

A comparison of SureSmile™, Insignia™, and Invisalign™, in treating non-extraction cases of mild to moderate crowding: a prospective clinical trial

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Objectives: To compare the ability of SureSmile™, Insignia™ and Invisalign™ to achieve predicted intra-arch tooth positions and further compare their objective grading scores for alignment/rotations, marginal ridge relationships and buccolingual inclination.

Materials and methods: The study was a prospective clinical trial of 145 arches from 44 females and 29 males (54 SureSmile™ arches, 35 Insignia™ arches, and 56 Invisalign™ arches). All arches were treated by a non-extraction approach and had ≤7 mm of crowding and 45° of tooth rotation. The manufacturer's recommendations were followed for each group and the final scans were acquired before refinements, rebonding, or wire bending. The virtual set-ups were superimposed on the final scans and the coordinates of 34 landmarks per arch were compared. One hundred and twenty-six end-of-participation arches were suitable for 3D printing and were compared using the American Board of Orthodontics Objective Grading Scores (OGS) for alignment/rotations, marginal ridge relationships, and buccolingual inclination.

Results: No statistically significant differences were identified in the mean deviation between the target and achieved the position of the anterior landmarks within the treatment groups. The exception was the Suresmile group which had greater vertical discrepancies in the position of the labial CEJ. Although the mean differences between the target and achieved anterior landmark positions for all groups were under 0.5 mm, the range of maximum discrepancy was between 0.7 mm and 4.1 mm. The Insignia™ system showed significantly greater deviation in upper posterior landmark positions in the transverse and sagittal dimensions, and lower posterior landmarks in the transverse dimension. However, this was due to the Insignia™ initial set-ups being wider. There was no statistically significant difference between the three systems in combined intra-arch OGS. However, the Invisalign™ system had a significantly poorer alignment/rotation score than the SureSmile™ group. The Insignia™ system performed better in achieving buccolingual tooth inclination compared to Suresmile™, and the Invisalign™ system performed better than the Suresmile™ system in the marginal ridge score.

Conclusions: The three systems were comparable in achieving the predicted tooth positions of the anterior teeth in non-extraction, mild-to-moderate, crowded cases. Large discrepancies requiring operator intervention were common within the three systems. Although the three systems had no statistically significant difference in overall intra-arch OGS scores, there were significant differences in the score components.

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Introduction

In the 1970s, Andrews' 'Straight Wire' Appliance (SWA) incorporated bracket base and slot modifications for each type of tooth which reduced, but did not eliminate, the need for first, second, and third order arch wire bends.¹⁻³ Variations in tooth morphology,⁴⁻⁸ the inaccuracy of bracket placement,^{5,7,9,10} and mechanical limitations^{5,7,11} have been suggested as possible reasons for the shortcomings of pre-adjusted bracket systems.

The introduction of computer-aided design and computer-aided manufacturing (CAD/CAM) technology has allowed clinicians to customise orthodontic care via virtual treatment planning and the computer-assisted fabrication of brackets, wires or clear aligners.

Insignia™ (Ormco, Orange, California, USA) is a custom appliance system which utilises digital intra-oral scans to create a virtual model of a desired final occlusion, and to subsequently reverse-engineer custom brackets and arch wires. Bracket positioning is determined virtually and application to the patient is via indirect-bonding transfer jigs.¹² Weber et al.¹³ retrospectively found that cases treated using the Insignia™ system received superior ABO scores, significantly reduced treatment time and had a lesser number of appointments when compared to cases treated using conventional bracketed appliances. Brown et al.¹⁴ retrospectively compared cases treated using the Insignia™ system to those treated with conventional self-ligating brackets and confirmed the shorter treatment duration and number of visits while achieving similar cast-radiograph evaluation scores.

SureSmile™ (Orametrix, Richardson, Texas, USA) is a custom wire system which uses three-dimensional models obtained via intra-oral surface scans or cone beam computerised tomography (CBCT) imaging to create virtual treatment plans, and to fabricate a series of customised, robot-bent, arch wires according to a specified plan.¹⁵ The system eliminates the error of bracket transfer during indirect bonding by scanning the actual bracket position which is a fundamental difference between the Insignia and Suresmile systems. The robot-bent wires reportedly show less than one degree of error in incorporated bends and twists.¹⁶ Alford et al.¹⁷ determined that cases treated using the

SureSmile™ system had significantly shorter treatment time and superior cast/radiographic evaluation (CREval) scores compared to those finished with manual wire bending. However, the SureSmile™ cases had a significantly lower discrepancy index (DI) at the beginning of treatment. Saxe et al.¹⁸ found that cases treated using the SureSmile™ system received better American Board of Orthodontics Objective Grading System (OGS) scores compared to cases treated by conventional pre-adjusted bracket appliances in the categories of maxillary rotations, maxillary marginal ridge levels, and maxillary buccal-lingual inclination.

Invisalign™ (Align Technology, San Jose, California, USA), a custom clear aligner system, emerged as an alternative to conventional brackets and wires. Clinicians submit to the manufacturer, a digital intra-oral scan or a silicone (PVS) impression to create a virtual treatment plan. A series of clear aligners is fabricated once the clinician has approved the treatment plan.

Djeu et al.¹⁹ compared Invisalign™ with traditional orthodontic treatment and concluded that cases treated using the Invisalign™ system received consistently poorer scores according to the American Board of Orthodontics objective grading Scores (OGS). Krieger et al.²⁰ concluded that the Invisalign™ system was very successful at relieving anterior crowding. Furthermore, it was found that all achieved tooth positions, with the exception of overbite correction, were largely equivalent to predetermined virtual predictions. A systematic review conducted by Lagravere et al.²¹ found that scientific evidence was lacking regarding treatment outcome and efficacy of the Invisalign™ system. Rossini et al.²² in a systematic review, concluded that clear aligners were effective at intruding anterior teeth but not extruding them, effective at controlling posterior buccolingual inclination but not anterior, effective in bodily distalisation of upper molars but not in rotating round teeth.

Few studies have investigated the accuracy of the various systems in achieving their virtually-planned tooth positions. Grauer and Proffit²³ found that cases treated using Incognito™ (3M Unitek, Monrovia, California, USA), a fully customised lingual bracket

and wire system, showed that discrepancies were within 1 mm and 4 degrees for most teeth between the planned and achieved positions, which was deemed clinically acceptable. Kravitz et al.²⁴ reported that the mean accuracy of tooth movement using the Invisalign™ system was 41% but varied significantly according to tooth and movement type. Larson et al.²⁵ superimposed 23 digital post-treatment models treated using the SureSmile™ system over their respective virtual prediction models and concluded that the accuracy of tooth movement varied according to tooth and type of movement. Muller-Hartwich²⁶ reported, in a retrospective study, that planned versus achieved tooth movements in cases treated using the SureSmile™ system showed a deviation of 0.19–0.21 mm in translational movements and 1.77–3.04 degrees in rotational movements.

