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ORIGINAL ARTICLE

Accuracy of crowns based on digital intraoral scanning compared to conventional impression—a split-mouth randomised clinical study

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Abstract

Objectives The aim of this prospective in vivo study was to evaluate the accuracy of the marginal and internal fit of crowns based on conventional impression (CI) or intraoral scan (IOS) in a randomised, split-mouth set-up.

Materials and methods Nineteen patients needing full coverage crowns, fitting a split-mouth design, were provided with two lithium disilicate crowns: one based on a CI and one based on an IOS. The marginal and internal accuracy of the crowns were assessed with the replica technique and clinically using a modified California Dental Association (CDA) quality evaluation system.

Results At the preparation margin, the median gap was 60 μm for IOS and 78 μm for CI. For the other points, the median gap ranged from 91 to 159 μm for IOS and 109 to 181 μm for CI. The accuracy of the IOS was statistically significantly better at all point except at the cusp tip. All crowns where rated R or S at both the 6- and 12-month follow-up appointments. The results for the clinical evaluation with CDA for marginal integrity showed no statistically significant difference between the two impression methods at both the 6- and 12-month evaluations.

Conclusions Crowns based on IOS show statistically significantly better marginal and internal adaptation before cementation compared to conventional impression. However, the clinical evaluation showed similar marginal adaptation.

Clinical relevance Crowns based on a fully digital workflow can provide clinically acceptable marginal adaptation, comparable to crowns based on CI.

Keywords Dental impression technique · Intraoral scanning · Digital impression · CAD/CAM · Dental crown · Clinical accuracy

Introduction

Prosthetic dentistry is shifting towards a more digitally based workflow, and intraoral scanners (IOS) provide the first and most important step in a fully digital workflow: a three-dimensional reproduction of the oral hard and soft tissues. With recent advances in IOS, a fully digital workflow is becoming more and more appealing to general dentists. Compared to the traditional workflow, a fully digital workflow is less labour intensive for the dentist as well as the dental laboratory, there is no need for disinfection or shipping of impressions and there is a possibility of one-appointment production of indirect restorations [1, 2]. IOS compared to conventional impression methods have been shown to be more patient friendly and time efficient [3–9].

General dentists are increasingly implementing IOS in their practices; however, little is known about the accuracy of restorations based on IOS. It is well documented that poor marginal adaptation of restorations can lead to gingival inflammation, dissolution of luting cement, increased plaque accumulation and subsequently secondary caries or periodontal disease [10–12]. A study by Mclean and von Fraunhofer [13] concluded that 120 μm was the maximum acceptable marginal misfit.

There are a limited number of in vivo studies on the accuracy of IOS with conventional impression (CI) as the control group. Most of these studies are on now obsolete scanners. Boeddinghaus et al. [14] and Berrendero et al. [15] have conducted in vivo studies on the Trios Standard Scanner (3Shape, Copenhagen, Denmark). Trios Standard is the first-generation

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scanner from 3Shape. The Trios 3 used in the present study was released in 2015 and is the third and so far the latest generation scanner from 3Shape.

The aim of this prospective in vivo study was to compare the accuracy of the marginal and internal fit of lithium disilicate crowns based on CI or IOS for posterior teeth in a randomised, split-mouth set-up.

Materials and methods

This clinical trial was approved by The Regional Scientific Ethical Committee, (reference number 44868) and was conducted in accordance with the Declaration of Helsinki and internationally accepted guidelines for RCT, including the CONSORT statement (www.consort-statement.org).

The participants were recruited by referrals from dental practitioners in private practice. The practitioners were informed of the purpose of the study by mail, and the participants were selected among the referred patients using the following inclusion and exclusion criteria.

Inclusion criteria:

- Premolars and first molars needing a crown
- Two contralateral-positioned teeth in the same jaw
- Similar proximal contact relations to adjacent teeth on both sides

Exclusion criteria:

- General diseases, e.g. xerostomia
- Endodontically treated teeth
- Periodontally involved teeth (i.e. bleeding on periodontal probing and probing pocket depth exceeding 4 mm)
- Teeth with apical lesion (examined with periapical radiographs)
- Teeth needing a preparation exceeding 1 mm subgingivally
- Manifest parafunctional habits (e.g. bruxism or clenching)
- Present high caries activity

