# Randomized Controlled Clinical Study on the Accuracy of Two-Stage Putty-and-Wash Impression Materials

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> Purpose: The accuracy of dental impression taking is one major factor influencing the fit of crowns and fixed partial dentures. The aim of this study was to determine the accuracy of three-dimensional (3-D) tooth surface and subgingival tooth surface reproduction using three different silicone materials and the two-stage putty-and-wash technique. Materials and Methods: From 24 probands, three impressions each were taken with Express STD Putty/Wash (3M ESPE), Optosil/Xantopren L (Heraeus Kulzer), and an experimental ultralight body/putty material (3M ESPE) in a randomized order. The preliminary impression was cut according to established procedures for the twostage putty-and-wash technique. Master casts were manufactured with a standardized procedure and optically digitized. The 3-D accuracy was analyzed with a computer-aided procedure. The Express STD putty-and-wash impressions were used as a reference. Linear models were used for the statistical analysis. *Results:* Mean deviations of 27.0 µm and -23.6 µm were found for Optosil/Xantopren L and 26.5 µm and -22.6 µm for the experimental material when analyzing 3-D surface reproduction. The tooth surface (buccal/oral) significantly influenced the accuracy of the surface reproduction. Optosil/Xantopren L showed a more complete reproduction of the subgingival tooth surface than either the experimental or reference materials. Conclusion: The accuracy of the 3-D tooth surface reproduction as well as the reproduction of the subgingival tooth surface was not favorably influenced when the ultralight wash material was used with established cutting procedures for the preliminary impression. Int J Prosthodont 2009;22:296-302.

Apprecise marginal fit of fixed restorations is an important factor in the durability of crowns and fixed partial dentures, as well as for the health of the surrounding tissue. The quality of fit of dental restorations is mainly influenced by the accuracy of the dental impression.<sup>1-6</sup> Mistakes or inaccuracies are not corrigible in the successful fabrication of restorations and have a considerable influence on the fit of the restorations. Clinical parameters have a major effect on impression accuracy and reproduction of the preparation margin.<sup>7-9</sup>

In Europe, condensation-curing silicone, additioncuring silicone (also known as polyvinyl siloxane [PVS]), and polyether are the prevailing impression materials.<sup>10</sup> PVS is popular because of its excellent elastic recovery, optimal accuracy, dimensional stability, adequate tear resistance, ease of use, and lack of unpleasant taste or smell.<sup>7,10-15</sup> Condensation-curing silicone impression materials have most of these qualities as well. The dimensional stability<sup>11</sup> and tear resistance<sup>11,16</sup> of condensation-curing silicones are not as good as those of PVS impression materials. However, condensation-curing silicones are less expensive compared to PVS and polyether impression materials.<sup>11,17</sup> PVS and polyether impression materials in principle show comparable accuracy<sup>11,18</sup> and optimal elastic

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Inclusion criteria	Exclusion criteria		
Aged between 18 and 80 y Complete set of either healthy or restored teeth in the left mandible including the second molar	Compromised legal competence Pregnancy Periodontal disease (Periodontal Screening Index > 2) Participation in another clinical study < 1 mo ago Alcohol or drug addiction Conflict of interest due to participation in another study Infectious diseases (such as hepatitis or HIV)		

### Table 1 Inclusion and Exclusion Criteria

recovery.16 While polyether impression materials are more hydrophilic,<sup>10,11</sup> PVS shows a superior dimensional stability over time.13

The one-stage putty-and-wash (two materials with different viscosities), the two-stage putty-and-wash (two materials with different viscosities), and the monophase (one material) impression techniques are commonly used. The different impression procedures involve either one impression material or two impression materials with different viscosities and are applied either simultaneously or in a two-step procedure. The accuracy of the different impression techniques has been controversially discussed in the literature. In some studies, the one-stage putty-and-wash impression technique was found to be more accurate,<sup>1,3,7,18</sup> and in others, it was the two-stage putty-and-wash impression technique.<sup>7,19</sup> Other studies did not show any significant difference.<sup>2,4</sup> Based on clinical experience, the two-stage putty-and-wash impression technique was recommended, especially for subgingival preparation margins. The improved representation of subgingival margins is supposed to be caused by the imposed pressure of the putty material on the light body impression material.<sup>1,7,10,18</sup>

