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Effects of Radial Extracorporeal Shock Wave Therapy in Reducing Pain in Patients with Temporomandibular Disorders: A Pilot Randomized Controlled Trial

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Abstract: Temporomandibular disorders (TMD) are primarily characterized by pain as well as issues concerning the proper functioning of individual elements of the stomatognathic system. The aim of the study was to assess the safety and efficacy of physical exercise, with or without radial Extracorporeal Shock Wave Therapy (rESWT), in patients with TMD. Eligible patients were adults (≥ 18 years) with diagnosed myofascial pain with or without mouth opening limitation (Group Ia, Ib) based on the Diagnostic Criteria for TMD (DC/TMD). Enrolled patients ($n = 15$) were randomly assigned 1:1 to receive physical exercise combined with rESWT ($n = 8$) or sham rESWT ($n = 7$) for four weeks. The primary endpoint was the pain intensity measured by a visual analogue scale (VAS). The secondary endpoints were muscle activity and function assessed through the surface electromyography evaluation of the anterior temporalis and the masseter muscles. The rESWT group (mean age: 28.50 ± 8.85 years) showed a statistically significant pain reduction (VAS Right side: $\Delta T0-T1$ MD = -3.00 ; $p = 0.023$, Left side: $\Delta T0-T1$, MD = 3.57 , $p = 0.021$), whereas patients in the sham WBV group (mean age: 30.71 ± 8.98 years), did not reach statistical significance (VAS: Right side: $\Delta T0-T1$ MD = 1.00 , $p = 0.155$; Left side: $\Delta T0-T1$ MD = 1.25 SE = 0.25 , $p = 0.094$). Concurrently, muscle activity and performance significantly improved in the active rESWT group, with an improvement in the percentage of the overlapping coefficient (POC) compared to the control group. No dropouts and no side effects were recorded. Taken together, the findings of this pilot RCT suggested that rESWT combined with physical therapy could be effective in relieving pain and improving function in muscle-related TMD patients.

Keywords: extracorporeal shock wave therapy; temporomandibular disorders; temporomandibular joint disorders; physical therapy; physical agent modalities; pain management; electromyography

1. Introduction

Temporomandibular disorders (TMD) are defined as a set of disorders affecting the masticatory muscles, temporomandibular joint (TMJ), and/or associated structures [1]. The Diagnostic Criteria for TMD (DC/TMD) are the most commonly used diagnostic criteria for TMD [2]. Providing excellent reliability and validity [3,4], the DC/TMD have two assessment components. Axis I includes the examination of patient signs and symptoms and leads to classify TMD into three groups: Group I, muscular disorders (Ia myofascial pain; Ib myofascial pain with mouth opening limitation); Group II, disc displacement (IIa

disc displacement with reduction, I Ib disc displacement without reduction with limited opening, I Ic disc displacement without reduction without limited opening); and Group III, arthralgia (IIIa), arthritis (IIIb), and arthrosis (IIIc) [3]. Axis II of the DC/TMD provides an evaluation of the pain-related disability, predicting the treatment outcome as well as the chronicity of pain [5]. Temporomandibular disorders are the most common cause of pain of non-dental origin in the maxillofacial region [6]. Particularly, muscle-related disorders are considered as the main cause of TMD, with an overall prevalence in the general population of approximately 90% [7].

The muscular-related TMD aetiology has been accepted as multifactorial, often associated with parafunctional habits, clenching of teeth, grinding, local or systemic diseases, as well as psychosocial issues, including anxiety [8,9]. Pain is the most common clinical manifestation of TMD, followed by irregular and limited jaw motion, that could lead to discomfort or difficulty in performing daily activities, such as chewing, talking, swallowing, yawning, with a significantly reduced quality of life [10–12].

