

Standard vs computer-aided design/computer-aided manufacturing customized self-ligating systems using indirect bonding with both: *A comparative study*

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ABSTRACT

Objective: To compare treatment duration and quality between standard vs computer-aided design/computer-aided manufacturing (CAD/CAM) customized self-ligating systems using indirect bonding with both.

Materials and Methods: This comparative trial included 24 patients: 12 treated with a CAD/CAM custom indirect bonding self-ligating system (CAD/CAM) and 12 others treated with an indirect bonding self-ligating standard system (I-STD). For each group, overall orthodontic treatment (OT) time was calculated and included the time needed to place each arch as well as the duration of the alignment and fine-tuning phases. The quality of the final result was analyzed using the American Board of Orthodontics Cast-Radiograph Evaluation. Patient-reported outcome measures (PROMs) were also evaluated.

Results: Patient characteristics were similar between the 2 groups except for age, which was slightly lower in the I-STD group. Overall OT time was increased by 26% in the I-STD group compared with the CAD/CAM group (497 ± 40 days vs 393 ± 55 days, $P = 0.0002$) due to a shorter fine-tuning phase in the latter group ($P < 0.01$). No difference was found between the groups for alignment phase. Quality of the final result was similar (I-STD, 25.7 ± 6.1 ; CAD/CAM, 21.6 ± 6.3) among the groups. Finally, no difference was found in the PROMs variables.

Conclusions: Despite a 26% longer OT time when compared with the CAD/CAM customized bracket system, the indirect bonding self-ligating bracket system demonstrated the same quality of treatment. PROMs demonstrated a high level of acceptance and satisfaction for both techniques. (*Angle Orthod.* 0000;00:000–000.)

KEY WORDS: Customized orthodontic; Tooth movement; Indirect bonding; CAD/CAM; Adult patients

INTRODUCTION

The major concern for an orthodontist is to provide high-quality treatment completed within a reasonable timeframe. As initially introduced by Andrews¹ in the 1960s, the straight-wire appliance developed the concept of an ideal bracket position. Indeed, the accurate positioning of brackets on each tooth is a critical component in reaching the orthodontic goals. To achieve optimal final results, bends are usually required after the alignment phase as a result of variations in tooth-surface morphology, inaccuracies of direct bonding, and mechanical deficiencies of edge-wise orthodontic appliances.² Some techniques have been developed to improve the quality of orthodontic treatment (OT) by using new techniques and technologies such as indirect bonding and custom brackets

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Accepted: May 2020. Submitted: January 2020.

Published Online: September 10, 2020

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and arches or by using computer-aided design (CAD) software.

Some authors have proposed the alternative of bracket placement using an indirect bonding method. However, the benefit of this technique remains controversial. Several publications have demonstrated that indirect bonding provides a more accurate ultimate OT result compared with the direct technique. This is attributed to brackets being easier to place on a dental cast, using this cast permits a visual control from different angles,³⁻⁵ and bonding errors are therefore reduced.⁶⁻¹⁰ In an *in vitro* study on 19 sets of duplicated Class II malocclusion models, Koo et al.⁸ investigated the accuracy of bracket placement with both techniques. The authors demonstrated an improvement of the bracket height in the indirect group, whereas no significant difference was found between groups for the angulation and the mesiodistal bracket position. In addition, indirect bonding was a more rapid and less stressful technique for the practitioner compared with direct bonding.^{4,11} On the contrary, Hodge et al.⁹ did not observe any accuracy difference between the direct and indirect bonding techniques, and Deahl et al.¹⁰ reported similar OT time, bracket failure, and number of appointments between the two techniques.

Recently, an increasing number of companies have used design software and technological advances in orthodontics to introduce CAD and computer-aided manufactured (CAM) customized appliances¹² combined with custom-made buccal bracket systems using indirect bonding transfer jigs.¹³ After approval of the final OT result on a virtual setup through a software planning system, the slots of the brackets can be individualized and the custom wires are manufactured by a wire-bending robot. However, the literature is still scarce about the comparison of direct, indirect, and CAD/CAM indirect bonding. In a retrospective study, Weber et al.¹⁴ compared the treatment efficiency and effectiveness of the CAD/CAM customized system with conventional direct bonding methods and found shorter treatment durations and lower American Board of Orthodontics (ABO) scores in the CAD/CAM group. In a retrospective study, although appointment intervals were not standardized between the groups, Brown et al.¹⁵ also demonstrated shorter overall OT time with the CAD/CAM self-ligating system compared with direct and indirect bonding with self-ligating systems. Conversely, in a randomized controlled trial, Penning et al.¹⁶ showed that the CAD/CAM self-ligating system was not associated with any significant reduction in OT duration or any difference in quality scores using the Peer Assessment Rating (PAR) index compared with direct bonding with a self-ligating system. Interestingly, none of these studies provided details of the different treatment times, for example, the timing of the

