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Abstract

Objectives: Rapid development of digital technologies and 3D printing provide new tools for orthodontic indirect bonding. The purpose of this *in-vitro* study is to evaluate the clinical acceptability of hard CAD/CAM indirect bonding tray.

Material & Methods: Ten soft silicone transfer trays and ten hard CAD/CAM trays were produced and 200 brackets were placed on them. The brackets were then transferred to twenty SLA-printed models by indirect bonding. These models were scanned and digitally compared to the reference model by three-dimensional superimpositions (GOM software). The linear and angular measurements were collected and analysed.

Results: For the CAD/CAM trays, 100% of the mesiodistal, vertical and transverse measurements of incisors were within the clinical acceptable range of the American Board of Orthodontists (ABO) standards. More specifically, the clinically acceptable linear measurements were between 97 to 100% for silicone trays while they were between 89 to 100% for CAD/CAM trays. The clinically acceptable angular measurements varied between 87% and 100% for the silicone trays and between 79% and 100% for the CAD/CAM trays. Silicone trays were more precise than CAD/CAM trays. The difference was significant for all linear and angular measurements.

Conclusions: While the CAD/CAM group shows clinically acceptable results according to the ABO, silicone remains to be more precise than CAD/CAM for transfer trays and is therefore still the reference.

Clinical relevance: We demonstrate here that the orthodontic indirect bondings, whether they are realized using silicone transfer trays or CAD/CAM trays, are clinically acceptable in terms of the repositioning accuracy of brackets.

Introduction

The advent of the straight-wire appliance and pre-adjusted brackets developed by Andrews frees clinicians from over 70 bends that were necessary to establish occlusion according to Tweed [1]. The prerequisite for the correct expression of the straight-wire appliance is the precise bonding of the brackets. Since 1972 and Silverman's works [2], the literature has shown the advantages of indirect bonding: accuracy, reproducibility, reduced chair time, decrease in saliva contamination with an incidence of detachment that is comparable to direct bonding [3–7]. Indirect bonding is based on the use of transfer trays; incidentally, the reliability of silicone was proven by photographic method by Castilla in 2014 [8].

The breakthrough of digital technology and three-dimensional superimpositions used for the first time by Yamamoto [9] can replace photographic measurement methods [3–5]. The precise analysis of orthodontic bracket displacement in the three dimensions of space is possible using three-dimensional superimposition [10–12].

The major increase in computer-aided indirect bonding protocols has led to a large number of available techniques. In January 2018, Christensen published data for the first time on the use of a flexible and transparent computer-aided design / computer-aided manufacturing (CAD/CAM) transfer tray [13]. Nevertheless, among these techniques, few have undergone analysis regarding their accuracy. The purpose of this study is to evaluate the clinical acceptability of bracket repositioning using CAD/CAM indirect bonding trays and then, to compare their accuracy with that of conventional silicone trays using 3D superimposition.

1 Materials and methods

1.1 Obtaining the STL file (RS) of the reference model (RM)

An optical impression (Trios2® Color, 3Shape Dental Systems, Copenhagen, Denmark) of a maxillary arch with mild crowding served for bracket positioning from the second premolar to the second premolar using the Bracket Placement Module (OrthoAnalyzer, 3Shape Dental Systems, Copenhagen, Denmark). The brackets used were Mini Master Roth .022-inch (American Orthodontics, Washington, DC, USA). The STL file “arch + brackets” was exported to the Appliance Designer software (OrthoAnalyzer, 3Shape Dental Systems, Copenhagen, Denmark) in order to fill the undercuts of the brackets, which generated a new STL file. This last was prepared for printing with the Preform software (Formlabs Inc, Somerville, MA, USA) by angulating the models on the platform at 20° as recommended by the manufacturer to reduce the surface area so that the print is subjected to less force as the build platform raises with every layer. It was then printed in stereolithography with Formlabs 1+, using FLGPGR04 resin with an X Y resolution: 140µm and z: 100µm (Formlabs Inc, Somerville, MA, USA). The model was handled following the protocol: isopropyl alcohol (IPA) bath 99% (surface cleaner, 3M Co, St Paul, MN, USA), twice 10 minutes; photopolymerization at 405nm for 30 minutes at 60°C (Lumamat 100, Ivovlar Vivadent SAS, Saint-Jorioz, France). This printed reference model (RM) was scanned to serve as a reference STL file (RS) in order to eliminate bias linked to the printing. The flow chart of the protocol is described in Figure 1.

