved that a Soldier is able to perform at least one of the listed tasks using our design.

4.3.3 Requirement: Fabrication Time

The device should be able to be fabricated in 15 minutes or less, similarly to previous lower extremity devices.

4.3.3.1 Associated Tests

The associated tests with this requirement are:

- Subsystem Assembly: This test (run separately on each subsystem) helped determine whether the assembly instructions of the Waist/Back/Belt subsystem and Modified Splint subsystem were simple and easy to understand to ensure Combat Medics in the field could assemble it.

Objectives:

The objectives associated with this test included:

1. Creating straightforward and easily understood assembly instructions.
2. Confirming that the assembly time can be accomplished in under 7.5 minutes for each subsystem.

Feature(s) Evaluated:

This test evaluated:

- Clarity of fabrication instructions: The volunteer was asked for their feedback on the instructions and any improvements that could be made to the instructions.
- Assembly time: A record of how long it took a volunteer that was not on the FIX team to assemble the prototype was also recorded.

Test Scope:

This test was performed by a volunteer (not in the FIX team) to ensure that the instructions were clear to those not familiar with the assembly. The instructions included pictures of the subsystem at each step of the assembly process accompanied by a typed description of the step. The volunteer was asked to provide feedback on the instructions as a way of ensuring that the instructions were clear and understandable or to identify necessary changes to the instructions.

Test Plan:

An individual not on the FIX team was asked to assemble each subsystem by following the instructions without outside guidance from the team. The volunteer was given 2 minutes before they began assembling to look at the assembly instructions since a Combat Medic would be already trained to apply the system, not seeing the instructions for the first time. A video recording was used to time each assembling process by the volunteer to determine the assembly time of the subsystems using the instructions. The quality of the subsystem built by the volunteers was compared to one built by a FIX team member by comparing how similar the two versions of the products were to each other. The Modified Splint instructions are shown in the Appendix Section 6.3. The WBBS instructions can be found in the Appendix Section 6.4.

Acceptance Criteria:

The assembly time of the WBBS and Modified Splint subsystem must each be under 7.5 minutes to be considered successful. Furthermore, all feedback on improvements must be resolved and the quality of the volunteer's subsystem must be comparable to that of a subsystem made by the FIX team by ensuring that all necessary components in the subsystem were correctly attached and made properly.

4.3.3.2 Tests Results

The WBBS successfully passed in the Fall Semester without requiring any revisions to the instructions where the recorded time was 2 minutes and 40 seconds. The Modified Splint failed in the first iteration of testing with a recorded time of 13 minutes and 40 seconds, which is past the 7.5 minutes allocated for fabrication. The Modified Splint Instructions were revised using the feedback that was given in the first iteration of testing. The use of Coban wrap was used in place of straps or duct tape because the method of application was more clear to the participants and quicker to apply. Better visual aid pictures were taken and attached to the final instructions that helped improve the quality of the instructions. These visual aids were taken based on feedback that the original visual aids were not very clear in some manner.

Using the final revised instructions, shown in the Appendix Section 6.3, the fabrication of the Modified Splint was retested. The recorded fabrication time was 6 minutes and 30 seconds, respectively. This was below the 7.5 minute maximum that was required for each. The resulting prototype was determined to be correctly assembled when the FIX team member that the volunteer applied the modified splint reported no discomfort or pain. The neckbrace was also stabilized correctly with enough Coban wrap to make sure that it was applying enough compression to the arm without being too tight or loose. In addition, feedback was taken from the volunteers that helped to improve the clarity of the instructions, with pictures being more helpful than words and different materials reducing fabrication time.

4.3.3.3 Evaluation

Both the WBBS and the Modified Splint were under the 7.5 minutes mentioned in the acceptance criteria, which means that both tests were successful. The total time for fabrication was 9 minutes and 10 seconds, which is under our overall assembly time of 15 minutes. Since both assembly tests were successful and all feedback about improvements of the instruction was resolved, the fabrication time and clarity of instructions requirement was therefore met.

4.3.4 Requirement: Minimize Damage

The device should improve upon current radial fracture methods by allowing the Soldier to accomplish certain tasks without any further damage to the distal radius fracture.

4.3.4.1 Associated Tests

The associated test with this requirement is:

- External System Maximum Fracture Displacement: This test evaluated whether the loads from the Waist/Biceps Belt System would each affect the fracture when the splint subsystem was applied.

Objectives:

The objectives associated with this test included:

1. Determining whether each external subsystem would minimize any further damage to the fracture site.

Feature(s) Evaluated:

This test evaluated:

1. WBBS Strap Tug - Maximum Fracture Displacement: This test focused on recreating the "buddy drag" pull on the surrogate arm based on the loads applied while using the WBBS and would determine the effect of the WBBS subsystem on the displacement of the broken bone segments at the fracture site.

Test Scope:

For this test we only used half the weight of a Soldier because only one arm was being tested instead of two. Therefore, the WBBS and splint subsystem were conducted using two 50 pound weights for a test of 50 and 100 pounds force, which adds up to nearly half of the weight of a soldier. Using 50 pound weights was the most convenient weight available to us. If the surrogate arm had been damaged at 50 pounds, the arm would not have been tested at 100 pounds.

Test Plan:

The test setup, shown in Figure 11, focused on placing the surrogate arm in a position similar to where it was in the "buddy drag" test with the volunteer. The other side of the arm was stabilized using tape and clamps. When performing the test procedure, a strap was placed around the arm and one or two 50 weights were attached underneath the arm with the strap. A very slow release of the weights was done to ensure there was no jerky movement in the arm that could cause anything to break. The test setup is shown below in Figure 11, where the weights applied are denoted by the arrow in the image. In addition, the assumptions included that: measurements were accurate in the surrogate arm, a displacement 10% greater than the standard SAM splint would be a failing result, the surrogate arm was comparable to a real human arm, and the tests would adequately simulate human movement. The data included the maximum fracture displacement using the hall effect sensors. A second surrogate arm was made specifically for the purpose of having a more accurate representation of a pulling motion with the WBBS in this test. This arm was calibrated to measure between 0.04 and 0.24 inch with a starting measurement around 0.1 inch with a displacement change greater than 0.1 inch being out of range of the calibration curve, and the test would need to be redone.

Figure 11. WBBS Test Setup with Second Surrogate Arm

Acceptance Criteria:

The WBBS will be validated if the distal radius fracture site is either not affected or minimally affected by the loads applied compared to the current standard of splinting care. A displacement above 0.4 inches or a displacement of the FIX team's splint being 10% higher than the standard of care will be considered a failing result.

4.3.4.2 Tests Results

The results for the WBBS maximum fracture displacement are shown in Table 5. As mentioned before, a negative displacement value denotes a maximum fracture displacement where the fracture was pushed closer together while a positive number referred to the fracture moving farther apart. A weight of 50 pounds and 100 pounds was taken, but the manner in which the 50 pounds and 100 pounds was placed on the arm could have created a difference in the positive and negative displacement. The 100 pounds consisted of two 50 pound weights placed to the sides of the arm while the 50 pound weight was placed directly underneath the arm. A possible explanation for the difference in positive and negative displacement could also be that the greater weight caused the sloped surface of the test apparatus to push the hand together more than the 50 pound weight. The 50 pound weight may have just pulled the arm down rather than pushing the top of the arm together.

Table 5. Fracture Displacement for the WBBS Strap Tug Test

	SAM Splint (in)	Modified Splint (in)	Percent Difference (%)
50 lbs	0.0081	0.0048	-40.8
100 lbs	-0.0011	-0.0011	0

4.3.4.3 Evaluation

The Modified Splint and SAM splint had a percent difference of -40.8% for 50 pounds, which means that the SAM splint caused a larger fracture displacement to occur in the surrogate arm compared to the Modified Splint. The 100 pound test had 0% difference between the two splints applied. Since the fracture displacement was smaller with the Modified Splint applied at 50 lbs, this test is considered successful. However, it is notable to comment on the fact that the effect of the splints were negligible compared to the effect of the weight on the arm at higher weights because the absolute value of the displacement was much less than the values at 50 lbs. The fracture displacement values for the Modified Splint and SAM splint were negligible and even decreased an order of magnitude compared to the overall Twist and Bump tests despite the increase in weight; this result is understandable since the weight applied for the WBBS Strap Tug test was applied to the biceps, while the weight in the Bump and Twist tests were applied at the forearm. Therefore, there was minimal effect on the displacement of the fracture for both splints while performing the "buddy drag", and the requirement for minimal damage was met.

4.3.5 Requirement: Fabrication Instructions

Instructions for both the fabrication of the FIX device, which includes the WBBS and Modified Splint, and use of the device should be provided to allow for easy, understandable, and timely use of the device.

4.3.5.1 Associated Tests

The associated tests with this requirement are:

- Clarity of WBBS Fabrication Instructions
- Clarity of Splint Modification Fabrication Instructions

The Fabrication Assembly test for both the WBBS and Splint Modification was previously defined and explained in Section 4.3.3.1.

4.3.5.2 Tests Results

For the WBBS fabrication instructions, the volunteer stated that the instructions were "pretty clear" except for step 4 in the instructions shown in Appendix Section 6.3, since the idea of getting the buckle through the carabiner was a little confusing. In addition, since there was not a buddy to attach the system, the volunteer was confused about when the system was considered complete. A FIX team member explained that there would be a backpack and person to test on in a real scenario that was not available at the time, so the test was considered complete at that point.

A different volunteer applied the Modified Splint onto a member of the FIX team. The volunteer stated that the C-curve in step 1, shown in Appendix Section 6.4, should be clarified better and that adjusting the neck brace took him a bit but eventually understood how to do it. Overall, the volunteer mentioned that the instructions were clear and easy to follow.

4.3.5.3 Evaluation

Both the WBBS and the Modified Splint were completed correctly without the direction from the

FIX team member the system or splint was being applied to. For the Modified Splint, it is important to note that although the C-curve and adjusting the neck brace were a bit confusing for the volunteer, these are steps that a trained Combat Medic would already know. Since there were no obvious errors or large issues with the directions, both sets of instructions were clear.

Since both assembly tests were successful, this requirement for fabrication instructions was met.

