UNIVERSITY OF WISCONSIN-MADISON
DEPARTMENT OF BIOMEDICAL ENGINEERING
BME 201 DESIGN

Temporomandibular Joint Disorder Device

Mid-Semester Report

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Client: Jill Pongetti

Abstract

In the case of temporomandibular joint disorders, TMJ, there are often no easy solutions to the problem. Over the years there have been many attempts at finding a solution to the pain and discomfort that comes with the disorder, but as of yet there is no device on the market that is capable of doing this effectively. A device is desired that will relieve our client, Jill Pongetti of the UW Department of Surgery, of her pain and discomfort. After evaluating out resigns in a design matrix and talking to Dr. John Doyle, Director of the Temporomandibular Joint Disorder Clinic, we decided on the massaging sling design. Future work involves further work on device components and testing on our client.

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Problem Statement

A device is desired that will effectively alleviate the pain that is associated with our client's temporomandibular joint disorder. The client, Jill, has been suffering from TMJ for the past 5 years and has been unable to find a solution to her problem. She desires a device that will most effectively take care of her problem. A potential to incorporate heating/cooling components to the device is also available.

Background and Motivation

TMJ is a highly complicated disorder that can vary greatly in its severity and origin. There is no solid science as to what causes TMJ in certain individuals or how it can most effectively be cured. TMJ is both a physical and mental ailment [1]. Stress and other factors can cause an individual t o grind their teeth and clench their jaw muscles, causing severe pain and discomfort. For some patients their TMJ involves the joint popping out of the socket while in others the muscles are straining and tightening. Devices on the market for TMJ today are highly varied in their design and functionality [2]. Our client has currently tried NTI devices (Figure 1) and full bite plates (Figure 2) but neither has supplied the level of comfort desired. These devices simply stop teeth grinding to protect

Figure 1. NTI Device.

Figure 2. TMJ bite plate, often referred to as a splint.

the teeth and prevent further damage from occurring but do nothing to stop the clenching or allowing the jaw muscles to relax [3]. A design that takes care of both the clenching and the grinding would be an optimal device like the client is looking for. Since there is currently no device like this out on the market this makes our project a very unique design.

Design Constraints

Due to the nature of the project there are few constraints on the design. The patient stated that she would be willing to use any design possible as long as it was able to supply her relief from her pain and discomfort. However, there are still some restrictions on the design. The budget for the project including materials, fabrication and testing is $100. The device must function at a level of vibration/massaging that will relax the patient's muscles while still being soft enough so as not to annoy or keep the client awake. The design must be easy to put on and take off with an easily adjustable strap to allow for specific placement of the vibrating sources.

Design Alternatives

Design 1

The first design we came up with was a partial coverage splint. The TMJ partial coverage splint is designed to be used during the nighttime sleeping. Our patient bites and grinds her teeth during the night and the constant strain on the jaw muscles causes headaches, neck pain, and jaw pain during the next day. The splint is designed to separate the teeth and absorb the force the patient exerts on the teeth when biting. The patient would wear two splints, one for the back left teeth and the other for the back right teeth.

Two splints would be composed of molded structures that wrap around the back teeth with prongs that hold the structure to the teeth; One mold for the top, the other for the bottom.

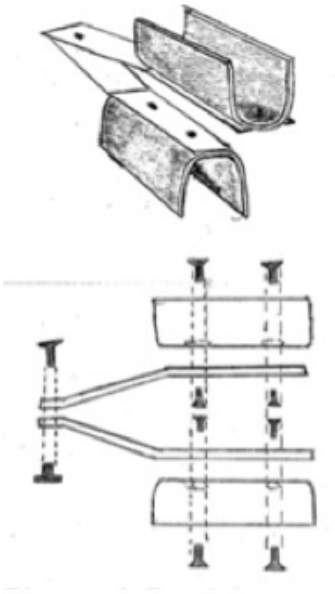


Figure 3. Partial coverage splint – front-right view (top) and side view (bottom)