1.2 Sample size calculation

Determination of the number of subjects necessary was evaluated based on the literature [11, 12]. With an observed sample size of 91 observations in each group, a power analysis for Mann–Whitney U tests (two-tailed) conducted *a priori* using the statistical analysis tool, G*Power (Version 3.1.9.4), indicated a 90% power to detect a moderate effect size (Cohen’s $d = 0.5$) at a significance level of 0.05 [14].

1.3 Preparation of the study models

Twenty models of the initial arch were obtained by stereolithography as described above. The choice of 3D printing has been imposed by the desire to work in a completely digital workflow, as is the case in a growing number of offices. These were used for the bonding of

orthodontic brackets, carried out fifteen days later. After printing, the models were stored in a dark room at room temperature for 15 days to ensure complete evaporation of the IPA and limit stickiness that could make bonding fail.

1.4 Preparation of silicone transfer trays

Based on the reference model (RM), ten indirect bonding (IDB) trays were made from transparent, addition-cross-linking polyvinyl siloxane (Memosil 2, Kulzer, Hanau, Germany, batch no. K010031). As recommended in the manufacturer's specifications, the silicone was stored below 25°C. The average thickness of the trays was 5 mm. The polymerisation time granted was 20 minutes before the bonding of brackets.

1.5 Preparation of the CAD/CAM transfer trays

Based on the RS, ten transfer trays for IDB were designed by CAD (Appliance Designer, 3Shape Dental Systems, Copenhagen, Denmark). They fitted the contour of the brackets by closely holding them in the apertures. These were joined on the vestibular surface by a cylinder 2 mm in diameter and on the palatal surface by an extension of the mucous support of 4mm. The CAM of these transfers was carried out by digital light printing in high elasticity biocompatible resin (40D shore hardness), class IIa (Anenke Laboratory, France).

1.6 Bonding of brackets

The brackets were replaced manually in both types of trays.

IDB of the 200 brackets was carried out: an average volume of 1 mm³ of bonding composite (Transbond XT, 3M Co, St Paul, MN, USA, batch no. IT8VT) was placed on the inside of the brackets. A fine layer of adhesive primer (Transbond MIP, 3M Co, St Paul, MN, USA, batch no. 948341) was applied on the vestibular surface of the teeth of the study models. Both types of transfer trays were applied on the models using light finger pressure and photopolymerization was carried out for 30 seconds per tooth. In both groups, the same bonding material was used to minimise the risk of a systematic error and all bonding procedures were performed on the same day by the same experienced orthodontist. The models bonded were split into two groups: 10 silicone transferred (group I) and 10 CAD/CAM transferred (group II).

1.7 Scan of the bonded models

After covering the brackets with a thin layer of scan spray (Cerec Optispray, Dentsply Sirona, Salzburg, Austria, batch no. S50704) to reduce reflection from the metal brackets, all bonded models were scanned with an intraoral scanner (Trios2® Color, 3Shape Dental Systems, Copenhagen, Denmark).

1.8 Superimpositions of STL files

All the STL files were superimposed on RS using the GOM Inspect software Version 8 SR1 as recommended by the constructor (GOM GmbH, Braunschweig, Germany). Millimeters (mm) were set as the standard unit of both model types. Superimpositions were automatically carried out by the software and then adjusted to best-fit on the palatal surfaces of the teeth (Figure 2).

1.9 Measurement method

A system of local coordinates using the “3-2-1” (plane-line-point) technique was carried out for each bracket. The plane was defined by three points centred on the external side of the bracket wings, the line by two points centred on the internal side of the slot and the terminal point was centred on the internal side of the occluso-distal wing. The linear displacements along the X Y Z axes (mesiodistal, lingual-vestibular and occluso-gingival respectively) and the angular displacements Phi(X), Theta(Y), Psi(Z) (torque, tip and rotation, respectively) have been evaluated (Figure 3). To evaluate repeatability, a second series of measurements was carried out on the same model by the same experienced operator with a two-day interval.

For the linear measurements, a negative value would indicate a distal, cervical or lingual displacement. For the angular measurements, a negative value would indicate a crown-vestibular ‘torque’, tipback angulation, or mesio-vestibular rotation of the bracket.

1.10 Acceptability assessment

The placement errors reported are compared to the standards of the American Board of Orthodontics [15]. The authors defined deviations from proper alignment of ≤ 0.5 mm as clinically acceptable. In the case of an average-sized molar, a marginal ridge discrepancy of 0.5 mm would lead to a crown-tip deviation of 2 degrees, which is why angulatory deviations of ≤ 2 degrees are considered to be clinically acceptable.

