Training of the lateral pterygoid muscle in the treatment of anterior temporomandibular joint disc displacement with reduction with pain

Physical exercises for temporomandibular disorders

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List of abbreviations

DC/TMD	Diagnostic Criteria for Temporomandibular Disorder
DDWR	Disc displacement with reduction
JFLS-8	Jaw Functional Limitation Scale
mm	Millimeter
NRS	Numeric rating scale
TMD	Temporomandibular Disorder
TMJ	Temporomandibular Joint

Abstract
Temporomandibular Disorders are a common clinical picture that appear in particular in people between the age of 20 and 40 years. About 33% of the total population shows symptoms and signs of TMD. Among the temporomandibular joint disorders anterior disc displacement appear to be the most common. In case of limitations of jaw movements and or pain conservative methods including combinations of behavior change, physiotherapy, stabilization appliance therapy and medication are most popular. The benefit of a self-treatment program to strengthen the lateral pterygoid muscle and to learn a properly executed lower jaw sideways movement to achieve pain reduction is up to now not well investigated. The aim of this study is to examine the effectiveness of muscle training for the treatment of patients with anterior disc displacement with reduction (DDWR). 60 patients with DDWR and pain (≥18 years) will be randomly allocated to two groups: 1. Physical exercises, 2. Stabilization appliance therapy. All patients receive a functional examination according to the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) at baseline.
The training in group 1 includes eccentric and concentric counter-movements of the lower jaw muscle to strengthen and restore a physiological lateral movement of the mandible. The muscle exercises should be performed once a day with 5-6 repetitions per side. The treatment with an equilibration appliance in the lower jaw serves as a comparison group. Patients are instructed to wear the appliance while sleeping. The wearing rhythm is described as intermittent. (three nights - wearing the appliance, one night – not wearing the appliance). The primary target variable is the occurrence of pain in the head and joint area before and during therapy. The variable is measured using a numeric rating scale (NRS; 0-10) during the baseline examination and control check-ups after 2, 4 and 6 months.

Scientific background

The literature describes the cause of a temporomandibular disorder (TMD) as a multifactorial event [20]. It can be influenced by anatomical, neuromuscular, traumatic or psychosocial factors [3]. Disturbances often occur in the condyle-disc complex of the temporomandibular joint [4]. The relationship between the articular disc and the condyle head is pathologically altered. The Diagnostic Criteria for Temporomandibular disorders (DC / TMD) describe the displacement of the disc in 4 different forms: disc displacement with reduction; disc displacement with reduction and intermittent locking; disc displacement without reduction with limited opening and disc displacement without reduction without limited opening [17]. TMDs are a common clinical picture that appears in particular in people between the age of 20 and 40 years. About 33% of the total population show signs and symptoms of TMD [16], [21].

Studies prove that the displacement of the disc with reduction is the most common disorder among temporomandibular joint disorders [6], [19]. According to the DC / TMD, this clinical picture shows intracapsular and biomechanical alterations. If the mouth is closed, the articular disc is often located in front of the mandibular condyle; if the mouth is opened, the disc moves back to its original position on the condyle. Anterior disc displacement appears to be the most common, although a medial or lateral displacement is also possible. During the disc repositioning clicking, popping or snapping noises are usually recorded [17]. Temporomandibular joint disorders such as disc displacement, can also cause pain [7], [8]. Overstretching of the posterior ligament and a compression of the bilaminar zone mandibular movements can be pain-related. Therefore, clicking, popping or snapping noises in the area of the temporomandibular joint (TMJ) correlate with pain in the surrounding tissue. Those complaints intensify when opening the mouth or chewing food [2], [15].

The treatment of TMD should be oriented on evidence-based procedures that are easy to implement in practice and have a long-term positive effect on the patient's symptoms [22]. Conservative methods including combinations of behavior change, physiotherapy, splint-therapy and medication are most popular [10], [13], [14]. The physiotherapeutic treatment should pursue different strategies, including manual therapy methods (e.g. mobilization and stretching of the temporomandibular joint and / or the neck area) and the demonstration of exercises in everyday life (e.g. self-mobilization and stretching of the masticatory muscles and / or cervical spine) and in addition educating the patient (e.g. about the perception of parafunctions or relaxation techniques) [11], [22]. Conservative attempts for patients with TMD should be the first choice. However, there is still no clear data situation and the data pool of randomized clinical studies on this topic needs to be improved. So far studies demonstrate a positive effect of the tested therapy forms. But the individual studies differ greatly in terms of the patient pool, diagnosis, treatment modalities and the result [18]. Furthermore, a precisely described procedure is missing in some papers. Therefore, an exact reproducibility for practitioners is not executable. More research is needed into the benefits of various non-invasive treatments for TMD.

