Ligature Material and Transport Device to Aid in Stabilization Procedures of Broken Jaw/Facial Bones

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Abstract

In order to stabilize a jaw or facial fracture, a procedure called maxillo-mandibular fixation must be performed. This procedure is currently done by attaching an apparatus called an archbar to the upper and lower teeth with a 24 gauge steel wire ligature material. This material is prone to causing lacerations in the patient's tissue and puncturing the surgeon's gloves, creating safety and sanitary concerns. Thus, a new ligature material or method is needed that will eliminate the risk of injury to the patient and surgeon, while maintaining the strength and stability provided by the current ligature material. After using a decision matrix and testing multiple ligature alternatives a polyurethane cap was designed to cover the sharp end of the 24 gauge wire. A device is also needed that will enable emergency personnel to stabilize jaw or facial fractures in patients during transportation to the hospital. The fractures may also need to be stabilized during waiting periods if operating rooms are immediately unavailable. The transportation device must be comfortable for the patient, be adjustable to fit a range of head sizes, and put vertical force on the jaw to hold it in occlusion. A prototype of this device has been constructed that satisfies the previously mentioned requirements. The prototype was tested for strength and comfort. Some modifications could be applied to both the wire cap and transportation device for further improvement.

Contents

Motivation

If a person suffers an injury or fracture in their jaw or facial bones they will generally have their teeth set together in a process called maxillo-mandibular fixation. Maxillo-mandibular fixation refers to the lower and upper teeth being held in occlusion – closed together in the correct alignment. Movement along the fracture line inhibits bone healing and predisposes the wound to infection[2]. Thus, it is important that the jaw be set in this way to provide a stable base for the fractured bones to heal; a process generally lasting between two and six weeks. It is also important that the fracture be immediately stabilized by emergency personnel during transportation from the site of the injury to the hospital. A head wrap referred to as the Barton Bandage is used for this transportation and for any necessary overnight stabilization if the maxillo-mandibular fixation operation cannot be immediately performed[5].

The client has specified two areas of focus for the project: to devise a new material and/or method of attaching the archbar to the teeth, and to design a transportation device.

Current Methods and Procedures

Maxillo-Mandibular Fixation

The UW hospital currently uses a device called an archbar to complete maxillo-mandibular fixation. The archbar is a thin band of metal with small hooks along its length. The archbar is bound to the teeth using 24 gauge wire, as seen in Figure 1. The wire is threaded through the teeth to wrap around a single tooth. One end of the wire is placed above the archbar and one end is placed below the archbar. The two ends are then twisted together, securing the archbar in place[1]. The wire is wrapped around four teeth on each side, on both the upper and lower teeth if possible. If teeth are missing the wire may be wrapped around fewer teeth. Once both the upper and lower archbars are in place rubber bands are connected from

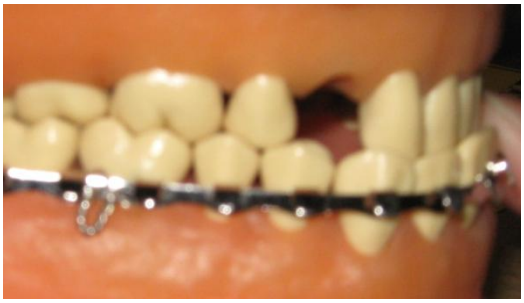

Figure 1. The archbar bound to the bottom teeth[8]

the upper hooks to the lower hooks. It is the rubber bands which secure the jaw in occlusion.

The problem with this method is that the ends of the wire can be quite sharp. These sharp ends can easily cause puncture wounds and lacerations in the patients already injured flesh, as well as the surgeon's gloves and fingers. This creates huge safety and sanitary concerns, as blood borne illnesses, such as Hepatitis or HIV, are at risk of transmission during surgery[1].

There are other methods on the market for performing this operation, all of which are centered on the idea of chemically bonding brackets to the teeth[2] (see figure 2). These brackets are prone to loosening over time, and commonly fall off when stressed.