4.3.6 Requirement: Budget: addressed in section 4.1.2

4.3.7 Adjustable Device

The prototype should be adjustable and adhere well to the individual's physical dimensions for maximum stabilization.

4.3.7.1 Evaluation

This requirement did not need to be tested since the assembly instructions for both the WBBS and Modified Splint have the same level adjustability and can adhere to the individual's physical dimensions. In addition, the prototypes were applied to two different FIX team members' arms as well as two volunteers. The WBBS is made of straps, which can be changed in length to better suit the Soldier. The Modified Splint is made of a SAM Splint and neck brace; the SAM splint can be trimmed to the length of the Soldier's arm, and the neck brace can be lengthened or shortened depending on the individual.

4.3.8 Requirement: Splint Pressure Application

The prototype should be able to apply enough pressure to immobilize the injury with enough room for swelling.

4.3.8.1 Associated Tests

The associated tests with this requirement are:

- Pressure Test
- Range of Motion Test
- Capillary Refill Test

Splint System Compression: This test determined whether the splint subsystem is effective in applying enough compression to treat the swelling of an arm with a distal radius fracture.

Objectives:

The objectives associated with this test included:

1. Demonstrating that the Modified Splint was able to compress the arm within +/- 10% of the pressure applied by the standard of care splint.
2. Quantifying the range of motion associated with the splint subsystem compared to the standard care of splinting.
3. Assessing the blood flow in the patient's arm after the Modified Splint has been applied.

Feature(s) Evaluated:

This test evaluated:

- Compression of Splint: This feature determined the amount of compression the splint is able to apply compared to the standard care of splinting.
- Range of Motion: Movement of the wrist should have been minimized in a way that was comparable to a SAM splint when performing certain activities.
- Capillary Refill: The amount of blood flow to the arm should remain consistent when the Modified Splint is applied compared to no splint.

Test Scope:

This test was conducted by applying both the Modified Splint and SAM Splint on a FIX team member. The calibration of the pressure sensors was limited to the range of 100 grams to 10 kilograms. The FIX team member did not have a distal radius fracture, which was a limitation of the test. Another limitation was that the pressure of each splint varied depending on the individual applying the splint.

Test Plan:

The Modified Splint was built by FIX team members and applied to one of the team members. The member was asked to move their wrist with the Modified SAM splint and the standard SAM splint to determine the range of motion that was possible. The motions that the volunteer was asked to perform were similar to wrist rehabilitation exercises shown below in Figure 12 and 13. A protractor was used to measure the angle of movement available with each respective splint. Pressure sensors from SparkFun (Manufacturer #: SEN-09376) were also placed on the team member's arm under each splint to determine the amount of force each splint applied. Figure 13 and 14 in section 4.2.8.2 illustrates locations of where the pressure sensors were placed. The pressure sensors were read and calibrated using an Arduino UNO and applied with a splint over the arm using plastic wrap. Since the pressure corresponding to each splint could be dependent on the individual applying the splint, two members of the FIX team applied the Modified Splint and SAM splint to another FIX team member. By doing so, the comparison between the pressure experienced from the splint subsystem and standard of care splinting could be seen. After the volunteer has been wearing the splint for 15 minutes, a FIX team member conducted a capillary refill test by noting the time that color returns to the fingertips after a small amount of pressure has been applied.

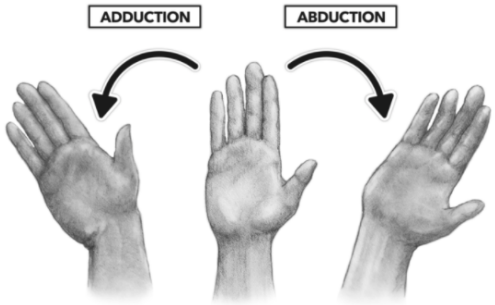


Figure 12. Wrist Abduction/Adduction [1]

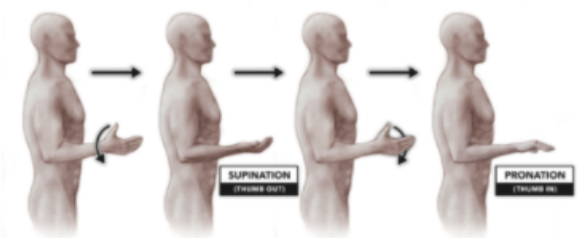


Figure 13. Elbow Supination/Pronation [2]

These tests quantified the range of motion and pressure applied to determine whether the splint subsystem was effective in applying compression to the injury compared to the standard of care.

Acceptance Criteria:

The Modified Splint was considered successful as long as the range of motion for the splint subsystem was at least 10% less than the SAM Splint, if the pressure applied to the surrogate arm by the Modified Splint was no more than 10% lower than the SAM splint, and if the capillary refill time was less than 3 seconds. The capillary refill time of less than 3 seconds was chosen since normal capillary refill time is 2 seconds or less, and anything greater than 3 seconds increases the likelihood of a decrease in health for the patient [3].

4.3.8.2 Tests Results

Both the standard SAM splint and the Modified Splint were applied to the arm of a FIX team member by two FIX team members. There were three trials conducted in total for the pressure sensor compression test. For all trials, the pressure sensors were placed on the FIX team member's left arm for the splint compression test, as shown in Figure 14 and 15.

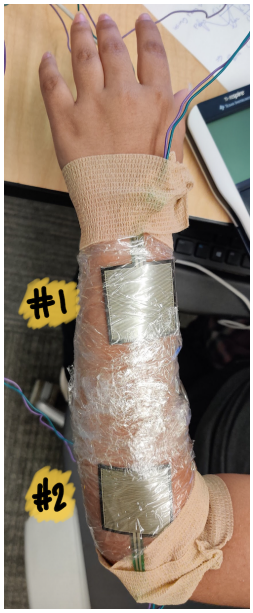


Figure 14. Pressure sensor arrangement on the top side of a FIX team member's left arm.

Figure 15. Pressure sensor arrangement on the bottom side of a FIX team member's left arm.

Figure 16 below presents the data from Trial #1 applied by FIX team member #1, where each pressure sensor corresponds to each numbered sensor seen in the previous figure. Table 6 presents the percent difference between the SAM Splint and Modified Splint for each pressure sensor in Trial #1; since a larger compression by the Modified Splint is preferred, a positive percent difference means that the Modified Splint compresses more than the SAM Splint, and vice versa.

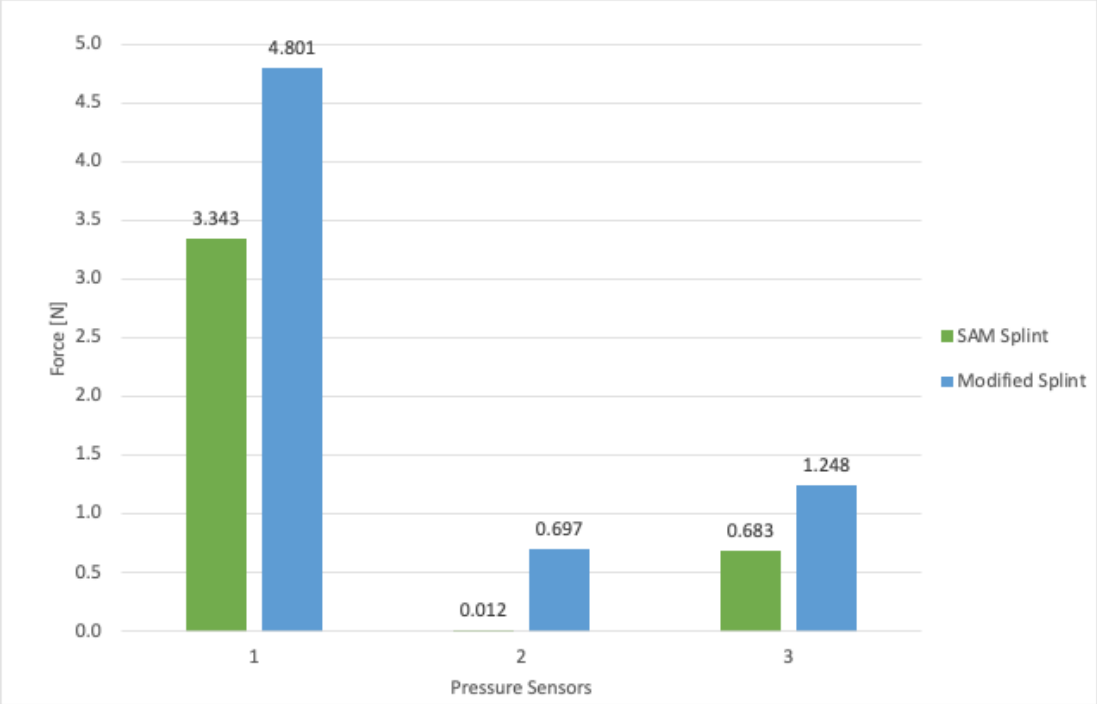


Figure 16. Average force measured by each pressure sensor in Trial #1 by FIX team member #1.

Table 6. Average percent increase in pressure applied by the Modified Splint applied in Trial #2 by FIX Team Member #1, as compared to the standard splint.

Trial #1	FIX Team Member #1
Percent Difference of Sensor #1 [%]	43.60%
Percent Difference of Sensor #2 [%]	5545.12%
Percent Difference of Sensor #3 [%]	82.81%

For all three pressure sensors during Trial #1, the pressure measured with the Modified Splint was greater than the pressure measured with the SAM splint. Furthermore, the capillary refill test was performed 15 minutes after the Modified Splint was applied, and the time taken for color to return to the fingertip was less than 3 seconds.

For the second and third trials, the splints were applied by FIX team member #2. The difference between the trials is that the SAM splint was re-applied for Trial #3 to demonstrate the variability that can typically be seen in the standard care of splinting in the first place. Figure 17 below presents the averaged data from Trials #2 and #3, where each pressure sensor corresponds to each numbered sensor seen in the previous figure. Tables 7 and 8 present the average percent difference between the SAM Splint and Modified Splint for each pressure sensor in Trials #2 and #3.

