

Mouth Guard for Treating Bruxism with Electrostimulation

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Abstract

Bruxism is the involuntary clenching or grinding of teeth during sleep. The goal of this project was to develop a mouth guard using an electrical stimulus to stop the patient from bruxing. The components of the device are a transducer to sense the bruxing, circuitry to convert the signal to pulse of a specific frequency and width, electrodes to stimulate the patient, and a mouth guard to contain the entire system. Initial testing was necessary to determine ideal frequency and pulse width for appropriate stimulation, specific to the human mouth. Force testing was performed to determine the force of biting down. The current prototype consists of an athletic mouth guard with 2 membrane switches, 2 carbon-rubber electrodes, and encased circuitry. The circuit consists of a 555 timer, 2 capacitors and 2 resistors. Future work should involve finding batteries for a power source and lowering the input voltage. Eventually this device requires human testing.

Problem Statement

A device is needed that can sense teeth bruxing (clenching and grinding during sleep). In response, an electrical stimulus will be applied to stop the patient from bruxing. This device should incorporate a mouth guard with embedded mechanical pressure sensors to detect the bruxing, and an electric source and electrodes to deliver a gentle stimulus to the patient's mouth.

This is the proposed design from our client, Michael L. Conforti, D.V.M., a research health scientist in the Department of Surgery at UW Hospital in Madison, Wisconsin.

Background

-Medical-

Bruxism is defined as the involuntary clenching and grinding of the teeth, usually occurring at night. Clenching is the application of a static normal force onto the teeth. Grinding is the back and forth movement of the mandible and maxilla, lower and upper jaw respectively (Figure 1). The average pressure between a top and bottom tooth during clenching is 300 psi, 2076 kPa (Attanasio, 1997). Physical and emotional stresses, Malocclusion, trauma or injury and drugs are common causes of bruxism (Attanasio, 1997). Problems resulting from bruxism can include headaches, muscle strain, jaw pain, tooth sensitivity, minor wearing of the tooth surface, oral infection and excessive tooth mobility (Attanasio, 1997).

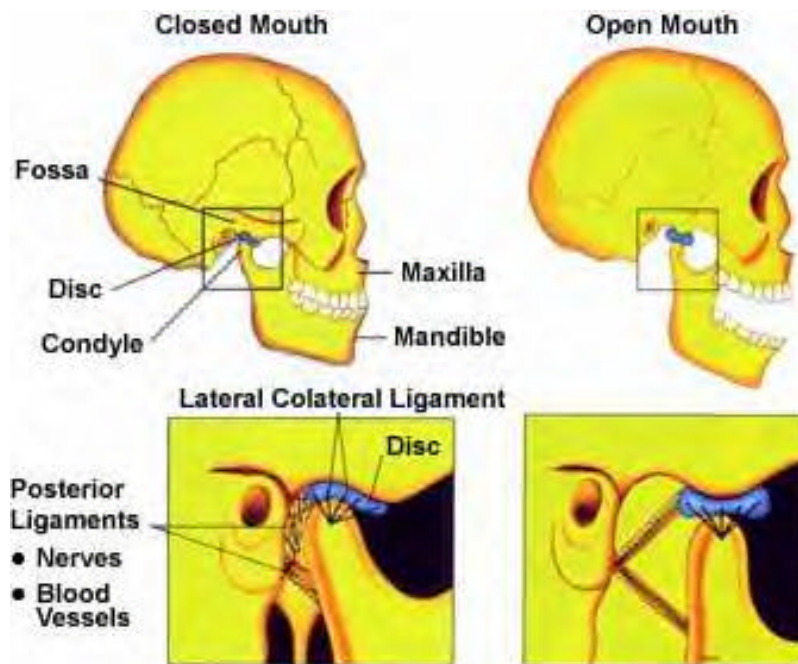


Figure 1. This figure shows the main bones involved in clenching. From Nissani, 2001.

Currently there are many treatments for bruxism. Many only relieve the symptoms of bruxism. There are no known methods which cure bruxing. Physical therapy is used as a treatment to strengthen the jaw muscles, increase jaw mobility, and decrease swelling and pain in the jaw. Therapy may reduce stress and therefore reduce teeth clenching. Other proposed treatments include psychotherapy, massed negative practice (a subject is instructed to clench), and exercise (Nissani, 2001). These all attempt to relieve stresses that cause bruxism.

-Competitive Products-

The most common treatment for bruxism includes a splint (or mouth guard) worn at night (Figure 2). This appliance reduces the tooth damage created by bruxing. Studies have shown that this splint merely protects teeth and does very little to alleviate symptoms associated with bruxism (Nissani, 2001). The splints must be worn throughout life. These splints are custom fit to the patient and molded from either hard acrylic or soft acrylic. Our future design will use the hard-acrylic mouth guards that Dr. Doyle currently prescribes to his bruxing patients. Since our design will be an addition to the mouth guard, the competitive plain mouth guard that Dr. Doyle offers will have a lower cost than our product.

Our client provided us with a copy of a patented device for the prevention of bruxism utilizing an acrylic mouth guard with a pressure switch and electrodes to deliver a stimulus to the patient when clenching or grinding occurs, see Figure 3 (US Patent # 5,490,520). The device uses four lithium dry cell buttons in series, each



Figure 2. Hard-acrylic splint, courtesy of Dr. Doyle.

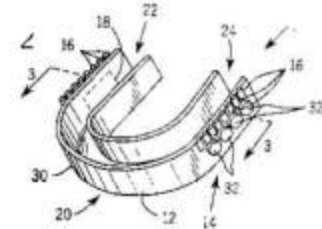


Figure 3. Sketch from Patent 5,490,520.

approximately 3 V, embedded within the outer wall of the mouth guard. 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.

