Clinical evaluation of all-ceramic crowns fabricated from intraoral digital impressions based on the principle of active wavefront sampling

Andreas Syrek a,*, Gunnar Reich b, Dieter Ranftl a, Christoph Klein a, Barbara Cerny a, Jutta Brodesser a

a 3M ESPE, Espe Platz, 82229 Seefeld, Germany
b Josef-Raps-Str. 5, 80805 Munich, Germany

1. Introduction

Dental computer-aided design and computer-aided manufacturing (CAD/CAM) techniques were developed with the intention of automating the production process as far as possible, the goal being to optimize the quality of restorations and to use new biocompatible and aesthetic materials, especially high performance ceramics. Since its introduction

The aim of the present study was to compare the fit of all-ceramic crowns fabricated from intraoral digital impressions with the fit of all-ceramic crowns fabricated from silicone impressions.

Methods: Twenty patients agreed to take part in the study to receive two Lava™ crowns each for the same preparation. One crown was fabricated from intraoral scans using the Lava™ Chairside Oral Scanner (Lava C.O.S.), and the other crown from a two-step silicone impression. Prior to cementation the fit of both crowns was clinically evaluated by two calibrated and blinded examiners; the marginal fit was also scored from replicas. Data from the replica scores were analysed by Anderson–Darling test, Levene’s test and Mann–Whitney test. All tests were performed with a-level of 0.05.

Results: Median marginal gap in the conventional impression group was 71 μm (Q1:45 μm; Q3:98 μm), and in the digital impression group 49 μm (Q1:32 μm; Q3:65 μm). Mann–Whitney test revealed a significant difference between the groups (p < 0.05). No differences were found regarding the occlusion, and there was a trend for better interproximal fit for the digitally fabricated crowns.

Conclusions:

1. Crowns from intraoral scans revealed significantly better marginal fit than crowns from silicone impressions.
2. Marginal discrepancies in both groups were within the limits of clinical acceptability.
3. Crowns from intraoral scans tended to show better interproximal contact area quality.
4. Crowns from both groups performed equally well with regard to occlusion.

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to dentistry, CAD/CAM technology has been largely limited to the realm of the dental technician. Many systems have been used for the design and fabrication of fixed dental prostheses, but for the past two decades, only one system (Cerec) capable of direct intraoral impression taking has been available to the dental practitioner. The Cerec system is based on the concept of “triangulation of light”, where intersection of three linear light beams is used to locate a given point in three-dimensional (3D) space. This concept has been used in a variety of industrial measuring devices, but surfaces that disperse light irregularly or do not reflect it evenly, and surfaces that are not continuous, adversely affect the accuracy of scans based on triangulation, consequently an opaque powder coating (titanium dioxide) is used to provide uniform light dispersion and enhance the accuracy of the scan. The Lava Chairside Oral Scanner (Lava C.O.S.) was recently introduced (3M Lexington, USA). This intraoral scanner is based on the principle of active (optical) wavefront sampling. Active wavefront sampling refers to getting 3D information from a single lens imaging system by measuring depth based on the defocus of the primary optical system. Three sensors capture the clinical situation from different perspectives. With these three images captured simultaneously, 3D surface patches are generated in real time by means of proprietary image processing algorithms using the in-focus and out-of-focus information. Twenty 3D datasets per second can be captured with over 10,000 data points in each, resulting in over 2400 datasets (or 24 million data points) for an accurate scan. According to the manufacturer the high data redundancy resulting from many overlapping pictures together with special image processing algorithms ensures excellent image quality and consequently high accuracy. However, there are no published clinical studies on the in vivo performance of this intraoral scanner. Marginal fit as well as fracture resistance and aesthetics are some of the most important criteria for long-term success of all-ceramic crowns. Sizable marginal discrepancies can expose the luting material to the oral environment, leading to a more aggressive rate of cement dissolution, caused by oral fluids and chemo-mechanical forces. Marginal gaps can promote plaque accumulation which may result in inflammation of the periodontal tissues as well as secondary caries at the crown margin. The aim of this randomized controlled examiner-blinded clinical trial was to test the accuracy of Lava C.O.S. by comparing the fit of all-ceramic zirconia crowns resulting from Lava C.O.S. scans with the fit of all-ceramic zirconia crowns fabricated from silicone impression. Marginal fit was chosen as the primary endpoint as marginal fit of a ceramic crown cannot be adjusted once the crown is finished. Occlusal and interproximal fit were chosen as secondary endpoints. The null hypothesis was that there is no difference in marginal fit between crowns fabricated from digital and silicone impressions.

