Original Article

Evaluation of pre- and post-treatment masticatory and bite force efficiency in patients undergoing fixed orthodontic treatment and orthognathic surgery using T-Scan Novus occlusal analysis: A factorial randomized controlled trial

ABSTRACT

Introduction and Background: Orthodontic and orthognathic surgical treatment require quantified occlusion finish to rule out any temporomandibular disorders. Hence, the present study was proposed to analyze the occlusal efficiency in patients undergoing fixed orthodontic and combined orthodontic–orthognathic surgery using digital occlusal analysis.

Methodology: A randomized multi-arm controlled trial was conducted on 55 patients divided into four groups, that is, group I: class I crowding/proclination required extraction for fixed orthodontic treatment, group II: class II div 1 required orthodontic treatment and/or myofunctional therapy, group III: skeletal class II required combined orthodontic and orthognathic surgical treatment, and group IV: skeletal class III required combined orthodontic and orthognathic surgical treatment. The pre-treatment, before debonding, and 1 year after debonding assessment of occlusion were carried out using T-Scan. The repeated analysis of variance (rANOVA) test along with post-hoc analysis was carried out for intra-group and inter-group assessments using SPSS (version 21, USA). The significance level was set at a '*P*' value less than 0.05.

Results: rANOVA measurement in groups I, II, and III showed a significant difference with respect to maximum bite force difference between right and left sides, anterior and posterior region, and left lateral disclusion time. However, group IV showed a significant difference with respect to maximum bite force in the anterior and posterior region as well as right and left lateral disclusion time only. Further application of the post-hoc Tukey test found a significant difference between the T_0 value to T_1 and T_2 among all four groups.

Conclusion: Improved bite force was found in all malocclusion groups which was gradual in improvement from pre-treatment to post-treatment and a subsequent retention phase. The study also reported the utility of digital occlusal assessment devices as reliable, repeatable, reproducible, and user-friendly in the determination of dynamic occlusion.

Keywords: Bite force, occlusion, orthodontics, orthognathic surgery, T-scan

Raj Kumar Maurya, Preeti Bhardwaj[1], Harpreet Singh[2], Rajat Mitra[3], Oonit Nakra[4], Harsh A. Mishra[5]

Dental Officer and Specialist, Government Dental Centre, Nagaland, [1]Department of Orthodontics and Dentofacial Orthopedics, Mansarovar Dental College, Bhopal, Madhya Pradesh, [2]Department of Orthodontics and Dentofacial Orthopedics, ESIC Dental College and Hospital, Rohini, Delhi, [3]Department of Orthodontics and Dentofacial Orthopedics, Central Government Dental Unit, Bangalore, Karnataka, [4]Department of Orthodontics and Dentofacial Orthopedics, Central Government Dental Unit, Jaipur, Rajasthan, [5]Department of Orthodontics and Dentofacial Orthopedics, Bharati Vidyapeeth (Deemed to be University) Dental College and Hospital, Navi Mumbai, Maharashtra, India

Address for correspondence: Dr. Harpreet Singh, Department of Orthodontics and Dentofacial Orthopedics, ESIC Dental College and Hospital, Sector-15 Rohini, Delhi, India.
E-mail: drhpreetesic@gmail.com

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INTRODUCTION

Orthodontic good finishing is based on sound subjective and fair objective clinical parameters which fulfill Andrew's six keys.

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Henrikson *et al.*[1] and Astrand[2] reported improved masticatory performance after orthodontics and orthognathic surgical correction, respectively. The major limitation in the delineating role of orthodontic treatment for quantification of masticatory and bite force efficiency is difficulty in quantification by conventional means, that is, articulating papers, impression paste, and subjective scales. With the advent of technology, biometric digital devices such as "the dental prescale system," "Occulsense (Bosch)," "MPX 5700 (Motorola, USA)," T-Scan Novus (TekScan, USA), and Dentoforce 2 (ITL AB, Sweden) have demonstrated capacity for digital occlusal analysis both qualitatively and quantitatively.[3-5]

T-Scan Novus (TekScan Inc. USA) is a valuable tool that aids in the assessment of the dynamic, quantitative occlusal analysis and bite pattern.[5] Uzuner *et al.*[6] reported successful use of T-Scan in assessing occlusal parameters after rapid maxillary expansion. Qadeer *et al.*[7] showed significant occlusal force discrepancy in post-orthodontic subjects by using T-Scan and recommended it for orthodontic finishing. Thumati *et al.*[8] reported that disclusion time reduction therapy helps in treating occluso-muscular pains by stabilizing mutually protected occlusion.