A new device called the Nociceptive Trigeminal Inhibition (NTI) device is currently available through dental offices (Figure 4). 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. A prefabricated matrix can be retrofitted by relining with acrylic, and then sculpted, in just one office visit.

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. This device ranges in cost between \$200 – 300.

Other devices use behavioral modification and include feedback devices such as sound alarms or electrical stimulation. These devices detect the bruxing with either electromyogram (EMG) or tactile sensors. EMG measures the flexing of the facial muscles. Tactile sensors measure the force applied between teeth (Nissani, 2001). Patents currently exist for TMJ treatments applying electrical stimulus to the jaw, lip, mouth, neck, and tooth.

An alternative to the hard acrylic mouth guard includes a splint model in which the patient bites down on a mouthpiece with fluid filled sacs, waking the patient as a result of the bursting and releasing fluid (Figure 5). The patient must replace these fluid filled sacs frequently. The fluid may contain a mix of hot peppers, horseradish, mustard, ginger, garlic, onion, salt, or denatonium benzoate. This device is not currently available commercially (Nissani, 2001).

One such device is the OralSensor (Figure 6) commercially available without a prescription for \$195. This device consists of a sensor and an auditory alarm near the ear. The device is preset to a certain threshold force that will trigger the alarm (Cycura Corporation, 2001).

Design Specifications



Figure 4. NIT Device (Pohlhaus, 2001)



Figure 5. Taste-based TMJ treatment



Figure 6. The Oral Sensor (Cycura Corp., 2001)

The most important design constraints are to maintain patient comfort and safety. Comfort can be ensured if the mouth guard is an appropriate size for the patient's mouth and does not slip out of the mouth easily. The device should contain minimum wires and not interfere with the patient's breathing and sleep. The electrical stimulus should not wake the patient during sleep. The device should also be safe: it should run on low voltage and current. It should be waterproof. The device should contain no small or sharp parts that could be swallowed or harm the patient's mouth.

It is also important for the device to be durable. Hard acrylic or plastic would be appropriate, but the device must also be lightweight and free standing. It must be able to withstand pressures over 2076 kPa, and temperatures over 37° C.

The device must also be cost-effective in order to be marketable to the patient. See Appendix A for extended design specifications.

Preliminary Testing Before Design

-Forces From Clenching -

Research

To design the mouth guard, it is important to know the range of force applied to the teeth during bruxing. Ideally a force of moderate bruxing will turn on the electric stimuli (complete the circuit). If a lower force than moderate bruxing force turns on the circuit, then the patient will receive the stimuli even when they are not bruxing. If a higher force than the moderate bruxing force is needed to turn on the circuit, then the patient may not receive the stimuli even when they are bruxing.

Although no measurements of biting force was found in the literature, it was found that the average pressures exerted during bruxing was stated to be 2076 kPa (Attanasio, 1997). Since the exact area of the biting surface of tooth is not known, the pressures can not be converted into exact forces for comparison purposes. Using an estimate of the surface area of a tooth to be 5 cm², and the 2076 kPa measurement of pressure, the estimated force exerted on the tooth is 103 N.

Preliminary Testing

An experiment was run to find the forces applied to the teeth due to biting. Instron – Model 1000 force loading machine contained the load cells used to measure the forces (Figure 7). Two L-shaped pieces of metal were attached to a load cell in the machine (Figure 8). The metal used was steel brass plated and 127 mm thick. The person then bit down on the metal, putting force on the load cell. This force on the load cell is what was measured. Forces of moderate and maximum clenching were measured for two subjects

The results for both a male and female clench can be seen in Table 1. The moderate values are relatively near the estimated force per tooth value of 103 N (calculated using 2076 kPa and tooth surface area of 5 cm²).



Figure 7. Pictures of both Kathleen (left) and Matt (right) clenching down on L-shaped metal pieces attached to a load cell.

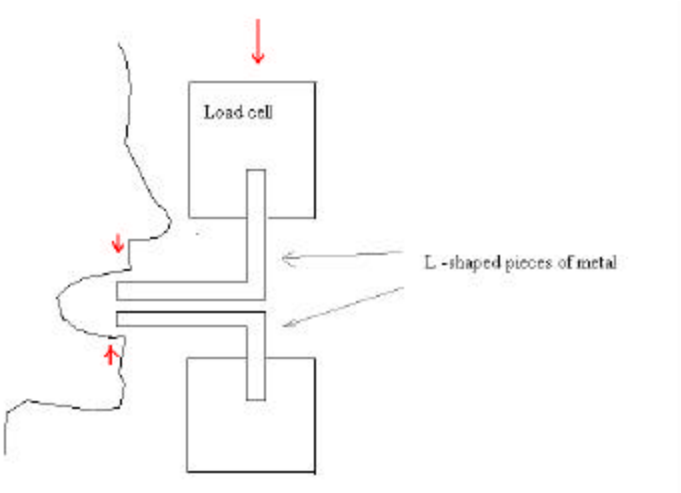


Figure 8: The set up of the Instran – Model 1000. As the teeth bite together the top load cell displaces downward and measures the force being put on it. The force from applied load cell should equal the force of the teeth biting down.

Table 1: The maximum and minimum biting forces. This table shows the forces the jaw puts on a tooth while biting down. The test subjects are both healthy and in their early twenties. The ranges may be different for people of different ages or with less than adequate health. *Note: for Kathleen’s moderate clench, she performed a grinding motion.

Subject	Max Clench (Right)	Max Clench (Left)	*Moderate Clench (Right)	*Moderate Clench (Left)
Matt	237.98 N	246.88 N	107 N	91 N
Kathleen	117.88 N	142.34 N	109 N	96 N

Evaluation

The ideal situation is that the force of the load cell equals the biting force, however there were some errors in the experiment that could lead to imperfect readings of the true forces. First, the subjects were biting down on hard metal, so this made it

uncomfortable to bite down with maximum force. The maximum forces may actually be higher than the values obtained from this experiment. Also, when Matt bit down on the metal, he bent the metal, causing the force reading on the machine to be lower than the actual force he was applying. Finally, the two subjects were in good health and in their early twenties. A more diverse sample of people should be used in the experiment to obtain a better idea of average forces applied during clenching throughout the general population.