The primary goal of this study is to decrease the ambiguity in this scientific field. In the past various manual and physiotherapeutic exercise methods have already been tested [9], [12].

This study is also intended to examine the effectiveness of muscle training for the treatment of patients with anterior disc displacement with reduction. The exercises are primarily supposed to train the lateral pterygoid muscle. The treatment with an stabilization appliance in the lower jaw serves as a comparison group.

Hypothesis

In this study, patients with anterior disc displacement with reduction are treated with muscle training of the lateral pterygoid muscle. The treatment with an stabilization appliance in the lower jaw serves as a comparison group.

1. By strengthening the lateral pterygoid muscle and learning a properly executed lower jaw sideways movement, pain reduction is achieved in patients with an anterior disc displacement with reduction.

2. By strengthening the lateral pterygoid muscle and learning a properly executed lower jaw sideways movement, the cracking phenomenon during jaw opening or jaw closing movements in patients with an anterior disc displacement with reduction is reduced.

Study design

Prospective, randomized study with control group, stratified by gender.
The type of therapy is assigned randomly.
The study is unblinded for the doctor and patient.
It is not possible to blind the practitioner because he is familiar with the forms of treatment. Since the practitioner and examiner are one and the same person in the practice, blinding is not possible here either.
It is also not possible to blind the patient, as they are able to research the form of therapy. During the last examination, the participants of the study are asked whether they have researched the respective form of treatment.

Target criteria

Primary outcome variable

The primary outcome variable is defined as the change of orofacial pain in the head and joint area after initiating the therapy measured by numeric rating scale (NRS; 0-10, 0: no pain, 10: worst imaginable pain) at the time of the follow-up appointments.

Secondary outcome variables

The following parameters are recorded as secondary target variables:

- Change in number of clicking noises in the TMJ during jaw opening or jaw closing movements
- Change in force degrees for lateral movement of the mandible according to Janda (modified scale from 4- to 5)

- Change in interincisal distance during maximum unassisted opening (in mm)

Sample size estimation

Determine the required sample size based on the numerical pain scale 0-10 for the primary target variable. Norms are pain scores of 3-5 (myofascial pain) in patients with craniomandibular dysfunction (CMD). To determine a mean difference of 2 level (standard deviation of 2 between the two treatment groups, they must each comprise 24 patients.

Test method: Wilcoxon-Mann-Whitney test with a two-sided $\alpha = 0.05$, a power = 0.90 assuming the family of logistic distributions (G * Power, version 3.1.) The net sample consists of 48 persons. Assuming a drop out 6 patients per group, a total sample of 60 persons must be calculated.

Methods of data collection

The data is collected electronically and saved in the patient file. The required values for each patient were taken from the computer system of Dr. med. dent. Falk Pfanne's dental practice.

The patient fills in a symptom-related questionnaire before the initial examination starts. The questionnaire is based on the current requirements of the DC / TMD. Demographic data as well as questions about general pain, headaches, jaw noises or locking are answered. In addition, each patient completes a questionnaire on the grading of chronic pain (Version 2.0), the Jaw Functional Limitation Scale (JFLS-8) and the Oral Behavior Checklist.
A functional examination is created during the baseline check-up. It is used to capture masticatory muscle and temporomandibular joint complaints based on a detailed anamnesis and subsequent clinical examination via palpation and inspection of the orofacial area. A standardized examination procedure adapted to the DC / TMD is used for this procedure.
During the screening examinations (after 2, 4 and 6 months), the functional status as well as the primary (pain when opening or closing the mouth) and secondary (occurrence of the cracking phenomenon when opening or closing the mouth, Janda degrees of strength for laterotrusion movement, interincisal opening) target variables will be collected.

Patient characteristics

Treatment groups

Treatment group 1: patients with anterior disc displacement with reduction
Therapy: Static stretching and isometric contraction exercises of the lateral pterygoid muscle are used to strengthen and restore a physiological lateral movement of the mandible. The training is supervised in the dental practice and continued with self-

exercises at home. The therapy is accompanied by an exercise movie on DVD produced by Dr.med.dent Falk Pfanne.