2. Materials and methods

The study was registered with the German Clinical Trial Register (DRKS ID 00000246) and with the World Health Organisation (UTN No. U1111-1112-3120). Ethic Committee approval was obtained from “Freiburger Ethik-Kommission International”, Freiburg, Germany, and from 3M IRB, St. Paul, USA. The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP). Twenty-four patients were screened; 20 subjects gave informed consent and were enrolled into the study (Fig. 3).

Inclusion criteria:

- Aged between 18 and 65 years;
- In need of a single crown in a posterior tooth;
- Study tooth free of clinical symptoms;
- No requirement for additional extended treatment (e.g. endodontic treatment);
- Acceptable standards of oral hygiene;
- Informed consent obtained.

Exclusion criteria:

- Advanced periodontitis affecting the mobility of the teeth (mobility degree higher than 2);
- Bruxing, clenching or grinding;
- Pregnant or lactating females, since crown preparation and impression means stress for the patient, potentially resulting in an increased adrenaline concentration in the blood;
- Patients with a medical or dental history which could potentially complicate the provision of the proposed restorations.

Ten men aged between 23 and 49 years and 10 women aged between 28 and 57 years were enrolled. Two patients dropped out; reasons for drop out were: pulp exposure during tooth preparation resulted in the need for root canal treatment; in the second case the test and control crowns were made by two different dental technicians, which was a protocol violation. Fourteen molars and four premolars were treated, seven in the upper jaw and eleven in the lower jaw. All patients received local anaesthesia prior to tooth preparation for an all-ceramic crown. To minimize the patient factor, only one crown preparation per patient was allowed. The marginal shoulder was prepared with rounded inner angles using Komet burs (Lemgo, Germany) REF 8850 314 018. In 53% the preparation margins were subgingival and in 47% par gingival. Occlusal reduction was done by means of Komet burs REF 8379 314 023. Preparation depth was 1 mm axially and 1.5–2 mm occlusally. The preparation had a divergence angle of around 6°. After tooth preparation a provisional restoration was placed using Protemp Crown (3M ESPE). Impressions were taken one week after tooth preparation. The sequence of the impressioning procedure (silicone versus digital) was randomized using randomization envelopes; the randomization envelope being opened after removal of the provisional restoration. Before taking the impression, retraction cords (Ultrapak #0 and Ultrapak #1, Ultradent, South Jordan, USA) soaked in alumina chloride (Gingiva Liquid, Roeko, Langenau, Germany) were placed in a double cord technique. The same retraction cord technique was used for both the conventional and digital impression. For all conventional impressions a VPS material was used in a two-step technique (Express Penta Putty as tray and Express Ultra-Light Body Quick as wash material, 3M ESPE). The antagonistic impression was taken
using Position™ Penta™ (3M ESPE), and the bite registration with Imprint™ Bite (3M ESPE). Digital impressions were produced using the Lava C.O.S. Prior to scanning, a titanium dioxide powder (Vita Cerec® Powder with Cerec® Propellant, VITA, Bad Saeckingen, Germany) was applied to the teeth. The powder particles created reference points on the smooth tooth surfaces to facilitate scanning and required only a light dusting to be applied. During scanning a dry field was maintained using Dri Angles® (Dental Health Products, Niagara Falls, USA) placed buccally and lingually to the teeth to be scanned. Scanning of the preparation commenced immediately after removal of the upper retraction cord. Once the preparation had been scanned, and the data saved, teeth in the other quadrant were scanned, followed by a scan of the antagonists, and finally a buccal scan with teeth in occlusion as a bite registration. The zirconia coping was designed from the uploaded scan data and concurrently a stereo lithographic model was produced by rapid prototyping. After milling and sintering the zirconia coping was placed on the stereo lithographic model and sent to the dental operatory for try-in. In the conventional impression procedure the impressions were disinfected and poured with type IV plaster (Picodent® Bayer, Langenau, Germany). The master model was scanned by means of Lava Scan ST, and a zirconia coping was designed from the scan data. After milling and sintering the zirconia coping was placed on the master model and sent to the dental operatory for try-in.