Acrylic plastic material would be used for the molds and rustproof wire for the prongs. To create the actual teeth platforms two metal rectangular platforms would be bent at two different places, one to creating an angle to separate the teeth and the other to create a flat surface to fasten the platforms together. Sheet metal that could bend from the force of biting, but still retain shape when no pressure is applied would be used for this part of the design. Four countersink rivets would be used to attach the molded structure to the metal platforms. This would ensure the rivets are flush and do not obstruct the teeth or irritate the mouth. One rivet would be used to attach the two metal platforms together; these rivets would have to be rustproof and durable enough to withstand the torque from biting and constant use. The two acrylic molded structures will be molded with the prongs in them (like a dental retainer). The acrylic structures will be riveted to the metal platforms and the metal platforms will be riveted to each other.

Current devices such as a biteplate separate the teeth, but the force of biting and grinding causes headaches and pain in the jaw muscles and neck muscles. This would be a solution because the metal platforms act like a spring and would absorb the force when biting down. The patient would have less strain on the jaw muscles resulting in less pain.

Benefits to this device revolve around the simplicity of the design. Because it is so simple this design has the potential to be easily commercialized. The adjustments necessary for the device to fit in other patients' mouths would be miniscule. Also this design would be very cheap to make; the material used is all relatively inexpensive, molds taken of the patient's mouth would be the most expensive part of the design. However, even though the design is simple it would still do an adequate job of absorbing the bite pressure from the client, effectively solving the problem. After talking to Dr. Doyle at the UW hospital we began to have second thoughts about this design. He informed us that the design placing pressure entirely on the back teeth would cause the front teeth to rupture as they would have little to no support where the design does not cover. This is why most splints today are full coverage. Also, this design simply compensates for vertical clenching and does nothing to alleviate the lateral grinding pressure. If the device does end up breaking in the client's mouth as the other devices she had made did there is also the risk of asphyxiation of the components. In order to confidently release this design to the patient an extraordinary amount of testing would be necessary to ensure its safety first.

Design 2

The second design solution takes a full coverage splint device similar to the bite plate the client currently uses and enhances it by adding springs to the top surface (Figure 4). This splint would be constructed from a hard acrylic, a common material among other bite plates on the market, and would be custom fit to the client's bottom teeth. While other bite plates just have grooves on the top surface of the splint for the upper teeth to fit into,

this splint will also have a raised ridge just around the back teeth that allows the upper molars to fit into place when the client bites down. However, the client will not be able to bite down completely because the small divot that is created by the raised sides will be occupied by several small springs (no taller than 1cm and with a diameter no larger than 0.75 cm) that have been adhered to the top surface of the splint. Then, a thinner layer of hard acrylic will be secured on top of the row of springs on each side of the splint, providing a springing surface between both the left and right molars. The purpose of the springs is to provide resistance against the client's biting force while wearing the splint. The springs will allow the client to bite down only a small distance, maintaining a small gap between the upper and lower teeth. This will hopefully reduce both the frequency and force of the client's biting and thus minimize the chronic pain resulting from clenching and grinding her teeth all night. While this design will not cause any teeth to rupture forward since it is covering all of the bottom teeth, the success of the device in reducing the pain and tension in the client's jaw and neck is unclear, and there are a few safety concerns with putting several small springs in the client's mouth over an extended period of time. Can it be ensured that all of the springs will remain attached to the splint and not loosen under the client's biting force? With concerns like these in mind, we developed another design alternative that did not involve any parts entering the client's mouth, greatly reducing the chance of a dangerous, or potentially life-threatening, situation from arising.

