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Original Article

Biometric Assessment of Temporomandibular Disorders in Orthodontics: A Multi-arm Randomized Controlled Trial

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Main Points

- The use of biometric equipment is a viable diagnostic and therapeutic modality, offering the advantages of non-radiating and easily reproducible digital quantitative assessment and documentation of temporomandibular disorder (TMD) signs and symptoms.
- Comprehensive fixed orthodontic mechanotherapy does not aggravate TMDs. Temporomandibular disorders attributable to unstable orthodontic malocclusion can be treated successfully with comprehensive orthodontic treatment.
- Temporomandibular disorders due to multifactorial temporomandibular joint (TMJ) and muscular components may usually require adjunctive splint therapy for at least 3 months.

ABSTRACT

Objective: This randomized controlled trial aimed to evaluate the role of fixed orthodontic treatment in the aggravation, precipitation, or alleviation of temporomandibular disorders in young adults.

Methods: Sixty patients were randomly assigned to 4 groups of 15 patients each (group I, orthodontic treatment in temporomandibular disorder-free orthodontic patients; group II, orthodontic treatment in patients with mild symptoms of temporomandibular disorders; group III, splint therapy accompanied by orthodontic treatment in patients with moderate symptoms; and group IV, control with no treatment). The biometric equipment used were the T-scan, to analyze the occlusal component; the BioEMG for muscular analysis; BioJVA for temporomandibular joint acoustic analysis; and JT3D for mandibular kinematic analysis. The paired *t*-test and ANOVA were used for intragroup and intergroup comparisons, respectively. The difference between groups was assessed using post hoc Tukey's test.

Results: Groups I and III showed significant difference in the occlusal, muscular, temporomandibular joint vibration, and kinematic mandibular assessment variables. Group II showed significant improvement in occlusal variables only. Group IV did not show improvement in any of the variables except for certain muscular components.

Conclusion: Successful practical utilization of biometric equipment revealed that fixed orthodontic treatment does not aggravate temporomandibular disorders. It was also found that temporomandibular disorders due to malocclusion can be treated successfully with orthodontic treatment, whereas temporomandibular disorders due to multifactorial temporomandibular joint and muscular components might require splint therapy before orthodontic intervention.

Keywords: JT3D, BioEMG, BioJVA, orthodontic treatment, temporomandibular disorder, T-scan

BACKGROUND

As the dentition is an integral component of masticatory system and plays an important role in maintaining harmony of temporomandibular joint (TMJ), malocclusions such as open bite, deep bite, and posterior crossbite

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have often been reported to be associated with temporomandibular disorders (TMDs) by various researchers.[1,2,3]

Temporomandibular disorders are a collective heterogeneous group of pathologies affecting masticatory apparatus with signs and symptoms of pain, myalgia, limited mouth opening, jaw clicking, crepitus, and subluxation. The myriad treatment approaches include remedial measures, pharmacological therapy, and splint therapy, as well as occlusal rehabilitation by orthodontics, prosthodontics, or surgical procedures.[4]

The possible pathognomic role of orthodontic therapy in precipitation of TMDs, whether at predisposing, initiating, or perpetuating levels, has been widely studied and often debated, especially following a well-publicized lawsuit ascribing orthodontic treatment as a main causative factor of TMJ pain after treatment.[5] However, a recent cross-sectional retrospective study by Manfredini et al.[6] demonstrated the relationship between orthodontic treatment and the presence of specific symptoms of the TMJ to be a "casual" one rather than "causal" one, thereby indicative of the neutral role of orthodontics in TMDs. Several other researchers also concurred, and no obvious cause–effect relationship between orthodontics and TMDs was reported.[7-10] Furthermore, extensive reviews and a few prospective studies have also concluded that irrespective of the orthodontic technique and mechanics employed, the extraction or non-extraction protocols and the type of presenting malocclusion, orthodontic therapy does not precipitate or increase the risk for development of TMD signs and symptoms.[11-16] Even so, the conflict has not been fully settled, as some studies have even reported less-prevalent TMD signs and symptoms in orthodontically treated patients compared with untreated subjects.[16,17]

Moreover, even with existence of well-designed studies elucidating the TMD–orthodontic interrelationship, there is lack of strong evidence-based literature and some orthodontists still suffer from anecdotal testimonials.[18] Thus, the need to supplement evidence-based literature with randomized controlled clinical trials has been stressed quite often.[7] The major limitation in delineating the role of orthodontic treatment for quantification of TMDs signs and symptoms is the lack of resources. With recent reports[3,19] documenting a higher prevalence of pre-existing painful TMD signs and symptoms in patients seeking orthodontic treatment, assessment of the masticatory system, and TMD signs/symptoms using simple TMD-related diagnostic screening and monitoring instruments becomes even more pertinent and indispensable prior to the initiation of orthodontic therapy. Literature has reported analyses based on case history, clinical examination, questionnaire, or radiographic assessments. Paesani et al.[20] reported accuracy of detection of TMDs using the inspection and palpation method, to be as low as 43–50%. With the advent of digital technology, it has been possible to assess the TMJ and associated masticatory complex, not only qualitatively but also quantitatively, which was practically not possible in earlier times. These equipment can be classified based on functional assessment capacity in relation to the craniofacial complex: examples are the digital occlusal analyzer, dynamic masticatory muscle recording devices, temporomandibular joint sonography, and kinematic assessors of the mandible, of BioRESEARCH diagnostic equipment (BioRESEARCH Associates, WI, USA) and the K7 evaluation system (Myotronics - Noromed, WA, USA). These devices augment human intelligence by quantifying occlusion, muscular activity, and TMJ using various parameters such as the dynamic graphical representation of occlusion and three-dimensional jaw movement, which augments the visual perception of occlusion. Additionally, synchronous guidance of muscle and TMJ using BioJVA and EMG aids in augmentation of the tactile assessment of the stomatognathic system.

Though isolated clinical utility of biometric-based bio-medical equipment in diagnosis and treatment planning in neuromuscular dentistry has been reported, till date, no study has reported the role of the muscular, occlusal, or TMJ components of TMDs using the above-mentioned biometric assessment devices in unison.[20-24] The null hypothesis was formulated that that there would be no precipitation, aggravation, or alleviation of TMDs after orthodontic treatment with or without splint therapy.

METHODS

The present study was conducted in accordance with the Declaration of Helsinki ICH Good Clinical Practice guidelines, with Institutional Ethical Committee approval vide letter number 14/IEC/ADCRR/2017, as a multi-arm randomized controlled trial (m-RCT).

Trial Design

i. Multi-arm design with 1 : 1 : 1 : 1 allocation ratio.
ii. No change in trial design was carried out while conducting the trial.

Eligibility Criteria

Patients enrolled for the trial met the following inclusion criteria: (a) all permanent dentition till the second molar minimum in both arches; (b) orthodontic malocclusion, either Angle's Class I, Class II, or Class III; (c) Piper Classification of TMD I, II, or IIIa; (d) Research and Diagnostic Criteria for Temporomandibular Disorders (RDC-TMD), criteria Ia, Ib, and IIa; and (e) symmetrical face with no gross mandibular asymmetry.

Dental occlusion was assessed on the basis of the following morphological occlusal dental relationships: overjet, overbite, crossbite, scissor-bite, anterior open bite, midline discrepancies, and presence of crowding/spacing in each arch. The clinical registration of retruded contact position to maximum intercuspation (RCP-MI) slide length was done in the 3 spatial axes following manual mandibular manipulation. When the RCP-MI slide value was less than 2 mm, it was considered "normal," and as "present" when the value was greater than or equal to 2 mm.[6]

As for the distribution of Angle classes, 38 subjects exhibited Class I malocclusion, 14 exhibited Class II, and 8 exhibited Class III malocclusion. Cephalometrically, the subjects with Class I malocclusion exhibited the following characteristics: upper incisor

to S-N plane angle (U1-SN) > 102°, lower incisor to mandibular plane angle (L1-Mand) > 99°, interincisal angle less than 124.8°, and normal to mild hyperdivergent growth pattern. Patients with Class II malocclusions had ANB angle between 4° and 7° with a hyperdivergent growth pattern, proclined maxillary, and proclined/retroclined mandibular incisors. Class III patients exhibited maxillary retrognathism (SNA ≤ 80°), ANB angle between 0° and −4° along with average to hypodivergent growth pattern. Dentally, Class III patients presented with retroclined upper incisors and anterior crossbite, and demonstrated the ability to achieve an edge-to-edge incisor position in retruded contact position. Negligible to minimal dental compensation was observed in the maxillary and mandibular incisors. The saddle, articular, and gonial angles ranged between 118° and 128°, 138° and 148°, and 124° and 135°, respectively, for included patients with Class I malocclusion; and between 110° and 120°, 135° and 140°, and 130° and 137°, respectively, for included Class III malocclusion. However, the articular angle was slightly larger (147^0 and 153^0) and posterior facial height was slightly reduced due to clockwise rotation of the mandible in Class II subjects.

The exclusion criteria were as follows: (a) orthodontic malocclusion requiring surgery; (b) severe TMDs such as Piper IIIb, IVa, IVb, Va, and Vb, and RDC-TMD IIb and above; (c) mixed dentition or permanent dentition with less than 28 teeth; (d) cleft-lip palate and syndromic patients; (e) presence of facial asymmetry and condylar hyperplasia; and (f) history of orthodontic treatment.