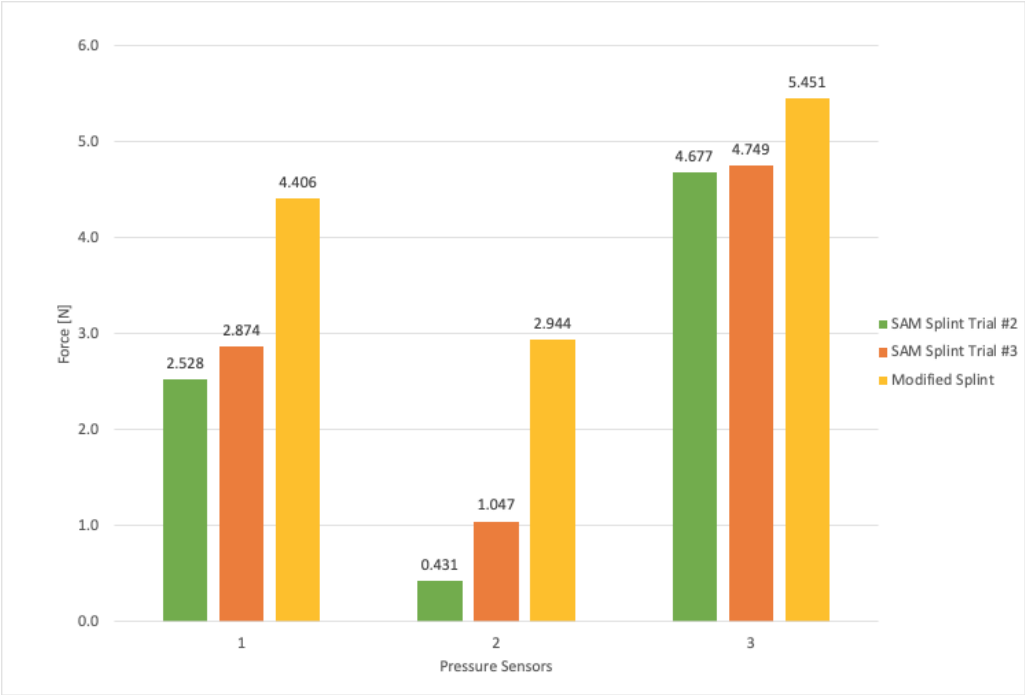


Figure 17. Average force measured by each pressure sensor in Trials #2 and #3 by FIX team member #2.

For all three pressure sensors during Trials #2 and #3, the pressure measured with the Modified Splint was greater than the pressure measured with the SAM splint. The SAM Splint was re-applied in Trial #3 and resulted in a decrease in the percent differences between the two splinting methods. Furthermore, the capillary refill test was again performed 15 minutes after the Modified Splint was applied, and the time taken for color to return to the fingertip was less than 3 seconds.

Table 7. Average percent increase in pressure applied by the Modified Splint applied in Trial #2 by FIX Team Member #2, as compared to the standard splint.

Trial #2	FIX Team Member #2
Percent Difference of Sensor #1 [%]	74.33%
Percent Difference of Sensor #2 [%]	583.35%
Percent Difference of Sensor #3 [%]	16.55%

Table 8. Average percent increase in pressure applied by the Modified Splint applied in Trial #3 by FIX Team Member #2, as compared to the standard splint.

Trial #3	FIX Team Member #2
Percent Difference of Sensor #1 [%]	53.31%
Percent Difference of Sensor #2 [%]	181.28%
Percent Difference of Sensor #3 [%]	14.80%

Afterwards, the FIX team member was also asked to perform a range of motion tests for each splint applied by the two FIX team members. The two gestures the volunteer was asked to perform included a wrist ab/adduction and an elbow pronation/supination, which were shown in Figures 11 and 12 above. The wrist ab/adduction involved motioning the hand like a wave from left to right with a flat palm, and the elbow pronation/supination involved rotating the hand. The range of motion found in the wrist ab/adduction case was measured with the 90° angle of the protractor right under the middle finger of the team member and rotating right and left from there. The range of motion found in the elbow pronation/supination case was measured with the protractor perpendicular to the tip of the fingers, where the 90° angle of the protractor was right above the finger tips and aligned with the thumb; the team member then rotates right and left from there.

The range of motion for each action can be seen in Table 9 below. The Range of Motion represents the total change in degrees the FIX team member was able to perform when splinted. The percent difference is the percent difference between the Modified Splint and SAM Splint; since a smaller range of degrees is desired for the Modified Splint, a negative percent difference would mean that the Modified Splint is more effective in restricting motion compared to the SAM Splint.

Table 9. Range of motion comparison of splints.

Range of Motion		FIX Team Member #1		FIX Team Member #2	
		SAM Splint	Modified Splint	SAM Splint	Modified Splint
Wrist Ab / Adduction	**Range of Motion [degrees]**	60	45	24	10
	Percent Difference [%]	-25.00%		-58.33%	
Elbow Pronation/Supination	**Range of Motion [degrees]**	30	15	20	13
	Percent Difference [%]	-50.00%		-35.00%	

The percent difference for both motions and applied by both FIX team members show that the Modified Splint was able to restrict the motion at least 10% more than SAM Splint.

4.3.8.3 Evaluation

The force applied in Trial #1 to #3 demonstrated that the Modified Splint was able to compress more than the SAM Splint at all three pressure sensor locations. All of the percent differences shown in Table 7 to 9 are positive values, which demonstrate that the Modified Splint was able to compress more than the SAM Splint by in all three trials. As mentioned, the capillary refill test resulted in a return of color to the fingertips under 3 seconds, revealing that the Modified Splint did not cut off blood flow in the arm, which would have suggested that the increased compression was too much.

An important note to make is that the pressure applied by both FIX team members across the three trials had different variations in pressure results. This difference is most likely due to each individual's level of compressing and style of splinting; for instance, pressure sensor #3 experienced less force when applied by FIX team member #1 compared to FIX team member #2. Based on the location of that pressure sensor, the difference in force was most likely due to splinting methods because that sensor was closer to the elbow, which required less focus on the splinting due to the central focus at the wrist. On a similar note, the pressure applied in Trial #2 for the SAM splint was greater than the pressure applied in Trial #3. These results showed that there is variability when splinting within one individual as well as across individuals, and that variability needs to be taken into account when determining if an arm is compressed enough with space for swelling.

For the range of motion test, the Modified Splint was able to restrict the motion at least 10% more than SAM splint when applied by each FIX team member. The data proves that the range of motion test was successful in terms of the acceptance criteria.

Overall, the entire compression test was successful in proving that the Modified Splint compressed more than the SAM Splint by satisfying all three acceptance criteria, where the Modified Splint applied was at least 10% less than the SAM Splint, the range of motion was restricted to at least 10% more than the SAM splint, and the capillary refill time was less than 3 seconds when applied by both FIX team members. Because the acceptance criteria were met, this requirement can be considered satisfied since the pressure test and range of motion test proved that there is enough pressure applied to immobilize the injury, and the capillary refill test proved that there is enough room left for swelling.

4.3.9 Requirement: Prevent Extra Pain

The design must not cause extra pain or aggravate the injury, such as creating wounds in the Soldier's skin.

4.3.9.1 Associated Tests

The associated tests with this requirement are:

- Pressure Test
- Capillary Refill Test
- WBBS Buddy Drag Test
- WBBS Comfort Test

The Pressure and Capillary Refill Tests were previously defined and explained in Section 4.2.8.1. Similarly, the WBBS Buddy Drag Test was also previously defined and explained in Section 4.2.2.1, but the relevant

evaluated features, test plan, and acceptance criteria for the comfort of the buddy drag can be in Section 4.3.9.1.1 immediately below. Below the comfort of the buddy drag test lists out the relevant information for the WBBS Comfort Test in Section 4.3.9.1.2.

4.3.9.1.1 WBBS Buddy Drag

Feature(s) Evaluated:

This test evaluated a key feature:

- Comfortability: A comfort questionnaire, combined with the previously mentioned questionnaire, was given to the volunteer evaluating their level of comfort, pain, confidence in the durability of the subsystem, differences between the two kinds of ammo carry, and perceived effect on the splint.

Test Plan:

A comfort questionnaire was given to the volunteer after the test had been completed to measure the comfort, pain, subsystem robustness, and effect on the splinted arm perceived by the user of the external system for each scenario.

Acceptance Criteria:

The WBBS system would be redesigned if the user experienced extreme discomfort and/or pain using the system and would be deemed successful if the user did not report any outstanding pain when using the system.

4.3.9.1.2 WBBS Comfort Test

As mentioned before, the testing details regarding the WBBS Comfort Test can be seen below.

WBBS Comfort: A "buddy drag" was performed for this test at 200 pounds to confirm if the discomfort of the straps at the biceps was reduced. The volunteer was asked to wear long sleeves to simulate what a typical Soldier wears in the field.

Objectives:

The objective(s) associated with this test include:

1. Verifying that by adding more layers of clothing reduces the discomfort of the WBBS straps at the biceps, since red marks were observed on the volunteer's arms during the WBBS buddy drag tests in Fall 2020.

Feature(s) Evaluated:

The test evaluated:

1. Comfortability: After the test was performed, the volunteer was asked whether the layers of clothing reduced the discomfort caused by the straps located at the biceps when compared to the test done without the layers of clothing.

Test Scope:

This test was similar to the WBBS subsystem test, previously explained in Section 4.2.2.1, performed last semester. However, in this test, the volunteer only performed a "buddy drag" at 200 pounds for 10 yards. The volunteer was asked to include more layers of clothing based on the assumption that Soldiers typically wear more layers when they are in the field. Once the test was completed, the volunteer was asked to compare the comfortability of the first scenario with the second scenario.

Test Plan:

This test was conducted across a flat surface for 10 yards, where the volunteer was asked to drag 200 pounds using the WBBS. To measure 200 pounds, the team used the scale found in the Makerspace to stack an extra 60 pounds onto a 140.5 pound MMA dummy. This test included more layers of clothing, specifically a long sleeve shirt, on the volunteer.