Treatment group 2: patients with anterior disc displacement with reduction.
Therapy: Stabilization appliance for the lower jaw

Group size: 30 patients per group (60 patients in total)

Description of the recruitment: The patients will be recruited in the dental practice

Inclusion Criteria

- Orofacial pain in the joint or muscles, degree NRS≥3
- Clicking phenomenon during TMJ opening or closing movement
- Deviation movement during opening of the lower jaw
- Age: ≥ 18 years
- Legal competence and presence of the signed declaration of consent

Exclusion Criteria

- Age <18 years
- Drug abuse
- Depression
- Polyarthritis

Test procedure

Examiners

All examinations and determinations of the individual measurement data are carried out by Dr. med. dent. Falk Pfanne, in his dental practice in Steina.
The exercise instructions are supervised by Christin Olbort in the dental practice in Steina.

Baseline examination

For the baseline examination the patient's anamnesis is recorded and the dental status is ascertained.
A panoramic radiograph must be available prior to the treatment in order to assess dental health and ensure the success of the treatment and it must not be older than 6 months. Such an X-ray can be realized by the volunteer’s general dentist or the specialized dental practice in Steina.
The functional examination is based on the standardized DC / TMD.
Also, the inclusion and exclusion criteria for the planned form of therapy are checked.
The assessment of the degrees of strength according to Janda during the lateral movement of the mandible requires a pain-free and coordinated sequence of movements. Subjects who experience unilateral or bilateral pain during this lower jaw movement cannot be included in the study.
The assessment of patients, who are assigned to the muscle training group and who are diagnosed with a pain-free, but uncoordinated movement pattern, is based on the

Groot Landeweer coordination scale (I-III). The subjects who only achieve Grade II or III must first perform exercises to improve coordination during laterotrusion (exercises with a spatula). The development of the coordinative ability is reassessed through weekly checks. By achieving level I (according to Groot Landeweer), the strength level (according to Janda) for the lateral movement of the lower jaw can be determined. Instructions in muscle training can be given.
These examination procedures are part of the routine examination in the “TMD Competence Center Westlausitz” for patients with temporomandibular disorders.

Coordination according to Groot Landeweer [1]:

I	Coordinated execution of the movement
II	Execution of the movement only by using facial muscles and / or masticatory muscles
III	Inability to perform the movement

Modified scale of the degrees of force according to Janda for laterotrusion [5]:

4-	Full movement against a slight resistance
4	Full movement against moderate resistance
5-	Full movement against clear resistance
5	Full movement against strong resistance / maximum strength

Randomization

The randomized grouping into blocks at a ratio of 1: 1 takes place generated random numbers by Excel. The assignment is stratified according to gender because gender is a strong predictor of temporomandibular dysfunctions.

Preliminary exercise

Coordination training for lateral movement of the mandible (spatula exercise):

1. A wooden spatula is loosely placed between the teeth of the upper and lower jaw; the head must be aligned with the body axis; the exercise should be performed in front of a mirror.
2. The lower jaw moves to the left and back to the center with little contact to the spatula
3. The lower jaw moves to the right and back to the center under contact with the spatula

Muscle Training

Treatment effects are considered to be a result of proprioceptive neuro- muscular facilitation, increased awareness, stretching, and reciprocal muscle inhibition. Exercises have also been proposed to produce hypoalgesia by activation of the endogenous opioid system.

Instructions for muscle training:

The training includes eccentric and concentric counter-movements of the lateral pterygoid muscle to strengthen and restore a physiological lateral movement of the mandible. The demonstration of the exercises takes place in the dental practice in Steina. Additionally, patients receive an exercise movie on DVD for self-instruction. It has been developed in the “CMD Westlausitz competence center”. The muscle exercises should be performed once a day with 5-6 repetitions per side.

Training of the left lateral pterygoid muscle:

1. The left palm is placed on the left temple region
2. Right hand forms a fist and is placed on the tip of the right chin
3. Both arms are aligned parallel to the surface of the floor
4. The lower jaw is moved to the right against a moderate resistance of the fist = concentric muscle work
5. With measured force of the fist, the lower jaw is brought back to the center = eccentric muscle work

(Right lateral pterygoid muscle training with opposite hands.)

