Innovative Wrist Splint Design

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Executive Summary

Wrist fractures require the immobilization of wrist and forearm. Plaster casts are the most common treatment option for fractured wrists. With multiple casts needed to treat a fracture, this method is expensive and time intensive. 4 design requirements were identified for a wrist immobilization device. First, the device needs to be formable during application. Once the device is positioned correctly, the device needs to be rigid, as to not allow movement of the healing bones. In the case of a pneumatic splinting device, an airtight seal is needed to maintain stiffness. Application time is another important design parameter.

This report describes and evaluates an innovative pneumatic wrist splint. This design follows the style of a bandage wrap and makes use of a flexible honeycomb core that becomes rigid under negative pressure. The splint contains a hole at one end intended for the patient’s thumb to be placed through. The splint then wraps around the back of the hand and overlaps as it is wrapped around the forearm. Velcro® secures the splint along the overlaps as well as on the back side of the hand. Once the splint has been placed, negative pressure is applied to the splint to create the necessary stiffness.

![Figure 1: A drawing of the pneumatic wrist splint before being applied is shown.](image)

Multiple tests were run to evaluate the proposed design of the pneumatic splint. A three point bending test was completed to determine the stiffness of the splint under negative pressure. Emergency Medical Technicians were timed while applying the splint to determine application time. To test formability, the smallest radius of curvature that could be achieved by the splint at atmospheric pressure was measured.

The splint was stiffer and had a lower average application time than plaster casts while also costing less. The minimum radius of curvature achieved by the splint was smaller than the minimum radius of curvature of an average human wrist. Reusability decreases overall cost, and allows the device to be adjusted during application for optimal fit.
Team Contributions

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1. Valve research.
2. Valve testing and selection.
3. Compiled final draft.
4. Assisted with testing.
5. Volume 1: Wrote Evaluation Results, abstracts for test reports,
6. Volume 2: Developed and wrote manufacturing plan, abstracts for test reports,
   a. Evaluation reports: radius of curvature lab report, compression lab report,
      compressive load lab report

**Colton Borg**
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2. Compiled Design Description section.
3. Constructed prototype.
4. Composite research.
5. Design show poster content.
6. Assisted with testing.
7. Volume 1: Wrote detailed design description,
8. Volume 2: Regulatory and safety considerations, contributed to annotated bibliography, and user need research.

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3. Assisted with prototype.
5. 3 point bending analysis
7. Volume 2: Concept selection, developed and wrote manufacturing plan, next steps, contributed to annotated bibliography.
   a. Evaluation reports: 3 point bending.

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4. Site Visit #2 Lead.
5. Assisted with prototype.
6. Printing and binding of final report.
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8. Volume 2: Wrote Executive Summary, bill of materials, contributed to annotated bibliography, and user need research.
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7. Volume 2: Contributed to annotated bibliography, user need research.

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2. Curved honeycomb computer model.
3. Computer model testing and analysis.
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2. Site visit #1 lead.
3. Complied Problem Definition Supporting Documents.
4. Created product design specifications document.
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6. Assisted with prototype.
7. Design show poster design and printing.
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   a. Evaluation reports: Material failure, weight, impact, and application.
3. Assisted with initial honeycomb prototyping.
4. Developed testing plan.
5. Performed tests on prototype splint.
6. Coordinated design show.
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1. Problem Definition

1.1 Problem Scope
Each year in the United States alone, approximately 6.8 million people seek medical help for fractures. [10] A fractured limb is an injury that requires limb immobilization and is a widespread medical condition faced by all ages, races, and genders. When limbs are injured, immobilization is critical to proper healing and recovery. [1] Numerous types of limb immobilization devices exist in today's medical industry. These devices are made of a variety of materials: plaster, fiberglass, plastics and thermoplastics. While all promote healing for a fractured bone, each device presents its own set of advantages and disadvantages. Splints using pneumatic vacuum structures offer some unique advantages. Patients, hospitals, medical professionals, insurance companies, emergency medical personnel, and outdoor enthusiasts are key customers for these devices targeted use.

