Performance of Fast-Setting Impression Materials in the Reproduction of Subgingival Tooth Surfaces Without Soft Tissue Retraction

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Purpose: Fast-setting impression materials may be prone to inaccuracies due to accidental divergence from the recommended mixing protocol. This prospective randomized clinical trial aimed to assess three-dimensional (3D) deviations in the reproduction of subgingival tooth surfaces and to determine the effect of either following or purposely diverging from the recommended mixing procedure for a fast-setting addition-curing silicone (AS) and fast-setting polyether (PE). ***Materials and Methods:*** After three impressions each were taken from 96 participants, saw-cut gypsum casts were fabricated with a standardized procedure and then optically digitized. Data were assessed with a computer-aided 3D analysis. ***Results:*** For AS impressions, multivariate analysis of variance revealed a significant influence of the individual tooth and the degree to which the recommended mixing protocol was violated. For PE impressions, the ambient air temperature and individual tooth showed significant effects, while divergence from the recommended mixing protocol was not of significance. ***Conclusions:*** The fast-setting PE material was not affected by changes in the recommended mixing protocol. For the two fast-setting materials examined, no divergences from the recommended mixing protocol of less than 2 minutes led to failures in the reproduction of the subgingival tooth surfaces. *Int J Prosthodont 2014;27:366–375 doi: 10.11607/ijp.3752*

It has been well established that precision in all stages of treatment is essential to fabricating accurately fitting dental restorations.[1] Impression making plays a key role in determining fit,[2–4] and longitudinal studies have shown that periodontal health depends on the accuracy of fixed restorations.[5,6] Dental caries is influenced by the marginal fit and is a common reason for the loss of fixed partial dentures.[7]

Conventional impressions remain the gold standard for transferring information from the patient to the dental laboratory when fabricating indirect restorations.[8] The most accurate elastomeric impression materials are polyvinyl siloxane (PVS), polyether, and vinyl siloxanether.[9,10]

Fast-setting variations of these materials have been developed to reduce the time needed for impression making and increase patient comfort. Two-dimensional in vitro measurements showed equivalent dimensional accuracy for fast-setting impression materials compared to traditional PVS and polyether materials and no negative influence of immersion disinfection.[11] Shark fin testing revealed a better flow profile of polyether compared to PVS.[12] Fast-setting polyether behaved similarly to the conventional material, but the flow profile of fast-setting PVS was reduced.

Low viscosity allows better flow of the impression material,[12] which is important for fine and detailed impressions.[13] Viscoelastic materials show the characteristics of both solids and fluids. The shear stress depends on strain and strain rate. During polymerization, freshly mixed impression materials show a more fluid-like behavior followed by a more elastic behavior with an increasing degree of cross-linking.[14] Oscillatory rheometric tests showed a major loss of

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viscoelasticity within the first two minutes after mixing.[14,15] Temperature represents another important factor for the viscoelastic properties. At temperatures of 33°C to 37°C, the loss tangent drops within the first 60 seconds.[14] In a light-bodied material used for syringing multiple preparations for the same final impression, the flow properties might change over time, with differences at the first syringed tooth compared to the last preparation covered when the tray is seated. For this reason, in addition to determining the flow itself, the flow profile will provide important information over time regarding critical material properties.[12]

Dimensional accuracy measurements offer a more complete and clinically relevant picture when multiple measurements[16–18] or three-dimensional (3D) digitizing[19] are applied. Digitizing technology and nondestructive 3D analysis have been applied in clinical trials[20] to evaluate the influence of clinical parameters,[21] impression technique,[22] viscosity,[23] and deviation from the recommended mixing protocol.[24]

It has been shown that the position of the preparation margin (subgingival) and the presence of moisture and blood significantly negatively influence the impression precision.[21] However, in most clinical trials on dental impressions, qualitative criteria for success or failure are used.[25–29] For different impression materials, consistencies, and techniques, between 60%[27] and 96.9%[25] of the impressions were rated clinically acceptable; the amount of impressions that needed to be remade ranged from 3.1%[25] to 8%.[28] In one study, 40% of the impressions made from one impression material were found to be clinically unacceptable.[27] Ratings for flawless impressions showed a wide range of 10.9%[29] to 89.4%.[25] In a clinical trial of regular addition-curing silicone and polyether impression materials, subjective ratings revealed no significant influence of the material used.[30] This result differs from the significant difference found between two PVS materials in the trial with the low success rate of 60%.[27] Similarly low success rates of 48% to 64%[30] and 35% to 51% (depending on the supragingival position of the finishing line) as well as a significant operator influence have also been shown.[18] In summary, subjective impression ratings in clinical trials produce a wide variety of results.