Luthardt developed an in vitro procedure applicable for the analysis of three-dimensional (3-D) changes of gypsum dies.<sup>3</sup> Later on, the procedure was modified in order to perform an analysis of impression taking in vivo.<sup>7</sup> This in vivo examination procedure facilitates the evaluation of the 3-D impression accuracy depending on the impression technique (one-stage putty-andwash, two-stage putty-and-wash, or monophase impression). Abutment teeth were reproduced more precisely by the one-stage putty-and-wash impression technique compared to the two-stage putty-and-wash. The latter reproduced the abutment teeth in a more scaled down manner compared to both the monophase and the one-stage putty-and-wash impression techniques. This reduction in size can be explained by the light body material's limited flow and elastic recovery after impression removal. By using the two-stage puttyand-wash impression technique, a newly developed ultralight wash material should allow for an enhanced representation of the gingival sulcus.

The aim of this study was to test, in a randomized controlled study, the hypothesis that the accuracy of the 3-D tooth surface reproduction, as well as the depth of flow of impression material into the gingival sulcus, was not influenced by the type of impression material when the two-stage-putty-and-wash technique was used.

# Materials and Methods

In this prospective, randomized clinical study, three two-stage putty-and-wash impressions were taken in a randomized order from six probands in the pilot study and 24 probands in the main study.<sup>20,21</sup> The study design was approved by the Ethics Commission of the Medical Faculty Carl Gustav Carus of the Technical University Dresden. The inclusion and exclusion criteria are shown in Table 1.

Following a detailed clinical examination, each proband received a professional teeth cleaning. Immediately after, three impressions were taken with Express STD Putty/Wash (3M ESPE), Optosil/Xantopren L (Heraeus Kulzer), and an experimental ultralight body/putty material (3M ESPE) in a randomized order. The impressions were taken with nonperforated, fullarch metal trays prepared with adhesive at least 10 minutes before impression taking. The timely succession of the Express STD Putty/Wash impression (REF), which was chosen as a reference, and the impressions taken with the experimental ultralight body/putty material (EM) and Optosil/Xantopren L (OX) was assigned on a randomized basis.1 The randomization was carried out in accordance with a randomization list with groups of six made by the Institute for Medical Informatics and Biometry at the Technical University Dresden. A scientific employee, who was not involved in the clinical process, kept and maintained the list.

The putty materials REF and OX were mixed by hand and carefully placed into the impression trays. An automatic mixing unit (Pentamix 2, 3M ESPE) was used to prepare the EM putty material. The mixing tip was constantly placed in the putty while filling the impression tray to avoid bubbling. The impression tray remained in the proband's mouth for the amount of time recommended by the manufacturer. All undercuts and Figs 1a and 1b (a) Measurement of the distance between the CAD reference model and the positive and negative curves of the inherent EM/OX data sets; (b) Zoom. Vertical red line between margins = 0.904 mm.





interdental septa were cut, thus ensuring the optimal repositioning of the preliminary impression. After successful repositioning, the preliminary impressions were thoroughly cleaned and dried.

The left mandibular first molar, chosen as a reference tooth, and the occlusal surfaces of all mandibular teeth were syringed with the wash material. Again, the mixing tip was constantly placed in the wash material in order to avoid bubbling. The preliminary impression was taken immediately after. The final impression was evaluated according to modified California Dental Association criteria.<sup>22</sup> The impressions were poured with super stone (class IV plaster: Esthetic-Rock 285 apricot, dentona) four hours later, thus guaranteeing a sufficient recovery time. The Zeiser II system (Amann Girrbach Dental) was used for cast fabrication. The master cast was sectioned into one segment with the teeth under examination, including the reference tooth and the adjacent teeth (left mandibular second premolar and second molar), as well as into two additional segments.

After another four hours, when the gypsum had a guaranteed highest possible stability, the casts were removed from the impressions. All remains of impression materials were meticulously removed from the master casts to ensure a triple blind evaluation and avoid bias. Prior to the evaluation phase, the master casts were blinded and coded by the scientific employee, who was not involved in the study. Another clinician, not knowing which material had been used clinically, carefully trimmed the segment of teeth under examination and marked the reproduction border of the subgingival tooth surface using a magnifying glass (magnification  $\times 2.3$ ) to assure the exact measurement of the subgingival tooth surface in the following process.