To date, there have been no prospective clinical trials which have compared the accuracy of the CAD/CAM systems and their ABO objective grading scores. Prospective clinical studies are necessary for an unbiased evaluation of the ability of virtual systems to achieve their predicted results. Furthermore, a comparison of the quality of their outcomes is required to justify the additional costs incurred by the patient and clinician. Therefore, the aim of the present study was to compare the effectiveness of the SureSmile™, Insignia™ and Invisalign™ systems in delivering their expected intra-arch outcomes and compare their OGS²⁷ in a prospective clinical trial setting.

Materials and methods

This prospective clinical study was approved by the institutional review board of Harvard University Faculty of Medicine and registered on ClinicalTrials.gov (NCT02221856). Appropriate informed consent was obtained from all participants in accordance with the approved study protocol. Patients were treated in two private offices in Lexington, MA (Office A) and Lancaster, PA (Office B) between May 2014 and March 2016 by two orthodontists with over 10 years of experience using digital set-ups and CAD/CAM orthodontics. Both practitioners were trained on the East Coast of the United States and started practising in similar demographic areas during the mid to late 2000s. Moreover, both were faculty staff at the same teaching institution at the time the study was conducted. The orthodontist in office “A” routinely

provided care using the Insignia™ and Invisalign™ systems. The orthodontist in office “B” routinely provided care using the SureSmile™ and Invisalign™ systems. All of the Insignia™ cases were treated in office A and all of the SureSmile™ cases in office B, while both offices treated Invisalign™ cases.

Patients were enrolled into three treatment groups: Insignia™ (Group 1), SureSmile™ (Group 2), and Invisalign™ (Group 3). All participants were healthy subjects over the age of 10 years with at least a first molar to first molar intact dentition and planned by their orthodontic providers to undergo non-extraction treatment. The exclusion criteria were: (1) the presence of systemic diseases affecting bone or teeth; (2) the presence of craniofacial anomalies; (3) the presence of prostheses; (4) a history of periodontal disease; (5) an intake of drugs affecting tooth movement or bone formation; or (6) severe crowding or dental protrusion requiring extractions. The initial intent was to randomise subjects into treatment groups but that was not possible because the providers were uncomfortable in the treatment of study cases using a technique for which they had no experience and patients seeking Invisalign treatment refused the randomisation process.

The sample size was computed based on a report by Larson et al.²⁵ The facio-lingual deviations in millimetres between the target and achieved dental positions (mean = -0.38 and SD = 0.56) were used for generating the required sample size. For identifying a clinically meaningful difference of -0.50 mm at an alpha of 0.01 (to account for multiple tests) and a power of 80%, a sample size of 30 arches per group was necessary.

A total of 102 patients were enrolled in the study (29 Insignia™, 36 SureSmile™, 37 Invisalign™). All of the cases were considered appropriate for either of the three treatment modalities. Enrolment into the Invisalign™ program was based on the patient's preference while enrolment into the Insignia™ or SureSmile™ groups depended on the patient's geographic location.

The following protocols were applied for the three treatment groups:

Group 1 (Insignia™). A digital impression was taken using a Lythos (Ormco, Orange, California, USA) scanner. Using the Insignia™ software, a virtual set-up was performed by the clinician, and the manufacturer fabricated and delivered custom-made self-ligating

brackets (Damon Q; Ormco, Orange, California, USA). The brackets were bonded using the orientating transfer jigs provided by the manufacturer. The following wire sequence was sequentially inserted: 0.013 CuNiTi, 0.018 CuNiTi, 0.014x0.025 CuNiTi, 0.018x0.025 CuNiTi, and 0.019x0.025 TMA (all provided by the manufacturer). The final arch wire was placed for a minimum of 8 weeks. A 'result' was acquired when the protocol was completed. No clinical intervention such as repositioning the brackets or bending the arch wire was conducted by the clinicians who were allowed to rebond broken brackets using sectioned, indirect, bonding jigs. The 'result' final scan, along with the virtual set-up (converted to STL files) was submitted to the investigators for analysis.

Group 2 (SureSmile™). 0.018-inch twin brackets (MBT prescription; 3M Unitek, Monrovia, California, USA) were placed using an indirect bonding technique and initial levelling and alignment were performed using 0.014 and in some cases 0.018 NiTi arch wires. Upon alignment, an iTero (Align Technology, San Jose, California, USA) arch scan was taken (Cadent iOC Optical Impression Device powered by iTero), and a virtual set-up was performed using the SureSmile™ software. Two custom SureSmile™ arch wires (either 0.016 × 0.016 CuNiTi/0.016 × 0.022 CuNiTi or 0.016 × 0.022 CuNiTi 50%/0.016 × 0.022 CuNiTi 100%, referring to the percentage of simulated tooth movements incorporated in each wire) were sequentially placed (for a minimum of 8 weeks). Broken brackets were rebonded using sectioned, indirect, bonding templates to reposition replacement brackets as closely as possible to the original position. The same procedure for obtaining the 'result' final scan was followed as described for group 1.

Group 3 (Invisalign™). Either an iTero (Align Technology, San Jose, California, USA) scan (Cadent iOC Optical Impression Device powered by iTero) or a PVS impression was taken and sent to the manufacturer. Tooth overcorrection was limited to correction stages which were excluded from the study participation period. The providers were also not allowed to change Invisalign's standard rate of tooth movement or double the aligners to slow down the movement. After a ClinCheck approval, a series of custom aligners was delivered and the orthodontists followed routine care for clear aligner therapy. Aligner changes occurred at 2-weekly intervals to accommodate individual variations in metabolism

and compliance. Lost or broken aligners were replaced and broken attachments were rebonded using sectioned, attachment templates. Once patients reached their final non-overcorrection aligners or the orthodontist decided to scan for a refinement (whichever came first) the final scan 'result' was accepted even if treatment continued using overcorrection aligners or the occlusion needed a refinement. If the patient went into refinement or mid-course correction, the refinement scans were used as the 'result' final scans only if they had successfully completed 80% of the planned aligners. If a refinement was necessary before 80% of the aligners were completed, the cases were excluded from the study.

Although the 'result' final scan was the end point for the subject's participation in the study, their care was continued by the clinician as necessary.