Although there was some error in the experiment, these measurements can be used to see the ranges of force the jaw applies when biting down, which is important for determining when the switch turns on or off. A spring in the switch can be used to relate the desired force to turning on the switch (Figure 9).

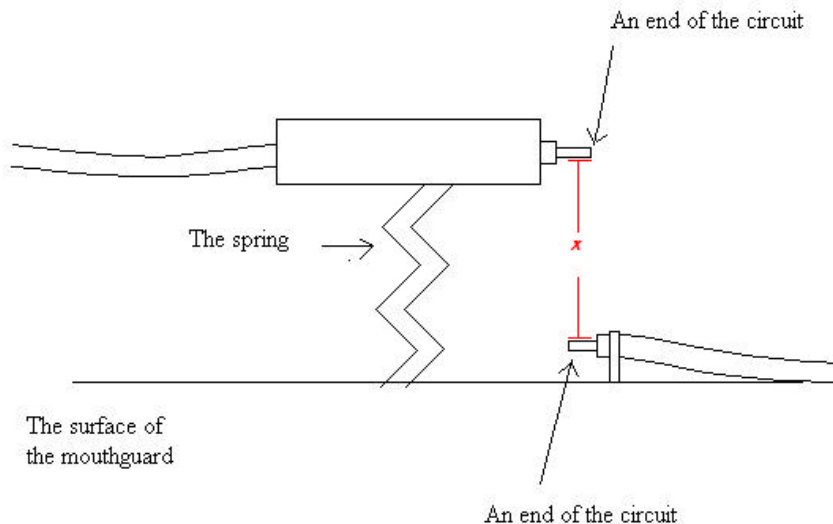
$$F = kx \quad \text{Where:}$$

F = force

k = spring constant

x = distance spring moves

The distance the spring must move to complete the circuit is set and the force is equal to the moderate bruxing force, therefore, k , the force constant, can be determined. This force constant will tell how stiff the spring must be to turn on the switch at the correct force.



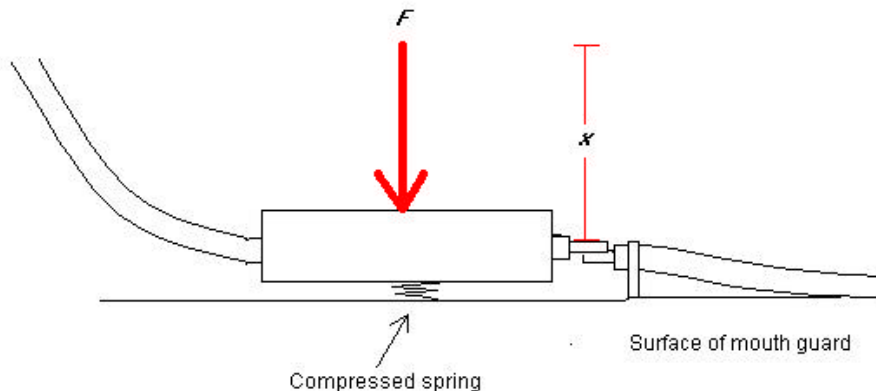


Figure 9. This switch compresses a spring with a specific spring constant completes the circuit. According to the spring equation, $F = -kx$, where k is the spring constant, and x is the amount the spring moves due to an applied force F . A spring with a specific spring constant could be used in the mouth guard switch so that when the force of moderate bruxing is applied to it, it will move the switch by the distance x that the ends of the circuit are separated, and the circuit will be completed.

-Electrical Stimulus –

The human mouth is more sensitive to electric current than other parts of the body. The type of electrical stimulus to be applied to the mouth of mouth guard patients was determined through preliminary testing with a TENS (Transcutaneous Electrical Nerve Stimulation) machine. This therapeutic device has a current range from 0 – 60 mA, a pulse rate range of 2 – 110 s^{-1} and a pulse width range of 40 – 200 μs . This unit requires a 9 V alkaline battery.

A short test was performed on 9 people to determine optimal values for current, pulse rate, pulse width. Small carbon-rubber electrodes were connected to the TENS machine and placed near the upper back molars against the cheek. Care was made to avoid contact with molars. Each subject adjusted the current, pulse rate, and pulse width knobs to find a desired electrical stimulus. They were instructed to search for settings that would be mild enough to not wake them up at night but strong enough to signal they were clenching and possibly signal them to cease clenching. If subjects were unable to hold the electrodes in their mouth and adjust the knobs, the experimenter assisted them. The experimenter asked questions to determine if the subject would like levels higher or lower and adjusted the knobs accordingly. The results for ideal ranges can be seen in Appendix C.

The final values for the ideal electrical stimulus were influenced by the separate male/female medians and averages along with subject feedback. There were notable differences between males and females. The current was chosen to be a perceptible value for all subjects without causing pain. The pulse rate was chosen to create a more noticeable tapping feeling. And the pulse width was chosen lower than the overall average because many subjects reported pain with higher pulse width values.

Components/Design Alternatives

-General Overview-

We have chosen electrical stimulation as the potential treatment for the method to prevent clenching and grinding. Electrical stimulation will not cause a muscle to relax, but rather to contract. The goal is provide relaxation by twitching a small cheek muscle through this electrical stimulation. It has been found that the best area to target with the stimulus was the upper back area of the cheek.

The basic design consists of several components (Figure 10). A transducer (5) is needed to sense the bruxing. Circuitry (2,3) including a battery (1) is needed to convert the signal into electric pulses of certain width and length to stimulate the patient. The patient is stimulated through electrodes (4).

