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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| For a 30 year old female who is diagnosed with temporomandibular disorder (TMD), do physical therapy treatment interventions which utilize therapeutic dry needling (TDN) result in significantly improved pain outcomes as compared to interventions which do not utilized TDN?  |

**AUTHOR**

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**CLINICAL SCENARIO**

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| The patient is a 30 year old female with a diagnosis of temporomandibular disorder (TMD) with associated functional deficits in speaking and eating secondary to pain and loss of mandibular range of motion. The patient’s symptoms have been growing worse over the past 4 months with a current presentation of right sided jaw pain and fatigue in the TMJ region, with occasional headaches she feels are related. The patient complains of pain when she wakes up in the morning and pain that is aggravated by excessive chewing, talking, or wide opening of her mouth. Clinical exam reveals subtle muscle weakness and marked loss of range of motion (mouth opening (mandibular depression), protrusion, and left side lateral extrusion. The patient reports tenderness to palpation of her right masseter, temporalis, and lateral pterygoid muscles with clinically identified highly sensitive trigger points within these muscles. The patient is currently in her fourth week of physical therapy which has focused on manual therapy of the TMJ and C-spine, passive and active range of motion exercises, relaxation techniques, diet modification to avoid maximum painful opening, education to promote conscious awareness of parafunctional behaviors including teeth clenching, and cryotherapy for pain management. The patient is also taking muscle relaxants and NSAIDs and Xanax for anxiety. She is not demonstrating significant progress with her current treatment plan, in large part due to increased pain which limits her ability to perform her exercises and only adds to her levels of anxiety. Therapeutic Dry Needling represents a possible intervention which could be used as part of her plan of care in conjunction with her other physical therapy interventions to reduce pain and potentially facilitate improved outcomes with other interventions. |

**SUMMARY OF SEARCH**

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| * Eleven studies were located that met inclusion/exclusion criteria, including 1 systematic review, 6 random control trials, and 4 case series. Three studies were reviewed in detail.
* Overall, the quality of evidence for my clinical question is poor to good. Out of 11 articles, 1 is a systematic review with 8/11 AMSTAR, 6 were RCT’s ranging from 3/5-5/5 Jadad, and 4 were Case Series ranging from 12/31-16/21 Downs & Black.
* There were significant improvements in pain, both statistically and clinically, with the use of therapeutic dry needling (TDN) among patients with masticatory muscle disorder and myofascial pain associated with a diagnosis of TMD.
* Measures of pain which rely upon pain pressure threshold appear to be the most sensitive to the treatment effects of TDN over comparisons to control interventions.
* TDN procedures which target trigger points (TrPs) in the masseter, temporalis, and lateral pterygoid muscles to elicit local twitch responses demonstrate greater effect sizes for improved pain than those observed with more superficial sham dry needling control interventions.
* The mechanisms underlying the effects of TDN on pain in persons with TMD are not fully understood but there is evidence to believe that these mechanisms are both centrally and peripherally mediated.
* TDN has been demonstrated to be a safe and advantageous alternative to pharmacological pain management in persons with TMD.
* Current best evidence suggests that use of TDN at trigger points (TrPs) within the muscles of mastication has the potential to improve pain in conjunction with physical therapy more effectively than interventions which do not rely upon TDM.
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**CLINICAL BOTTOM LINE**

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| Overall, high quality evidence for the effects of TDN on pain when used in conjunction with other physical therapy interventions in treatment of persons with TMD is lacking but generally supportive of the potential benefits of this intervention for persons with myofascial dysfunction components of TMD. Further research is needed which examines TDN when utilized as a part of a comprehensive treatment approach including other physical therapy interventions with long-term outcomes and larger sample sizes. |
| This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor |

**SEARCH STRATEGY**

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| **Terms used to guide the search strategy** |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| Filter Females 19-44 years old -Temporomandibular Disorder -Temporomandibular Joint Disease -Temporomandibular Joint Diseases -Craniomandibular Disorders -Temporomandibular Joint Syndrome-TMJ-TMD | Physical Therapy PTPhysiotherapyPhysioJoint MobilizationSoft Tissue MobilizationTherapeutic ExerciseExercisesHome Exercise ProgramHEPPatient EducationModalitiesPhysical Therapy ModalitiesAND(Therapeutic Dry NeedlingOR Acupuncture OR intramuscular OR Trigger Point OR Dry Needling OR NeedlesOR Dry Needl\*MTrP\*) | Physical TherapyPT PhysiotherapyJoint MobilizationSoft Tissue MobilizationTherapeutic ExerciseExerciseHome Exercise ProgramHEPPatient EducationModalitiesPhysical Therapy Modalities | PainPressure SensitivityPain ReliefTenderness on palpationPain Pressure Threshold |

**Final search strategy:**

1. Filter for HUMAN, Adults Age 19-44, (Temporomandibular Disorder OR Temporomandibular Joint Disease OR Temporomandibular Joint Diseases OR Craniomandibular Disorders OR Temporomandibular Joint Syndrome OR TMJ OR TMD)

2. Physical Therapy OR PT OR Physiotherapy OR Physio OR joint mobilization OR soft tissue mobilization OR therapeutic exercise OR exercis\* OR home exercise program OR HEP OR patient education OR modalities OR physical therapy modalities

3. Therapeutic Dry Needling OR Dry Needling OR Acupuncture OR intramuscular OR Trigger Point OR Dry Needling OR Needles OR Dry Needl\* OR MTrP)

4. Pain OR pressure sensitivity OR pain relief OR tenderness on palpation

5. #1 AND #2 AND #3 AND #4

6. Physical Therapy OR PT OR Physiotherapy

7. #1 AND #6 AND #3 AND #4

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| * Pubmed
* CINHAL
* Web Of Science
* Cochrane
 | **211****50****48****138** | **464 results before Humans and Age: 19-44 applied.****Original Search yielded zero results. Physical Therapy search terms were limited to Physical Therapy OR PT OR physiotherapy.** |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| -Published in English-Published up to November 2015-Protocol that included TDN or acupuncture by some name to the muscles of mastication involved with TMD pathology.-Studied a population of adults within the age ranges of 19-44 |
| **Exclusion Criteria** |
| -Published in another language without translation-Experiments which do not involve outcome measures for pain.-Abstracts, narrative reviews, editorials, presentations.-Studies which did not include a diagnosis associated with TMD. |

**RESULTS OF SEARCH**

A total of 11 relevant studies were located and categorized as shown in the following table (based on Levels of Evidence, Centre for Evidence Based Medicine, 2011) using the PEDro quality assessment rating scale for RCTs and qualitative analyses based on the Quality Appraisal Checklist (Jewell 2009) for systematic reviews.

**Summary of articles retrieved that met inclusion and exclusion criteria**1–11

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| **Author (Year)** | **Study quality score** | **Level of Evidence** | **Study design** |
| **(Jung, Shin, Lee, Sim & Ernst, 2011)** | **8/11 AMSTAR** | **1A** | **Systematic Review** |
| **(Gonzalez-Perez et al., 2015)** | **5/5 Jadad****8/11 PEDro** | **1B** | **RCT** |
| **(Fernandez-Carnero et al., 2010)** | **5/5 Jadad****9/11 PEDro** | **1B** | **RCT** |
| **(Smith, Mosscrop, Davies, Sloan, & Al-Ani, 2007)** | **5/5 Jadad** | **1B** | **RCT** |
| **(Diracoglu, Vural, Karan, & Aksoy, 2012)** | **5/5 Jadad****9/11 PEDro** | **1B** | **RCT** |
| **(McMillan, Nolan, & Kelly, 1997)** | **4/5 Jadad** | **1B** | **RCT** |
| **(Itoh, Asai, Ohyabu, Imai, & Kitakoji, 2012)**  | **3/5 Jadad** | **1B** | **RCT** |
| **(Noiman, Garty, Maimon, Miller & Lev-Ari, 2010)** | **13/31 Downs and Black** | **3** | **Case Series** |
| **(Gonzalez-Perez, Infante-Cossio, Granados-Nunez, & Urresti-Lopez, 2012)** | **15/31 Downs and Black** | **3** | **Case Series** |
| **(Shin, Ha, Song, & Lee, 2007)** | **12/31 Downs and Black** | **3** | **Case Series** |
| **(Gonzalez-Iglesias, Cleland, Neto, Hall, & Fernandez-de-las-Penas, 2013)** | **16/31 Downs and Black** | **3** | **Case Series** |