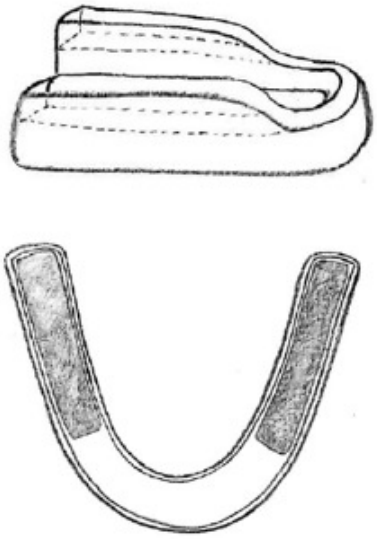


Figure 4. Full coverage splint with springs – side view (top) and top view (bottom)

Design 3

The third design we came up with was a massaging device. This device is designed to optimally supply the patient with the much needed jaw relaxation that is needed. This design is completely different from our previous designs as it is placed entirely outside the patient's head and nothing goes inside the mouth. The main strap component of the device that wraps around the client's head and holds everything in place is made out of nylon with a soft interior on the surface contacting the patient's head. This allows for the strap to be strong while also supplying the desired comfort level for the device. The actual massaging components of the device are shiatsu massagers. These massaging components would be attached to a supporting strap that allows them to be moved up and down to wherever the patient desires more massaging or heat at the time. The support strap has a belt buckle on the external side of the device that makes this possible. (Figure 5)

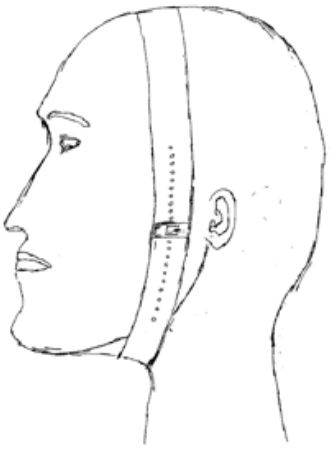


Figure 6. Side view of the massaging device, showcasing the adjustable belt strap.

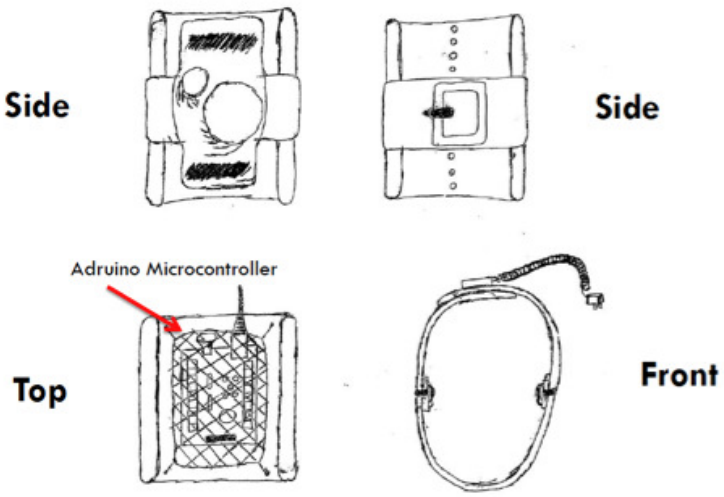


Figure 5. Massaging Device

The device would be powered my an Arduino microcontroller that would allow us to program the massager to turn on and off whenever the patient desired.

Research and testing would be necessary on the patient to see when exactly during the night she is experiencing the most excruciating pain [4]. Before this pain starts to occur we would be able to program the device so that it turns on automatically and massages the jaw muscles before they even begin to contract.

