

More effective device for patients suffering from temporomandibular joint disorder

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Function: 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 mouth/joint more open and relaxed, particularly during long periods (i.e. during sleep).

Client requirements:

- Alleviate muscle soreness that results from TMJ
- Reduce the ability of the mouth to clench by keeping molars separated
- Provides a high degree to comfort and fit
- Stays secure in the mouth
- Durable and easy to clean

Design requirements:

1. Physical and Operational Characteristics

- 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 insert and remove easily and fit comfortably in the mouth without causing harm to the teeth, tongue and gums. The device should also withstand a bite force of about 150 lb/in².
- Safety:* The material used for the device should be safe for the client to have in her mouth for extended periods of time. The material should also be durable in order to minimize the chance of breaking or chipping while inside the mouth. The material that contacts the gum is soft so as to not cause any harm to these sensitive areas.
- Accuracy and Reliability:* The device should have a high level of accuracy so that it fits the client's mouth, and it should also have a high level of reliability since the client will possibly use the device every night.
- Life in Service:* The device should be durable enough to withstand 8-10 hours of use daily for 10 years.
- 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.
- Operating Environment:* The device should endure a temperature range of 0°F - 150°F. This allows for the device to be left outside in its container or cleaned in the dishwasher, as well as everything in between.
- Ergonomics:* The client should be able to easily place the device in her mouth and push into place with her fingers. It should not create a force strong enough that causes harm to the client's teeth.
- Size:* The size of the device depends on the client's mouth since it will be custom-fit to her mouth.
- Weight:* The device should not exceed 500 g.
- Materials:* A sterilizable, non-corrosive, durable, and water-resistant material should be used.
- Aesthetics, Appearance, and Finish:* The device should be smooth so as not to chafe the inside of the patient's mouth.

2. Production Characteristics

- Quantity:* One device per client.

b. *Target Product Cost*: Current devices sell for \$200-500. The budget for this project is set at \$100-200.

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 many devices currently on the market but none of them have been effective solutions. The client has used an NTI device and currently uses a bite plate.