Assessment of Treatment Response to Splint Therapy and Evaluation of TMJ Function Using Joint Vibration Analysis in Patients Exhibiting TMJ Disc Displacement with Reduction: A Clinical Study

Abstract

Context, Aim, and Objectives: Diagnosis of temporomandibular joint (TMJ) disc displacement with reduction (DDR) is difficult. Literature combining different subjective parameters of TMJ function with an objective evaluation of TMJ function using joint vibration analysis (JVA) is limited. Hence, the study was planned to diagnose temporomandibular disorder accurately, to do a subjective and objective evaluation of TMJ function, and to assess the effectiveness of different types of splint therapy over the conventional anterior repositioning appliance (ARA) group. Design: Single-blind, randomized, comparative clinical trial conducted in thirty patients, 18–55 years of age, allocated to three groups, i.e., ARA conventional group, centric stabilization splint (CSS), and Soft splint (SS) groups. Subjects and Methods: Preoperative values of comfortable mouth opening (CMO) in mm, maximum mouth opening (MMO) in mm, TMJ clicking and tenderness (grading 0–3), visual analog scale pain score (0–10 cm), and total energy (TE) integral values of both TMJs using JVA were recorded. Postoperative values were taken at the time of delivery of splint at 1st, 2nd, 6th, and 10th week. Statistical Analysis and Results: Intergroup comparison – Kruskal–Wallis test showed no statistically significant difference in CMO, MMO, and TE values of right TMJs among three groups at any point. No significant difference was seen in TMJ clicking and tenderness among groups at any point of time except at 10 weeks and at 2 weeks, respectively, by Chi-square test. Intragroup comparison - Wilcoxon signed-rank test showed the significance of difference \( P < 0.05^* \) in postoperative visits for CMO, MMO, pain score, and TE values. Clinical effect size, extent, consistency, and percentage of cases showing improvement were maximum for CSS group.

Conclusions: The study concludes that the use of JVA for diagnosis along with history and clinical examination increases the accuracy of the diagnosis of DDR. ARA group was used as a conventional treatment option. Although statistically significant difference in pre- and post-treatment values was obtained in all the three groups, CSS group patients showed consistent clinically effective responses and more significant improvement in the subsequent follow-up visits than SS group. Hence, it is advisable to start therapy with CSS splint in TMJ DDR patients to get sooner and effective results without minimum side effects.

Keywords: Clicking, disc displacement, pain, splints, temporomandibular disorder, vibration

Introduction

Temporomandibular disorder (TMD) is a cluster of coexisting conditions and clinical problems, where the occurrence of muscle-related TMDs is more than intracapsular joint-related TMDs.\(^1\) Due to diverse clinical presentations, corresponding different modifications were done in original Research and Diagnostic Criteria for Temporomandibular Disorders (RDC-TMD criteria)\(^2\) and multiple treatment options are being devised. Apart from thorough history, clinical examination, and instrumental and diagnostic casts analysis, the advanced electronic recording techniques such as electromyography, electromechanography, electrovibratography (EVG), electrosonography, thermography, and electrokinetic and axiographic measuring were documented since the 1980s for better diagnosis and more efficient treatment of disc displacement with reduction (DDR).\(^3,4\) The recording of temporomandibular joint (TMJ) sounds is an important tool for the diagnosis and clinical examination of TMDs. So far, only palpation or auscultation (with stethoscope) methods were used, and joint clicking could be classified based on the frequency or velocity of the clicking sound, but its degree could not be classified or quantitatively...
measured.\textsuperscript{[5]} The joint vibration analysis (JVA) based on EVG was such a quantitative technique with 70%–85% sensitivity and specificity in diagnosing DDR which measured the small vibrations produced by condyle during translation.\textsuperscript{[6,7]} The SonoPAK Q/S recording system (BioResearch System Inc., Wisconsin, USA) gives accurate values of intensity, frequency, duration, and precise closing or opening point of occurrence of joint noises of bilateral TMJs of reduced displaced discs by generating vibrations which are distinguishable from vibrations of normal joints on visual inspection of the wavelet transforms.\textsuperscript{[8]} Reliability of the phenomenon (vibration) was evaluated by two studies, which found a large range of reliability values of joint sounds.\textsuperscript{[9,10]}

As TMDs share multifactorial etiology and many coexisting factors contribute in the progression and management of disease, it becomes disorienting to treat a TMD in the correct manner. Hence, the treatment of all TMDs cannot be same, and treatment plan for each type of TMD should follow a specific guideline by starting with conservative therapies such as physical therapy, pharmacotherapy, splint therapy, and more stringent nonconservative therapies (comprehensive occlusal rehabilitation and TMJ surgeries) should be considered only when former fails. As the nonconservative therapies are irreversible, they should be used only as the last resort; also reevaluation and long-term follow-up are obligatory for nonconservative therapies to ensure complete remission of the disease.\textsuperscript{[11]} While treating TMDs, challenge for clinician is to choose the correct type of splint although some studies suggested that success of splint therapy has less to do with the splint make or type and more to do with the primary disjunction of ingrained neuromuscular reflexes due to partial nonengagement of maxillary and mandibular teeth.\textsuperscript{[10,11]}