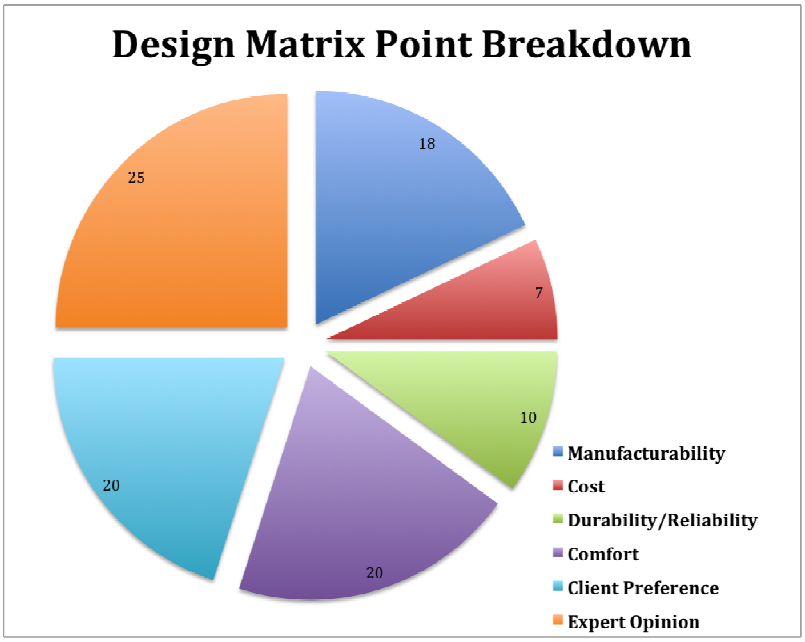
Since the device needs power to run the microcontroller and massagers this sill be supplied by a power adapter on the Arduino microcontroller. This adapter has the capability of plugging into the wall and continuously powering the circuit. With this component it eliminates worries about the Arduino or massagers drawing too much power from a battery source and shutting off in the middle of the night. However, the cord brings up the possibility of the client getting tangled in the wire. We solved this problem by using a curly cord that will contract as slack wire is produced. This will pull the excess wire towards the wall outlet and eliminate any worries about entanglement.

There is also the concern about the cost of the device. The massager device will be the most expensive design to implement for production but we decided that the benefits that come with the device far outweigh the extra cost that the device might incur. Used in unison with the bite plate that the client currently uses this device is capable of solving every facet of the problem.

Design Matrix

The design matrix for the report was split into 6 different categories; manufacturability, cost, durability and reliability, comfort, client preference, and expert opinion. Figure _____ illustrates the point breakdown for each of the individual categories.

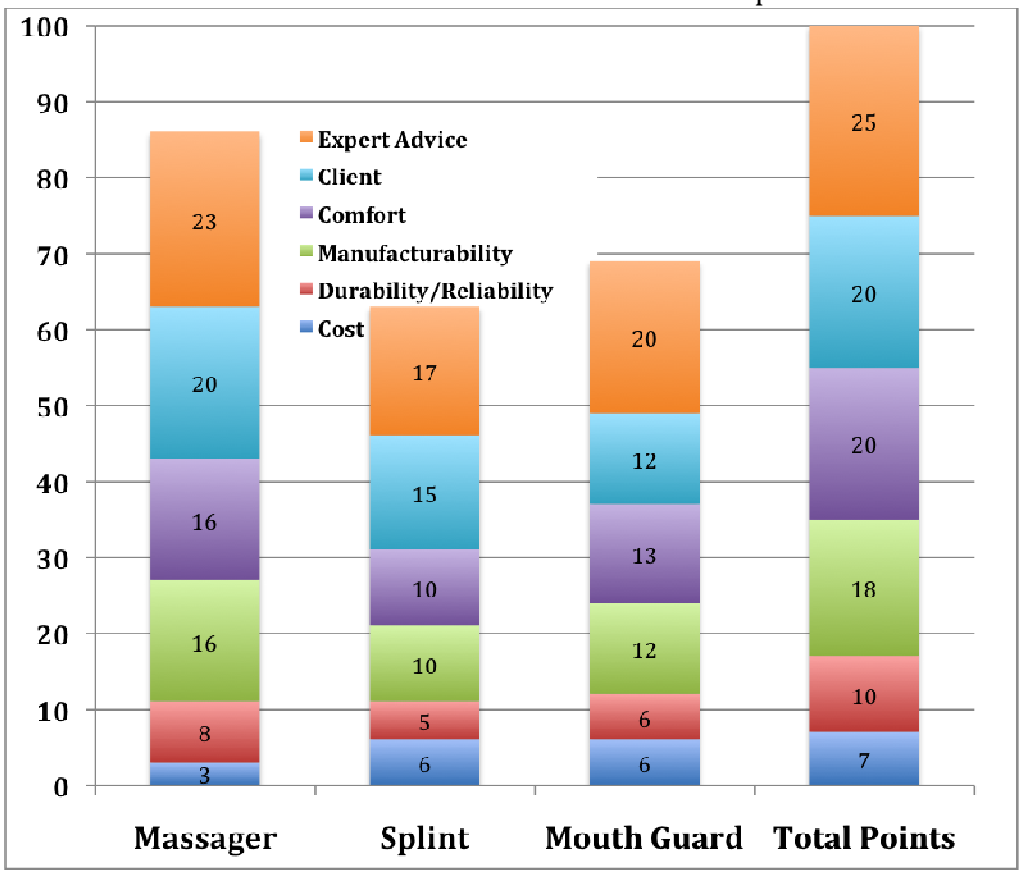
The first category, manufacturability, received a total of 18% of the total points. Manufacturability is a necessary component of this design as it the device must be custom fit to the client. Cost and durability were the next two categories and together they received



