Jaw Fracture Shrink Support

An alternative to Erich Arch Bars

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1.0 Product Definition Supporting Documents

1.1 Annotated Bibliography

Summary

Research is a quintessential aspect in any product design and was one of the first steps that we took in as a group for our senior design project to design an alternative to arch bars for application for fractured mandibles. The initial research that was conducted was background research on a variety of characteristics involved with our project such as bone healing, muscle forces, patents and costs. The next research conducted includes interviews with experts in the field of arch bars application as well as a former patient for customer feedback in order to generate a user needs list. The information in these papers provided some of the concept designs that we have generated.

References


This is the final report for the Fall 2007 Human Jaw Simulator Technical Design Team. It contains design, specifications, tests, and results of their apparatus meant to replicate the motion and forces present in the human jaw. It was used as background information for our project for force representation on the jaw.


This article contains information on the muscle forces exerted at specific angular positions of the jaw for a range of males and females. It was used to give us a background on the minimum requirements for our product.

This article contains information on the finite element analysis on the human mandible. It was used to give us a background on the application of finite element analysis for our project.


This article describes an experiment set up to validate a model of a human mandible. It was used to obtain property values on bones for finite element analysis.


This document describes the use of finite element analysis to design and optimize a bone plate for fractures on the mandible. It was used to understand the use of finite element analysis for our product.


This journal provides some visual aid in explaining the stages of bone healing. It also goes into more detail in maintain the ideal track towards healing. Different theories of bone healing are also included for instance the effect of mechanical stress on the fracture site and its implications. This journal article showed us that mechanical stress to a union site had showed to increase bone strength after healing. However it showed the importance of maintaining the soft callus in order to avoid complications like non-union.


This journal went into detail of the healing process of bones. It goes into detail on the cellular level and covers complications and factors in non-union. It also goes into detail pharmacological aspects that could improve bone healing. Avenues of decreasing heal time were taken into account with this journal. Also this article gave insight on treatment of elderly patients.

[8] Cienfuegos, Ricardo; Cornelius, Carl-Peter; Ellis III, Edward; Kushner, George, 2008, “AO Foundation.” From https://www2.aofoundation.org/wps/portal/lut/p/c1/04_SB8K8xLLM9MSSzPy8xBz9CP0os3hng7BARyd DRwN3Q1dDA08XN59Qz8AAQwMDA688Jk8haG6yg6nqKezn7GTH1DahlBuP4_83FT9gtyLcgbBttnJy/dl2/d
This website provides a variety of possible mandible bone fractures as well as current methods of repair. It was used for the final design requirements when considering user interact with user needs.


This link just gave an overview of bone healing in a general manner. It described the 3 stages of bone healing and activity on a cellular level. This article was used to provide general background in bone healing so that concepts could be constructed as to avoid non union and complications.


This site was used as a resource for evaluation of costs related to the entire process of jaw reconstruction. Costs vary region-by-region, so the price estimates are based on values provided for the ZIP code 55455, corresponding to Minneapolis MN.


This lecture was used for heat transfer analysis of the enamel, dentin, gums, and tooth pulp with regards to approximate geometries and thicknesses.


This study was used to find the temperature limits before necrosis occurs in the tooth pulp in addition to the temperature in the dentin before patients experience sensitivity to heat.


This article describes the Vention’s PET heat-shrink tubing mechanical and thermal properties. It was used for the yield strength for our ANSYS simulations.

This was used to find Poisson’s Ratio for PET. It is a relatively stiff polymer based on comparison with other polymers in this data set.


This site contains stress/strain data for high strength PET films and was used to extract the elastic modulus for our PET heat-shrink thread.


This resource provided useful cost and timing estimates from previously compiled cost data which is not generally trivial to acquire.


This source provided the primary baseline estimate for OR costs by time, from which a separate more conservative estimate was made.


This data was used to ascertain an estimate for the overhead of a clinic with respect to time used in a room; this makes the assumption that overhead costs for a dental clinic and ENT-clinic are effectively equal.


This site was used to glean the statistical data for weighting costs by assuming past statistical trends will serve as an accurate model of probability for future instances of similar studies.

This site was used as a source for how much PET is created annually.


This textbook confirmed the fatigue life of our PET heat-shrink thread by quantifying the life of PET under a 26.23 MPa load by slightly extrapolating a stress amplitude vs. cycles to failure graph.


This article discusses the tension band technique used to address fractures occurring in between teeth for horses; the technique is also used for humans as well.


This is just a source for a picture of applied arch bars that looks analogous to our picture of the applied solution on the 3D model skull for side-by-side comparison.


This textbook contains the equations and some figures used for the heat transfer analysis in ANSYS.


pp. 215-220
1.2 Patent Search

Objectives

The objective of this patent search is to research on devices that were made to fixate the lower human jaw to the upper jaw through the teeth. Since the team is working with the University of Minnesota’s Medical Device Center, we are designing our product with the possibility of the design being patented.

Search Criteria

The patents listed were found using Google patents when searching with combinations and variants of the following keywords:

- Maxillo-Mandibular Fixation
- MMF Device
- Polymer Intermaxillary Fixation Device
- Jaw Fixation Device
- Jaw Fracture Fixation
- Arch Bar Alternative

Findings:

Pat. 2502902 Intraoral Fracture and Orthodontic Appliance (Benjamin F. Tefflemire): The device described in this patent consists of metal fasteners that slip over individual teeth with a band that can be tightened to create sturdy support. Metallic bars are then attached to these fasteners and have hooks that have wires or elastics to create enough tension to maintain proper occlusion and prevent the jaw from moving.

Pat. 5613853 Mandibular Fixation System (Paul E. Chasan et al): This device essentially utilizes the novel design of zip-ties as a way to fix arch bars to teeth instead of using wires.

Pat. 6120288 Device and Method for Mandibular Fixation (Richard J. Deslauriers): This device consists of a flexible strip of polymer or fibrous material that can be adhered directly to the teeth using an epoxy or other adhesive. When the epoxy or adhesive cures, the strip becomes rigid, giving enough support to fixating wires or elastics to induce MMF. The wires or elastics are fixated to each strip via hooks or protrusions from the strips. Etching of the teeth is required prior to applying each strip. Removal can be facilitated by “lift-tabs” that can be made from materials such as Teflon.

Pat. 6257884 Maxillomandibular Fixation Device (Peter Chang): The device described in this patent consists of an inner bar that goes behind the teeth which has numerous cylindrical protrusions to insert
between teeth. Each protrusion has a tapped hole at the end to accommodate small screws which are used to fix another bar to the first but on the outside of the teeth. This is done to the mandibular (bottom) teeth as well as the maxillary (bottom) teeth. At this point, the protruding screw ends provide attachment points for wire or elastics to be used in order to keep the top and bottom segments in tension sufficient to keep the proper occlusion and prevent jaw motion.

Pat. 8062032 Apparatus, System, and Method for Maxillo-Mandibular Fixation (Scott E. Bulloch et al): The apparatus in this patent is a strap-like belt that attaches to the underlying bone in the mouth. The belt can be adjusted to have variable tension and therefore the closing force on the mouth can be adjusted to induce proper occlusion.

Pat. 8118850 Intermaxillary Fixation Device and Method of Using Same (Jeffrey R. Marcus): The primary advantage of this device is the ability of a patient to maintain proper dental hygiene. This is done by attaching bars to the underlying bone via screws, similar to that of IMF. The bars contain hooks or other types of fixation points that allow for wires or elastics to attach. The wires or elastics, much like in arch bars, help to keep the proper occlusion of the mouth by preventing any motion in the jaw.

Pat. 8303300 Intermaxillary Fixation Bonded Bracket Assembly (Lewis Pitnick et al): In this patent application, a small wire attachment point is adhesively bonded to individual teeth such that wires or other kinds of looping fixtures can be applied between one on the upper and one on the lower teeth, in order to create enough tension overall to induce MMF.

Pub. 2005/0282115 Maxillo-Mandibular Fixation System & Method (Tewodros Gedebou): The concept of this patent is a wire that can be used to replace the wire used in arch bars. The “interdental floss or chord” as described in the patent has an alternating thickness or diameter characteristic that can be utilized to weave the wire in between the teeth and around the arch bars.

Pub. 2010/0124727 Intermaxillary Fixation Device and Method of use (Bharat Shah et al): The device described in this patent application incorporates a polymeric version of the arch bar that is attached to the teeth by using zip-ties in a novel manner. The zip-ties go around and in-between the teeth, then are inserted through a hole in the polymer bar and fastened via a locking mechanism on the zip-tie. This is done multiple times until proper stability is achieved. Then, a modified version of the zip-tie is inserted into a locking mechanism on the upper jaw and on the lower jaw arch bar such that the lock prevents jaw motion and keeps the proper occlusion.

Pub. 2011/0152946 Flexible Maxillo-Mandibular Fixation Device (Robert Frigg et al): The device described by this patent incorporates IMF screws to fix a single semi-flexible bar to the bone areas of the mouth. The bar can be in a wave-like shape that alternately crosses over to the mandible and maxilla, being fixed by a screw(s) at each point. This bar can vary in shape and size to fit the patient.

Pub. 2011/0152951 Arch Bars for use in Maxillofacial Surgery and Orthodontics (Stephen B. Baker): In this patent application, modified arch bars are used to induce Maxillo-Mandibular Fixation. The arch bars are attached to the underlying bone of the mouth via screws or nails, and then are connected by
using wires to hold the mouth in its proper occlusion. A variant described in the application describes a way in which only a single bar could be used with an external fixture for support.

Pub. 2011/0288551 Maxillo-Mandibular Fixation Apparatus and Method (Russell B. Walther): The concept of this patent is a device that assists in the attachment of modified arch bars to the teeth by looping a thin wire around individual teeth and tightening them with a fastener. The fastener is comprised of a clip and a tightening nut to hold the wire in place and increase the tension respectively.

Pub. 2012/0029577 System and Method for Bone Fixation using Biodegradable Screw having Radial Cutouts (Sean Kerr et al): A biodegradable screw is discussed in this patent application which has the potential to be used in the intermaxillary fixation (IMF) process. By using a screw such as this, the need for removal is eliminated. It is ideally composed of a polymeric blend which may include homopolymers, copolymers, or a combination of each, such as polylactide, polycaprolactone, polyglycolide, polydioxanone, polycarbonates, and derivatives.
Cover pages of each patent:
A method for fixing a patient’s mandible such that a fracture therein can be healed. A plastic cable tie is utilized to attach an arch bar to the patient’s upper and lower teeth. The shape of the cable tie is designed to easily fit between the teeth and to have a low profile to allow for maximum patient comfort.
United States Patent

Deslauriers

[54] DEVICE AND METHOD FOR MANDIBULAR FIXATION

[21] Appl. No.: 09/159,638

Related U.S. Application Data
[60] Provisional application No. 60/059,087, Sep. 25, 1997.

[51] Int. Cl. 7 \………………………………... A61C 3/00
[52] U.S. Cl. \………………………………... 433/9, 433/23, 433/39

[58] Field of Search \………………………………... 606/74, 151; 433/9, 433/23, 39; 602/7

References Cited

U.S. PATENT DOCUMENTS
3,874,876 4/1975 Dari et al.
3,881,473 5/1975 Corvi et al.
4,089,485 12/1978 Eda \………………………………... 433/9
4,094,188 2/1990 Blaunstein
5,102,332 5/1992 Uhoff
5,480,001 12/1995 Fieser-Kin et al. \………………………………... 433/9

FOREIGN PATENT DOCUMENTS
2684539 12/1991 France

OTHER PUBLICATIONS


Primary Examiner—Michael Buiz
Assistant Examiner—Julian W. Wuo

[57] ABSTRACT

A device and method for mandibular fixation are disclosed. The bondable bracket brace includes a cloth-like body having a first surface for attachment to a tooth surface and a plurality of attachment points on the cloth-like body. The cloth-like body may be made of Kevlar®, nylon, fine metal mesh, or combinations thereof. The bondable bracket brace may also include lift posts for removing the bondable bracket brace, and may also include fiber straps for securing the bondable bracket brace to a tooth surface. A method of mandibular fixation includes the steps of: (1) preparing a surface of the teeth, (2) applying a first adhesive layer to the prepared surface; (3) positioning a bondable bracket brace with a cloth-like body on the first adhesive layer, (4) curing the adhesive; and (5) securing an object to the bondable bracket brace with a linking member. A system of mandibular fixation includes a first bondable bracket brace having a plurality of attachment points for attachment to a tooth surface, a bondable bracket brace having a plurality of attachment points for attachment to a tooth surface, and linking members for securing the attachment points on the first bondable bracket brace to the attachment points on the second bondable bracket brace. A bone immobilization system is also disclosed and includes a flexible cloth-like body for surrounding a bone to be immobilized and a curable adhesive applied to the cloth-like body. When the curable adhesive is cured the cloth-like body becomes rigid, immobilizing the bone.