The casts were optically digitized using the diGident-Digitizer (Amann Girrbach Dental) 12 to 72 hours after fabrication. The three teeth under examination were digitized from two different directions (oral and buccal). The data were processed following a procedure developed by Luthardt et al<sup>7</sup>: For the first visual control of each of the measured data sets (REF, EM, and OX), as well as the first processing, the visualization and processing software ARGUS (Fraunhofer Institute for Applied Optics and Precision Mechanics) was used. For further processing, the data were exported into the software package Surfacer (Surfacer V10.6, Imageware). Two data sets were acquired from each cast by measuring from both the buccal and oral directions. The EM and OX data sets were aligned to the REF computeraided design (CAD) model of the respective proband. The root mean square (RMS) error was calculated in order to determine the precision of each 3-D alignment of the data sets to the corresponding reference.

For any EM and OX data set aligned to the REF CAD model, the 3-D tooth surface reproduction and the depth of flow of impression material into the gingival sulcus was analyzed. In the process, the 3-D deviations between each single point of the datasets were measured and the REF CAD models were calculated (Surfacer). The deviations of the points were displayed on the surface of the REF CAD model with a colorcoded map. Based on the color-coded representation. the areas with maximum deviations were determined.<sup>7</sup> In order to assess the depth of flow of the impression material into the gingival sulcus, curves were generated out of the deepest points of each EM or OX data set and compared to the respective REF CAD model curve (Figs 1a and 1b). The distance between the points of each of the two curves (REF versus OX or EM) was calculated and visualized (color-coded graphs) (Fig 1b). The analysis of the depth of flow of the impression material into the gingival sulcus was limited to the area between the mesial and distal cusps of the molars (distance between the black bars in Fig 1a) and to the area between the mesial and distal marginal ridges of the premolar. By definition, positive values indicated a deeper flow of EM or OX impression material into the gingival sulcus and negative values indicated a deeper flow of the REF impression material into the gingival sulcus.

The study design was based on a balanced threeperiod design with four repeats for six possible sequences. To statistically analyze the accuracy of the impression techniques, the hypothesis that neither the 3-D tooth surface reproduction nor the reproduction of the subgingival tooth surface was being influenced by the kind of impression material used when the twostage putty-and-wash technique was applied was

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**Table 2**Mean (MD) and Standard Deviations (SDs) of EM and OX Compared to REFfor the Reference Tooth and Segment Under Examination\*

	Mea	Mean positive deviations		Mean negative deviations			
Material	MD (µm)	SD	Adjusted P values	MD (µm)	SD	Adjusted P values	
Segment under examination							
EM	26.5	19.8	.7750	-22.6	14.8	.5037	
OX	27.0	19.9		-23.6	12.5		
Reference t	ooth						
EM	18.4	6.7	.3969	-15.9	3.9	.0337	
OX	19.4	9.2		-18.1	7.2		

\*α = .05



Fig 2 RMS error for the alignment of all data sets.

tested in linear models for repeated measures factors. Intraindividual factors (timely succession, tooth), impression material, and tooth surface (oral/buccal) were used for the statistical analysis. All mean value comparisons were based on Tukey-adjusted contrasts with a global significance level of .05. In addition to the descriptive statistical analysis, the deviations between REF and either EM or OX data sets were analyzed with the SAS procedure MIXED (SAS/STAT Software, SAS Institute). The statistical procedure was performed with blinded data.

## Results

Seventy-two impressions were taken from the 24 probands in the main study and analyzed. The results for the 3-D tooth surface reproduction regarding only the reference tooth amounted to mean deviations between 18.4  $\mu$ m (SD = 6.7) and -15.9  $\mu$ m (SD = 3.9) for



**Fig 3** Difference in reproducing the subgingival tooth surface of the segment under consideration for EM and OX (FDI tooth numbers). \* = Outlying data.

EM. As for OX, mean deviations between 19.4  $\mu$ m (SD = 9.2) and -18.1  $\mu$ m (SD = 7.2) were determined.

The analysis of the segment under examination resulted in mean deviations between 26.5  $\mu$ m (SD = 19.8) and -22.6  $\mu$ m (SD = 14.8) for EM. The mean deviations for OX over all teeth ranged between 27.0  $\mu$ m (SD = 19.9) and -23.6  $\mu$ m (SD = 12.5) (Table 2). The RMS error for the alignment of all data sets was 20.5  $\mu$ m (SD = 2.7) on average (Fig 2).