Working times for impression materials have been mainly determined in vitro.[31,32] Tan et al found a deviation between the manufacturers' suggested working times and the working times determined by dimensional accuracy.[33] Based on the measurements of uncut master casts, one study recommended seating the impression tray within 60 seconds after mixing.[34]

Fast-setting impression materials may be prone to inaccuracies resulting from accidental divergence from the recommended mixing protocol, which requires coordination between the dentist and dental assistant. Therefore, this prospective randomized clinical trial, stratified for tray size (medium and large), was conducted to assess potential 3D deviations of the subgingival sulcus reproduction when the recommended mixing procedure is either followed or intentionally breached.

The analysis focused on the sulcus reproduction abilities of two fast-setting impression materials when applying the one-stage/two-phase impression technique. To avoid the confounding impacts of clinical parameters such as a subgingival position of the preparation margin and the presence of moisture and blood, this study used unprepared teeth. The hypothesis was that there is a difference in the reproduction of subgingival tooth surfaces depending on *(1)* the fast-setting impression material used and *(2)* the degree to which the recommended mixing protocol is violated.

Materials and Methods

Fast-setting impression materials are recommended primarily for single-unit or short-span restorations. Following common impression-making protocols, the unprepared first molar (in a clinical scenario, the tooth would be prepared) was first syringed with light-body impression material followed by application of a line of light-body material only into the main fissure of the neighboring teeth. After covering the mandibular right first molar with light-flow material, the main fissures of the second molar and then the second premolar were filled with the light-body material. A tray filled with heavy-body material was then inserted. Stock trays were used to avoid the time and effort needed to fabricate custom trays. Saw-cut gypsum casts were made from each impression with a standardized procedure. A fast-setting polyether (PE) impression material (Impregum Penta H/L DuoSoft Quick, 3M ESPE) and fast-setting addition-curing silicone (AS) material (Aquasil Ultra LV Fast Set Smart Wetting, Dentsply DeTrey) were used.

Ninety-six study participants provided informed consent to the trial, which was designed in accordance with good clinical practice. The trial was approved by the ethics committee of the Medical Faculty Carl Gustav Carus of the Technical University Dresden (EK 180092004) and has been registered in the International Standard Randomized Controlled Trial Number Register (ISRCTN73608522).

Only candidates with clinically healthy gingiva (Periodontal Screening Index ≤ 2) were included (Table 1). All participants received professional tooth cleaning prior to impression making. The correct metal stock tray size was chosen. A distal dam was added to the trays, and the appropriate tray adhesive (PE: Polyether Adhesive, 3M ESPE; AS: Universal Adhesive, Heraeus Kulzer) for each impression material was

Table 1 Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
Age: 18–80 y	Alcohol or drug abuse
Provided informed consent	Legally incapable
All teeth healthy or sufficiently restored	Periodontitis (Periodontal Screening Index > 2)
All teeth present in fourth quadrant	Tooth loss in fourth quadrant (not counting wisdom tooth)
	Pregnancy
	Infectious disease (eg, hepatitis, HIV)
	Conflict of interest due to participation in another clinical trial

Table 2 Manufacturer's Recommended Mixing Protocol

Material	Viscosity	Processing time (from start of mixing)	Setting time (intraoral)
PE	Heavy body	1 min	3 min
	Light body	1 min	3 min
AS	Heavy body	1 min 10 s	3 min
	Light body	35 s	3 min

evenly applied. The minimum drying time for the tray adhesive was 10 minutes.

In each case, three impressions from the mandible were made in randomized order and with randomized material selection (AS or PE): a baseline impression with materials mixed and applied according to the manufacturer's recommended mixing protocol (Table 2), and two impressions purposely diverging from the recommended mixing protocol using the same impression material. Table 3 shows how and to what extent these divergences were performed. Based on these diverging time protocols, a block design of 2 × 24 was run twice (96 participants). In between impressions, participants were asked to thoroughly rinse their mouths with water. Water spray was used to remove any loose pieces of impression material. All excess material still remaining was removed meticulously with forceps and a dental probe before making the next impression.

The impression materials were stored in a climate cabinet at 20°C until just before use. For moisture control, dental mirrors were used to hold back the tongue (dentist) and cheek (dental assistant). The small suction was placed sublingually (Fig 1) until immediately before syringing of the teeth with light material and picking up and inserting of the impression tray by the dentist. For impressions made while purposely diverging from the recommended mixing protocol, the suction was placed sublingually again after applying the light-body material until picking up and inserting of the impression tray. The teeth were gently air dried by the dental assistant. For this procedure, a second assistant was needed because the first had to mix the heavy-body material and fill the tray. The first molar was completely syringed with light-body material, whereas only the occlusal main fissures of the neighboring teeth (second molar and second premolar) were filled with light-body material. The trays remained in the mouth for 3 minutes as per the manufacturer's instructions.

