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Original Article

Comparison of efficacy between MBT preadjusted edgewise appliance and clear aligner therapy among class I crowding cases: A randomized controlled trial

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ARTICLE INFO

Article history:
Received 9 April 2021
Accepted 21 September 2021
Available online 24 November 2021

Keywords:
Clear aligner therapy
MBT appliance
Treatment duration
Chairside time
Acceptability

ABSTRACT

Background: To compare the efficacy of McLaughlin Bennett Trevisi (MBT) appliance and Clear Aligner Therapy (CAT) among nonextraction Class I crowding cases.

Methods: The study sample (60 patients) was allotted into two equal groups (30 patients each) using block randomization wherein Group 1: treated with 0.018" MBT appliance and Group 2: treated with CAT for correction of malocclusion. At the end of treatment (T1), treatment duration, chairside time, laboratory time, number, and type of appointments were noted from treatment record cards. For comparing the acceptability among patients treated with both modalities at T1, the patients were interviewed regarding the comfort and ease of using an appliance with a questionnaire-based survey.

Results: The median number of nonscheduled/emergency and finishing stage appointments was significantly higher in Group 1 compared to Group 2 (P-value <0.001). The median duration of treatment at the scheduled, finishing, and overall appointments, was significantly higher in Group 1 compared to Group 2 (P-value <0.001). The median chairside time of all appointments was significantly higher in Group 1 compared to Group 2 (P-value <0.001). The experience with treatment and overall acceptability was significantly higher in Group 2 compared to Group 1 (P-value <0.001). However, mean laboratory time per aligner fabrication in Group 2 was 30.26 ± 3.45 min against no laboratory time consumed in Group 1.

Conclusions: CAT significantly reduces treatment duration, chairside time, number of nonscheduled/emergency, and finishing stage appointments in nonextraction Class I crowding cases. Prospective studies with 3D aligner systems are recommended to add further evidence in this regard.

Clinical Trials Registry-India Registration No: CTRI/2018/04/013301.

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https://doi.org/10.1016/j.mjafi.2021.09.006

Introduction

The Clear Aligner Therapy (CAT) has emerged as an aesthetic alternative to conventional orthodontic therapy with metal brackets, especially among the adult population. This may be attributed to benefits such as better aesthetics and comfort with the aligners[1,2] and also due to the aggressive marketing strategies implemented by various manufacturers of aligners.[3,4]

The progressive orthodontic tooth movement with sequential use of aligners made of thermoplastic material, though not a very new concept, was popularized toward the last part of the 20th century when Invisalign®clear aligners were introduced by the Align technology (San Jose, California). The above aligners were based on Computer-Aided Design and Computer-Aided Manufacturing (CAD-CAM) technology, thereby providing more precise control over tooth movements and saving time on the cumbersome Kesling setups. Subsequently, a number of aligner systems have evolved over a period of time, which has provided a plethora of options to the clientele.[5–7]

The treatment with McLaughlin Bennett Trevisi (MBT) prescription orthodontic brackets is a standard protocol for the treatment of malocclusion worldwide, and this modality has shown high efficacy in the past two decades.[8] However, the major concern with labial metallic appliances has been aesthetics that made the orthodontic patients, especially the adults and teens to opt for more aesthetic and invisible alternates like clear aligners. The other perceived benefits with CAT are the absence of prominent metallic brackets that irritates the cheeks and gingiva, ease of brushing and eating due to removability of the aligners, reduced number of treatment appointments, etc.[9,10]

Although there are studies that claim that CAT is capable of treating malocclusion ranging from a mild to severe degree, as per the current literature, CAT is primarily effective in treatment of mild to moderate degree of crowding.[9,11–13] Although some literature compares the efficacy of preadjusted edgewise appliance and CAT, the quality evidence that compares the efficacy of both modalities in terms of resolving mild anterior crowding and time efficacy is still scarce.

