Clinical Efficacy Of CAD/CAM Vs Conventional Self-Ligating Orthodontic Bracket System: A Randomised Trial

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Abstract

Aim:
To evaluate the clinical effectiveness and efficiency of CAD/CAM designed custom orthodontic brackets vs. conventional pre-adjusted self-ligating brackets in patients receiving full fixed appliance treatment.

Material and Method:
This randomised trial included patients with mild to moderate crowding and require non-extraction or premolar extractions. 80 participants were allocated into two equal groups (n=40): Group A received CAD/CAM-designed customized brackets with indirect bonding and Group B received self-ligating brackets bonded directly. Total treatment time and number of visits required to complete orthodontic treatment were measured. Data were collected and analyzed using SPSS software. Normality was assessed using the Shapiro–Wilk test; intergroup comparisons used independent t-tests or Mann–Whitney U tests for continuous data, and chi-square or Fisher's exact tests for categorical data.

Results:
Total treatment time was significantly shorter in the CAD/CAM group (18.2±3.1 months) than in the conventional group (21.7±3.8 months; p=0.001). CAD/CAM patients required fewer active visits (16.0±3.0 vs 18.5±3.5; p=0.01). There was a significant decrease in alignment and finishing duration when using CAD/CAM brackets, but space closure were similar in both groups. Final PAR scores and percentage of cases with ideal finish were not statistically significant. Bracket failure and adverse clinical events were low and statistically comparable. Patient satisfaction score was slightly higher in the CAD/CAM group than self-ligating group.

Conclusion:
CAD/CAM customized orthodontic bracket systems were highly effective in reducing total treatment time and number of appointments, whereas occlusals and bracket failure rates were similar between self-ligating and CAD/CAM systems.

Introduction

Orthodontics aims at establishing best esthetic and occlusal appearance. Nonetheless, it takes a longer period to achieve these outcomes. Despite the experience of the clinician, bracket

positioning errors, inaccuracy during direct bonding and requirement of subsequent adjustment of the wire remains constant throughout the course extending the duration of treatment.[1,2]

Digital technologies have revolutionized the practice of contemporary orthodontics, in large part due to three-dimensional imaging and virtual treatment planning as well as CAD/CAM milled appliances.[3] The foundation for CAD/CAM customized brackets was laid by Weichmann's moving traditional approach towards individualized approach.[4] In this regard, CAD/CAM-designed customized bracket systems were specifically introduced to compensate for disadvantages of stock brackets used in conventional treatment approaches like the inaccurate location of these brackets, limited torque and tip control and the requirement of elaborate wire bending in the finishing stage.[5] By the aid of digital models, clinicians virtually move teeth, create customized scripts then produce patient-marked brackets and appliance base or indirect bonding jigs;expectation is that it will provide a more predictable and efficient treatment.[6]

Some commercial systems provide torque, tip, in–out compensation,and base morphology—Insignia, Incognito, OroMetrix, LightForce, KLOwen and other 3D printed bracket platforms.[7] Laboratory and in vitro studies demonstrate better slot precision,as well as more uniform contact between the bracket bases that might result in improved torque expression and control of play in the bracket–archwire relationship.[8,9] Recent overviews of mechanical and clinical properties of CAD/CAM and 3D-printed bracket systems describe encouraging trends in decreased duration for treatment as well as better precision in bracket placement, stressing however the heterogeneity among systems and underpinning studies.[10,11]

Recent systematic reviews and meta-analyses revealed that custom CAD/CAM bracket systems reduce the treatment time by 3–4months on average, with no clear evidence of superiority in final alignment or occlusal quality, nor consistent differences in early bond failure rates.[12-14] In addition, the literature is rather limited concerning current 3D-printed individualized labial brackets and newer configurator solutions.

In the era of life-long use of digital workflows and in light of the higher investment needed for custom-made CAD/CAM systems, sound clinical evidence with respect to patient derived-outcomes as well as treatment effectiveness is necessary to underpin their ubiquitous usage. This prospective, randomized clinical study aims to evaluate the clinical effectiveness and efficiency of CAD/CAM designed custom orthodontic brackets vs. conventional pre-adjusted self ligating brackets in patients receiving full fixed appliance treatment.