Sonnesen and Bakke[9] reported no significant variation in bite forces and masticatory efficiency in different angle malocclusion. However, Ahlgren[10] found reduced masticatory performance in subjects with class II and III malocclusions. Recent studies by Roldan,[11] Alam,[12] and Turkistani[13] have further reiterated the association between malocclusion and improper bite force distribution across different ages, genders, and malocclusion. Because there is a scarcity in the literature reporting changes in masticatory and bite force efficiency using quantitative methods in orthodontic and orthognathic surgical treatment, a study was proposed to determine the masticatory and bite force efficiency in subjects undergoing fixed orthodontic treatment and combined orthodontic–orthognathic surgery using digital occlusal analysis.

Null hypothesis

There is no difference in masticatory and bite force efficiency between different malocclusion before and after comprehensive orthodontic, orthodontics–orthognathic surgical, and orthodontic myofunctional therapy.

MATERIALS AND METHODS

Settings and locations where the data were collected

The present study was conducted in accordance with the "Declaration of Helsinki ICH Guidelines of Good Clinical Practice" as a multi-arm factorial randomized controlled trial (m-RCT). Ethical Clearance was obtained from Army Dental Centre (R and R), New Delhi with ref no 14/IEC/ADCRR/2017 dated 16 Aug 2017. The trial was registered with the Central Trial Registry of India vide trial registration number CTRI/2019/02/017534. The study was carried out between 2017 to 2019 and reported as per the extension of CONSORT 2010 Statements[14] [Figure 1].

Study design

Trial design

i. Factorial multi-arm design
ii. No change in the trial design was carried out during the conduct of the trial.

Participant sample size

The study was carried out in the dental wing of the outpatient department of a tertiary-care hospital. A total of 55 patients (22 males and 33 females) matching the inclusion and exclusion criteria were recruited based on the below-mentioned sample size calculation. A minimum of 11 patients were required per arm to cater for at least 80% power, 5% alpha, a mean difference of 0.7, and a standard deviation of 0.4 from a previous study, and a 10% drop-out based on the below-mentioned sample calculation formula.[7]

$$n = (Z_{\alpha/2} + Z_{\beta})^2 \times 2\sigma^2/(\mu_1 - \mu_2)^2$$

$$N_{final} = 2n/1\text{-}0.1$$

Selection criteria

Patients with permanent dentition having Angle class I type 1 or 2, class II div 1 due to retrognathic mandible requiring growth modification or orthognathic surgical correction, and class III requiring mandibular setback were included. Patients with temporomandibular joint disorders, periodontally compromised dentition, history of cleft lip, and palate were excluded.

Interventions

Group allocation

- Group I: Class I crowding/proclination required extraction for fixed orthodontic treatment ($n = 15$)
- Group II: Class II div 1 required orthodontic treatment and/or myofunctional therapy ($n = 15$)
- Group III: Skeletal class II required combined orthodontic and orthognathic surgical treatment ($n = 15$)
- Group IV: Skeletal class III required combined orthodontic and orthognathic surgical treatment ($n = 10$)

Case history, clinical examination, and routine orthodontic essential diagnostic investigations such as photographs, OPG, lateral cephalogram, and study models were carried out before and after treatment. 0.018 × 0.025-inch Roth (Orthox, US Orthodontics, USA) prescription brackets were used in