The majority of published research on CAT comprises case reports/series, retrospective studies, and nonrandomized controlled trials, which may interest the clinician but do not add significantly to evidence-based patient care. Therefore, it is prudent to add quality evidence in this aspect. Quantitative analysis and comparative studies are required to establish the efficacy of the CAT system to well establish a contemporary fixed appliance system such as MBT. Therefore, this prospective randomized controlled trial was conducted to compare the efficacy between MBT Preadjusted Edgewise Appliance and Clear Aligner Therapy among Class I crowding cases. This would facilitate the clinician in choosing the evidence-based best treatment modality on a case-to-case basis.

Aim

To compare the efficacy between MBT Preadjusted Edgewise Appliance and Clear Aligner Therapy among nonextraction Class I crowding cases.

Objectives

i) To compare the overall efficacy between MBT appliance and Clear aligner therapy to resolve crowding.
ii) To compare the acceptability among patients treated with both modalities.
iii) To check the total treatment time, total number of appointments and type of appointments in crowding cases among patients treated with both modalities.

Material and methods

Study design

Prospective randomized controlled trial.

Study settings

This study was conducted at the Department of Orthodontics and Dentofacial Orthopedics of a tertiary care postgraduate teaching institute. The approval of the Institutional Ethical Committee (IEC) was obtained prior to the start of the study. The trial was registered prospectively at Clinical Trials Registry-India (CTRI Registration No CTRI/2018/04/013301). Written informed consent was obtained from the subjects for participation in the trial.

Inclusion criteria

(a) Age above 14 years for both genders
(b) Permanent dentition with fully erupted teeth up to second molars
(c) Angle's Class I malocclusion
(d) Non-extraction cases with crowding of $\leq$ 5mm in anterior region
(e) Overjet of $\leq$ 5mm
(f) Overbite of $\leq$ 4mm

Exclusion criteria

(a) Presence of anterior or posterior crossbite
(b) Presence of anterior or lateral open bite
(c) Presence of any local/systemic problems or trauma, which may affect the growth and development of facial structures of the body
(d) History of previous orthodontic or interceptive treatment

Study sample

The relevant literature was searched to determine the sample size for the present study. The parameters selected for the present study, such as treatment duration and the number of visits for both treatment modalities were considered. The retrospective power analysis of median and IQR/2 for treatment duration[9] and the number of visits[13] was done to ascertain the study sample. The maximum sample worked out to be seven in each arm. However, 60 patients (30 in each arm) were recruited for the purpose of the study.

Randomization

The patients selected for the study (n = 60) were allotted in two equal groups using block randomization as:

Group 1 consisted of 30 patients treated with 0.018″ MBT Preadjusted Edgewise Appliance (3M Oral Care, 2724 Peck Rd, Monrovia, CA 91016, United States) with standard protocol for correction of malocclusion (standard treatment or control group). The wire sequence followed for all cases was: 0.016″ NiTi, 0.016″ × 0.022″ NiTi, 0.016″ × 0.022" (Stainless Steel) SS, and 0.017″ × 0.025″ SS archwires.

Group 2 consisted of 30 patients treated with CAT for the correction of malocclusion. The aligners were fabricated for all patients using the CA®SMART 2D, version 4.0 software (Scheu Dental, Germany) with a standardized technique as defined by the manufacturer.

The follow up for MBT cases was planned for 4 weeks. For CAT cases, the patients were recalled every third week so that the set of three aligners could be fabricated in the departmental lab and delivered on the fourth week. At each appointment, the patients were given a package consisting of three aligners for gradually increased force application for better comfort and better adaption of the periodontium and alveolar bone:

Aligner 1: CA® splint material soft (0.5 mm thick Biostar®sheet, Scheu Dental, Germany) - 1 week.

Aligner 2:CA®splint material medium (0.625 mm thick Biostar®sheet) - 1 week.