The virtual set-ups and 'result' scans were superimposed via a best-fit alignment method using Geomagic Control (3D Systems, Rock Hill, South Carolina, USA). Initial alignment was conducted using 300 surface points and fine adjustments were achieved using an additional 1500 points. This process was repeated as necessary. Once a satisfactory superimposition was performed (Figure 1), the *x*, *y*, *z* coordinates (mm) of 34 dental landmarks (Table I) identified on the set-up and resulting arches were exported and analysed. Intra-examiner reliability of dental landmarking had previously been tested and verified by measurements between dental landmarks having an ICC above 0.9. The 34 analysed landmarks were grouped into posterior and anterior points for ease of presentation. The mesial marginal ridge of the canine often shared a contact with the anterior teeth and was considered an anterior landmark since it often experienced buccal/lingual movements in the same direction as the incisors. However, the canine

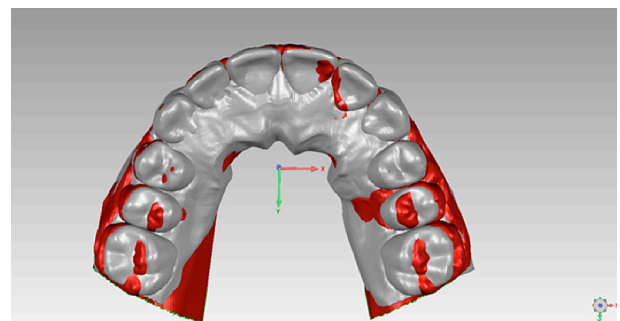


Figure 1. Sample superimposition (X-axis: Transverse, Y-axis: Sagittal, Z-axis: Vertical).

Table 1. List of dental landmarks used in the study on each type of tooth.

Tooth type	Landmark 1	Landmark 2	Landmark 3	Landmark 4
Right First Molar	Distobuccal Cusp Tip	Mesiobuccal Cusp Tip	Distal Marginal Ridge	Mesial Marginal Ridge
Right Second Premolar	Buccal Cusp Tip	Distal Marginal Ridge	Mesial Marginal Ridge	
Right First Premolar	Buccal Cusp Tip	Distal Marginal Ridge	Mesial Marginal Ridge	
Right Canine	Buccal Cusp Tip	Mesial-incisal Point	Distal-incisal Point	
Right Lateral Incisor	Distal-incisal Point	Mesial-incisal Point	Labial CEJ	
Right Central Incisor	Distal-incisal Point	Mesial-incisal Point	Labial CEJ	
Left Central Incisor	Mesial-incisal Point	Distal-incisal Point	Labial CEJ	
Left Lateral Incisor	Mesial-incisal Point	Distal-incisal Point	Labial CEJ	
Left Canine	Buccal Cusp Tip	Mesial-incisal Point	Distal-incisal Point	
Left First Premolar	Buccal Cusp Tip	Mesial Marginal Ridge	Distal Marginal Ridge	
Left Second Premolar	Buccal Cusp Tip	Mesial Marginal Ridge	Distal Marginal Ridge	
Left First Molar	Mesiobuccal Cusp Tip	Distobuccal Cusp Tip	Mesial Marginal Ridge	Distal Marginal Ridge

cusp tip undergoes buccal/lingual changes in the same direction as the posterior teeth and so it was also considered a posterior landmark.

All of the 'result' final scans were exported as .STL files for printing and sent to the New England Orthodontic Laboratory (Wilmington, MA, USA) for printing. Printed models were de-identified and sent to a single observer who was calibrated as an ABO examiner and blinded to the treatment system of each case. The casts were used to assess intra-arch measurements by applying the ABO's objective grading system's criteria. "The American Board of Orthodontics Grading System for Dental Casts and Panoramic Radiographs" guidelines²⁷ were followed in order to score each case. Since none of the systems had the ability to correct overjet and occlusal relationships, the examining investigator only assessed the following three components of the OGS: the alignment of the teeth, the position of the marginal ridges, and the buccolingual tooth inclination. Points in each category were allocated for any digression from the ideal. The sums of the points were computed and higher scores indicated a greater deviation from ideal standards. All measurements were conducted utilising the ruler provided by the ABO for Objective Grading scoring.

Statistical analysis

The outcome variables (mm discrepancies) were compared between the three groups (SureSmile™,

Insignia™, Invisalign™) by using the One-Way Analysis of Variance (ANOVA). Multiple pair-wise comparisons were performed (independent sample *t* tests) to identify significant differences between the groups. A total of six pair-wise comparisons were conducted. To avoid introducing the possibility of Type 1 errors due to multiple pair-wise comparisons, Bonferroni corrections were applied. The *p*-value for multiple pair-wise comparisons was set at 0.01 to be of statistical significance. A regression analysis controlling for gender, age and degree of crowding was used to determine if the measured factors had a significant confounding role in any clinically and statistically significant differences between the groups. The outcomes between offices for the Invisalign cases were compared using the Mann–Whitney *U* test since dividing the Invisalign group by office reduced the sample size per group. The *p*-value for this test was also set at 0.01. The data were analysed on an intention to treat basis. All statistical analyses were conducted using SAS Version 9.3 software (SAS Institute, Cary, NC).

Descriptive statistics were used to summarise the OGS data. The differences in the distribution of gender, age, alignment/rotations, marginal ridges, buccolingual inclinations, and combined intra-arch OGS scores were computed for each of the three treatment groups. A multivariable linear regression model was applied to examine the differences in alignment, marginal ridge height, buccolingual inclination and total OGS score by treatment group, after controlling for the effects

of age, gender, and initial crowding. The multivariable regression model was applied using the Ordinary Least Squares approach. All statistical tests were two-sided. A p -value of <0.05 was deemed to be statistically significant for the multivariable regression model. The statistical analyses were conducted using SPSS Version 23 software (IBN Corp, New York).

Results

A total of 102 patients were enrolled in the study (29 Insignia™, 36 SureSmile™, 37 Invisalign™). Six subjects were excluded due to problems related to scan quality or target .STL files. Twenty-three subjects were excluded due to incorrect timing of the follow-up scan which was not taken within the study observation period or Invisalign™ scans taken prematurely (less than 80% of trays worn). In total, 29 subjects were excluded from data analysis. The final sample size for comparison of the coordinates was 145 dental arches (54 SureSmile™ arches, 35 Insignia™ arches, and 56 Invisalign™ arches) from 44 females and 29 males. The descriptive characteristics of the treatment groups are detailed in Tables II–VI. Four upper arches and 2 lower arches had first premolars that could not be adequately landmarked. The ranges for the mean deviation between the virtual set-ups and actual treatment results for the grouped landmarks are summarised in Table VII. Descriptive statistics for each individual landmark in each axis at the 95% confidence interval are available in supplementary Table A. Although the mean differences between the target and achieved position landmarks were generally under 0.5 mm,

Table III. Lower and upper arch age distribution (years).