At the crown fit appointment, the provisional crown was removed and the preparation thoroughly cleaned with pumice and a rotating brush. Replicas of the intermediate space between the inner surface of the crown and tooth surface were made using a standard technique.15–23 No adjustments were performed for either the prepared tooth or crown before replication. The copings were filled with a low viscosity A-silicone (Express™2 Ultra-Light Body Quick), seated on the replication. The copings were filled with a low viscosity A-silicone in all cases 2:30 min (intraoral setting time of the impression material) the pressure to simulate clinical cementation of the crown. After setting each silicone replica was carefully removed from the coping and sectioned into four pieces, buccolingually and mesiodistally, using a sharp razor blade. All samples were prepared and measured by the same operator. Replica film thickness was measured by means of a stereomicroscope (Stemi SVII, Zeiss, Germany) at 66× magnification at the buccal, lingual, mesial and distal margin, resulting in 12 (4 data points × 3 replica) marginal data points per coping. Film thickness was recorded at the margins as the shortest distance from the internal surface of the crown to the prepared tooth surface close to the preparation finish line, representing the marginal gap according to Holmes et al.18 Only the marginal gap width was measured, since the film thickness in other areas of the crown represented the envisaged cement gap as designed by the dental technician.

2.2. Clinical evaluation of the finished crowns

After veneering of the copings, the crowns were clinically evaluated by two calibrated and blinded examiners, who scored the margins, occlusion and interproximal contacts. Calibration was done in vivo before commencement of the study with four patients who received a single ceramic crown each. At the study the inter-examiner agreement was 78% for marginal contours, 92% for marginal gap, 89% for interproximal contact and 86% for occlusion. Any disagreement between the examiners was resolved by forced consensus. The margins were scored with a sharp dental probe (Aesculap DA412R, Tuttingen, Germany); any explorer catch was further evaluated as recommended by Hickel et al.24 using probes with defined tip diameters of 150 and 250 μm (Deppeler, Rolle, Switzerland) to clinically examine the range of the gap size before cementation. In addition to gap size, the marginal contours were scored using nine criteria25:

1. exact fit,
2. crown does not reach the preparation margin,
3. small positive step,
4. large positive step,
5. crown does not reach preparation margin plus small positive step,
6. crown does not reach preparation margin plus large positive step,
7. balcony,
8. margin overhang and
9. tooth without step, crown with step.

The occlusion was checked with occlusion foil (Hanel, Langenau, Germany), using the following criteria:

1. Clinically excellent: occlusal contact points on the crown and adjacent teeth, equally strong; no supra- or infraocclusion.
2. Clinically good: occlusal contact points on the crown and adjacent teeth present, but unequal in strength; no supra- or infraocclusion.
3. Clinically unsatisfactory: no occlusal contact points on the crown (infraocclusion).
4. Clinically poor: contact points only on the crown (crown too high = supraocclusion).

Interproximal contact points were checked with dental floss (Reach®, Dentotape® Waxed Floss, Johnson&Johnson):

1. Clinically excellent: normal contact point; dental floss can be easily inserted.
2. Clinically good: contact slightly tight, but dental floss can still be inserted.
3. Clinically unsatisfactory: contact too tight, dental floss cannot be inserted, or contact too open with food impaction likely to occur.
4. Clinically poor: no contact point, or papilla damage, or crown cannot be seated.
2.3. Statistical evaluation

Replica data were analysed using PASW 17 software (SPSS Inc., Chicago, USA). Sample size calculation was based on the number of patients required for a 2-sample t-test to demonstrate a 30 μm difference in mean maximum marginal gap between the two groups. The sample size was calculated as 17 patients per group, based on a significance level of 0.05, a power of 80%, and a standard deviation of 20 μm in both groups for the marginal gap.