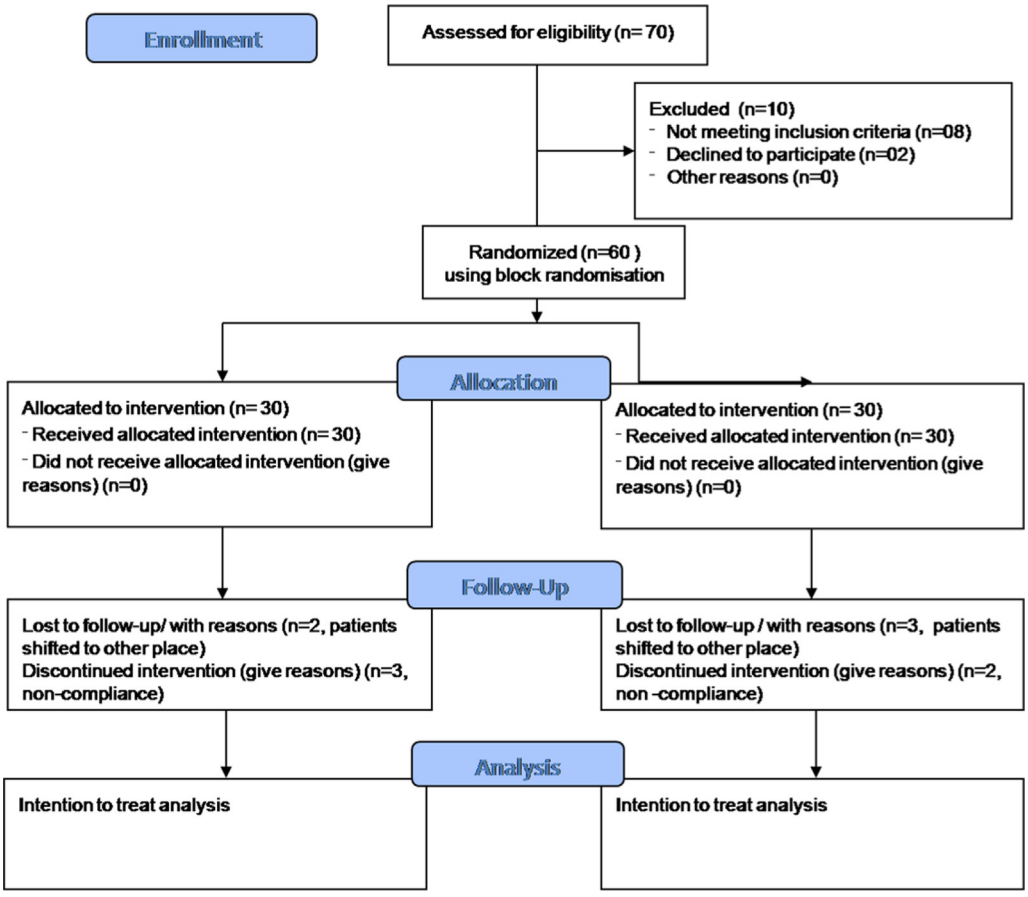
Aligner 3: CA®splint material hard (0.75 mm thick Biostar®sheet) - 2 weeks.

The treatment records i.e. Orthopantomogram (OPG), Lateral cephalogram, study models, intraoral and extraoral photographs, were taken for all patients at the following time frames:-

T0: Pretreatment.

T1: After completion of treatment.

Five patients dropped out of the study in each group. Therefore, the final study sample consisted of 25 patients in each group, the data of which is presented in the present study. The Consolidated Standards of Reporting Trials (CONSORT) flow diagram for the trial is given below:



A record regarding gender, age, amount of crowding, treatment duration, number, and type of appointments was maintained in the treatment record cards at every appointment.

For comparing the overall efficacy between MBT appliance and CAT to resolve crowding, the total treatment duration, total chairside time, total laboratory time, total number, and type of appointments were noted from the treatment record cards and compiled in Microsoft (MS) Office Excel Sheets for statistical analysis.

The types of appointments were divided into initial, scheduled, nonscheduled/emergency, and finishing appointments. The total treatment duration was calculated as the duration in weeks from separator placement (in MBT group) or initial impression making (in CAT group) to the delivery of retainer. The chairside time at each appointment was measured with a stopwatch and recorded in the treatment record cards. The laboratory time (in the case of the CAT group) was recorded in a similar fashion and documented.