alignment phase and the fine-tuning phase, which would allow a better understanding of the effect of these technologies on the potentially improved kinetics. As already stated by some authors, well-designed trials are needed to clarify the benefits of indirect bonding and CAD/CAM customized orthodontic appliances to reduce OT time and improve the accuracy of the final results.

The aim of the present study was to evaluate the effect of custom-made brackets on treatment duration and quality using indirect bonding and self-ligating orthodontic systems. The primary objective was to evaluate the overall OT time in addition to the respective duration necessary for the alignment and fine-tuning phases in the two groups. The secondary objectives were to compare the quality of the treatment by using the ABO index between the two groups and to investigate patient-reported outcome measures (PROMs).

MATERIALS AND METHODS

Experimental Design and Participants

The study was designed as a comparative, single-center study conducted on two separate groups of patients from the Orthodontics Department of the University Hospital of Liège, Belgium. Group I (CAD/CAM) consisted of 12 adult patients with minor to moderate crowding who received OT using the CAD/CAM customized indirect bonding self-ligating system (Insignia, Ormco, Calif). This group of patients was one arm of a previously published randomized controlled trial,¹⁷ which was approved by the ethics committee of the University Hospital of Liège (file number B707201629875). Group II (I-STD) enlisted 12 consecutive and eligible patients during the same time period who received OT using the indirect standard self-ligating bonding system (Damon Q, Ormco, Calif). There were no changes to the protocol after trial commencement. Institutional ethical committee of the University Hospital of Liège had no ethical objection to conduct this study.

For both groups, the inclusion criteria were as follows: (1) adults needing OT in the maxilla and the mandible, (2) irregularity index ≤ 6 ¹⁸ (minimal to moderate overcrowding), (3) satisfactory oro-dental health, and (4) American Society of Anesthesiologists stage I or II. The exclusion criteria were as follows: (1) gingival recession >2 mm, (2) smoking, (3) altered bone metabolism, (4) pregnancy; and (5) previous periodontitis with a loss of alveolar support $\geq 10\%$.

Pretreatment Analyses

Patients of both groups received a pretreatment procedure as follows: alginate impressions (Cavex

Colorchange, Cavex Holland, Netherlands), panoramic and lateral cephalogram X-rays (Planmeca Inc., Helsinki, Finland), and extra-oral and intra-oral photographs.

Orthodontic Procedures

Group I (CAD/CAM). Patients of group I received an additional precise Polyvinyl Siloxane impression (Kulzer, Hanau, Germany). Indirect bonding CAD/CAM self-ligating brackets (Insignia) were manufactured for each patient according to digital three-dimensional planning. The sequence of customized archwires for alignment consisted of 0.014-in, 0.018-in, 0.014 × 0.025-in, and 0.018 × 0.025-in copper nickel-titanium archwires followed by 0.019 × 0.025-in stainless steel archwires for fine-tuning.

Group II (I-STD). After applying a thin layer of separator on the dental casts, self-ligating brackets (Damon Q) were placed on the dental cast of each patient, and a private laboratory supplied the double-vacuum trays to perform the indirect bonding.⁶ The alignment sequence consisted of 0.014-in, 0.018-in, 0.014 × 0.025-in, and 0.018 × 0.025-in copper nickel-titanium archwires followed by 0.019 × 0.025-in stainless steel archwires for fine-tuning.

All patients were recalled every 2 weeks. The OT was respectively performed by two calibrated orthodontists from the same Orthodontic Department of the University Hospital of Liège, Belgium. The two calibrated orthodontists were invited to attend two calibration meetings in which the objectives of the study, the orthodontic protocol, and the assessment method were reviewed. A third blinded orthodontist confirmed the appliance removal or requested adjustments based on the model without any group indication. Fixed and removable retainers were placed after removal of the appliance.