Settings and Locations Where the Data Were Collected

The present study was conducted in the Department of Orthodontics, Tertiary Care Dental Institution from 2017 to 2020, and being reported as per extension of CONSORT guidelines-2010 for multi-arm RCT.[25] The trial was registered with the Central Trial Registry of India vide trial registration number CTRI/2019/02/017534.

Interventions

Groups were divided into 4, according to categories of TMD severity assessed using the Fonseca Anamnestic Index (FAI)[26] (Figure 1):

Group I (n = 15) requiring fixed orthodontic treatment, who had no TMD symptoms, such as absence of clicking, muscle pain, limited jaw opening, or deviation. Mean FAI Score of Group I = 0

Group II (n = 15) requiring fixed orthodontic treatment, who had mild TMD symptoms, such as the presence of clicking, muscle pain, limited jaw opening, or deviation. Mean FAI Score Group II = 23.53.

Group III (n = 15) requiring splint therapy followed by fixed orthodontic treatment, who had moderate TMD symptoms such as presence of clicking, muscle pain, limited jaw opening, or deviation. Mean FAI Score Group III = 60.

Group IV (n = 15) acted as control, comprising 15 patients from the hospital staff, who had mild to moderate TMD symptoms such as presence of clicking, muscle pain, limited jaw opening, or deviation. Patients not willing to undergo any therapeutic interventions but agreeing for follow-up constituted the controls. Mean FAI Score Group IV = 30

Case history, clinical examination, and routine orthodontic essential diagnostic investigations such as photographs, OPG, lateral cephalograms, and study models were carried out before and after treatment. Complete TMJ evaluation was done clinically, and features assessed in accordance with RDC (TMD) guidelines[27] and the Fonseca Anamnestic index.[26] The FAI, comprising 10 questions with 3 possible answers: "Yes" (10 points), "No" (0 points), or "Sometimes" (5 points), was utilized to classify patients based on TMD severity by summating the scores of all the questions: absence of TMD (0-15 points), mild TMD (20-40 points), moderate TMD (45-65 points), and severe TMD (70-100 points). Fifteen patients (33%) were treated without extractions, while 30 patients (67%) underwent premolar extractions. Four premolars were extracted in 24 patients, while 2 maxillary premolars were extracted in the remaining 6 patients. In non-extraction cases, the methodology employed included consolidation of existing spaces, interproximal stripping, and en-masse distalization for retraction of upper and lower incisors. The average duration of treatment varied from 18 months to 32 months among all groups.

The centric stabilization splint (CSS), with a smooth surface permitting for free multidirectional contact movements, preferably from and to a centric jaw position, was used for a period of 3-6 months for condylar guidance before institution of active orthodontic therapy in Group III patients (Figure 2). Based on subjective reporting and clinical examination involving the bilateral manual manipulation technique, the patients in Group II did not show any centric relation occlusion and maximum intercuspal position discrepancy, nor any tendency toward dual bite, thereby indicating orthopedically stable joint position of the mandible. Hence, splint therapy was not used in Group II patients. For visualization and determination of the quantitative amount of centric relation/centric occlusion discrepancies in 3 spatial planes, pretreatment dental models were mounted on a semi-adjustable articulator. The full maxillary coverage acrylic splint was fabricated according to a centric bite registration while ensuring that the maxillary flat acrylic occlusal pad touched every buccal cusp or incisal edge of the mandibular teeth. Following delivery of the splint, regular follow-ups were scheduled at 4-week intervals during which the condylar position was assessed with a mandibular position indicator device. At each visit, adjustments were made by reducing the vertical dimension of the splint in order to maintain a flat occlusal plate and an optimal mutually protected occlusion in accordance with Klasser and Greene's recommendations,[28] patients were instructed to wear splints for a minimum of only 12 hours per day to avoid permanent damage to TMJ structures. Evaluation of improvement in TMD symptoms following splint therapy was performed directly by TMJ palpation and muscle palpation tests, and indirectly using the pain intensity questionnaire. Quantitative evaluation of pain was done using a 10-cm long visual analog scale (VAS) with extremes labeled as "No pain" and "Worst possible pain." For assessment of patient's response to palpation of the lateral surface of TMJ,

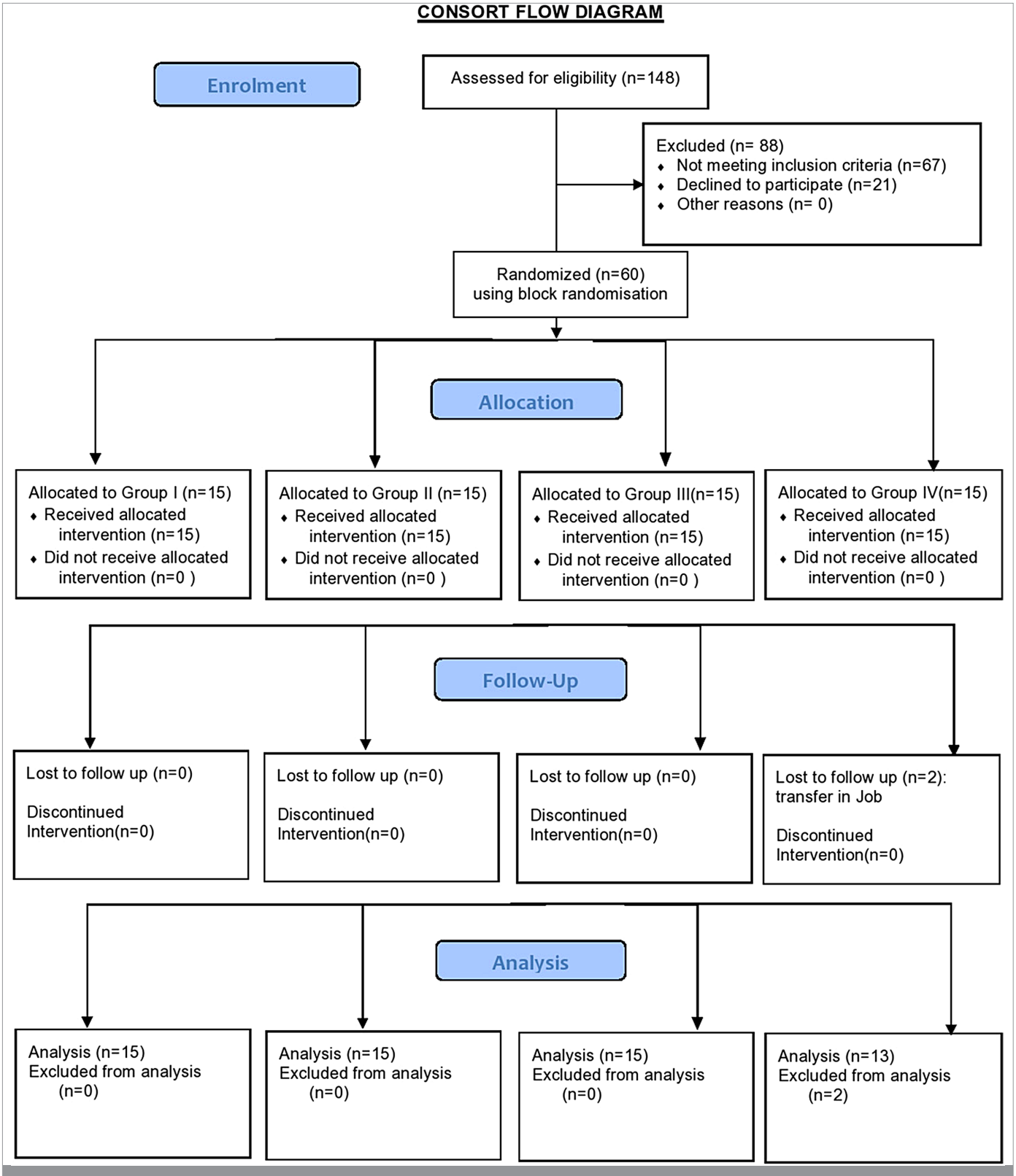

Figure 1. Consort flow diagram depicting the randomization process

the VAS with scores ranging from 0 to 3 was utilized: 0 indicates absence of pain on palpation; 1, mild pain; 2, moderate pain; and 3, severe pain, palpebral reflex, or "jump sign."[29] As for the muscle tenderness, the direct palpation method was employed for the anterior temporalis (posterior, medial, and anterior) and masseter (superficial and deep) muscles. The activity and tenderness of the lateral pterygoid and medial insertion of medial pterygoid were checked indirectly during contraction, using the resistance of fingers or hands of the examining physician. Based on the patient's response, each muscle was also scored from 0