**BEST EVIDENCE**

The following 3 studies were identified as the ‘best’ evidence and selected for critical appraisal. Reasons for selecting these studies were:

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| * **(Diracoglu et al., 2012)** This study is a double-blind, prospective, randomized, placebo-controlled trial (RCT), level of evidence 1b, that uses multiple established outcome measures for pain to compare the impact of TDN to sham TDN. This article has a Jadad score of 5/5 and PEDro score of 9/11 and a sample population most similar to the patient in the clinical scenario.
* **(Fernandez-Carnero et al., 2012)** This study is a double-blind, randomized, cross-over, placebo-controlled trial, (RCT), level of evidence 1b, that investigates the effects of dry needling of the masseter on short term pain relief and range of motion, in comparison to sham dry needling. This article has a Jadad score of 5/5 and PEDro score of 9/11 and a sample population similar to the patient in the clinical scenario. The studies unique cross-over design and use of multiple outcome measures for pain and range of motion, along with its clear TDN methodology make it ideal to identify genuine effects on pain from TDN which would be relevant to this clinical scenario.
* **(Gonzalez-Perez et al., 2015)** This study is an open, randomized, single center controlled trial, (RCT), level of evidence 1b, that compares TDN to TrPs in the lateral pterygoid muscle (LPM) to pain medication with multiple outcome measures relevant to this clinical scenario. Pain medication is commonly used in conjunction with physical therapy interventions to manage pain associated with TMD. The comparison to this method of pain management represents the potential to establish the therapeutic benefits of TDN used in conjunction with other physical therapy interventions. This trial also has a similar sample population to the individual in the clinical scenario and evaluates a TDN in a specific tissue (LPM) which is frequently targeted in TDN interventions with this presentation with TMD. While other studies were appraised with higher quality levels than the Jadad 4/5 and PEDro 8/11 score of this study, the methods and outcome measures of this study were most applicable to the clinical scenario.
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**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of “Effectiveness of dry needling for the treatment of temporomandibular myofascial pain: A double-blind, randomized, placebo controlled study” by Dıracoglu et. al. (2012)**

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| **Aim/Objective of the Study/Systematic Review:** |
| The aim of the study was to determine if dry needling is more effective than sham dry needling in relieving myofascial pain of the temporomandibular muscles. |
| **Study Design** |
| * The study was a double-blind, prospective, randomized, placebo-controlled trial.
* Specific recruitment methodology is not included but it is implied that participants were recruited from a sample of convenience of patients seen at the multidisciplinary training and research hospital mentioned above.
* Participants were randomly assigned to either treatment group or placebo group using randomized numbers obtained from QuickCalcs GraphPath Software.
* Study group received dry needling therapy with intramuscular stimulation applied to trigger points using 0.22mmx30mm needles 3 times at 7 day intervals.
* The trigger point was stimulated 3-5 times with the needle which was inserted into the depth allowed by the guide tube.
* The placebo group received sham dry needling to the areas away from the trigger performed by the same physicians using the same needles and amount of time as the study group.
* The sham dry needling inserted no deeper than the subcutaneous stratum.
* Outcome measures were collected immediately before the first intervention and at 1 week following the last needling.
* Statistical analysis with SPSS 15.0 was used to:
* Compare parametric variables before and after intervention in each group.
* Compare values between groups with two-way ANOVA
* Assess statistical significance with Chi-Square test with p value set at p>0.05.
* No a priori power calculation was discussed. The power was found to be 0.99 in post-hoc power analysis for algometric measurements.
* There was no intention to treat data or analysis.
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| **Setting** |
| * Multi-disciplinary Temporomandibular Joint Disorders Unit of Dr. Sadi Konuk Training and Research Hospital in Istanbul, Turkey. Disciplines include dentists, plastic surgeons, psychiatrists and physiatrists who evaluated the participants.
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| **Participants** |
| * 52 total subjects (N=52)
* 102 patients assessed for eligibility
* 21 excluded due to failure to meet inclusion criteria
* 26 excluded due to meeting exclusion criteria
* 3 refused to participate
* 1 participant in study group and 1 participant in placebo group lost to follow up with reasons given: “Did not benefit from treatment”
* Gender: 45 female/7 male
* Age: 18-57 years
* Study Group (n=25)
	+ Age: (mean ± SD): 33.00 ± 12.70
	+ Sex: 22 Female/3 Male
	+ Occupation: 10 Housewives, 6 students, 1 Official, 1 Retired, 7 Other
	+ Mean algometric Measure (kg/cm2) (mean ± SD): 2.64 ± 1.05
	+ VAS-pain score (mean ± SD): 6.32 ± 1.54
	+ Unassisted jaw-opening without pain (mm) (mean ± SD): 41.20 ± 7.69
* Placebo Group (n=25)
	+ Age: (mean ± SD): 35.88 ± 9.60
	+ Sex: 21 Female/4 Male
	+ Occupation: 9 Housewives, 2 students, 6 Official, 1 Retired, 7 Other
	+ Mean algometric Measure (kg/cm2) (mean ± SD): 2.69 ± 0.38
	+ VAS-pain score (mean ± SD): 5.68 ± 1.37
* Unassisted jaw-opening without pain (mm) (mean ± SD): 39.50 ± 4.72
* There were no significant difference between the two groups with regard to age, sex, and education level.
* There were no significant difference between the two groups for all 3 outcome measures including algometric values, VAS, and pain free active jaw-opening distance (p > 0.05)
* Enrolment: The study does not indicate how patients were recruited for enrolment.
* Inclusion Criteria: Must have had symptoms lasting 6 weeks or longer with 2 or more myofascial trigger points in the temporomandibular muscles.
* Trigger points diagnosed if exhibiting pain referral after application of a force 1.5 kg/cm2 at 0.5 kg/s rate with pressure algometry.
* Exclusion Criteria: Presence of any of the following: inflammatory diseases involving the TMJ, reducible or non-reducible disc replacements, TMJ degeneration, TMJ neoplasms, TMJ subluxation, trigeminal neuralgia, blood disorders, major psychiatric disorders, hypermobility syndrome, occasion anomaly or major anomalies in the mandible, teeth, and gums, radiotherapy to the TMJ region, TMJ surgery, TMJ ankyloses, TMJ bone fracture.
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| **Intervention Investigated** |
| *Placebo* |
| * Sham dry needling using (0.22mm x 30mm) single-use sterile acupuncture needles with plastic tubes.
* Once a week for 3 weeks (total of 3 treatments)
* Applied to masseter and temporalis in areas away from trigger points
* Needle insertion no deeper than subcutaneous stratum
* All subjects were provided with an educational program about TMJ disorders.