1.11 Statistical analysis

The repeatability of the measurements was evaluated by Lin’s concordant correlation coefficient using the NCSS statistics package (NCSS LLC, Kaysville, UT, USA). The data were sorted into X, Y, Z, Phi(X), Theta(Y), Psi(Z) in relative and absolute values for each group of teeth: incisors, canines and premolars. The comparability of intra-group bonding was evaluated by a nonparametric Kruskal-Wallis test using the XLStat package (Addinsoft, Paris, France). A Mann-Whitney U test for two independent samples was then performed to evaluate the accuracy of both techniques. A Chi square test or a Fisher’s exact test was performed to evaluate the contingency of bonding errors using GraphPad Prism 6.0 (GraphPad Software, San Diego, CA, USA).

2 Results

2.1 Reliability of bonding

Five brackets were lost during the transfer to the study models and were not included in the evaluation. Altogether, the transfer accuracy of 195 brackets was examined: 97 from group I and 98 from group II, allowing for 1170 bracket positioning measurements.

2.2 Repeatability of measurements

The repeatability of the “3-2-1” technique measurement method was evaluated using Lin’s concordant correlation coefficient. The results showed coefficients in the order of 0.9 ($\alpha=5\%$) 0.9987; 0.9989; 0.9920; 0.9531; 0.9640; 0.9589 respectively in X, Y, Z, Phi(X), Theta(Y) and Psi(Z).

2.3 Comparison of intra-group accuracy

The bonding accuracy was verified within each group and neither the methods nor the type of tooth considered showed a significant difference. All the scans from the same group were comparable with each other. For group I, the most significant error in the mesiodistal, lingual-vestibular and occluso-gingival measurements appeared in the lingual-vestibular direction (0.113 +/- 0.10 mm), whereas in group II the three values were close, between 0.198 +/- 0.11 and 0.200 +/- 0.11 mm. For the angular values (torque, tip and rotation), group I showed that the most significant error concerned torque (1.210 +/- 0.74°), for group II the three measurements were close between 1.336 +/- 0.78 and 1.566 +/- 1.10° (Table 1).

2.4 Prevalence of clinically acceptable transfer errors

The contingencies were established based on ABO acceptability criteria for positioning errors. The Chi2 tests showed no statistical difference between the two groups (Table 2). However, slightly better results were found in group I.

2.5 Comparison of inter-group accuracy

The comparison of accuracy between groups was highly significant in favor of group I. Specifically, all linear values (mesiodistal, lingual-vestibular and occluso-gingival) for all teeth in group I showed minor errors as compared to those in group II. In group I, for incisors, the accuracy was between 0.072 mm and 0.134 mm, for canines, measurements were between 0.067 mm and 0.087 mm and for premolars it was between 0.095 mm and 0.109 mm. In comparison, the value for group II was measured to be between 0.151 mm and 0.181 mm for incisors, 0.175 mm and 0.239 mm for canines and 0.215 mm and 0.234 mm for premolars (Table 1).

In terms of angular values, no difference was found between the two groups for canines (all values were between 0.666 and 1.478 degrees). In group I these measurements were

between 0.459 and 1.011 degrees for incisors, 0.895 and 1.371 degrees for premolars whereas for group II, the incisors were between 1.013 and 1.410 degrees and the premolars were between 1.677 and 1.769 degrees. No difference was found between groups for torque positioning on premolars (Table 1).

2.6 Comparison of errors of placement

On a global analysis, there is a significant difference between the two transfer techniques ($p=0.0478$) as explained by the premolar ($p=0.003$). Moreover, for both groups, 100% of bondings appeared to be too facial (Table 3).

3 Discussion

The purpose of this study was to evaluate the clinical acceptability of CAD/CAM indirect bonding trays. Altogether, 200 brackets were bonded with a failure rate of 2.5% comparable to that found in the literature.

The silicone tray technique constitutes the reference: the dimensional stability and elastic properties ensure reliable and repetitive bracket transfer. The use of transparent silicone makes it possible to use photopolymerizable bonding agent.

Several possible uses have been described. The first with a single layer of silicone is the most conventional, especially for buccal bonding. However, it is possible to add a second layer of silicone. This is the technique used by the WIN individualized lingual orthodontic system and formerly by Incognito. A study shows the precision and effectiveness of this type of treatment, attesting to the reliability of this bonding technique [16].

Another possibility is to vacuum-form a rigid layer over the silicone [17]. In lingual orthodontics, this technique is now used by 3M for the Incognito “clear precision tray” but no independent studies have evaluated its accuracy. However, the accuracy of the bonding does not seem to be improved in the conventional buccal technique [8]. This is why we have concentrated our work on single-layer transfers.

