Jaw Fracture Shrink Support

An alternative to Erich Arch Bars

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2.0 Executive Summary

The purpose of this project was to analyze and redesign the method currently being used for treating jaw fractures. Maxillomandibular fixation (MMF) is a technique of treating these fractures by fixating the lower jaw (mandible) to the upper jaw (maxilla). The most common method involves an invasive means utilizing metal wires to attach “arch bars” to the teeth through the gingiva. This procedure can be painful and expensive; the latter primarily due to its application time. Alternatives do exist, but they have not been widely used. At the conclusion of the project, a modified version of Erich Arch Bars (a preexisting industry standard) was proposed, a prototype was built, and the design was validated.

Design requirements were specified from the various customer requirements that were received from patients and surgeons. Overall, the device needed to withstand jaw forces while allowing the patient to be comfortable without limiting the applicability from patient to patient. After many design iterations, the proposed solution retained the arch bars, but replaced the metal wires with a heat-shrink thread to avoid invasively puncturing the gums while maintaining the same hold of the arch bar on the teeth. Additionally, the thin geometry of heat-shrink thread allows it to be threaded easily in between the teeth. The thread wraps around both the teeth and the arch-bars such that when heated a tension band was created to hold the bars in place.

To validate the solution, physical prototypes and computer simulations were analyzed. Tests on the opening strength of the device, calculations of fatigue life, analysis of heat transfer, and the dimensions of the device were considered. All of the tests performed validated the solution as viable while meeting the design requirements set. Our method of MMF was able to withstand a 30 lb opening force, lasting three times as long as the estimated 500 cycles under the stated force over a 6-8 week treatment period without damaging the teeth or gums when heated. The device does not protrude more than 3 mm from the front surface of the teeth and the components used in the device do not puncture nitrile gloves when a 3.5 lb force is applied. Finally, the device is able to address the same mandible fractures as the Erich Arch Bars. In addition, a cost analysis performed on the device resulted in a possible 20% in savings using probabilistic modifiers.

![Figure 1: Erich arch bar application and the proposed application, respectively.](image)
Contributions:

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- ANSYS Lead
- Reaction Force ANSYS Static Structural Analysis and Report
- Stress ANSYS Static Structural Analysis and Report
- Deformation ANSYS Static Structural Analysis and Report
- Primary Concept and Product Sketch Artist
- Jaw Muscle Force Analysis and Presentation
- Design Show Video Editor
- Brochure
- Carried out Tensile Test on Heat-Shrink Floss and Sample Materials
- Functional Block Diagram
- Design Report Editing
- Created & analyzed molar band ANSYS model
- Report Formatter and Compiler
- Searched and identified bone material properties for ANSYS use
- Compiled and formatted Volume I for the Design Report Assignment #2

Paul Williams:

- Team Lead
- Primary Concept Designer
  - Floss, Heat-Shrink, Mouth Guard, Tooth Jimmy, Adhesive Strip,
- Patent Research and Presentation
- Heat Shrink Prototyping and Report
- Opening Force Prototype Test
- Design Report Final Editing
- Product Design Requirements Development and Editor
- Anna Wikan Patient Interview
- Writer for Statement of Work
- Heat Source Design
- Writer for the Intellectual Property Disclosure Form
- Interview with Dr. Alan Johnson
- Prototyping Materials Purchase
- Video Capture of Application
- Heat Shrink Material Research
- Adhesive Research
Alexander Lin:
- Bone Healing Research and Presentation
- Research in Ultrasound healing
- Research in Electrical Stimulation
- Research in Application of Tissue and STEM Cell Engineering
- Design Show Brochure
- Early prototypes using heat shrink tubing
- Mouth Guard Concept Prototyping + report
- Adhesive Band Concept Prototyping + report
- Primary Concept Prototyping + iterations in floss technique
- Gantt Chart
- Work Break Down Structure
- Patent search on alternative bone healing
- Obtained Access Tensile Testing Machine
- Design Show Poster Design
- Research on Heat shrink materials
- Research on Adhesives (UV, heat, compression curing)
- Research on moldable polymers (toxicity, mold temperature, biocompatibility)
- Contributions and final edits to Design Report.
- Contributed to IP Disclosure Form
- Contacts with Dental School and Biomedical Engineering Program
- Physical models of alternative concepts for Design Show.