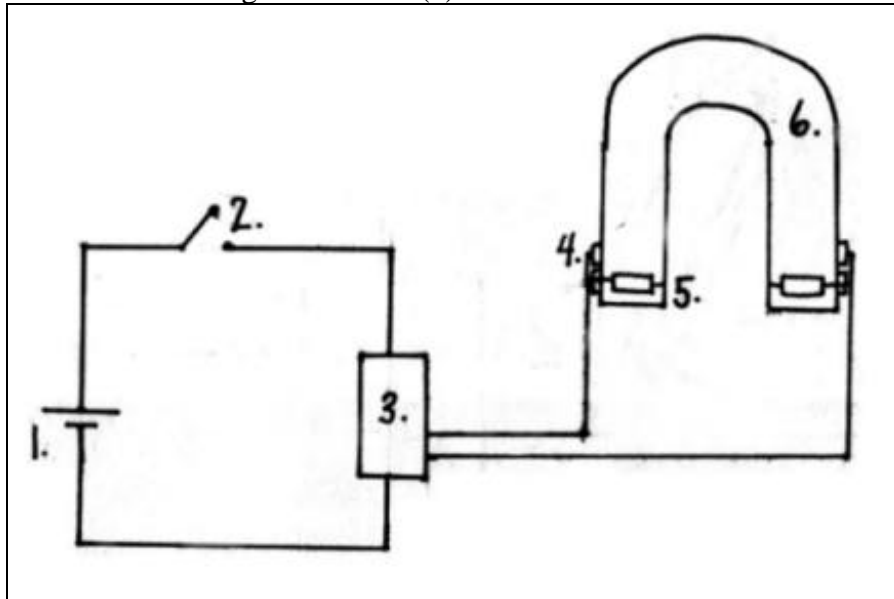


Figure 10: Design concept. Battery (1) provides voltage. Transducers (5) on the mouth guard sense bruxing. Circuitry (2) creates electric pulse with specific frequency and current. The patient is stimulated through electrodes (4).

-Transducer-

Research

A type of pressure sensor is needed that would be placed in the mouth, probably near the cusps of the back teeth, that respond to clenching or grinding. It must be able to withstand the forces of the jaw (average 2076 kPa) and the environment of the mouth. The sensor must also send an electrical signal or output voltage to deliver a gentle stimulus to the patient. .

Our client, Dr. Michael Conforti, specifically stated that he was very interested in trying a piezoelectric sensor. This seemed a reasonable choice because they are small, flexible, durable, and outputs voltage, not just a signal. A piezoelectric sensor would also be an inexpensive choice.

Piezoelectric materials generate charge when mechanically deformed. When the material is compressed, the deformation causes a change in the surface density and a voltage between electrode surfaces is generated. The electrical response of piezoelectric sensors varies depending on the force and the direction of mechanical stress or strain.

The output voltage of piezoelectric material can be determined by the equation:

$$V = gxt. \text{ Where: } \begin{array}{l} g = \text{piezoelectric coefficient} \\ x = \text{stress applied in relevant direction} \\ t = \text{thickness of film} \end{array}$$

The two basic types of piezoelectric sensors are ceramics/crystals and plastics. Ceramics/crystals, such as zirconate titanate or potassium sodium niobate, must be handled carefully. If they are dropped or bent too much, they will break, which is obviously a huge disadvantage. It's also difficult to find and obtain thin enough crystals to be useful in this project. Size limitations inside a person's mouth and the position of the jaw have to be considered. Using a thicker material between the upper and lower teeth would force the user to maintain an open mouth position, which may cause further problems with the jaw.

Plastics are very flexible and will obviously not break by bending or dropping. Thin plastics, called piezo polymer film sensors, are inexpensive and easily obtained. Therefore, our research focused on plastic piezoelectric sensors. We were able to obtain several piezo films that are polarized fluoropolymers, commonly called PVDFs (Polyvinylidene fluoride). Please see photo and detailed sketch (Figure 1).

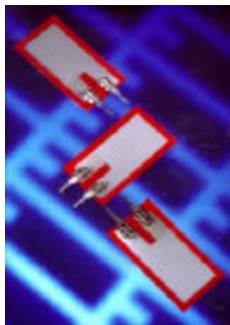


Figure 11. (a) Photo of piezoelectric film—top view (Measurement Specialists, 2001)

Another sensor considered for the device was a membrane switch. Membrane switches are used in a wide variety of devices. A few of the common devices they can be found in are televisions, telephones, and typewriters. These switches are composed of two layers with conductive material. When inactive these layers are separate and the switch is incomplete. When a light pressure is applied, these two layers will contact and the circuit is complete.

Some switches allow a tactile feedback response to signal they have been switched on. The user feels a “click” when a certain force is applied. This force depends on the snap ratio which is determined by $(F1 - F2)/F1 * 100$. When the force changes from $F1$ to $F2$ the user can feel the force against them change.

Binary pressure sensors, piezoresistive sensors, capacitive sensors, optoelectric sensors, and fluid filled tubes were also discussed in the design for this device. Specifics about these sensors are outlined in Table 2.

Preliminary Testing

The piezoelectric sensor was tested first. The piezoelectric material was hit by an hammer to simulate the high force of bruxing while the output voltage was observed on an oscilloscope. The piezoelectric material provided an adequate voltage (approx. 20 V) but the pulse occurred over an extremely short time interval and could not be felt on the skin or in the mouth. Furthermore, the piezoelectric material produced minimal voltage when a slow force was applied. This was tested by pushing on the material with a finger instead of hitting it with a hammer. This is important because when clenching especially, the force may occur over a long period of time.

Membrane switches were obtained from the keypad on a cell phone. When pressing the switch, a certain amount of force had to be applied to close the switch. These switches were not tested extensively due to time constraints.