The conventional routinely followed design, i.e., anterior repositioning appliance (ARA) requires regular and repeated evaluation with risk of posterior open bite in the long run. There are studies in literature suggesting centric stabilization splints (CSSs) show fewer problems in comparison to ARA after treatment\textsuperscript{[5,12]} and that soft splints (SSs) should be used more in cases of myofascial pain dysfunction syndrome (MPDS) than intracapsular TMDs\textsuperscript{[1]}

Whether to use JVA or imaging or any other technique for diagnosis of DDR, this decision should be made depending on many factors such as patient condition, affordability, radiation exposure, and invasiveness. In confusing situations where diagnosis is difficult, JVA comes out as an easy, noninvasive radiation free quantitative technique to assist in diagnosis.\textsuperscript{[6,7]} The plausive natural course of DDR justifies active treatment reserved for symptomatic cases where primary treatment is a conservative, nonsurgical reversible splint therapy which focuses on hastening the natural process of pain alleviation and increased mouth opening. Although literature contains numerous studies about the treatment of TMDs using ARA or CSS or SS either alone or with other modalities such as physical therapy or counseling, there is no study in the past which combines the use of JVA with other parameters of TMJ function and compares three different splints simultaneously and this is from where the current study finds its basis.

Objectives

The current study thus intends to give diagnosis-based treatment and evaluation of its response subjectively and objectively using JVA and compare the effectiveness of three different types of splints in TMJ DDR patients while focusing on the specific individual needs rather than relying on preconceptualized notions or on an universally applicable stereotyped concept as radiographic diagnostic techniques such as arthrography, computed tomography, and magnetic resonance imaging (MRI) which are either invasive, with radiation risk, or expensive.

Subjects and Methods

Study design

This was single-blind, randomized, parallel group, and comparative clinical trial carried out at the Department of Prosthodontics of Maulana Azad Institute of Dental Sciences, New Delhi in the year 2012–2014.

Ethics

The Ethical Committee of the institution approved the study, and the participants also provided their informed consent to participate in the study after receiving a full explanation of its purpose and methods by patient information sheet.

Inclusion and exclusion criteria

After diagnosis of DDR cases of 18–55 years of age group complaining of TMJ pain and/or clicking (palpable or audible stethoscope not used) and/or reduced mouth opening and/or deviated mandibular movements/any other symptom with the help of RDC-TMD criteria, total thirty dentate patients were selected and divided randomly into three groups (ten each): ARA group (conventional treatment), CSS group, and SS group. Patients having pacemakers, metallic stents, etc., having TMJ ankylosis; having symptoms related to other stomatognathic system diseases (e.g., toothache and neuralgia); having cervical spondylitis referring to TMJ; and having systemic diseases with referred pain to TMJ (e.g., rheumatoid arthritis, etc.) were excluded from the study.

Sample size

The planned sample size was ten patients in each treatment group with a total sample size of thirty based on the previous study conducted by Mazzeto et al.\textsuperscript{[8]} which had a total sample size of 31 ($n_1 = 23, n_2 = 8$); hence, in the
current study, final sample size was fixed at ten patients per group (total 30).

The characteristics of participants included in each group (age, sex, and other important variables) were assessed and analyzed before intervention to see if groups were comparable.

**Study procedures**

**Step 1: Preoperative examination**

Preoperative baseline values of comfortable mouth opening (CMO) in mm [Figure 1a]; maximum mouth opening (MMO) in mm [Figure 1b]; TMJ clicking/noise (Grade 0–3 for no clicking/noise; faint clicking/noise only on palpation; clicking, clearly felt on palpation; and loud audible clicking even without palpation) [Figure 1c]; TMJ tenderness (Grade 0–3 for no pain/pressure only on palpation; mild pain on palpation; moderate pain on palpation; and severe pain on palpation) [Figure 1d and e]; pain score (measured on a visual analog scale [VAS] of 0–10 cm); and total energy (TE) integral values of right and left TMJs obtained by JVA record were taken.

**Step 2: Joint vibration analysis record**

JVA sensors (BioJVA™, BioResearch) [Figure 2a] were placed over the patient’s TMJs, and sensor wires were plugged into the amplifier [Figure 2c]. Patient was trained to achieve synchronization of the jaw movements with the metronome on laptop (with Windows XP or latest). Both right and left TMJs vibrations were recorded by asking the patient to follow the metronome of opening and closing movements [Figure 2b], and summary was stored in the software [Figure 2d]. Joint vibrations recorded also helped in the reverification of diagnosis of DDR with the help of flowchart provided with the software [Figure 3].