29 Claims, 12 Drawing Sheets
MAXILLOMANDIBULAR FIXATION DEVICE

Inventor: Peter Chang, 14702 Forest Wood Ld., Midlothian, VA (US) 23112

Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

Appl. No.: 09/418,363
Filed: Oct. 14, 1999

Int. Cl. A61C 5/00
U.S. Cl. 433/18; 433/215
Field of Search 433/18, 19, 20, 433/215

References Cited
U.S. PATENT DOCUMENTS
274,367 3/1983 Patrick
1,797,461 3/1931 Preston
2,481,177 9/1944 Jolliffe
2,502,092 4/1950 Tdikman
3,346,511 * 10/1967 Weissman
3,526,561 9/1970 Keesing
3,913,228 10/1975 Weisblum
4,096,299 5/1978 Williams
4,202,328 5/1980 Solkin
4,230,004 10/1980 Richter
4,292,025 9/1981 Forster
4,316,194 * 3/1982 Klein 433/22
4,813,869 3/1989 Gateswood
4,875,449 10/1989 Becuolkes, III
4,960,246 * 11/1990 McCollum et al. 433/18
5,328,364 * 7/1994 Doyle 433/18
5,842,856 12/1998 Casey
6,086,366 * 7/2000 Fields 433/18

FOREIGN PATENT DOCUMENTS
601635 8/1934 (DE) 831743 * 2/1952 (DE) 433/18

OTHER PUBLICATIONS
R. Hopkins—Mandibular fractures: treatment by closed reduction and indirect skeletal fixation (no date)
* cited by examiner

Primary Examiner—Ralph A. Lewis
Attorney, Agent, or Firm—Pitts & Brittain, P.C.

ABSTRACT
A maxillomandibular fixation apparatus for locking teeth of the lower jaw and/or teeth of the upper jaw together to allow a fractured maxilla or mandible to heal. The apparatus includes a flexible arcuate arch bar that is positionable on the interior side of the teeth of a fractured jaw. A plurality of flexible receptacle segments are anchored onto the interior arch bar and include arms positioned to project from the arch bar between the teeth of the upper or lower jaws. Each segment arm includes a distal end that extends outward from each side of respective teeth towards the patient's cheeks. A separate exterior receiving bar can be aligned around the exterior surfaces of the teeth, the exterior receiving bar having holes therethrough for insertion of the distal ends of the segment arms. A plurality of lug nuts can be fastened to the distal ends, clamping the exterior receiving bar against the exterior side of the teeth, and drawing tight the interior arch bar against the inside of the teeth. During wear, the lug nuts are adjusted to change the distance between exterior and interior arch bars. The exterior lug nuts may be attached to upper and lower interior arch bars, to fixate the maxilla and mandible teeth and jaws together for healing.

20 Claims, 4 Drawing Sheets
United States Patent
Bullock et al.

(54) APPARATUS, SYSTEM, AND METHOD FOR MAXILLO-MANDIBULAR FIXATION

(75) Inventors: Scott E. Bullock, St. George, UT (US); Russell G. Olsen, Cedar City, UT (US)

(72) Assignee: Intrinsic Medical, LLC, Cedar City, UT (US)

(34) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 457 days.

(21) Appl. No.: 12/257,013

(22) Filed: Oct. 23, 2008

(65) Prior Publication Data
US 2010/0105001 A1 Apr. 29, 2010

(51) Int. Cl.
A61C 3/40 (2006.01)

(52) U.S. Cl. .................................................. 433/18, 433/215

(58) Field of Classification Search .................................. 433/18, 433/215, 19, 27/21.1, 606/105, 606/5.17, 602/902, 128/848, 859.862

See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS
1,870,566 A 4/1934 Holm
2,086,626 A * 7/1932 Woodward .......................... 602/1
2,172,125 A * 4/1939 Mogen
2,803,902 A * 4/1950 Tofflemire .......................... 606/54
4,239,101 A 10/1980 Richer
4,813,809 A 3/1989 Gateswood
4,972,649 A 10/1990 Beavers, III
5,562,045 A 10/1990 Devincenzo et al.

5,842,856 A 12/1998 Casey
5,914,574 A 6/1999 Casey
6,086,865 A 7/2000 Fields
6,142,779 A 11/2000 Siegel et al.
6,206,551 B1 7/2001 Sargent
2008/0175185 A1 7/2008 Williams


OTHER PUBLICATIONS

* cited by examiner

Primary Examiner — John J. Wilson
(74) Attorney, Agent, or Firm — Kunstler Neeldam Mussey & Thorpe

(57) ABSTRACT
Described herein are various embodiments of an apparatus, system, and method for maxillo-mandibular fixation. For example, according to one representative embodiment, an apparatus for maxillo-mandibular fixation includes a plurality of connectors, a fixation belt, and a release. The connectors include one or more anchors configured to attach to bone and a fixation belt attachment. The fixation belt includes a plurality of fasteners each fastener attachable to a fixation belt attachment and a flexible mesh disposed between the plurality of fasteners. The release is disposed on the fixation belt and has an engaged position restricting movement between the plurality of fasteners and a disengaged position allowing movement between the plurality of fasteners.

23 Claims, 12 Drawing Sheets
(12) United States Patent
Marcus

(54) INTERMAXILLARY FIXATION DEVICE AND METHOD OF USING SAME

(76) Inventor: Jeffrey R. Marcus, Chapel Hill, NC
          (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 141 days.

(21) Appl. No.: 12/329,263

(22) Filed: Dec. 5, 2008

(51) Related U.S. Application Data
       Provisional application No. 61/012,557, filed on Dec.
       10, 2007; provisional application No. 61/012,561,

(52) U.S. Cl. 17/04, 17/84

(58) Field of Classification Search ................. 435/22, 175, 334/5, 666/61, 285, 810, 284, 285, 286, 300, 105;
       602/302, 17, 128/286

See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

6,086,365 A 7/2000 Fields
6,237,261 B1 5/2001 Carthy
6,237,274 B1 7/2001 Chang
6,595,274 B1 7/2003 Iwase
2001/0618176 A1 4/2001 Heenan

Continued

FOREIGN PATENT DOCUMENTS

Continued

OTHER PUBLICATIONS

005645 dated Feb. 6, 2009.

Continued

Primary Examiner — cris L. Rodriguez
Assistant Examiner — eric Rosen
Attorney, Agent, or Firm — Foley & Lardner LLP

(57) ABSTRACT

A medical apparatus for intermaxillary fixation or stabilization
has a bar with a first attachment loop, a second attachment
loop, and a plurality of hooks wherein the bar is an arch
bar and the first attachment loop and the second attachment
loop are located distally to one another. Another medical
apparatus has a bar having a first attachment loop assembly,
second attachment loop assembly, and a plurality of hooks,
wherein the bar is an arch bar and the first attachment
loop assembly and the second attachment loop assembly are
movably engaged to the bar. The bar may also have one or more
additional attachment loop assemblies located between the
first and second attachment loop assemblies. The attachment
loop assemblies may each have a bracket, an attachment loop,
a stem, and a set screw. The attachment loops are capable of
receiving a screw to attach the arch bar to a mandible, a
maxilla, and/or a prosthetic device.

18 Claims, 7 Drawing Sheets
(54) INTERMAXILLARY FIXATION BONDED BRACKET ASSEMBLY

(76) Inventors: Lewis Pitnick, Boca Raton, FL (US); Matthew J. Pitnick, Boca Raton, FL (US)

(74) Attorney, Agent, or Firm — Phillip Vallee; Patent CEO

(12) United States Patent

Pitnick et al.

(10) Patent No.: US 8,303,300 B2

(45) Date of Patent: Nov. 6, 2012

(56) References Cited

U.S. PATENT DOCUMENTS

4,639,249 A 1/1987 Goggin
5,184,935 A 2/1993 Hour et al.
6,086,365 A 7/2000 Fields

(*) cited by examiner

Primary Examiner — Cris R. Rodriguez
Assistant Examiner — Mimi Y. A. Aponte

(19) Abstract

An inter-maxillary fixation bracket having a top section having a mechanism for permitting attachment of a connection device and a base integrally with the top section where the base has grooves embossed on its underside for application of a dental adhesive such that a bracket can be fixed to a patient's tooth. An assembly includes a bracket with a connector attached to it utilizing a bracket connection mechanism, a linkage device, and another bracket and connector attached similarly. A method is also described for immobilizing a patient's jaws including the modeling of a bracket assembly proximate to the patient's teeth to determine if the bracket assembly must be adjusted. And if so then adjustments to the linkage and connectors are made as appropriate. Adhesive is applied to bracket pads before attachment of the bracket pads to selected teeth and repeating the process for more brackets.

4 Claims, 5 Drawing Sheets
Improved maxillo-mandibular fixation systems and methods that deploy an inter-dental segment of flosscord that can be substituted for conventional inter-dental wires. The inter-dental segment comprises an elongate segment of flexible, malleable material formed as a cord or floss having alternating portions formed thereon that are defined by a first floss portion having a first smaller size designed to be positioned or flossed between adjacent teeth, and a second segment or portion having a larger size that is operative to be interconnected with a conventional arch bar. In an alternative embodiment, the segment may comprise an inter-dental floss segment having first and second ends having a first larger size and an intermediate portion having a smaller size, the latter being operative to be looped around and flossed between opposed sides of one of a patient's teeth.
INTERMAXILLARY FIXATION DEVICE AND METHOD OF USE

Inventors: Bharat Shah, Springfield, MO (US); Kara Childers, Grovespring, MO (US); Keola Davis, Springfield, MO (US)

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SPRINGFIELD, MO 65808-4288 (US)

Appl. No.: 12/622,485
Filed: Nov. 20, 2009

Abstract

An apparatus and method for fixing a patient's jaw by using arcuate arch bars which are fastened to both the upper and lower teeth using a plurality of zip ties. The arch bars are provided with bores and zip ties are passed through these bores and fastened to the patient's teeth. Each arch bar is provided with interarch receptacles which receive and engage a zip tie. The receptacles are rotatable and are generally aligned between the upper and lower arch bars. Additional zip ties with opposed teeth are passed through the upper and lower pairs of arch bar receptacles and tightened to fix the lower jaw to the upper jaw.

Related U.S. Application Data

Provisional application No. 61/199,823, filed on Nov. 20, 2008.
Flexible Maxillo-Mandibular Fixation Device

Inventors: Robert Frigg, Langendorf (CH); Jens Richter, Oberdorf (CH); Samuel Lenzinger, Oberdorf (CH); Carl Peter Cornelius, Munich (D); Ross Jonathan Hamel, West Chester, PA (US)

Assignee: SYNTHES USA, LLC, West Chester, PA (US)

Filed: Nov 23, 2010

Related U.S. Application Data
Provisional application No. 61/263,542, filed on Nov 23, 2009.

Abstract
A system for achieving maxillo-mandibular fixation includes a bone fixation device including a bone fixation body formed from a plurality of links. The links define corresponding crests and valleys so as to impart flexibility into the bone fixation body. Thus, the bone fixation body can be aligned with the dental arch of the mandible and maxilla as necessary, and subsequently fastened to the underlying bone. Each bone fixation device includes at least one securement location on the fixation body that can attach to a securement device, such that the securement device fixes or stabilizes the mandible and the maxilla with respect to each other.
ARCH BARS FOR USE IN MAXILLOFACIAL SURGERY AND ORTHODONTICS

Inventor: Stephen B. Baker, Med. Ex., VA (US)

Appl. No.: 13/061,119
PCT Filed: Aug. 27, 2009
PCT No.: PCT/US09/55212
§ 1371 (c)(1), (2), (4) Date: Feb. 25, 2011

Provisional application No. 61/092,204, filed on Aug. 27, 2008.