Several studies have examined the effects of conservative therapies, such as oral non-steroidal anti-inflammatory drugs, orthodontics, electrotherapy, physical therapy, occlusal splints, oxygen-ozone therapy, and extracorporeal shockwave therapy (ESWT) in patients affected by TMD [13–23]. Among them, ESWT has been demonstrated to be effective in reducing pain and improving the function of the stomatognathic system; however, this treatment is relatively slow in relieving pain for patients and needs additional functional therapy to preserve the long-term therapeutic result [23]. In this scenario, the radial ESWT (rESWT) is a pneumatic pressure physical agent modality with direct mechanical stimulation, which develops maximum energy on the skin surface and radially diffuses into the tissues, that might be used for musculoskeletal pain relief [24,25]. Radial ESWT has been widely recognized as a biological modulator that results in differentiation of mesenchymal stem cells, neovascularization, and release of angiogenetic factors [26]. In 2020, Li et al. conducted a preliminary study showing that ESWT was effective in reducing pain in patients affected by myofascial pain-related TMD [23]. While rESWT is a more widespread and a more manageable physical agent modality, a better understanding of the therapeutic effects for the treatment of TMD is still needed.

Surface electromyography (sEMG) is an important tool for the analysis of muscle performance during orofacial activities [27–29]. It is also useful to assess the physiopathological changes affecting muscles, joints, and related structures [27–29]. Although not all investigators agree with the clinical use of sEMG, it has been offered either to supplement the diagnosis of TMD, or to monitor the effects of the relevant treatments [30]. Surface electromyography is particularly useful when standardized/normalized data are very repeatable, and allows the assessment of both healthy subjects and patients with several disturbances; moreover, it permits an objective differentiation among different diagnostic categories defined according to the DC/TMD, and discriminated between patients with TMD and patients with a ‘neck pain’ problem with 0.86 sensitivity and 0.92 specificity [31,32]. In this scenario, the EMG of the masseter and temporalis anterior muscles has been proposed for an objective recording of muscular function and dysfunction [33,34].

ESWT has already been considered a favourable treatment for pain relief in patients with TMD [23]; however, despite the greater availability and the lower cost than focused ESWT, there was still a lack of evidence on the effects of rEWST in TMD patients.

Therefore, this pilot randomized controlled trial (RCT) aimed at evaluating the effects of rESWT in terms of reduction of pain and changing muscle activity in patients affected by muscle-related TMD.

2. Materials and Methods

2.1. Participants

We recruited patients from the Outpatient Service of the Department of Physical and Rehabilitation Medicine, University Hospital “Mater Domini”, Catanzaro, Italy. Study participants were included if they were older than 18 years and had been diagnosed with

myofascial pain with or without mouth opening limitation (Group Ia and Ib) based on the DC/TMD criteria [35]. They were also included if they had a Visual Analogue Scale (VAS) score ≥ 3 for myofascial pain and pain lasting for at least three months in at least one masseter muscle. On the contrary, the following were excluded: (i) Important cognitive deficits (Mini-Mental State Examination score < 24); (ii) disc dislocation, arthralgia or arthrosis of the TMJ; (iii) Previous or concomitant therapy with occlusal splint or concomitant therapy for bruxism; (iv) Presence of removable oral prosthesis, metal implants in the skull or hearing aids; (v) Concomitant therapy with anti-inflammatory drugs or rehabilitation therapies; (vi) Neoplastic, coagulopathic, neurological, vestibular, visual or psychiatric disorders; (vii) Pregnancy; (viii) Pacemaker. This pilot RCT was performed in accordance with the CONSORT Guidelines [36] and approved by the Ethical Committee of Calabria Region (protocol number: 422/2021). All the participants were asked to carefully read and sign an informed consent form before their inclusion, and researchers provided it to protect their privacy and the study procedures according to the Declaration of Helsinki.

2.2. Intervention

After enrolment, all patients were divided through a randomization scheme with a 1:1 allocation into two groups: Group A (study group), subjected to four sessions of bilateral manual therapy lasting 20 min and 3 min of rESWT therapy (Swiss Dolorclast[®] device, EMS—Bern, Switzerland) applying 2000 shots, at a 1.8 bars energy density flux and at a 18 Hz frequency, one session per week for 4 weeks; Group B (control group), subjected to the same protocol as Group A, but with sham rESWT therapy. All the study participants underwent a 4-week semi-standardized rehabilitative treatment protocol.

2.3. Outcome Measures

The TMD pain was the primary outcome measure, assessed by the VAS, using a 10-cm ruler with the left and right sides corresponding to no pain (0) and unbearable pain (10), respectively.

