Article

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Abstract: Background: Currently, the degree of improvement in patients with TMDs is measured through subjective questionnaires and clinical examination This study aimed to investigate the properties of an objective quantitative measure of jaw-opening forces to assess clinical improvement in temporomandibular disorder (TMD) patients following treatment. Methods: Baseline jaw-opening forces were recorded for TMD-patients (n = 62) and a comparison group of TMD-free participants (n = 56), using a jaw-opening forces measuring device. TMD patients were divided into three subcategories (myofascial pain, disc-displacement, and myofascial pain and disc-displacement combined) and received a combination of treatment for six months; meanwhile, TMD-free participants did not receive treatment. Jaw-opening forces for each participant in both groups were measured at their six-month review appointment. Results: Jaw-opening forces were reliable at baseline (single measure ICC 0.98, 95% CI 0.97–0.98, ICC ≥ 0.94 for all groups and subcategories). Jaw-opening forces increased in the TMD group following treatment at six-months (18.6 N at baseline and 32.4 N at six-months, $p < 0.001$) and did not change significantly in the TMD-free group (49 N at baseline and 48.3 N at six-months). There was a small improvement in the disc displacement group (27.8% higher forces, $p = 0.002$). However, the myofascial-pain and myofascial-pain-and-disc-displacement groups showed significant improvement following treatment (93.5% higher forces, $p < 0.001$; 91.1% higher forces, $p < 0.001$; respectively). Conclusion: This study demonstrated that the measurement of jaw-opening forces could potentially be used to assess the clinical improvement in TMD patients following diagnosis and treatment.

Keywords: temporomandibular disorders; orofacial pain; diagnostic systems; myofascial pain; jaw biomechanics

1. Introduction

Temporomandibular disorders (TMDs) are a group of conditions that cause pain and dysfunction of the jaw joint and associated structures. They are the second most common musculoskeletal condition, resulting in pain, following chronic lower-back pain [1,2]. Currently, in the International Statistical Classification of Diseases and Related Health Problems 11th Revision (ICD-11), chronic-TMD (cTMD) is classified as a subgroup under Chronic Primary Pain, and this directs the management pathway toward a non-surgical protocol [3]. The prevalence of TMD is between 9.0% and 48.7% of the population, as evaluated by the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) and the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) [4,5], with a female predominance of 1.5:1 amongst younger people (age 18–44) [6,7]. Although TMD is not

life-threatening, up to 70% of people experience signs or symptoms of TMD at some point in their life. TMD has also been associated with impaired general health and socioeconomic factors, as symptoms can become chronic and difficult to manage [8,9]. The main signs and symptoms of TMDs are pain and tenderness in the masticatory muscles or around the temporomandibular joint (TMJ), altered jaw function, reduced range of movement of the mandible, and locking and joint noises, as well as associated ear and headache symptoms [10,11]. The most frequent type of TMD in the adult population is myofascial pain (42%), followed by disc displacement (32.1%) and arthralgia (30%) [12].

The diagnosis of TMDs is not always straightforward, and patients with TMD may seek help from many different experts, such as dentists (including oral surgeons, oral medicine specialists, oral and maxillofacial surgeons, orthodontists, and prosthodontists) or ear, nose, and throat (ENT) surgeons, in search of pain relief, before achieving proper diagnosis and treatment [6,12]. An early diagnosis can often bring a marked improvement to chronic symptoms in the head, neck, and jaw. Until now, several protocols have been used to diagnose and classify TMDs. The Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) protocol is the most commonly used in TMD diagnosis [13]. The DC/TMD protocol is based on indirect and subjective measures that rely on the patient's history and clinical examination; it is time-consuming, involves a face-to-face interview, and has a low diagnostic accuracy [14]. Imaging techniques such as dental X-ray imaging, computed tomography scans, magnetic resonance imaging (MRI), and arthroscopy, which evaluates the joint's bone morphology and pathology, are used to diagnose TMDs [14,15]. However, imaging techniques are expensive, and several studies have shown that a poor agreement was found between clinical diagnosis and MRI findings in TMD patients [16–18]. In our previous study, we showed that a novel jaw-opening-forces measuring device could be used as a potential diagnostic tool to screen TMDs [19,20].