Data Collection

Baseline Data. Baseline characteristics including space analysis data were collected for each patient. In addition, the ABO Discrepancy Index (DI) was recorded to evaluate the relative severity of the initial malocclusion of each subject. Different orthodontic times were recorded as follows: the overall treatment time (days), timing of the placement of each arch during the alignment phase (days), the overall alignment phase duration (days), the overall fine-tuning phase duration (days). Adverse events were recorded as the number of debonded brackets. Quality of orthodontic results were calculated after treatment using the ABO Cast-Radiograph Evaluation (CRE) system score. PROMs were recorded using a visual

analog scale of 0 to 10, including apprehension before treatment and, after the completion of the treatment, in terms of level of satisfaction (final result, treatment duration), whether the patients would recommend the procedure to a friend, and whether they would undergo the treatment again. Daily analgesic consumption (g) following orthodontic appliance placement was recorded.

Statistical Analysis

Sample size calculations showed that, with at least 10 participants in each group, a reduction of 20% in the total OT duration could be discerned with a power of 80% at the 5% significance level.

For quantitative data, the results were summarized as mean ± standard deviation (SD). Categorical data were expressed as a frequency table (numbers and percentages). Boxplots were used to display variable distribution. Mean comparisons were performed by one-way analysis of variance or the Kruskal–Wallis nonparametric test. Proportions were compared by the chi-squared test. The results were considered significant at the 5% critical level ($P < 0.05$). All calculations were performed with SAS 9.4 (SAS Institute Inc., Cary, N.C.) and R 3.2.5 statistical software (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Patient Characteristics

Patient characteristics in the two groups are displayed in Table 1. No difference was found between CAD/CAM and I-STD groups except for age, which was significantly lower in I-STD patients (20.1 ± 4.6 vs 26.6 ± 7.0 years, $P = .019$). The ABO DI scores evaluated on the study models and initial cephalograms were comparable.

Orthodontic Treatment Times

The duration of visits was of 30 minutes.

Although treatment completion was reached in 393 ± 55.7 days in the CAD/CAM group, it amounted to 497 ± 40.8 days in the I-STD group, corresponding to a 26% increase ($P = .0002$) (Figure 1).

The timing of each arch placement in the maxilla and the mandible during the alignment phase recorded in CAD/CAM and I-STD patients is displayed in Figure 2. The duration of the alignment phase was not significantly different between the two groups. In the CAD/CAM group, it was 251 ± 36.4 days for the maxilla and 259 ± 47.9 days for the mandible. In the I-STD group, durations were 239 ± 65.4 days for the maxilla and 268.4 ± 61.1 days for the mandible, respectively.

Table 1. Baseline Characteristics of Patients in the CAD/CAM and I-STD Groups

	Group I (N = 12) CAD/CAM	Group II (N = 12) I-STD	Comparison <i>P</i> Value
	Mean ± SD	Mean ± SD	
Age (y)	26.6 ± 7.0	20.1 ± 4.6	.019
Sex (no. men/women)	4/8	3/9	1.0
Space analysis (mm)			
Maxilla	2.0 ± 1.2	1.8 ± 1.3	.60
Mandible	3.1 ± 1.6	2.7 ± 0.73	.22
ABO DI			
Overjet	1.3 ± 1.6	1.8 ± 0.94	.26
Overbite	1.0 ± 1.3	1.6 ± 1.0	.27
Ant open bite	0.25 ± 0.62	0.17 ± 0.39	.93
Lateral open bite	0.17 ± 0.58	0.0 ± 0.0	.32
Crowding	1.3 ± 0.65	1.3 ± 0.49	.89
Occlusal relationship	3.0 ± 1.6	1.5 ± 1.7	.045
Lingual posterior X-bite	0.17 ± 0.39	0.08 ± 0.29	.55
Buccal posterior X-bite	0.0 ± 0.0	0.17 ± 0.58	.32
Cephalometrics	3.3 ± 3.7	5.1 ± 6.0	.63
Other	4.2 ± 3.5	1.6 ± 1.9	.035
Total DI score	14.8 ± 7.3	13.3 ± 5.8	.71

As illustrated in Figure 3, the overall fine-tuning phase duration in the CAD/CAM group was shorter when compared with that of the I-STD group in both the maxilla and the mandible (142 ± 60.5 days vs 258 ± 73.4 days in the maxilla [$P = .0011$] and 134 ± 59.4 days vs 226 ± 76.0 days in the mandible [$P = .0056$]).