Treatment group	Mean	Median	SD
<i>Lower arch</i>			
Insignia	13.9	14	1.4
Invisalign	29.1	28	10.2
SureSmile	16.5	14	7.5
<i>Upper arch</i>			
Insignia	14	14	1.4
Invisalign	29.1	28	10.2
SureSmile	16.5	14	7.5

Table IV. Lower and upper arch initial crowding/spacing (positive value indicates crowding in mm).

Treatment group	Mean crowding (mm)	Median	SD
<i>Lower arch</i>			
Insignia	2.0188	2.25	1.0742
Invisalign	2.8318	2.83	1.99914
SureSmile	2.207	1.92	1.47366
<i>Upper arch</i>			
Insignia	2.4261	2.415	1.73217
Invisalign	2.7546	2.5	1.60262
SureSmile	2.7359	2.42	1.54442

especially for the anterior teeth, the maximum discrepancies between the target and achieved positions for the anterior landmarks ranged between 0.7 mm and 4.1 mm. The greatest discrepancies

Table II. Lower and upper arch gender distribution.

Treatment group	Female lower arches	Male lower arches	Total
<i>Lower arches</i>			
Insignia (all from office 1)	6	11	17
Invisalign (11 from office 1, 17 from office 2)	22	6	28
SureSmile (all from office 2)	16	11	27
Total	44	28	72
<i>Upper arches</i>			
Insignia (all from office 1)	6	12	18
Invisalign (11 from office 1, 17 from office 2)	22	6	28
SureSmile (all from office 2)	16	11	27
Total	44	29	73

Table V. Intermolar and intercanine mean target width and SD by intervention.

System	Mean target intercanine width (mm)	Target intercanine width standard deviation	Mean target inter molar width at first molars (mm)	Target intermolar width standard deviation
Insignia	27.53	1.06	54.92	2.21
Invisalign	25.39	1.696	51.12	3.41
Suresmile	26.34	1.18	52.33	2.53

Table VI. Mean and SD of observation period in months for each intervention.

System	Mean to observation period (months)	Observation period standard deviation (months)
Insignia	12.5	1
Invisalign	8.4	2.9
Suresmile	11.5	3.1

occurred in the Z-axis (vertical discrepancies) for the three treatment groups.

The multiple pair-wise comparisons for each landmark are shown in Table VIII with statistical and clinical significance indicated. Due to the large number of data points, only those of statistical significance

($p < 0.01$) are included and those of clinical significance (>0.5 mm) have been highlighted. Information regarding the remaining pair-wise comparisons may be found in supplementary Table B. Since both offices treated patients using the Invisalign™ appliance, their outcomes are compared in Table IX and supplementary Tables C and D.

Upper and Lower Anterior Dental Landmarks: There was no significant difference between the 3 treatment groups or differences between the Invisalign™ cases between the two offices in mean deviation of predicted versus actual coordinates in any of the three axes (transverse, sagittal, vertical). The exception was the Suresmile group which had greater vertical discrepancies than the other treatment groups related to the position of the labial CEJ. The 0.5 mm to 1 mm difference between the groups was the result

Table VII. Ranges of mean difference between predicted and actual locations of Anterior & Posterior Landmarks.

	Transverse difference (X)	Sagittal difference (Y)	Vertical difference (Z)
<i>Insignia</i>			
Upper Anterior	0.27–0.48 mm	0.42–0.81 mm	0.33–0.57 mm
Upper Posterior	0.47–1.27 mm	1.15–2.22 mm	0.26–0.61 mm
Lower Anterior	0.31–0.50 mm	0.28–0.43 mm	0.36–0.57 mm
Lower Posterior	0.40–1.01 mm	0.40–0.81 mm	0.27–0.57 mm
<i>Suresmile</i>			
Upper Anterior	0.21–0.56 mm	0.32–0.68 mm	0.33–0.63 mm
Upper Posterior	0.30–0.84 mm	0.28–0.63 mm	0.31–0.62 mm
Lower Anterior	0.16–0.44 mm	0.30–0.46 mm	0.29–0.47 mm
Lower Posterior	0.30–0.80 mm	0.40–0.70 mm	0.28–0.58 mm
<i>Invisalign</i>			
Upper Anterior	0.23–0.45 mm	0.32–0.45 mm	0.31–0.60 mm
Upper Posterior	0.26–0.50 mm	0.18–0.41 mm	0.17–0.48 mm
Lower Anterior	0.13–0.37 mm	0.29–0.52 mm	0.34–0.51 mm
Lower Posterior	0.28–1.0 mm	0.47–0.83 mm	0.18–0.46 mm

Note: Anterior Landmarks: Mesio-incisal edge of canine to the contralateral landmark, Posterior Landmarks: First molar to cusp tip of canine on each side.

Table VIII. Multiple pair-wise comparisons of mean differences between the predicted and actual location of each landmark.

Landmark	Reference system	Comparison system	Mean difference	Std. error	P value
Upper right first molar DB cusp x_Actual_Goal	Insignia	Invisalign	0.709	0.174	0.000
		SureSmile	0.449	0.175	0.037
Upper right first molar DMR x_Actual_Goal	Insignia	Invisalign	0.892	0.170	0.000
		SureSmile	0.435	0.171	0.039
Upper right first molar MMR x_Actual_Goal	Insignia	Invisalign	0.666	0.156	0.000
		SureSmile	0.521	0.157	0.004
Upper right second premolar B cusp x_Actual_Goal	Insignia	Invisalign	0.536	0.135	0.001
		SureSmile	0.359	0.136	0.031
Upper right second premolar DMR x_Actual_Goal	Insignia	Invisalign	0.738	0.160	0.000
		SureSmile	0.650	0.161	0.000
Upper right second premolar MMR x_Actual_Goal	Insignia	Invisalign	0.504	0.121	0.000
		SureSmile	0.413	0.122	0.003
Upper left first molar DB cusp x_Actual_Goal	Insignia	Invisalign	0.512	0.157	0.005
		SureSmile	0.257	0.158	0.326
Upper left first molar DMR x_Actual_Goal	Insignia	Invisalign	0.526	0.157	0.004
		SureSmile	0.294	0.158	0.203
Upper right first molar DB cusp y_Actual_Goal	Insignia	Invisalign	1.825	0.214	0.000
		SureSmile	1.788	0.215	0.000
Upper right first molar MB cusp y_Actual_Goal	Insignia	Invisalign	1.660	0.206	0.000
		SureSmile	1.650	0.207	0.000
Upper right first molar DMR y_Actual_Goal	Insignia	Invisalign	1.665	0.204	0.000
		SureSmile	1.612	0.206	0.000
Upper right first molar MMR y_Actual_Goal	Insignia	Invisalign	1.770	0.194	0.000
		SureSmile	1.736	0.196	0.000
Upper right second premolar B cusp y_Actual_Goal	Insignia	Invisalign	1.534	0.195	0.000
		SureSmile	1.346	0.197	0.000
Upper right second premolar DMR y_Actual_Goal	Insignia	Invisalign	1.429	0.179	0.000
		SureSmile	1.399	0.180	0.000
Upper right second premolar MMR y_Actual_Goal	Insignia	Invisalign	1.364	0.178	0.000
		SureSmile	1.359	0.179	0.000
Upper right first premolar B cusp y_Actual_Goal	Insignia	Invisalign	1.103	0.210	0.000
		SureSmile	0.906	0.208	0.000
Upper right first premolar DMR y_Actual_Goal	Insignia	Invisalign	1.114	0.168	0.000
		SureSmile	1.011	0.166	0.000
Upper right first premolar MMR y_Actual_Goal	Insignia	Invisalign	1.064	0.153	0.000
		SureSmile	0.978	0.151	0.000
Upper right canine disto-incisal y_Actual_Goal	Insignia	Invisalign	0.668	0.143	0.000
		SureSmile	0.591	0.144	0.000