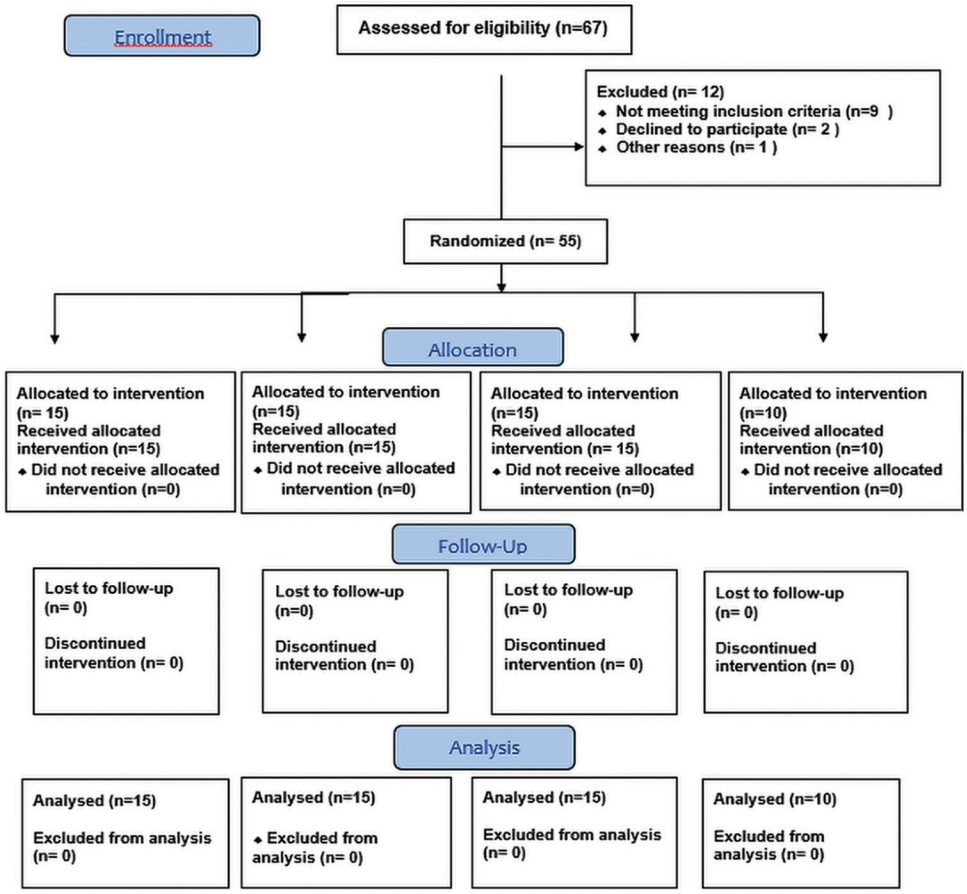

Figure 1: Consort flow diagram depicting the randomization process

all treatment groups for orthodontic correction. A standard twin-block appliance was used in group II for the correction of skeletal malocclusion.

Outcomes

Digital Occlusal Analysis: All 55 patients underwent biometric data recording involving digital occlusal analysis at T0 (pre-treatment) using "T-Scan" Novus™ (T-scan III, Software Version 10.0.1, TekScan Inc, Boston, USA) following finalization of the treatment plan and before placement of appliances. The T-Scan Novus computerized occlusal analysis system was used to record occlusal contact in real time, progressively from the first tooth contact till the maximum inter-cuspal position (MIP) [Figure 2]. The seven variables of occlusal forces were recorded, that is, distribution of maximum bite forces on the right and left sides, anterior and posterior sides, along with disclusion time in right and left lateral excursion. Each parameter was assessed at T0, that is, before starting the orthodontic intervention, T1, that is, 1 month after debonding, and T2, that is, 1 year after debonding. The 'T' scan assembly consisted of a hardware device and pressure-sensitive and corresponding tray in large and small sizes with corresponding software of version 10.0.1. The system's sensor was made of ultra-thin plastic with a thickness of 0.004 inches. The sensor tray was selected in accordance with the buccal corridor clearance all across the teeth at maximum occlusion. The mesio-distal width of upper and lower central incisors was recorded using a digital vernier caliper (AEROSPACE, Shanghai, China). Once the tray size of the sensor was established, it was attached to the T-Scan device, which was connected to a laptop through the USB mode. Patients were demonstrated the desired mandibular movements to be recorded and instructed to repeat the process three times for each movement, that is, maximum biting, right lateral, and left lateral excursion. In the case of a display of a couple of pink vertical towers mixed with blue and dark blue towers, the sensitivity of optimal biting forces was deemed appropriate. For analysis, the average of three recordings was used.

Randomization

Sequence generation

Patients were divided randomly with age–sex match control using the block randomization technique with the central computer-generated method by using random block sizes of four by an independent investigator.