The treatment goals for TMD focus on relieving pain, restoring normal masticatory and jaw function, and improvement in quality of life [21]. Treatment for TMD traditionally has included self-management instructions, physical therapy, pharmacotherapy, physiotherapy, occlusal appliance therapy, and trigger-point injection [21–23]. Despite improvements in diagnostic techniques and treatment advances in the long-term management of TMDs, clinical tools to assess the degree of improvement in TMD patients are still lacking. Presently, the improvement in TMD patients is measured through questionnaires based on pain scales, which are prone to bias [14,24]. This observational study aimed to evaluate whether changes in jaw-opening forces can be used as an adjunct quantitative measure to identify TMDs and assess the clinical improvement following diagnosis and treatment in TMD patients. The test hypothesis is that jaw-opening forces will increase in the TMD patients after treatment.

2. Materials and Methods

In this study, 62 TMD patients and 56 TMD-free participants aged 15–84 were recruited from March 2018 to February 2019, with follow-up appointments completed in August 2019. This includes 4 additional TMD patients from our earlier analysis of baseline results [20]. Ethical approval was obtained from the Health and Disability Ethics Committees (HDEC) (approval number 17/NTB/171), and the study was conducted in full accordance with the World Medical Declaration of Helsinki. The clinical trial was registered in the Australia New Zealand Clinical Trials Registry (https://www.anzctr.org.au, accessed on 19 April 2018) and received the registration ID ACTRN12618000607279.

Due to a lack of clinical data to base power calculations on at the start of the study, the target sample size was informed by blinded power calculations, looking at baseline differences between groups (TMD and TMD-free) prior to completing recruitment of participants. Details are included in our earlier publication [20], but, briefly, a 20% difference in geometric mean forces was determined likely to be of clinical importance, and, given an SD on the log-scale of 0.42, 80% power to detect this with a two-sided test at the 0.05 level required n = 57 participants in each group (114 in total).

All participants were provided with a detailed explanation of the study. After obtaining written informed consent, oral-medicine specialists screened the participants according to the DC/TMD protocol (examining the range of mandibular movements, pain, joint sounds, occlusion, oral behavior, and musculoskeletal state) [5], and TMD patients were divided into three subcategories, based on TMD symptoms:

(1)　Presence of myofascial pain (n = 17),
(2)　Disc displacement (n = 20),
(3)　Myofascial pain and disc displacement combined (n = 25).

The inclusion and exclusion criteria for patients in both the TMD and TMD-free groups are given in Table 1.

Table 1. Inclusion and exclusion criteria for patient selection.

	Inclusion Criteria	Exclusion Criteria
TMD	• Age > 18 • Males and females • Patients with symptomatic temporo-mandibular joint disorders	• Patients with osteoarthritis • Patients using muscle relaxants • Patients undergoing current orthodontic treatment • Absence of a natural dentition • Participants who had previous trauma to the head, face, and neck
TMD-free group	• Age > 18 • Males and females	• Patients with osteoarthritis • Patients with myofascial pain • Patients with symptomatic temporo-mandibular joint disorders • Patients using muscle relaxants • Absence of a natural dentition • Current orthodontic treatment • Absence of a natural dentition • Participants who had previous trauma to the head, face, and neck.

Baseline jaw-opening forces were recorded for both TMD patients and TMD-free participants [20]. In brief, the adjustable head device consisting of a 3D-printed headgear and chin caps connected to a 1000 N load cell was placed on the participants' head and tightened until there was a stable connection with the chin cap (Figure 1) [19,20].