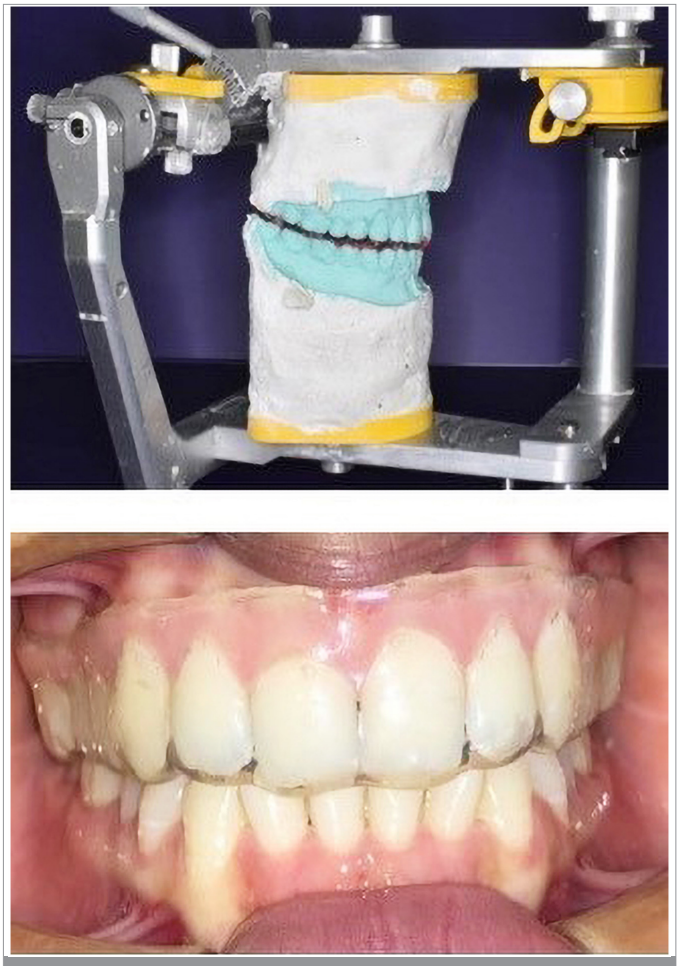

Figure 2. Centric stabilization splint used for Group III patients

to 3 points according to the tenderness on palpation: 0, normal tone; 1, mild tenderness; 2, moderate tenderness; and 3, severe tenderness.[30]

Outcomes

Once the treatment plan was formulated and before placement of appliances, all the 60 patients underwent biometric data recording at T_0 (pretreatment) involving digital occlusal analysis using the T-Scan™ (T-Scan III, version 10.0.1, Tekscan Inc., Boston, MA, USA), Electromyography using BioEMG™ (BioRESEARCH Associates Inc., WI, USA), TMJ Vibration analysis using BioJVA™ (BioRESEARCH Associates Inc.), and mandibular movement analysis using JT3D™ (BioRESEARCH Associates Inc.). The same data were recorded after satisfactory completion of treatment, at T_1.

Digital Occlusal Analysis: The 7 variables of occlusal forces were recorded, that is, distribution of maximum bite forces on the right and left sides and anterior and posterior sides along with disclusion time in the right and left lateral excursions (Figure 3). The T-scan consists of a hardware device, a pressure-sensitive and corresponding tray in large and small sizes, and corresponding software (version 10.0.1). The sensor used in the system was ultrafine plastic with a thickness of 0.004 inches. The software interface allowed for provision of patient recording, archiving, and integration with BioPAK software for other devices such as BioEMG. First, the patient was asked to sit upright comfortably on the dental chair with the occlusal plane parallel to floor. The sensor tray was selected based on the clearance of buccal corridor all over the teeth in maximum occlusion position. The mesiodistal widths of the upper and lower central incisors were recorded with digital Vernier calipers (AEROSPACE, Shanghai, China). Once the tray size of sensor was established, it was attached with the T-scan device, which was connected to the laptop through the USB mode. Patients were shown, by demonstration, the desired mandibular movements to be recorded. They were then instructed to repeat the same 3 times for each movement, that is, maximum biting, and right lateral and left lateral excursion. The sensitivity of optimal biting forces was considered appropriate in case of display of a couple of pink vertical towers mixed with blue and dark blue towers. The average of 3 recordings was taken for analysis.

Digital Muscular activity recording: Chair-side kinematic assessment of activity of the muscles of mastication was done using the surface EMG machine of Bio-EMG™ (Figure 4). The present study utilized 4 channels to record masseter and temporalis activity. The BioEMG equipment allowed the clinician to evaluate the efficiency of the patient's musculature during rest, chewing, and clenching. The electrodes were inserted in the BioEMG amplifier and hung around the patient's neck with a strap. The other end of the electrodes was attached over the skin of the temple region, just above the lateral third of the eyes for anterior temporalis and around

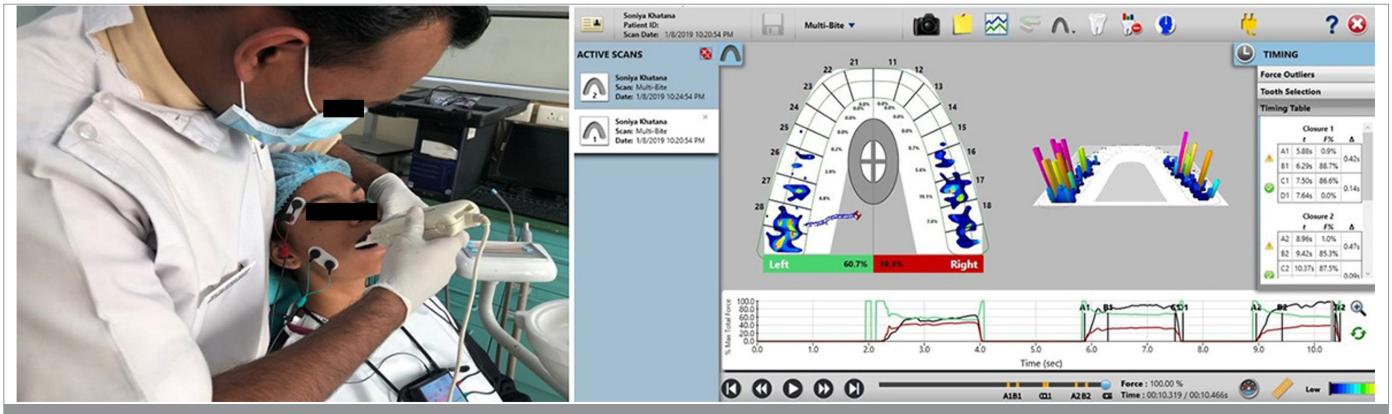

Figure 3. Multi-bite T-scan representing quadrant-wise force distribution and disclusion time

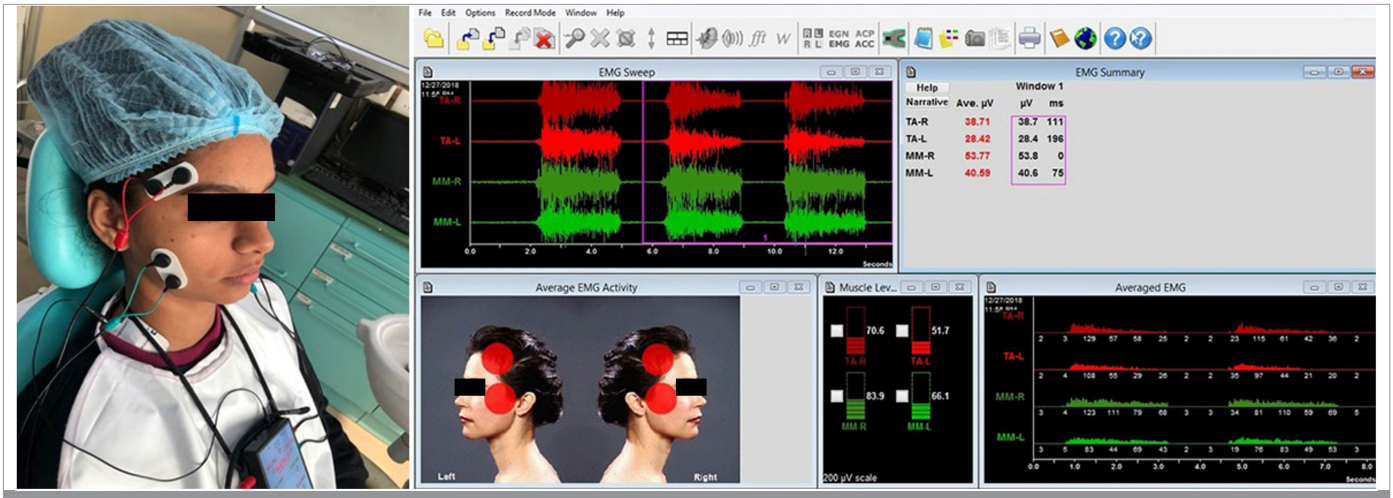

Figure 4. Assessment of activity of temporalis and masseter muscles using BioEMG 4-channel electrode

the anterior border of the mandibular ramus for masseter activity. The ground earthing was provided from the right supra-clavicular region near the posterior border of the sternocleidomastoid muscle. The desired mandibular movements were recorded during maximum biting, right lateral excursion, and left lateral excursion. The software interface depicted the rhythmic activity of muscle firing as a red and blue graph against the true horizontal *X*-axis. Due to the collaboration of Tekscan and BioRESEARCH firms, the simultaneous assessment of digital occlusal reading and muscular movements was possible for coordinated analysis using BioPAK software. A total of 10 variables depicting right and left masseter and temporalis activity at rest and during clenching were analyzed. The activity index and the asymmetry index were determined with the following formula[31]:

- Asymmetry index = (Root mean square$_{right}$ − Root mean square$_{left}$)/(Root mean square$_{right}$ + Root mean square$_{left}$) × 100
- Activity Index = (Root mean square$_{masseter}$ − Root mean square$_{temporalis}$)/(Root mean square$_{masseter}$ + Root mean square$_{temporalis}$) × 100

TMJ Vibration Analysis: Bio-JVA Joint Vibration Analysis is a unique tool which determines the morphological changes in TMJ components which can cause gritting, clicking, crepitus, and subluxation. It consists of a headphone design with 2 acoustic sensitive transducers which were placed on the TMJ complex externally. The 3.5 mm audio jack of BioJVA was inserted into the BioPAK amplifier console, which was also used for BioEMG. The patient was trained to achieve synchronization with the metronome on the laptop. The recording was depicted as a wave form against the horizontal *x*-axis; and any click, crepitus, or subluxation and normal joint sound was seen as varied amplitude and frequency (Figure 5). A total of 6 variables were assessed, that is, the total integral energy in relation to right and left TMJ, its proportion in relation to 300 Hz for both right and left TMJ, peak amplitude, and peak frequency.