Table 1: Descriptive statistics of T_0 to T_2 changes within Group I (ANOVA test)

Variable	(Mean+SD)			rANOVA *'P'*	rANOVA *'F'*
	T_0	T_1	T_2		
Maximum bite force right side (%)	48.53+15.81	51.73+5.21	51.13+6.71	0.525	0.65
Maximum bite force left side (%)	51.46+15.81	48.26+5.21	48.86+6.717	0.525	0.65
Difference between right and left	28.26+12.39	8.53+6.61	12.26+8.27	0.0001*	28.25
Maximum bite force anterior region (%)	10.93+2.34	8+2.69	7.2+2.51	0.0002*	11.37
Maximum bite force posterior region (%)	89.06+2.34	92+2.69	92.8+2.51	0.0002*	11.37
Right lateral excursive DT (seconds)	0.64+0.27	0.54+0.16	0.58+0.17	0.159	1.96
Left lateral excursive DT (seconds)	0.73+0.22	0.56+0.13	0.54+0.17	0.001*	7.95

Table 2: Results of Tukey HSD post-hoc test showing the levels of significance between T_0, T_1, and T_2 for significant parameters within group I

Variable	T_0	T_1	T_2
Difference between right and left			
T_0	-	0.0001	0.0001
T_1	0.0001	-	NS
Maximum Bite force anterior region (%)			
T_0	-	0.0002	0.0002
T_1	0.0002	-	NS
Maximum Bite Force Posterior region (%)			
T_0	-	0.0002	0.0002
T_1	0.0002	-	NS
Left Lateral excursive DT (seconds)			
T_0		0.001	0.001
T_1	0.001	-	NS

Allocation concealment

The allocation was concealed by using sequentially numbered, opaque, sealed, and stapled envelopes, which were further made impermeable to light using an aluminum foil inside the envelope. 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 independent workers. The treatment procedure was carried out by the principal investigator. The study was carried out with an "intention to treat" all patients.

Blinding

To ensure blinding, the entire biometric data recording was carried out by two independent investigators, not aware of the group of patients. The data interpretation and analysis were carried out by the principal investigator. Because the patients were aware of their treatment modalities, blinding was done at the level of data recording and data analysis to help eliminate the influence of cognitive bias on the results of the assessments.

Statistical analysis

Data were processed using SPSS 21 (IBM Corps, USA) software for Windows. Application of the Shapiro–Wilks *t*-test showed normality of data distribution for recorded measurements at pre-, mid-, and post-treatment variables. The pre- and post-treatment and follow-up intra-group comparison was carried out using the rANOVA test, and the subsequent difference was assessed by the post-hoc Tukey test. The significance level was set at '*P*' < 0.05.

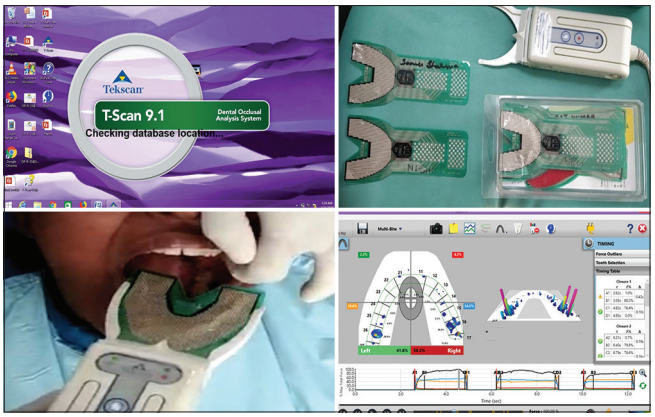

Figure 2: T-scan software, device, and sensors used in the study

RESULTS

To account for intra-observer and inter-observer errors, 40% of randomly chosen measurements were repeated by the same investigator after 4 weeks and by a second investigator, respectively. Both the intra- and inter-observer repeatability and reproducibility of the measurements showed excellent agreements with intra-class correlation coefficients (ICCs) ranging from 0.92 to 0.95 and from 0.89 to 0.92, respectively. The reproducibility of double determination of measurements was done using the Dahlberg formula which showed minimal error (within 0.05 mm) that did not affect the reliability of the measurements.