With their jaw held together, participants opened their mandible seven times as forcefully as possible for an average 2-s period before closing and pausing for a 3-s period between each attempt [19,20]. Jaw-opening forces were recorded in a data-capture system (Biotronics Ltd., Dunedin, New Zealand) and analyzed by using the PicoLog Software (Biotronics Ltd.). Each of the seven jaw-opening attempts was recorded as a graph of mV variation during each movement, and the highest peak observed during each jaw-opening movement was recorded and measured. Mean force values were calculated for each participant after discarding the first (practice) and last attempt. The last attempt was discarded due to possible muscle fatigue. The output in mV was converted into force in Newtons by loading the 1000 N load cell with known force outputs, using a 5 KN load cell in an Instron universal testing machine (Instron 3369, Norwood, MA, USA), as described in our previous study [20]. During the initial visit to the clinic, TMD patients received a combination of treatments and were instructed to continue treatment for six months. Treatments included TMD self-management therapy (education and awareness, avoiding extreme jaw movements, avoid eating hard foods, applying cold and hot packs, and relaxation techniques, such as facial massage), non-steroidal anti-inflammatory drugs (NSAIDs), and the use of stabilization splints, depending on the severity of the TMD. The TMD-free group (comparison group) did not receive treatment. After six months, the maximum jaw-opening forces for TMD patients and TMD-free participants were measured again, using the same procedure.

Figure 1. (**A**) Jaw-opening device consisting of a 3D-printed headgear, load cell, and chin cap connected to a data capturing system. (**B**) During maximum opening.

Statistical Analysis

Appropriate summary statistics (means and SDs for approximately normally distributed variables, geometric means and SDs for approximately log-normally (positively skewed) distributed variables, and medians and IQRs for other continuous variables; and counts and percentages for categorical variables) were presented. Using baseline data, intra-class correlation coefficients were calculated overall, by TMD status, and for each TMD subgroup, using the two-way mixed effects model for absolute agreement to assess reliability over the five measurements retained (as described above). Linear mixed models were then used to examine measurement sequence number effects to determine if there was evidence of fatigue. The measurement sequence number was examined for non-linear effects through the addition of a quadratic term and effect-modification by each of the TMD statuses and TMD subgroups through the addition of interaction terms. Binary logistic regression was used to examine the discriminating ability of the mean force (of the five measurements, as described above) for TMD at baseline, and multinomial logistic regression was similarly used for the discriminating ability in terms of subtypes. Initially unadjusted models were investigated, followed by likelihood ratio tests to assess whether adding each participant characteristic (age, sex, height, and weight) improved these models. This was followed by models adjusting for all of these variables simultaneously. A Chi-squared test was used to compare loss to follow-up between the two groups and between the sexes, with Fisher's exact test used where more than 20% of cells had expected counts below 5. Given the skew in age and baseline forces, Mann–Whitney U tests were used to compare these between those retained and lost to follow-up. Spaghetti plots were used to visualize the changes in jaw-opening forces for the two groups (TMD patients and TMD-free participants) and by TMD subgroups. Linear mixed models were used to estimate and compare the changes in forces in the two groups, with a random participant effect included to accommodate the repeated measures. Similar models using only the TMD patients compared the three subgroups of TMD. Standard model diagnostics were used, including inspecting histograms of residuals and scatter plots of residuals against fitted values and continuous predictors and examining the approximate normality of the random effects. Where positively skewed model residuals were improved by log-transformation, as was the case here, this transformation was retained, and differences are reported as ratios of geometric (reflecting the positive skew) means (being back-transformed differences on the log-scale). Statistical analyses were performed by using Stata 16.1, with two-sided $p < 0.05$ considered statistically significant, except for Chi-squared tests, which were one-sided.

3. Results

The demographic details of participants (TMD patients and TMD-free participants) are summarized in Table 2.

At baseline, reliability was high for the forces measured overall (single measurement intraclass correlation coefficient (ICC) 0.98, 95% CI 0.97–0.98); for TMD-free participants (0.96, 0.95–0.98) and TMD patients (0.96, 0.94–0.97); and for those with disc displacement (0.95, 0.89–0.98), myofascial pain (0.97, 0.95–0.99), and both (0.94, 0.89–0.97). There was evidence of an overall decrease in forces following multiple trials, with evidence that this differed by TMD status (interaction $p = 0.026$) and was observed only in the TMD-free group (1.3% lower forces per measurement taken, 95% CI 0.5–2.0%, $p = 0.002$) and not in the TMD group (effectively 0.0% change per measurement taken, 95% CI 0.8% lower–0.8% higher, $p = 0.997$). There was no evidence of differences in repeated measurement effects at baseline within the TMD patients' group by subtype (interaction $p = 0.684$).