**Step 3: Bite registration and splint fabrication**

ARA and CSS fabrication: Casts were poured in dental stone for maxillary and mandibular irreversible hydrocolloid impressions made using perforated impression trays. JT-3D Jaw Tracker equipment (JT/TENS™, BioResearch Associates Inc.) capable of measuring three dimensions of translational movement: Vertical, lateral, and anterior/posterior and Magnet (BioPAK) secured on labial surface of mandibular anterior with Stomahesive tape (BioPAK) were used for making bite registration with PVS material (CADBITE, IVOCLAR) [Figure 4a-d]. Casts were mounted with plaster on HANAU Wide-Vue 183-2 articulator with the help of HANAU Spring bow and the bite registration record. The wax-up of splint with modeling wax; processing with transparent clear heat cure resin Dental Products of India (DPI, Mumbai, India) was done; splint was retrieved and polished.

**Step 4: Insertion of splint and follow‑ups**

Splint was checked for retention and any occlusal interferences present on the day of delivery and on subsequent appointments were adjusted using articulating paper (BAUSCH, 40 µ thickness) and Miller’s forceps accordingly in each patient [Figure 5a-f]. Patients were recalled at 1st, 2nd, 3rd, 5th, and 10th week after therapy for follow-up assessment.

**Statistical analysis**

Data obtained were fed to Statistical Package for the Social Sciences (SPSS software, IBM, Bangalore, India) and following tests were performed.

**Intergroup comparison**

Kruskal–Wallis test was used to determine significant intergroup differences in mean values of CMO, MMO,
Devi, et al.: Assessment of splint response in TMJ DDR using JVA

Figure 3: Joint vibration analysis flowchart provided with the software

Figure 4: Bite registration record using jaw tracker. (a) Materials used. (b) Electroganthographic (EGN) trace showing three-dimensional position of mandible in sagittal and frontal plane. (c) Bite registration for anterior repositioning appliance. (d) Bite registration for centric stabilization splint

VAS pain score, and TE values of right and left TMJs; thus to evaluate the change in variables in each subsequent follow-up visit and from appliance delivery to 10 weeks to assess the treatment response.

Clinical effect size was calculated using ARA group as control group applying Morris pretest–posttest control group design formula comparing CSS with ARA and SS with ARA.[13]

**Results**

A total of thirty participants were randomly selected and allocated to a splint therapy group. Baseline demographic variables of three groups such as age, gender, and other variables such as CMO, MMO, pain VAS score, and TE energy of right and left TMJ were comparable before intervention [Table 1].

**Intergroup comparison**

No statistically significant difference was present in mean values of CMO, MMO, VAS pain score, and TE value of right TMJ among three groups at any point of time after therapy which shows that groups were comparable even after the intervention [Tables 2-6]. There was no statistically significant difference in number of patients with present or absent TMJ clicking or noise among three groups at any point of time except at 10-week visit (P = 0.015* with Pearson Chi-square test); in TMJ tenderness on palpation among three groups at each point of time except at 2-week visit where it was significant (P = 0.015* with Pearson Chi-square test).
Devi, et al.: Assessment of splint response in TMJ DDR using JVA

Figure 5: Insertion and adjustment of splints. (a and d) Intercuspal and occlusal view of anterior repositioning appliance. (b and e) Intercuspal and occlusal view of centric stabilization splint. (c and f) Intercuspal and occlusal view of SS

Table 1: Baseline demographic and clinical characteristics of study groups

| Characteristics                                      | ARA group          | CSS group          | SS group          | Significant P value* (between groups) |
|------------------------------------------------------|--------------------|--------------------|-------------------|---------------------------------------|
| Age (years)                                          | 27.1±7.19 (18-40)  | 30.8±10.36 (19-55) | 32.1±15.23 (19-60) | 0.602                                  |
| Gender (male:female)                                 | 6:4                | 7:3                | 5:5               |                                       |
| CMO (mm) at the time of appliance delivery           | 39.9±7.37 (28-52)  | 34.90±8.39 (20-45) | 34.90±8.85 (28-55) | 0.219                                  |
| MMO (mm) at the time of appliance delivery           | 46.8±5.1 (40-54)   | 43.0±8.15 (25-50)  | 42.9±8.54 (33-58)  | 0.330                                  |
| TMJ clicking or noise (Grade 0, 1, 2, 3)             | 0:1:5:4            | 0:4:6:0            | 0:3:4:3           | 0.210                                  |
| TMJ tenderness on palpation (Grade 0, 1, 2, 3)       | 4:2:2:2            | 1:2:6:1            | 0:3:3:4           | 0.131                                  |
| Pain VAS score (0-10 cm)                             | 3.1±2.47 (0-7)     | 4±2 (0-8)          | 4.2±2.27 (2-9)    | 0.587                                  |
| TE integral value right TMJ                          | 84.68±126.10 (4.3-318.7) | 10.50±11.22 (2.9-40.4) | 24.71±40.26 (2.4-106.9) | 0.095                                  |
| TE integral value left TMJ                           | 70.85±82.04 (2.9-198.5) | 11.43±12.63 (3.8-46.0) | 18.91±36.73 (2.6-121.4) | 0.244                                  |