17% of the total points. The cost of the three devices was similar for each design so this category was given limited weight. Durability was also given limited weight as the durability of the designs would be quite similar after production. Next comfort and client preference both received 20% of the total points each. Comfort is highly necessary as if the client is uncomfortable and does not want to wear the device it will not do any good. This ties into client preference as if the client is not happy with the design she has at the end of the semester we have not done our job correctly. Lastly the expert opinion was given the most weight; while talking to Dr. John Doyle at the hospital he brought out interesting information that we had never heard before. Also he is the head of the TMJ department so any experience he has would greatly help our design.

For the manufacturability of the devices both the splint and mouth guard designs required molds be taken of the client's mouth to ensure the device fit perfectly. This led us to give the splint and mouth guard 10 and 12 points respectively while the massager received 16 points are no molds had to be taken as the massager is used externally. For the cost of each

design the splint and mouth guard would both be very close with a relatively cheap cost. The massager was the most expensive design and therefore received 3 out of the 7 points. For the durability and reliability of the design the splint and mouth guard both require the ability to hold up to the pressure of the jaws clenching and strain. Since the massager is external and does not need to withstand these extreme pressures it received the highest

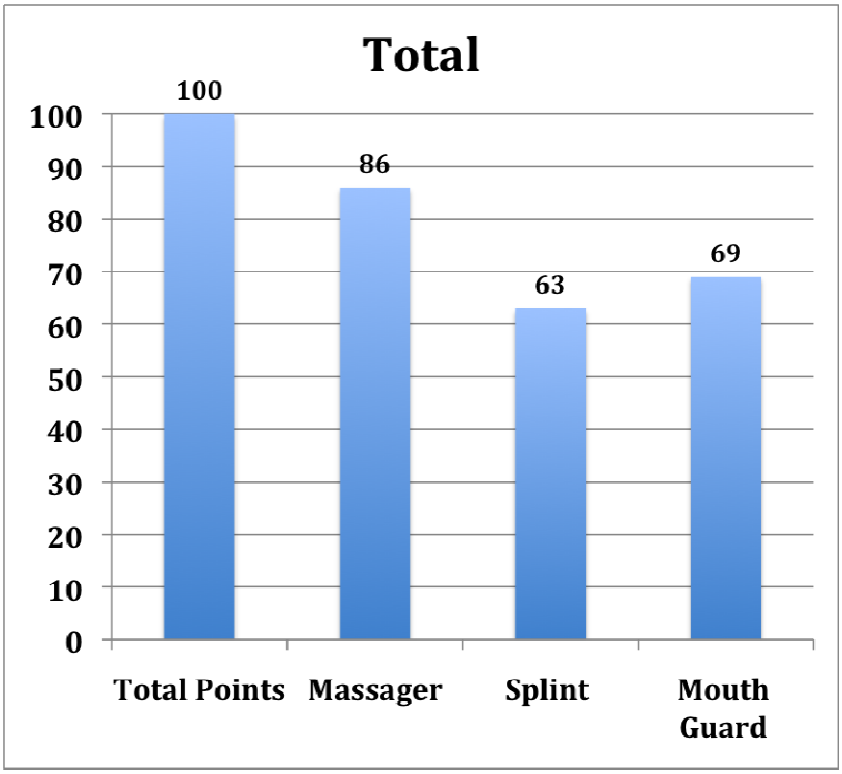


marks in the reliability and durability area. Next the comfort of the device was considered. The splint and mouth guard both require a perfect fit to be comfortable to the client. If even a small piece of the plastic mold is out of place it was be very irritating to the individual with the mold in their mouth. The mouth guard and splint are also relatively hard and unforgiving; if the patient desired to alter the device slightly it would be highly difficult to accomplish and new devices would become necessary if the client's teeth ever ended up moving slightly. However, the massager is highly adjustable and can be adjusted very quickly to the patient's preference. If they wanted to move the massager to a different spot on the side of their head all that would be necessary is the

adjustment of the belt buckle strap holding the device in place. Also one side of the device could be removed if the client desired to sleep on her side instead of her back or if she wanted to temporarily take the massager and heat off of one side of her face. The next area we took into consideration was the client preference. The client already has a mouth guard that has been unsuccessful in supplying her with the level of comfort that she desires. The massaging device has the potential to solve every facet of her TMJ problem and she was very excited about implementing it and seeing if this is the solution she has been searching for all