Andrew Wollenberg:
- Cost Analysis Research and Presentation
- Environmental Impact Analysis
- Executive Summary
- Gantt Chart
- Treasurer
- Interview with Jason Meyers
- Interview with Dr. Alan Johnson
- Brochure
- Aided in Opening Force Prototype Test
- Aided in Heat-shrink prototyping
- Compilation of Design Reports
- Design Report Final Editing
- Work-Breakdown Structure

Alexander Schoolov
- Aided in developing questions for Anna Wikan Phone Interview
- Interviewed Jason Meyers
- Interviewed Alan Johnson
- Solidworks & ANSYS modeling and troubleshooting
- Adhesive research on 10 orthodontic adhesives with respect to applicability, human use, and tensile/shear strengths
- Created & analyzed mouth guard ANSYS model
- Aided in heat-shrink prototyping
- Found tooth spacing in our ANSYS model
- Attempted to convert anatomically correct skull model from surfaces to volumes
- Worked on 3D printing logistics of the working jaw model, met with Peter Zimmerman
- Ordered, dimensioned, and found material properties for molar bands
- Discussed welding feasibility with expert welder Nathan K.
- Design Report Editing
- ANSYS Heat Transfer Analysis and Report
- ANSYS Molar Band Analysis and Report
- ANSYS Heat-Shrink Thread Analysis and Report
- Tensile Test and Cyclic Fatigue Life Test Logistics
- Functional Block Diagram
- Additional Uses
- ANSYS Video Capture
- Primary References Manager
- Report Formatter and Compiler
- ANSYS Image Capture
- Contacted Vention® Engineers for production feasibility of PET thread
- Primary Concept Prototyping + floss technique development
- Gathered materials and performed Prototype Opening Force Test
3.0 Problem Definition

3.1 Problem Scope

In facial trauma, fractures in the jaw, specifically the mandible, are not uncommon. To treat these fractures, it is a standard practice to affix the mandible (the lower jaw) to the maxilla (the upper jaw), and is widely termed as maxillomandibular fixation (MMF). The current standard method of achieving MMF involves the use of arch bars and wires. Metal wires are wrapped around the teeth and used to fix the arch bars; one bar to the upper teeth, and one to the lower. The bars then have wires or elastic bands wrapped between the two which hold the bars together. These arch bars and wires are effective at achieving MMF by binding the jaw shut. However, the installation of arch bars can be painful, time-consuming, expensive and uncomfortable to wear. The objective of this project is to find an alternative to the application of wires and arch bars which will be faster to apply and remove, less expensive, and more comfortable. This will improve the process of MMF for the patients, surgeons and physicians.

3.2 Technical Review

Background

Evidence of the treatment of jaw fractures has been found dating as early as 1650 BC. Treatment is typically internal-fixation, sometimes in combination with a means of external fixation. Jaw fractures are classified by the segment of the jaw where the fracture is located. Figure 2 illustrates the segments of the jaw and their respective names. [7]

![Figure 2: Various fracture zones](image)

The process of bone healing occurs in three phases – the reactive, reparative and remodeling phases. In the reactive phase a clot forms around the fracture site while fibroblasts replicate. This step stabilizes the bone pieces so that the healing process can continue. The fibroblasts serve as a scaffold for ossification from which a soft callus is formed at the end of the reactive phase. This phase typically lasts 1-5 days. Next is the reparative phase where the soft callus is replaced by hard bone. Chondroblasts are formed from mesenchymal stem cells – they differentiate close to the fracture site and form fibrocartilage which bridges the gap. Cells farther away from the fracture site differentiate into osteoblasts which
replaces the soft callus by lamellar/hard bone. After 1-4 months in this stage, the tissue can move onto the remodeling phase in which the ossified bone is finalized into compact bone. [6]

Currently, the most common practice is to implement just MMF (Figure 3) for minor fractures and adding internal plate fixation between bones for severe fractures. Internal plate fixation utilizes titanium plates that are attached across the fracture site with screws. The arrow in Figure 3 points to the location of one of the two arch bars; in this image there are no titanium plates being used to fixation the fracture site directly. This may be due to the lack of the severity of the fracture. MMF is a technique that uses two arch bars that are attached to the top and bottom dentition, with a series of metal wires looped around the teeth. Dentition is the technical term referring to the arrangement or condition of the teeth unique to each individual person. The two arch bars are then wired shut to immobilize the jaw. The main function of the treatment is to immobilize the jaw so that the bone can heal with proper dental occlusion. [7]

This type of treatment has been used consistently since its inception in the 1970’s. The treatment itself is very effective: only 2.4% of cases have occurred where the implementation has resulted in non-bony union. [8] The current design has several flaws that will be discussed below.