1.2 Technical Review
Fractured bones can happen anywhere in the body, and are generally caused by trauma, osteoporosis, overuse, or a combination of the three. Arm, wrist, and hand injuries are particularly common; wrist fractures account for the majority of fractures that occur before the age of 75. [10] There are different types of fractures that range in level of severity. Stable fractures are the least severe, and are classified by the broken ends of the bone being lined up. [10] Comminuted fractures are some of the most severe fractures, and are classified by the bone shattering into three or more pieces. Figure 2 shows an example of three types of fractures. [10]

![Figure 2: A diagram of different types of bone fractures is shown.][10]
Since plaster casts are the most common prescribed treatment for fractures, they will serve as the benchmark. [10] According to the American Academy of Orthopedic Surgeons, patients with wrist fractures wear their first plaster cast for two to three weeks before being replaced by another cast, which remains on the patient for another three to four weeks. [10] The cast is replaced due to a decrease in swelling of the limb, causing the original cast to become loose and ineffective. Swelling can decrease in an injured limb in just 48 hours, so the plaster cast could have improper positioning on the fracture for weeks afterwards before a new one is applied. [24] The improper placement of a cast can result in nerve damage and pressure points can be triggered to provide extreme discomfort on top of the fractured limb. [24]

The application of each new plaster cast requires time and materials. Once removed, the casting material is discarded. [20] It can take as long as 30 minutes to apply a new cast. [20] Since plaster materials cannot be adjusted once they are applied, a great deal of skill is needed to set the cast properly the first time. The permanent nature of the casts also increases the chance that improper casting will go uncorrected. When removing a cast, a saw is used to cut through the material. Each year, approximately 1% of cast removals result in abrasions or burns from the oscillating circular saw. [1]

A pneumatic splinting device can eliminate the downsides of plaster casts that have been outlined. Both positive and negative pressure pneumatic devices have been developed. Degun et al created a positive pressure pneumatic splint that contains at least one rigid member and at least one air-bag with valves for both pressure regulation and inflation. [17] Daugherty et al created a negative pressure pneumatic splint that utilizes a body containing small particles and air that is vacuumed to remove the air and form a rigid structure. This design incorporated a valve containing a filter to prevent the particles from being vacuumed out of the body. [8] Kuchamba et al created a negative pressure splint also. This splint is comprised of a chamber that contains mesh with beads inside. The patent cites friction between the beads and the mesh as the source of rigidity when the chamber has been vacuumed. [16] Marble created a splint that uses both positive and negative pressure pneumatics. In this design, a bladder full of small particles can be vacuumed or inflated depending on application. [17]

In addition to these pneumatic splints, a major commercial splint available is the Sam Splint. Produced by Sam Medical Products, this splint is comprised of an aluminum core surrounded by a foam material that is wrapped around the injured limb and then taped into place. [23] Thermoforming materials have also been used to create splints. Joseph created a three layer cast system, with the first layer providing padding and heat dissipation against the skin. The second layer is thermoformable and forms the rigid structure of the splint. The third layer provides insulation and general cushioning. [13]

These current solutions have left room for multiple improvements. The particles used in the splint developed by both Daugherty et al and Marble may be non-uniformly distributed throughout the cast. [7, 17] The Sam Splint is a temporary immobilizer and is not intended for long term use. [23]
1.3 Design Requirements

Table 1: A list of design requirements for a splint is shown.