Mandibular Movement Analysis: The JT3D Jaw Tracker equipment was used for measuring the 3 dimensions of mandibular movement. A small magnet was placed on the vestibular side of the lower anterior teeth using a special sticky wax, and a headgear containing a bilateral electromagnetic controller mechanism facilitated sensing of the *xyz* position of the magnet with an accuracy of 0.1 mm (Figure 6a). Physiologic movements which occurred during chewing, and non-physiologic movements such as maximum opening/closing or maximum lateral excursions-border movements were assessed. Exact positions of the mandible were recorded by simultaneous use of the JT3D and the JVA (Figure 6b).

Sample Size

Based on a significance level of α = 5% and 80% power (with an allowable error of 20%), a mean difference of 1.4 along with a

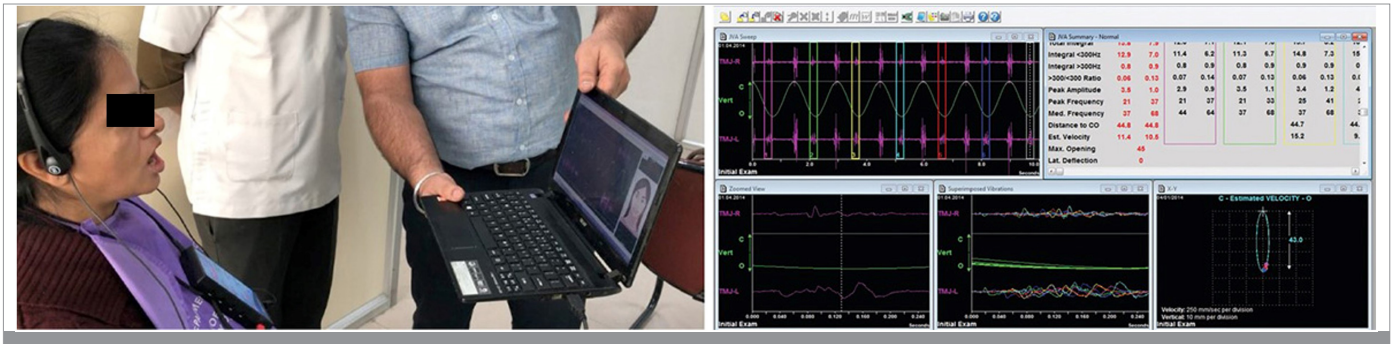

Figure 5. TMJ vibration analysis using BioJVA with the patient trained to achieve synchronization with the metronome on the laptop

Figure 6. a, b. (a) Mandibular movement assessment using Jaw Tracker JT3D (b) Simultaneous representation of TMJ movements and vibrations using BioJVA and Jaw Tracker JT3D

standard deviation 0.8, and considering a 10% drop-out, a minimum sample size of 58 patients was required as confirmed using a sample size calculator, by employing the *t*-statistic (Cytel's East Lite [Cytel Inc., Waltham, MA, USA] application). However, in order to maintain a 1 : 1 : 1 : 1 allocation ratio, a total of 60 patients (29 male, 31 female; mean age: 29.58 ± 5.85), distributed into 15 per group, were recruited in the trial after strict application of the inclusion and exclusion criteria.

Randomization

Sequence Generation

Patients were divided randomly into 4 groups of 15 each with age- and sex-matched controls using the variable permuted block randomization technique. The randomization sequence was generated using Excel 2011 (Microsoft, USA) by employing 2, 4, and 6 sizes of blocks.

Allocation Concealment

The allocation was concealed by using sequentially numbered, opaque, sealed and stapled envelopes which were further made impermeable to light using aluminum foil inside the envelope. The corresponding envelopes were opened only after the enrolled participants completed all baseline assessments and were ready for intervention allocation.

Implementation

The randomization and treatment allocation were done by an independent worker. The treatment procedure was carried out

by the principal investigator. The study was carried out with the "intention to treat" for all patients.

Blinding

Blinding was done at data recording and at result assessment levels. To ensure blinding, the entire biometric data recording was done by 2 independent investigators who were not aware about the group of patients. The data interpretation and analysis were done by the principal investigator.

Consent

Informed written consent was obtained from the patients after explaining the entire treatment procedure to them in their native languages.

Statistical Analyis

Data were prepared in the Excel sheet and analyzed using PAST (version 3) statistical software. The Shapiro–Wilk *t*-test was done, and it showed normality of data distribution. There was no statistical difference between age and sex distribution at baseline level ($P > .05$). The pretreatment and posttreatment intragroup comparison was done using the paired *t*-test. The intergroup comparisons between all 4 groups were performed using ANOVA. Tukey's HSD post hoc test was applied to determine the periods at which the measurement changes were significant. The significance level was set at $P < .05$. To account for intraobserver and interobserver errors, reassessments of 30% randomly chosen measurements by the same investigator after 3 weeks and by a second investigator were analyzed with intraclass correlation coefficients, which showed excellent intraobserver and interobserver reliabilities of 0.978 and 0.932, respectively. The reproducibility of double determination of measurements using Dahlberg's formula showed minimal error (within 0.05 mm) that did not affect the reliability of the measurements.

RESULTS

The participant flow diagram according to the PRISMA guidance depicting the numbers of participants who were randomly assigned, received the intended treatment, and were analyzed for the primary outcome for each group along with losses and exclusions after randomization, together with reasons (Figure 1). The distribution of the 4 groups for mean age, gender, malocclusion type, overjet, and overbite are reported in Table 1.

Intragroup comparison of pretreatment and posttreatment measurements within Groups I and III showed significant difference among all T-scan variables except for maximum bite force on the right and left sides (Tables 2 and 4). However, Group II showed significant difference in the right and left differential biting forces and disclusion time (Table 3). There was no significant difference in Group IV in relation to any occlusal variables (Table 5).

Pretreatment intergroup comparison using ANOVA found statistically significant difference for all variables except maximum bite forces on the right and left sides and their differential (Table 6). Post treatment, significant intergroup difference was observed for right and left disocclusion time, the maximum biting forces' differential between the right and left, as well as in the anterior region (Table 7). However, the post hoc test revealed significant difference between groups I and II, II and III, and II and IV only for the left lateral disclusion time before treatment. Post treatment, Groups I, II, and III showed significant differences from group IV for all occlusal variables except for the maximum posterior biting force (Table S1).

Intragroup comparison between Groups I and III showed statistically significant difference in all the muscular variables. However, Group II and Group IV showed difference only for activity and asymmetry index variables, and left-side masseter activity during function and asymmetry index, respectively (Tables 2, 3, 4, and 5).

An intergroup comparison at pretreatment showed significant difference between Groups I and II, II and III, and II and IV for the right anterior temporalis at rest. Similarly, significant difference was observed between Groups I and II, I and III, I and IV, and II and IV for right masseter activity at rest. At pretreatment, significant differences were observed between Groups I and II, I and III, and I and IV for right anterior temporalis, right masseter, and left masseter muscle at function. However, post

Table 1. Demographic distribution of groups in the total sample

SN	Group	Age	Gender	Malocclusion (Class)	Treatment duration (months)	Overjet (mm)	Overbite (mm)
1	Group I	27.92 ± 5.02	F = 8 M = 7	I = 10 II = 4 III = 1	27.2 ± 4	3.33	4.06 ± 1.33
2	Group II	29.53 ± 5.85	F = 9 M = 6	I = 10 II = 3 III = 2	23.80 ± 3.05	2.66 ± 1.63	4.66 ± 1.34
3	Group III	29.53 ± 6.82	F = 8 M = 7	I = 7 II = 6 III = 2	31.93 ± 3.54	2.86 ± 1.45	4.6 ± 1.4
4	Group IV	31.30 ± 5.42	F = 6 M = 9	I = 11 II = 1 III = 3	18 ± 0	2 ± 1.6	3.15 ± 1.5

Data are presented as mean ± SD where applicable; SD, standard deviation; F, female; M, male.