From an unadjusted model using baseline data, the force measure had good discriminating performance, with an area under the curve for a ROC curve (AUC) of 0.932 (95% CI 0.889–0.975) (ROC curve is shown in Figure 2).

Using Youdon's J, a cut-point of 28.7 N was obtained, with lower values being associated with TMD. This would provide a sensitivity of 81% (exact 95% CI 69–90%) and a specificity of 91% (80–97%). To achieve a sensitivity of at least 90%, a cut-point of 35.4 N would be needed, also providing a specificity of 77%; a sensitivity of at least 95% would be achieved with a cut-point of 37.5 N, with a specificity of 75%. Adding the age, sex, height, and weight, each, incrementally did not improve this model (each likelihood ratio test $p \geq 0.469$, combined likelihood ratio test $p = 0.899$). A multinomial logistic regression model did not find evidence that forces could discriminate between subtypes (unadjusted Wald $p = 0.127$, adjusted for all the variables listed above Wald $p = 0.235$).

Of the 118 baseline participants (62 TMD and 56 TMD-free), 104 (88%) were followed up at 6 months, with eight TMD and six TMD-free participants lost to follow-up (Chi-squared $p = 0.713$ for between-group differences in retention). There was no evidence of differences between those followed-up and those not followed-up in terms of sex (Fisher's exact test $p = 0.544$) or age (Mann–Whitney U $p = 0.077$), with the median age of those lost to follow-up 22.0 versus 25.5 years). There was also no evidence of differences in baseline jaw-opening forces for those followed-up versus lost to follow-up for either group (Mann–Whitney U, TMD: $p = 0.613$, TMD-free: $p = 0.160$). For the TMD patients, subtype was not associated with loss to follow-up (Fisher's exact test $p = 0.310$).

Jaw-opening forces increased in the TMD patient group (n = 54) from a geometric mean (geometric SD, with these used due to the positive skew of the data) of 18.6 N (1.63) to 32.4 N (1.67), a 74.2% improvement (95% CI 60.5–89.0%, p-value for change <0.001) (Figure 3). In the TMD-free group (n = 50), forces were relatively unchanged at 49.0 N (1.54) and 48.3 N (1.53) at the two time points—a non-significant decrease of 1.5% (95% CI −9.6–7.2%, $p = 0.720$) (Figure 3). This closed the baseline difference from baseline when the TMD group's forces were 62.5% lower (54.7–68.2%) to 32.9% lower at follow-up (19.8%–43.8%), a statistically significant relative improvement ($p < 0.001$).

Table 2. Demographic details of TMD patients and TMD-free participants at baseline and follow-up.

		Baseline						Follow-Up					
		Combined (n = 118)		TMD-Patients (n = 62)		TMD-Free (n = 56)		Combined (n = 104)		TMD-Patients (n = 54)		TMD-Free (n = 50)	
Age (years) *		24.5	(19.0)	27.0	(30.0)	24.0	(12.5)	25.5	(19.5)	30.5	(33.0)	24	(13.0)
Sex [†]	Male	37	(31)	13	(21)	24	(43)	34	(33)	12	(22)	22	(44)
	Female	81	(69)	49	(79)	32	(57)	70	(67)	42	(78)	28	(56)
Ethnicity [††]	Māori	4	(3)	0	(0)	4	(7)	4	(4)	0	(0)	4	(8)
	European	81	(69)	56	(90)	25	(45)	71	(68)	48	(89)	23	(46)
	Asian	30	(25)	6	(10)	24	(43)	26	(25)	6	(11)	20	(40)
	Other	3	(3)	0	(0)	3	(5)	3	(3)	0	(0)	3	(6)
Height (cm) [‡]		168.5	(10.5)	166.7	(10.4)	170.5	(10.4)	168.5	(10.5)	166.4	(10.6)	170.8	(10.0)
Weight (kg) [‡‡]		69.3	(1.26)	67.4	(1.27)	71.4	(1.24)	69.1	(1.26)	67.4	(1.28)	70.9	(1.24)
TMD Subtype													
	Disc			17	(27)					13	(24)		
	Muscle			20	(32)					18	(33)		
	Both			25	(40)					23	(43)		