Statistical analysis was carried out using the Anderson–Darling test to test for normal distribution, Levene’s test to test for homogeneity of variance and the Mann–Whitney test to test for equality of two populations’ median. All tests were performed with α-level of 0.05. For all three tests statistical significance was set at p < 0.05. Descriptive statistics were applied to the clinical data obtained from the two blinded examiners.

3. Results

Two hundred and sixteen data points (18 patients × 4 tooth surfaces × 3 replica/coping) per group were measured. The Anderson–Darling Normality distribution test revealed a non-normal distribution of the data in the two groups (p < 0.05). Levene’s test revealed significantly unequal variances (p < 0.05). The median marginal gap for the conventional impression group was 71 μm (Q1: 45 μm; Q3: 98 μm). The median marginal gap for the digital impression group was 49 μm (Q1: 32 μm; Q3: 65 μm) (Fig. 1). Mann–Whitney test revealed a significant difference between the two groups (p < 0.05). Thus the null hypothesis was rejected. With regard to tooth surfaces the median marginal gaps in μm in the conventional group were: mesial 52/69/84, distal 50/70/97, buccal 47/74/104 and lingual 27/67/102. Median marginal gaps in the digital group were: mesial 36/50/72, distal 43/55/67, buccal 27/54/28 and lingual 32/51/66 (Fig. 2). Clinical evaluation of the crown margins demonstrated a superior fit for crowns generated from digital impressions (Tables 1 and 2). No statistically significant differences were found with regard to the occlusal evaluation (Table 3). Interproximally there was a trend towards a better fit for the crowns resulting from the digital impressions (Table 4). Overall, each crown was considered to be acceptable for placement.

4. Discussion

There are many clinical factors, besides impression material and technique, which influence the quality of an impression, including location of the finish line, periodontal health, sulcus bleeding during impression taking or saliva flow rate, and patient compliance. In addition, if the impression is taken by means of an intraoral scanner, the accessibility of the preparation for the scanner wand becomes critical for the success of the impression. Accessibility can be limited especially in the retromolar region of patients with limited

<table>
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<tr>
<th>Table 1 – Marginal contour.</th>
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<td>Marginal contour</td>
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<tr>
<td>Mesial</td>
</tr>
<tr>
<td>Exact fit</td>
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<tr>
<td>Small positive step</td>
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<td>Crown overhang</td>
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<td>Crown does not reach preparation margin</td>
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<td>Crown does not reach preparation margin plus small positive step</td>
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Fig. 1 – Overall mean marginal gaps.

Fig. 2 – Mean marginal gaps by tooth surface.
opening or an ascending ramus of the mandible situated close to the buccal surface of the last molar. Therefore a clinical design was chosen to evaluate the performance of Lava C.O.S., although for a straightforward scanner accuracy analysis a laboratory study would have been sufficient. The clinical approach had the disadvantage that evaluation of crown fit was more difficult compared to an in vitro study, where for instance direct measurement of marginal discrepancies by means of microscopy would have been possible. To overcome this, a replica technique for determination of the marginal gap size was adopted in addition to a clinical evaluation with dental probes. The replica technique is accepted as a reliable and non-invasive means to determine the in vivo adaptation of crown-to-tooth surfaces.17,19–21 Besides its reliability of this method, the replica technique has several other advantages that make it a method of choice for the evaluation of marginal fit20:

- The technique allows accurate in vivo measurement of marginal adaptation just prior to cementation and thus reflects clinical reality. This is important because many clinical situations (e.g. subgingival margins, posterior teeth) may create difficult working conditions that compromise the quality of the final restoration.
- The technique is ethically acceptable as the data collected is of direct clinical benefit to the patient without deleterious effects.
- The technique is easy and efficient to carry out, and relatively inexpensive.

Table 2 – Clinical marginal gaps.