*P<0.05, based on ANOVA, Chi-square and Kruskal-Wallis test. SD=Standard deviation, ANOVA=Analysis of variance, ARA=Anterior repositioning appliance, CSS=Centric stabilization splint, SS=Soft splint, CMO=Comfortable mouth opening, MMO=Maximum mouth opening, TMJ=Temporomandibular joint, VAS=Visual analog scale, TE=Total energy

Table 2: Mean comparison of comfortable mouth opening without pain or discomfort (mm)

| Group                                      | Mean±SD (minimum-maximum) | Significant P value* (between groups) |
|--------------------------------------------|---------------------------|---------------------------------------|
| ARA (n=10)                                 |                           |                                       |
| 1 week after splint therapy                | 41.0±7.20 (30-54)         | 0.120                                 |
| 2 weeks after splint therapy               | 42.3±6.50 (32-55)         | 0.154                                 |
| 6 weeks after splint therapy               | 43.3±6.60 (33-55)         | 0.169                                 |
| 10 weeks after splint therapy              | 43.9±6.69 (33-56)         | 0.291                                 |
| CSS (n=10)                                 |                           |                                       |
| 1 week after splint therapy                | 37.50±7.03 (22-50)        | 0.120                                 |
| 2 weeks after splint therapy               | 38.10±7.52 (23-50)        | 0.154                                 |
| 6 weeks after splint therapy               | 39.70±7.65 (24-51)        | 0.169                                 |
| 10 weeks after splint therapy              | 40.80±7.25 (25-51)        | 0.291                                 |
| SS (n=10)                                  |                           |                                       |
| 1 week after splint therapy                | 35.50±9.53 (27-57)        | 0.120                                 |
| 2 weeks after splint therapy               | 36.40±10.53 (21-58)       | 0.154                                 |
| 6 weeks after splint therapy               | 36.80±10.08 (23-58)       | 0.169                                 |
| 10 weeks after splint therapy              | 38.40±10.36 (25-59)       | 0.291                                 |

*P>0.05=Insignificant; *P<0.05=Significant. SD=Standard deviation, ARA=Anterior repositioning appliance, CSS=Centric stabilization splint, SS=Soft splint

Table 3: Mean comparison of maximum mouth opening even with pain or discomfort (mm)

| Group                                      | Mean±SD (minimum-maximum) | Significant P value* (between groups) |
|--------------------------------------------|---------------------------|---------------------------------------|
| ARA (n=10)                                 |                           |                                       |
| 1 week after splint therapy                | 47.90±5.38 (41-56)        | 0.287                                 |
| 2 weeks after splint therapy               | 49.40±4.70 (44-57)        | 0.282                                 |
| 6 weeks after splint therapy               | 50.60±5.30 (44-58)        | 0.253                                 |
| 10 weeks after splint therapy              | 51.20±4.76 (45-58)        | 0.315                                 |
| CSS (n=10)                                 |                           |                                       |
| 1 week after splint therapy                | 44.40±7.91 (27-52)        | 0.287                                 |
| 2 weeks after splint therapy               | 44.60±8.61 (27-54)        | 0.282                                 |
| 6 weeks after splint therapy               | 46.80±7.84 (30-55)        | 0.253                                 |
| 10 weeks after splint therapy              | 48.30±6.88 (34-56)        | 0.315                                 |
| SS (n=10)                                  |                           |                                       |
| 1 week after splint therapy                | 43.50±9.55 (30-59)        | 0.287                                 |
| 2 weeks after splint therapy               | 44.70±10.31 (30-60)       | 0.282                                 |
| 6 weeks after splint therapy               | 45.30±10.12 (32-62)       | 0.253                                 |
| 10 weeks after splint therapy              | 46.60±10.08 (32-62)       | 0.315                                 |