The impressions were rinsed with water, gently dried, and rated either Romeo (excellent and flawless impression), Sierra (impression with minor flaws but acceptable for clinical use), or Victor (major flaws ruling out clinical use) after removal. Impressions with flaws (caused by movement of the tray while in the mouth, contamination with saliva, etc) or large voids were considered to require a remake. After disinfection (Impresept, 3M ESPE), the impressions rested 4 hours to ensure maximum elastic recovery and were then poured with Class IV gypsum (Esthetic-Rock 285 Apricot, Dentona). Saw-cut casts were fabricated with a high-precision drilling unit (Giroform, Amann Girrbach).

The segment of the involved teeth (mandibular right second premolar, first molar, and second molar) was digitized twice to capture the lingual and buccal aspects at an optimal angle with a noncontact optical coordinate measuring system using fringe projection (digiSCAN, Amann Girrbach). According to the manufacturer, the measuring uncertainty of this system is approximately 16 µm. The maximum timeframe for data acquisition was 72 hours after making the casts.

Cast fabrication and data analysis were performed by three different investigators. The saw-cut casts were labeled with a code, and an investigator not involved in any other part of the study meticulously removed the excess impression material from the casts to ensure the blinded evaluation. The subgingival surfaces of the involved teeth were carefully exposed using 2.5-fold magnification glasses. The resulting groove was blackened with a soft pencil before digitizing.

Data handling and calculation of the 3D deviations of the subgingival surface reproduction from the baseline cast were carried out with computer-aided software (Surfacer 10.6, SDRC Imageware). After surfacing the baseline casts using Delaunay triangulation (ce.novation, ILMCAD,) the casts made from impressions of the same participant but with diverging time protocols were aligned separately for the buccal and lingual aspects, resulting in four datasets per participant (Fig 2).

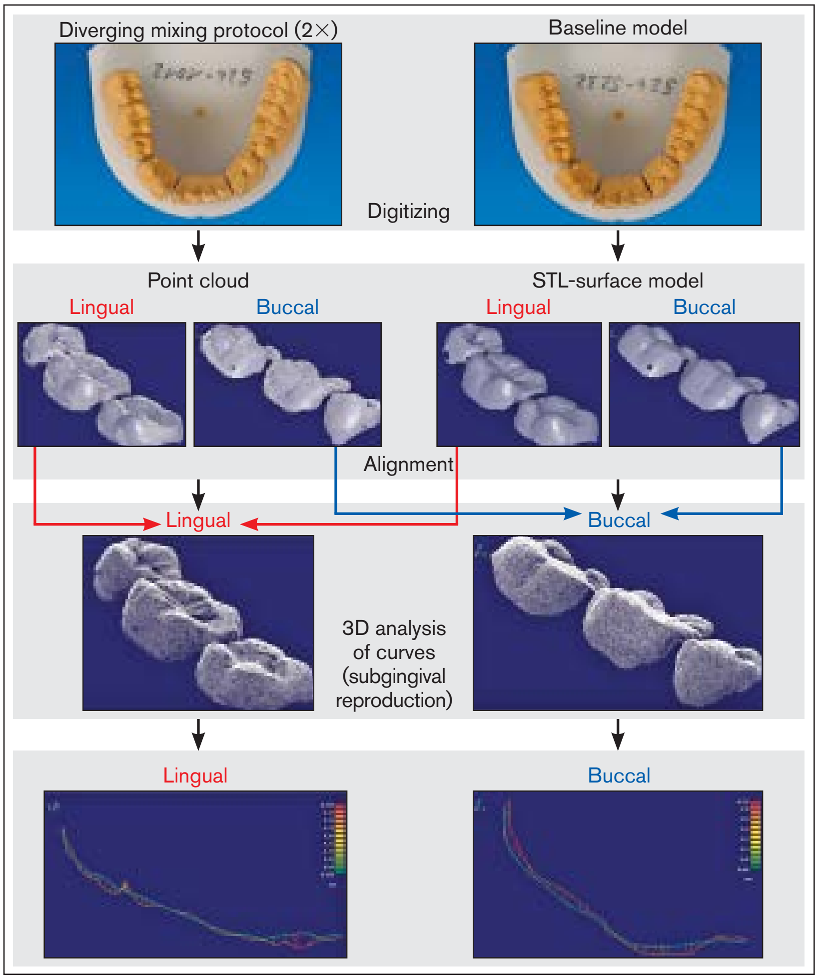
The subgingival tooth surface boundaries were represented by curves for each tooth on the buccal and lingual sides. Maximum and mean positive and negative deviations were calculated between the subgingival surface boundaries for each tooth and side