along. We therefore gave the massager 20 out of 20 points and ranked the other devices according to her perceived responses. Lastly we considered the expert opinion of Dr. John Doyle and gave it the most weight of 25 points. Dr. Doyle brought up considerations we had not thought of or even knew existed before such as the rupturing of certain teeth with the splint design [5]. This informed us that uniform pressure was required across the entire teeth line if a splint or mouth guard was to be used. Dr. Doyle seemed very interested in out massager design as there is nothing like this out on the market today. He suggested we pursue this design and incorporate a warming or heat device into the design to help alleviate the client's pain as much as possible.

Final Design

After the design matrix was complete the totals for each design were accrued. The massager design emerged as a clear winner with a much higher percentage of the total possible points than the two other designs. These compelling results proved to us that the massaging device was clearly the best design option available. Although it may have been possible to design a splint or mouth guard that adequately addressed our clients problem



there are already so many devices available on the market today the chances of coming up with an entirely unique and original design is quite slim. The massager is therefore our final design and is the one that we will be manufacturing the second half of the semester. The massager has the potential to take care of every facet of our client's TMJ problem when used in unison with the mouth guard she currently uses.

Ethical Considerations

With the final design selected, it is important that the client's comfort and safety continues to be one of the chief concerns heading forward. Since the massaging device will likely be used while the client is sleeping, it is absolutely pertinent that we design the device so that the client can wear it safely and comfortably while lying down. Should there be an electrical cord attached to the device, it should not be able to get tangled around the client. As well, the heating components of the device should not overheat but instead stay at a soothingly warm temperature that is pleasing to the client.

Future Work

Now that the basic design has been chosen, materials must be purchased. For the massaging component of the device, a Shiatsu-style massager must be purchased, and a heating component if it is not already included with the massager. A microcontroller must be purchased to control the periods of time spent heating and massaging by the device. Finally, an adjustable belt-like head strap that ensures a safe, comfortable fit of the device on the client's head. Once all of the materials have been purchased, the team will assemble them to construct the massaging device. Next, the client will use the device for a few nights to develop an opinion so client feedback can be gathered. Once input has been given and the team has made appropriate adjustments to the device, additional cycles of testing and adjustments will take place as much as time allows before the final presentation.

