Study Protocol

Development of electromyographic indicators for the diagnosis of temporomandibular disorders: a protocol for an assessor-blinded cross-sectional study

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ABSTRACT

Background: Noninvasive and easy-to-use surface electromyography (EMG) is frequently utilized for the diagnosis of temporomandibular disorders (TMDs). However, few EMG parameters that consider TMDs in addition to the cranio-cervical-mandibular system have been regarded as important in traditional Korean medicine.

Methods: This clinical trial will be conducted as an assessor-blinded cross-sectional study. The participants will be classified based on the Diagnostic Criteria for TMDs Symptom Questionnaire (DC/TMD SQ) and 30 TMD patients and 30 healthy controls will be enrolled. The primary outcome will be the percentage overlapping coefficient (POC; %) in the masseter and sternocleidomastoid muscles between the patient group and healthy control group in clenching and cervical side flexion. The secondary outcomes include the score from temporomandibular joint-related questionnaires, the difference in the absolute values of EMG for the healthy group and TMD group before/after wearing intraoral appliances, and the change in the location of the temporomandibular joint as determined by X-ray imaging and 3D face photography.

Discussion: This study will provide information about the objective diagnostic method for TMD using surface EMG and will verify the effectiveness of surface EMG in diagnosing TMD. Furthermore, the method or device for diagnosis TMD will improve the expansion of treatment area to TMD by accumulating evidence for the efficacy of TKM treatment.

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1. Introduction

Temporomandibular disorders (TMDs) include a cluster of symptoms related to a number of disease entities, including pain in the masticatory muscles and temporomandibular joint (TMJ), headache, disturbances in jaw movements, and sounds in the joints while opening and closing the mouth.[1–3]. In particular, TMDs are caused by the impaired function of the neuromuscular system are accompanied by diverse symptoms, including depression, sleep disorders, and fatigue. Moreover, these disorders often become chronic, thereby prolonging patient pain.[4,5]

In general, the anatomic structure of TMDs is diagnosed by X-ray imaging, computed tomography, and magnetic resonance imaging. However, these examinations are expensive, frequently not readily available and have limitations in recording clinical symptoms. Thus, the International Research Diagnostic Criteria (RDC) for TMDs Consortium utilized clinical symptoms to record and diagnose TMDs.[1,6] In addition, various studies have reported that mandibular kinesiography, electromyography (EMG), and sonography hold potential as diagnostic techniques for TMDs.[7–11]

Among these diagnostic techniques, EMG senses and records the electrical potential created when muscular cells are activated by neural or electrical stimulation, and the results provide information on muscular contraction, muscular tone and, muscle fatigue.[10,12] In particular, it is easy to adjust the attachment position for EMG electrodes, and this approach provides time-series data with high temporal resolution.[8] Moreover, surface-type EMG, unlike needle-type EMG, is noninvasive and can analyze the total synergistic activity of a muscular movement unit as a whole withoutany pain.[13] Thus, surface-type EMG has been widely used in the diagnosis of repetitive strain injuries,[14] work-related musculoskeletal disorders,[15] myofascial pain syndrome,[16] chronic fatigue,[17] fibromyalgia,[15] and rehabilitation training.[18]

In traditional Korean medicine (TKM), doctors of Korean medicine (DKM) regard the effect of imbalance of the TMJ on the cranio-cervical-mandibular system as important and thus consider the balance of the TMJ and the location of the mandible as critical factors for treating not only TMD but also a wide range of diseases of the cranial nerve and musculoskeletal system.[19,20] However, few methods used to diagnose TMDs consider the relationship among cranio-cervical-mandibular systems, which can be easily utilized by DKM.

Thus, we aimed to design a protocol to develop EMG indicators that also considered the cranio-cervical-mandibular system, in order to objectively and scientifically diagnose TMD using noninvasive and easy-to-use surface EMG measurement equipment. We will further confirm the effectiveness of this approach by analyzing the change in EMG indicators after the application of the TMJ balance appliance (TBA).

2. Methods

2.1. Study design

This clinical study will be conducted as an assessor-blinded cross-sectional study. Individuals who agree to participate in

the study and provide written informed consent will be eligible for inclusion.

Participants will be classified into the normal and TMD groups based on the diagnostic criteria for TMDs symptom questionnaire (DC/TMD SQ, available at http://www.rdc-tmdinternational.org/TMDAssessmentDiagnosis/DCTMD.aspx), as recommended by the International RDC Consortium, and the final diagnosis of TMD or imbalance of TMJ will be confirmed by DKM. Next, all of the participants will be investigated for TMJ-related functional, behavioral, and psychological factors. Facial asymmetry, the TMJ position, and differences in muscle power between the left and right masseter and sternocleidomastoid muscles during clenching and cervical side flexion, repectively, will be measured using 3D photography, X-ray imaging, and surface EMG, respectively. In addition, patients will wear the TBA between the upper and lower teeth to secure the TMJ free space and then will be retested using 3D photography, X-ray imaging, and surface EMG. The flow chart of this study is summarized in Fig. 1.

Subjects will be gathered at the Woosuk University Korean Medicine Hospital in Jeonju, South Korea, in accordance with the Declaration of Helsinki and Guidelines for Good Clinical Practice. This protocol has been registered with the Clinical Research Information Service, Republic of Korea, which is a registry in the World Health Organization Registry Network.

2.2. Types of participants

2.2.1. Inclusion criteria for all participants
1. Males and females aged 19–59 years.
2. Individuals who agree to participate in the study and sign the written consent after receiving a clear explanation of the objectives and characteristics of the clinical study.

2.2.2. Exclusion criteria for all participants
1. Individuals with neurological disorders.
2. Individuals with involuntary muscle movements.
3. Individuals with skin disease or trauma in the area to be measured.
4. Individuals with a history of wearing an intraoral device.
5. Individuals who cannot use a TBA.
6. Individuals who have intraoral inflammation diseases and dental diseases and/or wear intraoral equipment such as dentures and implants.
7. Pregnant women.
8. Individuals who are unable to fill out the form related to the study.
9. Other persons who are judged inappropriate for the study by the investigators.

2.3. Sample size

This study aims to verify a TMD-specific EMG indicator, i.e., the percentage overlapping coefficient (POC), between the left and right masseter muscle and sternocleidomastoid muscle during maximum voluntary clenching and cervical side flexion. However, there are no previous data available to undertake a formal power calculation to determine the required sample size. Thus, we designed the current study as a pilot to provide the initial data needed to perform the power calculation