Materials and Methods

This single-centre, prospective, parallel-group randomized clinical study conducted in the Department of Orthodontics at a tertiary care dental teaching hospital. The protocol received approval from the Institutional Ethics Committee, and written informed consent was obtained from all participants (and guardians in the case of minors). The study was conducted in accordance with the CONSORT guideline (Figure 1).

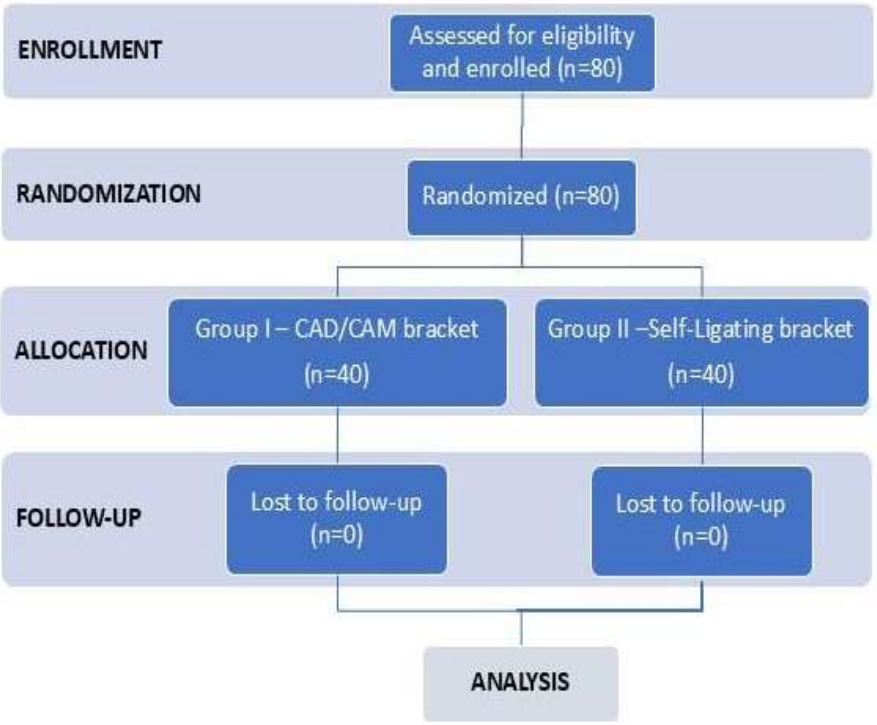

Figure 1 CONSORT flowchart

Sample size

Sample size was calculated to detect a minimum clinically relevant difference of 3 months in overall treatment duration between groups, assuming a standard deviation of 4 months, 80% power and 5% alpha (two-sided). The required sample size was 36 subjects per group; to compensate for drop-outs, 40 patients were recruited in each group (Total n=80).

Inclusion criteria

- Age 15–30 years.
- Permanent dentition up to at least second molars.
- Mild to moderate crowding (Little's irregularity index 3–8 mm) in at least one arch.
- Angle Class I or mild–moderate Class II malocclusion amenable to non-surgical therapy.
- Indication for comprehensive fixed appliance treatment with and without premolar extraction.
- Good general health and periodontal status.

Exclusion criteria

- Previous history of orthodontic treatment.
- Craniofacial syndromes or cleft lip and palate or severe skeletal deformities which require orthognathic surgery.
- Generalized periodontal degree or active caries that require extensive restorative treatment.
- Poor oral hygiene (non-compliance) at the first observation.

- Systemic conditions or medications which cause effect in bone metabolism.

Procedure

A single centre, prospective, parallel group randomised clinical trial was conducted in patients presenting mild to moderate crowding, requiring full orthodontic treatment (non-extraction or premolar extraction protocols). Eighty people were recruited in the study. Due to effects of learning curves associated with new treatment protocol, patients were selected consecutively from mid age range for each treatment arm. Eligible subjects were allotted through quasi-random system of allocation, in which patients were alternately assigned to either group by the clinicians, in order to ensure optimal levels of cooperation and avoid waiting periods. All subjects and their treatment information were randomly assigned code numbers by a research assistant in order to blind the evaluator (M.W.B.) during the data scoring and analysis process. Participants were allocated in a 1:1 ratio to Group A (CAD/CAM-customized brackets, n=40) and Group B (conventional self-ligating brackets, n=40).