Table 3 Recommended and Diverging (Time) Mixing Protocols

Protocol	Start mixing heavy body first, begin filling tray	Start mixing light body	Apply light body and insert tray	Waiting time	Start mixing heavy body after applying light body
Recommended	35 s	15 s	10 s	–	–
T + 1		15 s	10 s	20 s	55 s
T + 2		15 s	10 s	30 s	55 s
T + 3		15 s	10 s	40 s	55 s
T + 4		15 s	10 s	50 s	55 s
T − 1	55 s	–	–	20 s	–
T − 2	55 s	–	–	30 s	–
T − 3	55 s	–	–	40 s	–
T − 4	55 s	–	–	50 s	–

Fig 1 *(above)* Moisture control during impression taking with dental mirrors, the small suction, and gentle air drying. The procedure requires the presence of a second dental assistant for approximately 5 minutes.

Fig 2 *(right)* Sequence of the computer-aided quantitative and qualitative 3D analysis.



(quantitative analysis). A more complete reproduction of the subgingival surface resulted in negative values. By comparing the baseline boundaries with those resulting from diverging time protocols, a more complete reproduction of the subgingival surface in the casts made from impressions with diverging time protocols led to positive values.

In addition to the quantitative analysis, color-coded images showed the differences between the curves.

Supplementary to the descriptive statistical analysis, the still-blinded data were analyzed with multivariate analysis of variance (MANOVA) for the two impression materials (SPSS 16.0, SPSS) at a level of significance of $\alpha = .05$. Factors considered included

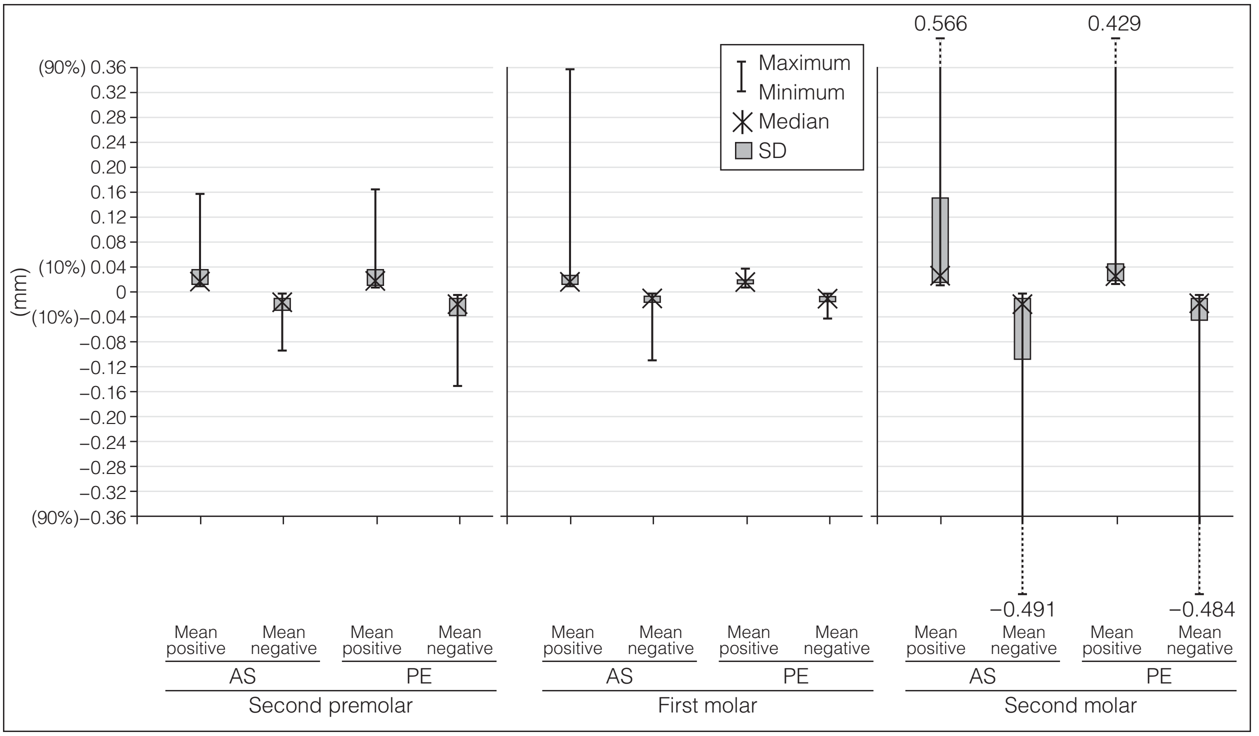


Fig 3 Mean deviations in the subgingival surface reproduction of the baseline cast compared to the impressions made with diverging time protocols.