As a secondary outcome, the activity of the masseter and anterior temporalis muscles was assessed by sEMG through a wireless medical device that was able to detect the electrical activity of masticatory muscles, reporting occlusal parameters representing the distribution of loadings on the dental arches [37,38]. Thus, we performed a complete sEMG analysis of the patient occlusion. The sEMG was performed with four surface electrodes with clip connection ($41.5 \times 24.8 \times 14$ mm mother electrode— $\varnothing 16 \times 12$ mm satellite electrode, FREE1000 BTS Bioengineering, Milano, Italy) using bipolar surface electrodes (diameter, 0.8 cm; interelectrode distance, 2 cm; disposable, surface Ag/AgCl Ambu Neuroline 720 electrodes (Ambu, Neuroline, Ballerup, Denmark) with 16 bit resolution, 1 kHz acquisition frequency, and a IEEE 802.15.4 wireless data transmission (probes—USB receiver) [27,39–43]. As shown in Figure 1, we have elaborated the following indices [32,44–46]:

1. POC (Percentage of Overlapping Coefficient), a symmetry index computed between the right and left temporalis (POC AT), and the right and left masseter muscles (POC MM). In details, the POC calculates the symmetry of activation between the right and left temporalis, and between the right and left masseter. The POC measure, expressed as percent, is the difference between the normalized (MVC) sEMG signal of the muscle considered. A normality range between 83% and 100% indicates a good symmetry.
2. BAR: Occlusal centre of gravity (anterior/posterior), obtained by calculating the ratio between the activities of the pair of temporalis muscles and the pair of masseter muscles. When the temporalis muscles are predominant with respect to the masseters, the occlusal centre of gravity is anterior; conversely, when there is a predominance of the masseter muscles, the occlusal centre of gravity is placed in the posterior sectors of the mouth.
3. TORS: Mandibular Torsion Index. It measures the horizontal mandibular torsion during occlusion. It is obtained by comparing the torque of the crossed muscle pairs:

comparison between the torque of the right temporalis and the left masseter and between left temporalis and the right masseter.

4. ASIM: Asymmetry index. It compares the activity of the right muscles (right AT and right MM) with the activity of the left muscles (left AT and left MM). A positive value indicates greater activation of the right side, conversely a negative value indicates greater activation of the left side. The normal condition varies between -10 and 10 .
5. IMP: Impact of total standardized muscle activity. The under the curve area of right and left AT and MM over time (5 s MVC). Reference value are between 85 and 115% .