Upper left canine disto-incisal y_Actual_Goal	Insignia	Invisalign	0.691	0.134	0.000
		SureSmile	0.545	0.135	0.000
Upper left first premolar B cusp y_Actual_Goal	Insignia	Invisalign	1.185	0.189	0.000
		SureSmile	0.953	0.187	0.000
Upper left first premolar MMR y_Actual_Goal	Insignia	Invisalign	0.875	0.146	0.000
		SureSmile	0.749	0.144	0.000
Upper left first premolar DMR y_Actual_Goal	Insignia	Invisalign	1.005	0.149	0.000
		SureSmile	0.891	0.147	0.000
Upper left second premolar B cusp y_Actual_Goal	Insignia	Invisalign	1.391	0.184	0.000
		SureSmile	1.243	0.185	0.000
Upper left second premolar MMR y_Actual_Goal	Insignia	Invisalign	1.320	0.150	0.000
		SureSmile	1.260	0.151	0.000
Upper left second premolar DMR y_Actual_Goal	Insignia	Invisalign	1.238	0.167	0.000
		SureSmile	1.232	0.168	0.000
Upper left first molar MB cusp y_Actual_Goal	Insignia	Invisalign	1.535	0.197	0.000
		SureSmile	1.418	0.198	0.000
Upper left first molar DB cusp y_Actual_Goal	Insignia	Invisalign	1.843	0.208	0.000
		SureSmile	1.804	0.209	0.000
Upper left first molar MMR y_Actual_Goal	Insignia	Invisalign	1.578	0.176	0.000
		SureSmile	1.442	0.177	0.000
Upper left first molar DMR y_Actual_Goal	Insignia	Invisalign	1.543	0.173	0.000
		SureSmile	1.526	0.174	0.000
Upper right lateral incisor CEJ actual_goal	Suresmile	Insignia	0.556	0.214	0.034
		Invisalign	0.831	0.189	0
Upper right central incisor CEJ actual_goal	Suresmile	Insignia	0.958	0.255	0.001
		Invisalign	0.746	0.226	0.005
Upper left central incisor CEJ actual_goal	Suresmile	Insignia	0.895	0.239	0.001
		Invisalign	0.804	0.212	0.001
Upper left lateral incisor CEJ actual_goal	Suresmile	Insignia	0.471	0.22	0.108
		Invisalign	0.645	0.195	0.005
Lower left first molar MB cusp x_Actual_Goal	Insignia	Invisalign	0.339	0.162	0.122
		SureSmile	0.570	0.164	0.003
Lower right second premolar B cusp x_Actual_Goal	Insignia	Invisalign	0.701	0.142	0.000
		SureSmile	0.469	0.143	0.005

Note: Only landmarks with statistical significance ($P < 0.01$) have been included in this table. Land marks with clinically significant differences (>0.5 mm) are highlighted.

of gingival margin changes since the other landmarks did not vertically change and the CEJ point did not vary between the groups in the other spatial planes. Table IX and supplementary Tables C and D compare the Invisalign cases by office and show that there were no statistically significant differences in

the mean deviations between the target and achieved locations of any anterior landmark. A regression analysis controlled for age and gender determined that these factors were not statistically significant confounders. Details of the regression models may be found in supplementary Tables E and F.

Table IX. Mann–Whitney Test comparing the Invisalign outcomes between the two offices. Only landmarks with significant differences included. Remaining non significant landmarks in supplementary table C.

Landmark	Mann–Whitney <i>U</i>	Wilcoxon <i>W</i>	<i>Z</i>	<i>p</i> -value
Upper left canine cusp x_Actual_Goal	39	105	-2.564	0.01
Upper right first premolar B cusp z_Actual_Goal	23	68	-2.774	0.006
Lower left first molar DB cusp y_Actual_Goal	33	99	-2.846	0.004
Lower right first premolar DMR y_Actual_Goal	36	102	-2.566	0.01
Lower right second premolar DMR y_Actual_Goal	27	93	-3.128	0.002
Lower left second premolar DMR z_Actual_Goal	39	105	-2.564	0.01

Upper Posterior Dental Landmarks: The Insignia™ system showed a greater mean deviation compared to the Invisalign™ and SureSmile™ systems in transverse (*x*) and sagittal (*y*) coordinates, but not in the vertical (*z*) coordinates. This was true for many landmarks, as shown in Table VIII. However, Table V shows that the Insignia™ system targets had intercanine and intermolar distances that were greater than the targets for the other two groups. This difference in the planned transverse target may account for the greater transverse and sagittal discrepancy between the target and achieved landmark locations for this group. The multiple regression analysis controlling for age and gender confirmed the findings but did not find these factors to be significant confounders (details in supplementary Table E). Table IX and supplementary Table C showed that the Invisalign cases had no statistically significant differences in the mean deviations between the target and the achieved location of the landmarks between the two offices with the exception of the cusp tip of the upper left canine in the (*x*) and (*y*) axes and the buccal cusp of the upper right first premolar in the (*z*) axis. These differences were under 0.5 mm and were not considered to be clinically significant.