Adverse Events

As seen in Table 2, no difference in adverse events was found between the two groups except for bracket debonding in the mandible, which occurred more frequently in the I-STD group ($P = .033$).

Quality of Orthodontic Treatment

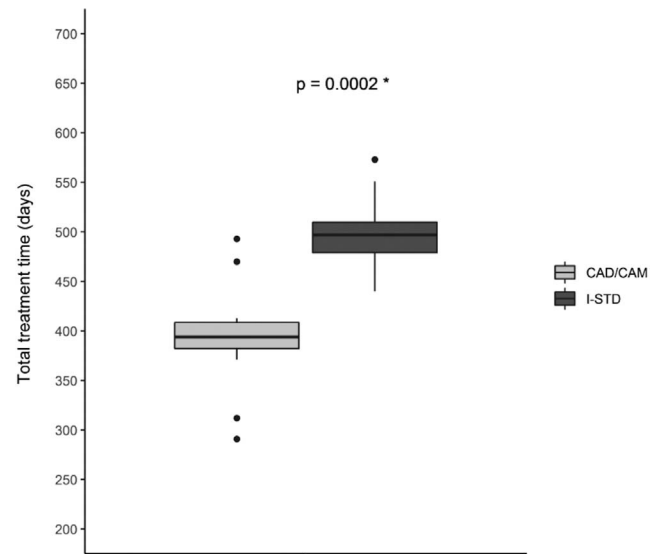
The final ABO CRE scores were 21.6 ± 6.3 for the CAD/CAM group and 25.7 ± 6.1 for the I-STD group (Table 3) and showed no significant difference.

PROMs

The level of apprehension before treatment was identical in the 2 groups. After treatment completion, the levels of satisfaction for the treatment outcome ($P = .25$) and for the duration ($P = .28$) were also similar (Table 4).

Analgesic Consumption

Table 5 shows the paracetamol consumption in the two groups after placement of the appliances and demonstrated no difference between the groups.

**Figure 1.** Overall treatment time in the two study groups.

DISCUSSION

The aim of this comparative study was to confront treatment duration and quality between standard vs CAD/CAM customized self-ligating systems using indirect bonding in both. The customized CAD/CAM brackets resulted in an OT time that was 26% shorter when compared with the standard self-ligating system (indirectly bonded). This acceleration process was mainly found in the fine-tuning phase, whereas no difference between the groups was observed in the alignment phase. Although the difference was not statistically different, the ABO score was lower in the CAD/CAM than in the I-STD group and also demonstrated a marginally better quality of final outcome with the customized system.

The PAR index, although being scientifically validated, is less accurate in highlighting minor differences in the dental position of teeth.¹⁹ Hence, to evaluate the quality of the final result, the ABO score was used owing to the fact that this objective grading system is the most complete (dental casts and radiography).²⁰ The groups were considered to be homogeneous aside from age, which was slightly higher in the I-STD group.

These findings could be explained by characteristics specific to the CAD/CAM system. The custom-made brackets are designed according to a digital orthodontic plan and the practitioner is able to carefully adjust the digital set up in three dimensions and refine several aspects of the OT such as the torque, tip, intrusion/extrusion, arch form, smile arc and dental contacts in addition to visualizing the final result. Also, the personalized shape of the brackets is perfectly adapted to the tooth surface, thus permitting accurate