Publication Classification
Int. Cl.
A61B 17/84 (2006.01)
US. Cl. 606,628

ABSTRACT
A dental arch bar system includes upper and lower dental arch bars having movable transverse arms and ligature connectors. Fintographs secure the transverse arms to a subject's maxilla and mandible. Ligatures are secured around upper and lower ligature connectors to achieve intermaxillary fixation. A method is also disclosed for using the arch bar system to achieve intermaxillary fixation by securing the arch bars against opposing dental arches with ligature connectors of the upper and lower arch bars generally aligned. In some embodiments, a single dental arch bar is utilized and one or more ligature connectors (such as screws) are fixed directly in the bone of the opposite jaw. Ligatures then are secured to arch bar ligature connectors and the opposing ligature connectors.
The present disclosure provides for an apparatus and method for supporting a maxillo-mandibular fixation by securing the maxillary teeth and mandibular teeth together in a faster and less harmful manner, includes a floss-wire component for circumferential wiring a tooth initially by flowing the interproximal space of a tooth therewith and thereafter causing circumferential wiring of a tooth when the floss-wire component is pulled, the floss-wire component having a distal portion composed of a floss-like material and a proximal portion composed of a wire-like material, a clip having an anchoring point and grasping point, the clip interacts with the floss-wire component, thereby causing the clip and the floss-wire to secure tightly to a tooth, and a bar positioned between the buccal surface of one or more teeth and one or more clips, the bar having a plurality of indices to increase the stabilization of one or more clips.
A system for bone fixation is provided including a biodegradable polymer screw and corresponding driver element. The screw is provided with a head having at least two regularly spaced notches. The driver element is provided with a distal end having at least two regularly spaced notches. The outer surface of the driver can correspond to the outer perimeter of the screw head and the notches and prongs are adapted to securely couple in a displacement fit to allow the drive to apply the screw into bone.
1.3 User Need Research

Summary of User Needs

This project’s objective is to provide an alternative to arch bars that fulfills customer feedback. Therefore, the user needs listed by our team comprised of a former patient and certified specialists involved in the application of arch bars. Table 1 provides a summary of the needs gathered from Dr. Alan Johnson, ENT surgeon resident Jason Meyers, and MMF patient Anna Wikan.

Table 1: Summary of User Needs

<table>
<thead>
<tr>
<th>#</th>
<th>NEED</th>
<th>Importance</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Immobilize mandible</td>
<td>5</td>
<td>Dr. Alan Johnson &amp; Jason Meyers</td>
</tr>
<tr>
<td>2</td>
<td>Be comfortable for duration of treatment</td>
<td>5</td>
<td>Dr. Alan Johnson &amp; Jason Meyers &amp;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Anna Wikan</td>
</tr>
<tr>
<td>3</td>
<td>Ability to temporarily move jaw</td>
<td>2</td>
<td>Dr. Alan Johnson &amp; Jason Meyers &amp;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Anna Wikan</td>
</tr>
<tr>
<td>4</td>
<td>Withstand entire treatment time (durable)</td>
<td>4</td>
<td>Dr. Alan Johnson &amp; Jason Meyers</td>
</tr>
<tr>
<td>5</td>
<td>Apparatus must be easy to properly install</td>
<td>5</td>
<td>Dr. Alan Johnson &amp; Jason Meyers</td>
</tr>
<tr>
<td>6</td>
<td>Application procedure must be timely</td>
<td>4</td>
<td>Dr. Alan Johnson &amp; Jason Meyers</td>
</tr>
<tr>
<td>7</td>
<td>Apparatus must not inhibit plating application when necessary</td>
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<td>Dr. Alan Johnson &amp; Jason Meyers</td>
</tr>
<tr>
<td>8</td>
<td>Treatment flexibility (i.e. fracture types)</td>
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<td>Dr. Alan Johnson &amp; Jason Meyers</td>
</tr>
<tr>
<td>9</td>
<td>Device must facilitate food intake</td>
<td>3</td>
<td>Dr. Alan Johnson &amp; Jason Meyers &amp;</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Anna Wikan</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Rating</td>
<td>Contributors</td>
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<td>-----------------------------------------------------------------------------</td>
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<td>-------------------------------------</td>
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<td>10</td>
<td>Apparatus shouldn’t require operating room or ENT specialist / maxillofacial surgeon</td>
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<tr>
<td>12</td>
<td>Maintain Immobilization until jaw heals</td>
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<td>Dr. Alan Johnson &amp; Jason Meyers</td>
</tr>
<tr>
<td>13</td>
<td>Ability to quickly open mouth in an emergency (i.e. vomiting)</td>
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<td>Dr. Alan Johnson &amp; Jason Meyers &amp; Anna Wikan</td>
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<tr>
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<td>FDA Requirement</td>
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<td>Anna Wikan</td>
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<td>16</td>
<td>Ability to close lips</td>
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<td>Dr. Alan Johnson &amp; Jason Meyers</td>
</tr>
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<td>17</td>
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<td>Apparatus does not cause any permanent damage to dentition</td>
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<td>19</td>
<td>Apparatus does not inhibit alignment of jaw for dental occlusion/interdigitation</td>
<td>5</td>
<td>Dr. Alan Johnson &amp; Jason Meyers</td>
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</table>

The user needs list is used to identify numbers 1, 2, 5, 7, 8, 14, 16, and 19 as being the most important needs. However, many of the needs met by our device are ones that cannot be met by existing pretreatments such as traditional Erich arch bars application.
We were told earlier that wires are used to force more rigidity in the initial periods of the healing process, and rubber bands replace those wires because they allow a small amount of freedom in moving the jaw.

Not exactly the case. Wires will relax in time, you can really achieve the same amount of force through rubber bands – even more force, realistically. Rubber bands allow the jaw to open and close primarily because they allow you to take some off, move the jaw around and put them back on. The rubber bands aren't really applied in order to let the patient just move their jaw around, but it allows day-to-day application or removal whereas the wires can't really just be pulled off. The wires can be cut and then they'd have to be re-applied altogether whereas the rubber bands can be.

How soon would a patient that has the rubber band method installed would the patient be able to take off some of the rubber bands in order to move the jaw around?

It depends on the patient. "You're not going to get a rule-of-thumb, 'after a few weeks you can do this,' etc." “You will probably see a full range of people being in MMF in a full range from 1 week to 6 weeks. The severity of the fracture, how quickly bones will heal, etc.

(Laura-Lee: Could try to create some sort of regiment related to this. If we were able to establish a technical knowledge that could be passed to a surgeon, that'd be very useful. For example, say to get
to the point of ossification it takes two weeks with a good union, and according to literature that
ossification site would take 10 Newtons to break again, you could argue from the strength of the MMF
apparatus that at some point the MMF is no longer needed.)

If you were to look at the fracture site in x-ray, would you be able to see if it's healing?

You can start to see that kind of stuff with a CT scan, but you won't be able to tell in a close-form
x-ray. You can't really try to gauge based on the 'brightness' of the line of the fracture site.

The wires prevent translational movement up and down as well as side to side – would rubber
bands be able to prevent side-to-side movement as well?

It's the vertical force stability that you can achieve with either rubber bands or wires. You would
still have circum-dental wires that would help against the translational force. The rubber bands (called
“fishwires" work against the side-to-side translation, but that doesn't necessarily speak to the fracture
site in and of itself.

Jason Meyers had said that the primary concern is assuring occlusion, and then just expecting
that if the fracture site is properly fixed, the bony union will span the gap.

“What you want to have as your best-fit goal is to have [occlusion]. The span of the fracture may
not be perfectly clean, can be bruising or alternative damage that can make it so that the fracture won't
align perfectly. There's usually some element of imperfection. There's probably a clot, there can be
some deformation of bone on either side of the structure. There are probably elements that make it
more complicated to try fitting the fracture together perfectly.”

Even if there is a large gap, is there anything else that you would put in if you can't locate all of
the bone?

No, it will heal in

So what exactly will affect the strength of the fusion?

Lots of considerations. Sometimes age can be a factor, a bit more of an offset can be okay.
Information exists in the literature in terms of strength curves for bone healing time. Try finding this sort
of curve for bone strengthening upon healing

Is the soft callous flexible?

Yes. It's really the calcification that makes the bone rigid. The calcification/ossification will really
be the last sort of bond. You get a more flexible polymer connection and then when it begins to be
mineralized it strengthens, becoming more like a ceramic.

Have you known of any cases where the treatment of a given jaw fracture caused weakening or
fracture in another part of the jaw?
It's all about the loading on the bone. Basically does boil down to a matter of losing it if you
don't use it. Not loading a bone for a while can cause considerable weakening of the bones. Example,
astronaut literature.

**Jason Meyers’s and Dr Alan Johnson Interview Notes**

12 – FEB – 2013

Interview with resident ENT surgeon Jason Meyers

(Alan Wellington Johnson, M.D. present as well)

Conducted by Sasha Schoolov and Andrew Wollenberg

How many jaw fractures have you treated with MMF? How many of those instances were with arch bars?

10 to 15. Just start doing it on patients straight-away: “It's kind of like a see-one, do one. And if you
get them on and you see that they're loose or anything, it's not going to hurt the patient to redo it.

If not every time, what alternatives were used?

Sometimes you just put the patient on a soft-diet. Sometimes you only need plates along the fracture line. Sometimes you need plating to hold the occlusion, sometimes you just hold it IMF screws rather than arch-bars.

If always arch bars, why not try one of the alternatives? Have you researched into alternatives at all? If so, any particular drawbacks to any given alternative?

It's whatever is available and what you're familiar with.

What are the biggest complaints you’ve received from patients?

I would say pain is the biggest complaint. Either the actual arch-bars themselves or if you use arch bars to hold the occlusion. (Injury to gums/gingiva/papilla), muscle-pain.

(Some surgeons go through the papilla and it can cause necrosis of that, receding gum-lines... sometimes you have to get through that tissue though. I'd say on every case we have to go through some part of the gums”)

(Alan “It's pretty controversial. Some dentists say it's really bad to do, some say it's a very robust area and will grow back quite quickly.)
How technically difficult is it to apply arch bars? What is the most difficult part of installing them?

When they have good dentition (the ideal patient) the biggest challenge would be getting them secure. When you get the wires through the bar you don't want there to be a lot of movement. If they don't have good dentition, sometimes it's hard to get it secure anyway. If really bad dentition, can use IMF screws, fix nasal to mandible

For a simple fracture, how much time in the O.R. does arch bar application take, on average?

Typically with residents, there are two people doing it. Depending on experience it would generally take 20 minutes to an hour. Can depend on soft-tissue injury, multiple fractures, but really the biggest variable is the level of skill and experience. There is a learning curve – not really in terms of getting them on and set right, but in terms of doing it fast

Do you have any specific complaints from the stand-point of being the person applying arch bars?

The time that it takes. “When we see someone with a mandible fracture, we think about any way we can avoid putting on arch bars... If you put arch bars on, that extends your case by an hour. It's really the time factor.” Also bad for patients.

What can they eat?

Pretty much anything that can get through a straw.

How close together do the two main edges of the fracture site have to be to ensure bony union instead of a fibrous union?

Ultimately the main goal of all of this is that you want the teeth to line up. “If somebody's teeth are off by the size of a grain of sand, they're going to know it.” try to line the fracture up as closely as possible, but if that's off by a little bit it doesn't matter so much so long as you get the teeth lined up. At the end of the day, you need the teeth lined up as closely as possible. There can be a gap and you can still get bony union. Bone can span a gap so long as there is rigid fixation. You'll get fibrous union when the fracture tends to move around a bit. Generally if the teeth are lined up, the jaw will be pretty well lined up. Ultimately to get the teeth to line up you have to get it pretty close

When patients have their jaws fixed with arch bars, how long would you estimate the period is to rehabilitate the jaw muscles back to an ordinary range of motion?

Not sure of exact numbers. See question on rubber bands for more

How can you tell if the pieces are lined up in terms of the displacement of the pieces?
When you put the bars on you don't really worry about the occlusion – it's more when you're doing the wiring that you have to really put forces on the jaw, manipulate the occlusion. So the actual application, you just worry about the gross alignment but then when you do the wiring you have to get the occlusion. “When you think about the mandible, the condyle – the TMJ – is really your only good reference... That's why you have to do it with two people; you need one person to hold the occlusion.”

When do you use the arch bars and when do you not?

Sometimes you just hold occlusion while putting plating on.

Would you ever consider it feasible to have someone who is more of a technician in the OR instead of another surgeon?