Lower posterior dental landmarks: There was no significant difference between the three treatment groups or between the Invisalign™ cases between the two offices in the mean deviation of coordinates in any of the three axes. However, there were two exceptions as the Insignia™ system showed a more transverse deviation of the mesiobuccal cusp of the lower left first compared to SureSmile™ and the Insignia™ system also showed a more mean transverse deviation of the buccal cusp tip of the lower right second premolar compared to the Invisalign™ cases (Table VIII). The multiple regression analysis did not find age nor

gender as statistically significant confounding factors (details in supplementary Table F). Table IX and supplementary Table D showed that the two offices had no statistically significant differences in the mean deviations between the target and the achieved locations of the landmarks with the exception of the distal marginal ridge of the lower left second premolar in the *z*-axis, the distobuccal cusp of the lower left first molar in the *y*-axis, and the distal marginal ridges of the lower right first and second premolars in the *y*-axis which were statistically, but not clinically, significant differences between the offices.

According to the technical laboratory, of the 145 arches included in the study, only 126 arches from 63 patients (26M and 37F) were considered suitable for 3D printing since 19 models had defects that would not allow accurate reproduction. The cross-tabulation analysis (Table X) revealed that the Insignia™ treatment group consisted of 20 (58.8%) male arches and 14 (41.2%) female arches. The Invisalign™ treatment group consisted of 10 (23.8%) male arches and 32 (76.2%) female arches after the exclusion of three subjects due to the need for refinement prior to completing 80% of the planned treatment. The SureSmile™ treatment group consisted of 22 (44.0%) male arches and 28 (56.0%) female arches. The chi-square test indicated that there was a significant gender distribution difference across the three treatment groups. Furthermore, there was a significant difference in age between the three groups. The mean age for the Insignia™ patients was 14 years, the mean age for the Invisalign™ patients was 30.4 years, and the mean age for SureSmile™ cases was 16.2 years. However, there was no significant difference in the severity of the initial crowding between the three groups: the Insignia™ group had a mean crowding value of 2.34 mm, the Invisalign™ group had a mean

Table X. Gender and Treatment Group Crosstabulation for arches used for objective grading scores.

	Treatment group			
	Insignia	Invisalign	SureSmile	Total
Sex				
Male				
Count	20	10	22	52
% within Female Gender	38.5%	19.2%	42.3%	100.0%
% within Treatment Group	58.8%	23.8%	44.0%	41.3%
% of Total	15.9%	7.9%	17.5%	41.3%
Female				
Count	14	32	28	74
% within Female Gender	18.9%	43.2%	37.8%	100.0%
% within Treatment Group	41.2%	76.2%	56.0%	58.7%
% of Total	11.1%	25.4%	22.2%	58.7%
Total				
Count	34	42	50	126
% within Female Gender	27.0%	33.3%	39.7%	100.0%
% within Treatment Group	100.0%	100.0%	100.0%	100.0%
% of Total	27.0%	33.3%	39.7%	100.0%

value of 3.04 mm, and the SureSmile™ group had a mean value of 2.4 mm.

The Insignia™ group demonstrated a mean OGS score of 2.56 for alignments and rotation, 0.91 for marginal ridge height discrepancies, and 1.56 for buccolingual

inclination (Table XI). The Invisalign™ group demonstrated a mean score of 3.26 for alignments and rotation, 0.38 for marginal ridge height discrepancies, and 2.21 for buccolingual inclination. The SureSmile™ group demonstrated a mean score of 1.98 for

Table XI. Objective Grading Score (OGS) descriptive statistics for each treatment category.

Treatment Group	Alignment/ Rotations	Marginal Ridges	Buccolingual Inclination	Total OGS Score	Age
Insignia					
Mean	2.56	.91	1.56	5.03	14
Std. Deviation	1.260	1.026	1.673	1.800	1.393
Percentile: 50	2.00	1.00	1.00	4.50	14.00
Invisalign					
Mean	3.26	.38	2.21	5.83	30.48
Std. Deviation	1.499	.795	1.920	2.626	13.74
Percentile: 50	3.00	.00	2.00	6.00	25.00
SureSmile					
Mean	1.98	.66	2.40	5.02	16.16
Std. Deviation	1.059	.895	2.157	2.386	7.536
Percentile: 50	2.00	.00	2.00	5.00	14.00

Table XII. Multivariable Linear Regression Analysis for (A) Alignment/Rotations Objective grading score, (B) Marginal ridge Objective grading score, (C) Buccolingual Inclination Objective Grading Score, and (D) Combined Intra-arch Objective Grading Score.

	Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B	
Model	B	Std. error	Beta	<i>t</i>	<i>p</i> -value	Lower bound	Upper bound
<i>(A) Alignment/Rotations Objective grading score^a</i>							
(Constant)	1.998	0.328		6.087	<0.001 *	1.348	2.648
Invisalign ^b	1.291	0.326	0.444	3.963	<0.001 *	0.646	1.936
Insignia ^b	0.57	0.289	0.185	1.97	0.051	-0.003	1.143
Female Gender	-0.06	0.249	-0.021	-0.24	0.811	-0.552	0.433
Age	0	0.013	-0.001	-0.01	0.992	-0.026	0.025
Crowding	0.007	0.073	0.008	0.098	0.922	-0.138	0.153
<i>(B) Marginal ridge Objective grading score</i>							
(Constant)	0.461	0.229		2.013	0.046 *	0.008	0.914
Invisalign ^b	-0.464	0.227	-0.239	-2.04	0.044 *	-0.914	-0.014
Insignia ^b	0.257	0.202	0.125	1.271	0.206	-0.143	0.656
Female Gender	-0.186	0.173	-0.1	-1.07	0.287	-0.529	0.158
Age	0.014	0.009	0.18	1.58	0.117	-0.004	0.032
Crowding	0.031	0.051	0.054	0.606	0.546	-0.07	0.133
<i>(C) Buccolingual Inclination Objective Grading Score</i>							
(Constant)	2.826	0.498		5.677	0.000 *	1.84	3.811
Invisalign ^b	0.277	0.494	0.066	0.561	0.576	-0.701	1.255
Insignia ^b	-0.891	0.439	-0.201	-2.03	0.045 *	-1.76	-0.022
Female Gender	0.177	0.377	0.044	0.47	0.639	-0.569	0.923
Age	-0.036	0.019	-0.213	-1.842	0.068	-0.074	0.003
Crowding	0.023	0.111	0.018	0.202	0.84	-0.198	0.243
<i>(D) Combined Intra-arch Objective Grading Score</i>							
(Constant)	5.314	0.601		8.848	0	4.125	6.503
Invisalign ^b	1.121	0.593	0.226	1.889	0.061	-0.054	2.295
Insignia ^b	-0.047	0.527	-0.009	-0.089	0.93	-1.09	0.997
Female Gender	-0.05	0.452	-0.011	-0.111	0.912	-0.946	0.846
Age	-0.024	0.024	-0.118	-1.012	0.314	-0.07	0.023
Crowding	0.05	0.134	0.034	0.371	0.712	-0.215	0.315

Notes: ^aDependent variable: Marginal Ridges. ^bReference: Suresmile. *Significance set at $p < 0.05$.

alignments and rotation, 0.66 for marginal ridge height discrepancies, and 2.4 for buccolingual inclination. When controlling for confounding variables (age, gender, crowding), the multivariable linear regression analysis (Table XIIA–D) revealed that there was a statistically significant difference (p -value: <0.01) for tooth alignment and rotation between Invisalign™

and SureSmile™ with the SureSmile™ group having a better OGS alignment and rotation scores than the Invisalign™ group. It also demonstrated that, compared to Suresmile, Insignia™ performed better in regard to buccolingual inclination correction, and Invisalign™ performed better in regard to marginal ridge correction after taking confounding variables into consideration.