Table 2. Comparison of pretreatment and posttreatment measurements within Group I by paired *t* test

Assessment Variables T' scan variables	Mean		Mean Difference	95% CI	*P*
	T_0	T_1			
Maximum bite force right side (%)	48.53	51.13	2.60	−6.28 to 11.48	.54
Maximum bite force left side (%)	51.46	48.86	2.60	−5.81 to 11.01	.531
Difference between right and left	28.26	3.06	25.20	18.48 to 31.91	.0001*
Maximum bite force anterior region (%)	10.93	7.26	3.66	2.28 to 5.04	.0003*
Maximum bite force posterior region (%)	89.06	93.00	3.93	2.66 to 5.19	.0002*
Right lateral excursive DT (seconds)	0.64	0.33	0.30	0.18 to 0.43	.0001*
Left lateral excursive DT (seconds)	0.73	0.28	0.44	0.34 to 0.53	.0006*
BioEMG variables					
Right anterior temporalis at rest (microV)	0.94	0.52	0.41	0.22 to 0.61	.002*
Right masseter at rest (microV)	1.02	0.58	0.44	0.26 to 0.63	.0001*
Right anterior temporalis at function (microV)	140.09	117.73	22.35	18.28 to 26.42	.0006*
Right masseter at function (microV)	158.96	134.32	24.63	18.071 to 31.198	.0001*
Left anterior temporalis at rest (microV)	1.02	0.73	0.29	0.18 to 0.40	.0006*
Left masseter at rest (microV)	1.48	1.018	0.46	0.24 to 0.67	.0006*
Left anterior temporalis at function (microV)	148.98	123.13	25.84	22.89 to 28.79	.0006*
Left masseter at function (microV)	161.13	130.92	30.20	24.15 to 36.25	.0006*
Activity index	5.75	4.48	1.27	1.05 to 1.48	.0001*
Asymmetry index	5.11	3.72	1.38	1.10 to 1.66	.0006*
BioJVA variables					
Total integral energy right TMJ	56.20	45.46	10.73	5.46 to 16.00	.0006*
Total integral energy left TMJ	61.13	48.93	12.20	9.23 to 15.16	.0001*
>300/<300 ratio right TMJ	0.18	0.16	0.01	−0.003 to 0.03	.092
>300/<300 ratio left TMJ	0.17	0.16	0.01	0.00 to 0.01	.0006*
Peak amplitude	24.51	21.45	3.06	2.11 to 4.01	.0006*
Peak frequency	71.13	64.66	6.46	4.48 to 8.45	.0006*
JT3D variables					
Maximum vertical mouth opening (mm)	45.33	46.40	1.06	0.14 to 1.99	.044*
Maximum sagittal movement (mm)	5.66	5.63	0.02	−0.09 to 0.14	.694
Lateral left (mm)	3.96	4.10	0.14	−0.02 to 0.30	.091
Lateral right (mm)	4.29	4.49	0.2	0.03 to 0.36	.016*

CI indicates confidence interval; T0, pretreatment; T1, posttreatment.
*$P < .05$ is significant.

treatment, the right anterior temporalis and right masseter at function revealed significant difference between Groups I and II, II and III, I and IV, and III and IV. Similarly, the asymmetry index showed significant difference between Groups I and II, II and III, and II and IV before treatment, and between Groups I and II, I and III, II and III, I and IV,II and IV, and III and IV after treatment (Tables 6, 7, and S2).

Intragroup comparison revealed statistically significant difference among all variables except for differential energy at right TMJ in Group I. However, Group II showed significant difference for 3 variables, that is, peak amplitude and differential at both right and left >300/<300 ratio TMJ. An intragroup comparison between Groups III and IV revealed significant increases in all TMJ vibration parameters (Tables 2, 3, 4, and 5).

An intergroup comparison between Groups III and IV revealed a statistically significant difference for all variables before treatment; however, Group III showed improvement in health but Group IV revealed deterioration. The total integral energy on both right and left sides showed significant difference between Groups I and II, I and III, and I and IV before treatment, and between Groups I and II, II and III, I and IV, and III and IV after treatment. Significant difference was observed between Groups I and III, II and III, I and IV, II and IV, and III and IV for differential ratio of right TMJ before treatment; and between Groups II and III, II and IV, and III and IV for differential ratio of left TMJ before treatment. Both the differential ratios of right and left TMJ showed significant difference between Groups I and IV, II and IV, and III and IV after treatment. The peak amplitude of TMJ sound showed significant difference between Groups I and III, II and III, and III and IV before and after

Table 3. Comparison of pretreatment and posttreatment measurements within Group II by paired *t* test

Assessment Variables 'T' scan variables	Mean		Mean Difference	95% CI	*P*
	T_0	T_1			
Maximum bite force right side (%)	46.80	51.06	4.26	−1.65 to 10.19	.148
Maximum bite force left side (%)	53.20	49.06	4.13	−1.93 to 10.20	.169
Difference between right and left	20.53	4.13	16.40	10.52 to 22.27	.0001*
Maximum bite force anterior region (%)	6.86	6.80	0.06	−2.99 to 3.12	.963
Maximum bite force posterior region (%)	93.13	93.20	0.06	−2.99 to 3.12	.963
Right lateral excursive DT (seconds)	0.39	0.22	0.17	0.084 to 0.26	.0006*
Left lateral excursive DT (seconds)	0.47	0.23	0.24	0.14 to 0.35	.0001*
BioEMG variables					
Right anterior temporalis at rest (microV)	3.04	2.48	0.55	−0.02 to 1.13	.056
Right masseter at rest (microV)	2.96	2.84	0.12	−0.27 to 0.51	.533
Right anterior temporalis at function (microV)	158.00	158.92	0.92	−3.63 to 5.47	.666
Right masseter at function (microV)	177.74	181.31	3.56	−0.95 to 8.08	.112
Left anterior temporalis at rest (microV)	3.38	3.04	0.34	−0.19 to 0.88	.194
Left masseter at rest (microV)	3.48	3.06	0.42	−0.06 to 0.92	.091
Left anterior temporalis at function (microV)	171.22	171.04	0.18	−5.68 to 6.04	.946
Left masseter at function (microV)	175.06	178.26	3.19	−2.62 to 9.00	.253
Activity index	4.70	5.140	0.43	0.12 to 0.75	.011*
Asymmetry index	6.65	6.98	0.32	0.06 to 0.57	.021*
BioJVA variables					
Total integral energy right TMJ	84.60	81.33	3.26	−1.88 to 8.42	.200
Total integral energy left TMJ	87.73	85.46	2.26	−2.19 to 6.72	.301
>300/<300 ratio right TMJ	0.15	0.14	0.004	0.0006 to 0.007	.008*
>300/<300 ratio left TMJ	0.147	0.143	0.003	0.001 to 0.006	.001*
Peak amplitude	22.16	24.12	1.95	0.50 to 3.40	.010*
Peak frequency	63.13	60.66	2.46	−0.33 to 5.26	.089
JT3D variables					
Maximum vertical mouth opening (mm)	44.66	44.86	0.2	−0.46 to 0.86	.687
Maximum sagittal movement (mm)	6.10	6.17	0.07	−0.07 to 0.22	.5
Lateral left (mm)	3.55	3.78	0.22	0.02 to 0.42	.022*
Lateral right (mm)	4.86	4.90	0.04	−0.11 to 0.19	.616

treatment. Similarly, significant difference was observed for peak frequency of TMJ sound between Groups II and III and between Groups III and IV before treatment; and between Groups I and III, II and III, and Groups III and IV after treatment (Tables 6, 7, and S3).

Intragroup comparison of movement analysis revealed statistically significant increases in only mouth opening and right lateral movement in Group I, but only left lateral movement showed significant increase in Group II (Tables 2 and 3). However, all variables showed significant changes in Group III and group IV, except for right mandibular movement in Group IV (Tables 4 and 5).

An intergroup comparison revealed that the maximum sagittal movement showed significant difference between Groups II and III and Groups II and IV before treatment; and between Groups II and IV after treatment. Mandibular movement on the left side showed significant difference between Groups I and III, I and IV, and II and IV before treatment; and between groups I and IV, II and IV, and III and IV after treatment. Similarly, mandibular movement on right side showed significant difference between Groups I and III, II and III, Groups I and IV, and II and IV, both before and after treatment (Tables 6, 7, and S4).

DISCUSSION

As orthodontics changes the position of teeth and jaws which further alters the stomatognathic equilibrium, various proponents have claimed its role in TMD, which often presents a complex diagnostic and management challenge.

The conventional methods routinely employed for analysis of TMDs include proper case history, clinical examination, questionnaires, and advanced supplementary diagnostic imaging

Table 4. Comparison of pretreatment and posttreatment measurements within Group III by paired *t* test

Assessment Variables 'T' scan variables	Mean		Mean Difference	95% CI	*P*
	T_0	T_1			
Maximum bite force right side (%)	53.80	50.66	3.13	−5.79 to 12.06	.464
Maximum bite force left side (%)	46.13	49.33	3.20	−5.76 to 12.16	.456
Difference between right and left	29.53	4.26	25.26	18.96 to 31.56	.0001*
Maximum bite force anterior region (%)	11.66	5.60	6.06	3.17 to 8.96	.0005*
Maximum bite force posterior region (%)	88.46	94.06	5.60	2.49 to 8.70	.0002*
Right lateral excursive DT (seconds)	0.80	0.38	0.41	0.26 to 0.56	.0001*
Left lateral excursive DT (seconds)	0.74	0.37	0.36	0.23 to 0.48	.0002*
BioEMG variables					
Right anterior temporalis at rest (microV)	1.34	0.65	0.69	0.55 to 0.83	.0006*
Right masseter at rest (microV)	2.92	0.87	2.046	1.72 to 2.37	.0006*
Right anterior temporalis at function (microV)	178.89	128.45	50.44	45.09 to 55.79	.0006*
Right masseter at function (microV)	190.24	135.95	54.28	49.13 to 59.43	.0001*
Left anterior temporalis at rest (microV)	2.21	1.006	1.20	0.87 to 1.53	.0006*
Left masseter at rest (microV)	2.35	0.79	1.56	1.26 to 1.85	.0006*
Left anterior temporalis at function (microV)	185.11	140.99	44.11	39.87 to 48.36	.0006*
Left masseter at function (microV)	177.60	175.67	1.92	−7.76 to 11.60	.014*
Activity index	5.14	2.73	2.41	2.19 to 2.62	.0006*
Asymmetry index	5.48	3.42	2.06	1.71 to 2.41	.0006*
BioJVA variables					
Total integral energy right TMJ	81.06	43.60	37.46	32.70 to 42.23	.0006*
Total integral energy left TMJ	75.86	40.80	35.06	26.37 to 43.76	.0001*
>300/<300 ratio right TMJ	0.31	0.18	0.12	0.09 to 0.15	.0001*
>300/<300 ratio left TMJ	0.33	0.19	0.14	0.12 to 0.17	.0006*
Peak amplitude	29.44	17.34	12.09	10.25 to 13.93	.0001*
Peak frequency	74.00	37.33	36.66	29.58 to 43.75	.0006*
JT3D variables					
Maximum vertical mouth opening (mm)	39.86	47.20	7.33	4.69 to 9.96	.0002*
Maximum sagittal movement (mm)	4.80	5.53	0.73	0.53 to 0.93	.0001*
Lateral left (mm)	3.24	3.92	0.67	0.33 to 1.01	.0007*
Lateral right (mm)	2.88	3.74	0.86	0.56 to 1.15	.0001*