To measure the user's comfort using the prototype, we created a questionnaire with statements that were specific to each round of testing during the Active Buddy Drag testing event. The questionnaire is divided into two parts. The first part contains questions that measure the strain on two main areas of the body that were used to perform the buddy drag: the bicep and the waist. The second part contains questions that gauge the effectiveness of the prototype. The questionnaire can be found in Appendix 6.5. The questionnaire was based on the Likert scale model, where scores are rated on a scale of 1 to 5 (1 represents strongly disagree, and 5 represents strongly agree) as a response to a statement.

Acceptance Criteria:

The WBBS comfort test was considered successful if the volunteer reported minimal discomfort after wearing more layers of clothing than just a t-shirt to simulate what a Soldier would wear in the field. The WBBS would not be redesigned if the discomfort that was caused by the straps was resolved. If the discomfort was the same or worse, the WBBS would be redesigned by adding padding to the straps at the biceps.

4.3.9.2 Tests Results

4.3.9.2.1 Fall Semester Results

Information about the WBBS "buddy drag" performed last semester can be found in the following paragraphs. As described in the Design Evaluation for Section 4 , the Healthy buddy drag related to dragging a dummy with both arms and assumed the user did not have any injuries. The Prototype test described the situation when the user had the FIX team's external system on them and a SAM splint. Lastly, the No Prototype test is related to the use of one arm, due to an injury, to drag the buddy. The average scores for strain or fatigue the user felt for all three scenarios are shown in Figure 17 below.

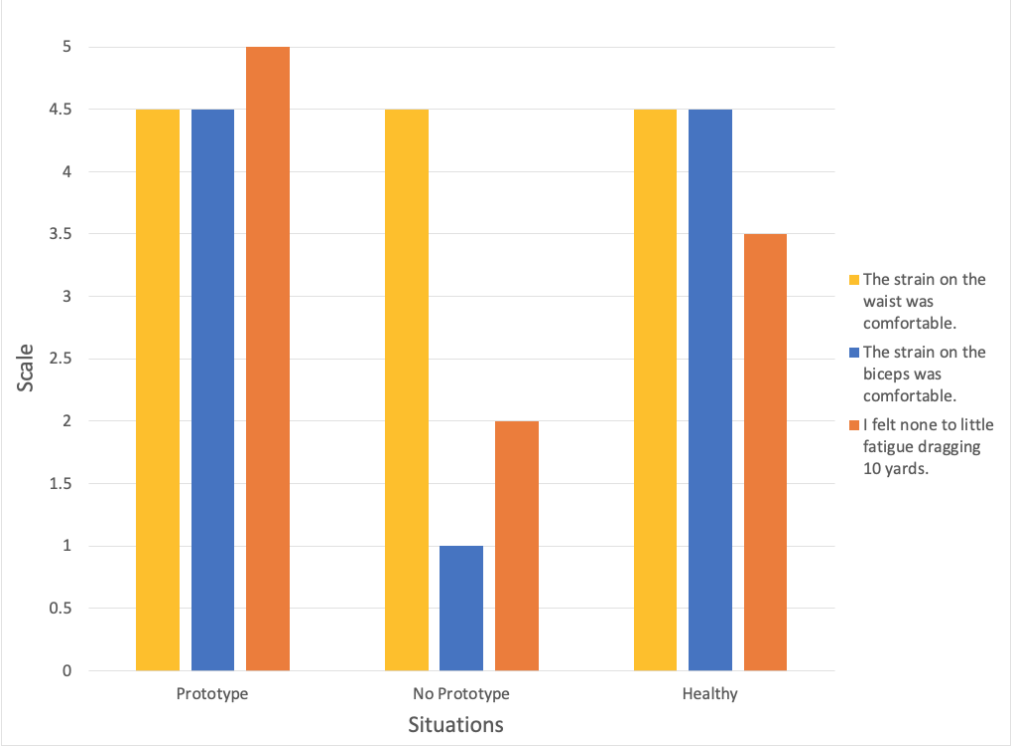


Figure 18. Statements regarding the strain experienced, where a value of 1 signifies "strongly disagree" and a value of 5 signifies "strongly agree" with the corresponding statement.

The data shown in Figure 18 reveals that the WBBS did not reduce any strain on the waist compared to the No Prototype and Healthy cases. However, the Prototype case did reduce strain on the biceps when compared to the No Prototype case. Finally, the user experiences less fatigue for the Prototype case compared to the other two cases.

A comparison between the Prototype and No Prototype data is made in this section for two categories: the effect on the wrist and effect of the splint. The effect on the wrist relates to whether the volunteer thought wrist pain would have been experienced if he was actually injured, with a higher value representing more pain. A limitation to this question is that it relies on the judgment of our tester, since he is healthy and has an opinion-based answer rather than a true rating of pain. The response from the volunteer can be seen in Figure 18. The Effect of Splint category was evaluated by asking if the splint affected the tester's arm while performing the buddy drag, and a higher value represents a lower likelihood of affecting the user's arm. These results can be seen in Figure 19.

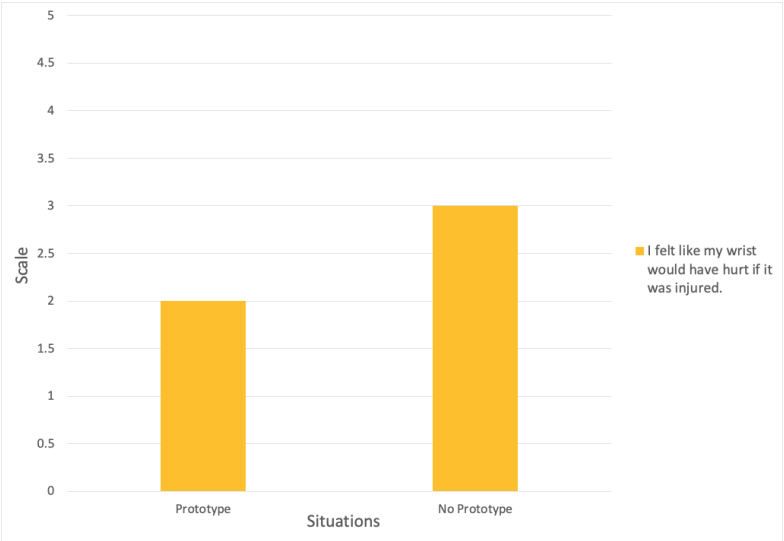


Figure 19. Comparing effect on the wrist between prototype and no prototype situations, where a value of 1 signifies "low to no pain" and a value of 5 signifies "high pain" with the corresponding statement.

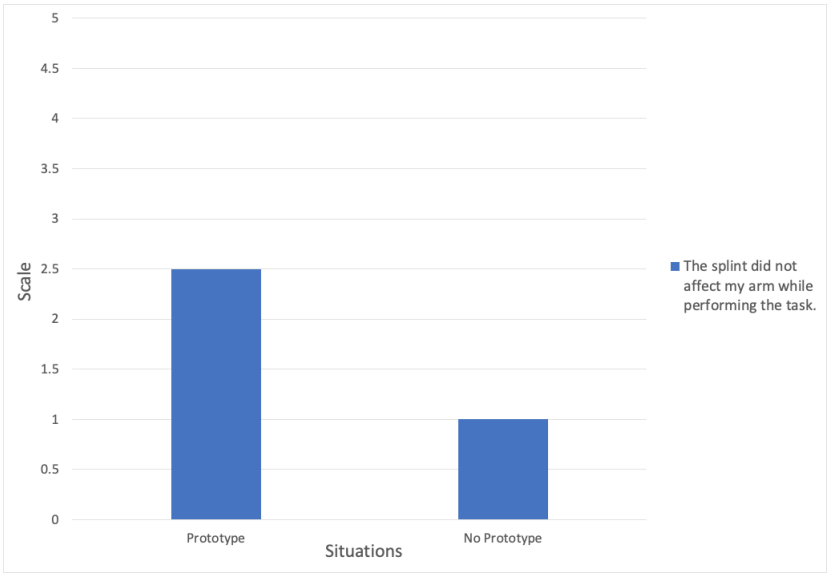


Figure 20. Comparing effect on the splint between prototype and no prototype situations, where a value of 1 signifies "strongly disagree" and a value of 5 signifies "strongly agree" with the corresponding statement.

Figure 18 shows that the effect on the wrist was lower for the Prototype compared to the No Prototype case. Figure 19 shows that the user felt that the splint did not affect their arm as much for the Prototype case.

Figure 20 shows the results of the questions that were asked about the ease of use of the system, how durable the system seems, and if the system causes any additional pain. These results include the Dummy Drag Round 2 Test and the Sled Rounds for evaluating only the Prototype tests. Dummy Drag Round 1 is omitted because the weight of the backpack the volunteer is wearing is lower than the other rounds performed and could potentially affect these results. A higher value for these 3 categories represents a higher approval rating by the user.

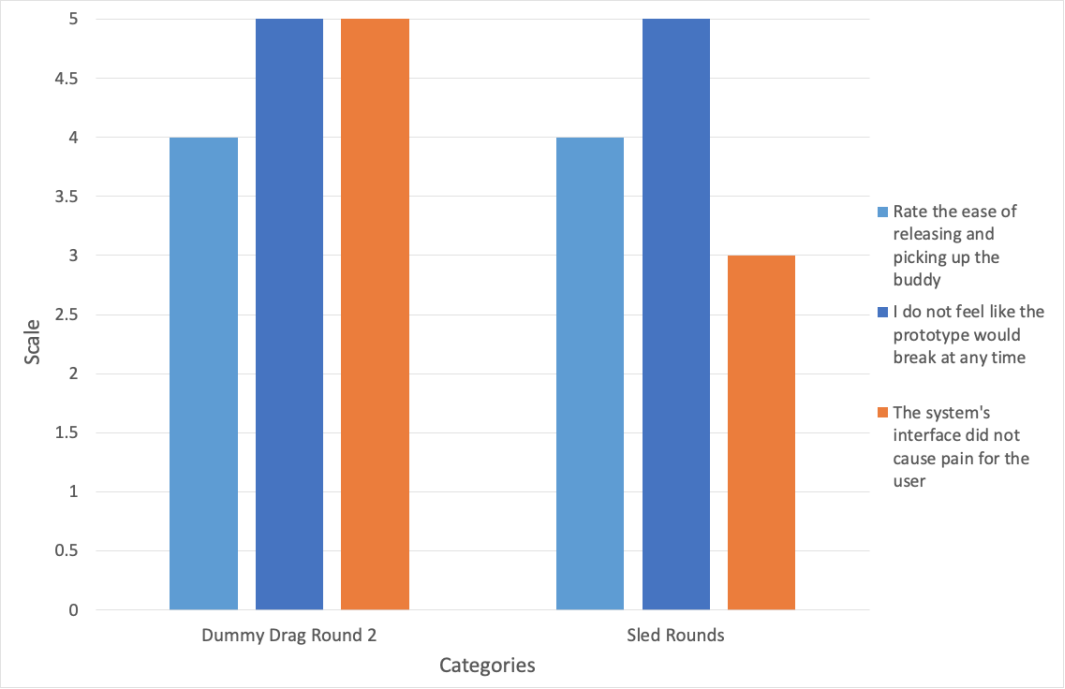


Figure 21. Rating of qualities in prototype-only situations, where a value of 1 signifies "strongly disagree" or "difficult" and a value of 5 signifies "strongly agree" or "easy" with the corresponding statement.