In group 1 patients, digital intraoral scans were obtained to generate virtual dental models. A dedicated CAD/CAM platform was used to plan the final occlusion, individual tooth positions, and bracket prescriptions. Based on this virtual setup, customized labial brackets, indirect bonding trays, and individualized archwires were fabricated according to the manufacturer's protocol. After final adjustment of the fabricated brackets, a virtual setup treatment plan was obtained. These brackets were indirectly bonded to self-ligating brackets with custom-made bases and bonding jigs. The archwires were customized according to the virtual treatment set up.

Group 2 patients received 0.022-inch pre-adjustable self-ligating brackets that were bonded directly using manufacturer-recommended bonding agents.

The archwire, anchorage control, elastic used for leveling, aligning, and finishing archwire was standardized for both the groups. Patients were recalled after 4-6 week, based on the clinical presentation.

The number of appointments for bonding, archwire adjustments, emergency visits, debonding; total duration of treatment in months, pre-treatment cephalometric radiograph, post-treatment panoramic radiograph, pre-treatment and post-treatment digital eModel cast were noted (GeoDigm Corp., Falcon Heights, MN, USA). Emergency visits to replace brackets, to change protruded archwire ends, visits to clip protruding archwire ends were not included in treatment visit records. The alignment/levelling, space closure, and finishing were measured by duration (in months) of treatment. The occlusal outcomes at baseline and at the time of debonding were determined with the help of Peer Assessment Rating (PAR) index. Percentage of PAR reduction and the percentage of cases having a near-ideal finish (defined as 70% or more PAR reduction or final PAR score 5 or less) were compared.

Bracket-related assessment included bracket failure rate measured by debonded brackets per total number bonded brackets and bracket repositioning episodes. The patient satisfaction outcomes were assessed using visual analogue scale (VAS) to measure pain or discomfort at 24 hours following initial bonding and placement of first archwire, and overall satisfaction with treatment after debonding were measured on a 0-10 scale.

Statistical analysis

The data were collected and entered in Microsoft Excel and analysed with SPSS software. The Shapiro-Wilk test was done to test normality. Independent -samples t-tests or Mann-Whitney U

tests were used to conduct intergroup comparison of continuous variables. Chi-square tests or exact test of Fisher were used to analyse categorical data. Multiple linear regression was used to adjust the treatment duration based on age, sex, baseline PAR and extraction status. Statistical significance was set at $p<0.05$.

Results

Table 1. Baseline characteristics of the study groups

Variable	CAD/CAM group	Conventional group	p-value
Mean age (years)	19.8 ± 3.4	20.1 ± 3.7	0.72
Female, n (%)	24 (60.0)	25 (62.5)	0.82
Class I / Class II, n	28 / 12	27 / 13	0.80
Mean Little's index (mm)	5.6 ± 1.2	5.7 ± 1.3	0.83
Extraction cases, n (%)	18 (45.0)	19 (47.5)	0.82
Baseline PAR score (mean ± SD)	27.9 ± 6.1	28.4 ± 5.8	0.69

* $p<0.05$ was set as statistical significance

The two groups were comparable at baseline in age, sex distribution, malocclusion type, crowding severity and initial PAR score, supporting the validity of subsequent inter-group comparisons. (Table 1)

Table 2. Primary outcomes: overall treatment duration and appointments

Outcome	CAD/CAM group	Conventional group	p-value
Total treatment duration (months)	18.2 ± 3.1	21.7 ± 3.8	0.001*
Number of active appointments	16.0 ± 3.0	18.5 ± 3.5	0.01*
Proportion finished ≤24 months, n (%)	33 (82.5)	25 (62.5)	0.04*

* $p<0.05$ was set as statistical significance

CAD/CAM-customized brackets significantly reduced total treatment time by approximately 3.5 months and required fewer appointments than conventional self-ligating brackets, with a higher proportion of cases completed within 24 months. (Table 2)