Table 4 Maximum and Mean Deviation Values (mm) Per Material and Tooth

	AS				PE			
Tooth	Maximum positive	Mean positive	Maximum negative	Mean negative	Maximum positive	Mean positive	Maximum negative	Mean negative
Second premolar								
Mean	0.334	0.023	–0.346	–0.019	0.329	0.023	–0.365	–0.022
Median	0.303	0.018	–0.310	–0.016	0.285	0.017	–0.317	–0.017
SD	0.166	0.017	0.153	0.016	0.179	0.019	0.177	0.020
First molar								
Mean	0.353	0.019	–0.361	–0.015	0.305	0.013	–0.357	–0.013
Median	0.296	0.012	–0.337	–0.012	0.276	0.012	–0.336	–0.012
SD	0.222	0.035	0.132	0.010	0.127	0.004	0.130	0.004
Second molar								
Mean	0.566	0.066	–0.491	–0.047	0.429	0.030	–0.484	–0.033
Median	0.451	0.026	–0.385	–0.022	0.373	0.023	–0.390	–0.021
SD	0.399	0.125	0.353	0.064	0.218	0.031	0.318	0.051

ambient air temperature, the individual tooth, the deviation from the recommend mixing procedure, and the combination of the latter two factors. In this context, the "tooth" factor denotes the technique used for covering the tooth with light-body material: either completely covered (first molar) or with only the fissures filled (second premolar and second molar).

Results

Ninety-six impressions were made following the manufacturer's instructions. Diverging time protocols were used to make 192 impressions. The root mean square error (RMS) of the alignment of the casts made using diverging time protocols to the respective baseline cast was between 14.5 and 27.8 µm (mean: 18.5 µm; SD: 2.1).

The range of deviations found in the 1,152 boundary comparisons (96 participants × 2 sides [buccal and lingual] × 3 teeth [second premolar and first and second molars] × 2 diverging time protocols per participant) was analyzed with three benchmarks: ± 20 µm, ± 50 µm, and ± 100 µm. Of all boundary comparisons, 65.4% showed mean deviations below ± 20 µm, 92.4%

showed mean deviations below ± 50 µm, and 96.8% showed mean deviations below ± 100 µm.

Quantitative Analysis

The mean deviations in subgingival surface reproduction for impressions made with diverging time protocols are shown in Fig 3. Maximum and mean values for deviations per material and tooth are listed in Table 4.

The maximum deviations resulting from impressions made with diverging time protocols were smallest at the first molar, which was the only tooth completely syringed with light-body material. The maximum deviations were largest at the second molar, where the occlusal surface was covered with only a line of light-body material (Fig 4).

For the first molar, the mean positive and negative deviations at the subgingival surface reproduction boundaries showed no correlation to the diverging time protocols when PE was used (Fig 5). For AS, the largest deviations were found for the diverging protocols T-1, T-2, and T+4 (see Table 3).

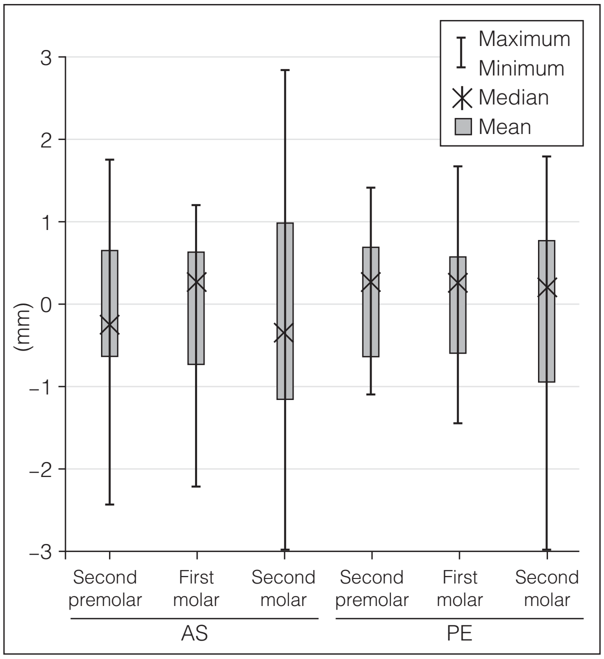


Fig 4 Maximum deviations compared to the baseline cast.

Ambient Air Temperature

When deviations at the first molar were sorted by room temperature at the time of impression taking, no correlation between the mean deviations and ambient air temperature was found for PE. In contrast, AS was found to be sensitive to temperatures above 22°C (Fig 6).

Subjective Rating

AS impressions were 3.5 times more likely than PE impression to be rated Romeo (Fig 7). Small bubbles in the area of the sulcus led to many of the Sierra ratings for PE. The diameter of the bubbles, estimated visually in reference to a millimeter scale (ruler), was below 0.5 mm. Impressions that showed larger deviations in the subsequent 3D analysis were rated Victor for both impression materials. However, several of the AS impressions rated Romeo showed deviations above the benchmark of ± 20 µm (Fig 8). Twenty-four PE impressions and six AS impressions had to be redone after subjective inspection.