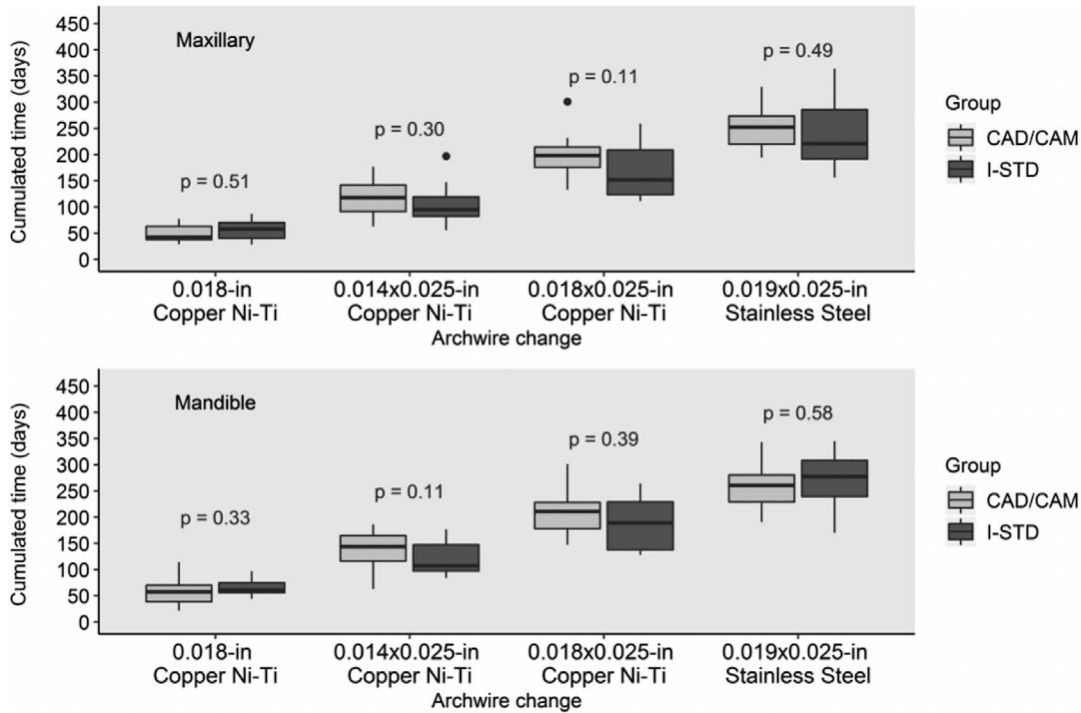


Figure 2. Cumulated orthodontic treatment time observed in the CAD/CAM group and I-STD group (Ni-Ti). The dots represent the outlier values. Ni-Ti, nickel-titanium.

indirect bonding and therefore a reliable placement of the bracket.¹³ Finally, the custom-made manufacturing of the brackets and archwires following the digital plan limits the need for archwire compensation or bracket repositioning during the fine-tuning phase, and this may play a role in the reduction in the overall OT time. The present results were consistent with retrospective studies in which OT time accelerations of 60% and

20% were found when using the individualized CAD/CAM system compared with standard brackets placed, respectively, with direct and indirect bonding.^{14,15} Despite some design limitations (retrospective studies, nonstandardized visit intervals, etc), these two studies suggested that a part of the treatment time reduction may be associated, on the one hand, to the individualized aspect of the brackets and on the other hand to the indirect bonding. In contrast, Plenning et al.¹⁶ described no influence of the CAD/CAM system on the overall OT time. In their study protocol, the number of checkup visits depended on the orthodontist, and patients were treated in two different clinical private practices ($P < 0.001$). No previous study has investigated the different system solutions with a differentiation between the alignment and fine-tuning phases.

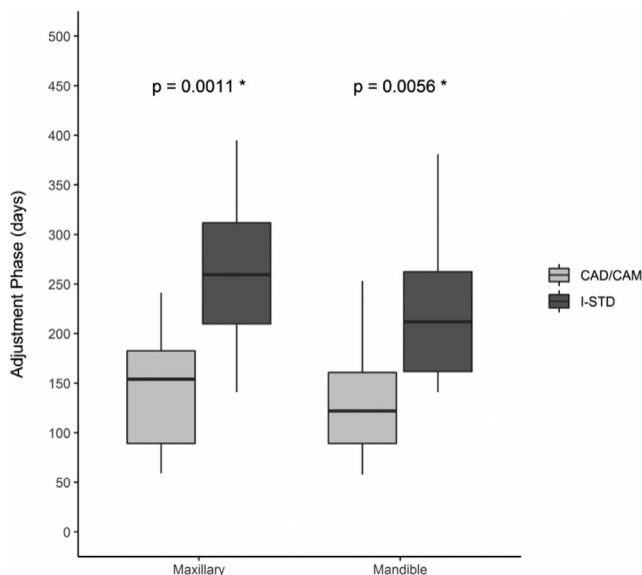


Figure 3. Fine-tuning phase in the CAD/CAM and I-STD groups.