Evaluation

Descriptions of different sensors considered for the device are summarized in the table below, as well as advantages and disadvantages for each sensor

Table 2. Advantages and disadvantages each sensor considered for the device (Webster, 1988)

Type	How it works	Advantages	Disadvantages
Piezoelectric Sensors	Changes mechanical to electrical energy when the dimension of the sensor are changed	-Flexible -Rugged -Resistant to corrosion -Thin -Outputs voltage -Can detect slippage	-Unable to respond to static pressure
Capacitive Sensor	Applied pressure decreases the distance between capacitor plates and increases the capacitance. This increase in capacitance can be measured. $C = K \cdot \text{area}_{\text{plate}} / \text{Distance}$	-Stray capacitance is a large part of the measured capacitance	-Very small -Low drift -Low creep -Low power
Optoelectric Sensor	Light is blocked when pressure is applied. The change in light intensity is can be measured.	-----	-Not miniature -Complicated
Fluid Filled tube	Compressible tube with a remotely located pressure sensor.	-Sensor can be located away from teeth -Thin	-Wear on tube
Membrane Switch	Two layers of conductive material are inactive when layers are separate. The switch is completed when a light pressure is applied and the two	-Small -Inexpensive (found in everyday appliances) -Variable sizes -Waterproof	-May wear quickly with large forces

	layers make contact.		
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Although it was not tested extensively, a membrane switch was chosen for the transducer in our final design. The piezoelectric material had many advantages, but testing revealed the output was too small for use in this device.

Membrane switches were an appropriate choice because they are inexpensive, and they come in various sizes. The membrane switch studied for this project was approximately 1 mm wide, 2 mm long, and less than 1 mm thick. The membrane switch is easily incorporated into the prototype because the plastic seal around the two pieces of conductive metal is waterproof. The switch would need no silicone rubber covering, and the switches would be in almost direct contact with the patient’s teeth, increasing accuracy.

**-Shape-
Research**

In developing different possible designs for the mouth guard, one of the most key components was shape. The comfort of the patient is of great importance, and therefore a good fit inside the mouth is essential. The two main physical aspects, which affect the fit, include the actual shape of the mouth guard, and the placement of the electronics.

Dr. John F. Doyle, D.D.S., F.A.D.I. from the Department of Surgery in Dentistry at the University of Wisconsin Hospital makes both full top and full bottom hard acrylic mouth guards for bruxism patients. Associated Dentists Inc. in Madison makes a durable plastic full top and full bottom mouth guard. In both labs, the full bottom mouth guard was fabricated more often, but both were possible to make. Both doctors indicated that whether the mouth guard was placed on the top or bottom teeth was not a significant factor in improving/preventing bruxism.

Preliminary Testing

First, we brainstormed different possible shapes and locations of the mouth guard. Each choice was built and then tested for comfort. A rating based on comfort, practicality, and fit was given with 0 being horrible and 10 being outstanding. Next, we brainstormed the placement of the electrodes. Many possibilities were considered because many different areas both inside and outside of the mouth could be stimulated and could cause the desired effect.

Evaluation

The results and evaluation of the different mouth guard shapes are summarized in table 2. The illustrated models are also shown.

Table 2. Evaluation of different mouth guard shapes.

Design	Testing Results	Rating (0–10)
1. Full top mouth Guard	Somewhat comfortable, bulky, but fit well	6
2. Full bottom mouth guard	Very uncomfortable. Would require much getting used to. Tongue often hindered.	2

	Caused us to decide on an upper mouth guard. Also, will not have room for circuitry.	
3. Partial mouth guard with wire on top	More comfortable than the top full mouth guard, however not as practical for placement of electrodes.	7
4. Full top mouth guard with full roof of mouth coverage	The roof compartment will help hold circuitry. May be most practical	8
5. Partial top mouth guard with bridge	The roof bridge will help hold circuitry, and may be more comfortable than the full mouth guard, however may not stay in place as well as other models.	8

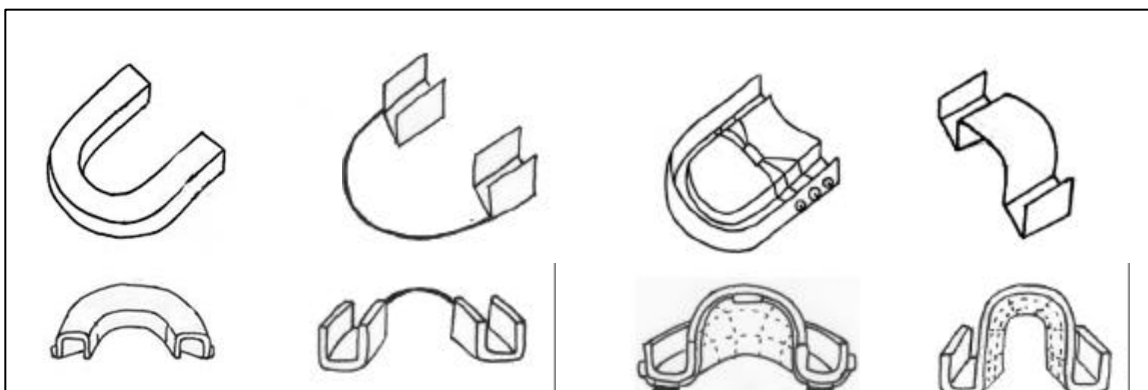


Figure 12. From left to right: models 1-2, model 3, model 4, model 5.

The shape of the mouth guard in the final design is the top mouth guard with full coverage on the roof of the mouth. This design received an “8” on the testing scale, the highest score. The partial top mouth guard with a bridge received the same score, but tended not to stay in place as well as the chosen model.

A top shape model was chosen so the electrodes attached to it would stimulate the inside of the cheek near the upper masseter muscle, the optimal placement for the electrodes (next section – Electrode Location). Having full coverage of the roof of the mouth is advantageous because circuitry can be placed there.