* Median (IQR); [†] precentage mean; [††] count (%); [‡] mean (SD); [‡‡] geometric mean (SD).
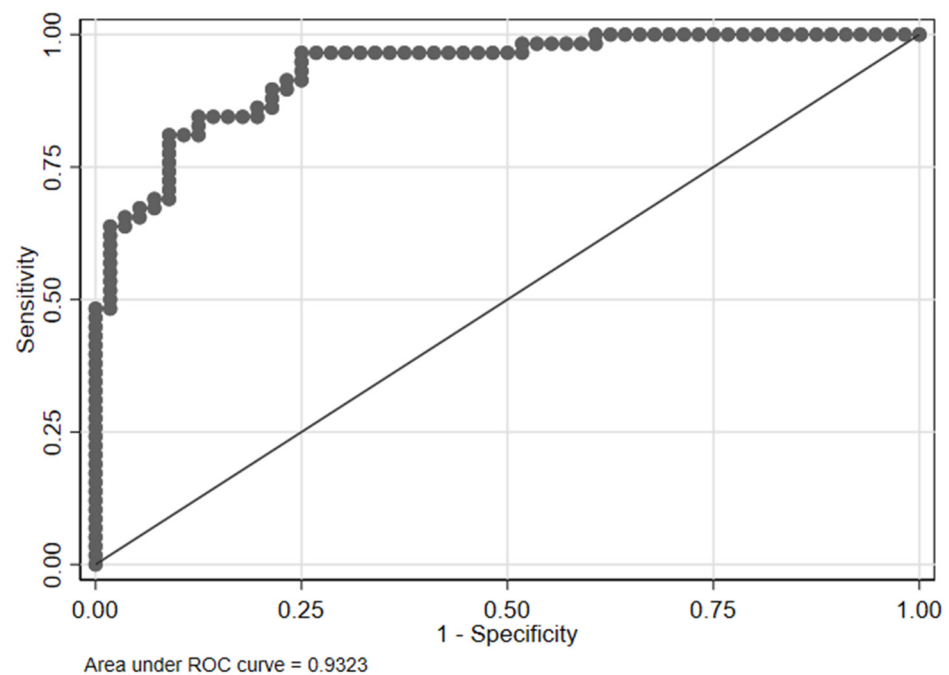
Figure 2. Receiver operating characteristics (ROCs) curve for forces at baseline.
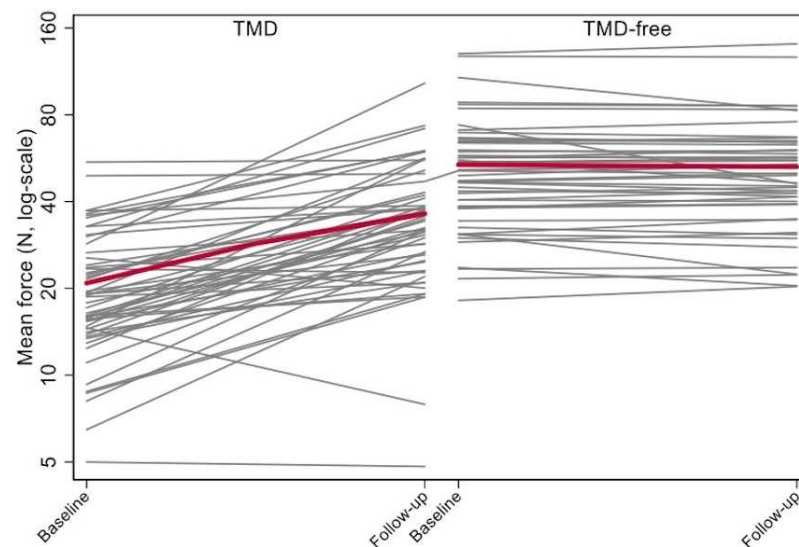
Figure 3. Spaghetti plot illustrating jaw-opening forces of TMD and TMD-free group at baseline and after 6-month follow-up. Red line indicates the mean increase in the jaw-opening forces.