Figure 21 tells us that the user is moderately confident in the ease of releasing and picking up the buddy. The user also has a high level of confidence that the prototype will not break at any time. For the Sled Rounds, the interface caused a medium amount of pain compared to the Dummy Drag Round 2.

Some feedback provided by the volunteer included the statement that he overall felt the most strain while performing the No Prototype buddy drag. In addition, the user suggested that the straps could create skin irritation if used excessively. At the end of testing, the volunteer had red marks on his biceps from performing the buddy drag. This feedback led to the WBBS comfortability test performed this semester, where the volunteer was asked to wear a long sleeve shirt, since a soldier in the field would likely be wearing a long sleeve uniform. The results from this test can be seen in the following paragraphs.

4.3.9.2.2 Spring Semester Results

Table 10 below shows the survey result collected from the volunteer for the WBBS comfortability test. The criteria were graded on a scale of 1 to 5, with 5 being the best for most questions, except for the "I felt like my wrist would hurt if it was injured" criteria, like before. The user's feedback showed similar results to the previous tests performed with the WBBS with minimal strain on the waist, slight but not uncomfortable strain on the biceps and the WBBS minimally affecting the wrist. Also, the system was easy to release, fairly robust, and did not interfere with the splint.

Table 10: Results of comfort questionnaire for WBBS

The strain on the waist was comfortable	The strain on the bicep was comfortable	I felt none to little fatigued dragging 10 yards	I felt like my wrist would hurt if it was injured	Rate the ease of releasing and picking up the buddy	I do not feel like the prototype would break at any time	The splint did not affect my arm while performing the task	The system's interface did not cause pain for the user
5	4	5	1	4	4	5	5

The user reported that the WBBS "didn't cause pain in the elbow crease," where the previous result was ranked at a 3 for the system's interface causing pain. The only difference between previous tests was that the volunteer was wearing a long sleeve shirt.

4.3.9.2.3 Other Relevant Results

The test results for the Pressure and Capillary Refill Tests can be seen in Section 4.2.8.2, where the Modified Splint applied more pressure to the arm compared to the SAM splint, and the Capillary Refill time was less than 3 seconds when the Modified Splint was applied for 15 minutes.

4.3.9.3 Evaluation

The Pressure and Capillary Refill Test results can be seen in Section 4.2.8.2, and the same conclusion can be made again with respect to pain. Since the Modified Splint was able to compress the arm more than the SAM splint and the capillary refill test was successful, the design of the Modified Splint would not cause any extra pain to the user. This conclusion can be made because a successful Capillary Refill Time proved that the Modified Splint did not cut off blood flow in the arm, which suggests that the increased compression was not too much for the volunteer to bear and no extra pain was caused.

With regards to any pain associated with the WBBS Buddy Drag test, the results from Figure 18 proved that the WBBS did reduce strain on the biceps when compared to the No Prototype case, and that there is less fatigue experienced with the Prototype case. Reducing pain and lessening the fatigue turns into reduced pain for the User with the WBBS.

Since the results in Figure 19 showed that the effect on the wrist was predicted by the participant to be lower for the Prototype compared to the No Prototype case, the WBBS would theoretically cause less pain for the user. As mentioned before, our user does not have a distal radius fracture, so this conclusion is not definitive proof that the WBBS would not affect the fracture site; however, the tests seen in Section 4.2.4 on the surrogate arm proves that the WBBS combined with our Modified Splint would reduce any motion at the fracture site compared to a SAM splint. Furthermore, the results in Figure 20 showed that the user felt that the splint did not affect their arm as much for the prototype case, which means that the WBBS has less of an effect on the splint than if the WBBS was not being used. Overall, both statements reveal that the WBBS is useful for preventing unnecessary wrist pain from using the device and will not affect the splint during the "buddy drag".

As seen in Figure 21, the user felt a higher amount of pain during the Sled Rounds compared to the Dummy Drag Round 2. This conclusion is understandable because the volunteer dragged up to 297.25 pounds in the Sled Rounds and only dragged 140.5 pounds for the Dummy Drag Rounds. An increase in the weight most likely causes an increase in discomfort, and the WBBS straps could cause more skin irritation at higher weights. As mentioned, the volunteer experienced red marks on his biceps after the Prototype drag case. Because of that, the WBBS comfortability test was performed this semester with the

addition of a long sleeved shirt to determine if the strap discomfort could be mitigated by following a typical Soldier's outerwear. The user did report that the problem with the strap discomfort at the elbow was resolved.

Since the volunteer's feedback included that he overall felt the most strain while performing the No Prototype buddy drag and the Prototype buddy drag produces less strain, there would be less fatigue overall if the buddy drag is being performed for a greater span of time or distance if the WBBS is used. Overall, by examining the data collected in Figure 18 to 21, we can conclude that the WBBS is a useful device that would help Soldiers perform the "buddy drag" in the field, especially if they have sustained a distal radius fracture, and would prevent any extra pain.

Since all four tests were deemed successful, this requirement of preventing extra pain was therefore met, and the prototype design would not cause any pain for the user.

4.3.10 Requirement: Comfort

The design must be comfortable for the Soldier to use compared to just using a SAM splint and it is measured through Comfort Questionnaires.

4.3.10.1 Associated Tests

The associated tests with this requirement are:

- Modified Splint Comfort Questionnaire.
- WBBS Comfort Questionnaire

Objectives:

The objective(s) associated with this test include:

1. Splint comfortability: Verifying that the Modified Splint has a degree of comfort that is comparable to the SAM splint
2. The objectives for the WBBS comfortability can be found in Section 4.2.9.1

Feature(s) Evaluated:

The test evaluated:

1. Splint Comfortability: After the SAM splint and the neck brace was put on, the volunteer was asked whether the neck brace had any effect on the comfortability compared to just the SAM splint.
2. The features evaluated for the WBBS comfortability can be found in Section 4.2.9.1

Test Scope:

1. Splint comfortability: The volunteer was asked to compare the degree of comfort when the SAM splint was applied first versus when the neck brace was additionally applied.
2. The test scope for the WBBS comfortability can be found in Section 4.2.9.1

Test Plan:

The comfort questionnaires are based on a Likert scale, where scores are rated on a scale of 1 to 5 (1 represents strongly disagree, and 5 represents strongly agree) as a response to a statement.

1. Splint comfortability: The volunteer first gauged how comfortable the SAM splint was when it was put on first. Then, when the neck brace is applied, the volunteer judged whether it affected the degree of comfort. The comfort questionnaire for the Modified Splint can be found in Appendix 6.6.
2. The test plan for the WBBS comfortability can be found in Section 4.2.9.1. The comfort questionnaire for the WBBS can be found in Appendix 6.5.

Acceptance Criteria:

1. Splint comfortability: The splint modification was considered successful if the volunteer reported no more discomfort after the neck brace was applied.
2. The acceptance criteria for the WBBS comfortability can be found in Section 4.2.9.1

4.3.10.2 Tests Results

1. Splint: The splint modification was put on a volunteer, and our volunteer responded to a set of 4 questions related to the criteria in Table 11. Overall, the splint scored high (4 or above) across all criteria, with the most impressive score of 5 in the robustness of the splint. Our volunteer also noted that putting on the neck brace did not make the whole splint more uncomfortable. There was not any difference when comparing the Modified Splint results with the SAM splint results. This shows that by adding the neck brace, it had no discernable effects on the user.

Table 11: Results of comfort questionnaire for Splint modification

Test case	I felt that my wrist was stabilized and prevented from moving	I did not think the splint would break or disassemble easily	I felt that my mobility was limited appropriately	I felt comfortable
SAM splint	4	4	5	4
Modified Splint	4	4	5	4

2. WBBS: The WBBS subsystem was evaluated by another volunteer who performed the buddy drag across 10 yards. Our volunteer then responded to a set of 8 questions related to the criteria in Table 10 in Section 4.3.9.2.2. Overall, the WBBS scored high (4 or above) across all criteria, except for the criteria "I felt like my wrist would hurt if it was injured" with the lowest score of 1, which is actually a positive result. Our volunteer also noted that the design did not hurt his elbow crease because he wore a long sleeve shirt during this test.

4.3.10.3 Evaluation

1. Splint: The splint modification with the neck brace did not cause any more discomfort for the user compared to just the SAM splint. Since the comfort level was high for the user, the splint modification does not need to be redesigned or tested again further.
2. WBBS: The user reported that the WBBS "didn't cause pain in the elbow crease." The only difference between previous tests was that the volunteer was wearing a long sleeve shirt, which resolved the problem with strap discomfort at the elbow that required this retest. Since all other testing was a sufficient proof of concept and the issue with the strap discomfort has been resolved, the WBBS does not need to be redesigned or tested again further.

5. Conclusions

The FIX team's full prototype, which consisted of the WBBS and Modified Splint, passed all tests and requirements and adhered to all constraints and codes and standards. The WBBS was made of straps, carabiners, and a belt that a soldier normally wears while assuming a Soldier is wearing long sleeves to prevent discomfort. The Modified Splint was made of Coban wrap, a neck brace, and a SAM splint. These materials were all found within a standard Field Medic Pack and other common items Soldiers would have. The FIX team spent less than half of the $1200 allotted budget from Trinity University, did not require authorization to buy a large pack of materials found in a Medic Pack, and was not majorly affected by changes caused by COVID-19. The project was also completed within the Fall 2020 and Spring 2021 semesters.