-Electrode Location-

Research

Our method to stop patients from clenching their teeth is through electrical stimulation. Electrodes of carbon rubber, a simple conductive material, will conduct a shock to the inner cheek. The patent (#5,490,520) recommended that electrodes be placed in contact with the gum line of the patient to spread the electrical stimulus throughout the tissue surrounding the teeth and the alveolar parts of the jaw.

Preliminary Testing

A variety of positions for electrodes have been considered. They include the gum line, tongue, roof of mouth, the frontal area near lips, and back area near molars. These positions were tested with a TENS machine and small carbon electrodes. Two female students both tested all of these positions and evaluated the electrical sensations in each location based on sensitivity, pain, and association with clenching muscles.

Evaluation

Through testing, the gum line, tongue, roof of mouth, and front part of the cheek were rejected. In particular, two locations, the gum line (recommended by patent) and roof of mouth, resulted in an electrical sensation in the teeth, which was painful. This could cause patients to wake up at night. Additionally, the tongue and front part of the cheek were rejected because the electric stimulus in these locations did not seem to trigger a behavioral cue to cease clenching. This is most likely because the location did not target the muscle groups that were performing the clench.

The most effective position was found to be the upper back cheek area (Figure 13). Specifically, this location is the inside of the cheek across from the molars. Stimulus in this area seemed to target the muscle groups that worked to clench the teeth, the masseter and the temporal muscles. The upper cheek was more effective than the lower cheek because the stimulus could be felt higher, in the jaw and facial area, rather than the chin area. For our design the optimal location is the side facing the cheek, near the molars.

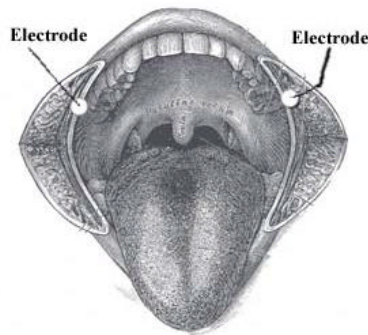


Figure 13. This figure shows the ideal electrode placement. Electrodes are indicated by white dots and will be separated from the teeth by the mouth guard. This figure was adapted from Gray's Anatomy (online version on 1918 book).

-Circuit-

Research

The purpose of the circuit is to deliver a desired voltage at a specific pulse rate with a specific pulse width. The main components of the circuit are: an input voltage, a 555 timer, the battery, two resistors, and two capacitors (Figure 14).

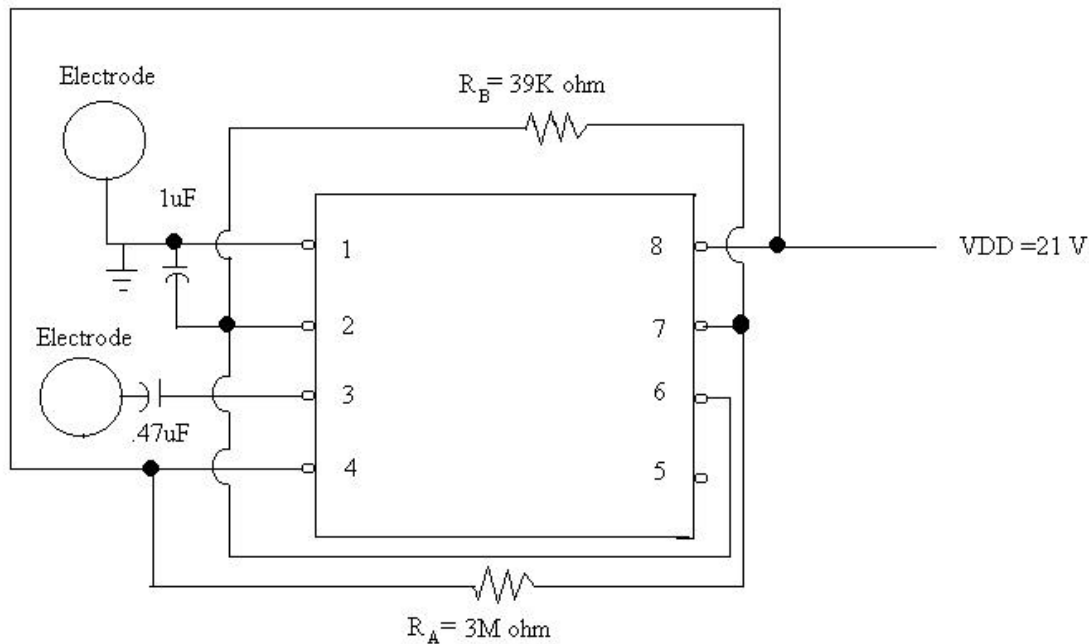


Figure 14. The circuit used in the mouth guard. The circuit uses a 555 timer on a bread board. The input voltage from the power source is around 21 V. The person feels the volts in a series of pulses emitted through the electrode. The 39KΩ resistor sets the voltage pulse width, while the 3 MΩ resistor sets the frequency that the pulse is emitted from the electrodes. Diagram is derived from a Technical Data Insert from Radio Shack, 2001.

The 555 timer, 1 µF capacitor, and resistors were used to create an astable multivibrator. For astable multivibrators, the capacitor will charge up, and the voltage across the capacitor will rise exponentially until the voltage reaches a specific threshold voltage. At this point a component in the 555-timer will flip-flop, and the capacitor begins to discharge until the voltage reaches a second threshold, and the cycle starts again. This type of circuit has an oscillating square waveform of its voltage, which is felt as a pulse through the electrodes (See figure 15).