Oral and written consent were obtained for all participants and approved by the local ethics committee. |
| *Experimental (Study Group)* |
| * Therapeutic dry needling using (0.22mm x 30mm) single-use sterile acupuncture needles with plastic tubes.
* Once a week for 3 weeks (total of 3 treatments)
* Applied to trigger points in the masseter and temporalis
* Needle insertion to depth allowed by plastic tubes and stimulated 3-5 times.
* All participants were provided with an educational program about TMJ disorders.
* Oral and written consent were obtained for all participants and approved by the local ethics committee.
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| **Outcome Measures** (Primary and Secondary) |
| Mean Algometric pain-pressure threshold was the primary outcome measure with VAS-pain score and unassisted jaw opening without pain as exploratory outcome measures.* Mean Algometric Measures (kg/cm2)
* A pressure algometer is an instrument which measures applied pressure to a 1 cmdiameter rubber disc which is pressed at a 90 degree angle against a region of maximal sensitivity on the masseter or temporalis muscle.
* The pressure of the algometer was increased at a speed of 0.5 kg/s, which is very slow.
* The pressure at which the participant reports feeling pain was recorded as the “pain threshold” in kg/cm2.
* This value was taken for all trigger points and averaged to create the “algometric mean value” for each participant.
* Higher values indicate larger pain tolerance and thus decreased pain levels. The algometer was capable of up to 10 kg/cm2,but averages were between and 1.59-4.27.
* VAS-pain Score
* The 10 cm VAS from 0-10 with 0 indicating no pain at all and 10 indicating the worst pain ever experienced was used capture pain in a day. This measure ranged from 2.19-7.86.
* Unassisted jaw-opening without pain (mm)
* Measured with a ruler before and after treatment. Specific procedure was not included in the methods but the typical protocol for this measurement is the distance between the maxillary and mandibular central incisors, repeated three times and then averaged. This measurement ranged from 35.78-48.89 mm.
* All three outcome measures were taken immediately before the first intervention and one week following the last needling intervention. The measures were taken by another physician other than the treating physician who was blinded to the participant groups.
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| **Main Findings** |
| * In the study group which received genuine therapeutic dry needling, from baseline to one week following final treatment, the following differences in the three outcome measures were observed:
* Mean algometric values (kg/cm2): Increased from:
	+ - Pre-treatment: 2.64 ± 1.05 to Post-treatment: 3.21 ± 1.06 (kg/cm2)
		- Mean ± SD: -.0.57 ± 0.57
		- P < 0.001
* VAS-pain Score: Decreased from:
	+ - Pre-treatment: 6.32 ± 1.54 to Post-treatment: 3.88 ± 1.69
		- Mean ± SD: 2.44 ± 1.73
		- P < 0.001
* Unassisted jaw-opening without pain (mm): No statistically significant difference.
	+ - Pre-treatment: 41.20 ± 7.69 to Post-treatment: 40.8 ± 6.10
		- Mean ± SD: 1.12 ± 4.79
		- P = 0.255
* In the placebo group which received sham dry needling, from baseline to one week following final treatment, the following differences in the three outcome measures were observed:
* Mean algometric values (kg/cm2): Increased from:
	+ - Pre-treatment: 2.69 ± 0.38 to Post-treatment: 2.75 ± 0.35 (kg/cm2)
		- Mean ± SD: -.0.06 ± 0.10
		- P = 0.005
* VAS-pain Score: Decreased from:
	+ - Pre-treatment: 5.68 ± 1.37 to Post-treatment: 3.80 ± 1.47
		- Mean ± SD: 1.88 ± 1.20
		- P < 0.001
* Unassisted jaw-opening without pain (mm): No statistically significant difference.
	+ - Pre-treatment: 39.50 ± 4.72 to Post-treatment: 39.6 ± 4,18
		- Mean ± SD: -0.08 ± 0.95
		- P = 0.679
* Comparisons between the Study group and Placebo Group demonstrated the following results:
* Mean algometric values (kg/cm2): Increased more for the Study Group
	+ - Study Group Post-treatment: 3.21 ± 1.06 to Placebo Post-treatment: 2.75 ± 0.35 (kg/cm2)
		- P < 0.001
* VAS-pain Score: Decreased from:
	+ - Study Group Post-treatment: 3.88 ± 1.69 to Placebo Post-treatment: 3.80 ± 1.47
		- P = 0.478
* Unassisted jaw-opening without pain (mm): No statistically significant difference.
	+ - Study Group Post-treatment: 40.08 ± 6.10 to Placebo Post-treatment: 39.6 ± 4,18
		- P = 0.411

The main findings of this study were that both groups demonstrated statistically significant improvement in VAS one day pain scale and mean algometric pain thresholds following 3 treatments of either therapeutic dry needling or sham dry needling applied three weeks and measured after the fourth week. Both the therapeutic dry needling into trigger points and sham dry needling into the skin not over trigger points improved reports of pain in the past day on VAS pain scale. Neither therapeutic dry needling nor sham dry needling had a significant impact on pain free jaw opening range of motion. Therapeutic dry needling was shown to be superior to sham dry needling for improvements in pain pressure thresholds has measured by the algometer. |
| **Original Authors’ Conclusions** |
| The authors of the study concluded that although both the VAS and mean algometric measurement yielded significant results from pre to post-test for both the therapeutic dry needling and sham dry needling groups. There were no statistically significant changes in either group with regard to unassisted jaw-opening without pain from pre to post-test. The authors conclude that the improvement of VAS from pre to post treatment in the placebo group may be the result of the sham effect of dry needling. While the results for algometric pain threshold and last day VAS were both significant, the authors felt that the change in VAS seemed to be clinically relevant. The authors also concluded that the inter-group comparison indicated a greater treatment result for the therapeutic dry needling group as compared to the placebo group receiving sham treatment with regard to the algometric pain threshold values. The same intergroup comparison for VAS Pain scale and unassisted jaw opening without pain did not yield statistically significant differences between the therapeutic dry needling group and the sham placebo group.The authors noted that further studies with large sample sizes and longer follow-up should be conducted to confirm their results. |
| **Critical Appraisal** |
| **Validity** |
| * Level of evidence 1B Random controlled trial.
* JADAD scale: 5/5 1-Randomization is mentioned; 1-method of randomization is appropriate; 1- blinding is mentioned; 1-method of blinding is appropriate; 1-the fate of all patients is known.
* PEDro: 9/11 based on eligibility criteria: YES; Random allocation: YES; Concealed Allocation: Yes; Baseline Comparison: Yes; Blind Subjects: YES; Blind Therapist: NO; Blind Assessors: YES; >85% participant outcomes: YES; Intention to treat analysis: NO; Between group comparison: YES; Point estimates and variability: YES

Limitations/weaknesses* Recruitment procedure: where did the patients come from? How were they recruited or compensated for participation?
* The timeline and number of treatments of the intervention for study group and placebo group are not included other than to say that the intervention was performed 3 times with seven day intervals.
* There was no a priori consideration of power and the method in which post hoc power was determined was not shared other than the results of 0.99 for algometric measurements.
* The study lacks a true control group which did not receive either therapeutic dry needling or sham dry needling. This control group would be helpful to determine the degree of placebo effect for both the genuine and sham treatments along with controlling for changes that may have occurred over time without any treatment.
* Comparison of the post-treatment values for both groups yielded differences which were smaller than SD for the values.
* Comparison between the Study Group and Placebo group was performed only for the post-test values themselves rather than for a comparison of the relative pre-test to post-test changes for each group. This is a poor design to determine the difference in effect size for therapeutic dry needling versus sham dry needling as it does not control for initial differences between groups.
* The authors fail to discuss the results of the right side of Table 4 including the Type III sum of squares, the df, Mean Square, F, and P values) in either the results section or the discussion section.
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| **Interpretation of Results** |
| The significant effect size for the Study group of an improvement of 0.57 kg/cm2 following therapeutic dry needling indicates that this intervention is effective in reducing pain as measured by this pain pressure threshold method. When compared to an effect size of only 0.06 kg/cm2 for the placebo group, if this was found to be statistically significant then it would appear that therapeutic dry needling is superior to sham dry needling in this ability to influence pain. Unfortunately, the authors of this study elected to perform statistical analysis on the post-treatment means between groups rather than the effect size. This analysis compared a post-treatment mean for the study group (3.21±1.06) to the placebo group (2.85±0.35), which was found to be statistically significant. This different does not account for the pre-treatment differences between groups however.With regard to VAS pain scale, there were significant effect sizes for both the study group (2.44± 1.73) and the placebo group (1.88±1.20), indicating that both therapeutic dry needling and sham dry needling are effective for reducing self-report of pain through this method. While, the effect size of the Study group was slightly larger than that of the placebo group, the authors chose to analyse the post-treatment results between groups rather than the effect size. The difference in post-treatment mean VAS pain scale was only 3.88-3.80=0.08 which was not statistically significant. The outcome measure for pain free jaw mandible depression range of motion yielded no statistically significant results in this study. The effect size for the study group indicated that the average unassisted jaw-opening without pain decreased by 1.12±4.79 mm. However, it should be noted that the 40.08 mm and 39.60 mm measured post-treatment are both within the window of normal range of motion for mandibular depression of 35-50mm.The authors did little to account for the how appropriate the sample size was with regard to a priori power analysis. It was stated that the post hoc power for the algometric measurements was 0.99, but no information was given with regard to the VAS or unassisted jaw-opening without pain in terms of power analysis. It is possible that there was insufficient power to sufficiently rule out a Type II error for an effect between groups for VAS scale change with intervention. It is unlikely that a statistically significant effect size to support the use of therapeutic dry needling over sham needling for improved range of motion was missed due to type II error given that the study group decreased distance of unassisted jaw-opening without pain in the study group following the intervention. Although the authors specifically stated that the physician performing the assessments was different than the one performing the interventions, there was little information provided regarding the total number, level of training, and back ground knowledge of the assessors or the physicians performing the interventions. This variability between physicians represents a potential source of bias.The results of this study indicate the potential for beneficial use of TDN at trigger points in the masseter and temporalis to reduce pain in patients with similar clinical features as the individual in my clinical question. The true value of this potential cannot be objectively evaluated when used in conjunction with other physical therapy interventions as this has not been directly examined in this experiment. Interventions which can have positive impacts on pain which do not demonstrate major side effects may be helpful in the creation of a state in which other physical therapy interventions are more effective and less uncomfortable for the patient. |