such as CT and MRI. Paesani et al.[20] reported high variability, low reproducibility, low repeatability, and subjective interpretation as the disadvantages of conventional methods. The authors also reported that the conventional methods have accuracy as low as 50% in diagnosing TMDs.[21] The MRI, a multiplanar imaging technique, on the other hand, provides an accurate assessment of both the bony and the soft tissues of the TMJ, including the position of the articular disc. It offers the advantages of being non-invasive, radiation-free, and providing superior contrast resolution with lesser bone-related artifacts compared to other imaging modalities. However, the utility of MRI imaging examination should be dictated by the potential ability of the acquired information to influence an already established treatment plan or prognosis.[29,33] High prevalence of detection of small abnormalities in TMJ images of asymptomatic individuals, such as flattening of condyles in older subjects, underline the fact that the results of TMJ imaging do not necessarily correspond to the patient's signs and symptoms.[29,34] Additionally, an overestimation of image findings accompanied by unnecessary irreversible treatment might present a risk, particularly for inexperienced clinicians.[29] Although the International RDC-TMD Consortium guidelines[33] propose utility of MRI imaging as an indispensable stage of a definitive diagnostic procedure from the patient's or research problem's perspective, the high costs/increased expenses and claustrophobia involved limit its use in routine clinical settings. Other methodologies such as CBCT and arthroscopy are too expensive for general orthodontic setup, involve radiation and an invasive component, and require special training and setup. However, the biometric devices used in the present study offer the advantages of being economical, chair-side-friendly, and non-radiating. They also do not require any specialized formal training or supervision.

Table 5. Comparison of pretreatment and posttreatment measurements within Group IV by paired *t* test

Assessment Variables 'T' scan variables	Mean		Mean Difference	95% CI	*P*
	T_0	T_1			
Maximum bite force right side (%)	46.84	47.30	0.46	−1.14 to 2.07	.607
Maximum bite force left side (%)	53.15	52.69	0.46	−1.14 to 2.07	.607
Difference between right and left	21.69	20.46	1.23	−1.79 to 4.25	.451
Maximum bite force anterior region (%)	15.00	15.53	0.53	−0.30 to 1.37	.253
Maximum bite force posterior region (%)	92.92	93.00	0.07	−3.45 to 3.60	.962
Right lateral excursive DT (seconds)	0.60	0.64	0.03	−0.008 to 0.08	.111
Left lateral excursive DT (seconds)	0.72	0.73	0.005	−0.02 to 0.03	.706
BioEMG variables					
Right anterior temporalis at rest (microV)	1.13	1.23	0.10	−0.01 to 0.21	.086
Right masseter at rest (microV)	3.16	3.43	0.27	−0.08 to 0.63	.143
Right anterior temporalis at function (microV)	170.21	170.85	0.64	−1.30 to 2.59	.473
Right masseter at function (microV)	186.11	186.96	0.85	−0.73 to 2.44	.256
Left anterior temporalis at rest (microV)	1.85	1.94	0.09	−0.10 to 0.29	.367
Left masseter at rest (microV)	2.30	2.20	0.10	−0.17 to 0.38	.433
Left anterior temporalis at function (microV)	170.89	172.36	1.46	−0.47 to 3.41	.121
Left masseter at function (microV)	177.26	179.48	2.21	1.20 to 3.22	.001*
Activity index	4.93	4.97	0.03	−0.29 to 0.37	.785
Asymmetry index	5.05	5.25	0.20	0.04 to 0.35	.020*
BioJVA variables					
Total integral energy right TMJ	81.53	87.69	6.15	0.92 to 11.38	.024*
Total integral energy left TMJ	85.84	91.00	5.15	3.09 to 7.21	.0002*
>300/<300 ratio right TMJ	0.21	0.25	0.03	0.006 to 0.06	.002*
>300/<300 ratio left TMJ	0.21	0.25	0.03	0.01 to 0.06	.003*
Peak amplitude	25.08	27.91	2.83	1.21 to 4.44	.004*
Peak frequency	64.84	67.84	3.00	1.08 to 4.91	.008*
JT3D variables					
Maximum vertical mouth opening (mm)	41.46	42.92	1.46	0.21 to 2.71	.032*
Maximum sagittal movement (mm)	4.87	4.98	0.10	0.001 to 0.21	.046*
Lateral left (mm)	2.75	2.83	0.08	0.01 to 0.15	.024*
Lateral right (mm)	3.13	3.21	0.08	−0.03 to 0.19	.156

As for the entire human race, digital automation has been a boon for dentistry as well; it benefits all domains, from examination and diagnosis to therapeutic assistance. The 3 biometric assessments in neuromuscular dentistry include the K7 evaluation system (Myotronics-Noromed, WA, USA), BioRESEARCH Associates, and Tekscan equipment. Our study chose BioRESEARCH Associates' equipment, as occlusal component detection facility was not available in the K7 evaluation system, and the T-scan has been shown to be compatible to other BioRESEARCH devices through BioPAK software.

In the present study, the T-scan Novus was used for digital occlusal analysis. Several investigators demonstrated a high degree of reliability with the T-scan in evaluating occlusal contact distribution.[35-37] The findings of the present study, showing improvement of the occlusal component after orthodontic therapy in all 3 active groups except control, suggest that orthodontic treatment helps in stabilizing occlusion by providing proper incisal and canine guidance, removing CR-CO discrepancy, and establishing mutually protected occlusion. Similar findings were also reported in the study of Agbaje et al.[38] Thumati[23] also reported the improvement in maximum biting force efficiency and reduced disclusion time after orthodontic treatment. The suggested improvement could be justified by the study of Brenan et al.[39] and Henrikson et al.[40] who reported that the masticatory ability was correlated to the number of teeth in contact, positively associated with oral-health-related quality of life and proving beneficial for self-perceived masticatory efficiency.

In this study, we used BioEMG to assess the pretreatment and posttreatment activity of the temporalis and masseter muscles using 4-channel electrodes. In accordance with the findings of Rodrigues Bigaton et al.[41] our study also found a predominant contributory role of the masseter muscle during isometric

Table 6. Comparison of pretreatment measurements between different groups by ANOVA test

Assessment Variables 'T' scan variables	Mean at T_0				ANOVA test	
	Group I	Group II	Group III	Group IV	*F* value	*P*
Maximum bite force right side (%)	48.53	46.80	53.80	46.84	0.81	.489
Maximum bite force left side (%)	51.46	53.20	46.13	53.15	0.83	.482
Difference between right and left	28.26	20.53	29.53	21.69	2.27	.090
Maximum bite force anterior region (%)	10.93	6.86	11.66	15.00	4.85	.004*
Maximum bite force posterior region (%)	89.06	93.13	88.46	92.92	4.08	.010*
Right lateral excursive DT (seconds)	0.64	0.39	0.80	0.60	6.05	.001*
Left lateral excursive DT (seconds)	0.73	0.47	0.74	0.72	4.70	.005*
BioEMG Variables						
Right anterior temporalis at rest (microV)	0.94	3.04	1.34	1.13	39.64	.001*
Right masseter at rest (microV)	1.02	2.96	2.92	3.16	16.73	.007*
Right anterior temporalis at function (microV)	140.09	158.00	178.89	170.21	13.51	.040*
Right masseter at function (microV)	158.96	177.74	190.24	186.11	13.60	.001*
Left anterior temporalis at rest (microV)	1.02	3.38	2.21	1.85	21.55	.030*
Left masseter at rest (microV)	1.48	3.48	2.35	2.30	13.18	.060*
Left anterior temporalis at function (microV)	148.98	171.22	185.11	170.89	21.01	.005*
Left masseter at function (microV)	161.13	175.06	177.60	177.26	6.28	.001*
Activity index	5.75	4.70	5.14	4.93	2.58	.040*
Asymmetry index	5.11	6.65	5.48	5.05	6.66	.001*
BioJVA variables						
Total integral energy right TMJ	56.20	84.60	81.06	81.53	7.52	.0003*
Total integral energy left TMJ	61.13	87.73	75.86	85.84	10.63	.001*
>300/<300 ratio right TMJ	0.18	0.15	0.31	0.21	23.29	.0001*
>300/<300 ratio left TMJ	0.17	0.14	0.33	0.21	53.46	.0008*
Peak amplitude	24.51	22.16	29.44	25.08	11.30	.001*
Peak frequency	71.13	63.13	74.00	64.84	5.38	.002*
JT3D variables						
Maximum vertical mouth opening (mm)	45.33	44.66	39.86	41.46	2.87	.060*
Maximum sagittal movement (mm)	5.66	6.10	4.80	4.87	5.92	.001*
Lateral left (mm)	3.96	3.55	3.24	2.75	6.89	.0004*
Lateral right (mm)	4.29	4.86	2.88	3.13	30.38	.001*