The wires that are used in the current treatment must be secure such that practitioners must often pierce the gingiva and results in the damaged gums often never heal to their previous state. The wires themselves are not comfortable in the mouth, being abrasive in nature due to their thin diameter and often coming in contact with the gums and cheeks. The thin wires also add a danger of puncturing the surgeons’ gloves and fingers during the installation which is a health risk.

The process of installing arch bars is tedious and time-consuming. As Section 5.3 will detail, it adds more than an hour to any given jaw fracture treatment, which comes to be very costly fiscally and in terms of using valuable hospital resources as the procedure must be performed by an Ear, Nose, Throat (ENT) surgeon or a maxillofacial surgeon in an operating room. While the materials used in the application of arch bars are cheap (to the order of $1.00 per treatment) the resource expenses come to a total of $10,000. [10]
In addition, the nature of the treatment requires the jaw to be shut tight to ensure dental occlusion, i.e. that the pre-fracture bite-pattern is restored. This places the jaw at an unnaturally clenched state. After the removal of MMF, many patients must go through a 3-4 week period of rehabilitation to regain a near-full range of motion, which some patients never achieve. There have been reported cases of permanent stiffness in the jaw or uncontrollable jaw spasms. During treatment, the only avenue of nutrition is through a liquid diet. While there are a multitude of alternative treatment devices and patients; there has yet to be one that has come close to replacing MMF as the primary option. Next, we will be discussing relevant existing products.

There are multiple methods for MMF popular in practice. The main types of techniques include Erich arch bars, Ernst ligatures, intermaxillary fixation (IMF) screws, and ivy loops. Other less-used techniques include Glimer wiring, Stout wiring and Kazanjian buttons. [9]

**Erich Arch Bars:** Arch bars are considered by many surgeons to be the primary method of MMF. This technique utilizes thin metallic bars that are attached to the maxillary teeth and to the mandibular teeth separately via thin wires. These wires are twisted over the bars and around the teeth in multiple locations to keep the support in place. Once the bars are attached, separate wires or elastic bands are looped over hooks or protrusions in the upper and lower bars and then tightened to provide enough force to prevent any motion of the jaw.

**Ernst Ligatures:** This technique is often used when there is a relatively simple localized fracture. Ernst ligatures are thin wires that are looped around the upper and lower teeth together and then tightened to provide enough supporting force to temporarily stabilize the fracture site. Substances such as methyl methacrylate (MMA) can also be used to cover over any sharp edges or protrusions to provide a smoother surface.

**Intermaxillary Fixation Screws:** IMF is often considered a “reserve method” that should be used in emergency cases or when the arch bar method cannot be used due to complications. In this technique, self-boring screws are drilled into the underlying bones of the maxilla and mandible to provide attachment points for wires or other supportive material. By tightening these wires or materials, the jaw is prevented from moving which then provides the fracture site(s) the necessary stabilization to heal.

In addition to these methods, there are other concepts that have been patented or published. However, based upon interviewing experts in the field, these techniques have not been widely used. Some of these concepts involve using adhesives to attach jaw support structures to the teeth. Others utilize ways of weaving wires, plastics or metal bands around the teeth and connecting to modify arch bars. Other patents found also involve screws that drill into the underlying bone of the mouth to provide fixation, often very similar to IMF.
### 3.3 Design Requirements

Table 1, found below, outlines the critical design requirements for a successful product.