**(2) Description and appraisal of “Short-term effects of dry needling of active myofascial trigger points in the masseter muscle in patients with temporomandibular disorders.” by Fernandez-Carnero J, et al. (2010)**

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| **Aim/Objective of the Study/Systematic Review:** |
| The aim of the study was to determine if deep dry needling of the masseter muscle is more effective than sham dry needling in short term pain relief and improving range of motion. |
| **Study Design** |
| * The study was a double-blind, randomized, cross-over, placebo-controlled trial.
* Participants were recruited from those presenting with pain to the Dental and Orofacial Pain Department of Universidad Rey Juan Carlos, Madrid Spain.
* All potential participants were systematically examined to determine a diagnosis of myofascial TMD according to the Research Diagnostic Criteria for Temporomandibular Disorder (RCD/TMD) by an experienced specialist dentist with 15 years of experience in orofacial pain.
* Of the 12 participants in the study, they were randomized by an external clinical assistant using a computerized randomization program which divided them into 2 groups of 5 (experimental vs sham)
* Pre-intervention outcome measures were performed by an external assessor in random order.
* Participants were not allowed to take any analgesic or anti-inflammatory drug for 48 hours prior to each session.
* The therapist was blinded to pre and post intervention outcomes and had 5 years of clinical experience in dry needling.
* Participants in the experimental group received the dry needling intervention from a therapist blinded to the pre-intervention data and then crossed over to receive the sham intervention at least 7 days later at the same time of day.
* Participants in the sham group received sham dry needling from a therapist blinded to the pre-intervention data and then crossed over to receive the dry needling intervention at least 7 days later at the same time of day.
* Post-intervention outcome measures were taken 5 minutes following treatment by the same external assessor who was blinded to the participants’ treatment group.
* Participants were asked with standardized questioning to determine if they were able to recognize whether their treatment was real or sham.
* Statistical analysis with SPSS 14.0 was used to:
* Calculate mean values and standard deviations (SDs) or 95% Cis for each variable.
* Calculate ICC and SEM to assess intra-examiner reliability.
* Compare pre-intervention values with independent t-tests.
* Compare the between participants variable of intervention (sham vs DDN) and time (pre-post test) as the within subjects variable using ANOVA to determine the effects of the intervention.
* Compare group x time interactions for PPT and active mouth opening using separate ANOVAs.
* There was no discussion of power.
* There was no intention to treat or data analysis.
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| **Setting** |
| * Dental and Orofacial Pain Department of Universidad Rey Juan Carlos, Madrid Spain. Study supervised by the Department of Physical Therapy, Occupational Therapy, Rehabilitation and Physical Medicine at the Universidad Rey Juan Carlos, Madrid, Spain.
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| **Participants** |
| * 30 consecutive patients were screened for eligibility between January and July of 2008.
* 12 total subjects (N=12) met inclusion criteria and agreed to participate.
* Gender: 12 Female (100%)
* Age: 20-41 years (mean 25, SD ± 6 years)
* Mean duration of facial pain: 49.2 months (95% CI 26.0-72.4)
* Numeric Pain Scale (NPS)
* Mean current level of pain: 3.4/10 (95% CI 1.9-5.0)
* Mean worst pain in the past 24 hrs: 6.2 (95% CI 4.8-7.5)
* Mean lowest level pain in the past 24 hours: 2.2 (95% CI 1.0-3.5)
* Pain Pressure Threshold (PPT) (kPa)
* PPT levels between groups over the masseter (P=0.4) and mandibular condyle (P=0.3) were not significantly different between groups.
* Masseter Pre-treatment Mean (95% CI)
* Dry Needling: 98.5 (81.1-115.7)
* Sham: 108.7 (91.4-126.1)
* Mandibular Condyle Pre-treatment mean (95% CI)
* Dry Needling: 91.5 (70.6-112.3)
* Sham: 113.3 (95.5-131.1)
* Pain-free maximal jaw opening
* Jaw opening (P=0.3) was not significantly different between groups.
* Jaw Opening Pre-treatment mean (mm) (95% CI)
* Dry Needling: 30.9 (26.2-35.5)
* Sham: 36.2 (29.8-42.2)
* Inclusion Criteria:
* Primary diagnosis of myofascial pain as defined by Research Diagnostic Criteria for TMD (RDC/TMD)
* Pain at the masseter muscle
* At least 6 months duration of symptoms
* Pain on palpation of jaw musculature
* Limited mandibular range of motion
* Mean weekly pain intensity of 3cm/10cm VAS
* Exclusion Criteria:
* Cervical trauma
* Systematic joint or muscle pathology
* Fear of needles
* Bleeding disorder
* Metabolic disease
* Neurological pathology
* Vascular disease

Previous exposure to acupuncture, dry needling or physical therapy in the 6 months prior |
| **Intervention Investigated** |
| *Placebo (Sham Dry Needling)* |
| * 2 treatments administered at least 7 days apart from each other randomly assigned to either placebo (sham dry needling) or experimental (deep dry needling) group with group crossover for the second treatment.
* Administered by a therapists with > 5 years of experience in therapeutic dry needling.
* Needles used: stainless steel, manufactured by Novasan (Maraca “Ener-Qi” CE0197);
* size: shorter (0.26x13mm)
* Location Selection:
* Most painful active trigger point (TrP) on the masseter.
* Procedure:
* Area disinfected with alcohol.
* Needles inserted perpendicular to skin with telescope device only “a few” mm into the skin without producing a local twitch response.
* Pressure applied upon removal of the needle for 10 seconds using a cotton swab.
* Needling site re-examined for soreness with participant prompted to report any painful reaction.
* Post-intervention outcomes assessed 5 minutes following the intervention by the same external assessor who performed the pre-intervention assessment.
 |
| *Experimental (Deep Dry Needling)* |
| * 2 treatments administered at least 7 days apart from each other randomly assigned to either placebo (sham dry needling) or experimental (deep dry needling) group with group crossover for the second treatment.
* Administered by a therapists with > 5 years of experience in therapeutic dry needling.
* Needles used: stainless steel, manufactured by Novasan (Maraca “Ener-Qi” CE0197);
* size: longer (0.26x25mm)
* Location Selection:
* Most painful active trigger point (TrP) on the masseter.
* Procedure:
* Area disinfected with alcohol.
* Needles inserted perpendicular to skin with telescope device.
* Needle directed into the TrP in the masseter muscle until provocation of first local twitch response and then repeatedly inserted and withdrawn rapidly to produce a total of 5 twitch responses.
* Pressure applied upon removal of the needle for 10 seconds using a cotton swab.
* Needling site re-examined for soreness with participant prompted to report any painful reaction.