I'd say for something like this, so long as they have a lot of experience – I don't really think a surgeon would need to perform this procedure at all.

What kind of cleaning regiment do you recommend?

Generally not allowed to brush. Sent home with an alcohol rinse regiment.

Why are rubber bands used sometimes instead of wires?

Usually for a few weeks we will have them in wires because they can't move around at all, but then after a few weeks we can put them in rubber bands where they can move around a little bit. If they have it completely shut then they'll get fibrosis in the TMJ. Ankylosis could be potentially permanent if you leave them wired shut. It's generally reversible. “trismas, pain with opening mouth.” Some of it is reversible, but if you have the wires on for like a month and a half it's probably not going to be 100% reversible even with exercise

So who all would be in the OR with you?

A scrub-tech, a circulating nurse, a resident, a staff, an anesthesiologist, and anyone who is helping the anesthesiologist. Outside of academic residence you would only have one surgeon instead of 2 or 3, but still everyone else.

Anna Wikan’s Interview Notes

- Occurred in the summer of 2010. Treatment lasted 8 weeks.
- Type of fracture: Clean break almost at the center of jaw (Symphysis?) and hairline fracture in the back of jaw under the ear (TMJ or Condyle?).
  - Front fracture had one tooth behind the other.
- Platting done for front fracture; MMF using arch bars to fix jaw.
- Very difficult experience overall. Swelling was problematic initially.
  - Clear liquids only until swelling decreased
A little bit of motion after about 4 weeks.
- Slightly thicker substances after swelling decreased.
- Strawberry milkshake even a problem – stuff gets stuck between the teeth.

- Rough wires – gouging lips
- Jaw tension problems even to this day – tendency to clench jaw too much.
- Big problem was having nausea and throwing up – couldn’t open jaw so where could the fluids go? Others might need to have scissors to cut wires/bands in case of an emergency like this.
- Preferred to have the same surgeon who put on the device to do the checkups.
- Loss of muscle strength after the 8 weeks due to lack of exercise – would be “kind of important” to have a way to keep some strength.

1.4 Concept Alternatives

After our down-selection process, we were left with 5 different categories of viable approaches. The ideas can be summarized by the following list: Mouth Guard, Tooth Jimmy, Putty Mold, Tooth Clamps, and Adhesive Strips across the Teeth.

Mouth Guard

The Mouth Guard concept was to use a plastic or rubber mold that would slip over the teeth in the same way that sports mouth guards are placed over teeth. There were three sub-concepts envisioned: One-Piece Mouth Guard with adhesive; Two-Piece Mouth Guard with adhesive; Mouth Guard with non-adhesive injection sealant. Each is described below.

One-Piece Mouth Guard + Adhesive

This iteration of the Mouth Guard concept uses adhesives to attach to the teeth. The adhesives are applied in the lip of the device and can be either placed there long before application (during manufacturing) or just before being applied. Because the adhesives completely cover the teeth, there is plenty of surface area available and thus a very firm support structure. The adhesive could be a number of different types, such as instant adhesive, light/UV cure adhesive, heat cure adhesive, moisture cure adhesive, or pressure cure adhesive. If light/UV cure adhesive is used, the mouth guard would need to be made of a transparent or translucent material.
Two-Piece Mouth Guard + Adhesive

This iteration of the Mouth Guard uses two separate attachments to induce MMF. Similar to the One-Piece Mouth Guard, the Two-Piece Mouth Guard uses adhesives to firmly attach each part of the device to the teeth. By having 2 parts the mouth guard could allow for some “swinging” of the jaw (allow for some motion when desired) to help prevent ankylosis in the TMJ and aid in patient comfort. Hooks or protrusions would come out of the device which would allow elastic or metallic bands to pull the teeth closed. This is similar to the way that Erich Arch Bars work.
Mouth Guard with non-adhesive solidifying materials

This next type of Mouth Guard uses a material that doesn’t adhere to the teeth or any oral tissue; instead, by using a “clay-like’ material that solidifies when desired, the attachment of the teeth to the device is facilitated by the gap-filling of the clay-like material around the teeth. This in effect holds the device to the teeth. This type of binding could be used with the One- or Two-Piece Mouth Guards listed above. Figure 3 shows a 3D model of the Mouth Guard on an early stage SolidWorks anatomical skull model.

![Figure 3: Mouth Guard Rendering](image)

Tooth Jimmy

The Tooth Jimmy concept is a device that can be considered as similar to a Chinese Finger Trap, where opposing teeth are inserted into a hard rubber-like material in order to mechanically restrict vertical separation of the teeth. The primary advantages of this concept are that it doesn’t require any adhesives or bonding agents; non-invasive; can select which teeth to apply the device onto; easy removal by cutting the middle. Some disadvantages are that it would have a smaller hold strength because it is elastic; alignment of the teeth are critical; hard to apply multiple at once.
Heat-Shrink

This concept uses a heat-shrink polymer to attach around the teeth and provide structural support or attachment sites that don’t require adhesives to be in contact with the teeth. There were multiple embodiments of this concept that were conceptualized, including: Tooth Trap; Pure Heat-Shrink Floss (tension band); Molar Band + Floss; Floss + Arch Bars; Heat-Shrink Sleeve; Tooth Trap Arch Bar Sleeve; Threading Floss.
Tooth Trap

This is the same as the Tooth Jimmy concept but uses the heat shrink material instead of a hard plastic. After slipping on a tube-like sleeve over both ends of the teeth, the surgeon would apply heat in order to tightly shrink the material in all directions to ensure close proximity between the upper and lower teeth in order to ensure occlusion. Figure 6: Tooth trap concept shows an image of this.
Pure Heat-Shrink Floss

This concept uses heat-shrinking material as a type of “tension band” to help support the teeth around the fracture site. The shrinking “floss” is interwoven around the teeth and then heated to cause shrinkage. This shrinkage is what creates tension and better restraint of the teeth and fracture. Figure 6 shows an image that helps to illustrate this idea.
Figure 7: Depiction of heat-shrinking floss which can be used as a tension band

Figure 8: Another view of the heat-shrink floss

**Molar Band + Floss**

Metallic band (such as 3M’s Molar Victory Series Bands) can be applied to some of the teeth and act as support structures for the heat-shrink floss described above. The could also be used as miniature arch bars by looping top and bottom teeth together with rubber bands or wires, thus inducing MMF.
The floss would still act as the tension band around the fracture site. Figure 10 shows an image of a standard molar band used in orthodontics that is normally used to act as an anchoring point for the wires used to hold braces. Figure 8 shows a depiction of the molar band and floss concept where we can see that rigid fixation can be achieved by simply restricting jaw movement at the molars. This can be achieved by using four separate bands on the rear-most molars in all four quadrants of the mouth. In order to link the upper and lower molar bands, rubber bands or traditional arch wire can be used to secure the hooks located (and shown in Figure 8). The mini-report shown in Section 3.1 details a stress analysis on the molar bands to investigate the feasibility of securing the jaw using only the molars as anchoring points.

![Figure 9: Molar Band + Floss concept drawing](image)

![Figure 10: 3M Victory Series Molar Bands](image)
Floss + Arch bars

In this sub-concept, heat-shrink floss is applied to the teeth such as in the Pure Heat-Shrink sub-concept, but instead of leaving it with only heat-shrink floss, arch bars are applied to the floss. Because the heat-shrink material is in front of the teeth, adhesives or other methods could be used to adhere the arch bars to the floss. After the arch bars are applied, rubber or metal bands could be used to induce MMF. One disadvantage to this concept is that the integrity of the device is linked to the shear strength of the adhesive. Figure 11 and Figure 12 illustrate this concept.

Figure 11: Heat-shrink floss is applied and then arch bars are adhered to the floss
Heat-Shrink Sleeve

This sub-concept uses a heat-shrinking polymer to seal around the teeth and provide attachment points for the arch bars or incorporate hooks/protrusions to be used for elastic bands. In one embodiment, the whole structure is composed of the heat-shrinking material; in another embodiment the heat-shrink material is used to pull two structural support sections together around the teeth. Figure 13 displays a series of concept drawings that help to illustrate this.
Tooth Trap Arch Bar Sleeve

This concept uses heat-shrink tubing to slip over the individual teeth and provide attachment points for arch bars. This can be done by either placing the tubes on the teeth then adding arch bars, or by having the tubes pre-attached onto the arch bars and then slid over the teeth. Using tubing in this way provides a very large surface area for the interface between the teeth and heat-shrink material.
Figure 14 (a & b): Tooth Trap Arch Bar Sleeve Concepts
Threading Floss

This sub-concept utilizes a thread of heat-shrinking material to wrap around regular arch bars and attaching them to the teeth.

Figure 15: Picture of the prototype threading floss concept, fully applied.

Figure 16: ANSYS model of the threading floss with arch bars.
Figure 17: ANSYS model of the threading floss without the teeth visible.

Putty Mold

This design concept uses a molding technique to either bind around the teeth or to make an impression of the teeth for further part construction. By solidifying around the teeth, a significant amount of surface area can be used to hold the teeth in place. To apply the device, a patient would bite down on a block of the putty material and allow it to solidify to provide the mechanical support necessary to hold the occlusion. Figure 18 shows a sketch exemplifying this.

Figure 18: Putty Mold Concept
Tooth Clamps

This concept uses 3M's molar bands that are micro-etched in order to aid in the use of a commonly used orthodontic adhesive. The etching provides almost four times the shear strength as non-etched bands and is easy to remove with an orthodontic tool. Placing these bands around the mouth and using them for attachment points can be done to reduce the amount of damage done to the teeth. A study shown in Section 3.1 shows how only 4 molar bands are required to restrict jaw movement, one in each quadrant of the mouth.

![Figure 19: Tooth Clamp Concept](image)

This last concept is simply an adhesive strip that can be placed along the teeth and, when cured, provide support for holding the mandible and maxilla together. Alternatively, two separate bands could be used to attach to the maxillary and mandibular (upper and lower) teeth. By placing hooks/protrusions in the strips, rubber bands could be used to induce MMF.

![Figure 20: Adhesive Strip across Teeth Concept](image)

1.5 Concept Selection

Seven criteria were chosen from the product design specification in order to narrow the field of our 7 original design concepts. The most important criterion was immobilization of the jaw. This is the primary function that was to be achieved, so a weight of 30% was assigned. 15% was assigned to comfort, ease of application and cost. These are also important concerns that are expected to be improved from current MMF application. Risk of identifying materials and ease to remove were assigned 10% as they were not absolutely necessary for proper healing but were an area for improvement.
Finally, 5% was assigned to temporary removal/separation. This was a stretch goal, but successful implementation would be a significant improvement on the current MMF treatment.

   Looking at Table 2, the current Erich arch bar treatment had a weighted score of 2.5 which was the lowest of the 7. The two highest scores were for the single sided adhesive mouth guard and the heat shrink concepts. The lowest criteria for the current treatment were comfort and ease of application for reasons covered in Volume I: Section 3.3. In contrast, the three mouth guard concepts had high marks for this. For instance, these concepts lack poking wires or procedures that damage the gingiva. These concepts also had application procedures that had fewer steps and could be replicated in shorter time. In contrast they had low marks of 2 to 3 for removal as they involve rigid frames and/or adhesives. Of the three Mouth Guard concepts, the one sided concept had one distinct difference. It was the one concept of the three that allowed temporary separation of the jaw. This would be one of the deciding factors that put it above the double side Mouth Guards.

   Looking at the last three concepts, the main criteria of immobilization were assigned grades of 2, 3, and 3 for the Tooth Jimmy, Heat-Shrink, and Tooth Clamp concepts. While the weighted scores in these criteria brought the overall score down, the deciding factor was ease of removal. Since these concepts did not require adhesives or molds, they had the highest marks in this category. The heat shrink method in particular had high marks of 4 in ease of application, comfort and cost. These factors combined gave this concept the highest weighted total.

   The concepts of heat-shrink and single sided mouth guard were selected for prototyping and analysis. In the case of the single sided mouth guard, it had more potential for immobilization than the current Erich arch bars. Comfort was also better as this design had smooth geometry and does not damage the gingiva. Application would be shorter and simpler as well. The most important aspect of this is the potential of separating the mandible temporarily which only the heat shrinks and tooth clamp concepts could have. These aspects were enough to overcome its deficiencies in removal and materials. While materials were given a low grade, this was because there were no concrete examples of documented use of adhesives for this sort of application, and required more research.