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Reason</th>
<th>Evaluation Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does not fail when a 30 lb opening force is applied *</td>
<td>Displacement at the fracture site can lead to either offset healing or non-bony union</td>
<td>Physical experimentation by application of forces to a prototype</td>
</tr>
<tr>
<td>Design cannot puncture latex or nitrile gloves when a force of 3.5 lb is applied</td>
<td>Surgeons and patients do not want to have to worry about sharp edges that can hurt</td>
<td>Physical test of the materials used in the device by applying a 3.5 lb force with the parts on a latex or nitrile glove. Check for puncture</td>
</tr>
<tr>
<td>Device can accommodate teeth where the maximum occlusion offset in the lateral plane of motion is 10 mm</td>
<td>The device needs to have a range of application for multiple types of patients and fractures</td>
<td>Distance measurements were done to verify that the device accommodated large lateral offsets</td>
</tr>
<tr>
<td>Device can handle 500 cycles of a 30 lb opening force without failure</td>
<td>The device needs to be able to withstand long-term usage</td>
<td>Finite-element Analysis of a model skull with the device attached, each having model properties consistent with the physical properties</td>
</tr>
<tr>
<td>Maximum thickness or protrusion distances from teeth/gingiva must be less than 15 mm</td>
<td>Having protrusions or large thicknesses can be uncomfortable and prevent lips from closing</td>
<td>Measurement of device when applied</td>
</tr>
</tbody>
</table>

* Approximately 2/3 of the maximum opening force of the jaw measured for 6 males with an average of 28 years
4.0 Design Description

4.1 Summary of Design

The Jaw Fracture Shrink Support Device (JFSSD) is a three component fixture that is comprised of heat-shrink thread, structural support braces often referred to as “arch bars,” and elastic or metallic bands. Maxillomandibular fixation is performed by attaching the arch bars to the teeth by alternately lacing the teeth and arch bar hooks with the heat-shrink thread, applying heat sufficient to shrink the thread, and connecting the upper and lower bars together with the rubber bands. When the thread is heated it will shrink, thus firmly binding it around the teeth and arch bars because of the reduced dimensions. In much the same way as with the current method of Erich Arch Bars, the rubber bands provide enough support to hold the teeth together to keep the proper occlusion during the healing process. An invention disclosure for the design and method was submitted to the Office of Technology Commercialization.

Before the described procedure is performed, the teeth need to be prepared by cleaning out the center spaces, properly aligning the fracture site, applying anesthesia as needed, etc. by the surgeon and support staff. The treatment will consist of 7 steps that will be applied to the maxillary and mandibular teeth separately, starting with the mandibular teeth: Tying, Weaving, Repeated Lacing, Heating, Tying, Repeating, and Closing.

1. **Tie:** The first step in implementing the described treatment is to tie the leading end of the heat-shrink thread around one of the teeth. This will prevent the end from moving or slipping off the teeth in the future.
2. **Weave:** Take the thread and floss it in between the teeth, weaving through the teeth as far back as possible. Continue to weave and floss the thread back again to the starting position and continue to the back teeth of the other side of the mouth. Weave back to the starting position again. Each tooth should have been wrapped around twice.
3. **Repeated Lacing:** Place the arch bar across the teeth so that it is relatively flush with the teeth (this may involve bending the bar) and close to the gums. The bars need to be stable, so clamps or another hand may be necessary to hold them in place. Take the thread and begin to alternate lacing it around a tooth and the hook on the arch bar. Do this about 5 times or until sufficiently secured. Move on to the next tooth and repeat the process. Keep doing this until each tooth has been attached to the arch bars.
4. **Heating:** After a tooth is properly laced, that section can be heated to induce the shrinking bond, or the heat can be applied at the end of the process (up to the surgeon’s preference).
5. **Tying:** Once each tooth has been laced, tie the lagging end of the thread down so that it will not slip off of the teeth.
6. **Repeat:** Repeat steps 1 – 5 for the maxillary teeth.
7. **Closing:** Once the bars are both properly fixed to the teeth, the mouth can be closed and the rubber bands applied around the hooks on the arch bars so that the mouth will stay closed.
4.2 Detailed Description

Functional Block Diagram

For a fractured mandible to heal properly, the JFSSD design is required to perform four major functions. These functions and components can be summarized in Figure 4.

![Functional Block Diagram](image)

**Figure 4: Functional Block Diagram.**

Functional Description

**Setting Occlusion**

Dental occlusion is simply the manner of which the maxillary and mandible come into contact. Proper occlusion is a result of an individual’s genetics and natural wear patterns. Occlusion is typically set by closing the jaw, and putting pressure between the mandible and maxillary in order to feel out the interdigitation of the teeth, where the natural crevices and wear patterns line up. This method even works for extreme cases where the jaw is fractured in multiple locations.