Repeated ANOVA measurement in groups I, II, and III showed a statistically significant difference with respect to the maximum bite force difference between the right and left side, in the anterior and posterior region and left lateral disclusion time ('*P*' < 0.05). However, group IV showed a significant difference with respect to the maximum bite force

Table 3: Descriptive statistics of T_0 to T_2 changes within group II (ANOVA test)

Variable	(Mean+SD)			rANOVA *'P'*	rANOVA *'F'*
	T_0	T_1	T_2		
Maximum bite force right side (%)	49.33+9.96	49.86+4.24	51.33+5.61	0.75	0.27
Maximum bite force left side (%)	50.66+9.96	50.13+4.24	48.66+5.61	0.75	0.27
Difference between right and left	16+10.11	6.66+4.93	9.66+5.87	0.001*	8.13
Maximum bite force anterior region (%)	2.46+1.76	8.13+2.29	7.33+2.05	0.0001*	34.31
Maximum bite force posterior region (%)	97.53+1.76	91.86+2.29	92.66+2.05	0.0001*	34.31
Right lateral excursive DT (seconds)	0.69+0.20	0.53+0.15	0.44+0.12	0.0003*	10.83
Left lateral excursive DT (seconds)	0.64+0.20	0.50+0.14	0.39+0.08	0.0004*	10.34

Table 4: Levels of significance following Tukey HSD post-hoc test within group II

Variable	T_0	T_1	T_2
Difference between right and left			
T_0	-	0.001	0.001
T_1	0.001	-	NS
Maximum bite force anterior region (%)			
T_0	-	0.0001	0.0001
T_1	0.001	-	NS
Maximum bite force posterior region (%)			
T_0	-	0.0001	0.0001
T_1	0.001	-	NS
Right lateral excursive DT (seconds)			
T_0	-	0.0003	0.0003
T_1	0.0003	-	NS
Left lateral excursive DT (seconds)			
T_0	-	0.0004	0.0004
T_1	0.0004	-	NS

in the anterior and posterior regions, as well as right and left lateral disclusion time. Further application of the post-hoc Tukey test found a significant difference between the T_o value to T_1 and T_2 among all four groups ('*P*' < 0.05) [Tables 1–8]. The subgroup and ancillary analysis were not carried out due to the restricted sample size as it was decided based on the primary outcome.

DISCUSSION

The present study evaluated the pre- and post-treatment masticatory and bite force efficiency in subjects undergoing fixed orthodontic treatment, myofunctional appliance therapy, and orthognathic surgery using digital occlusal analysis.

Sonnesen *et al.*,[9] Ahlgren,[10] Roldán,[11] Alam,[12] and Turkistani[13] reported decreased masticatory performance and bite force efficiency in people with malocclusion. Similarly, Varrela[15] reported that though every individual has a set genetic pattern of achieving normal occlusion; however, environmental factors play a significant role in inducing plasticity in genetically driven occlusion. As the positions of teeth and jaws tend to change from their existing state after treatment, not only the aesthetics improves but the entire stomatognathic equilibrium is also altered, and if not managed properly, it can lead to various system disorders such as attrition, muscle pain, temporomandibular disorders, gastric disturbance, and ulcers, thereby affecting the overall quality of life. The present study also found reduced bite forces in the pre-treatment group of respective malocclusion which improved after completion of therapy, suggesting that the sample population was also debilitated with reduced masticatory and bite force efficiency due to malocclusion, which can be improved with orthodontic and orthognathic surgical treatment intervention. Following careful and strict adherence to inclusion and exclusion criteria and a mean difference of 0.7, a standard deviation of 0.4, an alpha value of 0.05, a beta value of 0.2, and to reduce potential confounding variables, 15 patients were recruited in each group. However, considering the low prevalence of Angle class III patients, only ten patients were recruited in group III. Previous other studies have also used lesser class III patients due to their low prevalence.