The Insignia™ group demonstrated a mean of 5.03 for the combined intra-arch OBS score, Invisalign™ received a mean score of 5.83, and SureSmile™ received a mean score of 5.02 (Table XI). When individually controlling for confounding variables (age, gender, crowding), the multivariable linear regression analysis showed that there was no significant difference in the combined intra-arch OGS score between the three treatment modalities (Table XIID).

Discussion

To date, no study has prospectively compared the effectiveness of multiple CAD/CAM fabricated orthodontic appliances in a clinical setting. The objective of the present study was to allow orthodontists to examine the effectiveness of Insignia™, Invisalign™, and SureSmile™ related to achieving the predicted tooth positions and compare the ABO objective grading scores for alignment/rotations, levelling of the marginal ridges, and buccolingual inclination after the first round of manufacturer-recommended intervention.

The present study revealed that the three examined CAD/CAM systems (SureSmile™, Insignia™, Invisalign™) had comparable abilities to reach their targeted three-dimensional coordinates for most of the landmarks. The mean discrepancies were usually under 0.5 mm especially for the anterior teeth but discrepancies greater than 2 mm were noted.

The clear aligner results were consistent with those reported by Krieger et al.²⁰ who found that the post-treatment models were nearly equivalent to the ClinCheck predictions. However, Kravitz²⁴ found the mean predictability of Invisalign™ tooth movements were only 41%. Although using a different method of evaluation, the present study suggested that clear aligner therapy is as effective as fixed appliances in achieving predicted tooth positions within the applied scope of planned movement and parameters. This perhaps can be attributed to the continued evolution of aligner materials and attachments as well as clinicians gaining experience in clear aligner therapy.

The results of the present study revealed that the Insignia™ cases showed significantly greater discrepancies compared to the SureSmile™ and Invisalign™ systems regarding the transverse and sagittal coordinates of the upper posterior dental landmarks. A noteworthy observation was that,

although the Insignia™ dental arches appeared aligned, they consistently had a narrower arch form compared to their respective virtual set-ups (targets), which resulted in the deviation of transverse and sagittal coordinate measurements (Figure 1). This did not mean that the cases finished with more narrowed arches but indicated that they were further away from their transverse targets. The information in Table V shows that the intercanine distance in the Insignia™ targets were over 2 mm wider than the Invisalign cases and were almost 4 mm wider at the molars. The set-ups might have requested more widening than that achieved within the present study's observation period, and so that finding may not be an indicator of the effectiveness of the system itself. The minor differences in the Invisalign cases between the two offices are also likely due to the differences between the target arch widths between the two offices.

The present OGS results found that the alignment score for the Invisalign™ group was significantly higher (inferior alignment) when compared to the SureSmile™ treatment group. In contrast, a retrospective cohort study conducted by Djeu et al.¹⁹ demonstrated that Invisalign™ and fixed appliances produced similar scores for alignment, marginal ridge relationships, and interproximal contacts, but that conventional orthodontic treatment received significantly superior scores for correcting buccolingual inclination, occlusal contacts, occlusal relationships, and overjet. Djeu et al.¹⁹ reported that Invisalign™ alignment results were comparable with conventional brackets, which are currently the gold standard of orthodontic treatment. Despite this study utilising the newer and supposedly superior Smarttrack™ material, the present results indicated that Invisalign™ did not obtain similar scores for alignment and rotation when compared to SureSmile™. Similarly, Kravitz et al.²⁴ found that the accuracy of rotation control was 52.4% successful for maxillary incisors, 32.2% for maxillary canines, and 29% for mandibular canines.

The differences between the present results and those reported by Djeu et al. may be due to the current sample comparing Invisalign to CAD/CAM fixed appliances instead of direct bonded traditional fixed appliances. This potential deficiency in clear aligner therapy may be due to the inability of Invisalign to entirely grip rotated teeth in order to achieve the complete correction of alignment. It is also important to note that Invisalign™ is a compliance-dependent

appliance, and results may be altered due to this confounding factor. It is a challenge to completely address this limitation but the researchers felt that eliminating cases that had stopped tracking before completing 80% of the aligners was a reasonable method of management. This might have put the Invisalign™ group at a disadvantage. However, refinements or additional operator intervention were not allowed during the participation period for any of the three groups. All refinements, bracket repositioning, and detailing bends were done after the final study scan was completed.

Despite the Suresmile™ group having a slightly better alignment score than the other groups, none of the evaluated CAD/CAM systems were able to consistently achieve ideal or even near ideal alignment without operator intervention. Orthodontists should therefore be prepared to perform revisions of their CAD/CAM cases and/or bend wires when finishing and detailing their cases to achieve ideal or near ideal alignment.

The results of the present study revealed that the score for marginal ridge height in the Invisalign™ group was significantly lower in comparison to the Insignia and SureSmile™ groups. This may suggest that even indirect computer-guided bracket placement and robotic wires can result in iatrogenic errors, creating marginal ridge height discrepancies. It also may indicate that the Invisalign™ system did not disturb marginal ridges that were naturally aligned. In contrast, Djeu et al.¹⁹ found that Invisalign and fixed appliances received comparable scores for marginal ridge height correction. Overall, the data indicate that Invisalign can appropriately manage the vertical control of posterior teeth.

The present findings also indicated that Insignia™ had significantly lower scores (superior torque control) in the buccolingual inclination category. These findings are consistent with those of Weber et al.¹³ who found cases treated using the Insignia™ system received better ABO scores related to root alignment, as well as arch coordination, when compared to conventional treatment methods. This may imply that the custom torque built into the bracket has a greater ability to be expressed compared to third order bends in the arch wire or clear aligners.

Lastly, the present study found that there was no statistically significant difference between the three systems in combined intra-arch ABO objective

grading scores. This result is misleading since it is the result of the different CAD/CAM systems excelling in different categories of the OGS.