<table>
<thead>
<tr>
<th>Metric</th>
<th>Current Cast</th>
<th>Pneumatic Splint Ideal Value</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stiffness</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Young’s Modulus (under a vacuum)</td>
<td>5-24 ksi</td>
<td>24 ksi</td>
<td>[5]</td>
</tr>
<tr>
<td><strong>Impact Resistance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joules</td>
<td>5J</td>
<td>1 J</td>
<td>[9]</td>
</tr>
<tr>
<td><strong>Radius of Curvature</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>inches</td>
<td>N/A</td>
<td>0.625”</td>
<td>[26]</td>
</tr>
<tr>
<td><strong>Airtight</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hold Vacuum Pressure</td>
<td>N/A</td>
<td>-14.7 psi</td>
<td>[21]</td>
</tr>
<tr>
<td><strong>Application</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Time</td>
<td>20-30 min</td>
<td>&lt; 10 min</td>
<td>[3]</td>
</tr>
</tbody>
</table>

**Stiffness**
Stiffness is a measures force per deflection. The key non-geometric parameter of stiffness is the elastic modulus. It is a good measure of how well the splint is performing because the splint must be able to support a force and have a small deflection when that force is applied. It is important that the splint does not bend much while keeping the bone set in the correct position. It also needs to protect against external forces to add protection from falls or other accidents while the splint is applied to the wrist.

**Impact Resistance**
The impact resistance is a measure of how much energy the splint is able to absorb from an instantaneous force. Splints provide better protection from injury with the greater amount of energy absorbed in the splint before it is distributed to the patient. Impact resistance of a splint must be considered as it should retain its shape with lower sudden force in addition to a greater sustained force from a deflection test.

**Radius of Curvature**
The splint needs to be flexible and have the ability to form around an arm when not under vacuum. Once negative pressure has been applied, the splint should be stiff and should retain the formed shape. In its formed shape, the splint must allow for sufficient circulation in the arm and hand. The radius of curvature of the wrist can be approximated as 0.72”, to be conservative. The minimum radius of curvature that needs to be achieved is 0.625”. [26]
Airtight
The splint needs to be airtight, preventing a loss of vacuum pressure. The seal used to attach the PAC cloth around the honeycomb needs to be strong and reliable so that there are no leaks. Any leak will compromise the splint’s design. The valve used to vacuum the splint also needs to be reliable. The valve must hold for the required amount of weeks between splint removals, and it must be able to be used several times without weakening or failing. If the splint is not completely airtight, the rigid, formed honeycomb will not hold its shape for the required amount of time the splint must be applied.

Application
The splint should take as much or less time to apply as current casting methods. Removal should take significantly less time than current methods. A benefit of this design is that the splint can quickly be removed and reapplied in order to fix any mistakes that may occur during application. The splint should be reusable and require a minimal amount of equipment to apply. Decreased application time will also decrease cost. Current application time for a splint is 20-30 minutes. [3] Application costs should be less than $50. [18]

2. Design Description

2.1 Summary of the Design
The proposed solution relies on three main components; honeycomb structure, metal mesh, and an airtight bag enclosure. The bag is created with a specific geometry that allows for the bag to be applied like a bandage wrap, as shown in Figure 3.
The honeycomb is the main structural component of the splint. Initially, the honeycomb must be flexible and near atmospheric pressure, so that it will form around the arm to be successfully applied like a bandage wrap. After the air is evacuated, the honeycomb structure becomes rigid. This provides protection for the arm against accidental bumps and keeps the bones held in proper position for healing.

At a physician’s office, the splint is wrapped around the patient’s arm and secured with Velcro®. To achieve greater flexibility around different shaped arms, the splint is 3 inches wide and wrapped in a helical pattern along the patient’s arm. After the proper alignment is achieved, the air will be evacuated and the fracture will be protected. A valve on the bag keeps the air evacuated and enables easy application and removal.
2.2 Detailed Description

The outside of the splint is a polyester blend with a polypropylene coating on the inside of the material. The outside can also be thought of as a bag because it will encompass all of the structural elements of the splint. The bag material was chosen for its high coefficient of friction with the mesh, which helps add stiffness to the overall structure. The bag is also cut into a long strip with a thumbhole in one end. The bag will then wrap in a helical manner around the patient’s arm. The bag, being made with this construction, helps reduce failure due to wrinkles in the bag material. The thin strips will also allow for one size to fit most or all adults. The total length of the bag is such that on a larger arm the bag will not extend very far up the arm, while on a smaller arm the bag may extend all the way to the elbow. This will reduce or eliminate the need for different sizes keeping the volume required for storage minimal in hospitals.