For the depth of flow of impression material into the gingival sulcus, OX showed a deeper flow of material (mean distance to the reference model: 1.694 mm) than EM (mean distance to the reference model: -0.0871 mm) regarding the left mandbular second premolar and first molar (Fig 3). Regarding the positive and negative average deviations, the completely syringed reference tooth showed the slightest deviations, while the left mandibular second molar diverged the most (Fig 4).



Figs 4a and 4b (a) Positive and (b) negative average deviations of EM and OX for the segment under consideration (FDI tooth numbers). \* = Outlying data.

## Analysis of Variance for the Reference Tooth

With regard to the reference tooth, tooth surface (buccal/oral) showed a significant impact on the mean positive (P=.0006) and negative deviations (P=.0058) between the REF CAD model and the EM and OX comparison models. The materials used also had a significant effect on the distance between the curves of the REF CAD model and the inherent EM and OX data sets of the syringed reference tooth (P=.0383).

# Analysis of Variance for the Segment Under Examination

The tooth used had a significant impact on the mean positive (P<.0001) and negative deviations (P<.0001) and on the distance between the curves of the REF CAD model and the inherent EM and OX data sets (P = .0005). With regard to all teeth under examination, surface (buccal/oral) showed a significant impact on the mean positive (P=.0174) and negative deviations (P=.0164) between the REF CAD model and the EM and OX comparison models.

# Discussion

The comparison of in vitro and in vivo study results is negatively affected by complex interactions of many different impact factors.<sup>1–3,7,9</sup> The advantage of in vitro studies is that they do not depend on a patient's compliance and there is no movement, bleeding, sulcus fluid, choking, or salivation. For those and other reasons, in vitro and in vivo studies are hard to compare, and additionally, the results of in vitro studies are difficult to apply to typical clinical situations.<sup>7–9</sup>

As a result of these limitations, this in vivo examination of the 3-D impression accuracy depending on the impression material was tested under clinical conditions. To simulate the worst-case scenario, impressions were taken of unprepared mandibular premolars and molars. These teeth have the largest crown inclination and consequently a large undercut, and thus are the most prone to impression faults. The complex 3-D geometry change, which occurs during impression taking, can be analyzed with an indirect measuring method, including model production, wax modeling, and casting of dental restorations.<sup>7</sup> Thus, clinical trials, with the exception of trials based on teeth to be extracted, only allow a relative comparison of impression techniques and materials.

The aim of this study was to measure the depth of flow of impression material by measuring the maximum possible representation of impression material in the gingival sulcus. Although conclusions based on the results of unprepared teeth cannot be drawn with regard to the possible reproduction of the preparation margin, it can be stated that a deeper spreading of impression material into the sulcus automatically results in a better representation of the preparation margin.

The left mandibular first molar was chosen to be the reference tooth and therefore completely syringed with the wash material, whereas only the occlusal and incisal surfaces of the other mandibular teeth were syringed. Figure 4b and Table 2 show the better performance of the reference tooth in comparison to the other teeth of the segment under examination.

An actual benefit, but a disadvantage for this study, is the expansion of the sulcus through an increased number of impressions. This leads to adulterated results since impression material flows deeper in an already

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In order to receive only the best quality data for the data analysis, the proximal areas between the teeth were left out. In this area, precision is limited due to the diameter of the burr (1 mm) used for the exposure of the subgingival tooth surface reproduction border. Thus, data in the proximal tooth contact areas were unaccounted for because of a lack of data quality. The reproduction of the subgingival tooth surface was limited to the area between the mesial and distal cusps of the molars and to the area between the mesial and distal marginal ridges of the premolar.

Previous studies found that faults can be generated during each stage of impression taking, which may cause imperfections in the impressions. Potential sources of error could be the impression technique, the mixing method, the viscosity of the impression material, or the mixing-tip diameter of the dispenser.<sup>7,17,23-26</sup> In this study, different impression materials with different viscosities, handling properties, and dispenser systems were used. Regarding REF, the putty material was manually mixed, whereas the wash material was mechanically mixed in a light material dispenser. For EM, both putty and wash materials were mechanically mixed, and for the third material (OX), both putty and wash materials were manually mixed. Furthermore, the mixed OX light material had to be hand-filled in the light material dispenser, which demands some manual skill. Summarizing the results of this study concerning the impression technique, mixing method, material viscosity, and dispenser systems, all materials provide satisfactory to excellent results as long as the clinician and the clinical assistant are a well-rehearsed team.