Table 2. Brackets Debonding (P Value, Kruskal–Wallis)

	Group I (N = 12) CAD/CAM	Group II (N = 12) I-STD	Comparison P Value
	Mean \pm SD	Mean \pm SD	
Maxilla			
Brackets debonding	1.5 \pm 2.6	0.75 \pm 1.1	.59
Mandible			
Brackets debonding	2.2 \pm 3.5	3.6 \pm 1.7	.033

Table 3. ABO Cast-Radiograph (ABO CRE) Scores in CAD/CAM and I-STD Patient Groups

	Group I (N = 12) CAD/CAM	Group II (N = 12) I-STD	Comparison P Value
	Mean ± SD	Mean ± SD	
Alignment/Rotations	2.8 ± 1.2	2.8 ± 1.1	.88
Marginal Ridges	4.2 ± 1.9	4.0 ± 2.0	.91
Buccolingual inclination	4.5 ± 2.2	4.5 ± 2.2	1.0
Overjet	2.4 ± 1.6	3.7 ± 2.5	.13
Occlusal contacts	4.5 ± 3.1	7.8 ± 3.7	.036
Occlusal relationships	1.7 ± 2.1	2.2 ± 3.7	.90
Interproximal contacts	0.50 ± 0.67	0.0 ± 0.0	.014
Root angulation	1.1 ± 0.90	0.75 ± 0.75	.34
Total CRE score	21.6 ± 6.3	25.7 ± 6.1	.11

The description of the CAD/CAM system given previously could explain the marginally superior results obtained in the CAD/CAM group compared with the indirect group. Weber et al.¹⁴ obtained a minimally significant difference between the groups, whereas Brown et al.¹⁵ found no difference in the quality of the final results. Finally, Penning et al.,¹⁶ using the PAR index, found no difference. Regardless of these conflicting findings, all authors agreed in their statements that the CAD/CAM custom system provided only a slight increase in the quality of OT. Interestingly, in this present study, the numbers of broken bonds was significantly higher in the I-STD group compared with the CAD/CAM group in the mandible, probably explained by the CAD/CAM design of the curvature of the bracket that fits the tooth surface perfectly. In the study by Weber et al.,¹⁴ no difference was found between the groups, whereas Penning et al.¹⁶ found significantly fewer broken bonds in the CAD/CAM group compared with the direct bonding group (3.5 breakages vs 5.47 breakages); this was attributed to the bulky design of the custom brackets. Finally, both systems evoked a high level of acceptance and satisfaction from a patient point of view, with no difference between the groups.

Table 4. PROMs in the CAD/CAM and I-STD Groups

	Group I (N = 12) CAD/CAM	Group II (N = 12) I-STD	P Value
	Mean ± SD	Mean ± SD	
Level of apprehension	3.5 ± 2.6	4.4 ± 2.4	.42
Satisfaction in terms of final result	8.6 ± 1.1	9.1 ± 0.9	.25
Satisfaction in terms of treatment time	6.6 ± 1.6	7.3 ± 1.8	.28
Would recommend the procedure to a friend	8.1 ± 1.6	8.6 ± 1.7	.37
Would undergo the treatment again	7.7 ± 1.7	8.2 ± 2.2	.38

Table 5. Paracetamol Consumption (Mean ± SD)

Paracetamol consumption (g)	Group I (N = 12) CAD/CAM	Group II (N = 12) I-STD	P Value
	Mean ± SD	Mean ± SD	
Day 0	0.79 ± 0.75	0.96 ± 0.92	.60
Day 1	0.67 ± 0.65	0.92 ± 1.0	
Day 2	0.25 ± 0.40	0.58 ± 0.97	
Day 3	0.17 ± 0.33	0.42 ± 1.0	
Day 4	0.083 ± 0.29	0.33 ± 0.89	
Day 5	0.0 ± 0.0	0.33 ± 0.89	
Day 6	0.0 ± 0.0	0.25 ± 0.87	
Total	2.0 ± 2.0	3.8 ± 5.9	
Average/day	0.28 ± 0.77	0.54 ± 0.84	

Limitations of the Study

Some limitations related to the study design of the present trial should be highlighted. Although the patients were included during the same time period and the methodology and the operators were the same, the patients were not randomized prospectively. This may have induced some bias too minimal to be appraised, but which could have affected the findings. In addition, the study was not blinded because the design of the brackets was different. Finally, the cost-benefit ratio was an interesting aspect that was not evaluated. Thus, additional studies are needed to more accurately quantify the clinical benefits of the two systems (eg, the accuracy of tooth movement in CAD/CAM customized OT could be evaluated by a superimposition of the virtual set up and the final result).

CONCLUSIONS

- Despite a 26% longer OT time when compared with the CAD/CAM customized bracket system, the indirect bonding self-ligating bracket system exhibited the same quality of treatment result. PROMs demonstrated a high level of acceptance and satisfaction for both techniques.

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