   The heat shrink idea had its advantage in this regard by not requiring contact between the teeth and adhesive as there was a layer of non-adhesive polymer between. Removal in this concept pushed its grade above that of the mouth guard as it can be simply cut off, with no need to worry about residual adhesives. Since a lower grade was given in immobilization compared to Erich bars, the ability to immobilize the jaw must be tested to determine the validity of this concept. It can be noted that our final design did not appear in this stage of early-development.
Table 2: Table of selected criteria to evaluate design concepts

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<tr>
<th>Selection Criteria</th>
<th>Weight</th>
<th>Erich Arch Bars (reference)</th>
<th>Mouth Guard: Single-Sided with Adhesive</th>
<th>Mouth Guard: Double-Sided with Adhesive</th>
<th>Mouth Guard: Injection, non-adhesive</th>
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2.0 Design Description Supporting Documents

The final design is a detailed process, but it is for implementation of specific materials that may or may not exist in the exact form necessary. For robustness, in addition to the implementation plan a manufacturing plan is included for the final product kit.

2.1 Manufacturing Plan

The final product is a kit containing the components necessary for an individual implementation of the final process. In order to meet the customer needs with the process, the product must be properly defined and created.

2.1.1 Manufacturing Overview

The first component of the kit is an extruded heat-shrinking Polyester thread. This is made by extruding PET to a diameter of 0.006 in (40 wt. thread). The thread is then heated to a temperature of 200 °C by radiation, stretched to double its length, and rapidly cooled to room-temperature by an air-jet. The pieces of stock will stay expanded until exposed again to a minimum temperature of 65 °C – at which point it will recover much of the original length. This stock will then be placed in spools of 6 ft. in length and placed in the kit. A potential company for the manufacture of this polymer spool would be Vention Medical, as they currently produce medical grade high strength heat-shrink tubing; a simple equipment modification to their extruding equipment is all that is needed to change extrusion capabilities from tubing to a solid stock. This was found to be true from a short discussion with a production engineer from Vention on April 15th, 2013. Detailed cost evaluations are not available with respect to this aspect because of logistical difficulties at current time.

The other components are readily available for purchase – since it would take a wide variation in a given facility to actually manufacture each of these components, the others will simply be included into the kit after purchase from existing wholesalers. There are several providers for these, so the exact products and vendors are only examples.

The second components are Arch Bars. For the sake of specificity, currently the kit will include two 13.0cm Erich Arch Bars as manufactured by Medicon.

The final component will be elastic bands. The kit should include (30) 3/16” diameter latex-free orthodontic elastic bands. These are available from Express Dental.
2.1.2 Part Drawings

Figure 21 shows the measurement-specific drawing of the heat-shrinking stock, and the technical drawings of the pre-existing components are shown in Figure 22 and Figure 23, respectively.

Figure 21: PET heat-shrink stock drawing (not to scale)

Figure 22: Erich Arch Bars

Figure 23: Detail A

SCALE 5: 1
2.1.3 Bill of Materials

Table 3: Component list for a single set

<table>
<thead>
<tr>
<th>Number</th>
<th>Item</th>
<th>Description</th>
<th>Supplier</th>
<th>Price ($)</th>
<th>Unit of Pricing</th>
<th>Quantity</th>
<th>Total Cost($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PET Heat-Shrink</td>
<td>Heat-Shrink material in extruded into a 0.006&quot; dia.</td>
<td>Vention Medical</td>
<td>[10.99]</td>
<td>/25ft</td>
<td>6ft</td>
<td>[2.64]</td>
</tr>
<tr>
<td></td>
<td>Polymer *</td>
<td>thread.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Arch Bars</td>
<td>Support structure and attachment points</td>
<td>Medicon</td>
<td>57.12</td>
<td>/12</td>
<td>2</td>
<td>9.52</td>
</tr>
<tr>
<td>3</td>
<td>Rubber bands</td>
<td>Fix the maxilla and mandible in place</td>
<td>Express Dental</td>
<td>5.5</td>
<td>/200</td>
<td>40</td>
<td>1.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>13.26</td>
</tr>
</tbody>
</table>

*This product is not currently manufactured. The pricing for this part is based on tubing costs.

2.1.4 Manufacturing Procedure

The manufacturing process is no more complicated than putting the previously described components into a practical and compact package. The assembly of these components for use by the customer is described in detail in the Implementation Plan (Section 2.2).
2.2 Implementation Plan

The collection of components described in Section 2.1 is to be used for acquiring fixation between the maxilla and mandible. The heat-shrinking ribbon is used for achieving a non-permanent strong mechanical hold - one ribbon for the upper teeth, one for the lower teeth. The arch bars are then secured to the ribbons, and then fastened to each other to achieve MMF.

2.2.1 Implementation Overview

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.

2.2.2 Implementation Figures

Figure 24: Drawing of the first step by knotting and lacing the thread around the teeth
Figure 25: Performing the initial step of weaving the thread onto a 3D printed skull

Figure 26: Drawing of the looping/lacing step with the arch bars
2.2.3 Component List

All components necessary for the implementation of the heat shrink floss treatment are already listed in Table 3 as a bill of materials.
2.2.4 Implementation Procedure

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 alternately lace 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.

2.3 Heat Source

For our design, a heat source is necessary to cause the heat-shrink thread to bind around the teeth and arch bars. The design of this heat source is beyond the scope of the project but it needs to be addressed. A device needs to be used that can apply heat in a localized manner to the heat shrink material such that the patient will not be harmed. In Section 3.1 a heat transfer analysis of a tooth is performed and it was found that, in the extreme case, that the teeth will not be harmed when the necessary temperature to activate the shrink thread is directly applied to them for a duration of 5 seconds (long enough for the thread to completely shrink). Thus, a tool can indeed be used.
The tool could conceptually utilize conduction, convection, or radiation for the method of heating the thread. For our prototyping of various heat shrink materials, convection using a standard heat gun was found to be the most effective for evenly distributing heat across the thread. It would be difficult however to prevent a convective method from dispersing out and affecting sensitive parts of the mouth, so a localized heat-jet would most likely need to be used.

For any tool using a conductive method, diffusion of heat throughout parts of the mouth will not be as large of a concern, but the amount of heat applied must still be properly controlled to avoid injury. A prototype heat clamp that uses 2 heating elements of Nichrome wire is shown in Figure 34 for illustration purposes.

Figure 31: Standard heat gun

http://homerenovations.about.com/od/houseexteriorframework/ss/Remove-House-Paint_2.htm
Figure 32: Concept for using a clamp for the heat source

Figure 33: MD4 Mead Forceps from Hu-Friedy that is used to pull teeth. By internally attaching heating elements to the end of the clamping mechanism, a heat source could be made.

Figure 34: Prototype conductive heat source for applying heat and clamping force to the heat-shrink material

Figure 35: Image of how the prototype heat-clamp would be used on the teeth
As a third option, radiation could be used to induce the shrinkage of the thread. Standard dental polymerization lamps are currently available and by using either UV light or a heating lamp, enough energy could reach the thread in a concentrated manner to begin its shrinkage. Experiments and a redesign could prove this possibility.

Figure 36: Dental LED cordless polymerization lamp.

3.0 Evaluation Supporting Documents

3.1 Evaluation Reports

Prototype Opening Force Test Report

Abstract

A failure test of a prototype MMF device is presented in this report. Our device, which includes arch bars that are attached to the teeth through heat-shrink embroidery thread, were applied using to different methods of application. For one method, we found the device failed at 7.5 lbs. of opening force which is below the required strength of 30 lbs. However, by testing the mandibular arch bar alone, a failure force of 25 lbs. was possible. Successive iterations saw a reduction in application time and improved rigidity, in which the full arch bars were able to be applied in 1 hour. In a second application method, a failure force of greater than 30 lbs. was discovered for the full arch bar application and 35 lbs. for the mandibular arch bar alone. Full arch bar application was completed in 40 minutes. Discussion shows that the device withstood forces greater than the average opening force of the jaw with no residual effects (stretching, snapped fibers). These tests were done with inferior heat shrink embroidery thread so we conclude that the intended PET material geometry will be more capable in opposing the jaw forces.

Introduction

Multiple analyses have been carried out in ANSYS to ensure the PET material will not fail under the opening forces of the jaw. The motivation for these tests is to validate the results from the computer simulations.

Methods

Standard gym weights were attached to the prototype using fishing wire to stimulate the opening force of the jaw. When testing the full application, the wire was placed between the lower 1st molars and lower 2nd bicuspid teeth. When testing the mandibular section alone, the wire and weights were evenly distributed across the hooks on the arch bar. The weights hung perpendicular to the ground and were added in 2.5 lb. increments until failure.

In Method #1, 40 wt. Polyester embroidery thread was alternately laced around the teeth and the arch bar (serpentine application). This was done approximately 3 times for both the upper and lower sections of teeth, at which point the thread was cut, tied and heated to increase binding. The usage of a
“flossing loop” was useful for the threading. After the top and bottom arch bars were applied, elastic bands were used to connect the arch bars and induce immobilization (see Figure 40).

In Method #2 the thread was flossed between the teeth in a loop around the each tooth and underneath the hook of the arch bar. Each tooth was circled approximately 5 times. Adjustments in this method were made in heat shrinking the threads along the way instead of at the very end.

Figure 37: 3D printed skull model used in this experiment.
Figure 38: Weights used for the force analysis

Figure 39: Arch bars are applied with the usage of heat-shrink embroidery thread. This image is from Method #1.
Figure 40: Fishing wire inserted between the lower 1st molars and lower 2nd bicuspid. Weights are hung from the end of the wire.

**Results:**

**Using Method #1, Full Device:**

<table>
<thead>
<tr>
<th>Trial #</th>
<th>Application Time (minutes)</th>
<th>Failure Force (lb.)</th>
<th>Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>60</td>
<td>7.5</td>
<td>Thread slipped off of teeth without breaking.</td>
</tr>
<tr>
<td>2</td>
<td>60</td>
<td>7.5</td>
<td>Thread slipped off of teeth without breaking.</td>
</tr>
</tbody>
</table>
Using Method #1, Single arch bar on mandible:

Table 5: Method #1 results, half device

<table>
<thead>
<tr>
<th>Trial #</th>
<th>Application Time (minutes)</th>
<th>Failure Force (lb.)</th>
<th>Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30</td>
<td>25</td>
<td>Thread snapped.</td>
</tr>
<tr>
<td>2</td>
<td>30</td>
<td>15</td>
<td>Thread slipped off of teeth without breaking.</td>
</tr>
</tbody>
</table>
Figure 42: Testing of Method #1 with the weights

Figure 43: Testing of Method #1

Using Method #2, Single arch bar on lower mandible:
Table 6: Results from Method #2, half model

<table>
<thead>
<tr>
<th>Trial #</th>
<th>Application Time (minutes)</th>
<th>Failure Force (lb.)</th>
<th>Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>30</td>
<td>20</td>
<td>Thread primarily slipped off teeth</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>35</td>
<td>Thread slightly slipped up teeth, but not all the way off. This is considered a failure due to ~4mm of displacement.</td>
</tr>
<tr>
<td>3</td>
<td>20</td>
<td>Did not fail after 35 lb.</td>
<td>Ran out of weights, exceeded design requirement of 30 lb.</td>
</tr>
</tbody>
</table>

Figure 44: Arch bars applied for Method #2
Using Method #2, Full Device:

Table 7: Results from using Method #2, full device

<table>
<thead>
<tr>
<th>Trial #</th>
<th>Application Time (minutes)</th>
<th>Failure Force (lb)</th>
<th>Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>40</td>
<td>&gt;30</td>
<td>Did not fail. Due to weight, rubber bands began large deformation.</td>
</tr>
<tr>
<td>2</td>
<td>40</td>
<td>&gt;35</td>
<td>Did not fail. Due to weight, rubber bands began large deformation.</td>
</tr>
</tbody>
</table>

Figure 45: Full application of arch bars with Method #2. Wire is where the weights were hung.
Conclusion:

These tests were primarily used to see if the prototype could withstand the opening forces of the jaw using the off-the-shelf heat shrink embroidery thread. Since the test was successful, it is reasonable to assume that the Vention PET material will not fail because it has slightly more than twice the tensile strength as the embroidery thread.