In the MBT group, the initial appointments comprised of separator placement, banding the first molars, bonding, and initial archwire placement. In the CAT group, the initial appointment comprised impression making, initial setup preparation, interproximal stripping (if required), and aligner delivery. The scheduled appointments in the MBT group comprised archwire changes as per standard protocol and proximal stripping appointments. The scheduled appointments in the CAT group comprised theimpression for respective aligners and aligner delivery appointments. The emergency or nonscheduled appointment comprised any breakages in appliance/aligner, pain/discomfort with appliances, debonding of brackets, or any other unplanned situation, which brought the patient to the orthodontic clinic. The finishing appointments in the MBT group comprised bracket repositioning, placement of finishing archwires, settling of occlusion, debonding, impression making for retainer fabrication, and retainer delivery. In the CAT group, the finishing appointments comprised theimpression-making appointment, and delivery of the final aligner to be used as a retainer.

For comparing the acceptability among patients treated with both modalities at the end of the treatment (T1), the patients were interviewed regarding the comfort and ease of using appliances with a questionnaire-based survey (Appendix 1). The seven-point survey required the patients to tick on a Visual Analog Scale (VAS) against the score of 1–10. The questionnaire surveyed pain/discomfort, problems in speech, problems in mastication, problems in aesthetics, problems in oral hygiene, experience with treatment, satisfaction with treatment, and overall acceptability with the treatment modality offered to them.

The entire study data was compiled in an MS Excel sheet and subjected to statistical analysis.

Statistical analysis

The data on categorical variables are shown as n (% of cases), and the data on continuous variables are presented as Median and Inter Quartile Range (IQR) across two study groups. The intergroup statistical comparison of the distribution of categorical variables was tested using the Chi-Square test. The intergroup statistical comparison of medians of continuous variables was made using Mann–Whitney *U* test. All results are shown in tabular, as well as graphical format (such as box-whisker plot or bar graph) to visualize the statistically significant difference more clearly.

In the entire study, the P-values less than 0.05 were considered to be statistically significant. All the hypotheses were formulated using two-tailed alternatives against each null hypothesis (hypothesis of no difference). The entire data was statistically analyzed using Statistical Package for Social Sciences (SPSS version 22.0, IBM Corporation, USA) for MS Windows.

Results

Intergroup distribution of pretreatment characteristics (Supplemental Table 1, Supplemental Figs. 1–3)

Five patients dropped out of the study in each group, and the final study sample consisted of 25 patients in each group (Group 1 = 9 males and 16 females, Group 2 = 7 males, 18 females). Statistically, no significant difference was observed in age groups between the two study groups (P-value = 0.212, median age in Group 1 was 20 years, and in Group 2 was 22 years). No significant difference was observed in the amount of crowding between the study groups (P-value = 0.647, 4.30 mm in Group 1 and 4.20 mm in Group 2).

Intergroup comparison of the average number of appointments between the two study groups (Table 1, Fig. 1)

- The median number of initial appointments did not differ significantly between the two study groups (P-value >0.05).
- The median number of nonscheduled/emergency appointments and finishing stage appointments was significantly higher in Group 1 compared to Group 2 (P-value <0.001).

Table 1 – Comparison of the average number of various types of appointments between the two study groups.

No of appointments	Group 1 (MBT appliance) (n = 25)		Group 2 (Clear Aligners) (n = 25)		Group 1 vs. Group 2
Type of appointment	Median	IQR	Median	IQR	P-value
Initial	3	0	3	0	0.999^{NS}
Scheduled	4	0	8	1	0.001***
Non-scheduled/ Emergency	1	0	0	1	0.001***
Finishing	3	0	2	0	0.001***
Overall	10	1	13	1	0.001***

P-values by Mann–Whitney U test. P-value <0.05 was considered to be statistically significant. ***P-value <0.001, NS – Statistically non-significant.