The honeycomb structure is Aramid paper dipped in resin. Many layers of paper are glued together by strips of adhesive, the adhesive sets, and then over many minutes the paper is pulled apart to form hexagonal cells between the sheets of paper. Then the process of applying resin and baking the resin onto the paper cells occurs. This process is repeated several times to obtain the honeycomb structure. This material has a high strength to weight ratio, which makes it ideal for the splint. The strength of the honeycomb structure is what gives the splint its support and helps increase stiffness. The frictional interaction between the honeycomb structure and the wire mesh and skin under vacuum pressure also adds stiffness to the structure. The other element that creates stiffness with the splint is the pressure difference that is put on the honeycomb. As air is vacuumed out of the splint, the area around the honeycomb is at a lower pressure than outside of the splint. This creates pressure acting on each face of the splint, minimizing movement and adding stiffness to the structure. The honeycomb also has strength when being compressed, so the structure will not fail if something unexpectedly hits the splint.

The skin must be airtight, as mentioned previously, but it also must be allowed to return to atmospheric pressure for application on and off of the arm. To accommodate for this need, a valve was attached to the bag. The valve attaches with quick-connect fittings to the vacuum pump hose, this allows air to be removed from the splint. After the maximum vacuum gauge pressure is reached the valve is switched to the no flow position and the vacuum pump is removed. The valve used prevents atmospheric air from entering the evacuated splint.
2.2.1 Functional Block Diagram

Figure 4: The functional block diagram of the innovative splint is shown.

2.2.2 Functional Description

**Stiffness**
The most important function of a plaster cast is the stiffness aspect that provides protection for healing of the fractured limb. The innovative splint utilizes a honeycomb core with a metal mesh backing to remain rigid once the air is vacuumed out. This provides solid support for the fracture and keeps the limb set in a healing position determined by a medical professional. The high amount of friction between the core and the outer skin material keeps the honeycomb core formed and positioned within the splint. The splint will not yield under a force roughly equivalent to a plaster cast. The stiffness of a cast prevents micro-fractures from forming while keeping the limb immobilized.

**Application**
The application function is another unique advantage over plaster casts. The splint is attached to a vacuum when the medical professional has placed it correctly on the injured limb. Within seconds the splint is evacuated of all the air and sealed so the patient spends less time in the hospital waiting for more layers of plaster to be applied and for the cast to dry. The materials used in the splint design do not have a memory of past applications so the splint can be reapplied on numerous occasions to account for swelling. Regular check-ups at the hospital can be completed in minutes with no extra materials needed for each visit. The hospital can care for a higher number of patients more effectively.
2.2.3 Overview Drawing

**Stiffness**
The splint will offer a high stiffness, or the force per deflection ratio will be large. This is shown in Figure 5 with the large forces on the material not causing a significant deflection. The splint is able to withstand a large impact force in addition to multiple smaller forces over a long period of time.

![Stiffness Diagram](image)

**Figure 5:** An overview drawing of splint stiffness with respect to force is shown.

**Application**
The application of the splint will make for easy corrections. In Figure 6, the splint was originally applied to the wrong position on the arm. If this were a plaster cast the whole section would likely have to be re-done if this occurs, due to the adhesiveness of the fiberglass material when wet. The application of the splint will allow for a simple correction to the desired position as shown in Figure 7.

![Application Diagram](image)

**Figure 6:** A drawing of the splint applied in an incorrect position is shown.

**Figure 7:** A drawing of the splint applied in a correct position is shown.
2.3 Additional Uses

In addition to the lower arm fracture application, there are other potential applications for the pneumatic splint. One potential use for the splint is a temporary arm immobilization for stroke victims. The arm needs to be set multiple times at greater and greater angles from the stomach for the patient to be able to regain that range of motion. A second potential use for the pneumatic splint is in an emergency setting. The splint could be used to quickly and temporarily immobilize a limb during or after a rescue operation. It is possible the design could be incorporated into a jacket for emergency medical technicians to quickly immobilize the back and neck of a person.