Nineteen individuals (10 men and 9 women) between the ages 42 and 61 were enrolled in the study. All participants were informed of the purpose of the study, and gave their written consent. Three pairs of first premolars, 6 pairs of second premolars and 10 pairs of first molars were treated. Of the 19 matching pairs of teeth, 6 were in the lower jaw and 13 were in the upper jaw (Table 1). All the clinical procedures were performed by the same operator (YH). The evaluations 6 and 12 months after treatment were performed by the operator and a blinded dentist not involved in the treatment (GB). The two evaluators were calibrated before the assessments. Any caries was excavated and amalgam restorations or defective composite restorations were replaced with resin composite (Filtek Supreme, 3M ESPE, Seefeld, Germany). Under local anaesthesia, the teeth were prepared for full coverage ceramic crowns. The margin of the preparation was placed equi- or subgingivally not extending 1 mm subgingivally. The preparation depth was at least 1 mm at the margin. A 1.5- to 2-mm occlusal reduction was performed, and the tooth reduction was controlled using an individually fabricated reduction guide in putty impression material (Extrude, Kerr, Orange, USA). Temporary crowns were fabricated in bis-acryl composite (Protemp, 3M ESPE, Seefeld, Germany).

The order of impression taking as well as which tooth is receiving which treatment, i.e. CI or IOS, was decided by a closed randomisation. In 9 patients CI was recorded first and IOS in 10 patients. Both impressions were taken in the same session.

Conventional impressions

Under local anaesthesia, the provisional crown was removed and the tooth cleaned. Gingival displacement was achieved with the two-cord retraction technique for all impressions (KnitTrax, Pascal international, Bellevue, USA). The cord size varied depending on the biotype of the gingiva. The knitted cords were soaked in 15% ferric sulphate solution prior to use. The first cord was in the whole circumference of the tooth placed below the preparation margin. Before impression taking, the upper cord was removed. The impression was taken with polyvinyl siloxane silicone (Extrude, Kerr, Orange, USA) in a full-arch prefabricated metal tray. Adhesive was applied to the inner surface of the tray (PVS adhesive, Coltene/Whaledent, Altstätten, Switzerland). A one-step two-viscosity technique (light-body/heavy-body) was used. Impression of the opposing jaw was taken in alginate (Aroma fine plus, GC, Japan). The interocclusal record was taken in polyvinyl siloxane silicone (Occlufast, Zhermack, Italy). To obtain the shade for the crowns in the CI group, VITA 3D-Master shade guide (VITA Zahnfabrik, Bad Säckingen, Germany) was used. The quality of each impression was assessed using a checklist (Fig. 1). When an impression was assessed as having a critical defect, the impression was retaken ($N = 4$).

Digital impression

Trios 3 intraoral scanner with software version 1.4.7.0 (3Shape, Copenhagen, Denmark) was used for the digital

Table 1 Distribution of pairs of teeth on jaw and tooth positions

	First premolars	Second premolars	First molars
Upper jaw	3	4	6
Lower jaw	0	2	4

Journal no	Dentist	Date

Material
Tray type
Restoration type
Tooth number

Defect	Not present	Present – not critical	Present - critical
Preparation margin not reproduced in entirety			
Air bubble in impression material			
Drags or voids in impression of prepared tooth			
Insufficient mixing of materials			
Detachment of impression material from tray			
Impression material unset			
Insufficient impression material in tray or around tooth			
Insufficient moisture control			
Incorrect tray position			
Other			

Overall evaluation

No defect – Impression usable	Defects not critical – impression usable	Defects critical – impression unusable

Fig. 1 Checklist for assessing a conventional impression. When an impression was assessed as having a critical defect, the impression was retaken

impressions. The tissue management was performed identical to CI. Prior to scanning, the scanner was colour and 3D calibrated. A sectional scan was performed for the abutment as well as opposing jaw. Shade selection was performed using the built-in shade feature in the Trios 3. After the interocclusal scan, the abutment jaw was additionally scanned until sufficient data was obtained for shade acquisition. The quality of each scan was assessed, using a checklist (Fig. 2). The scan was continuously assessed during the scanning procedure. When assuming the scanning was complete, a checklist (Fig. 2) was used to assess the quality of the scan. If a critical defect was observed, the scan was corrected by rescanning the flawed area ($N = 1$).

The results regarding operating time and patient perception associated with impression taking, as well as presence and strength of proximal contact points and need of occlusal adjustments, have previously been published [9].