Stabilization appliance therapy

Upper and lower jaw impressions are registered by using an intraoral scanner. The arbitrary hinge axis position is determined using a face bow.
The stabilization appliance with anterior canine guidance is manufactured in the Lexmann laboratory in Dresden.

Integration:
The stabilization appliance is incorporated by the dentist and the static and dynamic occlusion is checked. A tension-free fit of the appliance on the lower jaw is necessary. Additionally, equal contacts in the side teeth area and incisors guidance in the case of mandibular protrusion are checked visually and by using occlusion foil. During mandibular lateral movement only the canine guidance takes place and is also registered optically and by using occlusion foil.Interference contacts should be adjusted.
The patient is instructed to wear the stabilization appliance while sleeping. The wearing rhythm is described as intermittent. (three nights - wearing the appliance, one night – not wearing the appliance).

Control appointment for stabilization appliance group (1 week after integration)

The first inspection takes place one week after the integration. The surface contacts in the side teeth area as well as the incisor and canine guidance are checked again.

First control appointment (2 months after start of therapy)

Two months after starting the therapy, an examination is carried out with a renewed assessment of the functional status. The primary (pain when opening or closing movements of the mouth) and secondary (occurrence of the cracking phenomenon when opening or closing movements, Janda degrees of strength in lateral movement of the mandible, interincisal opening distance) target variables are recorded.

Second control appointment (4 months after start of therapy)

A second check is carried out 4 months after starting the therapy. The functional findings as well as the primary (pain when opening or closing the mouth movement) and secondary (occurrence of the cracking phenomenon when opening or closing the mouth movement, Janda strength levels for lateral movement of the mandible, interincisal opening distance) target variables are recorded.

Third control appointment (6 months after the start of therapy)

The last examination takes place 6 months after starting the therapy. The functional status as well as the primary (pain when opening or closing the mouth movement) and secondary (occurrence of the cracking phenomenon when opening or closing the mouth movement, Janda strength levels for lateral movement of the mandible, interincisal opening distance) target variables are recorded.

Patient Safety

Adverse events are recorded and the connection (certain, likely, unlikely) assessed. Serious or unexpected side effects are recorded on a separate form.

Risks of the treatment execution

There are no additional risks for the patients because the treatment methods of the study are based on routine clinical procedures.
During the muscle training, the volunteers may occasionally experience an increase in pain (similar to muscle soreness) and headache or dizziness may occur. However, these side effects should disappear after the first week and regular exercising.
In addition, the untrained muscles can be overloaded in the beginning.
The basic risks of stabilization appliance therapy include allergic reactions to the material or incompatibilities in the oral cavity.
Temporary side effects can include: dry mouth or increased salivation, changes in occlusion, feeling of tension / pain in teeth, oral mucosa or tongue, gagging or bad taste. Loss of tooth crowns, fillings or other dentures can only occur in rare cases.
When wearing an stabilization appliance over a longer period of time (months to years), permanent changes in the teeth can be established in some cases, such as tooth migration, opening of interdental spaces, loss of teeth with periodontitis or missing molar contacts.
In their entirety, risks and side-effects of these two treatment methods could be deem insignificant.

Termination Criteria

Adverse events can lead to premature termination of treatment. The following reasons could be possible:

- Intolerance or allergic reactions

- Pain on teeth, muscles or jaw joints that cannot be controlled
- Loosening of teeth
- Changes in tooth position or occlusion that cannot be tolerated
- Other physical or mental illnesses

A study termination must be documented in the patient's file by stating the corresponding reasons. A final examination of the volunteer is carried out.
Patient safety must not be compromised. All safety and health examinations and treatments must be continued.
The justification for an early termination of the study is only necessary under the points given above.

Ethical and Regulatory Aspects

This study is carried out with special attention to the content of the following laws and guidelines:

- Declaration of Helsinki in its current version (Fortaleza, 2013)
- Medizinproduktegesetz – MPG
- Medizinprodukte-Betreiberverordnung – MPBetreibV
- Landesdatenschutzgesetz – DSG M-V
- Datenschutzgrundverordnung – EU-DSGVO

Independent ethics committee

The investigation will begin after consultation and approval by the responsible ethics committees and only if there are no ethical concerns. The head of this study (Prof. Dr. Olaf Bernhardt) is responsible for submitting applications to the ethics committee of the University Medical Center Greifswald. The application to the ethics committee of the Free State of Saxony is submitted by Christin Olbort and Dr. med. dent. Falk Pfanne.