There was evidence that the jaw-opening forces in the three TMD subtypes changed differently from each other ($p < 0.001$), with smaller improvements in the disc-displacement group (27.8% higher forces, 95% CI 9.8–48.8%, $p = 0.002$) compared to the myofascial-pain group (93.5%, 70.0–120.2%, $p < 0.001$) and disc-displacement-and-myofascial-pain combined group (91.1%, 70.4–114.2%, $p < 0.001$) subtypes (Figure 4). At follow-up, there was still evidence of lower-jaw-opening forces in all three subtypes compared to TMD-free participants (all pairwise $p \leq 0.003$) (Figure 4).
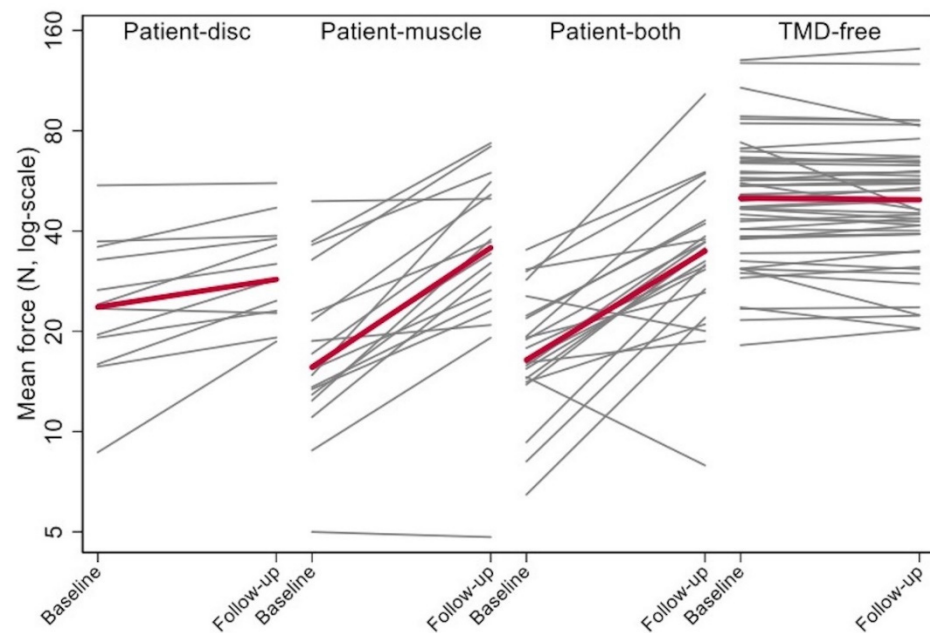
Figure 4. Spaghetti plot illustrating the jaw-opening forces of the TMD subgroups and TMD-free group at baseline and after 6-month follow-up. Red line indicates the mean increase in jaw-opening forces in the TMD subtype.

4. Discussion

Our previous study demonstrated that jaw-opening forces in TMD participants were significantly lower than in TMD-free participants [20]. Furthermore, the study also showed no statistically significant differences in jaw-opening forces between the three TMD sub-types (myofascial pain, disc displacement, and myofascial pain and disc displacement combined) (Supplementary Materials) [20]. The current study investigated maximum jaw-opening forces at baseline and again after a 6-month follow-up in patients who underwent treatment for TMDs. Specifically, we examined the measurement's reliability and potential fatigue effects, how well it discriminated at baseline between TMD-free participants and TMD patients (and their subtypes), and whether jaw opening forces could be used as a quantitative measure to assess clinical improvement following treatment.