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<tr>
<th>Clinical marginal gap</th>
<th>Digital impression</th>
<th>Silicone impression</th>
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<tr>
<td></td>
<td>Mesial</td>
<td>Distal</td>
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<tr>
<td>Clinically excellent (no gap)</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>Clinically acceptable (gap &lt;150 μm)</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Clinically unsatisfactory (gap &gt;150, &lt;250 μm)</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Clinically poor (gap ≥250 μm)</td>
<td>0%</td>
<td>0%</td>
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Maximum finger pressure was used as the seating force during replication of the crown gap the reflect the clinical situation.53 While the seating force has been reported as nonsignificant for the magnitude of marginal discrepancies,23 the location of the measuring point at the buccal, lingual, mesial and distal areas does have an influence on the measured gap size. Therefore three replicas per coping were analyzed. The median marginal gap size in this study was 49 μm for the digital impression and 71 μm for the conventional impression. Most authors agree that a marginal discrepancy in the range of 100–150 μm is clinically acceptable with regard to longevity.17,19,21,27,28 However, in one study on cement dissolution a gap size of 150 μm resulted in a significantly higher dissolution rate compared to marginal gaps in a range 25–75 μm.29 While there is no clinically adequate, generally accepted and scientifically approved definition of “crown fit”,30 the gap values reported in this study fall into a range that most authors would consider to be clinically acceptable. Compared to other studies the marginal gaps measured in this study were equivalent or smaller. Tsitrou et al.22 found a mean marginal gap of between 91 and 105 μm for Cerec crowns using a replica technique. For anterior Cerec crowns, Bindl et al.31 measured marginal widths of 60 μm, which was significantly different from both machined (73 μm) and slippcast In-Ceram spinell crown copings (76 μm). Marginal gaps reported for Procera AllCeram crowns were between 80 and 95 μm in anterior teeth and 90 and 145 μm in posterior teeth.16 In a study by Tinschert et al.32 on alumina and zirconia based fixed partial dentures, marginal fit measurements exhibited mean discrepancies in a range between 61 and 74 μm, which corresponds closely to the values reported in the present study. Wostmann et al.26 investigated the influence of impression technique and material on the marginal accuracy in vivo by extracting the teeth after impression taking and measuring the marginal gap under a microscope. Using a VPS impression material they found gaps of 118 μm for the two-step versus 128 μm for the one-step technique. The one-step technique was considered to
be slightly inferior to the two-step technique particularly for infragingival margins. Based on this outcome a two-step technique was chosen for the control group in the present study. The digital impression demonstrated significantly smaller marginal gaps than the conventional impression. This might be explained by the traditional workflow where a master model is created which is the basis for the construction of the crown, while in the digital workflow the crown coping is designed directly from the intraoral scan without creating an intermediate model. The stereo lithographic model is built simultaneously from the same set of data. Thus the digital workflow eliminates the need for a master model for fabrication of a coping, and since every step in a workflow contributes to the risk of overall failure, the elimination of a step would result in higher accuracy. A trend towards better marginal integrity for the digital group was also noticeable on clinical evaluation by the two blinded examiners. Probes with defined tip diameters (150 and 250 μm) as well as a conventional sharp probe were used to quantify the gap size. When the data from the clinical evaluation were compared with the data from the replica technique it became clear that marginal gaps cannot be detected as precisely with a probe as with a silicone replica technique, particularly as the interproximal and subgingival areas are difficult to assess with a probe. With regard to quality of the interproximal contact area the digital group performed better than the conventional group. A potential explanation for this is that in the conventional group a dental stone model is used and as the restoration is taken on and off the model to check the fit this could cause abrasions on the model in the interproximal areas resulting in clinical contacts that are too tight, whereas in the digital group this does not apply as the model exists only virtually and is cut digitally without the risk of abrading adjacent contact points.

5. Conclusions

Within the confines of the study the following can be concluded:

1. All-ceramic crowns resulting from intraoral scans with Lava C.O.S. demonstrated significantly better marginal fit than all-ceramic crowns fabricated from conventional 2-step impressions.
2. Marginal discrepancies in both groups were within the limits of clinical acceptability.
3. All-ceramic crowns resulting from intraoral scans with Lava C.O.S. showed better interproximal contact point quality compared to all-ceramic crowns from conventional two-step impressions.
4. Crowns from the two groups performed equally well with regard to occlusion.

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References