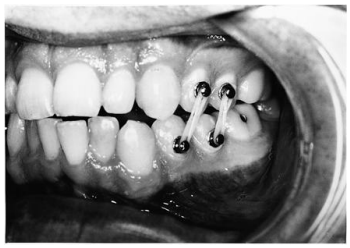

Figure 2. Buttons - an example of chemically bonded brackets[3]

A clean and dry environment is also required to achieve a solid bond between the bracket and the tooth[3]. This is often not feasible as patients with facial fractures have most often sustained a blow to the jaw/face which has also caused considerable tissue damage and bleeding within the mouth. Thus, the client is disinclined perform a method of maxillo-mandibular fixation that will rely on chemically bonds with the teeth.

The Barton Bandage and the Jaw Bra

The hospital is also challenged with the problem of stabilizing the patients injured jaw before entering surgery or during transportation. This is currently done by applying a wrap, called the Barton bandage, to the patient. An ace bandage is wrapped around the patients head as seen in Figure 3. The bandage that wraps vertically from the top of the forehead to the bottom of the chin provides the primary force vector. This is essentially the only force keeping the teeth in occlusion. The bottom bandage serves primarily to stabilize the main vertical bandage. The upper bandage also serves a similar stabilizing purpose. It is undesirable for the bandage to apply force in the

Figure 3. The bandage is wrapped around the top of the head, horizontally around the chin, and vertically around the front of the face[5]

horizontal direction as this could easily cause the jaw to be held in incorrect alignment[5]

Figure 4. The Jaw Bra – Applies horizontal and vertical forces[7]

This wrap is also used to transition patients who have recently had archbars removed. Patients will often prefer to have extra support to help them stabilize their jaw while they sleep. The Barton Bandage wrapping method stabilizes the jaw well, but it is not a device which is easily transferrable from one patient to the next, it is prone to slipping out of place, and it is time consuming and inefficient to apply.

There is also an alternative device called the Jaw Bra (figure 4). This was the only modified Barton bandage the team was able to find. Although the Jaw Bra holds the jaw in place, it does not comply with some specifications made by the client. First, vertical force vectors; the Jaw Bra fails utilize this necessity; it pulls backwards too much on the jaw. Second, the client specified that the material should be inelastic, as shown in figure 4, the Jaw Bra uses an elastic, ace bandage-like material.

Ligature Material

Design Specifications

The new ligature material must eliminate the risk or injury associated with the 24 gauge wire current ligature. The surgeon cannot be at risk of puncturing his glove, and the possibility of adding lacerations to the patient's tissues must be minimized. The ligature must maintain its strength and stability for the entire two to six week healing process, despite continuous vertical pressure from the jaw, and exposure to saliva, food, and toothpaste. If a new material is used it must be flexible enough to enclose the tooth and archbar, yet rigid enough to prevent any movement of the teeth or jaw. Finally, the ligature material must not cause unnecessary discomfort for the patient.

Ligature Design Process

After considering all of the specifications, the team considered four ligature alternatives: the 24 gauge steel wire, suture material, and zip ties, and a capped wire design.

The 24 gauge steel wire is currently able to maintain its strength for the jaw fixation time period. It provides a secure attachment to the teeth and does not corrode. During application, the client inserts the wire between the teeth easily. The wire is twisted to tighten and hold in place. When the wire is twisted it changes color at a point well before the tension will cause it to break. This indication of when to stop tightening the ligature is a specific and beneficial characteristic of the 24 gauge steel wire. The wire has sharp ends that create a concern for safety.

Suture material was the first alternative material considered for the ligature. There are many different types of suture materials available. Suture materials have tensile strength ranging from 10 – 15 N^4. Non-absorbable suture materials do not lose strength over time. With their flexibility, the suture materials are able to bend around the teeth easily and avoid risk of piercing the doctor or patient. In general, suture materials take at least three knots to fasten into place adding to the time of application. There are no wire ends to cause patient discomfort and the material has minimal tissue reactivity. The difficulty with suture material as a ligature option was finding a knot tight enough that the archbar would not slip out of place. There are a variety of knots that would be feasible to use with suture material: the square knot, granny knot, half-hitch, and surgeon's knot. Even the best of these knots, the square knot, proved difficult to tighten to the extent needed for the mandibular-fixation procedure.

