Project Statement
TMJD Diagnostics Device

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Statement of Need

The purpose of this project is to develop a wearable device to record bruxism (tooth grinding and clenching) events and joint sounds during sleep. Patients with temporomandibular joint disorder (TMJD) frequently engage in bruxism, which wears down the fibrocartilage disc in the temporomandibular joint leading to chronic problems. Popping and clicking sounds are audible and frequently cause significant discomfort. Patients often have a difficult time in completely opening and closing the jaw, making it difficult to adequately masticate food. Over time, the condition may worsen and pain may develop in the temporomandibular joint region. TMJD often goes unnoticed until the fibrocartilage disc is finally worn down to the point where the symptoms become self-evident. Current screening methods are ineffective at diagnosing this condition.

Diagnostic screening of bruxism is currently conducted in sleep labs through the use of electromyography (EMG) and electrosonography (ESG). EMG and ESG require patients to wear adhesive electrodes with numerous wire attachments, which limit the patient’s mobility and comfort during sleep. Studies utilizing these methods can produce inconsistent results due to the patient’s discomfort in a different environment and the complexity of the equipment attached to their body.

This design project seeks to eliminate the necessity for sleep labs and allow patients to be screened comfortably in their homes while maintaining the accuracy and efficacy of standard sleep labs. The end product will be user-friendly for both the patient and the clinician and will ideally improve the screening and diagnosis of TMJD.

Preliminary Requirements

The entire project will consist of four separate entities, including a wearable device with embedded electrodes and amplification/processing circuitry, a wireless communication module to transmit the data obtained from the electrodes, a personal computer to run a LabVIEW program for data acquisition, and a USB storage device.

The electrodes embedded in the wearable device will record EMG and ESG simultaneously to provide sufficient data to the clinician for adequate diagnosis of TMJD. The EMG signals will be placed on the left and right Temporalis muscles, and on the left and right Masseter muscles. Electrodes on the Digastricus and Pterygoid muscles will be considered pending advice from our client. The clicking and popping sounds emanating from the TMJ may be detected by ESG. The vibration from the joint will be transduced through the use of a piezoelectric sensor placed directly over the temporomandibular joint.

Preferably, gel-based adhesives will not be used for the purpose of fixing electrodes to the patient’s skin. As an alternative, electrodes that do not require the
use of an adhesive will be used. This will provide for superior comfort, a simple set up process, and the electrodes will not have to be interchanged after use. If the electrodes are found to be significantly more inaccurate, however, adhesive electrodes may have to be considered in the final product.

The device will be comfortable, wireless, user-friendly, and stylish. There will be several sizes to accommodate for different head sizes. The data acquired from this device will be sufficiently accurate for the diagnosis of TMJD, and will also be easy to save and send to a clinician. Signal processing techniques will be used to reduce noise and provide amplification to the signal.

**Basic Limitations**

This project will be relatively inexpensive; however a budget should be established and strictly conformed to throughout the design process to ensure that there is no unnecessary spending. Communication amongst the group members and client about spending will help the project comply to the proposed budget. Off-the-shelf components will be purchased from various manufacturers to reduce production cost and time.

Since this project acquires data from a human, extreme care must be considered in the circuit design to ensure that microshock and macroshock do not occur at any time. Diode protection circuits will be designed and implemented into the device both in development and the final product. Before the device is tested, the group will seek assistance from a professor or teacher’s assistant to ensure that current will not pass into the subject. Two of the group members have TMJD, so basic tests will be conducted to examine the device’s efficacy, without the necessity for clinical trials.

The final product will not consist of any parts that may be considered choking hazards; however, it is important to eliminate the possibility of strangulation. This is a major safety concern due to the fact that the patient will be using the device during an unconscious period of sleep.

Since this project seeks to acquire data from the human temporomandibular joint, clinical trials must be conducted on patients with TMJD. Therefore, a study must be carefully constructed and an Institutional Review Board (IRB) must be submitted to the Food and Drug Administration (FDA). This process is extensive and approval may take six to eight weeks, causing a limitation of time for the study to be completed.

**Other Data**

The combination of EMG and ESG will be useful to clinicians in the diagnosis of TMJD. There exist current products on the market that address one of these methods or another biosignal, but not multiple sources. Other devices also do not
accommodate for patient comfort and do not utilize wireless technology. These bulky products have numerous wires emanating from the patient’s head that connect to the device, making it nearly impossible to sleep. The connections also frequently disconnect during sleep, creating the need to discard data. By combining several biosignals, wireless technology, LabVIEW data acquisition, and an ergonomic design, this project will ideally provide clinicians with a useful instrument in the diagnosis of TMJD.

The client, Dr. Mark Litt, Ph.D., is a clinical psychologist at the UConn Health Center. His research interests include the cognitive, behavioral and affective processes that lead to changes in behavior in many health-related domains, including chronic orofacial pain such as temporomandibular joint disorders. He has spoken at numerous seminars and colloquia regarding his interests in TMJD.

The UConn Health Center, the UConn School of Dental Medicine, and the Dental Research Clinic will likely be involved in this project as well, particularly in the process of clinical trials. Likewise, other clinicians and professionals will likely become involved in the project. Contact information will be updated as it becomes available.

Questions

Are there any other methods for TMJD diagnosis besides EMG and ESG that should be incorporated into the device?

What types of electrodes should be used? Is it possible to implement electrodes that do not require an adhesive?

What is our budget?

What will be our source(s) for materials?

What circuitry is necessary to prevent electric shock to the patient?

What type of design should be considered to provide absolute comfort to the patient? What materials might be advantageous to aid in comfort?

Are there any constraints to the patient’s sleep habits that should be mentioned to protect the circuitry (i.e. sleeping on one side)?

What must be done in order to obtain an IRB?

If clinical trials are conducted, how should the study be constructed to provide a comprehensive analysis of the device and its diagnosis efficacy?
Will the UConn School of Dentistry or Health Center be able to assist in acquiring subjects for clinical trials?