Feasible variations of our design include a splint for immobilizing further up the arm. Additionally, a leg or neck splint could be generated from our original arm splint design. The splint could also be modified to work efficiently with a hand pump, so that the splint could be applied in remote locations without access to electricity for a vacuum pump. Furthermore, the pneumatic splint design could be altered so that a larger range of stiffness could be achieved by the same splint.

3. Evaluation

3.1 Evaluation Plan

Impact Resistance
The strength requirement involves the impact resistance of the innovative splint. To test impact resistance mass was dropped on a formed and vacuumed splint around a patient's arm. The mass drop distance was increased until the impact caused discomfort to the patient's arm or until structural damage to the splint would affect the healing bone. Structural damage was defined by a change in the inside geometry of the splint around the arm, or an increase in space that allows the arm to move freely.

Stiffness
A three point bending test was conducted to determine the stiffness of the splint, which is force over deflection. The resulting stiffness was then used to find an elastic modulus. The resulting modulus was compared to the known modulus of current plaster casts to determine if exceeded the stiffness of the target value. The comparison of stiffness between the two can be directly related to the elastic modulus since both are modeled in the same geometry. During the three point bending test, deflection and the force applied were monitored. Fifteen tests were done to determine repeatability. Forces of 6, 9, and 12 Newtons were applied five times each. Deflection and other distances were measured with a high-resolution caliper. In addition, an immobilization test was conducted.
Radius of Curvature
Formability of the design was established by determining the minimum radius of curvature that did not permanently deform the honeycomb material. The splint prototype was wrapped around dowels of decreasing size until it could no longer maintain surface contact around the circumference or until the honeycomb material permanently deformed. The radius of the dowel at which the honeycomb material deformed, or the splint could no longer be formed properly, was deemed the minimum radius of curvature. This was completed multiple times for repeatability and to establish an average minimum radius of curvature.

Airtight
The airtight requirement involves the puncture strength of the PAC cloth material, the seal of the bag (which contains the core materials) and the valve (used to add/remove air). The PAC cloth maintains the splint-atmosphere pressure difference and holds the core materials in place. To find the puncture strength of the PAC cloth use conditions were mimicked. PAC cloth, with mesh underneath, was stretched tight across a hollow span and a force was applied to a sharp object until the material was punctured. Puncture strength was determined from the force required to puncture. To determine if the bag was airtight, a vacuum was applied to the airtight splint prototype, which was then monitored for leaks. The valve function was tested by applying a vacuum to the airtight splint prototype. The splint was monitored for 24 hours to ensure the valve retained a vacuum.

Application
The application constraint was tested by monitoring the time required for medical professionals to apply the splint prototype to an arm. Two certified EMT's were briefly instructed on how to form the prototype splint around an arm. The participants were then timed on the application process of the splint. The time results were averaged in order to get an estimate of the time required to apply the splint.

3.2 Evaluation Results

Strength and Impact Resistance
To test impact resistance, mass was dropped on a formed and vacuumed splint section. The mass drop distance was increased until the impact could be felt on patient’s arm or until structural damage to the splint would affect the healing bone. The resulting impact resistance was found to be 1.88 Joules. This impact resistance is greater than the target value of 1 Joule. This evaluation is described in more detail in Section 3.1 of Volume II.

Stiffness
A three point bending test was conducted on a formed portion of the prototype to determine the stiffness. A force gauge was used to record the applied force and a caliper was used to record deflection. Fifteen trials were completed, 5 trials at each 6, 9, and 12 pounds. The resulting stiffness values were used to find an average modulus of elasticity of 25.75 ± 1.64 ksi for the prototype design. This modulus value is higher than the target value of 24 ksi for a fiberglass wrapped cast. [5]
Radius of Curvature
The ability to form the splint to the contours of an arm is fundamental to complete limb immobilization and proper healing. The formable criterion was verified by determining the minimum radius of curvature that could be achieved by the splint without permanently deforming the honeycomb material. The splint prototype was tightly wrapped around dowels of decreasing radius. This process was repeated multiple times for different positions on the splint for repeatability and to establish an average minimum radius of curvature. A minimum radius of curvature was found to be .25 inches and was consistent for all positions on the splint prototype. The minimum radius of curvature exceeds the formable criterion as it is less than the ideal value of .625 inches. This evaluation is described in more detail in Section 3.1.1 of Volume II.