Zip ties are the third ligature alternative. Zip ties are made from nylon and there is equipment which makes it easy to apply and tighten. The zip ties are fairly bulky and would not be very comfortable to wear inside the mouth; however, they do not have the sharp ends presented by the 24 gauge wire. Zip ties come in different sizes, the smallest being 10.16 inches long and 1.98 mm wide with a tensile strength of eighteen pounds.

The final ligature design option was to add a polyurethane cap on the ends of the 24 gauge wire. Polyurethane is bio-safe, and will not erode in the mouth. When using capped wire

ends an extra 15 minutes of preparation time would be needed. This design would not be changing the actual material used for ligature, and thus would maintain the strength and durability present in the current material.

Decision Matrix

In order to evaluate potential ligature alternatives, a decision matrix was set up. The categories used to evaluate the alternatives were determined from the client's specifications (Table 1). The categories chosen to evaluate the designs were: strength, safety, ease of application, ease of removal, and patient comfort.

The strength category covered the overall tensile strength of the material and the ability to maintain its strength during the jaw fixation time period. The safety category considered patient and doctor safety throughout the procedure. Next, the ease of application assessed how well the material could be guided through the teeth. This category also took into account the ease of securing the ligature material. Ease of removal referred to the simplicity of removing the material once the jaw had healed. Lastly, patient comfort considered whether or not the material would cause irritation to the patient. The categories were weighted on their importance, and given a score out of 100 total points. Safety was given 30 points, patient comfort was given 10 points, and the remaining three categories were given an equal weight of 20 points each.

	24 Gauge steel wire	Suture material	Zip ties	Polyurethane capped steel wire
Strength (20)	20	10	10	20
Safety (30)	15	30	30	30
Ease of application (20)	18	10	0	16
Ease of removal (20)	18	15	17	18
Patient comfort (10)	5	10	6	6
Total (100)	76	75	63	90

Table 1. Decision matrix summarizing criteria and results for the ligature alternatives. The capped 24 gauge steel wire won due to its high scores in every category

The polyurethane capped steel wire won with a total of 90 points out of the 100 possible. It received relatively high scores in every category, especially safety and strength. The suture material, although safe, failed to tighten securely around the teeth. Thus, it lost a majority of its points in the strength and ease of application. The 24 gauge steel wire lost points in safety due to the jagged ends. To fix this, a polyurethane cap provides the necessary safety, while maintaining the strength and stability of the wire.

Final Design

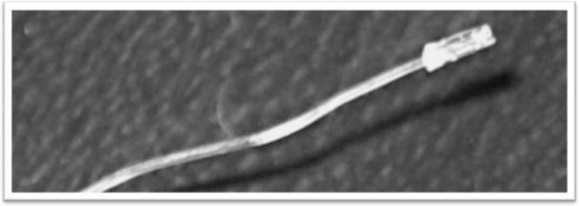

Figure 5. Wire capped with the polyurethane tube[8]

The final design for the ligature is a polyurethane cap for the 24 gauge wire. This cap is made from 21 gauge polyurethane tubing (figure 5). It has an outer diameter of 0.81 mm that can easily fit between the teeth for insertion. The tubing has an inner diameter of 0.58 mm that fits tightly around the 24 gauge wire, which has a diameter of 0.56 mm[6].

In order to secure the cap onto the wire, two mosquito clamps are used. One mosquito clamp holds the wire while the other guides the tubing to the wire. The tubing is pushed 3 to 4 mm onto the wire.

Testing

The wire cap was tested for its ability to stay on through one procedure. The teeth model and archbar simulated the procedure. Eight wires were prepared as described earlier. The wires were then threaded around the teeth and secured into place. A wire cap failed if it came off of the wire. Table 2 shows the results from each trial. There was only one cap that fell off in only one trial for an average failure rate of 1.56%.

Trial #	Percentage of failures during mock procedure
1	0/16
2	0/16
3	1/16
4	0/16
Average	1.56%

Table 2. Ligature cap testing results. Mock procedures were performed and the number of failures were recorded. There was a possibility for 16 failures per trial.

Cost Analysis

The polyurethane tubing (BPU-T30, size 3 French) costs $180/108 ft. The addition of the 16 caps, each 5 mm long, will add a total of 26 cents per surgery.