There were several limitations associated with the present study that require appreciation:

Two different operators: This leads to differences in virtual set-ups, bracket slots (0.018 versus 0.022) and exact protocols. This limitation could not be avoided due to the few clinicians who utilised the three systems in their private practices. Furthermore, there were the differences related to the manufacturer's recommended protocol for each system.

Each clinician had their individual aligner preferences built into their ClinCheck prediction. Clear aligner preferences were impossible to fully control since there is constant evolutionary change. The amount and timing of interproximal reduction was also left to the clinician to determine as necessary for individual patients. Interproximal reduction has the potential to modify the interproximal landmarks and affect the accuracy of landmark identification and so, if a greater amount of clinical reduction was performed, the results could have potentially been influenced. The present study attempted to control the overtreatment/overcorrection aspects of the preferences by requiring all overcorrection to occur during the overcorrection stages which were excluded from the study participation period. The clinicians were also not allowed to change the Invisalign system's standard rate of tooth movement or double the aligners to slow down the movement. Once patients completed their final non-overcorrection set of aligners, the final study scan was taken even if treatment continued through an overcorrection phase or needed a refinement. As a result, when the Invisalign™ outcomes were compared between the two offices no meaningful differences were detected.

The office that provided the cases treated by the Insignia system had a higher number of participants who were excluded due to deviations in the study protocol (mostly intra-oral scans not taken at the correct time). This applied to the fixed appliance cases as well as their clear aligner cases and likely did not result in a systematic error that would substantially affect the results or conclusions. The Insignia clinician planned more arch expansion in the cases which affected the sagittal and transverse discrepancy between the planned and achieved positions of the posterior landmarks.

Experimental design: The end point of the present study was the completion of the protocol for each system. No intervention by the orthodontist (revision of set-ups, arch wire bends, changes in bracket placement) was allowed until after participation was completed. This design was intended to evaluate the effectiveness of each custom appliance system, without clinician intervention beyond the initial set-up. The nature of clear aligner therapy which involved compliance complicated the comparison and made it difficult to manage cases that stopped tracking early in treatment. This issue was addressed by excluding cases that required refinements before completing 80% of the aligner sequence since the prescribed protocol was technically not completed. It could be argued that the excluded cases would have worsened the performance of the Invisalign group since the tracking problems might not have been related to patient compliance. However, it could also be argued that including patients who needed refinements after completing 80% of their aligners meant that some non-compliant patients were included which unavoidably may have disadvantaged this group.

The study intentionally avoided using treatment time as an evaluated outcome since the manufacturer's protocols related to time intervals are arbitrary and change over time. The Invisalign group had shorter observation periods which were likely related to the group's less frequent appointments and less affected by scheduling limitations.

A final study problem was the method of dental model superimposition. The nature of comprehensive orthodontic treatment involves the movement of all teeth which eliminates a stable landmark for the superimposition of an entire dental arch. As the best available method, a best-fit superimposition was applied for the three groups. The limitations and inaccuracies associated with this method are recognised but the data from the three groups would have similar superimposition inaccuracies.

Lack of randomisation and different demographic distribution: Although the study had every intention of randomly distributing the cases, this was found impossible due to the strong preference of some participants for clear aligner treatment. The clear aligner group attracted an older sample group and proportionally more females (Table III). Although the difference in age and gender distribution would be expected to result in differences in growth,

metabolism, and the rate of tooth movement, the primary outcomes were related to intra-arch changes that should not be significantly affected by growth. The upper limit of aligner and arch wire change intervals (minimum of 2 weeks per aligner and 8 weeks in final wires) was also used to accommodate metabolic variations that could affect bone turnover and therefore tooth movement. Finally, the multiple regression analysis indicated that age was not a statistically significant confounding factor.

Complexity of treatment: Although the three treatment groups did not differ in mean levels of crowding or spacing, the descriptive data indicated that the complexity of malocclusion in the present study was mild. The mean level of crowding was between 2 mm and 3 mm but the standard deviation often approached 2 mm and many cases that had moderate crowding in one arch received treatment in a less crowded opposing arch which lowered the mean reported crowding. Including more complex cases would have likely resulted in different outcomes.

Using coordinate differences as an outcome: Although this method had advantages it made it difficult for the clinicians to quantify the difference in clinically familiar terms such as tip, torque and rotation. This was due to software limitations at the time the study was conducted, which may be overcome in the future by using ABO grading tools or newer programs that are capable of directly or indirectly measuring those variables. The CEJ points on the incisors were digitised to infer torque differences between the treatment groups but that landmark only produced significant differences between the treatment groups in the vertical dimension. That the treatment groups did not have CEJ differences in the AP dimension and the other hard tissue landmarks (the incisal edges) did not have similar vertical differences between the groups, indicated that the change to that landmark was a result of changes in the gingival margins rather than torque. The Suresmile group had co-ligation while the final levelling and aligning arch wires were in place which might have affected the patient's ability to clean the gingival margin and may have contributed to the 0.5 to 1 mm vertical difference in the position of the labial CEJ point compared to the other treatment groups.

Although CAD/CAM orthodontics is a promising treatment protocol that has the potential to reduce the number of visits and clinical chair time, operator intervention in the form of revisions, or bracket/wire

modification is necessary to achieve the target outcome. Further prospective clinical studies in a more controlled environment are needed to evaluate the effectiveness of these products and validate the manufacturer's claims.

Conclusion

1. Despite the study's limitations, the three examined systems had similar abilities to reach predicted tooth positions of the upper and lower anterior teeth in non-extraction cases.
2. Although the mean differences between the planned and achieved positions of the anterior teeth were small, the anterior landmarks had maximum discrepancies that ranged between 0.7 and 4.1 mm which were common in the three treatment groups.
3. Operator intervention was necessary in the three treatment groups.
4. The Insignia™ system fell short of reaching its transverse objectives for the posterior teeth but its set-ups were broader which may have been planned but not achieved within the observation period of the present study.
5. Although the three systems had no statistically significant differences in overall intra-arch OGS scores, there were statistically significant differences in individual score components.
6. Invisalign™ had a significantly poorer alignment/rotation score than the SureSmile™ group (3.26 vs 1.96 $p < 0.01$), Insignia™ performed better in buccolingual inclination correction compared to Suresmile™ (1.56 vs 2.4 $P < 0.05$), and Invisalign™ performed better than Suresmile™ in marginal ridge correction (0.38 vs 0.66 $P < 0.05$).
7. None of the evaluated systems were able to achieve ideal or near ideal alignment without clinical intervention by the operator.

Conflict of Interest

The authors declare that there is no conflict of interest.

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