Post-intervention outcomes assessed 5 minutes following the intervention by the same external assessor who performed the pre-intervention assessment. |
| **Outcome Measures** (Primary and Secondary) |
| It appears x is the primary outcome measure was the Pressure Pain Threshold over the mandibular condyle and active TrP of the Masseter muscle with the pain-free maximal jaw opening and numerical pain rating scale as exploratory outcome measures.* Numerical Pain Rating Scale (NPRS)
* 0-10 with 0=no pain and 10=maximum pain.
* Used to asses current, highest and lowest pain level in the past 24 hours.
* Pressure Pain Threshold (PPT) (kPa/s)
* An electric algometer (Somedic AB) is an instrument which measures applied pressure to a 1 cm2 rubber disc which is pressed at a 90 degree angle over the mandibular condyle and point of maximal sensitivity on the masseter which elicited referred pain (indication of an active TrP)
* The pressure of the algometer was increased at a speed of 30 kPa/s.
* The participants pressed a switch to indicate the pain threshold.
* The mean was taken for 3 trials with a 30 second rest period between each trial.
* Masseter Muscle [ICC] = 0.94 (95% CI 0.88-0.97) SEM: 4.3 kPa
* Mandibular Condyle [ICC] = 0.916 (95% CI 0.83-0.96) SEM: 4.9 kPa
* Higher pressures indicated decreased pain sensitivity with an observed range of maximum=204.1 kPa and minimum=70.6 kPa.
* Pain-Free Active Maximal Jaw Opening (mm)
* Participants asked to open mouth as wide as possible without causing pain or discomfort
* Measured as the distance between the upper and lower central incisors.
* Specific procedure was not included in the methods but is typically done with a tape measure.
* Larger distances indicate greater range of motion for mandibular depression with an observed maximum=47.7 mm and minimum=26.2 mm.
* [ICC] 0.95 (95% CI 0.9-0.97) SEM: 1.22 mm.
 |
| **Main Findings** |
| * For the experimental (deep dry needling) intervention (both before and after the crossover)the differences in the three outcome measures were observed for pre-intervention and post-intervention:
* PPT masseter muscle (kPa): Mean (95% CI)
	+ - Pre-treatment: 98.5 kPa (81.1-115.7) to Post-treatment: 176.5 kPa (157.2-195.9)
		- % Mean difference: 79.1% (57.4-98.8)
* PPT mandibular condyle (kPa): Mean (95% CI)
	+ - Pre-treatment: 91.5 kPa (70.6-112.3) to Post-treatment: 182.0 kPa (159.9-204.1)
		- % Mean difference: 98.9% (78.5-125.6)
* Active mouth opening (mm)
	+ - Pre-treatment: 30.9 mm (26.2-35.5) to Post-treatment: 41.5 mm (35.2-47.7) mm
		- % Mean difference: 34.3% (7.7-13.5) mm
* For the placebo (sham dry needling) intervention (both before and after the crossover)the differences in the three outcome measures were observed for pre-intervention and post-intervention:
* PPT masseter muscle (kPa): Mean (95% CI)
	+ - Pre-treatment: 108.7 kPa (91.4-126.1) to Post-treatment: 100.0 kPa (80.6-119.4)
		- % Mean difference: -8.0% (-21.8-4.4)
* PPT mandibular condyle (kPa): Mean (95% CI)
	+ - Pre-treatment: 113.3 kPa (95.5-131.1) to Post-treatment: 104.9 kPa (86.9-123.7)
		- % Mean difference: -7.4% (-20.7-4.0)
* Active mouth opening (degrees)
	+ - Pre-treatment: 36.2 mm(29.8-42.2) to Post-treatment: 36.1 mm (29.8-42.3)
		- % Mean difference: -0.2% (3.0-2.8) mm
* ANOVA was performed to detect interaction of intervention and time for all 3 outcome measures.
* PPT masseter muscle: F=62.5; P<.001
* PPT mandibular condyle: F=50.4; P<.001
* Active mouth opening: F=34.9; P<.001
* The difference in % mean increase between pre-post intervention for the deep dry needling (DDN) was significantly greater than that following the sham dry needling (SDN) for all 3 outcome measures (P<.001)
* PPT masseter muscle: % Mean difference: DDN: 79.1% ± 44% vs. (SDN): -8% ± 14%
* (P<.001)
* PPT mandibular condyle: % Mean difference: DDN: 98.9% ± 53% vs. (SDN): -7.4% ± 13%
* (P<.001)
* Active mouth opening: % Mean difference: DDN: 34.3% ± 17% vs. (SDN): -0.2% ± 8%
* (P<.001)

The main findings of this study were that pain as measured by PPT and range of motion as measured by pain-free active mouth opening were significantly improved 5 minutes following deep dry needling to active TrPs in the masseter muscle as compared to sham dry needling. These results were demonstrated at statistically significant levels (P<.001) and observed in the same participants who received both interventions with the cross-over design of this experiment. |
| **Original Authors’ Conclusions** |
| The authors of the study concluded that dry needling of active trigger points in the masseter muscle demonstrates significant short-term beneficial effects on pain and range of motion in patients with myofascial TMD. These beneficial effects were only assessed in the short-term, with the authors indicating the need for further exploration of long term clinical application through future RCTs of TDN incorporated into multimodal treatment of patients with myofascial TMD, with larger sample sizes and long-term outcome assessments. The authors interpret the results of this study to be consistent with previous research on the central and peripheral effects of TDN on pain and muscle activation, without drawing specific conclusions about which of these underlying mechanisms is responsible for the findings of this experiment. The authors acknowledge limitations of the study including the lack of long-term assessments and small sample size. The authors also acknowledge the potential of contamination of outcomes due to carry over effects of previous interventions from the crossover design but conclude that this was minimal given the seven day rest between interventions and lack of significant difference between pre-intervention outcomes. |
| **Critical Appraisal** |
| **Validity** |
| * Level of evidence 1B Random controlled trial.
* JADAD scale: 5/5 1-Randomization is mentioned; 1-method of randomization is appropriate; 1- blinding is mentioned; 1-method of blinding is appropriate; 1-the fate of all patients is known.
* PEDro: 9/11 based on eligibility criteria: YES; Random allocation: YES; Concealed Allocation: Yes; Baseline Comparison: Yes; Blind Subjects: YES; Blind Therapist: NO; Blind Assessors: YES; >85% participant outcomes: YES; Intention to treat analysis: NO; Between group comparison: YES; Point estimates and variability: YES
* ICC of repeated measures were provided to establish the reliability of the measurement methods used for each of the outcome measures.