References

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[3] "TMJ Disorders." NIDCR. National Institute of Dental and Craniofacial Research. Web. 28 Feb. 2011. <http://www.nidcr.nih.gov/OralHealth/Topics/TMJ/TMJDisorders.htm>.

[4] “Timer.” Arduino Playground. Arduino Forum. Wed. 28 Feb. 2011. http://www.arduino.cc/playground/Code/Timer1

[5] Doyle, John. (February 25th 2011) Personal Communication / Interview

Appendix

Product Design Specifications

Problem Statement: Temporomandibular joint disorder, or TMJ disorder, encompasses both acute and chronic inflammation of the temporomandibular joint, which connects the mandible to the skull. Currently, patients with chronic and severe TMJ disorder use bite guards or bite plates. These devices help relieve pain but mainly serve to protect the teeth. However, these devices have proven to be ineffective since patients with bruxism clench and/or grind their teeth on the bite guards, resulting in chronic pain and inflammation due to increasing pressure on the joint and strain on the jaw and neck muscles. The purpose of this project is to develop a better night and/or day-time device for TMJ patients that keeps the jaw more relaxed, particularly during long periods (i.e. during sleep).

Client requirements:

- Alleviate muscle soreness that results from TMJ
- Durable and easy to clean
- Stays in place for full night's sleep
- Turning on and off at time intervals that would be effective and still conducive to the client's sleep
- Provides a high degree of comfort

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device should be able to be worn on a daily basis for 8-10 hour periods. It should be easy for the client to put on and remove easily and fit comfortably on the head without causing discomfort no matter what sleeping position the client uses.

b. *Safety*: The material used for the device should be safe for the client to have on her head for extended periods of time. The device should be built in a manner to minimize the risk of strangulation by the device and its attached power cord.

c. *Accuracy and Reliability*: A high level of accuracy is not too necessary, since the fit should be adjustable. However, the massaging device should be accurate enough to target the key muscles and jaw areas to be effective. The electrical components need to have a high level of accuracy to give the correct amount of power without breaking down or short-circuiting. Also, the device should only consume a reasonable amount of power since it will be used on a nightly basis. Since this product will be used every night, it needs to have a high level of reliability.

d. *Life in Service*: The device should be durable enough to withstand 8-10 hours of use daily for 10 years.

e. *Shelf Life*: This device is custom made so it will not have a shelf life. After it is created, the client will begin using the device immediately.
f. *Operating Environment*: The device should endure a storage temperature range of -20^{o}C to 45 ^{o}C, and operate in a temperature range of 0^{o}C to 35^{o}C. The outer fabric of the device should be machine-washable.
g. *Ergonomics*: Client should easily be able to put the device on her head and strap it by herself. Also, it should not impede the client's sleep during the night.
h. *Size*: The device should be adjustable, but the size of the device should be able to fit the client's head. The massagers and microcontroller should be no larger than 8 centimeters wide.
i. *Weight*: The device should not exceed 500 g.
j. *Materials*: The strap should be nylon, with the adjustable component being buckle-like. The device will also consist of an Adruino microcontroller and the massaging and heating components.
k. *Aesthetics*, *Appearance, and Finish*: The device should be soft enough to not irritate the client's skin. The Shiatsu massager shouldn't cause discomfort.

2. Production Characteristics

a. *Quantity*: One device per client.
b. *Target Product Cost*: There are no current devices, but the budget is about $100.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is not required by the client.
b. *Customer*: The client is willing to try any solution that will provide pain relief.
c. *Patient-related concerns*: The device should be easy to clean whenever necessary.
d. *Competition*: There are no devices on the market. However the client could see a masseuse to have the same task accomplished.