The CI as well as the scan file were sent to the same laboratory technician for fabrication of two lithium disilicate crowns. All crowns were designed using the same milling settings (cement gap at the margin 0.020 mm; after 1.2 mm from the margin line, the cement gap gradually increases to 0.080 mm) in the Dental System design software (software version 2015-1, 3Shape, Denmark,) For fabrication of the crown based on CI, the CI was poured high-strength dental stone (Nova Die Stone, BK Giulini, Ludwigshafen, Germany). The saw-cut model was scanned in a laboratory scanner (D640, 3Shape, Denmark). All crowns were milled with the same milling station (Röders RXD5, Röders GmBH, Soltau, Germany).

Cementation

At the cementation appointment, both teeth were cleaned meticulously with pumice. A silicone replica of the gap between the abutment tooth and restoration was obtained using the replica technique previously described by Molin and Karlsson [16], and Boening et al. [17]. The inside of the

Journal no	Dentist	Date

Scanner type
Scan area
Restoration type
Tooth number

Defect	Not present	Present - not critical	Present - critical
Preparation margin not reproduced in entirety			
Insufficient scan data on prepared tooth			
Insufficient scan data on adjacent teeth			
Insufficient moisture control			
Wrong stitching of data			
Other			

Overall evaluation

No defect – Scan usable	Defects not critical – Scan usable	Defects critical – Scan unusable

Fig. 2 Checklist for assessing an intraoral scan. When a scan was assessed as having a critical defect, the scan was corrected

crowns was filled with light-body silicone and seated on the tooth, and the patient was asked to occlude firmly on a cotton roll. The crown was kept in place with finger pressure. Once set, the crown was removed with the thin silicone layer adhering to the inner surface of the crown. Heavy-body silicone in another colour was then used to stabilise the thin light-body layer. The crowns were cemented using a dual-cure resin cement (Multilink Automix, Ivoclar Vivadent, Lichtenstein) (Fig. 3).

Replica measurement

A sharp scalpel (10A, Swann Morton, Sheffield, England) was used to section the replicas. Molar replicas were sectioned in mesiodistal, buccolingual, distobuccal to mesiolingual and mesiobuccal to distolingual cuts. Premolars were sectioned in mesiodistal and buccolingual cuts, resulting in eight cross-sections for molars and four for premolars. The width of the cement gap corresponding to the light-body silicone material thickness was measured at five predetermined locations: marginal gap (MG) as defined by Holmes et al. [18], internal angle (IA), axial wall (AW), cusp tip (CT) and occlusal (OC) (Fig. 4).

Measurements were made using a Wild Macroscope M420 (Wild, Heerbrugg, Switzerland) and digital camera (Zeiss Axiocam MRc5, Carl Zeiss Micro Imaging GmbH, Gottingen, Germany) with × 40 magnification on the computer screen.

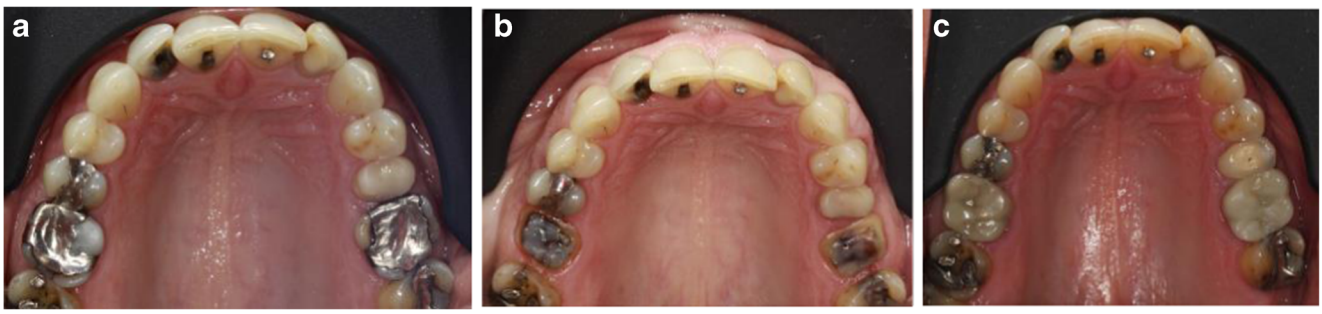

Fig. 3 **a** Patient needing crowns on the upper left and right first molars. **b** Both teeth prepared for full coverage restorations. **c** Crowns based on either CI (left side) or IOS (right side) in place after 12 months

