

Problem Statement

The goal of this project is to design a mouth guard for our client, Mike Conforti, DVM, which will detect the teeth clenching and/or grinding of a patient during sleep. The device should provide a gentle stimulus to the patient, causing the individual to unclench or stop grinding his/her teeth.

Background

Bruxism, involuntary excessive teeth clenching or grinding, is thought to be a common problem. Since people tend to clench or grind at night, they are often unaware of it. It's important to note that most people clench their teeth occasionally, but it's not bruxism unless it is **excessive** clenching or grinding. Diagnosis of bruxism is usually made by assessing clinical signs in the patient, or the patient's family noticing the grinding noise while sleeping. The following symptoms are the most common: joint pain; headaches/migraines; photophobia; phonophobia; tooth surface wear; tooth sensitivity; neck stiffness or pain; and jaw clicking or catching.

Literature Search

In order to develop a device to treat and/or prevent bruxism, we needed to know how the muscles and joints are affected. When bruxing, the forces generated are three to tens times stronger than when chewing. (Castaneda, 1992) The temporomandibular joint (TMJ) is where the condylar process of the mandible (lower jaw bone) and the glenoid structures of the skull articulate with the mandibular fossa. A disk which sits within this joint moves with the bones, lubricating the joint. Often it is this disk that becomes caught in the wrong place after the trauma of bruxism, leading to TMJ disorders. The main muscles involved with mandibular or masticatory motion are: masseter, temporalis, and the medial and lateral pterygoids. All of these muscles are innervated by the mandibular trigeminal nerve.

Prior Work

Our client provided us with a copy of a patented device for the prevention of bruxism utilizing an acrylic mouthguard with a pressure switch and electrodes to deliver

a stimulus to the patient when clenching or grinding occurs. (US Patent # 5,490,520)
The device uses four lithium dry cell buttons in series, each approximately 3 Volts, embedded within the outer wall of the mouthguard. Metal or plastic electrodes are also embedded in the wall, except in the back of the mouth against the gum line where saliva is needed to complete the circuit and give an electric stimulus to the patient. When the patient bruxes, the dynamic tube-shaped switch is compressed and the circuit completes giving a stimulus to the patient. This stimulus reaches the trigeminal nerves, and in theory causes the masticatory muscles to relax and the jaw to open.

We performed our own patent search and found that many devices to prevent or treat bruxism exist. For example, one of the patents we found involves a tooth guard that incorporates a pressure sensitive surface that is electrically coupled to an alarm mechanism, very similar to the patent Dr. Michael Conforti gave us. (United States Patent # 5,586,562)

In another patent, however, the invented apparatus is worn on the outside of the patient's head. This invention consists of electronics mounted in a headband, and it may be worn comfortably by a user while sleeping or awake. Electrodes placed within the headband pick up surface EMG voltage signals indicative of bruxism, and finally a biofeedback signal is provided to the user through an earphone. (United States Patent #6,270,466)

Nearly 90 patents exist that are related to the treatment of bruxism. Many different methods of mouth guards have been tried. For example, shown in Figure 1, a splint with saline-filled wax capsules is intended to startle the patient, thus disrupting the bruxism behavior, but does not show evidence of relieving symptoms. The hydrostatic splint, shown in Figure 2, is a water-bearing pressure equalizing appliance. (Lerman, 1987) This is supposed to be one size fits all, which really can't be true. Human mouths and teeth occlusion vary substantially.



Figure 1: Metal appliance with saline-filled wax capsules



Figure 2: Hydrostatic splint

The most common treatment we found is the use of a rubber or acrylic splint. (See Figures 3 and 4) This device dates back several decades at least. The splint rests on the upper or lower teeth, preventing damage to the teeth by not allowing contact, and in theory reducing the severity of the symptoms listed previously. Although, studies have shown that this splint merely protects teeth and does very little to alleviate symptoms associated with bruxism.



Figure 3: Rubber Splint (Matthews, 1942)



Figure 4: Acrylic splint, courtesy of Dr. Doyle, DDS, UW Hospital, Madison, WI

The patent (#5,490,520) that Dr. Conforti is interested in described its method of action as involving the stimulation of the trigeminal nerve. This concept seems like it should work—the masticatory muscles are all innervated by the trigeminal nerve. Further research on this idea led us to a new device called the Nociceptive Trigeminal Inhibition (NTI) device. This device also involves the stimulation of the trigeminal nerve, but without any electric circuitry. It's a small polycarbonate plastic splint that fits on the two upper incisors. (See Figures 5 and 6) A prefabricated matrix can be retrofitted by reline with acrylic, and then sculpted, in just one office visit. Some dentists prefer to have two visits to make sure the device fits properly and to make sure the patient's symptoms have decreased.

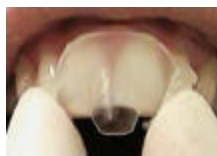


Figure 5: Fitting an NTI



Figure 6: NTI device

We also had meetings with dentists, including Dr. Doyle, DDS, at University Hospital, Madison, Wisconsin, and interviewed Dr. Clark, DDS, Total Care Dental, Madison, Wisconsin. Dr. Doyle advocates the use of a full hard acrylic mouth guard,

stating that he believes its efficacy is near 85%. However, Dr. Clark has prescribed the NTI for one year and states that every patient has done well. Dr. Clark's associate Dr. Salzmann, DDS, Total Care Dental, has prescribed the NTI for about three years and has only had "a couple" of patients who required more extensive treatment to relieve their symptoms.