Heat shrink floss is similar to that of traditional wires in that they do not prevent a health practitioner from ensuring proper occlusion. It does not hinder visual inspection of wear patterns.
Tightly Capturing the Teeth

To ensure that the arch bars are secured and stable, the mechanical hold between the floss and the teeth must be adequately rigid. The floss is able to provide the required stability and support after the floss has been heat-treated and conforms around the teeth and sets to a tightly wrapped state. By wrapping the floss around each tooth more than once, good purchase is ensured in the floss-tooth contact.

Restricting Mandibular Motion

The action of the heat-shrink floss wrapping around the teeth provides a suitable site of adhesion for the arch bars in addition to ensuring that the teeth are set for alignment. This is due to the absence of material on the biting surface of the teeth. The arch bars, in turn, keep the teeth set in occlusion while preventing lateral and rotational movement from all three axes, providing a restriction of all six degrees of freedom. The combination of the heat-shrink floss, adhesive, arch bars and rubber bands provide the support necessary to secure the mandible during extended recovery times of up to 8 weeks. This allows the fractured mandible to heal properly through bony union without compromising dental occlusion.

Patient and User Comfort

The utilization of the heat-shrink floss is an alternative to the metal wiring used in the conventional arch bars method. Figure 5 illustrates the replacement of arch wires where, in traditional MMF procedures using arch bars and arch wire, arch wire would lacerate the gums both during application as well as during the subsequent recovery time after the procedure. The floss eliminates the need to pierce through the patient's gum during application but still provides sufficient rigidity when compared to the metal wiring. The possibility of the patient's gums becoming infected will be significantly reduced.
Overview Drawings

Figure 5: Setting Occlusion

Step 1: Securing teeth together

Figure 6: Tightly Enveloping the Teeth

Step 2: Securing Archbar

Threaded several times per tooth before threading next tooth
Threaded under hook to secure archbar
Figure 7: Restricting Mandibular Motion

Step 3: Heat treatment & Bond Application

Figure 8: Arch bars are applied using the heat-shrink embroidery thread prototype.
4.3 Additional Uses

In addition to the long term MMF uses of the heat-shrink thread, there is a closely related short term use of the thread for use as a temporary tension band. Dr. Alan Johnson, an ENT surgeon, mentioned in an interview that he likes to use arch wire as a tension band when the need arises in the same fashion shown in Figure 9.

Figure 9: Tension band through use of arch wire modeled on a horse mandible. [22]

Figure 9, although picturing a horse's mandible, exemplifies the use of arch wire as a tension band, where the result of its use will temporarily aid in securing the fracture site during MMF using arch bars; this makes occlusion easier to set because it is easier to handle the mandible when it acts as one piece instead of two. Additionally, tension bands are useful for holding the fracture site during plating. Our device works well to replace this function that arch wires currently serve by wrapping multiple times, approximately 5 or more as needed, and then applying heat to set and shrink the thread.

5.0 Evaluation

The evaluation of the JFSSD design consists of both physical experiment evaluations as well as finite element analysis using ANSYS. The critical design requirements are listed in Table 1. However, these are not the only requirements that are being evaluated. An additional requirement received special focus specific to the implementation of our design, specifying that the heat-transfer to the patient during implementation did not cause damage to any part of the mouth.

5.1 Evaluation Plan

The first design requirement stems from the opening forces of the jaw muscles. It dictates that the device must be able to withstand an opening force of 30 lbs without failure. In order to do an evalua-
tion of the device with respect to this requirement, failure test of a prototype was conducted. The test consisted of attaching the device to a model skull with realistic geometries and applying known forces to the device to observe how it would fail.

The second requirement of Table 1 was that the device would not be able to puncture Nitrile gloves when a force of 3.5 lbs was applied. To test this, a weight of 3.5 lbs would be placed on the components which would be placed on a Nitrile glove, orienting them such that the “sharpest” edge is pushing on the glove.

The third requirement was that the device would be adaptable enough to accommodate teeth with occlusion offsets of up to 10 mm in the lateral plane. This requirement is necessary because of the wide variation of mouth geometries between patients. The evaluation of this requirement was unnecessary since our device is similar to Erich Arch Bars in this regard, and so it will pass the requirement. If the design had been significantly different than the current method, the test would be performed by varying positions of the lower jaw laterally with respect to the upper jaw and verifying that the device could be implemented without failing the 30 lb force requirement.