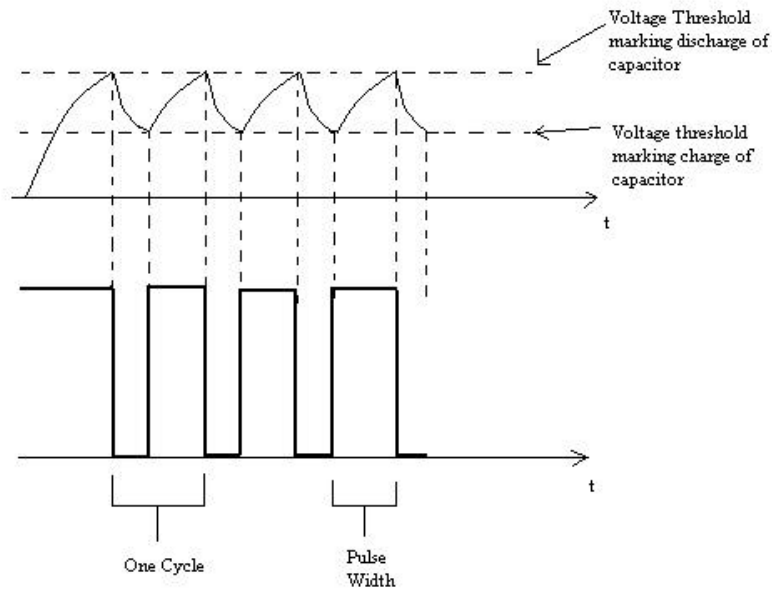


Figure 15: The waveform of the circuit. The top graph shows the voltage versus time of an ascending multivibrator. The threshold voltage marking where the capacitor charges and discharges are marked. The Bottom graph shows a square waveform that is produced from the astable multivibrator. A stable voltage is given out when the capacitor is charging, and the voltage is zero when the capacitor is discharging (Sedra and Smith, 1991).

To build the circuit, the size of the resistors was needed to determine a specific pulse rate and pulse width.

The equation for the duty cycle of the square wave can be used to find the resistor size needed to produce a desired pulse rate and pulse width. The equation of the duty cycle is as follows:

$$\text{Duty Cycle} = (R_A + R_B) / (R_A + 2R_B)$$

The duty cycle is the time that the voltage is on, and R_A and R_B are the sizes of the resistors. In our circuit, R_A determines the rate of the pulse and R_B determines the pulse width (Sedra and Smith, 1991).

The duty cycle equation helped reveal the relationship of the resistors to the pulse rate and width, but when fine-tuning the size of the resistor that should be used, a method of trial and error was used.

Testing

To test the circuit, it was set up on a breadboard, connected to a power source, for the input voltage, and hooked up to an oscilloscope and electrodes to physically measure and feel the output voltage coming from the circuit.

After testing the circuit, size of R_B was increased to increase the pulse width and therefore increasing the current through the electrodes.

Also after testing the circuit, the initial 5 V predicted to create the desired stimuli was increased to 21 V. This increased voltage also increased the current to the electrodes. The higher current at the electrodes was necessary for the electrical stimulus to be felt in the mouth. The final outcome of the circuit is that it delivers pulses with a peak of 21 V, a rate of about 9 Hz, and a pulse width of 2.5 ms.

Final Design Summary-

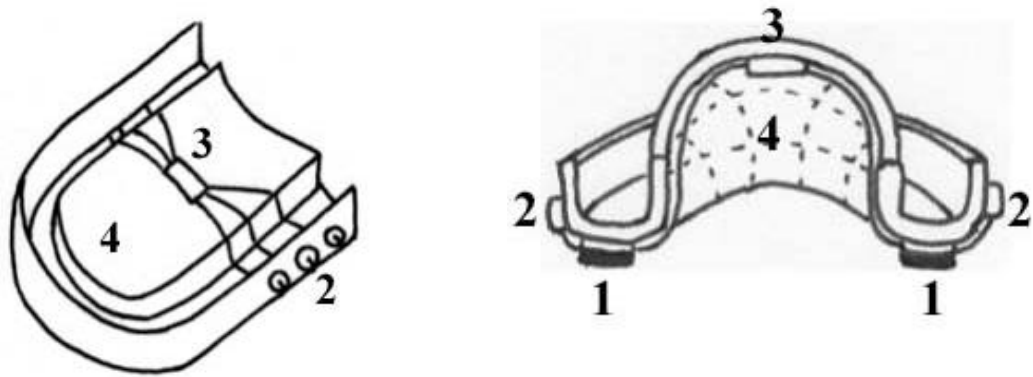


Figure 17. Back and top view of final design.

The final design solution is illustrated in Figure 17. Membrane switches were chosen for the final design (1). The switches are placed so that they come into contact with the back molars when the patient grinds or clenches the teeth.

When the patient bruxes, the switches close and current runs through wires to the circuit. The circuit, including a 555 timer, a battery, two resistors, and two capacitors (3) is placed at the top of the dome of the mouth guard (4). The battery supplies 21 V to the circuit. The 555 timer in the circuit sends out pulses of current at a frequency of approximately 9 Hz to the electrodes. Electrodes on each side of the mouth guard stimulate the patient's cheek (2).

All circuitry is covered with silicone elastomer to waterproof the device.

Conclusions

-Ethical Issues-

Encompassing this project are several ethical issues that should be carefully considered. First of all, is it safe to put a mouth guard with an electrical stimulus in a patient's mouth? Many people may feel uncomfortable and unsafe with the concept of an electrical shock applied to their inner cheek as they sleep. Clearly, they will be most fearful of the electrical shock. They may be unaware that the electrical stimulus would

be so faint that it should not wake them during the night. Ultimately, if the developed product is not presented cautiously, potential patients may reject the idea before they are well informed of the benefits of this treatment.