Qualitative Analysis

The qualitative analysis provided additional information on the location of the calculated differences (Fig 9). Due to the two-dimensional visualization, an optical illusion may suggest greater deviations than the indicated maximum deviation, which is always calculated based on the surface normal.

Statistical Analysis

For AS impressions, the MANOVA revealed a significant influence of the technique used for covering the teeth (completely vs fissure only) as well as the degree to which the recommended mixing protocol was violated (Table 5). For PE impressions, ambient air temperature and the technique used for covering the teeth were of significance, while the diverging mixing protocols were not of significance.

A separate statistical analysis considering all impressions needing to be redone as lost was also performed, but this analysis did not change the results.

Discussion

In this study, the mandible was chosen for impression taking as a kind of worst case scenario; moisture, movement of the tongue, and swallowing have a stronger influence on impression accuracy in the mandible than in the maxilla. At the position of the preparation line, sulcus fluid and blood were shown to have a significant influence on impression results in previous clinical trials.[21] In this study, impressions were made from unprepared teeth to avoid these confounding factors. A similar analysis of sulcus reproduction has been successfully applied in prior studies.[23]

3D analysis of digitized gypsum master casts has been previously used for clinical accuracy assessment of different impressions materials and techniques.[20,22,24] An important factor in such analyses is the alignment of the baseline datasets and the

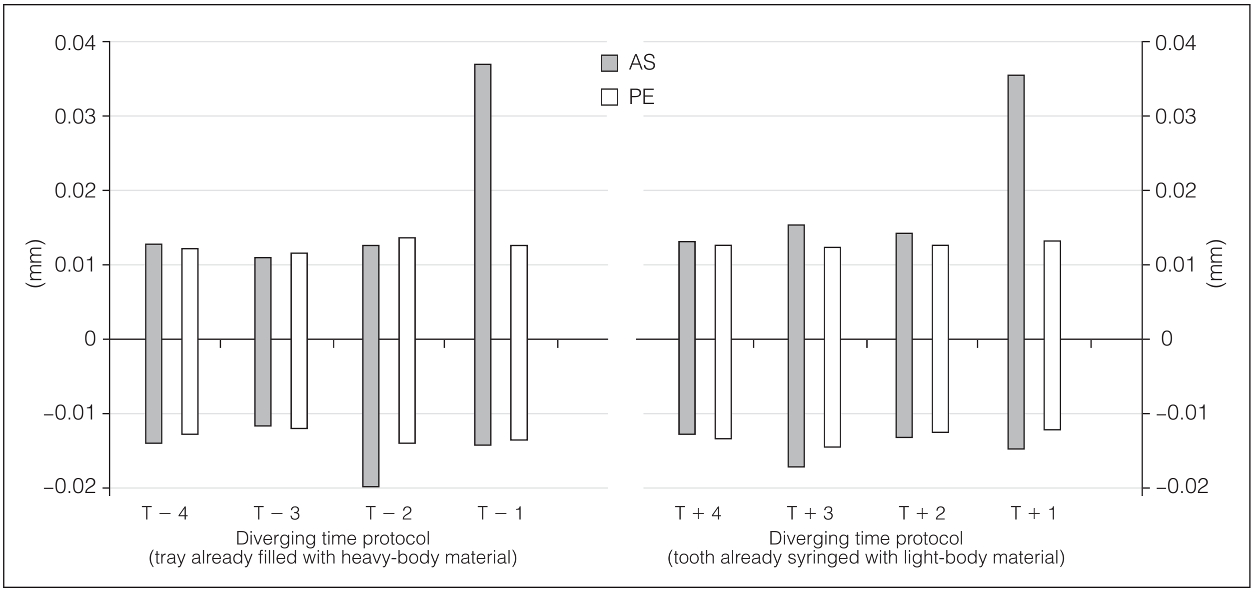


Fig 5 Mean positive and negative deviations at the subgingival surface reproduction boundaries of the first molar for each diverging time protocol (see Table 3).