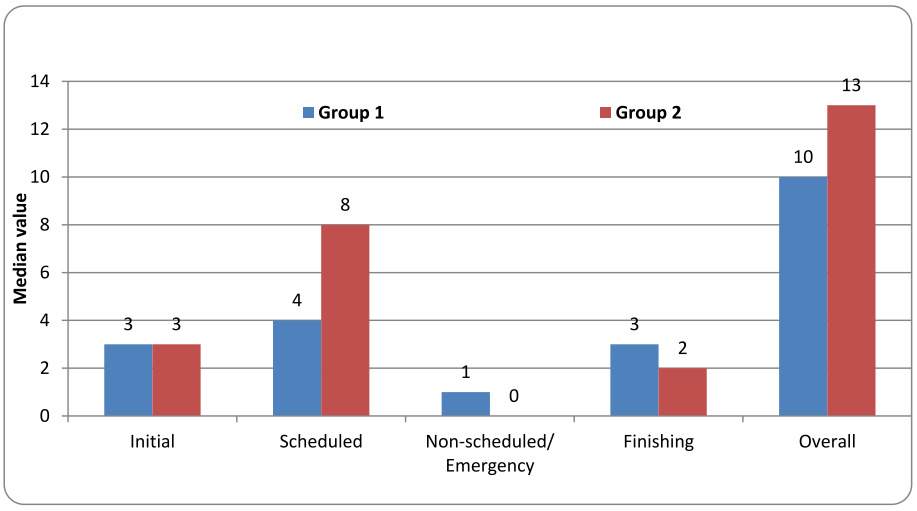


Fig. 1 – Comparison of the average number of various types of appointments between the two study groups.

Table 2 – Comparison of average treatment duration between the two study groups.

Treatment duration (wks)	Group 1 (MBT appliance) (n = 25)		Group 2 (Clear Aligners) (n = 25)		Group 1 vs. Group 2
Type of appointment	Median	IQR	Median	IQR	P-value
Initial	1	0	1	0	0.999^{NS}
Scheduled	20	4	16	2	0.001***
Non-scheduled/ Emergency	4	2	2	0	0.024*
Finishing	7	5	4	0	0.001***
Overall	27	8	21	2	0.001***

P-values by Mann–Whitney U test. P-value <0.05 was considered to be statistically significant. *P-value <0.05, ***P-value <0.001, NS – Statistically non-significant.

- The median number of scheduled and overall appointments was significantly higher in Group 2 compared to Group 1 (P-value <0.001).

Intergroup comparison of average treatment duration between the two study groups (Table 2, Fig. 2)

- The median duration of treatment at the initial appointments did not differ significantly between the two study groups (P-value >0.05).
- The median duration of treatment at the scheduled appointments was significantly higher in Group 1 compared to Group 2 (P-value <0.001).
- The median duration of treatment at the nonscheduled/ emergency appointments was significantly higher in Group 1 compared to Group 2 (P-value <0.05).

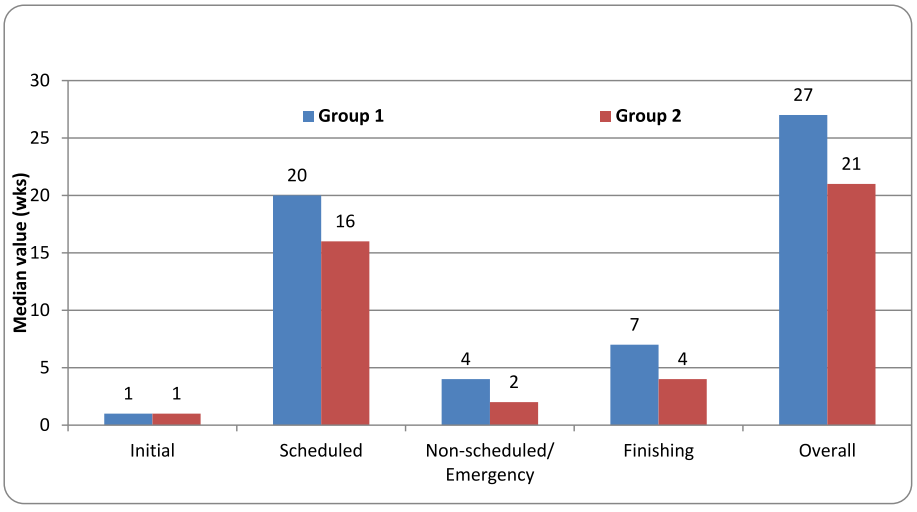


Fig. 2 – Comparison of the average treatment duration between the two study groups.