contraction, and of the anterior temporalis during rest position, in TMD-affected patients. The present study showed that muscular improvement in Group II and control was negligible in comparison to significant improvement in Group I and III, indicating that the muscular response observed in Group II orthodontic-alone patients was as good as no treatment. We also observed that orthodontic treatment combined with occlusal splint therapy resulted in significant improvement in muscular health than without splint orthodontic treatment. A few control group participants reported mild worsening of muscular health, which indicate that unequal activity of the right and left side muscle movement and antagonist muscle activity might occur if no treatment is provided. However, the reported improvement with orthodontic treatment in the healthy patient group, and the results of orthodontics in conjunction with occlusal splint therapy in the TMDs group support the findings of Miralles et al.[42] who also reported greater improvement in masseter and temporalis muscles in healthy subjects than in non-healthy subjects with right-side dominance while clenching. The present study contradicts the findings of Wieczorek and Loster[43] who observed no significant differences in occlusal contact, asymmetry, or activity indexes among healthy orthodontically treated or untreated young adults. However, the authors reported significant difference between females and males, with a higher activity index in females. The present study did not assess the gender and malocclusion-wise differentiation in any of the parameters involved with TMD due to limited sample size in sub-variable categories. Ferrario et al.[44] reported the predominance of right-side involvement in their study, stating predominantly a right-handed general population; however, our study did not corroborate a similar finding. The difference could be due to the mixed sample size of the present study.

Table 7. Comparison of posttreatment measurements between different groups by ANOVA test

Assessment Variables 'T' scan variables	Mean at T_1				ANOVA test	
	Group I	Group II	Group III	Group IV	*F* value	*P*
Maximum bite force right side (%)	51.13	51.06	50.66	47.30	1.33	.270
Maximum bite force left side (%)	48.86	49.06	49.33	52.69	1.30	.280
Difference between right and left	3.066	4.13	4.26	20.46	9.50	.0001*
Maximum bite force anterior region (%)	7.26	6.80	5.60	15.53	15.77	.001*
Maximum bite force posterior region (%)	93.00	93.20	94.06	93.00	0.66	.578
Right lateral excursive DT (seconds)	0.33	0.22	0.38	0.64	9.97	.0001*
Left lateral excursive DT (seconds)	0.28	0.23	0.37	0.7	21.12	.001*
BioEMG variables						
Right anterior temporalis at rest (microV)	0.52	2.48	0.65	1.2	40.95	.001*
Right masseter at rest (microV)	0.58	2.84	0.87	3.43	49.78	.0001*
Right anterior temporalis at function (microV)	117.73	158.92	128.45	170.85	31.22	.001*
Right masseter at function (microV)	134.32	181.31	135.95	186.96	36.83	.060
Left anterior temporalis at rest (microV)	0.73	3.040	1.006	1.94	32.13	.080
Left masseter at rest (microV)	1.01	3.060	0.79	2.20	33.34	.001*
Left anterior temporalis at function (microV)	123.13	171.04	140.99	172.36	58.95	.003*
Left masseter at function (microV)	130.92	178.26	175.67	179.48	35.44	.001*
Activity index	4.48	5.14	2.73	4.97	23.77	.001*
Asymmetry index	3.72	6.98	3.42	5.25	29.50	.010*
BioJVA variables						
Total integral energy right TMJ	45.46	81.33	43.60	87.69	22.51	.006*
Total integral energy left TMJ	48.93	85.46	40.80	91.00	37.61	.004*
>300/<300 ratio right TMJ	0.16	0.14	0.18	0.25	10.50	.0001*
>300/<300 ratio left TMJ	0.16	0.14	0.19	0.25	16.09	.001*
Peak Amplitude	21.45	24.12	17.34	27.91	25.34	.001
Peak Frequency	64.66	60.66	37.33	67.84	42.31	.003
JT3D variables						
Maximum vertical mouth opening (mm)	46.40	44.86	47.20	42.92	1.76	.160
Maximum sagittal movement (mm)	5.63	6.17	5.53	4.98	3.68	.017*
Lateral left (mm)	4.10	3.78	3.92	2.83	7.87	.0002*
Lateral right (mm)	4.49	4.90	3.74	3.21	22.01	.001*

Healthy human joints produce little noise. Subsequent surface changes due to TMD can cause increased friction and vibration. It has also been reported that different disorders produce different vibration patterns. The present study utilized the joint vibrations and jaw trackers simultaneously to locate and compare the signs and symptoms of TMD such as click, crepitus or pop, limited mouth opening, and jaw deviation. The BioJVA is based on the electro vibratography concept with 70%–85% sensitivity and specificity as reported by various investigators.[45,46] Durrani et al.[47] and Devi et al.[24] have reported significant reliability of BioJVA in the healthy Indian population and TMD-affected patients, respectively. The present study found significant difference in TMJ vibration, with greater improvement in Group I, compared to Group II which did not show any significant improvements in most of the variables after orthodontic treatment. Group III patients showed improvement in all variables after treatment. The control group showed deterioration of most of the variables related to TMJ vibration. Thus, the present study infers that that merely orthodontic alignment of teeth may not improve the signs and symptoms of TMD-affected patients, unless preceded by splint therapy.

Orthodontic treatment of patients with TMDs often presents a complex clinical challenge due to muscle incoordination, bony alterations, and the patient's unstable condylar position, all of which together cause the occlusion to change constantly during treatment.[29] Stabilization of the TMJ structures by splint therapy is necessitated in such patients to identify and maintain the true mandibular position and predict patients' response before institution of orthodontic mechanotherapy.[48] Among the 3 splint designs, namely, the anterior repositioning appliance (ARA), the CSS, and the soft splint, correct choice of the splint design is often a unique challenge for a clinician.[24] In accordance with the recommendations of Chang et al.[49]

who reported fewer problems with CSS in comparison to ARA after treatment, we used CSS for a period varying from 12 weeks to 24 weeks depending on severity of pretreatment TMJ symptoms. The findings of this study, showing significant improvement in TMJ symptoms after splint therapy, further corroborated those of previous reports, which showed that splint therapy helps restore a novel functional equilibrium in the stomatognathic system by permitting smoother condylar translation beyond disc surface inhomogeneity and reducing joint noises by increasing the joint space. Additionally, numerous studies have also demonstrated improvement of clinical symptoms during orthodontic treatment by virtue of therapeutic effects of the splint and elimination of the impact of occlusal interferences, thereby allowing for physiologic-seated condylar position and optimizing final treatment results by attaining maximum intercuspation-seated condylar position coincidence.[48,50-52]

The findings of this study, showing improvement in all variables of mandibular movement in the splint orthodontic group in comparison to the other 3 groups, further indicate that orthodontics play a limited role in management of TMD in orthodontic patients. Similar findings have also been reported by Imai et al.[50] who also found significant beneficial effects of combination of splint therapy and orthodontic treatment in reducing pain and restriction of mandibular movement. This study demonstrated substantial improvement in relation to muscular and occlusal parameters in the healthy group in comparison to the TMD group. In accordance with the findings of StieschScholz et al.[46] and Suvinen and Reade,[53] the significant improvement observed in Group III could be attributed to disclusion of posterior teeth and relaxation of elevator muscles owing to condylar guidance in all movements, which helps maintain jaw position and contributes to decreased muscle hyperactivity and subsequent TMD symptoms.

It has been consistently reported that realization of the goals of optimal occlusion, functional stability in masticatory structures, muscle equilibration, and an orthopedically stable relationship between the occlusal position of the teeth and the joint position with orthodontic treatment might play an important role in preventing or diminishing the risk factors associated with development of TMDs.[14,54]

To the best of our knowledge, the present study is first of its kind to rule out the suspected role of orthodontics in the etiopathogenesis of TMD using biometric assessment. The major advantages of these biometric equipment were digital documentation, repeatable measurement, and non-radiating and quantitative assessment of TMD signs and symptoms. However, the present study recommends the hands-on experience of these devices before accurate interpretation and reporting. The finding of present study rejected the null hypothesis, partially as there was no precipitation or aggravation of TMD signs and symptoms, and definite symptomatic improvement and relief after comprehensive orthodontic treatment in tandem with splint therapy was obtained.

Our study could not report the different demographic-based biometric data such as different malocclusions, gender, and age group, due to paucity of samples and resources; hence demonstrating limited generalizability and external validity. However, the issue can be addressed with multicentric trials involving a larger sample size in different populations and over a longer observation period.

CONCLUSION

This study reported the successful role of biometric assessment equipment in orthodontic patients. Based on the results of this randomized control trial, the following can be concluded:

- Comprehensive fixed orthodontic treatment does not aggravate TMDs.
- TMDs attributable to unstable orthodontic malocclusion can be treated successfully with comprehensive orthodontic treatment.
- TMDs due to multifactorial TMJ and muscular component are less likely to benefit with orthodontic treatment alone and usually require splint therapy at least for 3 months.

Ethics Committee Approval: 'Institutional Ethical Committee' approval vide letter number 14/IEC/ADCRR/2017.