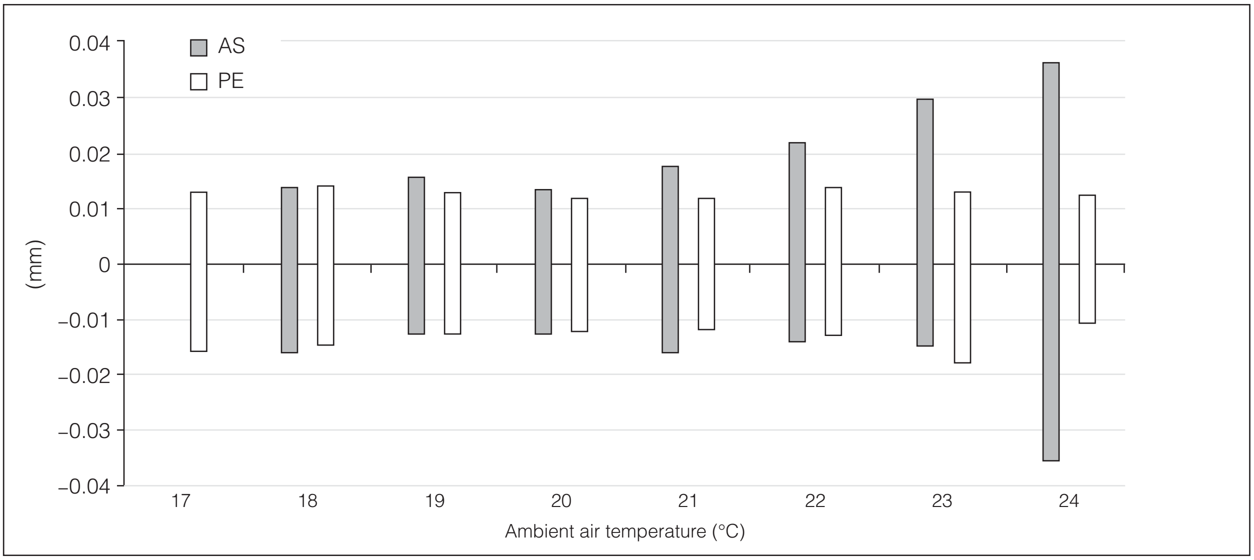


Fig 6 Mean positive and negative deviations at the subgingival surface reproduction boundaries of the first molar in terms of ambient temperature. A room temperature of 24°C was only measured when PE impressions were made.

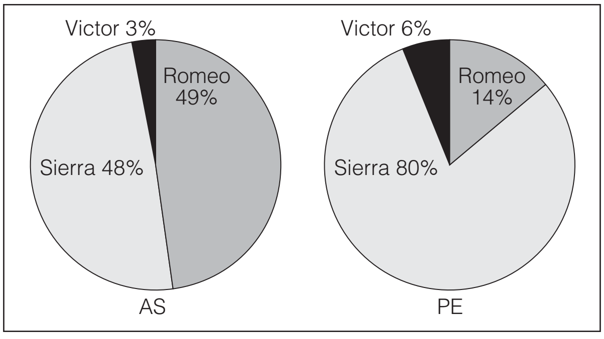


Fig 7 Subjective ratings of the 288 impressions (not including redone impressions).

intervention or follow-up digital data, which must be as accurate as possible to avoid concealing any differences. Alignment accuracy can be assessed via RMS analysis and should be below 10 µm for single teeth.[20,35] Larger segments of a gypsum cast or full arches will necessarily show larger RMS values.[23] The RMS values in this study were in the expected range when using a device with a 16 × 16 cm measuring area and a measuring uncertainty of approximately 16 µm.[23,24]

When making repeated impressions, light-body material may flow more easily into the sulcus when

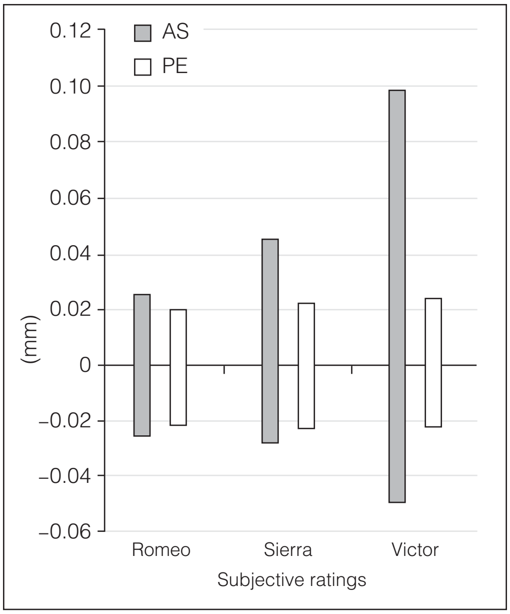
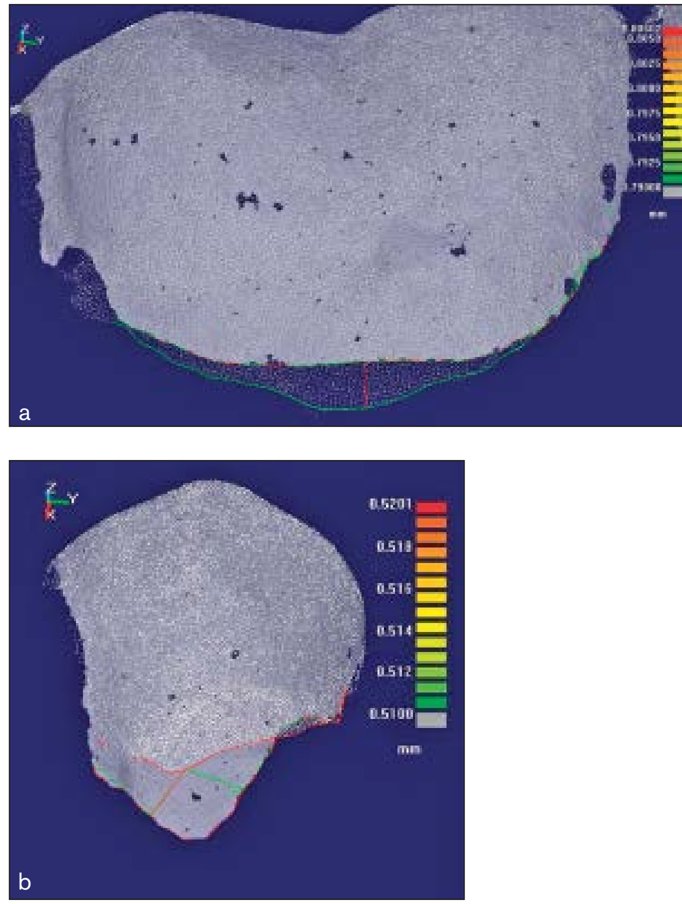


