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

3/10/2010

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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/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 to differentiate between the current ligature, suture material, and zip ties, it was determined that the zip ties will be the best option for ligature, but due to very close scores suture material will continue to be considered as an option. A device is also needed which will enable emergency personal to stabilize jaw/facial fractures in patients during transportation to the hospital and during waiting periods until operating rooms are available for maxillo-mandibular fixation to be performed. This device must be comfortable for the patient, be able to fit a range of head sizes, and put vertical force on the jaw to hold it in occlusion. A rough prototype of this device has been constructed, yet there are many aspects which will need to be modified before a final design can be developed.

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 to infection and nonunion of bone[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 personal 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 possibly for overnight stabilization until the maxillo-mandibular fixation operation can be 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. 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, and the two ends are 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 the upper hooks to the lower hooks. The

Figure 1: The archbar bound to the bottom teeth

problem with this method is that the wire, being pushed in between the teeth with a fair amount of force, can easily cause puncture wounds and lacerations in the patients already injured flesh, and often punctures the surgeon's glove 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 to performing this operation, all of which are centered on the idea of chemically bonding brackets to the teeth[2]. These brackets are prone to loosening over time, and commonly fall off when stressed. 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.

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

The Barton Bandage

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

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]

This wrap is also used to transition patients who have recently had archbars removed, as patients will often prefer to have extra support to help them feel their jaw is more stable 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.

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. The new material 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 be comfortable for the patient.

Ligature Material Options

After considering all of the specifications, the team chose three ligature alternatives: the 24 gauge steel wire, suture material, and zip ties.

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. However, the client has trouble when creating a loop around the tooth with the steel wire. The sharp ends of the wire create a safety concern.

There are many different types of suture materials available. Suture materials have tensile strength ranging from 10 – 15 N^4. The non-absorbable suture materials do no lose strength over time. With its 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.

Zip ties are the last ligature alternative. Zip ties are made from nylon and there is equipment which makes it easy to apply and tighten. The zip ties will not be the most comfortable to wear inside the mouth; however, they may be a better option than the 24 gauge wire. Zip ties come in different sizes but the ones the team is currently looking are four inches long with a tensile strength of eighteen pounds.

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 takes 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. Last, 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
Strength (20)	20	18	19
Safety (30)	15	30	30
Ease of application (20)	18	16	19
Ease of removal (20)	17	12	17
Patient comfort (10)	5	7	5
Total (100)	75	83	90

Table 1. Decision matrix summarizing criteria and results for the ligature alternative. The zip ties won due to its high scores in each category, especially safety.

Zip ties accumulated the most points with a total of 90. Zip ties achieved relatively high scores in every category, especially ease of application and safety. Suture material came in a close second with 83 points. The main difference between suture material and zip ties was the ease of application and ease of removal. Suture material would need to have three or four knots to secure, and would require tying without gaining any slack. This would be difficult to manage, especially in the trauma room. However, the alternative suture material as ligature will continue to be considered even while further investigating the zip ties.

Transportation Device

Transportation Device Specifications

To alleviate these undesirable aspects of the Barton Bandage, we were asked to construct a reusable Barton Bandage.

This design would need to have a few specifications that address the current issues with the Barton Bandage. The first, which has been stated previously, is that it will be reusable. The second requirement is that the straps that touch the parts of the face should be soft or comfortable

enough to not irritate the injured area. Many times, the patient will have lacerations externally around the area of the fracture. If the straps of the new design are two rough or tight, they may irritate the affected area and further discomfort the patient. So the inside of the straps will be lined with a soft, nonabrasive material that will avoid irritating the injured area. In addition to these specifications, it will also obviously need to be adjustable. We have implemented Velcro on the one side of the vertical strap, as well as a moveable chinstrap. This will allow for application to patients with varying lengths of the front of the face. The strap traveling around the back of the head will be adjustable in a similar manner as well.

Transportation Device Prototype

Figure 4: Front view of the transportation device prototype

The transportation prototype is essentially a modified and reusable Barton Bandage wrap. There will be one main strap applying a force in the vertical direction, a strap wrapping around the head as stabilization, and a horizontal and axial strap ensuring the device does not slip off the head (figure 4 and figure 5). In order to avoid irritating infected areas, or causing discomfort to the patient the inside of the straps will be lined with a soft, nonabrasive material. 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 will be adjustable in a similar manner as well.

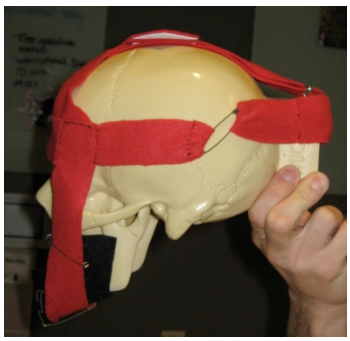

Figure 5: Side View of the transportation device prototype

Once fabricated, this new Barton Bandage will be far more efficient to use for both the patient and the surgeon. It will save 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.

Future Work

The future work focuses on two aspects of our project. As for the Sling Jaw, it needs to be made from such materials so that it provides enough strength to keep the teeth in occlusion, while being very comfortable to the patient. After research has been done and the prototype has been manufactured, the next step in process would be to test it and make sure that it meets the client's requirements. If the results are positive, the design will be manufactured in two sizes; one being the adult and the other being the pediatrics size to be available to all age group.

With regards to the ligature material and based on the design matrix, we will be pursuing sutures and nylon zip ties into greater detail. The suture material will be a better option for the clients due to their familiarity with using sutures; however, we must find a way to use the sutures so they provide enough strength to keep the archbar in place without being decomposed inside the mouth. We need to explore different types of knots and see if they can provide enough stability. As for the type of sutures, we believe that the nylon suture will be our best option because it will not decompose inside the mouth while providing enough rigidity; however, there is a possibility of the nylon sutures grinding against the archbar and breaking. As of now, more research and experiments needs to be done in upcoming future to see if sutures can be used to replace the 24 gauge wires.

Our other option is to replace the 24 gauge wire with nylon zip ties. We are currently looking into zip ties that will fit through the teeth without major discomfort but have the tensile strength similar to the steel wire. If we can find zip ties that are either thin enough or if we can manufacture such zip ties, then it will simplify the process of applying the archbar while saving time and decreasing the cost.

References

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Appendix

Project Design Specifications

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