Table 3. Phase-specific treatment duration

Phase	CAD/CAM group (months)	Conventional group (months)	p-value
Alignment/levelling	4.5 ± 1.0	5.8 ± 1.3	<0.001*
Space-closure	7.0 ± 1.8	7.6 ± 1.9	0.16
Finishing/detailing	6.7 ± 1.6	8.3 ± 1.9	0.002*

* $p<0.05$ was set as statistical significance

The greatest efficiency gains with CAD/CAM brackets were observed in the alignment and finishing phases, whereas the duration of space-closure was comparable between groups. (Table 3)

Table 4. Occlusal outcomes at debonding

Outcome	CAD/CAM group	Conventional group	p-value
Final PAR score (mean ± SD)	3.2 ± 2.1	3.5 ± 2.4	0.56
Mean PAR reduction (%)	88.5 ± 6.7	87.2 ± 7.4	0.41
Cases with ≥70% PAR reduction, n (%)	36 (90.0)	35 (87.5)	0.74
"Near-ideal" finish (PAR ≤5), n (%)	34 (85.0)	33 (82.5)	0.77

* $p<0.05$ was set as statistical significance

Both groups achieved comparable and substantial improvements in occlusal status, with no significance statistically in final PAR scores or the proportion of patients attaining a near-ideal finish. (Table 4)

Table 5. Bracket failure and repositioning

Variable	CAD/CAM group	Conventional group	p-value
Total brackets bonded (n)	960	960	–
Debonded brackets (n)	30	36	0.38
Bracket failure rate (%)	3.1	3.7	–
Patients with ≥1 debond, n (%)	14 (35.0)	16 (40.0)	0.65
Mean repositioned brackets per patient	0.8 ± 0.9	1.4 ± 1.2	0.02*

* $p<0.05$ was set as statistical significance

Early bracket failure rates were low and similar between groups, but the CAD/CAM group required significantly fewer bracket repositionings, reflecting improved initial placement accuracy associated with indirect bonding and customized bases. (Table 5)

Table 6. Patient-reported outcomes

Patient-reported measure	CAD/CAM group	Conventional group	p-value
VAS pain at 24 h after bonding (0–10)	5.8 ± 1.5	6.1 ± 1.4	0.39
VAS pain at 24 h after first working archwire	6.2 ± 1.6	6.4 ± 1.5	0.56
Overall satisfaction with treatment (0–10)	8.6 ± 0.9	7.9 ± 1.1	0.004*
Willing to choose same system again, n (%)	35 (87.5)	30 (75.0)	0.16

* $p<0.05$ was set as statistical significance

Pain levels during the initial stages of treatment were comparable between groups. Overall satisfaction scores by patient were slightly higher among patients treated with CAD/CAM-customized brackets, possibly reflecting perceived modernity, shorter treatment time, and fewer repositioning visits (Table 6).

Discussion

This prospective randomized clinical trial evaluated the clinical outcomes and treatment duration of CAD/CAM customized bracket systems vs conventional self-ligating brackets in patients receiving orthodontic alignment.

In the present study, CAD/CAM group completed treatment approximately 3.5 months earlier than the conventional group (18.2±3.1 vs 21.7±3.8 months; p=0.001), with significantly fewer clinical appointments. This reduction in treatment duration is consistent with Jackers et al.[15] observed a 26% reduction in total treatment duration, supporting the premise that customized orthodontic appliances can enhance clinical efficiency. Our study is in accordance with Brown et al.[16], however, suggested that part of this efficiency gain may be attributable to more frequent visits and the use of indirect bonding techniques, rather than customization alone.

In contrast, Hegele et al.[17] did not identify statistical difference in total treatment time between CAD/CAM and conventional self-ligating systems. This discrepancy may be explained by variations in sample size, case complexity, operator experience, and treatment protocols. Notably, the smaller CAD/CAM cohort and wide range of treatment durations reported by Hegele et al. may have limited the ability to detect statistically significant differences.