Patient information and consent

Participation in this study is only possible by a written consent. After Dr. med. dent. Pfanne or Christin Olbort have advised the patients, both orally and in writing, about the nature, meaning and scope of the study in an understandable manner, they will provide sufficient time to make a decision. By signing the consent, the volunteers declare their agreement with the recording of data required for the study.
The patient can withdraw his consent at any time, without giving any reason and experiencing any disadvantages.
The patient receives an original copy of the written patient information and consent in written or digital form. A second original is kept safe in the "CMD Competence Center Westlausitz".

Insurance

The study describes approved clinical forms of therapy that have successfully passed the conformity assessment procedure and are CE marked.
No additional invasive or stressful examinations are performed on the patient. The course of this study is based on clinical routine. Therefore, the patient is not exposed to any study-related risks.

The treatment process and the check-up examinations are based on the clinical routine and the volunteer does not have to spend extra time due to the study. Therefore, it is not necessary to propose an additional insurance.

Data protection

The provisions of the data protection laws (in particular DSG MV and EU-DSGVO) are observed. All test materials and data are adequately pseudo-anonymized in accordance with the privacy policy. An assignment of the personal data to the study data may only be carried out by employees of the dental surgery of Dr. med. dent. Falk Pfanne in Steina.

Statistical analysis plan

Number of cases

The total number of cases in the study was 60 people. 30 patients are assigned to the muscle training group and 30 patients are included in the comparison group with an equilibration splint.
In addition, the study groups are differentiated according to the categorical factor of gender.

Statistical analysis

The evaluation of the target variables is carried out using descriptive and inductive statistics.
In the descriptive statistical representation, the usual characteristic values such as frequency, mean values, standard deviation and range of values (minima, maxima) are used.
Possible differences in the study groups are analyzed using parametric (double t-test) and non-parametric (Mann-Whitney U-test) methods. The Chi^2- test is used to analyze possible relationships between the nominally scaled values (e.g. gender). The interpretation is based on a 95% confidence interval. The hypothesis testing procedure is based on an error probability of 5% [p = 0.05], which is often used in studies.

The evaluation of the blinded data is carried out by Christin Olbort.

Data management

Data collection

The data for each patient are taken from the electronic patient file of Dr. med. dent. Falk Pfanne in Steina. This includes the questionnaire consisting of the baseline exmaination, x-rays, functional status, as well as the primary (pain when opening or closing the mouth) and secondary (occurrence of the cracking phenomenon when opening or closing the mouth, Janda degrees of strength in laterostrusion movement, interincisal opening distance) target variables.

The forms are filled out, dated and signed by the test subjects or persons who are authorized to document them (dental practice employees).

Data processing

The data entry in the electronic patient file is carried out by the examiner Dr.med.dent. Falk Pfanne or his employees. All questionnaires and findings sheets that have been filled out by hand are scanned and also saved in the electronic file of each volunteer.

The use of the data takes place in accordance with legal regulations and requires a voluntarily submitted and signed declaration of consent by the test persons before participating in the clinical study.
The collected data may be passed on to Christin Olbort and the study director in pseudo-anonymized form for the purpose of scientific evaluation.
Pseudo-anonymization is the replacement of the name and other identification features with a label in order to exclude the identification of the person concerned or to make it much more difficult (according to BDSG Section 3, Paragraph 6a).
In comparison, **anonymization** means changing personal data in such a way that the individual information about personal and factual circumstances can no longer be assigned to a specific or identifiable natural person, or only with a disproportionately large amount of time, cost and labor (according to BDSG §3 Para. 6).
The study participants declare their consent for the scientific publication of the research results in compliance with the data protection regulations (a conclusion to individual persons is excluded).
Participation in the clinical study can be terminated at any time by the volunteer or the study director, even without giving reasons. When withdrawing their consent to participate in the study, participants have the right to request the deletion of all personal data stored up to that point. It is not possible to delete data that has already been analyzed.
All data will be retained for at least ten years after the study is completed or discontinued. Thereafter, personal data will be deleted, unless there are statutory retention periods to the contrary.

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