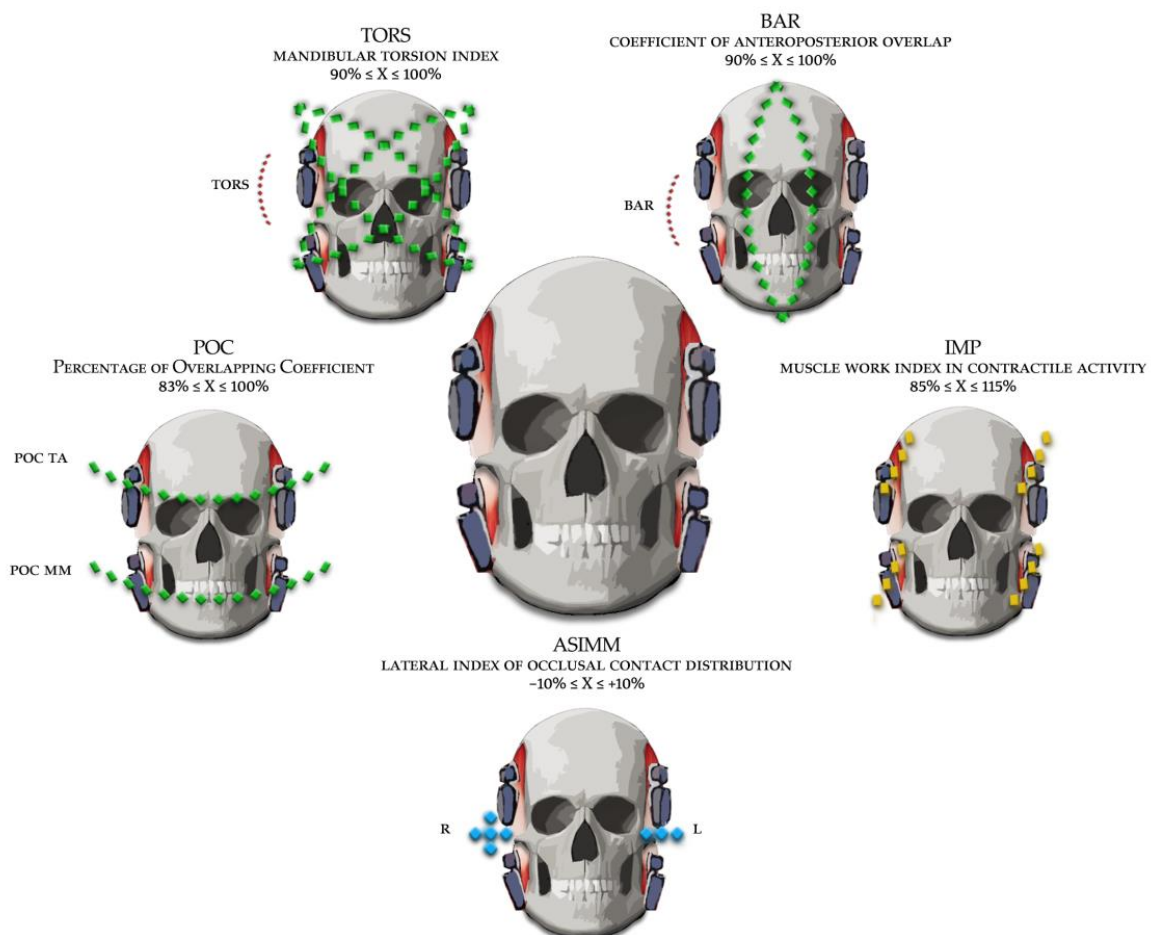


Figure 1. Functional sEMG Indices. Blue lines: representation of the polarity of asymmetry. Green lines: overlap plans. Yellow lines: representation of muscle activity. POC TA and MM: Percentage overlapping coefficient (anterior temporalis muscles or masseter muscles), measuring of the predominance of the right or left anterior temporalis in the anterior teeth contacts and masseter muscle in the posterior occlusal contact. BAR: Barycenter as percentage overlapping coefficient between posterior and anterior teeth contact. A measure of the predominance of the posterior or anterior teeth contacts. TORS: Torsion index is obtained by comparing the torque of the crossed muscle pairs. IMP: Impact index as the work performed by the muscle during its contractile activity. The work is represented geometrically by the area subtended to the curve of electrical activity of the muscles examined over time. ASIM: Asymmetry index. The distribution of the occlusal contacts considering the right and left parts of dental arches, on the frontal plane. The pairs of muscles examined are represented by the temporalis and masseter muscles.

Outcome measures were assessed at the following time-points: T0: Baseline; T1: at the end of the treatment; T2: 12 weeks after the end of the treatment; T3: 24 weeks after the end of the treatment.

2.4. Statistical Analysis

We used the Shapiro–Wilk test to evaluate the parametric distribution. Considering a small sample, we assessed the differences between groups at baseline using the Mann–Whitney U test for both demographic and outcome measures, as well as for differences between groups (intergroup analysis) for primary outcomes. Wilcoxon’s test to analyse the differences between single variable measurements in each group at T0 and T1 (intra-group analysis). Finally, we measured the differences in effect sizes for nonparametric distributions as a biserial rank correlation. Higher coefficients denote a greater entity of the relationship between the variables; as positive correlations, it denotes a relationship traveling on the same trajectory, as negative correlations it denotes a relationship traveling in different directions. A p value < 0.05 was considered statistically significant. Statistical analysis was performed with JASP 0.16 software (JASP Team, Amsterdam, The Netherlands).

3. Results

Out of 21 TMD patients assessed for eligibility, six were excluded (four did not meet inclusion criteria, two declined to participate). Fifteen patients were enrolled after providing informed consent and were randomized to rESWT therapy plus physical therapy ($n = 8$) or physical therapy alone ($n = 7$), as depicted in Figure 2.