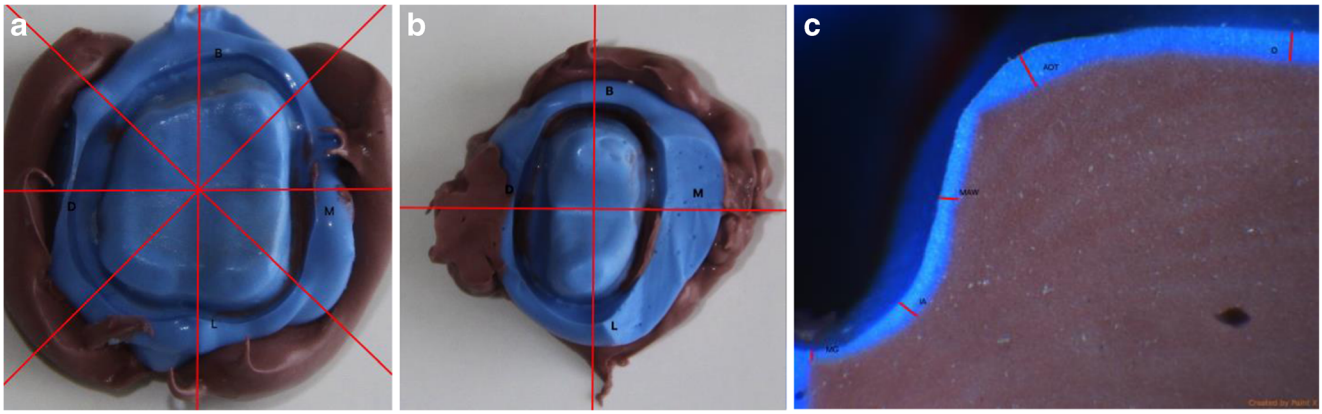

Fig. 4 **a** Shows where molar replicas were sectioned. **b** Shows where premolar replicas were sectioned. **c** Shows where measurements were made on each cross-section

All patients were recalled for follow-up examinations after 6 and 12 months where a form based on a modified California Dental Association (CDA) quality evaluation system was completed by the clinician who performed the treatments as well as a clinician who was blinded with regard to which impression method had been used on which tooth. A fin tipped explorer (ASH spiral explorer no. 12, DensplySirona, Erlangen, Germany) was used at the clinical examinations at the recall appointments. The marginal integrity, anatomic form, as well as surface and colour were evaluated using CDA.

At 6 months, 17 patients attended the follow-up evaluation. One did not wish to attend, and we were not able to reach another. At 12 months, 17 patients attended the follow-up. The person, who did not wish to attend at 6 months, did not attend at 12 months either. One participant fractured one of the included teeth due to trauma and was therefore excluded from the study. The participants, who we were unable to reach at 6 months, did attend at 12 months.

Statistical analysis

Data was analysed using STATA 14 (STATACORP, Texas USA). QQ-plots and Shapiro-Wilks test were used to test replica data for normality. As the data was not normally distributed, non-parametric Wilcox signed-rank test for paired data was used to test for significant difference between groups. The median, 25th–75th percentile, maximum value (Max) and minimum value (Min) were calculated. There was no statistically significant difference between similar measuring points on the different cross-sections for both methods. Therefore, for further statistical analysis, means of similar points from the different cross-sections were calculated, resulting in six calculated values for each impression/scan (MG, IA, AW, CT, OC). The largest marginal discrepancy was analysed with a paired *t* test since the data was normally distributed. Distribution of CDA scores between the two treatments was analysed using McNemars test. Distribution of CDA scores in relation to values higher or lower than the median value of the replica margin data was analysed using Fishers exact test.

Statistical significance was accepted at $p < 0.05$ for all statistical tests.

Results

For the replica measurements, the mean, median, 25th–75th percentile and minimum and maximum values for both methods are presented in Table 2. At the preparation margin, the median gap was 60 μm (25th–75th percentile = 39–94) for IOS and 78 μm (25th–75th percentile = 55–107) for CI. For the other points, the median gap ranged from 91 to 159 μm for IOS and 109 to 181 μm for CI. The accuracy of the IOS was statistically significantly better at all points except at the CT. (see Table 2 for *p* values).