The conventional methods routinely employed for the analysis of occlusion include case history, clinical examination, questionnaires, study models, photographs, articulating papers, and bite force analyzer. However, Paesani *et al.*[16] reported high variability, low reproducibility, low repeatability, and subjective interpretation as disadvantages of conventional methods such as articulating papers and visual examination. Other methodologies such as electromyography are too expensive for the general orthodontic setup and require special training and infrastructure. In contrast to the above-mentioned traditional methods, biometric devices used in the present study were not only affordable and easy to use but also were chair-side-friendly and non-radiating. Hence, the present study used T-Scan Novus as the biometric device for the quantitative assessment of occlusal changes due to intervention. Lyons *et al.*[4] and Cerna *et al.*[5] reported a high degree of reliability with 'T' scan in evaluating occlusal contact distribution. By utilizing T-Scan, Thumati *et al.*[8] also reported the improvement in the maximum biting force

Table 5: Descriptive statistics of T_0 to T_2 changes within group III (ANOVA test)

Variable	(Mean+SD)			rANOVA *'P'*	rANOVA *'F'*
	T_0	T_1	T_2		
Maximum bite force right side (%)	50.06+6.95	48.60+3.29	51.13+5.91	0.54	0.62
Maximum bite force left side (%)	49.93+6.95	51.40+3.29	48.86+5.61	0.54	0.62
Difference between right and left	10.8+6.75	6+3.62	10.53+5.15	0.04*	3.43
Maximum bite force anterior region (%)	1.46+1.06	7.9+2.21	7.2+1.47	0.0001*	67.63
Maximum bite force posterior region (%)	98.53+1.06	92.06+2.21	92.80+1.47	0.0001*	67.63
Right lateral excursive DT (seconds)	0.67+0.17	0.51+0.13	0.39+0.13	0.0001*	21.56
Left lateral excursive DT (seconds)	0.60+0.19	0.44+0.10	0.36+0.07	0.0002*	14

Table 6: Levels of significance following Tukey HSD post-hoc test within group III

Variable	T_0	T_1	T_2
Difference between right and left			
T_0	-	0.04	0.04
T_1	0.04	-	NS
Maximum bite force anterior region (%)			
T_0	-	0.0001	0.0001
T_1	0.0001	-	NS
Maximum bite force posterior region (%)			
T_0	-	0.0001	0.0001
T_1	0.0001	-	NS
Right lateral excursive DT (seconds)			
T_0	-	0.0001	0.0001
T_1	0.0001	-	NS
Left lateral excursive DT (seconds)			
T_0	-	0.0002	0.0002
T_1	0.0002	-	NS

efficiency and reduced disclusion time after orthodontic treatment. The findings of the present study also showed a precise three-dimensional representation of dynamic occlusal data from initial contact to maximum intercuspation. It also helped in assessing the occlusal forces and masticatory efficiency by providing details such as the maximum bite force on the right and left sides, anterior and posterior sides as well as the time to disocclude the canine on right and left sides.

Prema *et al.*[17] and Wieczorek and Loster[18] reported that fixed orthodontic treatment can alter the bite forces as high as 50% from the pre-treatment value in the first week itself. The present study concurs with the finding of the above-mentioned studies in relation to orthodontic treatment as it found significant improvement in bite force distribution on the right and left sides as well as the maximum bite force in the posterior region and left lateral disclusion time after orthodontic treatment and the subsequent follow-up period in group I treated with orthodontic-alone therapy. The suggested improvement could be justified by the study of Brennan *et al.*[19] and Henrikson *et al.*[1] who reported that the masticatory ability was correlated with the number of teeth in contact, positively associated with oral-health-related quality of life, and proved beneficial for self-perceived masticatory efficiency.

Pancherz and Anehus-Pancherz[20] and Antonarakis *et al.*[21] reported the transient reduction in masticatory and bite force efficiency after continuous bite jumping with the Herbst appliance in class II malocclusions. The authors further reported that the masticatory efficiency however recovered after completion of treatment. In contrast to the above studies, Al-Khateeb *et al.*[22] reported no significant difference in occlusal bite force, although overall efficiency was found to be lower than normal patients. The present study also found improved masticatory and bite force efficiency after myofunctional therapy in class II malocclusion and subsequent retention phase. The suggested improvement could be attributed to the new position of the lower jaw after sagittal advancement which alters the entire neurosensory gram of the stomatognathic system and provides a favorable environment for mastication and bite function along with the functional trajectories.

Astrand[2] and Shiratsuchi *et al.*[23] reported the improved masticatory and bite force efficiency among the dentofacial deformity patients managed with orthognathic surgical procedures. In contrast, Braber *et al.*[24] reported that orthognathic surgery did not change the chewing efficiency and maximum bite force. However, the present study was found to be in concurrence with the above-mentioned and showed improved mastication variable, balanced occlusion parameters, and force distribution among skeletal class II patients managed with surgical mandibular advancement. The suggested improvement was however found more in the retention phase than immediately after the removal of the appliance due to the new favorable mandibular position.