Other than having reduced mechanical properties compared to Vention’s PET, the diameter of the embroidery thread is slightly smaller than ideal. The embroidery thread is 40 weight thread, which is the diameter of thread required to weigh 1 kg when there is 40 kilometers of length; this was calculated to be 0.00575” using a density of 1380 kg/cm³. Thus, there is less surface contact with the teeth with the embroidery thread and so it will be more likely to slip.

The application time for our device was able to be reduced to 40 minutes which is competitive to the current method of Erich arch bars. Also, it was noted that heating each segment at a time during the flossing process yielded a tighter fit than heating at the conclusion of flossing.

In future tests, samples with the correct geometries and material properties should be obtained. More weight increments should also be obtained in order to test for the precise failure force. A test bench could also be set up incorporating the entire ABS skull in a tensile tester. Also, an analysis of which thread diameter is ideal should be completed. The mechanical properties of the embroidery thread as well as the Vention PET will be tested with a Tensile testing machine in order to validate the results from these physical tests. Without this data, we conclude that using PET heat shrink material will not fail even above the opening force of the jaw.

Computational Force Analysis Using Simplified Geometry

Abstract

Computer simulation software was used to validate the structural feasibility of the heat-shrink floss method using a simplified geometry due to meshing errors initially encountered. With the material properties of the mandible and force muscles present on the mandible obtained, the appropriate analytical setup was made using the static 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 0.004mm, the design concept was shown to be a good candidate for our needs.

Introduction
The purpose of this analysis was to provide a basic means of validating the proof-of-concept of the heat shrink method. A design requirement of the device is that there is less than 0.01 mm of displacement between the top and bottom segments when a normalized opening force is applied.

**Method**

In order to carry out the analysis, computer simulations were used - in particular the Finite Element Analysis (FEA) software, ANSYS Workbench 14.0. Utilizing their static structural analysis system and with an accurate, to-scale geometry of a human mandible CAD (computer aided design) file, a simplified geometry of a mandible was created. The concept to test is dependent on the effectiveness of the heat shrink thread, hence only the thread was modeled around the structure of the teeth as a simple figure ‘8.’

![Figure 46: Geometry of the Mandible and the Thread Constructed](image)

With the geometry defined, material assignments were made for each component using material properties found for the enamel, dentin, periodontium, cortical bone, cancellous bone, and the PET thread. [4, 13, 14, 15]

<p>| Table 8: Material properties [4,13,14,15] | 69 |</p>
<table>
<thead>
<tr>
<th>Material</th>
<th>Young’s Modulus [MPa]</th>
<th>Poisson’s Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enamel</td>
<td>72700</td>
<td>0.33</td>
</tr>
<tr>
<td>Dentin</td>
<td>18600</td>
<td>0.31</td>
</tr>
<tr>
<td>Periodontium</td>
<td>50</td>
<td>0.45</td>
</tr>
<tr>
<td>Cortical Bone</td>
<td>11500</td>
<td>0.33</td>
</tr>
<tr>
<td>Cancellous Bone</td>
<td>431</td>
<td>0.30</td>
</tr>
<tr>
<td>PET Thread</td>
<td>2700</td>
<td>0.37</td>
</tr>
</tbody>
</table>

With the material assignment complete, the geometry required is ready to be meshed as a finite-element object. The mesh requires the geometry to be meshed as small as possible to provide mesh-independent results. A body sizing on the cortical and cancellous bone was set with a hard behavior element sizing of 0.0023 m. Another body sizing was made on the enamel with a hard behavior element sizing of 0.001 m. The dentin received similar treatment with an element sizing of 0.002 m. The resultant mesh gave a node of count 223740, which is nearing the limit node count allowed on ANSYS with a student license.

Figure 47: Node Count
With the mesh generated, the analysis settings were set up to place the environmental boundaries on the mandible. To replicate the muscle forces [3] on the mandible involved during jaw opening, the individual muscle forces and their locations were acquired using jaw muscle anatomical diagrams found online and placed on the geometry. Additionally, a frictionless support was placed on the upper surface of the condyle to replicate the point of contact between the mandible and the bone surface of the skull. To replicate the placement of the arch bars on the mandible through the use of the
thread, a fixed support was placed on the underside of the thread. Figure 52 and Figure 53 show the magnitudes and placements of each of the four muscles used.

Figure 50: Placement of Arch bars on Teeth
Figure 51: Boundary Condition Setup

Figure 52: Max forces in various jaw muscles; only the opening forces are used (bottom four)
Figure 53: Muscle Force Diagram

Figure 54: Fixed Support of Thread
With the analysis completely set up, the analysis was solved and the results shown below.

Results

The results observed were the total deformation on the mandible and the stress analysis.

![Total Deformation on Mandible](image)

**Figure 55: Total Deformation on Mandible**

Conclusion

Based on the solved solution, the mandible made a maximum deformation displacement of 0.004mm, which is much less than the design requirement needed in any single direction. This provides a good estimate that the concept is a viable option for our design requirements. Further analysis of mesh independence and cyclic fatigue is performed later in Section 3.1.
Heat Transfer Analysis Report

Abstract

The heat clamp, one of a handful of methods to introduce heat to our heat-shrink thread, is analyzed using ANSYS Transient Thermal® 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 .84 mm 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 necessarily pain.

Introduction

The motivation for this experiment arose from the necessity to apply a heating device to our heat-shrinking thread. The material used in our PET thread requires a temperature of 85 degrees Celsius to shrink to its final size. Because we want localized heating strictly to the bands while avoiding heating the heat-sensitive dentin and tooth pulp, we chose to use heating by conduction as opposed to convection; convection would be harder to control and apply to a localized area which would result in collateral heating. We found that it takes less than one second for the tubing to shrink upon contact with an 85°C heat source, but we wanted to explore the temperatures in the teeth and surrounding area after two seconds in case the clamp was unintentionally held on too long in practice by the surgeon.

Methods

Using ANSYS® Transient Thermal, we analyzed two models; one using a simplified one-dimensional heat flow simulation and the other using two-dimensional. This experiment details the two-dimensional heat-transfer experiment. Material properties were found using scholastic literature searches to find articles that utilized heat transfer properties of three different tooth-related bodies. They are the gums, enamel (the outside surface of the teeth), and dentin (the pain-sensitive surface directly beneath the enamel). Through further literature searching, it was found that patients experienced tooth sensitivity when dentin temperature exceeded 14.7°C above body temperature (37°C) for an absolute temperature limit of 51.7°C \cite{12} anywhere in the dentin. Additionally, tooth pulp necrosis (the death of tissue) occurs at 5.3°C above body temperature (37°C) for 15% of patients in the pulpal tissue \cite{12}, so the max temperature at the interface between the dentin and pulp will be monitored to maintain this requirement. Heat transfer properties are shown below in Figure 55. The geometry of the gums, dentin, and enamel were approximated from the image shown in Figure 59, which is a graphical representation of an anatomical drawing found in a lecture by Dr. Jeff Carlson in 2009 \cite{11}. Thermal properties of the tooth pulp were not available, so instead the temperature of the dentin that would be interfacing with the pulp will be of interest. The region highlighted in green shows
the region that was modeled. Label #1 points to the enamel, #2 points to the dentin, #3 points to the tooth pulp, and #4 points to the gums. Figure 60 shows the model mesh and geometry labeled as such: E is enamel, D is dentin, and G is gum tissue. The contact region was estimated as having a length of .84 mm, which is the same length as the thickness of the enamel on the side of the tooth. This is fairly small because the heat-shrink wrapping would protrude from the tooth surface and PET is a good thermal insulator. This contact region size is more or less based on accidental direct tooth-to-clamp contact.

<table>
<thead>
<tr>
<th>Properties of Outline Row 4: enamel</th>
<th>A</th>
<th>B</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Property</td>
<td>Value</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Density</td>
<td>2.8</td>
<td>g cm⁻³⁻³</td>
</tr>
<tr>
<td>3</td>
<td>Isotropic Thermal Conductivity</td>
<td>0.00223</td>
<td>cal cm⁻¹ s⁻¹ K⁻¹⁻¹</td>
</tr>
<tr>
<td>4</td>
<td>Specific Heat</td>
<td>0.17</td>
<td>cal g⁻¹ K⁻¹⁻¹</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Properties of Outline Row 5: gums</th>
<th>A</th>
<th>B</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Property</td>
<td>Value</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Density</td>
<td>1038</td>
<td>kg m⁻³</td>
</tr>
<tr>
<td>3</td>
<td>Isotropic Thermal Conductivity</td>
<td>0.001195</td>
<td>cal cm⁻¹ s⁻¹ K⁻¹⁻¹</td>
</tr>
<tr>
<td>4</td>
<td>Specific Heat</td>
<td>3521</td>
<td>J kg⁻¹ K⁻¹⁻¹</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Properties of Outline Row 3: dentin</th>
<th>A</th>
<th>B</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Property</td>
<td>Value</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Density</td>
<td>1.98</td>
<td>g cm⁻³⁻³</td>
</tr>
<tr>
<td>3</td>
<td>Isotropic Thermal Conductivity</td>
<td>0.00139</td>
<td>cal cm⁻¹ s⁻¹ K⁻¹⁻¹</td>
</tr>
<tr>
<td>4</td>
<td>Specific Heat</td>
<td>0.38</td>
<td>cal g⁻¹ K⁻¹⁻¹</td>
</tr>
</tbody>
</table>

Figure 56: Material properties

\[ \dot{Q}_{\text{cond}} = -kA \frac{dT}{dx} \]

Equation 1: One-dimensional heat conduction equation
Figure 57: One-dimensional heat conduction through a material [24]

\[
\begin{align*}
Q_x &= -kA_x \frac{\partial T}{\partial x} \\
Q_y &= -kA_y \frac{\partial T}{\partial y} \\
Q_z &= -kA_z \frac{\partial T}{\partial z}
\end{align*}
\]

Equation 2: Fourier's heat conduction equations for multiple directions
Figure 58: Image that represents Fourier’s heat transfer \(^{[24]}\)

Figure 59: Finite-difference approximation \(^{[24]}\)
Equation 3: Finite-difference approximation equation \(^{[24]}\)

ANSYS uses fundamental equations 1-3 when calculating heat transfer results across nodes by numerically solving a system of equations using variational methods to minimize an error function and produce a stable solution.

Figure 60: Tooth anatomy \(^{[11]}\)
Because we are performing a two-dimensional heat transfer analysis, the mesh was modeled as one element thick. Adiabatic boundary conditions were used for all surfaces except for the one pictured in Figure 61, which was set at a constant 85 degrees Celsius; the surface shown in Figure 61 shows the left-hand face of the square piece of the enamel second down from the top, it is highlighted in red on the left end of the image.
Figure 62 shows the results of the heat transfer analysis. The temperature the tooth pulp would see would barely be above body temperature, which is represented by the far right side of the dentin; consequently it will not be damaged and will not undergo necrosis. The portion of the dentin that is closest to the heat source will experience a temperature increase of approximately 17°C; this results in the patient experiencing sensitivity, but not necessarily pain or discomfort. This may not be problematic, as the patient will be under local anesthesia (where the patient is conscious) and may not notice the discomfort. Additionally, because the analysis is taken after 2 seconds of constant temperature heat applied, the patient is not likely to experience discomfort after a typical application time of one second. The temperature of the gums reaches only 5°C above body temperature, which is trivial because the gum temperature only reaches 108°F.
Further study such as specifying a contact region that envelops the entire outside region of the enamel would be useful. This would exemplify an extreme case where heat would be constantly applied to the comparatively large surface which may occur from extraordinarily poor clamp finesse. Additionally we may consider implementing heat-shrink thread into our model to consider the intermediary heat absorption effects through the thread. For this case, we would expect the temperature reaching the critical areas (the dentin and the tooth pulp) to be less than we have for this experiment.
FEA Analysis Using More Precise Geometry

An evaluation of mesh independence and subsequent cyclic fatigue analysis

Introduction

The purpose of this analysis was to provide a comparison of the first model used in the beginning of this section in order to evaluate mesh independence and the resultant force at the teeth in order to analyze cyclic fatigue in the PET to be used in our device.

Method

In order to carry out the analysis, computer simulations were used using the Finite Element Analysis (FEA) software, ANSYS Workbench 14.0. Utilizing the static structural analysis system and with an accurate, to-scale geometry of a human mandible CAD (computer aided design) file, a simplified geometry of a mandible was created. The concept to test is dependent on the effectiveness of the heat shrink thread, hence the thread was modeled around the structure of the teeth as a simple figure ‘8.’ The problem was modeled as a symmetrical model; hence the geometry was only modeled in half.