Therefore, we proposed to compare the one-layer soft silicone tray to an innovative process stemming from CAD/CAM, whose reliability has not yet been evaluated in the literature. This type of process is already well distributed in our practices and will continue to increase. In order to register in a digital flow, we conducted this study only with recent technologies: intra-oral scanner and 3D printer.

Four technologies are used today in 3D printing: SLA (stereolithography), DLP (Digital Light Processing), FFF (Fused Filament Fabrication) and PolyJet. Hazeveld proposed to replace the traditional dental cast study models with DLP or PolyJet prints, the latter two being more precise than SLA [18]. International Standard ISO 5725 defines two distinct parameters to evaluate the accuracy of objects printed. The first, known as “trueness”, is used to evaluate

the consistency of a printed object with its initial STL file. The second, “precision”, evaluates the consistency of several prints with the same object.

Our preliminary tests (data not shown) indicate a lower correlation between the models printed and the initial STL file, which is comparable with data found in the literature [19, 20]. The “trueness” parameter which is thus evaluated, leads to a bias which must be reduced during the study. Conversely, the “precision” parameter must be maximised. To do this, in accordance with the literature, the models are printed in SLA [20]. In addition, limited bonding of premolar to premolar reduces the imprecision caused by posterior transverse contraction inherent to the SLA printing technique [21]. In the context of the limit imposed by the “trueness” parameter, it was decided not to compare the scanned models to the initial file stemming from Bracket Placement module. This last file was then printed as the reference model (RM) and then scanned to serve as a reference STL file (RS). The bias linked to the printing is therefore camouflaged as all the printed models are comparable with each other with a precision of $94 \pm 33 \mu\text{m}$ linked to the scanning and printing errors of a model with brackets [20]. Lastly, to minimise any distortions during printing, the models were printed according to the manufacturer’s recommendations and those in the literature as described in the materials and methods section [22–24].

The prevalence of acceptable linear values is comparable to the results of similar studies, almost at 100% for both groups [11, 12]. The positioning is acceptable for the three dimensions. The angular results in the light silicone used in group I (torque 92%, tip 99%, rotation 95%) indicate the superiority of silicone transfers as compared to heavy PVS studied by Grünheid [11]. Concerning the CAM/CAD group, the angular measurements are less acceptable (78%; 85%; 81%) than the group I and relatively similar to the results found by Grünheid [11]. The CAD / CAM trays, with the design described here are therefore equivalent to the conventional silicone as reported in the literature, and are thus clinically acceptable.

In a second step, we sought to compare the precision between the two groups and finally the distribution of placement errors. Our results are in favor of the silicone tray except for the canines’ angular values and the premolars’ torque. In the literature, a microphotography study [4] found a mean vertical deviation of $0.31 \pm 0.25 \text{ mm}$, horizontal of $0.18 \pm 0.14 \text{ mm}$ and angular of $2.43 \pm 2.03^\circ$ for a double PVS + vacuum formed tray in relation to indirect bonding. The results found in our study showed a greater accuracy for vertical ($0.085 \pm 0.08 \text{ mm}$ for group I and $0.197 \pm 0.23 \text{ mm}$ for group II) and angular measurements ($0.677 \pm 0.48^\circ$ for group I and $1,422 \pm 1.06^\circ$ for group II). Meanwhile, for the horizontal measurements, the accuracy of bonding tested is only slightly better in our study ($0.088 \pm 0.07 \text{ mm}$ for group I and $0.197 \pm 0.23 \text{ mm}$ for group II). The results of Schmid [12], comparing the reliability of indirect bonding using heavy silicone trays to double-vacuum formed trays were superior, however, the comparison with our results is difficult because of different evaluation methods: plaster and non-printed models, superimposition technique. Moreover, no evaluation of the repeatability was realized [12]. These methods do not seem to correspond to the techniques currently used in orthodontics. It should be noted that the two groups do not show

differences in the distribution of placement errors for the incisors and canines. However, in a global way, bondings with CAD / CAM trays are too mesial and too occlusal.

Our results showed significant placement errors between groups only at the premolars. These could be related to the lack of precision of the CAD / CAM trays on the terminal areas. Indeed, 3D printing is less accurate in the transverse direction in the posterior areas [21]. Perhaps the addition of a posterior extension to stabilize the trays or a transverse junction at the level of the premolars of sectors 1 and 2 would improve the accuracy of the CAD / CAM trays.