In the present study, stage-specific analysis revealed that the greatest efficiency gains with CAD/CAM systems occurred during the alignment/levelling and finishing phases, while the duration of space closure was comparable between groups. These findings support the concept that accurate three-dimensional bracket positioning and customized prescriptions reduce the need for extensive wire bending and bracket repositioning, particularly during finishing. Similar observations were reported by Jackers et al.[15], who found a significantly shorter fine-tuning phase in CAD/CAM-treated patients. Conversely, the absence of differences during space closure suggests that biological constraints of tooth movement and anchorage demands may limit the influence of appliance customization during this phase, as also emphasized by Brown et al.[16]

Despite the improved treatment efficiency observed with CAD/CAM systems, no statistical difference in treatment quality were identified between two groups. Final PAR scores and the proportion of cases achieving near-ideal occlusal outcomes (PAR ≤ 5) were comparable, with more than 85% of patients in both groups attaining clinically acceptable finishes. These results align with Jackers et al.[15], Brown et al.[16], and Hegele et al.[17] studies, all of whom reported no clinically meaningful differences in final ABO-OGS or PAR scores between customized and conventional bracket systems. These findings show that while CAD/CAM systems may streamline the treatment process, well-executed conventional orthodontic therapy remains capable of achieving comparable occlusal outcomes, particularly in experienced hands.

Bracket failure rates in the present study were low and similar between groups, corroborating earlier reports that found no clear difference in bond failure between custom-made and standard brackets. However, significantly fewer bracket repositionings were required in the CAD/CAM group, reflecting improved initial transfer accuracy. This observation is consistent with in-vivo and ex-vivo studies demonstrating enhanced precision with 3D-printed indirect bonding trays and customized bracket bases. Hegele et al.[17] and Jackers et al.[15] similarly reported fewer repositioned brackets and adverse bonding events in CAD/CAM-treated patients, mostly in mandibular arch.

Clinically, reduced repositioning translates into shorter chairside time, fewer appointments, and improved workflow efficiency. While Czolgosz et al.[18] reported a higher immediate debonding rate with CAD/CAM indirect bonding, their study focused specifically on bonding procedures rather than full orthodontic treatment outcomes. Differences in adhesive protocols, operator experience, and timing of failure assessment may explain the contrasting results.

Patient-reported pain during the early stages of treatment did not show any significance between groups, supporting the concept that orthodontic discomfort is primarily related to force magnitude and tissue response rather than bracket design. These findings are in agreement with those of Jackers et al.[15] and Czolgosz et al.[18], who reported comparable discomfort levels and analgesic consumption between CAD/CAM and conventional systems. Nevertheless, overall patient satisfaction was higher in CAD/CAM group. This trend may be due to shorter treatment duration, fewer visits, and the perceived advantages of advanced digital technology, as previously suggested in cohort studies and narrative reviews on digital orthodontic workflows. Although few studies did not demonstrate statistical difference in satisfaction scores, patient preference for aesthetics and technological innovation may play an influential role in treatment acceptance.

This study has limitations. It was a single-site study involving a small sample size and limited mainly to mild to moderate malocclusions; findings cannot be generalized to severe skeletal disharmonies or complex multidisciplinary cases. Despite randomization that reduced baseline imbalances, the inability to blind clinicians to treatment arm may have resulted in performance bias. Cost-effectiveness analysis and outcomes over the longer term were not evaluated in this study, but are important in making decisions -especially in low-income settings.

Further research using large and multicentre randomised controlled trials of heterogeneous patient groups is required as no direct comparative analyses between different individualised systems (milled and 3D-printed; lingual and labial) have been carried out yet; cost-utility assessments and patient-reported outcome measures have not been studied in previous literature satisfactorily. Patient-specific orthodontic treatment planning and adaptive prescription optimization are other current prospects to make the process of planning more efficient and predictable by using artificial intelligence.

Conclusion

Customised CAD/CAM designed orthodontic bracket systems proved to be more effective than traditional self-ligating brackets with significantly reduced overall treatment time and reduced clinical visit. The results of occlusal outcome, measured with the help of PAR scores and the ratio of near-ideal finishes, were similar in both groups, and bracket failures were low. In the frames of current research, the use of CAD/CAM-customised appliances can be approved as the option to increase the efficiency of the workflow and patient experience, especially in digitally oriented practices, but it is necessary to add that the highest results can also be achieved when the conventional approach is carefully executed.

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