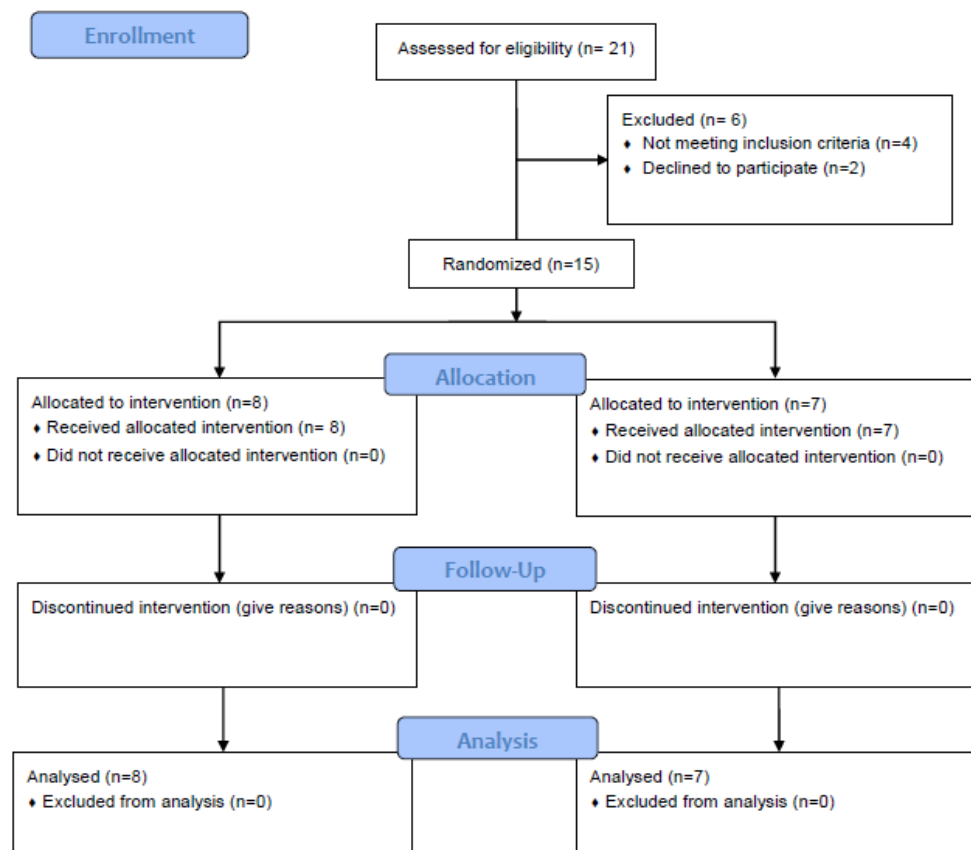


Figure 2. Study flow-chart.

There were no differences between groups in terms of sociodemographic, clinical characteristics and pain (Table 1).

Table 1. Baseline sociodemographic and clinical characteristics.

	Group A (n = 8)	Group B (n = 7)
Sociodemographic characteristics		
Age, years	28.50 ± 8.85	30.71 ± 8.98
Gender, male n (%)	2 (25.00%)	1 (14.29%)
Clinical characteristics		
Additional diagnosis n (%)		
Migraine	2 (25.00%)	2 (28.57%)
Chronic tension-type headache	1 (12.50%)	-

Values are expressed as means ± standard deviations if not otherwise denoted.

We demonstrated a statistically significant difference between the groups at T1 (Right side: $p = 0.040$; RBC = -0.46 [$-0.85, 0.23$]; Left side: $p = 0.033$; RBC = -0.64 [$-0.91, -0.02$]) and T3 (Right side: $p = 0.031$; RBC = -0.61 [$-0.89, 0.04$]; Left side: $p = 0.032$; RBC = -0.68 [$-0.92, -0.09$]) (see Table 2 for further details). Moreover, our findings showed a significant VAS reduction in group A (Right side: T0 = 4.71 ± 2.56 vs. T1 = 1.71 ± 1.89 , $p = 0.02$, mean difference (MD) = 3.00, standard error (SE) = 0.58; Left side: T0 = 4.86 ± 1.57 vs. T1 = 1.29 ± 1.11 , $p = 0.02$, MD = 3.57, SE = 0.84) and only a trend in group B (Right side: T0 = 3.75 ± 1.71 vs. T1 = 2.75 ± 1.71 , $p = \text{n.s.}$, MD = 1.00, SE = 0.54; Left side: T0 = 3.75 ± 1.71 vs. T1 = 2.5 ± 1.29 , $p = \text{n.s.}$, MD = 1.25, SE = 0.25) at the end of treatment (T1), as demonstrated in Table 2.