It is also important to note that although we successfully completed one of the three tasks mentioned in section 4.3.2, the team was close to completing a second task of carrying ammunition. Seven iterations of testing were tested in the Fall Semester, where five out of the seven were successful. Successful in this test is considered to be where the "injured" scenario is 15 seconds within the healthy scenario. Since the two unsuccessful iterations were caused by the carry ammunition can becoming loose and falling out of the subsystem during the carry ammo run, some improvements that could be implemented include using duct tape to ensure that the straps do not slip and securing the position of the straps that caused the strap attached to the ammo can to unbuckle, seen in Figure 22 below.

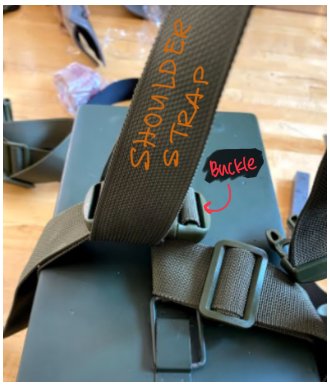


Figure 22. Image of the shoulder strap causing the strap on the ammo can to unbuckle.

As for testing the maximum fracture displacement, "buddy drag" times, and "buddy drag" weights, the maximum fracture displacement contained only negative or zero percent differences for the twist test, bump test, and WBBS strap tug external system test. These results proved that the Modified Splint is, in fact, an improvement of the standard of care SAM splint. For the "buddy drag," all times for the WBBS tests were within 3 seconds of the healthy times. In addition, all "buddy drags" were under 10 seconds for a 10 yard drag. The maximum weight dragged was 297.25 pounds. The comfortability questionnaire results showed that the WBBS was a useful system for preventing pain and lessening any discomfort from the strain of dragging a buddy. The total fabrication time of the prototype was 9 minutes and 10 seconds, with 6 minutes and 30 seconds for making the Modified Splint and 2 minutes and 40 seconds for making the external subsystem. The fabrication instructions were also made more clear based on the feedback provided by volunteers. The adjustability of the splint was proven by applying the SAM splint to different volunteers and FIX team members. The prototype was proven to prevent any extra pain by the success of the WBBS comfortability test, WBBS buddy drag test, and the pressure and capillary refill tests. The pressure sensor tests were performed at a stationary motion, while performing a range of motions and a capillary refill test. These tests showed that the Modified Splint was able to compress more

than the SAM splint without preventing blood flow to the injured arm. A comfort questionnaire was filled out for the splint that showed the user felt that the Modified Splint did not cause any discomfort compared to the SAM splint. Overall, the prototype successfully improved upon the standard of care SAM splint and passed all defined criterion for testing given by the team.

6. Appendices

6.1 Materials Commonly Found in a Field Medic Pack

Provider	Description
Amazon	SAM Splint
North American Rescue	Tourniquet - squeezes to stop blood loss
North American Rescue	Surgical Tape (6 per pack)
Chinook Med	Israeli Emergency Bandage
North American Rescue	2 Rescue Hyfin Chest Seal Gauze - Designed for the prevention, management and treatment of an open and/or tension pneumothorax potentially caused by a penetrating chest trauma
North American Rescue	2 Rescue Hyfin Chest Trainer - helps practice with using seal and less aggressive adhesive
North American Rescue	Combat Gauze Z-Fold Hemostatic
Amazon	ACE Elastic Bandage Wrap with Hook Closure
Tactical Medical Solutions	Nose Hose NPA with Lube - used to secure an air passage through the nose
North American Rescue	ARS for Needle Decompression -length needle/catheter to penetrate the pleura (lung)l space of 99% of patients
North American Rescue	NAR Compressed Gauze - ultra-compact roll of sterile, high quality 100% cotton gauze that utilizes a unique crinkle weave that has excellent fluid absorption.
North American Rescue	Tactical Crickit - Nylon Pouch, 2 Antimicrobial Wipes, Gauze 2pk Pads, Scalpel, NAR Tracheal Hook, Securing Strap, CricTube 6mm, 10 cc Syringe Luer-Lock
Amazon	Kerlix Gauze Bandage Rolls - typically for burns or open wounds, lacerations etc.
North American Rescue	IV Pack (Saline Lock Kit) - 1 IV constricting band, 1 IV raptor securing, 2 alcohol prep pad, 2in x. 2in gauze pads, clear adhesive dressing, locking saline plug, 18 ga needle catheter, 1.5 in 18 ga hypodermic needle, 10 cc luer-lock syringe
Chinook Medical Gear Inc.	IV Admin Set Coiled Tubing, 10-Drop (Single Unit)-This 10-drop IV Administration Set with coiled tubing is designed for confined spaces and patient transportation.
Amazon	Natural Saline IV Bag - may not need for project and would need to buy the saline separately, but this is the bag
North American Rescue	Fox Eye Shield With Garter -(used to protect eyes after blasts/injuries
North American Rescue	Sharp Shuttle - helps focus point of needle to injured area
North American Rescue	Cyclone Pocket BVM - ventilator support who are not breathing or struggling to breath
North American Rescue	King LT-D- airway device tool
North American Rescue	Tactical Suction Device- vacuum for clearing airway in emergency
North American Rescue	Nar BP/Stethoscope Combo Kit - has blood pressure cuffs of varying sizes, stethoscopes, etc.
North American Rescue	Medic/Leg Rig Kit - 2 C-A-T Tourniquet, 2 ETD 6 in Dressing, Gauze S-Rolled, 28F Naso Airway and Lube, Gauze Petrolatum, SgL Hyfin Occlusive, ARS Needs 14 g, BOA IV Band, Saline Lock Kit, Large Nitrite Gloves, 1 Lg Trauma Shears (Scissors), Scissor Leashm 2

	Tag Triage Card, Casualty Reference Card, 4 PES Eye Shield, Surgical Tape 2in,
North American Rescue	SAM Pelvic Sling- Stabilizes pelvic fractures
Amazon	Safety Pins- Good for a variety of uses if you're creative
North American Rescue	Benchmade Personal Safety Cutters- quick cutting tool,
North American Rescue	ACE Cervical Collar - used for stabilizing neck and spine
North American Rescue	Army CLS Resupply Kit- 2 C-A-T Tourniquet, 2 ETD 6 in dressing, 1 ETD abdominal, 2 gauze compressed, 2 combat gauze z-fold, 28F NASO airway and lube, 2 Sgl. Hyfin Occlusive , ARS 14 g needle, survival blanket, Blanket ready heat, Sam Splint II, 3 Triangular bandage, Elastic wrap 6 in. bandage, Lg. Trauma Shears, 2in Surgical Tape, 4 PES eye shield, 4 Large Nitrite gloves, 6 alcohol prep pads, small permanent marker
North American Rescue	ENT Pocket Exam Light - shines bright light for examinations
Amazon	Tongue Depressors - allows examination of mouth and throat

6.2 Building the Surrogate Arm

6.2.1 Bone models

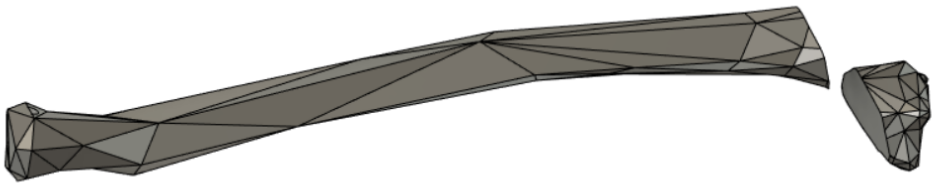


Figure A-1: Radius with fracture (First Surrogate arm)

Figure A-2: Ulna (First Surrogate arm)

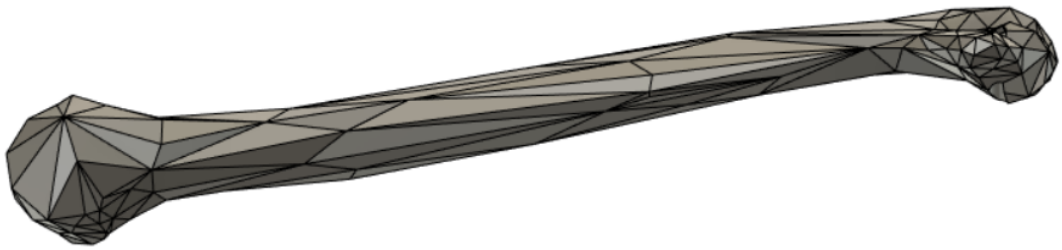


Figure A-3: Humerus (First Surrogate arm)

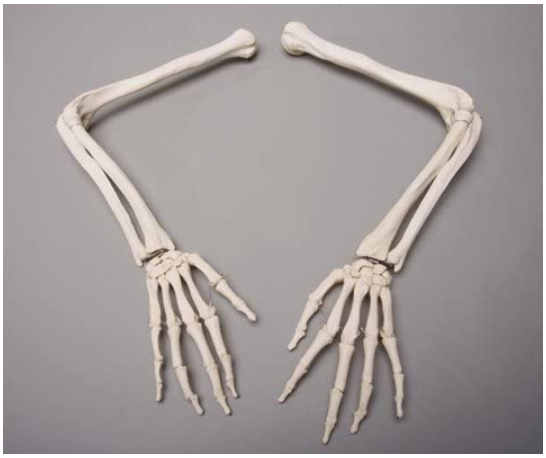


Figure A-4: Bone model purchased on Amazon (Second Surrogate arm)

6.2.2 Molding

Figure A-5: Molding (Second Surrogate Arm)