Transportation Device

Transportation Device Specifications

The design for the new transportation device was required to have a few specifications to address the current issues with the Barton Bandage. The first requirement is that the device be reusable. The second requirement is that any straps touching the face should be soft or comfortable enough to avoid irritation of the injured area. Many times, the patient will have external lacerations, thus if the straps of the new design are two rough or tight, they may irritate the affected area and further discomfort the patient. The device must also incorporate vertical force vectors and avoid forces in the horizontal direction. This is to ensure the jaw is held in occlusion and not forced into an unnatural position. Lastly, the device must be adjustable to fit varying head sizes.

Transportation Device Final Prototype

The transportation prototype is essentially a modified and reusable Barton Bandage wrap. There is one main strap applying a force in the vertical direction. This strap goes down along both cheeks and wraps around the chin (strap 3 figures 6.a,b). A strap wrapping around the head as stabilization (strap 2 figures 6.a,b,c), and a vertical strap attached to a triangular shaped strap (straps 1,4 figures 6.a,b,c) ensuring the device does not slip off the head. In order to avoid irritating infected areas, or causing discomfort to the patient the inside of the straps is lined with a soft, nonabrasive, microfilament material. This material lines the entire chin piece (strap 3 figures 6.a,b), the front side of the horizontal strap (strap 2 figures 6.a,b,c), and the two triangle straps (strap 4 figures 6.a,b). Velcro has been added on one side of the vertical strap, as well as a moveable chinstrap, allowing the device to be adjustable and usable for patients with varying head sizes. The strap traveling around the back of the head is adjustable in a similar manner as well.

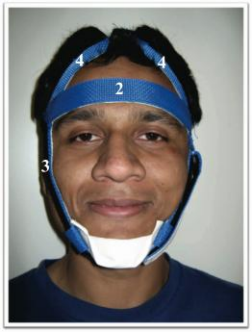

Figure 6.a. Front view of the SlingJaw[8]

Figure 6.b. Side view of the

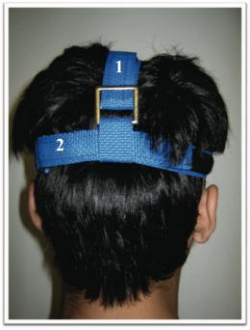

Figure 6.c. Back view of the SlingJaw

The SlingJaw is far more efficient than the current method for both the patient and the surgeon. It saves the clinician administering the Barton Bandage valuable time and resources from the previous method. It will be also be a far easier process upon removal. Another important feature of a non-disposable Barton Bandage is patient usability. A patient can bring the apparatus home and if they feel the need for extra support during sleep or simply while moving around, they may put it on relatively easy by themselves. Thus, this new design will be extremely beneficial for patients as well as doctors, and will be a much sought after device.

Dimensions of the SlingJaw

	Strap lengths (in.)	Soft Velcro Lengths (in.)	Hard Velcro Lengths (in.)	Inside Liner Lengths (in.)
1	15.25	3.5	10.5	NA
2	29	2.5	12.25	10
3	19	2.5	15.5	18.5
4	6	NA	NA	5

Table 3. Dimensions of the final SlingJaw Prototype. The numbers in the table correlate with figure s 5.a,b below

Figure 7.a Front view of SlingJaw. Each numbered strap correlates with Table 3 seen above[8]

Figure 7.b Side view of SlingJaw. Each numbered strap correlates with Table 3 seen above[8]

Each of the four straps were measured in centimeters. The triangle shaped strap (strap 4 table 3) is shown as one length, although there are actually two straps of this length that form the triangle at the crown of the head. This triangle strap was measured to have an obtuse angle of 120°, while the two acute angles were measured at 50°. The dorsal strap (strap 1 table 3) that runs across the top to the back of the head was found after fabrication to be slightly too long. A modified version of the SlingJaw will have a shorter dorsal strap. The Velcro lengths can also be shortened in general, they were placed initially like this to deal with different sizes, but after testing we noticed that they can be shortened. After speaking with the client and showing him our final design, he mentioned a couple changes that could be made. First, the straps will be slightly thicker to allow for a tighter hold on the patient. Secondly the triangle on the crown will be moved upward toward the very top of the head to make the vectors more vertical.