Bonding inaccuracies recorded here are only clinically significant on condition that the entire bracket prescription is read. Two parameters lead to the information only being partially read. The first is arch play in the bracket slot. For a .022x.028-inch slot, the theoretical amount of play of a .019x.025-inch arch is 7.2° [25]. The second: even by increasing the size of the arch used, and therefore minimising the play, prescription expression could be limited by inaccuracies linked to the machining of the brackets and the arches [26–29].

To date, no study concerning the accuracy of CAD/CAM full arch trays has been published. A single article found dealt with the subject and with the bonding accuracy of jigs in relation to the different cusp heights of premolars and molars [10]. This publication from 2018 is also the only one to use printed models as a bonding support, but gives no details on the printing protocol chosen (orientation, layer thickness, etc.). The other publications used plaster cast models.

The tests performed for this *in-vitro* study have shown the successful repeatability of the measurements. As it concerns mechanisms that are applicable to clinical routines, it is necessary to test the reproducibility of these results *in vivo*.

4 Conclusion

This study compared two transfer mechanisms, silicone versus CAD/CAM, for orthodontic bonding in terms of clinical acceptability and accuracy. The results showed that both mechanisms are clinically acceptable according to the ABO standards: 97% and 89% respectively. However, the silicone group showed superiority over the CAD/CAM group in terms of accuracy.

Conflict of Interest: All the authors declare that they have no conflict of interest.