Shiratsuchi *et al.*[23] and Iwase *et al.*[25] reported improved masticatory functions post-operatively in Angle class III malocclusion patients treated with the mandibular setback procedure. The present study also found improvement in occlusion parameters after mandibular setback surgery

Table 7: Descriptive statistics of T_0 to T_2 changes within group IV (ANOVA test)

Variable	(Mean+SD)			rANOVA *'P'*	rANOVA *'F'*
	T_0	T_1	T_2		
Maximum bite force right side (%)	47.80+7.08	51.70+5.03	50.4+4.76	0.32	1.91
Maximum bite force left side (%)	52.20+7.08	48.30+5.03	49.60+4.76	0.32	1.91
Difference between right and left	12.4+7.16	8.6+5.66	8.4+3.62	0.3	1.28
Maximum bite force anterior region (%)	0	4.8+2.48	8.4+2.17	0.004*	14.51
Maximum bite force posterior region (%)	100	95.2+2.48	91.60+2.17	0.004*	14.51
Right lateral excursive DT (seconds)	0.107+0.08	0.31+0.11	0.36+0.068	0.0002*	23.18
Left lateral excursive DT (seconds)	0.13+0.11	0.29+0.07	0.36+0.06	0.0002*	20.92

Table 8: Levels of significance following Tukey HSD post-hoc test within group IV

Variable	T_0	T_1	T_2
Maximum bite force anterior region (%)			
T_0	-	0.004	0.004
T_1	0.004	-	NS
Maximum bite force posterior region (%)			
T_0	-	0.004	0.004
T_1	0.004	-	NS
Right lateral excursive DT (seconds)			
T_0	-	0.0002	0.0002
T_1	0.0002	-	NS
Left lateral excursive DT (seconds)			
T_0	-	0.0002	0.0002
T_1	0.0002	-	NS

in class III. It could be due to a significant increase in the number and intensity of occlusal contacts, thus facilitating better masticatory efficiency after combined orthodontic and surgical treatment.

The present study found a comparative increase and better masticatory efficiency and bite force from T_0 to T_1 to T_2 in all four groups irrespectively improved the bite force capacity and masticatory efficiency immediately after debonding but reduced in comparison to pre-treatment, which recovered during the retention phase. It could be due to the adaptability of neuromuscular relation within minutes of debonding the orthodontic appliance and subsequently, as has been reported by Varga *et al.*[26] and Winocur *et al.*[27]

Limitations

The present study had some limitations. Any subgroup or ancillary analysis with respect to gender, age, body mass index (BMI), or ethnicity could not be performed due to the restricted sample size. However, a greater number of randomized trials can be planned with a larger sample size and involving long follow-up periods.

Generalizability

The finding of the present study had a power of 80%, suggesting good external validity.

Future scope/relevance

The present study reported dynamically changing masticatory and bite force efficiency with the change of occlusion either due to orthodontic or surgical treatment. The quantitative analysis of occlusion can be further substantiated in more complex malocclusion and varying populations with different ethnicities. The stratified analysis to assess the difference in gender and age can be performed using a larger sample size.

CONCLUSION

The present study reported the significant difference among occlusal variables showing masticatory and bite force efficiency in different Angle malocclusions managed with different treatments such as orthodontic, myofunctional, and orthognathic surgical approaches. Improved masticatory efficiency and bite force were found in all malocclusion groups, which showed gradual improvement from pre-treatment to post-treatment and the subsequent retention phase. The study also reported the utility of digital occlusal assessment devices as reliable, repeatable, reproducible, and user-friendly in the determination of dynamic occlusion.

Registration

The trial was registered prospectively on the Central Trial Registry of India vide trial registration number CTRI/2019/02/017534.

Protocol

The protocol of the trial was registered prospectively on the Central Trial Registry of India vide trial registration number CTRI/2019/02/017534.

Financial support and sponsorship

The present trial is based on AFMRC project number 4994/2018 sanctioned by O/o DGAMFS, MoD, New Delhi.

Conflicts of interest

There are no conflicts of interest.

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