Another issue is the question of how much electrical stimulus is ethical? If the shock is strong enough, the customer may wake frequently during the night. With higher levels of current the customer may feel discomfort and pain. Consequently, many tests must be performed on a diverse group of patients before the final electrical stimulus can be determined. After this stimulus has been determined more questions arise: Do different customers require different electrical stimuli? Is there a gender difference? Our preliminary testing show females may require a lower current than males. Dental work such as fillings may also cause customers to have increased sensitivity to the stimulus. How can our design account for this? A doctor may need to test a subject for individual preferred levels of current and pulse width. In preliminary testing, subjects were most sensitive to longer pulse widths and current. In addition to the custom fitting of the mouth guard, doctors may need to custom fit the electrical stimulus to the customer.

Any testing on human subjects performed under the University of Wisconsin must follow the UW Multiple Project Assurance (MPA). Subjects must consent to participate in any study and obtain maximum benefits and minimum harm (HSC, 2001). If we were to perform future testing with mouth guards, we would need to apply for approval. We would be expected to submit an abstract of our work on a 7-page application to the UW Institutional Review Board. This application contains numerous questions to allow the committee to evaluate if our human testing is ethical.

The public often questions whether using human subjects in testing is humane. In fact, people may argue that testing various degrees of electrical stimuli on humans is immoral. Note, however, that if humans are not used in this case that the safety of the mouth guard would not be fully known until the final product was made and put on the market, a potential disaster. To avoid this problem, careful testing procedures and techniques simply have to be applied. These procedures would include maximum limits of pulse width and current (in mA range) applied to the subject.

Also medical information about subjects needs to be kept confidential. Our testing would be most effective if the study participants were bruxism patients. We need to collect confidential information about bruxing activity along with dental records or filling and other metal work (or other conductive materials) in the mouth.

There is also always the slight chance for other unpredicted outcomes or defects to occur. As an example, maybe some patients would become dependent on the product and not be able to sleep without it. Patients must realize that although the developed product was designed with the full intent of treating bruxism, nothing works one hundred percent of the time. Side effects may also result. Patients have the right to be informed of these side effects.

-Future Work-

In the future, the circuit has to be completed, tested, and incorporated into the device. The circuit is currently working on a breadboard. It delivers electrical pulses using an input of 21 V at a rate of approximately 9 Hz. The voltage was increased from what was originally planned (approximately 6 V) to 21 V because after testing the circuit with the smaller voltage, impulses could not be felt in the electrodes. A smaller voltage

would be optimal to decrease battery size and increase patient safety. This may be possibly by reducing current and increasing pulse width (personal comm., John Webster). Further testing is required to choose an optimum voltage and current. The circuit also has to be incorporated into the device. It has to be minimized and attached to the mouth guard.

Membrane switches have to be tested/researched further. The amount of pressure they can withstand should be studied. Possible damages to the switch while bruxing should also be examined. The next step would be to incorporate the switch into the device if this is feasible.

We also need to develop a method for storing batteries that allows the patient to change them when necessary. One idea is to have round recessed areas in the top portion (against the roof of the mouth) of the mouth guard just large enough to fit small round batteries, such as lithium button cells. The round shape allows a watertight seal, which would be absolutely necessary in the mouth environment. We would then have round semi-flexible plastic “snaps” which would snap into place, securing the battery and forming a seal. They may need to have grooves for screwing them in and out.

When the prototype is finalized, the next step is human testing. Individual tests have determined which individual parts/placement of parts is most comfortable. The device as a whole has to be tested for patient approval.

Finally, testing as to whether the device prevents/treats bruxism is necessary. This requires finding bruxism patients that are willing to spend nights in the University of Wisconsin--Madison sleep lab. Possible tests include attaching EMG electrodes to the skin near the jaw muscles during nights. Tests must be performed both with a plain mouth guard and also with our electrical stimulus mouth guard. If we find that the average length of time per clench is reduced, it would suggest our device is working properly to prevent excessive bruxing.

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Resources (alphabetic order)

Michael Conforti D.V.M. - client
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John W Dreger - helped with force testing
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Rita M. Lohrbach - provided information about electrodes
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Jeff Schowalter – provided piezoelectric strips for testing
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Appendix A – PDS

Product Design Specification (PDS)

October 19, 2001

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

Team Members: Kathleen Agard, Jackie Gerhart, Matt Harris, Carla Maas, Darcee Nelson, Julie Sauer, 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:* Nontoxic 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 least 1.2 GPa
Circuitry should deliver 20 – 25 V
- d. *Life in Service:* 3-4 years
- e. *Shelf Life:* Hard-acrylic mouth guard – indefinite

Electrodes – several years
Battery – 150 hours
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. 60 mm by 57 mm
- i. *Weight*: 124 – 180 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
Consumer cost approx \$300 - 350

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

Appendix B – Human testing data

Table 3. Human testing data from 9 subjects tested with a TENS machine.

	Gender	Age	Current (mA)	Pulse Rate (s)	Pulse Width (msec)	Has Fillings?
	F	21	10	4	40	YES
	F	20	8	5	60	YES
	F	21	6	12	80	YES
	M	24	15	29	105	
	M	20	15	20	100	NO
	M	20	10	14	110	NO
	M	22	12	30	120	
	F	20	10	25	100	YES
	M	69	6	2	60	YES
	AVERAGE		10.22	15.67	86.11	
	FEMALE AVE		8.5	11.5	70	
	MALE AVE		11.6	19	99	
	MEDIAN		10	14	100	
	FEMALE MED		9	8.5	70	
	MALE MED		12	20	105	

Appendix C - Money spent on project

Table 4. Summary of money spent on mouth guard project.

Item	Cost
555 timer and 556 timer from RadioShack	Less than \$2.00
2 binary switches from RadioShack	Less than \$1.00
10 mouth guards Walmart	\$20.00
2 L-shaped metal pieces from Menards	\$3.00
Tube of silicone rubber elastomer from Ace Hardware	\$4.00
Miscellaneous circuit materials from BME Design Lab: 555 timer, resistors, and wires.	-----
TOTAL	\$30.00