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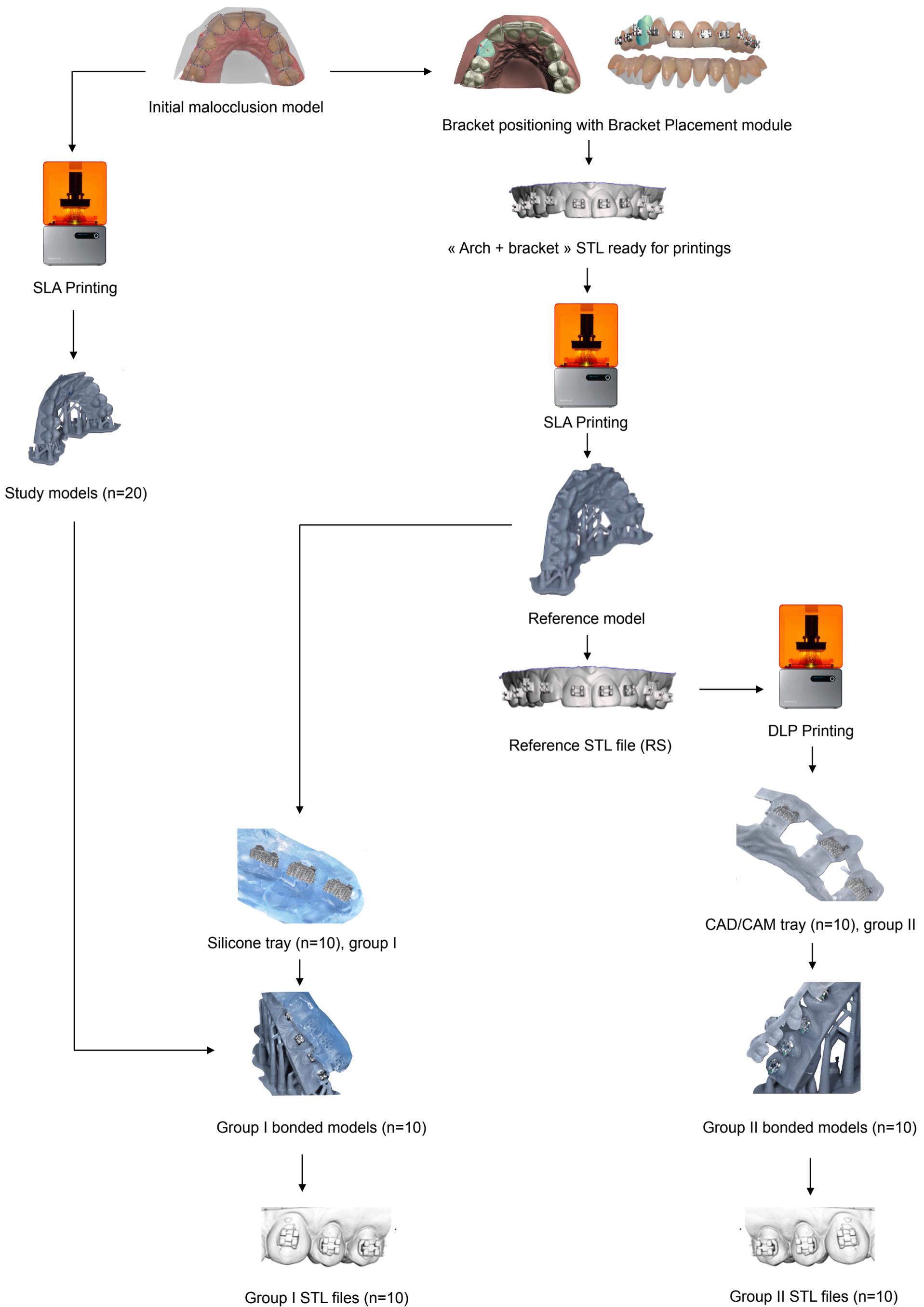
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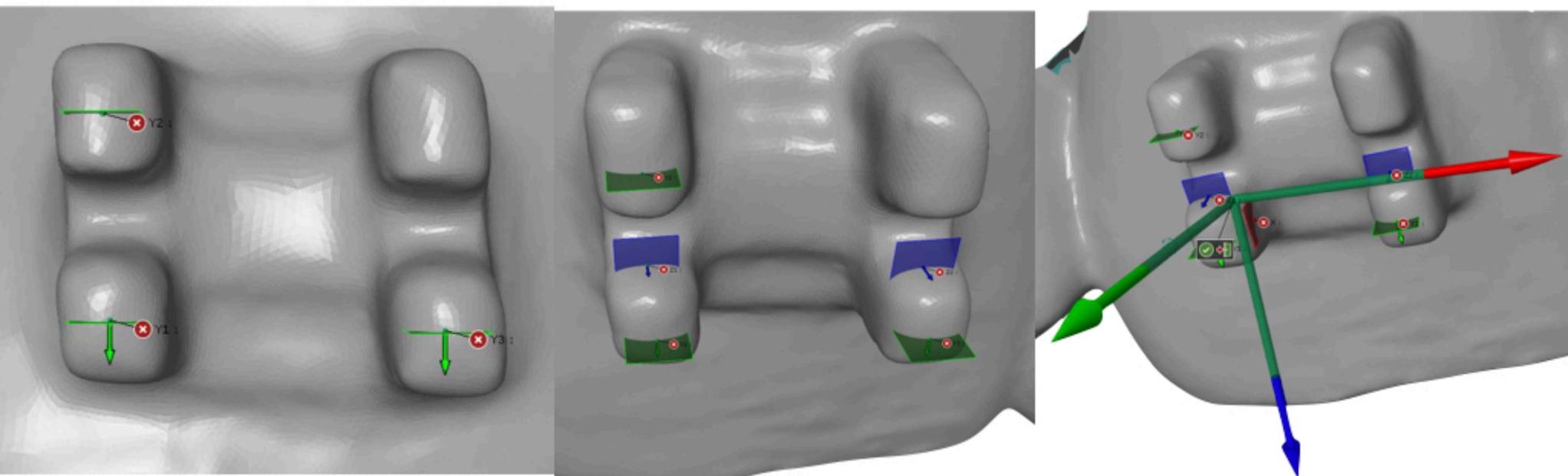
Captions

Figure 1: Flow chart of the protocol.

Figure 2: Definition of a local coordinate system by "3-2-1" technique.

Figure 3: Superposition and analysis of bonding inaccuracies on GOM inspect software