Table 2. Differences in Temporomandibular Disorder Pain.

Between-Group Differences						
Outcome	Group A (rESWT)	Group B (sham rESWT)	<i>p</i> value	RBC	95%CI	
T0 VAS R	4.71 ± 2.56	3.75 ± 1.71	0.631	0.21	[−0.48, 0.74]	
T0 VAS L	4.86 ± 1.57	3.75 ± 1.71	0.384	−0.36	[−0.81, 0.35]	
T1 VAS R	1.72 ± 1.89	2.75 ± 1.71	0.040 *	−0.46	[−0.85, 0.23]	
T1 VAS L	1.29 ± 1.11	2.50 ± 1.29	0.033 *	−0.64	[−0.91, −0.02]	
T2 VAS R	1.71 ± 1.90	2.75 ± 1.71	0.292	0.43	[−0.28, 0.83]	
T2 VAS L	1.29 ± 1.11	2.50 ± 1.29	0.182	−0.54	[−0.87, 0.14]	
T3 VAS R	1.00 ± 1.83	2.50 ± 1.29	0.031 *	−0.61	[−0.89, 0.04]	
T3 VAS L	0.86 ± 1.86	2.50 ± 1.29	0.032 *	−0.68	[−0.92, −0.09]	
Intra-Group Differences						
Group A (real rESWT plus physical therapy)				<i>p</i> value	MD	SE
T0 VAS R	4.71 ± 2.56	T1 VAS R	1.71 ± 1.89	0.020 *	3.00	0.59
T1 VAS R	1.71 ± 1.89	T2 VAS R	1.14 ± 1.46	0.452	0.57	0.85
T2 VAS R	1.71 ± 1.90	T3 VAS R	1.00 ± 1.83	0.064	0.71	0.92
T0 VAS L	4.86 ± 1.57	T1 VAS L	1.29 ± 1.11	0.021 *	3.57	0.88
T1 VAS L	1.29 ± 1.11	T2 VAS L	1.29 ± 2.63	0.732	0.00	1.23
T2 VAS L	1.29 ± 1.11	T3 VAS L	0.86 ± 1.86	0.603	0.43	0.89
Group B (sham rESWT plus physical therapy)				<i>p</i> value	MD	SE
T0 VAS R	3.75 ± 1.71	T1 VAS R	2.75 ± 1.71	0.155	1.00	0.56
T1 VAS R	2.75 ± 1.71	T2 VAS R	2.25 ± 0.96	0.501	0.5	0.51
T2 VAS R	2.75 ± 1.71	T3 VAS R	2.50 ± 1.29	0.653	0.25	0.66
T0 VAS L	3.75 ± 1.71	T1 VAS L	2.50 ± 1.29	0.094	1.25	0.26
T1 VAS L	2.50 ± 1.29	T2 VAS L	2.25 ± 0.96	0.689	0.25	0.29
T2 VAS L	2.50 ± 1.29	T3 VAS L	2.50 ± 1.29	0.732	0.01	0.43

Values are expressed as means ± standard deviations. Abbreviations: * = Significant inter-group difference assessed with Mann–Whitney U test; significant intra-group difference, assessed by Wilcoxon paired test; %95 CI: Confidence Interval; L: Left side; MD: Mean difference; R: Right Side; RBC: Rank biserial correlation; SE: Standard Error; VAS: Visual Analogue Scale.

Concerning the secondary outcome, Group A patients showed a statistically significant reduction in BAR (at T2: Group A with 63.9 ± 14.78 versus Group B with 81 ± 11.74 , $p = 0.04$, $RBC = -15.29 [-44.12, -8.05]$; at T3: Group A with 67.5 ± 22.83 versus Group B with 84.4 ± 4.88 , $p = 0.03$, $RBC = -37.05 [-51.18, -11.62]$). Moreover, the real rESWT group reported a significant increase in total standardized muscle activity (IMP, IMPACT score) compared to the sham group ($\Delta T0$ -T4: Group A: MD of 15.00 ± 19.89 versus Group B: MD of 9.30 ± 25.09 , $p = 0.03$) and a significant POC in masseter muscles at T1 ($RBC = -11.60 [-11.40, -1.34.]$, $p = 0.04$). Furthermore, there were significantly between-group differences in muscle activity in sEMG indexes (POC MM, BAR, IMP, ASIM) at specific time-points (see Table 3 for further details).