*P>0.05=Insignificant; *P<0.05=Significant. SD=Standard deviation, ARA=Anterior repositioning appliance, CSS=Centric stabilization splint, SS=Soft splint
Table 4: Mean comparison of pain score (visual analog scale score 0-10 cm)

| Group                           | ARA (n=10) | CSS (n=10) | SS (n=10) | Significant P value* (between groups) |
|---------------------------------|------------|------------|-----------|--------------------------------------|
| 1 week after splint therapy     | 2.10±2.69 (0-8) | 3.60±2.55 (0-8) | 3.90±3.25 (0-10) | 0.261 |
| 2 weeks after splint therapy    | 1.60±2.01 (0-6) | 2.60±2.32 (0-6) | 3.40±3.06 (0-9) | 0.322 |
| 6 weeks after splint therapy    | 0.80±1.87 (0-6) | 1.80±2.04 (0-6) | 2.70±3.34 (0-9) | 0.238 |
| 10 weeks after splint therapy   | 0.60±1.27 (0-4) | 1.50±1.65 (0-5) | 2.50±3.24 (0-9) | 0.220 |

P>0.05=Insignificant; *P<0.05=Significant. SD=Standard deviation, ARA=Anterior repositioning appliance, CSS=Centric stabilization splint, SS=Soft splint

Table 5: Mean comparison of total energy integral right temporomandibular joint

| Group                           | ARA (n=10) | CSS (n=10) | SS (n=10) | Significant P value* (between groups) |
|---------------------------------|------------|------------|-----------|--------------------------------------|
| 1 week after splint therapy     | 44.09±83.72 (3.9-279.4) | 15.97±18.28 (3.2-51.3) | 28.30±39.30 (2.1-113.8) | 0.545 |
| 2 weeks after splint therapy    | 32.59±55.54 (2.0-187.3) | 12.46±11.72 (3.1-40.3) | 18.44±27.22 (3.4-92.1) | 0.587 |
| 6 weeks after splint therapy    | 27.51±43.97 (2.2-150.3) | 9.97±10.46 (2.3-35.4) | 9.97±10.46 (2.3-35.8) | 0.326 |
| 10 weeks after splint therapy   | 23.98±35.64 (2.7-121.4) | 7.65±7.78 (2.2-27.8) | 11.07±13.02 (2.0-36.4) | 0.236 |

P>0.05=Insignificant; *P<0.05=Significant based on Kruskal-Wallis test. SD=Standard deviation, ARA=Anterior repositioning appliance, CSS=Centric stabilization splint, SS=Soft splint

Table 6: Mean comparison of total energy integral left temporomandibular joint

| Group                           | ARA (n=10) | CSS (n=10) | SS (n=10) | Significant P value* (between groups) |
|---------------------------------|------------|------------|-----------|--------------------------------------|
| 1 week after splint therapy     | 48.94±56.21 (4.8-160.4) | 14.28±14.38 (3.0-49.1) | 16.16±30.67 (2.9-102.8) | 0.134 |
| 2 weeks after splint therapy    | 35.35±47.20 (3.4-146.1) | 8.79±5.95 (2.5-20.8) | 9.69±9.17 (2.7-32.6) | 0.346 |
| 6 weeks after splint therapy    | 24.79±36.81 (3.2-124.3) | 9.79±9.93 (2.1-33.4) | 8.53±6.24 (2.5-19.7) | 0.305 |
| 10 weeks after splint therapy   | 23.98±33.45 (2.7-121.2) | 7.06±5.44 (1.7-15.6) | 6.54±5.57 (2.1-19.3) | 0.181 |

P>0.05=Insignificant; *P<0.05=Significant based on Kruskal-Wallis test. SD=Standard deviation, ARA=Anterior repositioning appliance, CSS=Centric stabilization splint, SS=Soft splint

Table 7: Wilcoxon signed-rank test for comfortable mouth opening without pain or discomfort

| P (difference between visits)    | ARA (n=10) | CSS (n=10) | SS (n=10) |
|----------------------------------|------------|------------|-----------|
| (difference between 1 week visit and appliance delivery visit) | 0.054 | 0.048* | 0.141 |
| (difference between 2 weeks visit and 1 week visit) | 0.102 | 0.196 | 0.106 |
| (difference between 6 weeks visit and 2 weeks visit) | 0.026* | 0.034* | 0.550 |
| (difference between 10 weeks visit and 6 weeks visit) | 0.084 | 0.026* | 0.019* |
| (difference between 10 weeks visit and appliance delivery visit) | 0.005* | 0.005* | 0.033* |

P>0.05=Insignificant; *P<0.05=Significant. ARA=Anterior repositioning appliance, CSS=Centric stabilization splint, SS=Soft splint

Table 8: Wilcoxon signed-rank test for maximum mouth opening even with pain or discomfort

| P (difference between visits)    | ARA (n=10) | CSS (n=10) | SS (n=10) |
|----------------------------------|------------|------------|-----------|
| (difference between 1 week visit and appliance delivery visit) | 0.008* | 0.064 | 0.551 |
| (difference between 2 weeks visit and 1 week visit) | 0.028* | 0.438 | 0.121 |
| (difference between 6 weeks visit and 2 weeks visit) | 0.014* | 0.005* | 0.288 |
| (difference between 10 weeks visit and 6 weeks visit) | 0.059 | 0.006* | 0.042* |
| (difference between 10 weeks visit and appliance delivery visit) | 0.005* | 0.005* | 0.024* |

P>0.05=Insignificant; *P<0.05=Significant. ARA=Anterior repositioning appliance, CSS=Centric stabilization splint, SS=Soft splint

Intragroup comparison

In Friedman test, there were statistically significant differences between pre- and post-treatment mean ranks in CMO, MMO, VAS pain score, and TE integral in the right and left TMJs in all the three groups.