TABLE 1

	<u>NTI</u>	<u>Patented device</u>
Approx. Cost to the patient	\$200-300	\$300 + cost of replacement parts and appointments for adjustments
Number of Adjustments	1-2	many
Ease of use for the patient	uncomplicated	complicated
Complexity of design	simple	complex
Parts requiring periodic replacement	none	batteries, possibly electrodes, and pressure switches
Method of action	Disruption of pericranial muscular tension by triggering nociceptive trigeminal reflex	SAME
FDA approved	YES	NO

Design Constraints (Also see PDS Appendix A)

Our client, Mike Conforti, is interested in a product that fits in the patient's mouth, and delivers a gentle stimulus when the patient clenches or grinds, in theory causing them to

relax the masticatory muscles. The device must be comfortable and easy for the patient to use, as well as having a reasonable cost.

Proposed Solution

When choosing our final design, we needed to decide what style of mouth guard to use. It's obvious that the acrylic full mouth guard has been very popular for a long time. But could the new NTI be a better design to treat bruxism? Table 1 illustrates the main similarities and differences between the NTI without electric stimulus, and the proposed patented device using a full mouth guard with circuitry. As you can see, the NTI clearly has more advantages. They both work by the same method of action, yet the NTI is so much simpler. Also, the full mouth guard can cause traumatic canine occlusion, whereas the NTI cannot. Traumatic canine occlusion is what happens when the canine reflex is stimulated. When bruxism is going on, and the canines have something to sink into, a reflex is stimulated which causes the jaw to clench even harder. Obviously, this can greatly aggravate the symptoms of bruxism. Since the NTI does not cover the canines, this reflex is never a problem.

However, if our client still desires a device that provides electric stimulus, we could develop a prototype using the NTI and the circuitry outlined in Patent # 5,490,520. The electrodes could drop down behind the bottom incisors, allowing a stimulus to be given at the gum line. The trigeminal nerves branch in this direction, therefore, it is not necessary to have the electrodes in the back of the mouth.

Problems

One potential problem is finding the miniature parts required for such a small device. Also, with all the added circuitry, the cost may become too high to be a marketable product. This electric stimulus could also be too disruptive to the patient's sleep.

To deal with the small parts issue, we may have to manufacture them ourselves. It's possible that with high demand and high production, the cost could still be reasonable to the patient. We will need to test a prototype on several people before we'll know if it is too disruptive during sleep.

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APPENDIX A

Product Design Specification (PDS)

October 19, 2001

Mouth guard with Electrodes and Pressure Switch For Treatment and Prevention of Bruxism

Team Members: Matt Harris, Tracy Stefonek

Advisor: John Webster

Client: Mike Conforti, DVM

Function: The device will provide the patient with a gentle stimulus that causes the person to stop grinding or clenching his or her teeth. It will contain an electric source, or battery, and pressure sensors embedded in it, as well as electrodes that come into contact with the patient's mouth.

Client Requirements: The mouth guard must be comfortable and it cannot disrupt a patient's sleep. The device should only be a few millimeters (2-3mm) thick and all the electrical components, except the electrodes delivering the stimulus should be encased inside the material of the mouth guard. The device must be as cost effective as possible to increase its chance of marketability.

Design Requirements: Circuitry must be small enough to fit within the NTI

Physical and Operational Characteristics

- a. *Performance requirements:* Must provide 6-9 V stimulus to patient when bruxing
- b. *Safety:* Non-toxic materials
Small parts must be secure to avoid choke hazard
Must eliminate risk of electric shock
- c. *Accuracy and Reliability:* Pressure switch must respond to any pressure up to at at most 175,000 psi
- d. *Life in Service:* 3-4 years

- e. *Shelf Life*: Polycarbonate plastic mouthguard – indefinite
Electrodes – several years
Battery – several years
Pressure Switch – several years
- f. *Operating Environment*: Inside mouth – saline solution, bacteria, approx. 37 degrees Celsius
- g. *Ergonomics*: Must be easy to place and remove
- h. *Size*: Approx. 20 mm by 15 mm
- i. *Weight*: 1.16 g plus weight of circuitry
- j. *Materials*: Polycarbonate plastic, stainless steel electrodes, lithium batteries
- k. *Aesthetics, Appearance, and Finish*: Smooth edges

2. Production Characteristics

- a. *Quantity*: Depends on demand
- b. *Target Product Cost*: Manufacturing costs approx \$100
Current product costs to consumer approx \$300
Circuitry cost additional \$50

3. Miscellaneous

- a. *Standards and Specifications*: FDA approval not necessary, but is preferable
- b. *Customer/Patient-related concerns*: Reasonable cost, prompt availability, adequate instructions for use
Taste, smell should not be offensive
- c. *Competition*: NTI without circuitry
Full acrylic mouth guard