For each crown, the largest gap measurement at the margin, in the whole circumference of the preparation, was also as assessed with the replica technique for both impression methods. For IOS, the mean was 104 μm (SD = 50) and 125 μm for CI (SD = 39). The paired *t* test showed that this difference was statistically significant ($p = 0.04$).

All crowns were rated R or S at both the 6- and 12-month follow-up examinations. The results for the clinical evaluation with CDA for marginal integrity showed no statistically significant difference between the two impression methods for either evaluator at both the 6- and 12-month examinations.

The CDA scores for the two evaluators were similar. At 6 months, the two evaluators gave the same CDA score for marginal integrity for 26 out of 34 crowns, and at 12 months, the evaluators gave the same score for 22 out of 34 crowns.

No association was found between the CDA scores and the replica measurements when these were divided in two categories (higher or lower than the median score (see Table 3).

Table 2 Results of the cement gap (the replica measurements) in micrometers at five locations: marginal gap, internal angle, axial wall, cusp tip and occlusal. Mean, median and 25th–75th percentiles and minimum, maximum and *p* values are shown

Point	Method	Mean	Median	25th–75th percentiles	Min–max	*p* value
MG	CI	83	78	55–107	17–205	0.04
	IOS	72	60	39–94	5–212	
IA	CI	129	125	97–153	20–276	0.0004
	IOS	100	100	68–129	5–231	
AW	CI	115	109	79–143	30–255	0.004
	IOS	95	91	65–114	25–233	
CT	CI	170	169	142–199	76–294	0.23
	IOS	162	159	123–183	70–329	
OC	CI	182	181	143–220	65–333	0.004
	IOS	156	149	113–198	67–332	

CI conventional impression, *IOS* intraoral scan, *MG* marginal gap, *IA* internal angle, *AW* axial wall, *CT* cusp tip, *OC* occlusal, *Min* minimum, *Max* maximum

Discussion

The aim of the present study was to compare the fit of crowns based on CI with crowns based on IOS. The replica technique was used to measure the internal and marginal fit of the crowns before cementation. A blinded and a non-blinded evaluator performed additional clinical evaluation of crown margins 6 and 12 months after cementation using a modified California Dental Association (CDA) quality evaluation system.

Our results showed that both crowns based on CI and IOS had a good marginal adaptation before cementation. However, the crowns based on IOS showed statistically significantly more accurate internal and marginal adaptation. All of the crowns showed satisfactory marginal adaptation when evaluated clinically at 6 and 12 months.

Although the study population in this study was relatively small, this was partly compensated for by the split-mouth design allowing for paired data analysis. The CDA results were statistically insignificant between the groups. However, a retrospective power analysis showed that with a sample size of 17 the power was 80%, when data from the 6-month evaluation was used. Moreover, in this study, we have been able to disclose statistically significant differences with the replica method.

Table 3 The distribution of CDA scores for marginal integrity as assessed by the blinded evaluator after 6 and 12 months for each impression method

	Conventional method				Digital method			
	6 months		12 months		6 months		12 months	
SCORE	R	S	R	S	R	S	R	S
N	3	14	5	12	5	12	5	12

Grade R denotes no visible or probable irregularity along the margin. Grade S denotes visible or probable irregularity along the margin but not needing correction

It can be difficult to compare the results of various in vivo studies. Several in vivo as well as in vitro studies have shown that there is a substantial difference in the accuracy of intraoral scanners from different manufacturers [14, 19–21]. A result based on one particular manufacturer's scanner is not applicable to other scanners as the underlying technology can be fundamentally different. Therefore, it is important to have a control group using a gold standard method, i.e. CI. It is also important to control the workflow parameters. In this study, a laboratory technician, using the same software (Dental System version 2015-1, 3Shape) with standardised design and milling parameters, designed all restorations. The same commercial milling station (Röders RXD Dental Milling Machine, Röders GmbH, Soltau, Germany) milled all restorations. Furthermore, it has been shown that the shape of the preparation may influence the accuracy of a digital impression depending of the device used. On the other hand, with the scanners used in the present study, this seems not to be a problem [22, 23].