The Wilcoxon signed-rank test showed statistically significant difference in CMO, MMO, pain VAS score, and TE integral right and left in different follow-up visits in all the three groups [Tables 7-11].

Medium to large clinical effect sizes were obtained in TE integral values of right and left TMJs [Table 12].

The variation in grading of clicking/noise and tenderness on palpation with the progression of therapy was displayed as graphs [Figure 6a-f], and percentage of
Devi, et al.: Assessment of splint response in TMJ DDR using JVA

Table 9: Wilcoxon signed-rank test for pain score

| Parameter | ARA (n=10) | CSS (n=10) | SS (n=10) | Effect size | Effect size |
|-----------|------------|------------|------------|-------------|-------------|
|           |            |            |            | d (CSS vs ARA) | d (SS vs ARA) |
| P (difference between 1 week visit and appliance delivery visit) | 0.194 | 0.389 | 0.160 | 0.237 | -0.06 |
| P (difference between 2 weeks visit and 1 week visit) | 0.059 | 0.024* | 0.059 | 0.033* | -0.098 |
| P (difference between 6 weeks visit and 2 weeks visit) | 0.066 | 0.023* | 0.038* | 0.024* | 0.249 |
| P (difference between 10 weeks visit and 6 weeks visit) | 0.317 | 0.083 | 0.157 | 0.0 |
| P (difference between 10 weeks visit and appliance delivery visit) | 0.017* | 0.011* | 0.009* | 0.636 | 0.495 |

Table 10: Wilcoxon signed-rank test for total energy integral right temporomandibular joint

| Parameter | ARA (n=10) | CSS (n=10) | SS (n=10) | Effect size | Effect size |
|-----------|------------|------------|------------|-------------|-------------|
|           |            |            |            | d (CSS vs ARA) | d (SS vs ARA) |
| P (difference between 1 week visit and appliance delivery visit) | 0.169 | 0.103 | 0.721 | 0.005* | 0.005* |
| P (difference between 2 weeks visit and 1 week visit) | 0.013* | 0.019* | 0.475 | 0.074 | 0.011* |
| P (difference between 6 weeks visit and 2 weeks visit) | 0.221 | 0.074 | 0.507 | 0.019* | 0.011* |
| P (difference between 10 weeks visit and 6 weeks visit) | 0.074 | 0.008* | 0.683 | 0.019* | 0.011* |
| P (difference between 10 weeks visit and appliance delivery visit) | 0.093 | 0.074 | 0.047* | 0.636 | 0.495 |

Table 11: Wilcoxon signed-rank test for total energy integral left temporomandibular joint

| Parameter | ARA (n=10) | CSS (n=10) | SS (n=10) | Effect size | Effect size |
|-----------|------------|------------|------------|-------------|-------------|
|           |            |            |            | d (CSS vs ARA) | d (SS vs ARA) |
| P (difference between 1 week visit and appliance delivery visit) | 0.507 | 0.102 | 0.260 | 0.237 | -0.06 |
| P (difference between 2 weeks visit and 1 week visit) | 0.025* | 0.036* | 0.838 | 0.033* | -0.098 |
| P (difference between 6 weeks visit and 2 weeks visit) | 0.005* | 0.074 | 0.507 | 0.024* | 0.249 |
| P (difference between 10 weeks visit and 6 weeks visit) | 0.241 | 0.022* | 0.007* | 0.0 |
| P (difference between 10 weeks visit and appliance delivery visit) | 0.203 | 0.074 | 0.011* | 0.636 | 0.495 |

Table 12: Effect size calculation and P values within groups from Wilcoxon signed-rank tests