Table 3. Between-group differences in muscle activity assessed by surface electromyography.

	Group A (rESWT)	Group B (Sham rESWT)	p Value
POC TA T0	80.7 ± 8.1	81.1 ± 10.5	0.651
POC TA T1	82.0 ± 9.8	78.6 ± 12.0	0.073
POC TA T2	79.7 ± 14.8	75.1 ± 19.4	0.061
POC TA T3	87.0 ± 2.0	84.3 ± 2.8	0.084
POC MM T0	81.2 ± 10.2	80.9 ± 7.7	0.672
POC MM T1	85.9 ± 8.9	81.3 ± 6.4	0.041 *
POC MM T2	84.8 ± 5.2	82.3 ± 3.6	0.331
POC MM T3	84.2 ± 6.1	81.7 ± 6.8	0.103
BAR T0	75.2 ± 19.8	73.7 ± 10.8	0.094
BAR T1	80.5 ± 10.7	75.9 ± 11.9	0.066
BAR T2	81.0 ± 11.7	63.9 ± 14.8	0.032 *
BAR T3	84.4 ± 4.9	67.5 ± 22.8	0.041 *
TORS T0	86.5 ± 5.5	89.9 ± 0.7	0.095
TORS T1	87.8 ± 3.6	89.2 ± 2.8	0.238
TORS T2	86.8 ± 7.2	84.4 ± 8.9	0.145
TORS T3	89.4 ± 3.0	88.6 ± 3.0	0.621
IMP T0	71.9 ± 28.9	87.2 ± 21.5	0.025 *
IMP T1	68.2 ± 20.2	80.3 ± 21.4	0.031 *
IMP T2	84.0 ± 19.0	74.5 ± 12.8	0.047 *
IMP T3	86.9 ± 14.0	77.9 ± 13.0	0.062
ASIM T0	-1.98 ± 13.9	8.72 ± 14.4	0.022 *
ASIM T1	2.35 ± 13.0	10.0 ± 15.4	0.021 *
ASIM T2	0.19 ± 8.1	4.96 ± 11.0	0.566
ASIM T3	2.19 ± 9.5	7.16 ± 9.4	0.431 *

Values are expressed as means \pm standard deviations. Abbreviations: *: Significant between-group difference, assessed by Mann–Whitney U test. rESWT: radial Extracorporeal Shock Wave Therapy. ASIM: Asymmetry index. The distribution of the occlusal contacts considering the right and left parts of dental arches BAR: Barycenter as percentage overlapping coefficient between posterior and anterior teeth contact. IMP: Impact index as the work performed by the muscle during its contractile activity. POC TA and MM: Percentage overlapping coefficient (anterior temporalis muscles or masseter muscles). RBC: Rank Biserial Correlation. TORS: Torsion index is obtained by comparing the torque of the crossed muscle pairs.

4. Discussion

This pilot RCT aimed at evaluating the effects of a multidimensional rehabilitation intervention consisting of the addition of rESWT to physical therapy, in terms of pain reduction and muscle functional improvement, in patients affected by muscle-related TMD.

Results of the present study showed that the synergistic approach between the rESWT and physical therapy reported a significant reduction in pain (assessed by VAS) and enhancement of the POC index on the masseter muscles compared with the only physical therapy.

By comparing the pain perceived by the two study groups at each timepoint, we reported an intergroup difference at the end of treatment (T1) and at 24 weeks from the completion of the intervention.

According to the DC/TMD, muscle-related TMD disorders are myalgia and myofascial pain [3]. Local myalgia is characterized by pain localized to the area of palpation on

examination, whereas myofascial pain extends beyond the area identified by palpation. Referred myofascial pain is characterized by extension towards areas distant from the area of palpation on examination. Among masticatory muscles, masseter and temporalis muscles are commonly associated with myofascial pain and considered as the main causes of TMD [47].