TMD is one of the common pain disorders in the orofacial region [25]. Studies have shown that chronic TMD pain tends to persist in most patients, although some chronic TMD patients show improvement with time [26–28]. In this study, the jaw-opening forces of TMD patients increased significantly after receiving conventional treatment for six-months, in comparison to their baseline values (geometric mean 18.6 N at baseline and 32.4 N at the six-month follow-up). In contrast, jaw-opening forces in the TMD-free group were relatively similar (49 N at baseline and 48.3 N after six months). The increase in jaw-opening forces in the TMD group suggests that patients improved following treatment, demonstrating that the treatment received by the TMD patients may have assisted in pain relief and, therefore, improved muscle function.

The relevant muscles involved in TMDs are the muscles of mastication, including the masseter, temporalis, and medial and lateral pterygoid muscles [29]. The improvement of muscle activity might be related to the restoration of the lateral pterygoid muscle function, as the superior and inferior lateral pterygoid muscles are involved in jaw opening and closing. However, there was a reduction in jaw-opening forces for four patients following their six-month follow-up appointment (Figure 3). All four patients were later diagnosed with osteoarthritis by clinical examination and MRI, suggesting that it is likely that continuing pain in the temporomandibular joint (TMJs) due to this degenerative condition is responsible for the lack of improvement in the reduction of jaw-opening forces. Temporomandibular joint osteoarthritis affects the cartilage, subchondral bone, synovial

membrane, and other hard and soft tissues, thus causing TMJ deterioration, which results in severe pain, stiffness, and limited movement [30,31]. In contrast, three participants in the TMD-free group were diagnosed with TMD during their six month-follow-up after their jaw-opening forces were measured, indicating that the device may be useful in diagnosis.

Intra-articular disorders are common TMJ conditions which occur due to abnormal positioning between the disc and condyle, articular eminence, or articular fossa [30,32]. Disc displacement with reduction may occur in asymptomatic individuals and is related to TMJ noise [33]. However, the range of mandibular movement is not limited, and patients with disc displacement with reduction usually do not have pain [33,34]. In disc displacement without reduction, the patient often complains of a limitation in jaw opening, with or without pain [32]. In the three TMD subtypes investigated in this study, the disc-displacement group had a smaller improvement (27.8% improvement) compared to patients with myofascial pain (93.5% improvement) and both myofascial pain and disc displacement (91.1% improvement) after treatment. Furthermore, patients with disc displacement had numerically higher jaw-opening forces at baseline (geometric mean 23.7 N) than patients with myofascial pain (17 N) and both myofascial pain and disc displacement (17 N) [20]. A possible explanation is that most patients diagnosed with disc displacement were asymptomatic, presenting no pain during their baseline measurement [32,33]. The above results indicate that the two groups, myofascial pain and myofascial pain and disc displacement, had similar jaw-opening forces both pre- and post-treatment. This could imply that, in these groups, the predominant problem was muscular with associated pain; this is in agreement with current treatment guidelines for these groups that recommend a non-surgical approach to the management of the condition [25,30,32].

Until now, the assessment of clinical improvement of TMD patients has been based on subjective measures, including questionnaires (e.g., graded chronic pain scale, dental anxiety scale, and McGill pain questionnaire), and physical examination, which assess the pain intensity (CPI), parafunctional activities, and psychological status [35–37]. However, questionnaires are invariably susceptible to recall bias, which limits the validity of such data [5,38]. In this study, the investigator involved in measuring jaw-opening forces was not blinded to the participant's TMD status, but the measurement process was objective, and this seems unlikely to introduce bias.

Despite the changes in jaw-opening forces reported here for TMD patients following treatment, this study has limitations. Limitations regarding the design of the jaw-opening device were described in our previous study [20]. Disc displacement with or without reduction was considered as one category, as we did not differentiate them into two subgroups. The association between jaw-opening forces and the specific form of conservative treatment adopted was not investigated here. Future studies should investigate the correlation between jaw-opening forces and the treatment provided to evaluate the degree of TMD improvement in regards to specific treatment modalities.

5. Conclusions

The measurement of jaw-opening forces in this study showed an increase in forces after treatment for the TMDs included in the study, and this aligned with the clinical improvement observed. Further research is needed to investigate muscle activity in conjunction with jaw-opening forces in order to elucidate which muscles are benefiting from treatment.

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