| Parameter | ARA group | CSS group | SS group | Effect size d | Effect size d |
|-----------|-----------|-----------|----------|---------------|---------------|
|           | CSS versus ARA (control) group | SS versus ARA (control) group |
| Mean increase in CMO (mm) from appliance delivery to 10 weeks visit (within group) | 43.9−39.9=4 | 40.8−34.9=5.9 | 38.4−34.9=3.5 | 0.237 | -0.06 |
| Mean increase in MMO (mm) from appliance delivery to 10 weeks visit (within group) | 51.2−46.8=4.4 | 48.3−43=5.3 | 46.6−42.9=3.7 | 0.13 | -0.098 |
| Mean decrease in pain VAS score (0-10 cm) from appliance delivery to 10 weeks visit (within group) | 3.1−0.6=2.5 | 4.0−1.5=2.5 | 4.4−2.5=1.9 | 0.0 | 0.249 |
| Mean decrease in TE integral value right TMJ from appliance delivery to 10 weeks visit (within group) | 84.68−23.98=60.7 | 10.50−7.65=2.85 | 24.71−11.07=13.64 | 0.636 | 0.495 |
| Mean decrease in TE integral value left TMJ from appliance delivery to 10 weeks visit (within group) | 70.85−23.98=46.87 | 11.43−7.06=4.37 | 18.91−6.54=12.37 | 0.712 | 0.534 |

Clinical effect sizes using Morris (2008) pretest-posttest control group design; 0.8 large, 0.5 moderate, 0.2 small; negative effect size indicates that the effect decreases the mean, and a positive effect size indicates that the effect increases the mean. Zero effect size indicates no change in the mean between groups. CMO=Comfortable mouth opening, MMO=Maximum mouth opening, TMJ=Temporomandibular joint, VAS=Visual analog scale, ARA=Anterior repositioning appliance, CSS=Centric stabilization splint, SS=Soft splint, TE=Total energy, P>0.05=Insignificant, *P<0.05=Significant
Devi, et al.: Assessment of splint response in TMJ DDR using JVA

Figure 6: (a-f) Graphs of how gradation of temporomandibular joint clicking or noise and temporomandibular joint tenderness on palpation varies in each group, respectively. Number of patients, along x-axis and follow-up visits, along y-axis

Figure 7: (a-f) Pie chart of percentage of cases showing improvement in temporomandibular joint clicking or noise and in temporomandibular joint tenderness on palpation, respectively in each group with progression of splint therapy

cases showing improvement in each group was shown in pie charts [Figure 7a-f]. For TMJ clicking, a maximum number (100%) of cases with improvement are found in CSS group. For TMJ tenderness on palpation, a maximum number of cases with improvement are found in CSS group (90%).

Discussion
This randomized trial was planned to evaluate and compare the effectiveness of three types of splint therapy. No study in the previous literature has combined different subjective parameters of TMJ function with an objective evaluation of TMJ function using JVA.

Intergroup comparison
No statistically significant difference seen between the groups before and after the intervention showed that the baseline characteristics were comparable in pre- and post-treatment phases. Statistically significant difference in TMJ clicking or noise at 10-week visit and in TMJ tenderness on palpation at 2-week visit could be due to patients responding differently to a given type of splint therapy which will help in proving which type of splint is better.

According to Stiesz-Scholz et al. (active jaw opening increased by a mean of 8.05 mm in stabilization splint therapy group patients versus 8.26 mm in pivot splint group), success of therapy was found independent of splint design and no significant difference was seen between two splint therapy groups they used in anterior disc displacement without reduction patients. In the current study, change in MMO was 4.4 mm for ARA, 5.3 mm for CSS, and 3.7 mm for SS splint therapy group. Other possible reason for no significant difference between groups could be small sample size. Efficacy may also be affected by psychological effects
such as an increase in the cognitive awareness for oral habits, a placebo effect, and spontaneous remission of symptoms.\[5\]

**Intragroup comparison**

**Comfortable mouth opening**

The CSS group patients showed earliest and consistent significant improvement, whereas SS group showed delayed improvement only after 6 weeks. Sato et al. found that CSS group was 13% more successful than the natural course control group, and Minakuchi et al. also found surmountable improvement of mouth opening in CSS group.\[16\] A study by Suvinen and Reade showed 7.4 mm betterment in mouth opening after therapy. Splint therapy in the present study similarly would have led to decreased TMJ pain and tenderness, thus increasing mouth opening.\[17\]

**Maximum mouth opening**

The ARA group patients showed a significant improvement at the earliest within 1 week. CSS group patients started showing a significant improvement from 2 to 6 weeks and continued to show improvement till 10th week, whereas SS group showed delayed significant improvement only after 6 weeks. A study using SS by Elhayes and Hassanien showed decreased TMJ and muscular pain and tenderness, apparently allowing an increase in MMO. Block et al. also showed complete or almost complete abatement of symptoms in 74% patients after 6 weeks of SS therapy.\[18\]

**Visual analog scale pain score**

For pain score, best treatment response was seen with CSS group. Ekberg et al. showed a successful significant decrease in the severity of arthrogenous TMJ pain using VAS over 10 weeks in the CSS splint group versus placebo splint. Raphael et al. found that SS had reduced the VAS scores and the number of painful muscles in 6 weeks for MPDS patients similar to the SS group patients who started showing a significant improvement from 2- to 6-week visit.\[19\]