Limitations/weaknesses* Recruitment procedure: it is unclear how many persons met inclusion criteria that were not interested in participating in the study. This may represent a possible source of selection bias for those who chose to participate. Participant compensation for participation is also not addressed by the article.
* The exact timeline other than “greater than seven days” between interventions was not discussed. Given the small sample size, and crossover design, the exact time between interventions has significant potential to mediate carry-over effects from the first intervention to the second. Furthermore, there is no discussion of how the time period of “greater than seven days” was selected as an appropriate wash-out period to limit carry-over effects.
* The Table with results indicates that active maximum pain free jaw opening is reported in degrees but the methods, SEM, and referenced ICC from a previous experiment all indicate that it was measured in mm, which would be consistent with data included in the table. It is likely that this was nothing more than a publication error in the table.
* The Numerical Pain Rating Scale (NPRS) was introduced as an outcome measure to be taken pre-intervention but no data from this measure or discussion of it was included in the article beyond the methods section. Similarly, the methods section indicates that participants were questioned following the intervention by the therapist concerning their ability to detect the particular intervention (DDN vs sham) which they received but the results of this questioning was not included or referenced in the article.
* The study lacks a true control group which did not receive either therapeutic dry needling or sham dry needling. This control group would be helpful to determine the degree of placebo effect for both the genuine and sham treatments along with controlling for potential effects of the sham dry needling intervention itself. Interestingly the sham dry needling interventions generally resulted in small increases in pain sensitivity as seen by the PPT for both the masseter muscle and mandibular condyle locations, but the potential mechanisms of this effect, albeit minimal, were not discussed in the article.
* There was no discussion of a priori or post hoc power analysis which would be especially pertinent with such a small sample size (n=12).
* There was no intention to treat analysis.
 |
| **Interpretation of Results** |
| * The effect sizes demonstrated in this experiment following deep dry needling of active trigger points in the masseter indicate a statistically significant and clinically relevant short term effect on pain and range of motion. The use of Pain Pressure Threshold measurements to assess clinical TMD pain in women has been validated with the finding that this measure has both discriminant and predictive validity for chronic pain over a 3 month period.12 Effect sizes of 78 kPa at the masseter and 90.5 kPa at the mandibular condyle and 10.6 mm of increased pain free mouth opening all following dry needling intervention represent meaningful clinical benefits. Given the lack of any benefits, even below the level of statistical significance indicate that the significant experimental effect sizes are not due to placebo effect (assuming that the sham acupuncture technique was an effective control).
* The limitation of this study to the evaluation of pain and range of motion to only five minutes following the treatment does significantly limit the assumptions regarding clinical utility for achievement of long-term lasting effects. It is important to keep in mind that this treatment modality is designed to be used in conjunction with other physical therapy interventions and in this way, a short-term effect can possibly facilitate further benefits through the ability to render subsequent intervention techniques more effective. Many other physical therapy interventions to address TMD can experience limitations due to pain and limited range of motion. In this way, even short-term benefits have the potential to allow for long-term benefits when used in combination with other physical therapy interventions for this patient.
 |

**(3) Description and appraisal of “Deep dry needling of trigger points located in the lateral pterygoid muscle: Efficacy and safety of treatment for management of myofascial pain and temporomandibular dysfunction.” by Gonzalez-Perez et al. (2015)**

|  |
| --- |
| **Aim/Objective of the Study/Systematic Review:** |
| The aim of the study was to determine if dry needling of trigger points in the lateral pterygoid muscle is more effective than oral methocarbamol/paracetamol pain medication in management of myofascial pain and temporomandibular dysfunction. |
| **Study Design**. |
| * The study was an open, randomized, single center controlled trial.
* Specific recruitment methodology is not included but it is implied that participants were recruited from patients seen at the multidisciplinary training and research hospital mentioned above.
* Participants were randomly assigned to either deep dry needling (DDN) treatment group or control (medication) group using Epidat 4.0.
* DDN group received dry needling to lateral pterygoid muscle (LPM) once per week for three weeks
* The control group received a combined drug (380 mg methocarbamol + 300 mg paracetamol) at dose of 2 pills taken every six hours for three weeks.
* Outcome measures were collected at days 0, 28, and 70 for both groups by the same experimenter.
* Statistical analysis with SPSS 19.0 was used to:
* Compare longitudinal data with Friedman test.
* Assess qualitative variables absolute and relative frequencies.
* Assess normality of quantitative variables with Shapiro-Wilk test.
* Assess non-normal data with non-parametric tests.
* Compare pre- and post- intervention outcomes between groups with the Friedman test.
* Assess intra-group variations over time with the Wilcoxon signed ranks test.
* Compare between groups at each 0, 28, and 70 days with the Mann-Whitney U test.
* Value of p<0.05 were determined significant.
* No a priori power calculation was discussed. The power was found to be 0.99 in post-hoc power analysis for algometric measurements.
* There was no intention to treat data or analysis.
 |
| **Setting** |
| * Outpatient Clinic of the Department of Oral and Maxillofacial Surgery at the Virgen del Rocio University Hospital, Seville (Spain)
 |
| **Participants** |
| * 48 total subjects (N=48)
* Gender: 19 Female/10 male
* Age: 20-48 years
* DDN Group (n=24)
	+ Age: (mean ± SD): 34.3 ± 13.8
	+ Sex: 19 Female/5 Male
	+ TMJ effected side: Right: 12 Left: 12
	+ # Participants who completed the study: 24
* Day 0 Baseline Outcome Measures:
* Median VAS Pain Score at rest [P25-P75]: 5.65 [4.65-7.17]
* Median VAS Pain Score on mastication [P25-P75]: 6.75 [5.77-8.40]
* Median Jaw Opening Movement [P25-P75]: 42.00 [35.00-46.75]
* Median Left Lateral Movement [P25-P75]: 6.50 [5.00-9.00]
* Median Right Lateral Movement [P25-P75]: 7.00 [5.00-9.00]
* Median Protrusion Movement [P25-P75]: 5.00 [3.00-5.00]
* Control Group (n=24)
	+ Age: (mean ± SD): 35.5 ± 11.2
	+ Sex: 19 Female/5 Male
	+ TMJ effected side: Right: 16 Left: 8
	+ # Participants who completed the study: 16 (8 withdrew during review phase due to personal difficulties preventing appointment attendance)
	+ Day 0 Baseline Outcome Measures:
	+ Median VAS Pain Score at rest [P25-P75]: 5.10 [2.92-6.80]
	+ Median VAS Pain Score on mastication [P25-P75]: 6.15 [1.15-8.17]
	+ Median Jaw Opening Movement [P25-P75]: 40.00 [36.50-48.75]
	+ Median Left Lateral Movement [P25-P75]: 8.00 [6.00-10.00]
	+ Median Right Lateral Movement [P25-P75]: 9.00 [5.25-10.00]
	+ Median Protrusion Movement [P25-P75]: 5.00 [4.25-5.00]
* There were no significant differences between groups at baseline for any outcome measure as indicated by Mann-Whitney U-test values p>0.05 with the exception of the functional dimension of the TMJ Affectation Questionnaire in which there was a statistically significant difference (p=0.030) at day 0 between the two groups but the article does not indicate which group scored higher.
* Enrolment: The study does not indicate how patients were recruited for enrolment but it appears to be a sample of convenience.
* Inclusion Criteria: Must have had myofascial temporomandibular pain for at least 6 months or with limited mandibular range of motion to <40 mm maximum opening and a passive stretch required to force the opening ≥5 mm in accordance with Group 1 criteria of the International RDC-TMD Consortium and have TrPs in the Lateral Pterygoid Muscle (LPM)
* Trigger points diagnosed in accordance with Simmons et al., 200413
* Strong tenderness to palpation in lower belly of LPM.
* Referred pain in maxillary sinus or TMJ region.
* Significant loss of active mandibular range of motion.
* All participants signed consent forms from the Committee for Research and Clinical Ethics of the Hospital