Berrendero et al. [15] performed a controlled clinical study comparing the first-generation Trios scanner with the conventional impression method for single crowns using the replica technique, they found a mean marginal discrepancy of 119.9 μm for CI and 106.6 μm for the Trios scanner. In contrast to our study and another study also using a Trios scanner [24], they found no statistically significant difference between the two groups. In our study, we used the so far latest version of the Trios scanner, which could explain the better results for IOS. The better results also for the CI group could possibly be due to patient inclusion and exclusion criteria. Boeddinghaus et al. [14] also conducted an in vivo study using different IOS, but no CI control group. Their marginal discrepancy results for Trios ranged from 111 to 121 μm depending on which tooth surface the assessment was performed on. However, their study also used a first-generation Trios scanner.

Other recent studies have looked at other intraoral scanners compared to CI for single crowns. Zeltner et al. [19] manufactured 5 crowns based on different impression techniques for each of 10 patients. Marginal adaptation was measured using the replica technique. Their results for marginal adaptation with CI were 90.4 μm (SD 66.1), quite similar to our results. The crowns based on LAVA COS had a mean marginal adaptation of 94.3 μm (SD 58.3) and crowns based on iTero 127.8 μm (SD 58.3). Sakornwimon and Leevailoj [25] used the replica technique as well as CDA and found no difference in marginal accuracy between the two impression methods with either of the evaluation methods using an iTero scanner (Align Technology, San Jose, USA) for the digital impression taking. In a recent study by Rudolph et al. 2016 [23] comparing various intraoral and extraoral scanners, in vitro similar accuracy was found between most systems including the intraoral scanner (Trios) and laboratory scanner (D640) used in this study.

Su and Sun [26] evaluated the marginal and internal adaptation of three-unit FPDs based on a Trios scanner and CI in vitro. They concluded that the marginal and internal fit of three-unit zirconia FPDs was better in the IOS than in the CI group.

Evaluating the marginal adaptation of restorations can be challenging. Although the replica technique has been validated for evaluation of the internal and marginal fit of crowns [27], it does have some shortcomings and can be technique sensitive. One of the shortcomings of this technique is a limited number of measurement points for each restoration. The replica can only be sectioned a limited amount of times. In this study, we sectioned the replica twice for premolars and four times for molars; this may not represent the true circumferential fit of the crowns. Also, getting an intact internal impression at the margin becomes increasingly difficult with increasing subgingival margin placement, which is one of the reasons why we in this study kept the preparation margin equigingivally or not extending more than 1 mm subgingivally. The light-body replica impression was assessed under loupes (magnification × 2.3), and if any defects were observed, the impression was redone. Combining the replica technique results with CDA evaluation and observing the restorations for 12 months, as we have done, gives a more clinically valid reflection of the marginal integrity of the crowns. To the best of our knowledge, there are currently no long-term follow-up studies on restorations based on IOS.

In the present study, the crowns based on IOS showed significantly better marginal fit before cementation, as assessed with the replica technique, than crowns based on CI. On the other hand, after cementation no difference was observed in the marginal integrity when evaluated with the CDA quality evaluation system. The lack of difference between the two methods when evaluated clinically after cementation could be due to resin composite luting cement is filling the marginal gap and, thereby, making the gap clinically undetectable with a probe. This may also explain why no association was observed between the largest gap measurements at the margin of the crowns and the CDA scores. On the other hand, if the excess luting cement masking the gap disappears overtime, the difference in marginal gap between crowns based on the two impression techniques, as observed before cementation, may influence the long-term survival of the crowns, since it has been shown that a poor marginal fit can lead to gingival inflammation, dissolution of luting cement, increased plaque accumulation and subsequently secondary caries or periodontal disease [10–12].

The results of this study should be interpreted with caution, as the teeth included were easy to treat, i.e. the margin of the preparation was placed equi- or subgingivally not extending more than 1 mm subgingivally, thereby also easy to take impression of. More difficult clinical situations might likely have detrimental effect on the quality of IOS scan as well as CI.

Conclusion

With the applied clinical and laboratory techniques and procedures, the results of this study indicate that tooth supported lithium disilicate crowns based on intraoral scans show statistically significantly better marginal and internal adaptation at all but one point before cementation than crowns based on conventional impression. However, the clinical evaluation showed similar marginal adaptation. For both methods, the marginal adaptation was within the clinically acceptable range.

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Compliance with ethical standards

This clinical trial was approved by The Regional Scientific Ethical Committee, (reference number 44868) and was conducted in accordance with the Declaration of Helsinki and internationally accepted guidelines for RCT, including the CONSORT statement (www.consort-statement.org).

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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