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Table S1. Results of Tukey HSD posthoc Test showing the intergroup levels of significance at T0 and T1 for parameters of Digital Occlusal Analysis

	Group I		Group II		Group III		Group IV	
	T0	**T1**	**T0**	**T1**	**T0**	**T1**	**T0**	**T1**
1	**Difference between right and left biting Force**							
Group I	-	-	0.56	0.87	0.08	0.6	0.65	**0.0001**
Group II	0.56	0.87	--	--	0.45	0.09	0.76	**0.0001**
Group III	0.08	0.6	0.45	0.09	--	--	0.98	**0.0001**
2	**Maximum Bite force anterior region (%)**							
Group I	--	--	0.34	0.67	0.08	0.10	0.094	**0.0001**
Group II	0.34	0.67	--	--	0.88	0.45	**0.002**	**0.0001**
Group III	0.08	0.10	0.88	0.45	--	--	0.06	**0.0001**
3	**Maximum Bite Force Posterior region (%)**							
Group I	--	--	0.50	0.65	1.3	0.90	0.32	0.45
Group II	0.50	0.65	--	--	0.78	0.92	**0.034**	0.66
Group III	1.3	0.90	0.78	0.92	--	--	0.23	0.80
4	**Right Lateral excursive DT (seconds)**							
Group I	--	--	0.54	0.79	0.12	0.09	0.10	**0.002**
Group II	0.54	0.79	--	--	0.80	0.34	**0.0005**	**0.0001**
Group III	0.12	0.09	0.80	0.34	--	--	0.09	**0.012**
5	**Left Lateral excursive DT (seconds)**							
Group I	--	--	**0.016**	0.20	0.89	0.23	0.50	**0.0001**
Group II	**0.016**	0.20	--	--	**0.011**	0.56	**0.025**	**0.0001**
Group III	0.89	0.23	**0.011**	0.56	--	--	0.78	**0.0001**

Table S2. Results of Tukey HSD posthoc Test showing the intergroup levels of significance at T0 and T1 for parameters of Digital Muscular activity using EMG

1	Right Anterior Temporalis at rest (microV)							
	Group I		Group II		Group III		Group IV	
	T0	T1	T0	T1	T0	T1	T0	T1
Group I	--	--	**0.0001**	**0.0001**	0.44	0.65	0.87	**0.006**
Group II	**0.0001**	**0.0001**	--	--	**0.0001**	**0.0001**	**0.0001**	**0.0001**
Group III	0.44	0.65	**0.0001**	**0.0001**	--	--	0.08	0.034
2	**Right Masseter at rest (microV)**							
Group I	--	--	**0.0001**	**0.0001**	**0.0001**	0.60	0.20	**0.0001**
Group II	**0.0001**	**0.0001**	--	--	0.56	**0.0001**	**0.0001**	0.32
Group III	**0.0001**	0.60	0.56	**0.0001**	--	--	0.09	**0.0001**
3	**Right Anterior Temporalis at function (microV)**							
Group I	--	--	**0.036**	**0.0001**	**0.0001**	0.80	**0.0003**	**0.0001**
Group II	**0.036**	**0.0001**	--	--	0.55	**0.0001**	**0.010**	0.08
Group III	**0.0001**	0.80	0.55	**0.0001**	--	--	0.07	**0.0001**
4	**Right Masseter at function (microV)**							
Group I	--	--	**0.004**	**0.0001**	**0.0001**	0.98	**0.0001**	**0.0001**
Group II	**0.004**	**0.0001**	--	--	0.06	**0.0001**	0.79	0.98
Group III	**0.0001**	0.98	0.06	**0.0001**	--	--	0.90	**0.0001**
5	**Left Anterior Temporalis at rest (microV)**							
Group I	--	--	**0.0001**	**0.0001**	**0.001**	0.78	**0.04**	**0.0003**
Group II	**0.0001**	**0.0001**	--	--	**0.001**	**0.0001**	**0.0001**	**0.001**
Group III	**0.001**	0.78	**0.001**	**0.0001**	--	--	0.06	**0.005**
6	**Left Masseter at rest (microV)**							
Group I	--	--	**0.0001**	**0.0001**	**0.042**	0.07	**0.04**	**0.0004**
Group II	**0.0001**	**0.0001**	--	--	**0.004**	**0.0001**	**0.004**	**0.011**
Group III	**0.042**	0.07	**0.004**	**0.0001**	--	--	0.09	**0.0001**
7	**Left Anterior Temporalis at function (microV)**							
Group I	--	--	**0.0002**	**0.0001**	**0.0001**	**0.00009**	**0.0003**	**0.0001**
Group II	**0.0002**	**0.0001**	--	--	**0.019**	**0.0001**	**0.004**	**0.011**
Group III	**0.0001**	**0.00009**	**0.019**	**0.0001**	--	--	**0.022**	**0.0001**
8	**Left Masseter at function (microV)**							
Group I	--	--	**0.012**	**0.0001**	**0.002**	**0.0001**	**0.004**	**0.0001**
Group II	**0.012**	**0.0001**	--	--	0.07	**0.0001**	0.40	**0.011**
Group III	**0.002**	**0.0001**	**0.004**	**0.0001**	--	--	0.60	**0.0001**
9	**Activity Index**							
Group I	--	--	**0.048**	**0.0001**	0.80	**0.0001**	0.56	0.009
Group II	**0.048**	**0.0001**	--	--	0.70	**0.0001**	0.45	0.55
Group III	0.80	**0.0001**	0.70	**0.0001**	--	--	0.89	**0.0001**
10	**Asymmetry index**							
Group I	--	--	**0.004**	**0.0001**	0.90	**0.0001**	0.80	**0.005**
Group II	**0.004**	**0.0001**	--	--	**0.014**	**0.0001**	**0.006**	**0.001**
Group III	0.90	**0.0001**	**0.014**	**0.0001**	--	--	0.30	**0.0007**

Table S3. Results of Tukey HSD posthoc Test showing the intergroup levels of significance at T0 and T1 for parameters of TMJ vibration analysis

1	**Total Integral energy right TMJ**							
	Group I		**Group II**		**Group III**		**Group IV**	
	T0	**T1**	**T0**	**T1**	**T0**	**T1**	**T0**	**T1**
Group I	--	--	**0.0007**	**0.0001**	**0.003**	0.08	**0.003**	**0.0001**
Group II	**0.0007**	**0.0001**	--	--	0.50	**0.0001**	0.60	0.65
Group III	**0.003**	0.08	0.50	**0.0001**	--	--	0.30	**0.0001**
2	**Total Integral energy Left TMJ**							
Group I	--	--	**0.0001**	**0.0001**	**0.033**	0.08	**0.0003**	**0.0001**
Group II	**0.0001**	**0.0001**	--	--	0.80	**0.0001**	0.45	0.90
Group III	**0.033**	0.08	0.80	**0.0001**	--	--	0.09	**0.0001**
3	**>300/<300 ratio Right TMJ**							
Group I	--	--	0.08	0.09	**0.0001**	0.50	**0.0003**	**0.0005**
Group II	0.08	0.09	--	--	**0.0001**	0.12	**0.023**	**0.0001**
Group III	**0.0001**	0.50	**0.0001**	0.12	--	--	**0.0002**	**0.013**
4	**>300/<300 ratio Left TMJ**							
Group I	--	--	0.08	0.07	0.80	0.40	0.70	**0.0001**
Group II	0.08	0.07	--	--	**0.034**	0.70	**0.0008**	**0.0001**
Group III	0.80	0.40	**0.034**	0.70	--	--	**0.0001**	**0.001**
5	**Peak Amplitude**							
Group I	--	--	0.90	0.40	**0.001**	**0.007**	0.70	**0.0001**
Group II	0.90	0.40	--	--	**0.0001**	**0.0001**	0.06	**0.019**
Group III	**0.001**	**0.007**	**0.0001**	**0.0001**	--	--	**0.009**	**0.0001**
6	**Peak Frequency**							
Group I	--	--	0.67	0.80	0.45	**0.0001**	0.70	0.23
Group II	0.67	0.80	--	--	**0.005**	**0.0001**	0.50	0.45
Group III	0.45	**0.0001**	**0.005**	**0.0001**	--	--	**0.030**	**0.0001**

Table S4. Results of Tukey HSD posthoc Test showing the intergroup levels of significance at T0 and T1 for parameters of Mandibular Movement Analysis

1	**Maximum sagittal movement (mm)**							
	Group 1		**Group 2**		**Group 3**		**Group 4**	
	T0	**T1**	**T0**	**T1**	**T0**	**T1**	**T0**	**T1**
Group I	--	--	0.80	0.56	0.06	0.08	0.60	0.09
Group II	0.80	0.56	--	--	**0.003**	**0.34**	**0.009**	**0.008**
Group III	0.06	0.08	**0.003**	**0.34**	--	--	0.90	0.50
2	**Lateral left (mm)**							
Group I	--	--	0.70	0.32	**0.02**	0.80	**0.008**	**0.0001**
Group II	0.70	0.32	--	--	0.60	0.70	**0.046**	**0.007**
Group III	**0.02**	0.80	0.60	0.70	--	--	0.09	**0.001**
3	**Lateral Right (mm)**							
Group I	--	--	0.09	0.07	**0.0001**	**0.006**	**0.0002**	**0.0001**
Group II	0.09	0.07	--	--	**0.0001**	**0.0001**	**0.0001**	**0.0001**
Group III	**0.0001**	**0.006**	**0.0001**	**0.0001**	--	--	0.70	0.08