6.2.3 Hall-Effect Sensor Calibration

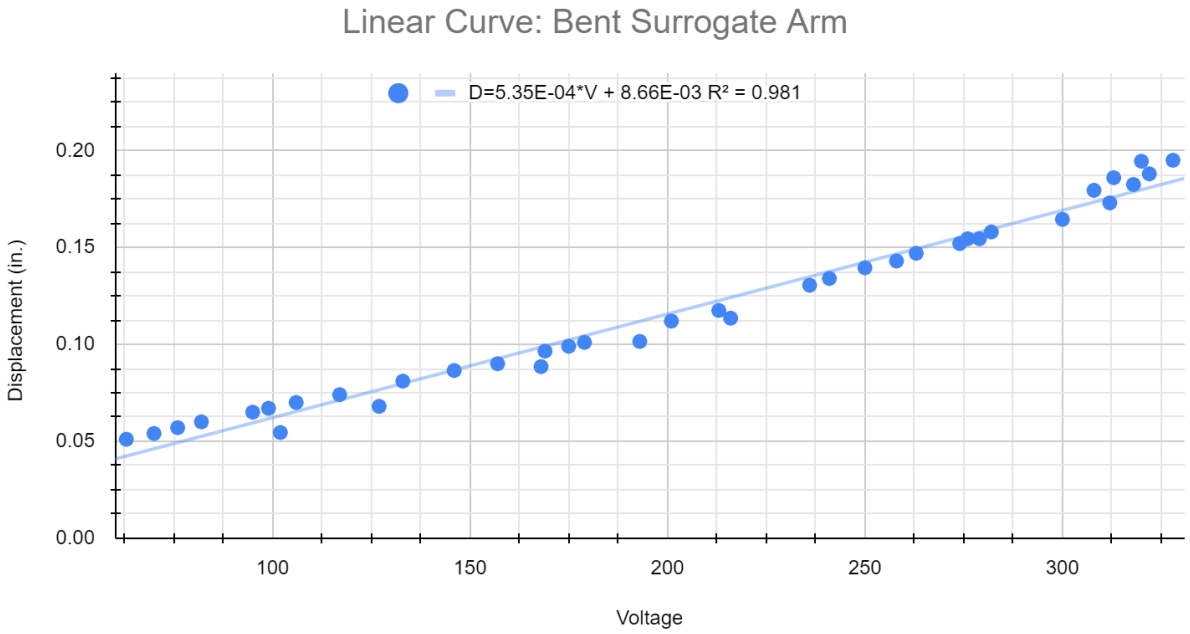


Figure A-6: Calibration curve of bent (second) surrogate arm for the range between 0.04 and 0.24 inch

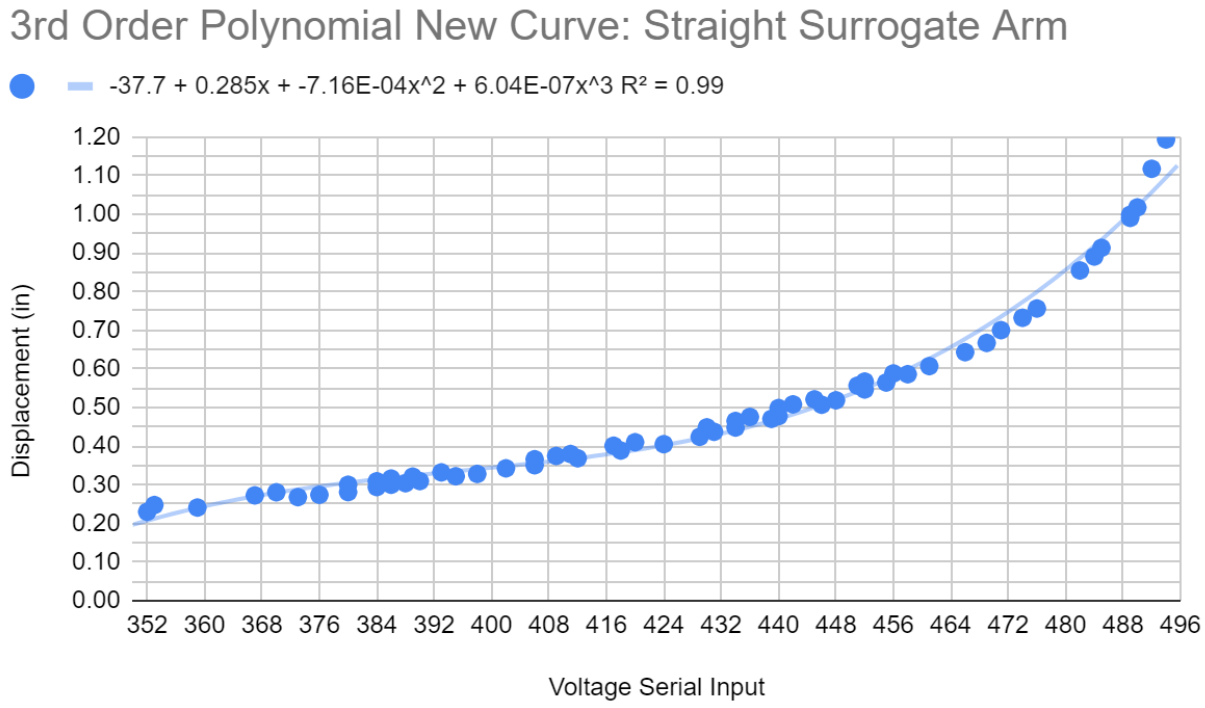


Figure A-7: Calibration curve of straight (first) surrogate arm for the range between 0.2 and 1 inch

6.2.4 Assembling for pouring Silicone

Figure A-8: Putting the hall-effect sensor into the bone model (Second Surrogate Arm)

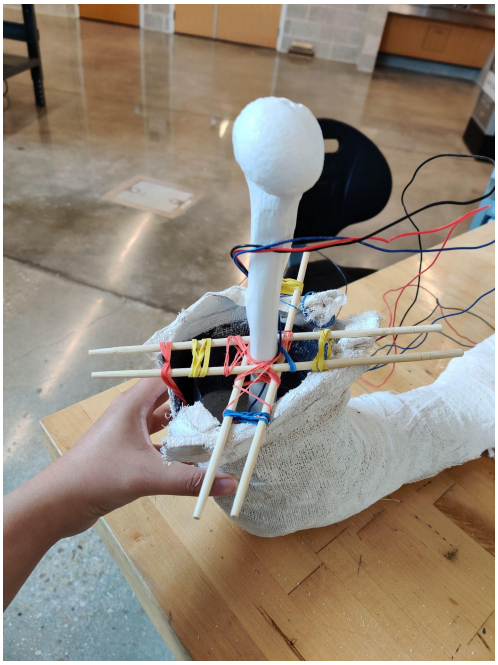
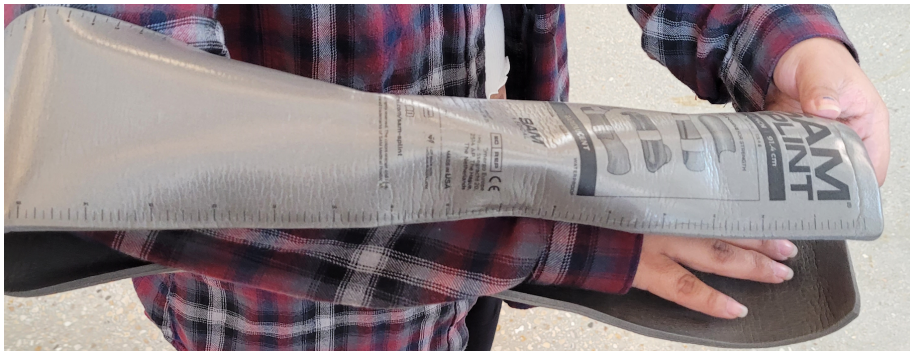


Figure A-9: Putting the bones inside the mold (Second Surrogate Arm)

6.3 Modified Splint Fabrication Instructions

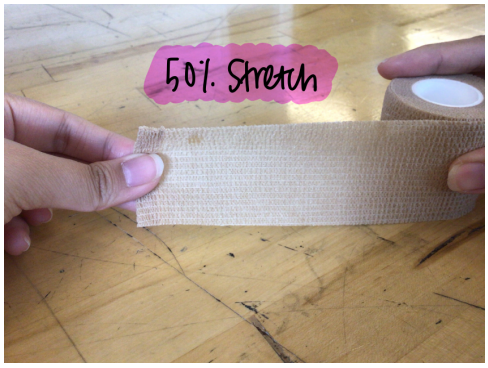
1. Take a SAM splint and unroll it. Recreate the illustration that is second to the bottom with the guidance given on the SAM splint for a C-curve.

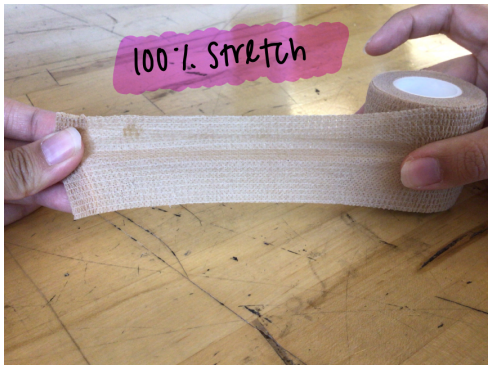


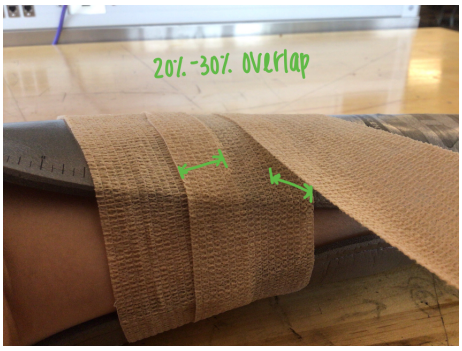
NOTE: C-Curve in the above photo

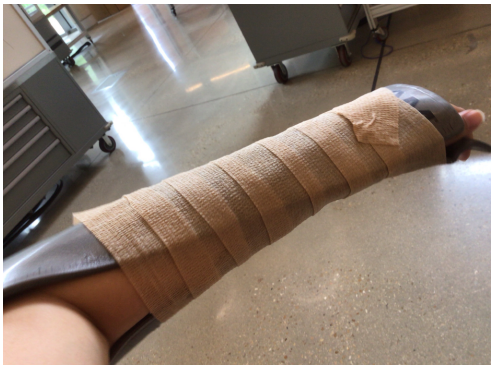
2. After making the C-Curve, attach the splint to the arm with medical Coban wrap (the roll of brown material) by wrapping the Coban along the entire arm. While wrapping, make sure to:

- Overlap the Coban by 20-30% as you wind across the whole arm
- Stretch the Coban to only 50% of its stretch capacity

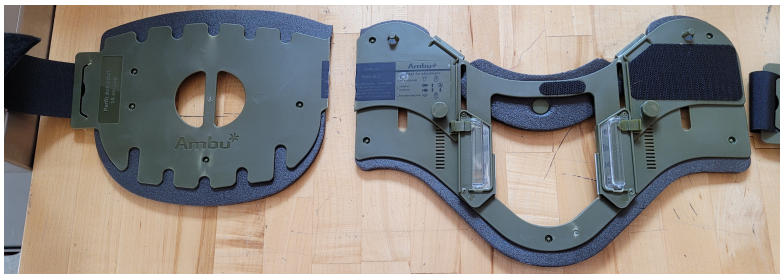






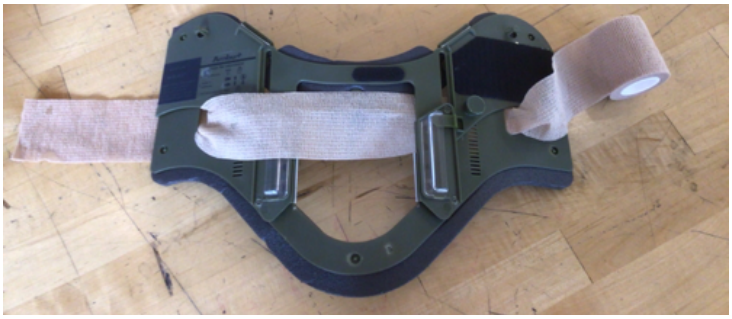


3. Cut an Ambu neck brace at the section where the round circular piece begins. The round circular piece is no longer needed, so it can be put to the side

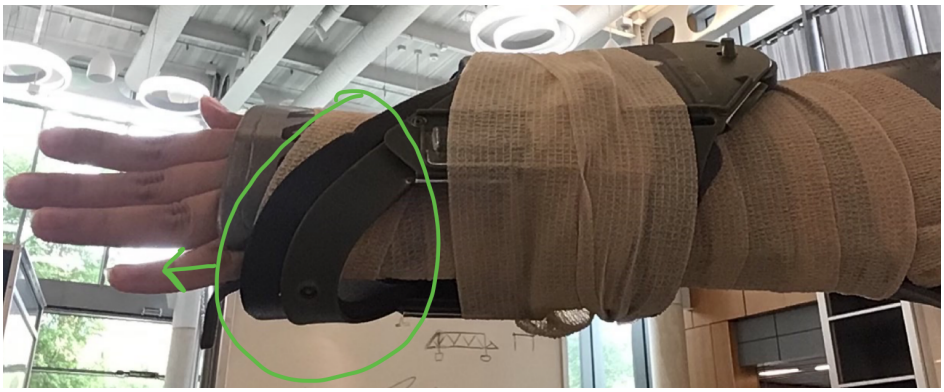


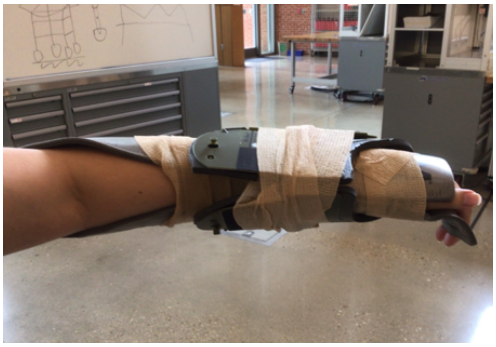
4. Follow the directions listed on the neck brace for extending the length of the neck brace. Using these instructions, make the neck brace as long as possible, which is usually the 6 position.

5. Lace Coban through the neck brace holes. Ensure that the holes are woven through in such a way that the entire neck brace wraps around the arm instead of part of it.

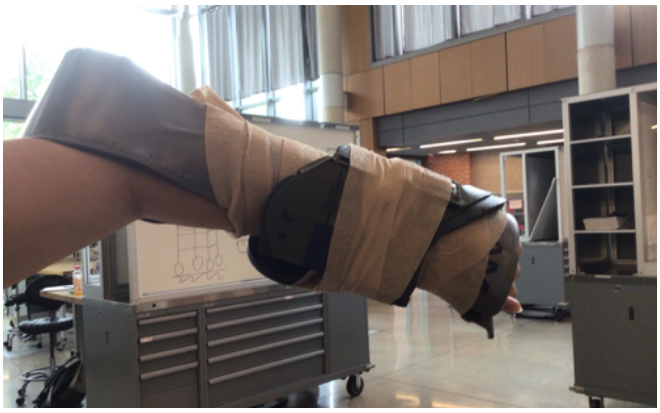


6. Tie the Coban placed in the neck brace together tightly around the arm while not increasing pain of the patient. Make sure that the **extruding curve** of the neck brace is pointed towards the **pinky finger** as shown.





7. If needed, add extra Coban wrap around the neck brace to ensure it fastens tightly and securely to the arm.



6.4 WBBS Fabrication Instructions

1. Tighten a belt around your waist and make sure that the belt will not loosen under a large amount of weight placed on it.

2. Attach a carabiner to the front of the belt on the center part of the waist, but not on the belt buckle.

3. Grab one strap and clip it into a loop. Grab a second strap and cross one side through the loop you made. Clip the second strap together into another loop. You should have two circles attached together.

4. Unclip one of the loops you made, and pull one side of the unclipped strap through the carabiner first and then pull the other unclipped side through the carabiner. Once you have both sides of the unclipped strap through the carabiner, clip them together again.

5. Put your arms through one of the loops created by the straps with the straps laying on the biceps of the arm.

6. Place the other strap closer to the ground around the buddy you are dragging in whatever way you please.

7. Attach extra carabiners or straps or adjust strap lengths as needed to make the buddy drag easier.

6.5 WBBS Comfort Questionnaire

FIX Team's Subsystem Prototype 1 Test

Feedback questionnaire for participants

* Required

1. Email address *

2. Which test was this?

Mark only one oval.

- ◯ With external system with SAM splint
- ◯ Without external system with SAM splint
- ◯ Healthy person

3. The strain on the waist was comfortable

Mark only one oval.

	1	2	3	4	5	
Strongly disagree	◯	◯	◯	◯	◯	Strongly agree

4. The strain on the bicep was comfortable

Mark only one oval.

	1	2	3	4	5	
Strongly disagree	◯	◯	◯	◯	◯	Strongly agree

5. Any pain felt in particular?

6. I felt none to little fatigued dragging 10 yards

Mark only one oval.

	1	2	3	4	5	
Strongly disagree	◯	◯	◯	◯	◯	Strongly agree

7. I felt like my wrist would hurt if it was injured (Tests 1 and 2)

Mark only one oval.

	1	2	3	4	5	
Strongly disagree	◯	◯	◯	◯	◯	Strongly agree

8. Rate the ease of releasing and picking up the buddy (Test 1 only)

Mark only one oval.

	1	2	3	4	5	
Lowest	◯	◯	◯	◯	◯	Highest

9. I do not feel like the prototype would break at any time (Test 1 only)

Mark only one oval.

	1	2	3	4	5	
Strongly disagree	◯	◯	◯	◯	◯	Strongly agree

10. The splint did not affect my arm while performing the task (Tests 1 and 2)

Mark only one oval.

	1	2	3	4	5	
Strongly disagree	◯	◯	◯	◯	◯	Strongly agree

11. The system's interface did not cause pain for the user (Test 1 only)

Mark only one oval.

	1	2	3	4	5	
Strongly disagree	◯	◯	◯	◯	◯	Strongly agree

12. Any extra feedbacks?

6.6 Modified Splint Comfort Questionnaire

Splint Subsystem Prototype 1 Test

Feedback questionnaire for participants

Email address *

Valid email address

This form is collecting email addresses. Change settings

Which test was this?

- Test 1: FIX team's splint
- Test 2: Standard of care SAM splint

I felt that my mobility was limited appropriately

	1	2	3	4	5	
Strongly disagree	○	○	○	○	○	Strongly agree

I felt comfortable

	1	2	3	4	5	
Strongly disagree	○	○	○	○	○	Strongly agree

I felt that my wrist was stabilized and prevented from moving

	1	2	3	4	5	
Strongly disagree	○	○	○	○	○	Strongly agree

I did not think the splint would break or disassemble easily

	1	2	3	4	5	
Strongly disagree	○	○	○	○	○	Strongly agree

If you felt discomfort, where did you feel discomfort in particular?

Short answer text

Any extra feedback? Example: any comments about a comparison between the two tests?

Long answer text

6.7 Carry Ammunition Subsystem

Figure A-10: Carry Ammunition Setup for the "Injured" Scenario

7. Bibliography (MLA)

[1] CrossFit. "*Movement About Joints, Part 3: Wrist.*" CrossFit, 15 03 2019 https://www.crossfit.com/essentials/movement-about-joints-part-3-wrist#:%7E:text=Adduction%20and%20abduction%20of%20the,and%20radial%20deviation%20(abduction).&text=Flexion%20of%20the%20wrist%20from,the%20hand%20forward%20and%20up.&text=Extension%20of%20the%20wrist%20from,and%20up%20(Figure%203)

[2] CrossFit. "*Movement About Joints, Part 2: The Elbow.*" CrossFit, 15 03 2019. https://www.crossfit.com/essentials/movement-about-joints-part-2-the-elbow

[3] StatPearls. "Capillary Refill Time." StatPearls, StatPearls Publishing, 22 Apr. 2021, www.statpearls.com/articlelibrary/viewarticle/82154/.

8. Signatures

Signatures		
Project Name: Field Improvised eXoskeleton (FIX)		
The undersigned have reviewed and approved the final version of this document.		
	Date Received	**Date Approved**
Team Members: *Kelly Liu* *Anh (Duncan) Dang* *Karla Peñaloza* *Emi Mondragon*		
Team Adviser: *Emma Treadway*	**4/24/21**	**4/31/21**