Myofascial pain is a complex musculoskeletal disorder characterized by the presence of trigger points, defined as hyperirritable spots within taut bands of skeletal muscle that are painful upon compression [48], characterized by a higher concentrations of protons, bradykinin, calcitonin gene-related peptide, substance P, tumour necrosis factor- α , interleukin-1b, serotonin, and norepinephrine [49].

It has been observed that the masseter and temporalis muscles are the muscles most frequently involved in active trigger points in patients with TMD of myofascial origin [50]. It is important to highlight that, without intervention, the pain could become chronic determining a restriction of the range of motion [51].

The ESWT is a mechanical (acoustic) wave with a low-frequency pressure that propagates rapidly and focally [23]. The rapid growth of rESWT in recent years has positioned it as an alternative to focal ESWT, because unlike focal shock waves, rESWT waves have linear pressure, low energy values, short duration of the rise time, and most of all a radial propagation [25]. These waves are characterized by a slow growing pressure that takes up to 5 μ s to reach 1–10 bar (0.1–1.0 MPa); moreover and is absorbed at a depth of up to 3 cm, with a typically dispersed (unfocused) beam shape [52].

The mechanism of action of the rESWT on musculoskeletal disorders has been investigated in animal studies. The beneficial effect of shock waves might be associated with micro-destruction, which is likely to result in micro-tears of non-vascularized or scantily vascularized tissues, and thus stimulate the revascularization by the local release of growth factors and mobilization of stem cells, leading to increased blood supply to the tissue [53]. Studies explored the effects of rESWT showing that the application of shock waves could generate the ingrowth of neovascularization through the up-regulation of angiogenic and osteogenic growth factors (e.g., endothelial nitric oxide synthase, vessel endothelial growth factor, proliferating cell nuclear antigen, bone morphogenic protein-2, and osteocalcin) [54,55]. Moreover, previous studies have suggested that these mechanisms also play a role in reducing the muscle tone for spasticity [24] and that the rESWT may generate an analgesic effect during the treatment that blocks the activation and transmission of pain signals by non-invasive stimulation of cell membranes and nerve endings [25,53].

The clinical effects of rESWT in patients with musculoskeletal disorders have been explored in the recent years [56–58], and it seems that this therapy could have a significant influence on the reduction of pain and on the improvement of the general functional state.

Results of the present study showed that the VAS scores of both groups declined after therapy, and that the decrease was greater in the study group. The significant increased mean values of POC MM that were obtained in rESWT group might indicate a low asymmetry between the right and left muscle pairs and balanced contractile activity [59]. Indeed, a measure of the predominance of the right or left masseter in the posterior teeth contacts provide an index of performance symmetry [46]. The improvement in POC MM of the rESWT group at the end of treatment could justify the improvements at 24 weeks in the significant difference in anterior-posterior BAR between the two groups. In this scenario, the significant pain reduction at the end of the treatment provides early lateral stability, which results in late anterior-posterior stability.

We are aware that the present pilot RCT has a main limitation of small sample size, albeit we retain that these findings might report a first proof of this novel intervention in the clinical management of muscle-related TMD. Moreover, the impact of the COVID-19 pandemic might have influenced the follow-up period that could have lasted more to highlight the long-term effects of this intervention.

However, to the best of our knowledge, this is the first study that has investigated the effects of rESWT in terms of pain relief and muscle activity improvement in patients affected

by muscle-related TMD. Indeed, we showed how a combination of physical therapy plus rESWT seems to be safe and well tolerated, with no dropouts in either group during the entire treatment. Lastly, the assessment of the masseter and the anterior temporalis muscle activity by sEMG should be underlined as a study strength.

5. Conclusions

Taken together, the findings of our study showed that rESWT combined with physical therapy seemed to be an effective treatment in pain relief, thus suggesting the need to define a precise rehabilitation intervention, including physiotherapy and other interventional physical agent modalities, such as rESWT, in patients affected by muscle-related TMD. Further research with larger samples and a longer follow-up is needed to confirm these preliminary data to provide scientific literature with stronger evidence for the rehabilitative management of TMD.

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