The fourth critical requirement would that the device could withstand 500 cycles of a 30 lb opening force to ensure that the device would not break over time. This cyclic fatigue analysis was necessary because the device is generally applied for 6-8 weeks, whereby the device would undergo repetitive stress from the patient. The more times the device is stressed, the more likely it is to fail; it had to be ensured that the device wouldn’t be broken from the fatigue of being “tested” by the patient.

The last requirement specified in Table 1 was that the maximum forward protrusion of the device from the teeth/gingiva had to be less than 15 mm, coming from the necessity for comfort that the patient must be able to close their lips. This was performed by direct measurement of the device.

An additional requirement of special attention was that the application of the heat source to apply the device would not cause harm to the patient. This was evaluated by simulation of conduction in ANSYS using material properties found in the structure of the teeth and gums and confirming that the temperature increase at all points was not high enough to cause damage.

5.2 Evaluation Results

A failure test of a prototype of our MMF device is presented in this report. Our device, which includes arch bars that are attached to the teeth through heat-shrink embroidery thread, was found not to fail under the prescribed loading of 30 lbs. The material used for the prototype was not a full representation of the final product due to different diameters of thread and a different variant of PET. Because the prototype was able to withstand the design requirements, it is assumed that the final product will perform equivalently or even better.
It was not necessary for us to test the second design requirement because the heat shrink thread would never be able to puncture Nitrile with a 3.5 lb force. Careful manufacturing of the arch bars would ensure that no sharp edges exist.

Computer simulation software was used to validate the proof-of-concept of the heat shrink method. An anatomically correct model\textsuperscript{[25]}, verified for accuracy by Dr. Alan Johnson, was found on a 3D modeling forum and was used in its entirety for one analysis; for another analysis, a simplified geometry based on the found model was used. With the material properties of the mandible and force muscles present on the mandible obtained, the appropriate analytical setup was made using the structural analysis system on ANSYS Workbench 14.0. The deformation of the mandible was observed as the outcome of the analysis. With a maximum displacement of less than 0.004 mm, the design concept was shown to be a good candidate for our project.

The evaluation of the fifth requirement was not necessary as again this area of the design was completely parallel to the current solutions which met this requirement already. The diameter of the thread is two orders of magnitude smaller than our 15 mm requirement and it does not add to the thickness of the arch bars.

The heat clamp, one of a handful of methods to introduce heat to our heat-shrink thread, is analyzed using ANSYS Transient Thermal\textsuperscript{®} to consider the potential damage that may occur to the pulp of the teeth and the gums. Additionally, discomfort due to a temperature increase at the surface of the dentin is considered. It is found that application of an 85°C heat source on a 0.84 mm\textsuperscript{2} contact region located on the surface of the enamel will not damage the gums or the pulp of the teeth. Additionally, the dentin will see an increase in temperature that would correlate to the detection of sensitivity in the teeth from a patient’s perspective, but not pain or any tissue damage. Computer simulation software was used to validate the proof-of-concept of the heat shrink method.

With the material properties of the mandible and force muscles present on the mandible obtained, the appropriate analytical setup was made using the structural analysis system on ANSYS Workbench 14.0. The deformation of the mandible was observed as the outcome of the analysis. With a maximum displacement of less than 0.007 mm, the design concept was shown to meet the design requirements of our project. Additionally, the equivalent stress that occurs on the device doesn’t exceed 26.423 MPa, which according to the slight extrapolation of Figure 1 quantifies the number of cycles to failure to a conservative estimate of at least 1500 cycles, greatly exceeding our marginal target of 500 cycles.

The cost of the material for each implementation of the heat-shrinking floss design is higher than that of traditional MMF – for each instance of this device, the cost of purchasing the heat-shrinking thread is at most $100 whereas the stainless steel wires in current use can cost less than $1 per procedure. The benefit of the heat-shrinking thread design lies in the discrepancy in implementation costs. Each instance of implementing this solution results in a conservatively-estimated savings of approximately $1970.
While it cannot be said that there would be no environmental effects in switching from using stainless steel wire to using PET thread, the effects are hardly worth noting. There would be an increase in produced PET of less than $2 \times 10^{-9}\%$ of the current production, and this does not account for the high recyclability of PET.

### 5.3 Discussion

#### Strengths and Weaknesses

The key feature of our design is the use of heat shrink material as an interface between a patient’s teeth and arch bars. Our device fulfills the status quo in all regards, but outperforms the current procedures in cost-effectiveness and convenience. The most important feature of the treatment is the immobilization of the jaw.