![Figure 64: Geometry of the Mandible and the Thread Constructed](image)

With the geometry defined, material assignments were made for each component using the same material properties previously found for the enamel, dentin, periodontium, cortical bone, cancellous bone, and the PET thread. [4, 13, 14, 15]
Table 9: Material Properties. [4, 13, 14, 15]

<table>
<thead>
<tr>
<th>Material</th>
<th>Young’s Modulus [MPa]</th>
<th>Poisson’s Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enamel</td>
<td>72700</td>
<td>0.33</td>
</tr>
<tr>
<td>Dentin</td>
<td>18600</td>
<td>0.31</td>
</tr>
<tr>
<td>Periodontium</td>
<td>50</td>
<td>0.45</td>
</tr>
<tr>
<td>Cortical Bone</td>
<td>11500</td>
<td>0.33</td>
</tr>
<tr>
<td>Cancellous Bone</td>
<td>431</td>
<td>0.30</td>
</tr>
<tr>
<td>PET Thread</td>
<td>2700</td>
<td>0.37</td>
</tr>
</tbody>
</table>

With the material assignment complete, the geometry required to be meshed as a finite-element object. The mesh requires the geometry to be meshed as small as possible to provide respective results. A body sizing on the cortical and cancellous bone was set with a hard behavior element sizing of 0.0023 m. Another body sizing was made on the enamel with a hard behavior element sizing of 0.001 m. The dentins received similar treatment with a element sizing of 0.002 m. The resultant mesh gave a node of count 230844, which is nearing the limit node count allowed on ANSYS with a student license.

Figure 65: Node count
Figure 66: Mesh Generated

Figure 67: Internal Mesh Generated
With the mesh generated, the analysis setting was set up to place the environmental boundaries on the mandible. To replicate the muscle forces on the mandible involved during jaw opening, the individual muscle forces and their locations were acquired and placed on the geometry. To replicate the placement of the arch bars on the mandible through the use of the thread, a fixed support was placed on the underside of the thread.

Figure 68: Placement of arch bars on teeth

http://en.academic.ru/pictures/enwiki/71/Gray177.png

Figure 69: Analysis Muscle setup

Figure 52 and Figure 53, used in the previous stress analysis and again here, show the magnitudes and placements of each of the four muscles used.
With the analysis completely set up, the analysis was solved and the results shown below.
Results

Total Deformation:

Figure 71: Total Deformation on Mandible

Figure 72: Stress amplitude vs. cycles to failure or S-N behavior of several commodity plastics. [21]
Stress Analysis:

Figure 73: Equivalent Stress on Mandible with Band Shown
Figure 74: Equivalent Stress on Mandible without Band Shown
Conclusion

Based on the solved solution, the mandible made a maximum deformation displacement of 0.007mm, which is much less than the design requirement needed. This provides a good estimate that...
the concept thread is a viable solution for our project. Additionally, from the 26.423 MPa maximum resultant stress on the threads, we were able to quantify the number of cycles to fatigue as 1500. Additionally, we can compare our results from the second report in this section to see that mesh-independence, the fact that the analytical results of a model are unique to the geometry of the mesh, is a non-issue due to significantly similar displacement concentrations and magnitudes.

Preliminary prototyping and design evaluation

Purpose

Describe the types of functional prototypes that have been attempted in detail and report the overall results from each trial.

Prototypes Developed

- Heat-Shrink Over-Mold
- Heat-Shrink Sleeve
- Heat-Shrink Floss

Description and Summary

Heat-Shrink Over-Mold:

A polyolefin heat-shrink tubing that was purchased at Radioshack was slit down the middle to form a “half-tube.” This was then placed over a set of push-pins, which simulate teeth (Figure 76), and then heated to the point of shrinkage with a soldering iron (Figure 77). The prototype worked well at creating a tight binding to the push-pins as well as became more rigid when it shrunk. It was noted that the push-pins did have a ridge on the top that greatly helped with the binding, something that will not be as prevalent in actual dentures.
Later, the 3D printed skull was used to simulate the proper geometry of the teeth and jaw for the prototype. After applying heat by using a heat-gun (for more uniform heating), it was evident that this particular technique may not be feasible because of the lack of binding that the tubing had on the teeth. It did not require much effort to pull off the material.

An additional concern that arose was that the tubing, applied in this method, would interfere with proper occlusion. The patient would be uncomfortable with a spacer in between the teeth.

**Heat-Shrink Sleeve:**

A larger heat-shrink tube was cut such that cylindrical sections of approximately 7mm were created. These cylindrical sections, or sleeves, were then placed over the make-shift push-pin teeth (Figure 78). Heat was then applied using a soldering iron (Figure 79) and the tubing shrunk snugly
around each tooth, such that it was extremely difficult to remove. Again, it was noted that there exists a ridge on the top of the push-pins that would not be there in an actual tooth.

At this point, objects could be applied to the shrink wrap around the teeth, such as arch bars, adhesive strips, or more shrink material (Figure 80).

Figure 79: Small sections of heat-shrink tubing being placed over the push-pin “teeth”

Figure 80: Heat-shrink tubing after being heated around the push-pin teeth
The next step was to use the 3D printed skull to check a more realistic representation of how well the tubing could be applied in this manner. It quickly became obvious that the material being used was thick relative to the gap between teeth. This created issues when trying to slip it over each tooth. Some of the teeth allowed for partial coverage, so some of those were used to qualitatively how well the tubing stuck to the teeth. After placing it over the tooth and shrinking it with a heat gun (Figure 81), the amount of force necessary to pull it off was not too great (on the order of 1lb).

For future experimentation, thinner and wider tubes should be considered and tried.
Heat-Shrink Floss:

Thanks to Alex and a piece of heat-shrink tubing that he was fiddling with, it was discovered that a kind of “Floss” could be created by cutting spirally down the tubes and making long strands. Each of these strands would then shrink across their length and not along their width (this is based upon the direction of shrinkage from the tubes). This floss was then used by weaving it through the teeth on the maxilla and also on the mandible. It was again noted that many of the teeth had gaps between them that were too small to effectively weave the floss through, so they were skipped. The heat gun was used to shrink the material, which held onto the teeth very well (Figure 82). At this point, the floss could be used as attachment sites for objects such as arch bars, adhesive strips or more heat-shrink material.

At this point, we wanted to see what kind of forces the heat-shrink floss could withstand before coming off of the teeth. 4 plastic zip-tie bars were attached using Loctite 435 adhesive to the top and bottom sections of the teeth (Figure 83) and a strand of wire was wrapped around the mandible such that a weight could be used to pull down on the mandible and separate it and the maxilla. A force of
about 10 lbs was what was required to cause the jaw to separate – and the failure mode was not in the heat-shrink floss but in the adhesive.

Figure 83: Heat-shrink “floss” interwoven between the teeth
Figure 84: Plastic bars applied to the top and bottom sections of the floss

For future experimentation of this concept, actual heat-shrink floss or ribbon that shrinks along its length should be used, as well as thinner material.

**Conclusion and Next Steps:**

Of the three heat-shrink variants, the interdental “floss” concept appeared to work the best. This is the one that should be pursued the most as of the time of this experiment, but the other concepts could also be simultaneously developed further. Different heat-shrink material should be ordered as soon as possible. This will later lead into further product development and is used as a prototype to exemplify our design progression.
**Alternative Concept Mock Ups**

**Abstract**

Our team came out of concept selection with a few different concepts including rough mockups of a mouth guard concept and adhesive band. The motivation was simply to verify the deficiencies of these concepts and find some inspiration for future design. One key concept of MMF is establishing occlusion. Practitioners assure that the jaw is in its natural conformation by pressing the teeth together to match points of interdigitation.

**Introduction**

The mouth guard concept consisted of either compression or injection molded polymer to create a form fitting fixture over the teeth. With a rigid material, this device is meant to attach to the teeth rigidly with no adhesive. The adhesive bar concept was a general concept involving use of adhesive to attach the bars to the teeth. While we ultimately decided to stray away from adhesives, it gives flexibility in the application of bars and attachment interface.

**Methods**

A Sawbone was used to model the human jaw. Actual human skull properties are unnecessary as we are mainly looking into the geometry of the jaw.

**Mouth Guard**

Plaster was used to simulate a moldable polymer. The plaster was allowed to set to a firmer state and poured into a cut out plastic cup. Then this was pushed onto the top and bottom set of teeth and set in place for 25 minutes to set.

**Adhesive bars**

A rubbery plastic tube of unknown composition was glue to the teeth using Loctite. Then various attempts were made to immobilize the jaw. This will be expanded upon in the following section.

**Results**

After the molds were applied and allowed to dry, it was clear that the attachment seemed quite strong Figure 21. The plaster itself does not have the properties of an adhesive, but it will fill in microscopic pores on the teeth. This is similar to many injection molded materials. When attempts were made towards failure, the plaster would chip off at points attached to the outside of the teeth. Obviously, these would be the areas subject to the most stress given translational movements. However, an actual set polymer would be made to be less brittle and would have much better elastic
properties. A solution towards this could be a thin layer of polymer just to ensure close contact and incorporate a rigid sleeve over this polymer to provide the structural support.

The natural position of the jaw is slightly relaxed with the teeth unclenched. When MMF is applied, the jaw is pushed up into an unnatural state, resulting in some side effects like tight jaw muscles and spasms. This device would inherently have a gap in between the teeth, and could allow for easy interface between top and bottom sections. However, analysis would have to be done on the thickness required of the mouth guard to support the required loads from opening the jaw.

![Figure 85: Plaster molded over mandible](image)

While this was a positive outlook, the space between the teeth is also the greatest downfall as there was no conceivable way to assure occlusion. Fitting the molds in the teeth for injection requires a lot of manipulation in order to get the proper fitting. Unless occlusion can be set, and fixed by some external device, this mouth guard concept is not viable because of this reason.

The adhesive concept had interesting qualitative results. The tube that was glue to the back of the teeth had the advantage of being hidden from view, which could be a very attractive option for patients. The hole through the middle was used to thread fishing wire between and knotted shut. We would have to use metal wire to do this to provide enough tension. Or we could use heat shrink material. Soon it was clear that the forces concentrate at the end of the tube, which doesn’t provide even distribution of forces from the opening muscles. Bars on the inside of the mouth would be tedious to work with which was apparent when working with the sawbone model. External adhesive concepts are well documented in
Conclusion

Overall, these results show that we should proceed with the shrink wrap concepts. While the mouth guard concept was attractive in its hold strength, it would be a complex process requiring machinery for injection molding or preparation of polymer. Also the main take away was that it would be difficult to obtain proper occlusion with this device. The adhesive method was easy to install, but the removal of adhesive was tough. Pursuing the shrink wrap idea gives us space to develop a more original idea that would also fit all the product requirements.

Prototype Material Tensile Test

Introduction

An MTS tensile tester was used to validate the material properties of the heat-shrink thread used in the heat shrink method device, in addition to comparing the thread’s properties with a potential replacement.

Method

To carry out the experiment, an MTS tensile tester model 42 was used to measure the constant tensile force exerted on the thread as well as the length of extension. With these values, the stress and strain relationship of the threads can be determined.

The heat-shrink thread was first tested as a single thread. Next, two threads were clamped together and tested as a means to validate the linearity of the thread’s properties with each thread added. Lastly, given the samples of tubing by Vention, the same tensile tests were carried out.
Results

![Stress vs Strain Curve](image)

Figure 87: Stress vs Strain Curve for the tensile test.

Based on the plot above, it was observed that the heat shrink thread had an ultimate tensile strength of approximately 500 MPa for a single thread. When two threads were used, the UTS displayed was approximately 1000 MPa. This validates the linearity of the thread. For the Vention tube, the UTS measured was approximately at 70 MPa. This could show that the heat shrink thread out-performs the Vention tube. However, it could possibly be due to the nature of the geometry as a tube that caused this result to occur. Further tests would be required to verify the possibility of stress concentrations found at the cleaves of the tubing. However, this implies that the current alternative provided by the heat-shrink tube used for our prototype is suitable for our device. As the current heat-shrink thread in use is not a medically approved thread, the company that we are in contact with, Vention Medical, is able to produce the medically approved heat-shrink thread with the similar properties with the one in use.
Molar Band Stress Analysis

Abstract

Computer simulation software was used to validate the structural feasibility of the molar band method using a simplified geometry due to meshing errors initially encountered. With the material properties of the mandible and force muscles present on the mandible obtained, the appropriate analytical setup was made using the static 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 0.004mm, the design concept was shown to be a good candidate for our needs, but was not chosen due to comparatively less robustness in application in comparison to the heat-shrink thread method.