Testing

In order to evaluate the SlingJaw's ability to maintain its strength, mechanical testing was performed using a force gauge. The SlingJaw was suspended from the dorsal strap. It was tested three times by applying a strictly vertical down force until failure. Failure was defined as when the Velcro started to show signs of defeat. This would normally produce a Velcro ripping sound. Table 4 shows the results from each trial. The average force withstood was 48.14 lbs, exceeding the amount of force possible from the jaw.

Trial #	Force Withstood (lbs)
1	47.40
2	46.30
3	50.71
Average	48.14

Table 4. Force test for the SlingJaw. Force was applied using a force gauge until signs of failure

Next, we assessed the comfort of the SlingJaw. Each group member wore the device throughout the course of one night and ranked the comfort level on a scale from 1 to 5. The results, in table 5, show that the average of the four rankings was 3.875.

Trial #	Comfort Score (out of 5)
1	4
2	4.5
3	3
4	4
Average	3.875

Table 5. Comfort test for the SlingJaw. 4 subjects wore the SlingJaw for the duration of a night and asked to rank the comfort level out of a possible 5 points.

Cost Analysis of the SlingJaw Prototype

Table 6 outlines the cost of materials required to make one SlingJaw prototype.

Item	Cost ($)
Nylon Belting Material	3.21
Velcro	3.48
Plastic Buckles	1.98
Metal Buckle	1.24
Thread	4.58
Total Cost	14.46

Table 6 Cost analysis of the SlingJaw prototype. The cost of the microfilament lining material is not included because cost is unknown; the team did not actually purchase this material. Costs such as thread cost would be distributed among many SlingJaws if it were to be produced in mass quantities.

Ethical Considerations

The project required many ethical considerations and the team wanted to not only to meet the standards required but to also exceed the expectations to maximize patient comfort and safety. The team considered all different types of patient population and evaluated the prototypes so the team could minimize any harm that may be caused by the ligature and by maximizing the benefits due to the design. The goal was to meet the client specification with the team's own ideas while having patient safety was the team's highest priority. The team followed proper guidelines to avoid any type of plagiarism or usage of any patent information. The team is considering continuation of the project for the upcoming semester and would like to make the SlingJaw design safer and more comfortable. The team would like to do more research and experiments in the future to see how durable they are and if improvement is possible upon the safeguards to minimize any misusage of the product.

Future Work

Ligature

Improvements can be made upon the procedure of applying the polyurethane tubing on the 24 gauge wire. A device needs to be manufactured to assist the process of application, reduce the time, and make it convenient for the client. This device will be very time efficient and make the application process easier. As for the urethane tubing, the color needs to be visible to the client and should be different than the color of the wire.

The 24 gauge wires could also be pre-prepared and be available to the client. They may be manufactured and cut into smaller sizes that could be used for tightening the archbar. If they were available premade, it could reduce the time that would be needed to apply the tubing during the procedure. If the polyurethane tubing is applied on the wire and made available to the customers, the tubing could be glued to the tube, which will reduce the chances of the polyurethane cap from coming off during or after they are applied on the patient.

Transportation Device

There are a few adjustments that would improve the current SlingJaw prototype. The "triangular strap section" could be modified to adjust the force vectors that only run vertically. It needs to be positioned so it pulls the "mandible strap" upwards and keeps the jaw occluded. Improvements can made for the inside lining material so it is very comfortable for the patient. Also, a wider strap could be used to improve stability and comfort.

A major improvement needs to manufacture a chin cup that will provide comfortable padding to the patient's jaw while being washable and reusable or dispensable. This cup will also need to be able to transform and fit into different sizes of jaws easily. It will provide comfort and stability to the injured jaw while reducing lacerations and decreasing the probability of reinjuring the jaw.

Conclusion

Throughout the semester, much time and effort was put into discovering the ideal material to use for the archbar fixation. Since the team was unable to locate or manufacture a zip tie with a diameter of 1 mm or suture material that would not slip, the team had to readdress the situation and focus on the real safety issue. The polyurethane cap equips the wire so that it prevents patient/doctor lacerations. It adds an additional 15 minutes for preparation. The team would like to design a device that can quickly insert the cap 3 to 4 mm. As for the SlingJaw, the team created a prototype that applied strictly vertical force vectors. After a few medications, it will be ready for use. The design team would like to thank our clients Laura Bonneau and Dr. John Doyle for this opportunity and for their enthusiasm about the work. The team would also like to thank advisor Prof. Thomas Yen for his assistance throughout the semester.