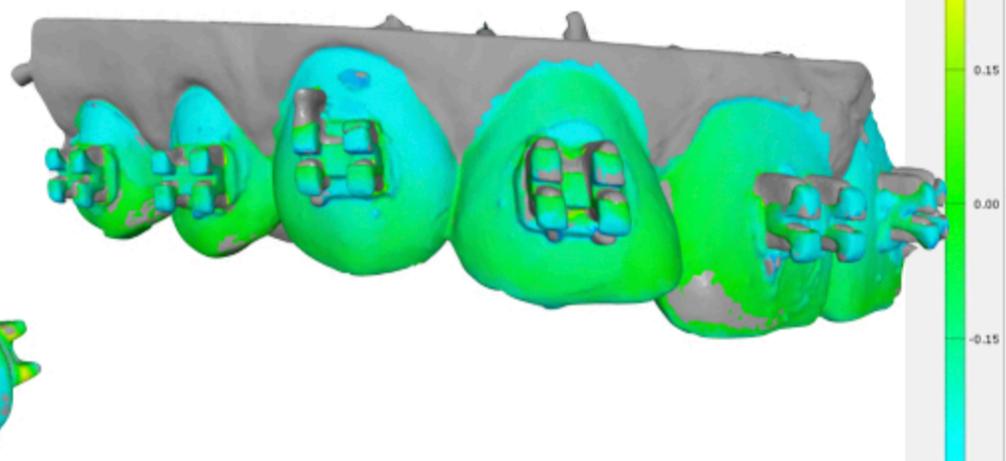
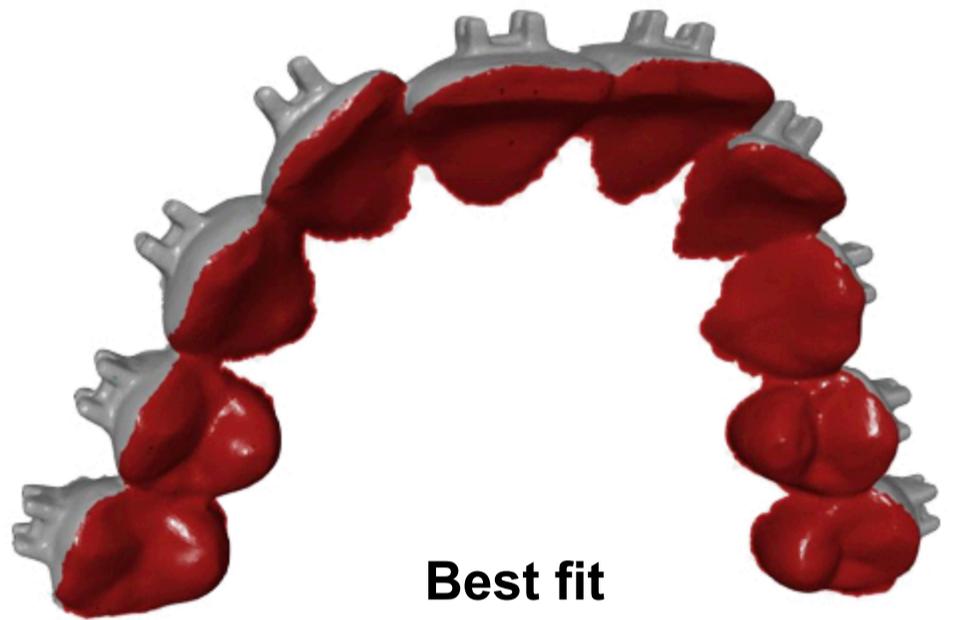
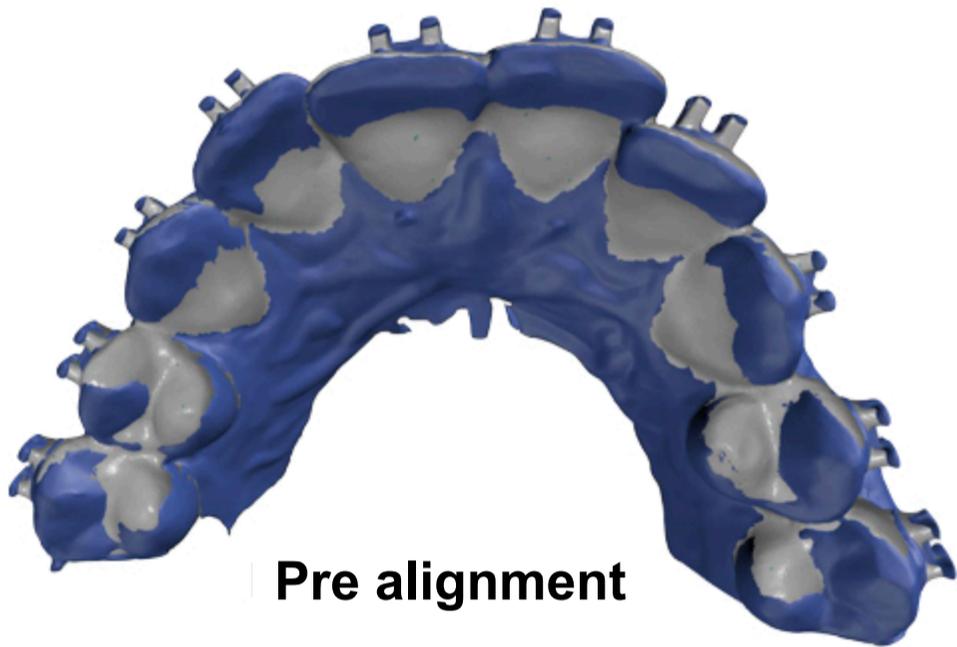


Table 1: Means, standard deviations and significance of transfer errors between the two groups following Student's test.