#### Immobilization of the Jaw

Our device is able to stay rigid when an average opening force of the jaw is applied. The device was also found able to withstand the jaw opening-forces in computational analysis using ANSYS. Material properties were obtained from the manufacturer and from experimentation. The device was applied to an ABS model of a skull; this physical prototype was also able to withstand simulated forces from the jaw. However, the strength of the heat shrink floss is inherently less than that of the traditional metal wires. In cases where the device is subjected to stresses much greater than this average opening strength, the traditional wiring method may hold better than our design. However, this can easily be overcome by the application of additional floss while the same cannot be done readily with wires. Another noteworthy disadvantage of the use of wires in this regard is that the twists in metal wires loosen over time. Based on the material properties of the heat shrink material, it is assumed that the material will maintain its hold strength over time better than the traditional method and avoids readjustments due to loose arch bars. While the heat shrink material would be susceptible to damage from cuts, this is not a concern as patients consume a mostly liquid during the treatment.

#### Comfort

With the lack of cut and twisted metal ends, our device is likely to be more comfortable than current designs for the duration of treatment. Metal wires are pushed through the gums in application which is painful, but even in wearing the device post-operation the wires can be abrasive if not just irritating to patients. This can lead to general discomfort, but in some cases results in permanent damage to the gums. Our design would avoid damage to the gingiva as well as likely reducing general discomfort to the patients.
Application and Removal

While the JFSS device was applied only a small number of times, these application results suggest that the proposed method is faster. Iterations of the proposed solution had an application time of roughly 40 minutes; because the context in which these tests were performed was idealized, actual implementation could be longer. Even if the application process took 120 minutes - three times as long as the prototype – it is still 21 minutes faster than the average application using Erich Arch Bars. The current method requires puncturing the gums with wires and tightening them to attach the arch bars to the jaw. In most cases, local anesthetics are used to relieve pain. With our device, the heat shrink thread simply needs to be looped numerous times around the teeth. The tension then comes from applying heat to the floss and inducing shrinkage. The proposed solution is also safer for surgeons since the elimination of wires also eliminates a puncture risk – a serious concern in medical procedures.

There is a substantial advantage to using the proposed method of MMF over the standard wires in the removal procedure. Not only is the removal of the JFSSD design faster than the wire method, it does not require anesthetic for removal as the application is non-intrusive. Additionally, the removal can take place in a clinic instead of the operating room, a major cost savings.

Effects on dentition and gingiva

Current practice wire fastened arch bars damages the gums. Our design avoids this by not puncturing the gums during installation. Other current methods use adhesive to secure the immobilizing structure the teeth, which can cause staining or demineralization on the teeth. In addition, the non-invasive aspect of the procedure helps to reduce infection.
## Costs

![Cost Prospective Chart](image)

Figure 10: Relative costs of the current process versus the proposed process. Application cost contributes the most, incorporating the $6500 range not shown.

The total material cost for the heat shrink floss was higher than traditional arch bar methods, adding up to $100 per implementation while the standard arch-bar wire has practically no cost. However as aforementioned there is a substantial potential for savings from the procedure itself, namely time to install and remove, facilities required and staff required. At the conclusion of the cost analysis, an average reduction of roughly $1900 can be expected per treatment using the heat shrink floss method. More detail on this analysis can be seen in Section 5.2, as well as in the supporting documents section 3.2.

Overall, our design matches or exceeds the performance of current designs. The only potentially negative aspects were in the material properties of the heat shrink floss which did not detract from the immobilization of the jaw under normal conditions.

## Next Steps

More rigorous testing can be performed after the provider of the ideal heat-shrinking floss is decided (Vention Medical is currently the best prospective source). Samples of heat shrinking floss would be acquired from a manufacturer. A formalized testing rig should be developed to test the device as well to better capture the jaw forces as well as cyclic loads as while the tests performed were adequate for
this stage in design, ideally a more definitively repeatable testing process and therefore fixture would be developed. Then a manufacturing plan can be laid out to produce these heat shrink materials.

Having materials finalized, clinical trials would be done. This should be done with a control group utilizing current arch bar treatments and a treatment group using the heat shrink floss method. This would give evidence comparing the effectiveness of the treatment in terms of bone healing, patient comfort and through having then collected a larger data-sample of the time required for application, the cost savings through time differentiation could be confirmed or refuted.