Table 3 – Comparison of average chair side time and lab time per appointment between the two study groups.

Time per appointment (Min)		Group 1 (MBT appliance) (n = 25)		Group 2 (Clear Aligners) (n = 25)		Group 1 vs. Group 2
Type of appointment		Median	IQR	Median	IQR	P-value
Initial	Chair time	28.22	1.70	4.39	0.61	0.001***
	Lab time	–	–	22.94	2.50	–
Scheduled	Chair time	28.50	5.94	6.18	1.26	0.001***
	Lab time	–	–	33.19	3.38	–
Non-scheduled/Emergency	Chair time	29.29	7.62	11.17	0.00	0.036*
	Lab time	–	–	64.00	0.00	–
Finishing	Chair time	22.83	10.50	6.67	1.12	0.001***
	Lab time	–	–	32.33	3.08	–
Overall	Chair time	26.45	2.74	5.82	0.95	0.001***
	Lab time	–	–	30.26	3.45	–

P-values by Mann–Whitney U test. P-value <0.05 was considered to be statistically significant. *P-value <0.05, ***P-value <0.001.

- The median duration of treatment at the finishing and overall appointments was significantly higher in Group 1 compared to Group 2 (P-value <0.001).

Intergroup comparison of average chairside time and laboratory time per appointment between the two study groups (Table 3, Fig. 3)

- The median chairside time of all appointments (i.e. initial, scheduled, nonscheduled/emergency, and finishing appointments) was significantly higher in Group 1 compared to Group 2 (P-value <0.001).
- The mean laboratory time per aligner fabrication in Group 2 was 30.26 ± 3.45 min against no laboratory time consumed in Group 1.

Intergroup comparison of average scores of acceptability of treatment between the two study groups (Table 4, Fig. 4)

- The median pain/discomfort score was significantly higher in Group 1 compared to Group 2 (P-value <0.05).

Table 4 – Comparison of average scores of acceptability of treatment between the two study groups.

Visual Analog Scale (VAS) Score	Group 1 (MBT appliance) (n = 25)		Group 2 (Clear Aligners) (n = 25)		Group 1 vs. Group 2
	Median	IQR	Median	IQR	P-value
Pain/discomfort	6.0	2.5	5.0	1.0	0.014*
Problems in speech	6.0	1.0	7.0	2.0	0.034*
Problems in mastication	6.0	2.5	0.0	0.0	0.001***
Problems in aesthetics	8.0	1.0	1.0	1.5	0.001***
Problems in oral hygiene	7.0	1.0	3.0	1.0	0.001***
Experience with treatment	7.0	2.5	8.0	1.0	0.001***
Overall acceptability	7.0	1.0	8.0	1.0	0.001***

P-values by Mann–Whitney U test. P-value <0.05 was considered to be statistically significant. *P-value <0.05, ***P-value <0.001.

- The median problems in speech score was significantly higher in Group 2 compared to Group 1 (P-value <0.05).