	Incisors			Canines			Premolars			Total		
	Group I	Group II	p-value									
Mesiodistal (mm)	0.082 ± 0.065	0.181 ± 0.095	< 0.0001	0.087 ± 0.065	0.200 ± 0.091	< 0.0001	0.095 ± 0.740	0.215 ± 0.134	< 0.0001	0.088 ± 0.071	0.198 ± 0.110	< 0.0001
Occluso-gingival (mm)	0.072 ± 0.054	0.151 ± 0.102	< 0.0001	0.067 ± 0.041	0.239 ± 0.350	0.040	0.108 ± 0.113	0.225 ± 0.249	< 0.0001	0.085 ± 0.080	0.197 ± 0.233	< 0.0001
Lingual-vestibular (mm)	0.134 ± 0.120	0.179 ± 0.104	0.029	0.082 ± 0.060	0.175 ± 0.072	< 0.0001	0.109 ± 0.083	0.234 ± 0.131	< 0.0001	0.113 ± 0.101	0.200 ± 0.111	< 0.0001
Torque (degrees)	1.011 ± 0.711	1.410 ± 0.659	0.003	1.403 ± 0.758	1.478 ± 0.654	0.238	1.305 ± 0.722	1.769 ± 1.530	0.702	1.210 ± 0.742	1.566 ± 1.100	0.008
Tip (degrees)	0.459 ± 0.335	1.245 ± 0.724	< 0.0001	0.666 ± 0.321	1.176 ± 0.931	0.072	0.895 ± 0.560	1.724 ± 1.335	0.001	0.677 ± 0.489	1.422 ± 1.067	< 0.0001
Rotation (degrees)	0.652 ± 0.538	1.013 ± 0.709	0.021	0.994 ± 0.849	1.318 ± 0.907	0.147	1.371 ± 0.545	1.677 ± 0.653	0.046	1.011 ± 0.691	1.336 ± 0.782	0.002

Table 2: Prevalence of clinically acceptable transfer errors and significance for both groups following Chi2 test.

	Incisors		Canines		Premolars		Total	
	Group I n (%)	Group II n (%)	Group I n (%)	Group II n (%)	Group I n (%)	Group II n (%)	Group I n (%)	Group II n (%)
Mesiodistal	38 (100%)	40 (100%)	20 (100%)	19 (100%)	39 (100%)	37 (95%)	97 (100%)	96 (98%)
Occluso-gingival	38 (100%)	40 (100%)	20 (100%)	17 (89%)	39 (100%)	37 (95%)	97 (100%)	94 (96%)
Lingual-vestibular	37 (97%)	40 (100%)	20 (100%)	19 (100%)	39 (100%)	37 (95%)	96 (99%)	96 (98%)
Torque	36 (95%)	32 (80%)	19 (95%)	18 (95%)	34 (87%)	31 (79%)	89 (92%)	81 (83%)
Tip	38 (100%)	38 (95%)	20 (100%)	19 (100%)	38 (97%)	31 (79%)	96 (99%)	87 (89%)
Rotation	37 (97%)	39 (98%)	18 (90%)	16 (84%)	37 (95%)	34 (87%)	92 (95%)	89 (91%)
p-value	0.4522		0.1050		0.3001		0.9988	

Table 3: Prevalence of placement errors and significance for both groups following Chi2 test.

		Incisors		Canines		Premolars		Total	
		Group I	Group II	Group I	Group II	Group I	Group II	Group I	Group II
Mesiodistal (mm)	Mesial	70%	92%	45%	95%	11%	90%	41%	92%
	n =	26	36	9	18	4	35	39	89
Occluso-gingival (mm)	Occlusal	35%	97%	70%	68%	69%	67%	57%	79%
	n =	12	38	14	13	27	26	53	77
Lingual-vestibular (mm)	Facial	100%	100%	100%	100%	100%	100%	100%	100%
	n =	38	40	20	19	39	39	97	98
Torque (degrees)	Facial crown	13%	10%	55%	84%	10%	49%	21%	40%
	n =	5	4	11	16	4	19	20	39
Tip (degrees)	Distal crown	66%	64%	50%	58%	36%	33%	51%	51%
	n =	25	25	10	11	14	13	49	49
Rotation (degrees)	Mesio facial	53%	70%	90%	26%	72%	72%	68%	62%
	n =	20	28	18	5	28	28	66	61
p-value		0.5267		0.4117		0.0030		0.0478	