References

1. Baig, M. Current Trends in the Management of Maxillofacial Trauma. Ann Ro Australas Collg Dental Surgery. 2002:16:123-127.

2. Blitz, M. & Notarnicola, K. Closed reduction of the mandibular fracture. Atlas Oral Maxillofacial Surg Clin N Am 17 (2009) 1-13.

3. J or Orthodontics, Vol. 27, No.4, 341-342, Dec 2000: Buttons and Elastics for the conservative Treatment of the Fractured Mandible. Burke & Mitchell.

4. Kim, Jin-Cheol. Comparison of tensile and knot security properties of surgical sutures. Journal of Materials Science: Materials in Medicine. Springer, Netherlands. 2007.

5. Murchison, David F. Jaw Fracture. The Merck Manuels Online Medical Library. http://www.merck.com/mmhe/sec08/ch117/ch117d.html. 2008.

6. Instech Laboratories, Inc. 2009. Online. http://www.instechlabs.com/Infusion/tubing/sizes.php.

7. "TMJ Jaw Bra." *Canfield, Inc.* Web. 01 May 2010.

   <http://www.canfieldinc.com/number-93.html>.

8. Pictures taken by Kelsey Hoegh. 4/22/10.

Appendix

Maxillo-Mandibular Fixation

02/03/10

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Problem Statement: When there are fractures in the face, the mandible must be fixed to the maxilla for a period of 2-6 weeks. Our objective is to create a device which will allow for this fixation with little to no risk of injury to surgeon or patient, and will still provide strength and stability for the entire duration of use.

Client Requirements:

- Only One trip to the OR necessary
- Procedure must be completed in a timely manner
- Avoid getting stuck with the wire

Design Requirements:

1.) Physical and Operational Characteristics:
    a. Performance Requirements:
        i. Used for only one patient
        ii. Period of 2-6 weeks
        iii. Must attach to the teeth in a secure manner
    b. Safety :
        i. Must avoid puncturing the surgeon's gloves or patient to ensure a sterile environment throughout the procedure
        ii. Mechanism to quickly allow opening of the jaw if patient needs to vomit
        iii. Nothing small enough to fall into open throat if falls during application
    c. Accuracy and Reliability:
        i. The device must be usable on patients with varying dental heath
    d. Life in service:
        i. Single use
        ii. Remains inside the mouth for 2-6 weeks
    e. Operating Environment:
        i. Blood and possibly other bodily fluids
        ii. Exposed to food and saliva for entire 2-6 week period of use
        iii. Body temperature
    f. Ergonomics:
        i. Withstand the force of a human jaw without breaking, bending, or in any other way allow shifting of the jaw
            - 0-100 N for incisal edge loading and 0-200 N for range of molar loading
        ii. At minimum must secure from cuspid back to first molar
    g. Size:
        i. Fit in the mouth

ii. Teeth fully touching when mouth is closed.
iii. Spacing between hooks must be large enough to allow bands to fit (assuming building off of archbar technique)

h. Weight:
    i. Comfortable weight to be held by the teeth
i. Materials:
    i. Safe for human mouth.
    ii. Cannot be degraded by saliva , toothpaste, or food

2.) Production Characteristics
    a. Target Product Cost:
        i. $30 or less per unit
3.) Miscellaneous:
    a. Standard and specifications:
        i. Approval by client (Surgeon)
    b. Customer: Prefers anything that will avoid hurting the surgeon's hands, or spreading of diseases passed through the blood.
    c. Patient-related Concern:
        i. Patient comfort is a priority
        ii. Avoid materials that will cut gums/lips
        iii. Allow cleaning of teeth as much as possible
        iv. Young, active people = general patients
    d. Competition:
        i. Buttons
        ii. Archbar
        iii. Screw technique (IMF Screws)
        iv. 4 hole locking mini-plates
        v. 6 hole non-locking mini-plates
        vi. 6 hole limited contact dynamic compression plates