**Total energy integral right and left temporomandibular joint**

For TE value of right TMJ, ARA group patients showed an earliest significant decrease in energy values and SS group patients showed delayed response, whereas CSS group patients continued to show a significant increase. For TE value of left TMJ, ARA group patients showed an earliest significant decrease in energy values, CSS also showed a significant response at the same time, but it continued to show a significant increase till 10 weeks, and SS group patients showed delayed response. Mazzeto et al. also obtained positive results in short-term assessment of TE value of right and left TMJs using ARA in anterior DDR patients and stabilizing splint in articular disc derangement patients. They concluded that stabilizing splints had satisfactorily reduced the total sound energies, but the use of ARA for no more than 4 weeks produced better results.\[14\]

Garcia et al. also deduced that decrease in joint vibrations was due to the reduction of displaced disc by interocclusal mandibular advancement device.\[21\] In the present study also, the mean values of vibratory intensities decreased, probably due to increased separation between the dental arches by ARA, which could have caused a forward rotation of condyle favoring disc recapture partially or allowing a softer movement.

**Temporomandibular joint clicking or noise**

In ARA group, improvement seen was similar to the study by Clark where temporomandibular repositioning was moderately to highly successful in 86% patients. For CSS group, similar study conducted by Chang et al. showed that splint decreased joint noises by increasing the joint space, permitting smoother condylar translation beyond disc surface inhomogeneity, and positional aberrations to form a novel functional equilibrium in stomatognathic system.\[3\] For SS group, similar study by Harkins et al. explained that splints with same intensity contact on all teeth, with disocclusion of posteriors and condylar guidance in all movements relaxes the elevator muscles which maintains jaw position and contributes to decreased muscle hyperactivity.\[22\]

**Tenderness on palpation**

Relief of symptoms in pain or tenderness in ARA group may be because of the tendency of acute symptoms to regress as seen in control groups of a study.\[24\] A second cause may be the natural course of disease to attain dormancy after long-term follow-up. A third cause may be ability of ARA to ease the adaptation of displaced retrodiscal tissues showing fibrosis.\[25\] For CSS group, pain relief might be credited to discal elongation and horizontal decompression of posterior attachment space as speculated by Levandoski\[26\] or due to force redistribution and stabilization. For SS group, Kovaleski and De Boever showed a similar significant reduction in TMJ clicking and tenderness after 2 months of splint therapy.\[27\]

To summarize, the clinical success of the splint therapy was made on the basis of the reduction in the leading symptoms, i.e., increase in comfortable and maximal mouth opening; decrease in TMJ clicking or noise, TMJ tenderness, pain score, and TE integral values for right and left TMJ inferring that patients were responding to the therapy.

The number of patients in the present study was limited. Repetitive measurements should have been used during longer period of time (months) until any device can be considered satisfactory for the treatment. Although a conventional treatment option ARA group was chosen, there was no passive control group so that the responses to the splint therapies could not be distinguished from possible placebo responses or from the natural fluctuations in the complaints.
In a recent systemic review by Sharma et al. concluded that this literature is unable to provide evidence to support the reliability and diagnostic validity of the JVA for diagnosis of TMD.[28] However, the current study was conducted before this review was available at the time when controversy about the use of JVA was still on. Moreover, the current study did not solely use JVA for diagnosis of DDR cases, RDC-TMD questionnaire was also taken into consideration along with proper history and clinical examination before starting the therapy. Although it was only in the year 2014 when Schiffman et al. suggested changes in the RDC/TMD to move on to the DC/TMD so that the latter can be used in both clinical settings and applied research settings.[29]

The extensive development process continues to be explored, and it is suggested that with increased sample size and with the use of new diagnostic criteria for temporomandibular disorders (DC/TMD) criteria, less reliability and discrepancy in the baseline TE integral values of right and left TMJs between the groups can be taken care of. It is also suggested that degree of clicking/tenderness before treatment and the prognosis after treatment should be correlated with actual degree of disc deformation present using MRI along with JVA whenever possible. Hence, in future randomized double-blinded trials with a larger sample size can be done to validate the effectiveness of one splint therapy over other using JVA.

Conclusions

In the current study, subjective analysis of TMJ function with parameters such as CMO, MMO, pain VAS score, TMJ clicking, and tenderness with objective evaluation of TMJ function using JVA TE integral values was done. The study thus concludes that the use of JVA for diagnosis along with history and clinical examination increases the accuracy of the diagnosis of DDR.

The study also compared the effectiveness of three types of splint therapy. ARA group was used as a conventional treatment option. Although statistically significant difference in pre- and post-treatment values was obtained in all the three groups, the CSS group patients showed consistent clinically effective responses and more significant improvement in the subsequent follow-up visits than SS group. Hence, it is advisable to start therapy with CSS splint in TMJ DDR patients to get sooner and effective results without minimum side effects.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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