Airtight
To find the puncture strength of the PAC cloth use conditions were mimicked. PAC cloth, with mesh underneath, was stretched tight across a hollow span and a force was applied to a sharp object until the material was punctured. Puncture strength was determined from the force required to puncture. For the needle like tip of a .25 inch wood screw, the minimum puncture strength of the PAC cloth was 3.5 lbs. and the average puncture strength was 4.375 lbs. For a #0 screwdriver, the minimum puncture strength was 14 lbs. The ASTM standard to protect clothing from needles is to reject at least a force of 7 lbs. [2] An extra layer of protection may be considered for the next design iteration. This evaluation is described in more detail in Section 3.1 of Volume II.

For the splint design to function properly a vacuum must be achieved within the bag. A vacuum must be attained by both the bag, which contains the core materials, and the valve, used to add/remove air, being airtight. The airtight bag seal was verified by applying a vacuum to the splint prototype and monitoring for leaks. The vacuum applied to the splint prototype resulted in irregular leaks and the bag did not consistently meet the airtight criteria. The valve function was tested by applying vacuum and monitoring for 24 hours. The valve used for the prototype design held a vacuum for 10 minutes. The shortfalls of the splint prototype in the airtight criteria are not a disheartening; they are a result of the production process and can easily be corrected in future work. This evaluation is described in more detail in Section 3.1.1 of Volume II.

Application
The application process of the design is an important aspect when it comes to consumer adoption. The application was judged by the amount of time required for one person to apply the prototype. Trained medical professionals were briefly instructed on how to apply the prototype around an arm. The participants were then timed as they applied the prototype onto an arm. The average time required to apply the prototype was 28.8 seconds, which is far less than the ideal application time of less than 10 minutes. This evaluation is described in more detail in Section 3.1.1 of Volume II.
3.3 Discussion

3.3.1 Strengths and Weaknesses
The pneumatic splint design has several strengths and weaknesses. One of the greatest strengths of the design is the capability for adjustment. With current casts the opportunity to quickly adjust the fit around the patient’s arm doesn’t exist but with the pneumatic splint the main advantage is that adjustments can be made quickly without having to cut off and remove the old cast. This allows for faster, safer, and more efficient protection.

With these improvements in application come potential weaknesses. The first is stiffness of the splint. To create a design that is applied flexible and becomes rigid will lack the stiffness of a fiberglass cast. Honeycomb material simply does not have the rigidity of fiberglass but as long as the splint has sufficient protection against accidental collisions the design will remain successful. Another weakness is the splint flexibility. Because the structural material of the splint is continually connected the ability to form around contours is reduced and could lead to a loose fit. Improving flexibility leads to a decrease in strength so the design will compromise between the two for optimal functionality.

3.3.2 Next Steps
With a working prototype, further testing should be performed. Additional valve and seal options should be tested and researched. The results from testing will determine which of these components will be used in a final prototype. With the final prototype, Wood River Technology can work to attract investors for future development work.

The bill of materials will be utilized to contact suppliers to obtain bulk material quotes. The final product designs can be sent to multiple potential manufacturers to obtain quotes and to move forward with large scale manufacturing. These quotes will allow Wood River Technology to accurately determine the full cost of production and the potential future market price.

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Figure 5: Overview drawing of splint stiffness with respect to force.
Figure 6: Drawing of the splint applied in an incorrect position.
Figure 7: Drawing of the splint applied in a correct position.

Table 1: List of design requirements for a splint.