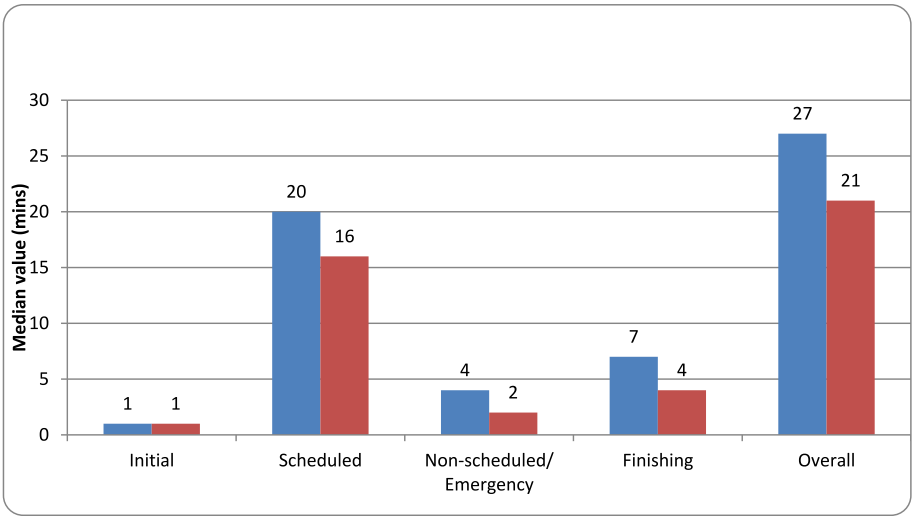


Fig. 3 – Comparison of the average chair side time per appointment between the two study groups.

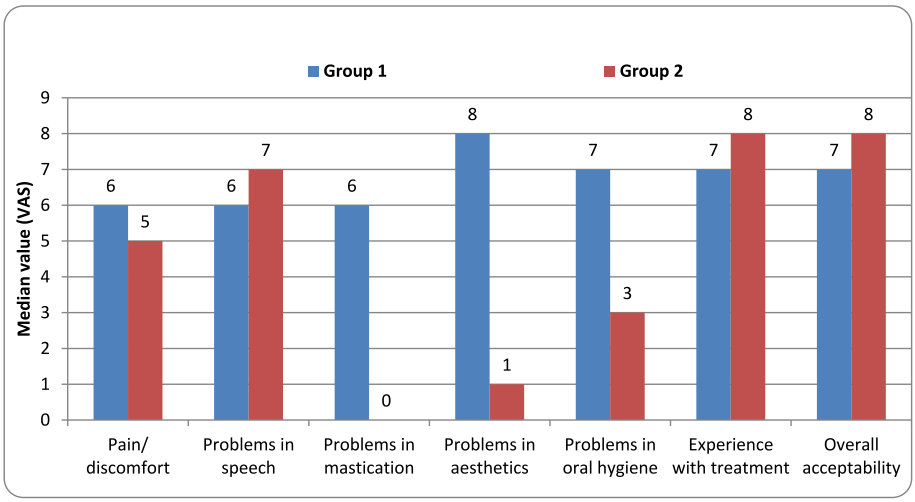


Fig. 4 – Bar graph showing the comparison of average scores of acceptability of treatment between the two study groups.

- The median scores of problem in mastication, problem in aesthetics, and problem in oral hygiene maintenance were significantly higher in Group 1 compared to Group 2 (P-value <0.001).
- The median scores of experience with treatment and overall acceptability were significantly higher in Group 2 compared to Group 1 (P-value <0.001).

Discussion

The number of adult patients seeking orthodontic treatment has increased in recent years. This has led to an increase in demand for more aesthetic alternates to conventional orthodontic treatment with labial metallic brackets.[1,14,15] Various invisible and aesthetic alternates, such as lingual appliances and tooth-colored brackets, have been introduced in the past to achieve better aesthetics and comfort. However, each modality had its own limitations. A recently popularized modality is clear aligners that consist of sequential tooth movement with a series of thermoplastic retainers.[16]

The results of this study show that the number of scheduled appointments was higher with clear aligners as compared to the MBT appliance. The average numbers of appointments were 13 in the aligner group compared to 10 in the MBT appliance group. These findings contradict earlier studies, which observed a lesser number of appointments with aligners as compared to fixed appliances.[9,17] This may be attributed to the fact that a 2D aligner system was used in the present study, which required a separate appointment for impression making and delivery of each aligner set and thereby increasing the number of appointments. This can be overcome by the use of 3D aligner systems based on computer-generated treatment simulation and the use of stereolithography (SLE) models for aligner fabrication. The findings of the present study, however, concur with the above studies[9,17] in significantly lesser numbers of emergency and finishing appointments associated with clear aligners as compared to MBT appliance.