Exclusion Criteria: non-reducing anterior disk displacement TMJ derangement, degenerative joint disease, jaw trauma, vascular pathology, history of tension headaches or migraines, history of infectious or inflammatory conditions in the TMJ region. |
| **Intervention Investigated** |
| *Control* |
| * Methocarbamol 280 mg and paracetamol 300 mg combined
* Dose of 2 tablets taken every 6 hours for a duration of 3 weeks.
* Outcome measures taken on days 0, 28, and 70 by the same experimenter.
 |
| *Experimental (DDN Group)* |
| * Therapeutic dry needling using (0.25mm x 40mm) sterile stainless steel acupuncture needles with cylindrical plastic guide (Agu-punt).
* Once a week for 3 weeks (total of 3 treatments)
* Applied to trigger points in the LPM
* Procedure
* Periauricular area swabbed with 90˚ F alcohol.
* LPM manually located unilaterally via intra and extra-oral palpation.
* DDN applied to myofascial TrPs in the LPM to provoke local twitch response (LTR)
* Compressive haemostasis applied for 1 minute.
* Needle insertion to depth allowed by plastic tubes and stimulated 3-5 times.
* All participants were provided with an educational program about TMJ disorders.
* Oral and written consent were obtained for all participants and approved by the local ethics committee.
 |
| **Outcome Measures** (Primary and Secondary) |
| It appears that primary outcome measure were VAS-pain score at rest and with mastication and range of motion measurements taken at Days 0, 28, and 70. Exploratory outcome measures included the TMJ Affectation Questionnaire, the overall efficacy ratings from participants and authors, and the type and frequency of reported adverse events at each visit.* VAS pain at rest
* The 10 cm VAS from 0-10 with 0=no pain at all and 10=the worst pain ever experienced. This measure ranged from 0.30-7.17.
* VAS-pain upon mastication
* The 10 cm VAS from 0-10 with 0 indicating no pain at all and 10 indicating the worst pain ever experienced. This measure ranged from 0.20-8.30.
* Mandible Range of Motion (mm)
* Measured with a Therabite ruler Specific procedure was not included in the methods but included measurements of:
* opening (mandibular depression): ranging from
* lateral excursion:
* Protrusion: were taken. This measurement ranged from 35.78-48.89 mm.
* TMJ Affectation Questionnaire
* 100 point scale with 0=worst state and 100=optimum state
* 3 dimensions
* Pain (40 points)
* Function (45 points)
* Mastication (15 points)
* Overall Efficacy Ratings
* Completed by both Patient and Authors
* Efficacy: 5 point scale with 0=worst and 4=optimum
* Tolerability: 5 point scale with 0=very bad; 1=bad; 2=acceptable; 3=good; 4=excellent.
* Type and Frequency of reported adverse events measured at each visit.
* All three outcome measures were taken immediately before the first intervention and one week following the last needling intervention. The measures were taken by another physician other than the treating physician who was blinded to the participant groups.
 |
| **Main Findings** |
| * The results of this study demonstrate statistically significant reduction in pain at rest and with mastication for both the control and experimental group between 0-28 days and 0-70 days as measured by median VAS scores. This reduction in pain was significantly better for the DDN group compared to the control group at both 28 and 70 days.
* Change in VAS Median Pain at Rest [P25-P75]=25th-75th Percentile
* Δ Day 0-28
* DDN Group: 4.10 [2.00-5.20] Control Group: 1.50 [0.30-2.38] P=0.005\*
* Δ Day 0-70
* DDN Group: 3.70 [1.90-6.00] Control Group: 1.80 [1.12-2.37] P=0.016\*
* Change in VAS Median Pain with Mastication [P25-P75]=25th-75th Percentile
* Δ Day 0-28
* DDN Group: 4.50 [2.12-5.75] Control Group: 1.40 [0.10-2.15] P=0.000\*
* Δ Day 0-70
* DDN Group: 4.40 [1.60-6.60] Control Group: 1.70 [0.02-3.55] P=0.011\*
* The experimental group showed range of motion improvements in maximum opening (2%), left (38%) and right (29%) displacement and protrusion (40%) at day 70. The control group showed improvement in maximum opening (13.75%) and left side displacement (13%) with no change in right side displacement and a decrease in protrusion (20%) after 70 days. The experimental group demonstrated statistically significant improvement compared with the control group for left displacement, right displacement, and protrusion but not maximum opening.
* Change in Median Jaw Opening [P25-P75]=25th-75th Percentile
* Δ Day 0-28
* DDN Group: 3.00 [0.50-6.00] Control Group: 2.00 [-1.75-5.00] P=0.218
* Δ Day 0-70
* DDN Group: 5.00 [-1.00-6.00] Control Group: 2.00 [-1.00-9.00] P=0.966\*
* Change in Median Left Displacement [P25-P75]=25th-75th Percentile
* Δ Day 0-28
* DDN Group: 1.00 [0.00-3.00] Control Group: 0.00 [-1.00-1.00] P=0.005\*
* Δ Day 0-70
* DDN Group: 2.00 [1.00-4.00] Control Group: -0.50 [-1.75-1.75] P=0.006\*
* Change in Median Right Displacement [P25-P75]=25th-75th Percentile
* Δ Day 0-28
* DDN Group: 1.00 [0.00-3.00] Control Group: 0.00 [-1.00-1.00] P=0.005\*
* Δ Day 0-70
* DDN Group: 2.00 [1.00-3.00] Control Group: 1.00 [-2.00-0.75] P=0.001\*
* Change in Median Protrusion [P25-P75]=25th-75th Percentile
* Δ Day 0-28
* DDN Group: 1.50 [0.00-3.00] Control Group: 0.00 [0.00-1.00] P=0.016\*
* Δ Day 0-70
* DDN Group: 2.00 [1.00-3.00] Control Group: 0.00 [-1.00-0.75] P=0.000\*
* The data results for the TMJ Affectation Questionnaire data were not presented but the results were discussed in the article.
* The functional dimension of the TMJ Affectation Questionnaire indicate that median scores of the DDN group improved by 56% in comparison to a 35% improvement in the control group over 70 days. This improvement on the functional dimension was statistically significant for both groups at both 28 and 70 days but the DDN group showed significantly greater improvement at day 28 when compared to the control group.
* The data for the overall efficacy ratings was not presented but the results were discussed by the authors.
* The percentage of participants who considered treatment outcome as optimal was 42% in the DDN group and 13% in the control group with the authors’ values of 50% in the DDN group and 8% in the control group.
* Tolerance was reported as excellent for 25% of participants in the DDN group and 4% of participants in the control group.
* The data for the type and frequency of adverse events was not presented but the results were discussed by the authors.
* No participants in the DDN group reported or exhibited side effects at days 28 or 70.
* 41% (n=10) of the control group reported side effects related to the medication with the most common side-effect reported being drowsiness.
* The main findings of this study were that both groups demonstrated significant pain reduction at rest and with mastication but that the group who received DDN to the LPM had significantly greater improvements in pain than the control (medication) group. This pain reduction in the DDN group was greater for persons with higher baseline pain levels. Measures of participant and author perceived efficacy favoured the DDN intervention to the medication and 41% of patients in the control (medication) group reported unpleasant side effects with no adverse effects reported in the DNN group. Improvements in active range of motion were observed to be significantly greater in the DDN group than the control group for left and right lateral deviation and protrusion at both 28 and 70 days. Greater improvements in jaw opening were observed for the DDN group in comparison to the control group for both periods, but these differences were not statistically significant.
 |
| **Original Authors’ Conclusions** |
| The authors of the study conclude that deep dry needling (DDN) of the lateral pterygoid muscle (LPM) is a safe and effective method of reducing pain, restoring range of motion, and improving function and is both objectively and subjectively superior the medication used on the control intervention for the treatment of myofascial pain syndrome and TMD associated with trigger points in the LPM. Given the key role of the LPM trigger points in this dysfunction and the challenges of other techniques to access this muscle clinicians should receive training to correctly perform TDN in this clinical scenario. This intervention appears to be especially effective in pain reduction among persons with high baseline pain levels. |
| **Critical Appraisal** |
| **Validity** |
| * Level of evidence 1B Random controlled trial.
* JADAD scale: 4/5 1-Randomization is mentioned; 1-method of randomization is appropriate; 1- blinding is mentioned; 0-method of blinding is appropriate; 1-the fate of all patients is known.
* PEDro: 8/11 based on eligibility criteria: YES; Random allocation: YES; Concealed Allocation: YES; Baseline Comparison: Yes; Blind Subjects: NO; Blind Therapist: NO; Blind Assessors: YES; >85% participant outcomes: YES; Intention to treat analysis: NO; Between group comparison: YES; Point estimates and variability: YES