Introduction

The purpose of this analysis was to provide a basic means of validating the proof-of-concept of the heat shrink method. A design requirement of the device is that there is less than 0.01 mm of displacement between the top and bottom segments when a normalized opening force is applied.

Method

In order to carry out the analysis, computer simulations were used - in particular the Finite Element Analysis (FEA) software, ANSYS Workbench 14.0. Utilizing their static structural analysis system and with an accurate, to-scale geometry of a human mandible CAD (computer aided design) file, a simplified geometry of a mandible was created. The concept to test is dependent on the effectiveness of the molar bands; hence the bands were modeled on the 2nd molars only for half of the jaw (mandible). Molar band dimensions were obtained from measuring a sample acquired from 3M’s Victory Series Molar Bands department. The bands are made from 306L Stainless Steel and have a varying thickness, depending on tooth size, that ranges from 0.0052” to 0.0073”. The average, 0.00652” was used in this analysis.
Figure 88: Geometry of the Mandible and the Band Constructed

With the geometry defined, material assignments were made for each component using material properties found for the enamel, dentin, periodontium, cortical bone, cancellous bone, and the molar band. \[4, 13, 14, 15\]

Table 10: Molar Band Analysis Material Properties \[4, 13, 14, 15\]

<table>
<thead>
<tr>
<th>Material</th>
<th>Young’s Modulus [MPa]</th>
<th>Poisson’s Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enamel</td>
<td>72700</td>
<td>0.33</td>
</tr>
<tr>
<td>Dentin</td>
<td>18600</td>
<td>0.31</td>
</tr>
<tr>
<td>Periodontium</td>
<td>50</td>
<td>0.45</td>
</tr>
<tr>
<td>Cortical Bone</td>
<td>11500</td>
<td>0.33</td>
</tr>
<tr>
<td>Cancellous Bone</td>
<td>431</td>
<td>0.30</td>
</tr>
<tr>
<td>306L Stainless Steel</td>
<td>193000</td>
<td>0.31</td>
</tr>
</tbody>
</table>

With the material assignment complete, the geometry required is ready to be meshed as a finite-element object. The mesh requires the geometry to be meshed as small as possible to provide mesh-independent results. A body sizing on the cortical and cancellous bone was set with a hard behavior element sizing of 0.0023 m. Another body sizing was made on the enamel with a hard behavior element sizing of 0.001 m. The dentin received similar treatment with an element sizing of 0.002 m. The
resultant mesh gave a node of count 246436, which is nearing the limit node count allowed on ANSYS with a student license.

<table>
<thead>
<tr>
<th>Statistics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Nodes</td>
<td>246436</td>
</tr>
<tr>
<td>Elements</td>
<td>113139</td>
</tr>
<tr>
<td>Mesh Metric</td>
<td>None</td>
</tr>
</tbody>
</table>

Figure 89: Node Count

Figure 90: Mesh Generated
With the mesh generated, the analysis settings were set up to place the environmental boundaries on the mandible. To replicate the muscle forces [3] on the mandible involved during jaw opening, the individual muscle forces and their locations were acquired using jaw muscle anatomical diagrams found online and placed on the geometry. Additionally, a frictionless support was placed on the upper surface of the condyle to replicate the point of contact between the mandible and the bone surface of the skull. To replicate the placement of the arch bars on the mandible through the use of the thread, a fixed support was placed on the underside of the thread.
Figure 92: Individual Molar Band Modeled

Figure 93: Mirrored Boundary Condition Setup

Figure 52 and Figure 53, used in the previous stress analysis and again here, show the magnitudes and placements of each of the four muscles used.

**Results**

The results observed were the total deformation on the mandible and the stress analysis.
Discussion

Based on the solved solution, the mandible made a maximum deformation displacement of 0.004mm, which is much less than the design requirement needed in any single direction. This provides a good estimate that the concept is a viable option for our design requirements. Because molar bands require the use of orthodontic adhesive, which has a maximum shear and normal holding strength of approximately 7 MPa \cite{26}, further analysis of the resultant stresses at the interface between the teeth and molar band should be assessed. Because of the lack of robustness in this design compared to our heat-shrink thread method, further analysis was not performed.

Additional Requirement Analyses

Maximum thickness between teeth: The thread used for the device is the only substance that will be between the teeth of the patient at any point in the procedure. As the proposed floss is only 0.006 inches thick, it is expected that nothing of a thickness greater than 1mm (0.035 in) will be between the teeth.

Radius of contours on device: As the arch bars themselves do not cause pain to the patients but instead the wires which fix the bars to the teeth do, the bars were not evaluated. There is no point in the proposed method at which the floss would have a radius of less than 0.5mm and be an an protrusive position, therefore this requirement was met.

Surface roughness: The surface roughness was assessed in order to determine the abrasive effects of the device on the gums and lips of the patient. The stainless steel arch
bars have a smooth polished finish, and the floss has a very smooth and soft finish as well ensuring that there will not be detrimental abrasion due to the device and therefore the surface roughness requirement was effectively met.

### 3.2 Cost Analysis

#### Abstract

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.

#### Introduction

The main cost in treating a jaw fracture does not come from the materials or equipment put into the treatment, but rather from the use of more valuable resources. The majority of the cost in any given treatment comes from the cost of time in the operating room, binding up the resources of a surgeon, a room, and other staff. While material costs for a closed reduction jaw fracture treatment is presently limited to less than $100, the cumulative cost averages between $7,000 and $12,000 \[^{16}\]. For surgeries requiring open fixation, costs can escalate to over $30,000 while the material costs are generally limited to less than $1,000. An itemized list of sources of expense for jaw fracture treatments is given in Table 11 – the values are weighted by the probability of that source of expense being present in a given treatment. The huge discrepancy in costs comes from the resource costs.

#### Costs Compared

While the cost varies regionally, it is a conservative estimate that the cost of time in the operating room is $50 per minute \[^{17}\]. It is estimated that wiring arch bars onto a patient takes 141 minutes; the removal of wired arch bars is estimated to take 20 minutes. This relates to $7,050 in cost for application, and $1000 in operating room costs for the removal.
Our proposed device will still be applied in the operating room, so the $50 per minute of application cost remains consistent. However, the proposed design is faster to apply, and simple enough to remove that no operating room is required – instead, it can be removed in a clinic. A safe estimate of the application time based on experimentation would be 120 minutes for the proposed design – a savings of 21 minutes. Multiplying this by the $50/min factor, this amounts to a $1050 savings in application. A conservative estimate for the clinic cost is $10 per minute \textsuperscript{[18]}. Not only can the proposed device be removed in a clinic, but because the design is not-intrusive in application and can be removed easily and gently there is no need for anesthetization and the removal is fast – approximately 10 minutes, including brief examination of healing as performed by the surgeon. This means the cost of removing the proposed device has an overhead cost of only $100. Collectively then, a savings of on average $900 in overhead costs comes from the clinic use per treatment and absence of need for an anesthesiologist creates a savings of $163.70 while an increased cost of material can add up to a weighted average of $91.18 to the procedure cost. We can then use a working estimate of $1969 savings at each implementation of our design over current practices. An itemized comparison of costs of the current and proposed solutions is shown in Figure 93.

![Cost Comparison Chart](Image)

**Figure 95:** Side-by-side comparison of the costs of jaw-fracture treatments using the current methods of MMF and the proposed alternative method of MMF (note that the Cost axis does not start at zero; application cost contributes the most to both designs).

Based on the calculated average estimate of $10,641 per current implementation, the $1969 savings is then roughly 20% savings per use. Since the overwhelming majority of jaw fracture treatment includes MMF and there are approximately 135,000 jaw fracture treatments in the US per annum, this
20% per implementation equates to a $131.3 million market in the United States alone. The numbers used for the calculations above for estimates of both current and proposed solutions are available below in and Table 12, respectively. Since there is variation in the treatments (specifically whether or not open treatment and/or hospitalization are necessary) the estimates are weighted by multiplying the likelihood of a specific circumstantial factor by the cost of said factor’s implementation.

Table 11: Itemized current patient costs for jaw fracture treatments.[16, 17, 18, 19]

<table>
<thead>
<tr>
<th>Source</th>
<th>Closed</th>
<th>Probability Closed</th>
<th>91.18%</th>
<th>Open</th>
<th>Probability Open</th>
<th>8.82%</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR application ($50/min * time)</td>
<td>7050</td>
<td>91.18</td>
<td>6428.19</td>
<td>15500</td>
<td>8.82</td>
<td>1367.10</td>
</tr>
<tr>
<td>OR materials</td>
<td>0</td>
<td>91.18</td>
<td>0.00</td>
<td>200</td>
<td>8.82</td>
<td>17.64</td>
</tr>
<tr>
<td>OR removal ($50/min * time)</td>
<td>1000</td>
<td>91.18</td>
<td>911.80</td>
<td>1000</td>
<td>8.82</td>
<td>88.20</td>
</tr>
<tr>
<td>OR anesthesia application</td>
<td>1</td>
<td>91.18</td>
<td>303.63</td>
<td>577.09</td>
<td>8.82</td>
<td>50.90</td>
</tr>
<tr>
<td>OR anesthesia removal (extrapolated)</td>
<td>163.7</td>
<td>91.18</td>
<td>149.26</td>
<td>163.07</td>
<td>8.82</td>
<td>14.38</td>
</tr>
<tr>
<td>Surgeon Charge</td>
<td>874</td>
<td>91.18</td>
<td>796.91</td>
<td>1148.93</td>
<td>8.82</td>
<td>101.34</td>
</tr>
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<td>---------------------------------------------</td>
<td>-------------------</td>
<td>-----------------</td>
<td>---------------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>OR application ($50/min * time)</td>
<td>6000</td>
<td>91.18</td>
<td>5470.80</td>
<td>14950</td>
<td>8.82</td>
<td>1318.10</td>
</tr>
<tr>
<td>OR materials</td>
<td>50</td>
<td>91.18</td>
<td>91.18</td>
<td>200</td>
<td>8.82</td>
<td>17.64</td>
</tr>
<tr>
<td>Clinic Removal ($10/min * 10min)</td>
<td>100</td>
<td>91.18</td>
<td>91.18</td>
<td>100</td>
<td>8.82</td>
<td>8.82</td>
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<tr>
<td>OR anesthesia application</td>
<td>333</td>
<td>91.18</td>
<td>303.63</td>
<td>577.09</td>
<td>8.82</td>
<td>50.90</td>
</tr>
<tr>
<td>OR anesthesia removal</td>
<td>0</td>
<td>91.18</td>
<td>0.00</td>
<td>0</td>
<td>8.82</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Table 12: Itemized patient costs for proposed alternative treatment of jaw fractures.\[16, 17, 18, 19\]
Conclusion

The savings seen in each implementation of our proposed design is considerable. Considering the potential market compared to the costs of implementing the proposed solution, there is great value in the design. A nearly 20% reduction in the cost of jaw fracture management would result from implementing this design.

3.3 Environmental Impact

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.

If it is estimated that the heat-shrinking floss has a diameter of 0.006in and each implementation requires 150 inches of floss, the volume of PET floss used in each treatment is 0.00135 in$^3$. Assuming the 135,000 jaw fractures that occur per year are all treated with the proposed solution, this equates to roughly 182.25 in$^3$ of PET per year, or 2987cm$^3$.

\[
Produced \text{ PET} = \frac{2987 \text{ cm}^3}{\text{ treatment}} \times \frac{135,000 \text{ treatments}}{\text{ year}} \times \frac{1.38 \text{ g}}{\text{ cm}^3} \times 1.102 \times 10^{-6} \frac{\text{ tons}}{\text{ g}} \approx 0.005 \text{ tons}
\]

The above calculation shows that using the generous estimates above, roughly 0.005 tons of PET would be used for just the production of this thread. In 2011, 308647167 tons of PET were produced\textsuperscript{20}. The calculated amount of additional PET produced to provide for this demand would be only $1.5 \times 10^{-9}$%
of what is already produced. This indicates that the additional creation of PET that would be all but unnoticed. The potential impact is made even more miniscule by the recyclability of PET.