Impression accuracy was evaluated by using a 3-D analysis method. The EM and OX data sets of the impressions to be compared were separately aligned to the reference CAD model by calculating the 3-D translation and rotation of the EM and OX data sets to achieve a best-fit registration.<sup>27</sup> For each measuring point in the data set, deviations from the CAD model were calculated and presented as the RMS error (a measurement for the quality of 3-D alignment).<sup>7,28</sup> The better the different data sets matched, the smaller the RMS error.<sup>27,29</sup> Peters et al defined an RMS error range between 10 and 20 µm suitable for clinical studies.<sup>30</sup> Depending on the size of the data sets to be aligned, an RMS of around 20.7 µm represents good alignment.<sup>7,30</sup>

The hypothesis that the 3-D accuracy of three different silicone materials (REF, OX, and EM) and the reproduction of the subgingival tooth surface is determined by the rheological properties of the impression material must be rejected because the newly developed ultralight wash material did not allow an enhanced representation of the the gingival sulcus. On the contrary, the condensation-curing silicone-based material OX came off well in this study, compared to other findings in which condensation-curing silicones in general did not obtain as good of results as PVS.<sup>10,11,14–16</sup> In some articles, it was also claimed that condensation-curing silicones have less tear resistance than PVS, but no difference between the tear strength of both materials could be established in this study.<sup>11,16</sup>

## Conclusions

The maximum possible clinical representation of the gingival sulcus is not determined by the rheological properties of the light body material. Clinical parameters, such as the oral or buccal surface of the tooth, have a significant impact on impression accuracy. Using an established cutting procedure for preliminary impressions, the use of an ultralight wash material showed no advantage in this clinical study when compared to common light materials. Ultralight materials can be applied only with modified cutting procedures for the preliminary impressions. While less cutting improves the clinical procedure, repositioning may be more difficult and less comfortable for the patient.

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### Literature Abstract

### Influence of irrigation regimens on the adherence of Enterococcus faecalis to root canal dentin

Refractory apical periodontitis is often associated with persistent bacteria present in the root canal. Enterococcus faecalis has been increasingly associated due to its ability to survive chemomechanical debridement and the ability to enter the canal during or even after root canal treatment. The chemical and physical factors predisposed to the tenacity of the bacteria in the root canal system are poorly understood. The aim of this paper is thus to investigate the effects of endodontic irrigants on the adherence of E. faecalis to root canal dentin. One hundred noncarious single-rooted teeth were sectioned at the level of the cementoenamel junction and the apical section was ground to produce uniform 8-mm-long root sections. The root sections were randomly divided into the following groups: (1) Group 1: specimens untreated (control), (2) Group 2: specimens were treated with 5 mmol/L EDTA (Merck KGaA) for 5 minutes and 5.2% NaOCI for 30 minutes, (3) Group 3: treated with 5.2% NaOCI for 30 minutes and 5 mmol/L EDTA for 5 minutes, (4) Group 4: treated with 5.2% NaOCI for 30 minutes, 17% EDTA for 5 minutes, and 5.2% NaOCI for 30 minutes, (5) Group 5: treated with 5.2% NaOCI for 30 minutes, 17% EDTA for 5 minutes, and 2% CHX for 30 minutes, (6) Group 6: treated with 17% EDTA for 5 minutes, 5.2% NaOCI for 30 minutes, and 2% CHX for 30 minutes, and (7) Group 7: treated with CHX alone for 30 minutes. The treated root sections were subsequently inoculated with E. faecalis and cultured overnight. Bacterial adherence assay was carried out using Baclight fluorescence stain and viewed under a microscope. Results showed that untreated specimens had the highest amount of bacteria. For the sections that were treated, it was observed that bacterial adherence was significantly affected by the last irrigant used. When comparing the various treatments tested, the use NaOCI to remove exposed collagen fibrils and subsequent irrigation with an antimicrobial such as CHX significantly reduced the adherence of E. faecalis to dentin. Observations from this study suggest that chemicals with the ability to alter the physicochemical properties of dentin may also influence the nature of bacterial adherence and adhesion force to dentin.

Kishen A, Sum CP, Mathew S, Lim CT. J Endod 2008;34:850–854. References: 45. Reprints: Dr Anil Kishen, Department of Restorative Dentistry, Faculty of Dentistry, National University of Singapore, 5 Lower Kent Ridge Rd, Republic of Singapore 119074. Email: rsdak@nus.edu.sg—S. K. Lim, Singapore

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