Limitations/weaknesses* The study lacks a true control group which did not receive either therapeutic dry needling or pain medication. This control group would be helpful in controlling for changes that may have occurred over time without any treatment.
* The decision to use the statistical medians for analysis rather than means was not addressed or justified.
* There is no control for the potential placebo effect of treatment although outcomes were evaluated at 7 and 49 days following the last TDN intervention. This could have greater potential to impact responses to the TMJ Affectation Questionnaire and ratings of overall efficacy.
* Potential experimental design which could achieve control for placebo effect could utilize placebo medication for the DDN group and sham dry needling for the control (medication) group.
* Outcome measures taken at 28 days were a full week following the discontinued use of oral pain medication which would no longer have meaningful influence on pain levels.
* There was limited data presented to determine group homogeneity at baseline.
* Thee was limited data presented relative to TMJ Affectation Questionnaire, overall efficacy ratings, and reported adverse events.
* There was no discussion of statistical power in either a priori or post hoc analysis which opens the possibility of potential Type II errors.
* There was no inclusion of or reference to intention to treat analysis.
 |
| **Interpretation of Results** |
| The effect sizes for improved pain as measured by the VAS at rest and with mastication are significantly larger for the group which received the DDN to the TrP’s in the LPM as compared to the medication group. This significantly larger effect size is true both after 28 days and 70 days. Between the baseline and the first 28 days the median VAS at rest improved by 4.10 in the experimental group compared to 1.50 in the control group. Given that the MCID for the 10 cm VAS for pain has been calculated at 1.37 mm, a change of 4.10 mm certainly seems clinically significant. With the MCID=1.37 mm, this would mean that the control group also demonstrated clinically significant change.14 This is quite possible even without the direct effects of the medication which the participants had not been taking for one week prior to this measurement, simply due to the fact that over 28 days, pain can improve even with no treatment. While this effect does decrease some when observed at 70 days with the DDN group 3.70 compared to the control group 1.80, this effect is still clinically significant. If these effect sizes can accurately be attributed to three quick DDN interventions during the first three weeks, then such an intervention with no reported adverse events, represents a promising treatment modality.Another important aspect of this particular intervention which is highlighted by the authors of the study is the unique challenges presented by TrPs in the LPM. These TrPs have been identified with muscle dysfunction not only in the LPM, but there are significant implications regarding TMD and orofacial pain specific to the LPM. Other physical therapy modalities are challenging for addressing LPM TrPs given the limited physical access to the muscle. In this way, DDN represents an even more valuable answer to this challenge. The results of this study further highlight the increased effect size for pain reduction in persons with elevated baseline measures of pain. It would seem that this treatment intervention is particularly suited for patients currently experiencing high levels of pain associated with TMD. With regard to comparison of the effectiveness of DDN to the pain medication, it should be noted that the outcome measures were administered both 7 days and 49 days after the last day of medication administered. Direct impacts on pain from the mediation would likely not be captured by outcome measures administered so long past the period where this medication is active. This also has bearing on the overall efficacy ratings as the medication is unlikely to be rated as efficacious once it is no longer taken. Furthermore, the dosage of 2 pills every 6 hours for three weeks represents requirements that may themselves reduce tolerability irrespective of side-effects from the medication. |

**EVIDENCE SYNTHESIS AND IMPLICATIONS**

|  |
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| Implications for PracticeThe evidence reviewed provides support for the use of therapeutic dry needling to help manage pain in the clinical scenario of interest. The 2012 RCT authored by Diracoglu et al. provides evidence to support this with significantly improved pain reduction following TDN in comparison to sham dry needling, as measured by pressure pain threshold using an algometer.5 These effects were observed after three treatment sessions of TDN focused at TrPs in the masseter and temporalis performed once per week with assessed after the fourth week. Interestingly, both the TDN and sham dry needling groups demonstrated significant improvement on VAS pain assessments indicating the possible impact of placebo effect on this measure.5 Significant changes in range of motion were not observed for either group but both groups were already within the window of normal range of motion values for pain free maximum opening.5 The 2010 RCT by Fernandez-Carnero et al. evaluated the short term effects of TDN applied to TrPs within the masseter on pain and range of motion.3 These short term effects were assessed five minutes following either TDN or sham dry needling, with the outcome measures of pressure pain threshold and maximal pain free jaw opening.3 These short-term impacts yielded the most powerful effect sizes observed indicating that many of the benefits of TDN on pain and range of motion are greatest immediately following the intervention.3 Furthermore, there minimal to no improvements observed for the sham dry needling intervention when assessed after five minutes with PPT and maximum pain free active jaw opening.3 Interestingly, this experiment was a cross over design which allowed for both groups to receive both TDN and sham dry needling.3 Unfortunately these two interventions were only separated by a seven day washout period and the data was presented in aggregate without adequate information to determine the potential contaminating influence of carry over effects from the first intervention to the second.3 Other studies have indicated more long term effects from just three weekly TDN interventions, with significant impacts on pain, range of motion, and function up to 49 days after the last intervention.2 It should be noted that this intervention focused specifically on TDN of TrPs within the lateral pterygoid muscle, which are highly related to TMD in many cases.2 Interestingly, TDN of the LPM did not result in significant improvement of jaw opening but did result in significant improvement in left and right lateral excursion and protrusion.2 While the LPM is a protagonist of each of these motions, it is possible that TDN of the masseter and temporalis are more instrumental in improvements of jaw opening as these muscles are more responsible for the restriction of this motion.2 In fact an article on a proposed diagnostic classification methodology for physical therapist to use when approaching TMDs stratifies different classifications of muscle masticatory disorders into two main categories.15 Those characterized by tenderness to palpation of the masseter and/or temporalis with associated painful and/or limited mouth opening along with the absence of pain or limitations with lateral excursion and protrusion represent one classification associated with TrPs in the masseter and temporalis.15 On the contrary, a second classification of lateral pterygoid dysfunction and related TrPs is characterized by lateral face pain, pain with resisted protrusion, power stroke, or a special test involving biting on bilateral separators, along with the absence of pain at end range mouth opening.15 Collectively this indicates the importance of matching the correct TDN treatment focus and methodology to the appropriate contributions to TMDs which are complex and overlapping. As a general rule, the use of TDN is most appropriate for TMDs with contributing components of myofascial dysfunction and TrPs present in the muscles of mastication.9,7,5,15 The information provided in the patient scenario is consistent with signs of myofascial dysfunction involvement but this patient does not appear to fit neatly into a single classification proposed by Harrison et al.15 Multiple overlapping contributions are not uncommon in patients with TMD and more information is needed to appropriately rule out other pathological contributions. Further special tests may provide increased insight into the particular dysfunctional muscles of mastication involved. For example, pain with resisted protrusion and pain with biting on bilateral separators, would indicate lateral pterygoid involvement.15 This would not mean that the lateral pterygoid is the only dysfunctional muscle involved, but it could indicate the potential for benefit from TDN targeted at TrPs in this muscle. While there is much concerning TDN’s effects on pain reduction in persons with TMD that is not yet fully understood, it does appear that persons with components of myofascial dysfunction can receive at least short term, significant pain reduction. Even the result of short term pain reduction can have meaningful clinical implications in the context of a physical therapy care plan with multiple interventions as this effect can break the cycle of pain and anxiety and allow for improved participation and effectiveness of other interventions.Implications for future researchThe complexity of TMD pathology and diagnosis in combination with the inconsistent methodology applied in TDN research result in considerable challenges to simplistic conclusions concerning the efficacy of this intervention in all persons with TMDs. There is a need for future research which utilizes more consistent and organized classification systems to identify specific patient characteristics which will benefit most from TDN. Additionally, TDN interventions themselves must become more standardized to draw meaningful conclusions from systematic reviews and meta-analysis. Much of the research on therapeutic benefits of needles in treatment of TMD involves acupuncture which has sometimes overlapping but often different methodological approaches to those of TDN. High quality studies of TDN with long-term outcome assessments and designs which include TDN as part of a comprehensive approach to treatment are currently lacking. A 2010 case series by Gonzalez-Iglesias et al. found that a multimodal treatment approach to TMD including mobilization with movement of the TMJ and cervical spine; cervical and thoracic spine manipulation; and trigger point dry needling resulted in statistically and clinically significant improvements in VAS pain intensity, TMD disability questionnaire scores, and maximum mouth opening range of motion.11 The current research suggests that TDN may be most effective in treatment of TMD when regions of focus are optimized with patient specific characteristics and used as a contributing component to a multimodal approach to treatment.  |

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