Although the average number of appointments was more with CAT in the present study, the duration of treatment was significantly lesser with CAT (21 weeks) as compared to the MBT appliance (27 weeks). This is attributed to the fact that a lesser time was spent in scheduled, emergency, and finishing appointments with CAT as compared to MBT appliance (median time of 16, 2, and 4 weeks, respectively, with CAT as compared to 20, 4, and 7 weeks respectively with MBT appliances). These findings are similar to other studies in literature.[9,17–20] The findings of the present study contradict a few studies, which observed longer treatment duration with CAT.[20,21] A few studies have observed no significant difference in treatment duration between both modalities.[4,22] The differences between various studies may be attributed to the differences in appliance and aligner selection, the complexity of malocclusion, sequencing of archwires, operator related differences, and variations in study designs. Further studies taking care of the above confounding factors will add better quality evidence on this aspect.

The treatment efficacy in terms of reduced chairside time is an important outcome parameter to be considered in orthodontic practice. The reduced clinical time is pleasing to both the clinician and patients; it allows the clinician to treat more patients and reduces the waiting time for patients.[9] In the present study, the median chairside time for all appointments i.e. initial, scheduled, nonscheduled/emergency, and finishing appointments was significantly higher in MBT group (median time of 26.45 ± 2.74 min per appointment) as compared to CAT group (median time of 5.82 ± 0.95 min per appointment). These findings are similar to earlier studies[23,24] and are considered as an important advantage of CAT.

The fabrication of clear aligners manually at the orthodontist's clinic is a cumbersome process and requires additional time at every appointment of trained technicians, which is usually not required in fixed appliances and aligners fabricated with SLE models and CAD-CAM technology. The mean laboratory time per aligner fabrication in the present study was 30.26 ± 3.45 min. This time may vary depending upon the expertise of the technician. The advantage of the manual method includes being cost-effective, review of treatment progress at every appointment, and allowing the

clinician to make changes (if required) at a particular appointment.

The better acceptance of the treatment modality leads to better patient compliance and ultimately leads to better treatment outcomes.[9] This is more important in CAT because of the removability of the aligners. In the present study, the acceptability was assessed by questionnaire-based survey scores. The pain/discomfort, problem in mastication, problem in aesthetics, and problem in oral hygiene maintenance scores were higher with MBT treatment. The problems in speech, experience with treatment, and overall acceptability scores were higher with CAT. These findings concur with earlier studies, which have cited aligners as a more comfortable and aesthetic alternate for correction of malocclusion.[16,25] The present study assessed acceptability scores in mild crowding cases, and the above scores may vary depending upon the complexity of malocclusion.

Conclusions

Although both treatment modalities studied were effective in the management of nonextraction Class I crowding cases, the CAT has been found to be more promising in reducing the number of nonscheduled/emergency, and finishing appointments. The treatment time spent in scheduled, emergency and finishing appointments is lesser with CAT. The overall treatment duration is also lesser with CAT. The chairside time spent for all types of appointments is also lesser with CAT. The acceptability of treatment and overall experience with the treatment is better among patients treated with CAT as compared to MBT appliances with lesser incidence of pain and discomfort, lesser problems in mastication, aesthetics, and oral hygiene maintenance, as reported in the present study. However, additional laboratory time was spent in the present study for the fabrication of aligners manually. Prospective studies with 3D aligner systems are recommended to add further evidence in this regard.

Disclosure of competing interest

The authors have none to declare.

Acknowledgement

This paper is based on Armed Forces Medical Research Committee project No 4854/2017 granted by the office of the Directorate General Armed Forces Medical Services and Defense Research Development Organization, Government of India.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.mjafi.2021.09.006.

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