Fig 8 Mean positive and negative deviations at the subgingival surface reproduction boundaries of the first molar in terms of subjective ratings.



Figs 9a and 9b *(right)* Qualitative analysis of the subgingival surface reproduction. Baseline casts *(gray)* and impressions with diverging time protocols *(white dots)* were aligned, and the differences between the boundaries *(green curves)* were calculated. **(a)** An impression made with a diverging time protocol reproduces more of the subgingival tooth surface than the baseline. **(b)** The baseline cast demonstrates a more accurate reproduction. The red lines indicate the largest deviation.

Table 5 Multivariate Analysis of Variance (*P* Values)

	AS		PE	
Factor	Mean positive deviations	Mean negative deviations	Mean positive deviations	Mean negative deviations
Ambient air temperature	.135	.214	.000*	.000*
Tooth†	.000*	.000*	.000*	.000*
Deviation from protocol	.018*	.006*	.553	.041*

*Statistically significant.
†The technique used for covering the tooth with light-body material (completely covered or fissures only).

already opened by the preceding impressions. Making the impressions in randomized order eliminates this advantage of the second and third impressions within a sequence. An alternative procedure would be to make the three impressions on separate occasions rather than on one occasion; however, this would considerably increase the time and effort required of the patients and researchers.

Regarding the choice of diverging time protocols, no deviation of less than 40 seconds was performed because no impact was expected below 60 seconds.[34] Further, diverging time protocols with process times of more than 130 seconds were not considered because it would be impossible to place the tray into the mouth due to the stage of setting.

Previous in vitro studies showed that early pouring of impressions does not negatively influence dimensional accuracy in the absence of undercuts. However, those results do not apply to the unprepared teeth in this study, which is why 4 hours were allowed for elastic recovery.[36,37]

Based on previous studies, mean deviations of ± 20 µm for in vitro conditions and ± 40 to 50 µm in clinical situations can be expected.[20,21,23,37] In the present study, the mean and standard deviations were within this range only for PE impressions and the first molar. Similar results in a study applying the same method of analysis were found for two impression materials using the two-stage putty-and-wash technique.[23] While the mean deviations for AS and the first molar were approximately equally small, the standard deviation was noticeably lager. The largest deviations were found for AS at the second molar. However, the subgingival tooth structure of teeth adjacent to the first molar is not of importance for the fabrication of a restoration, which depends on accurate proximal and occlusal tooth surfaces. The second molar was the most challenging to capture accurately due to the limited access to this area of the posterior mandible.

A higher sensitivity of AS impression materials to temperature changes, characterized by reduced flowability, was assumed based on rheology and shark fin testing.[12,14] This may explain the negatively influenced sulcus representation of AS in the present study. Maximum deviations of up to ± 1 mm have also been reported for addition-curing and condensation-curing regular-setting impression materials.[23] The larger standard deviations found in this study may be attributed to the deviations from the recommended mixing protocol.

In opposition to the results of the descriptive statistical analysis, the MANOVA showed a significant influence of ambient air temperature for PE and not, as would be expected after explorative data analysis, for AS. While PE showed small mean and standard deviations, AS showed much larger standard deviations. Together with the influence of the diverging mixing protocols, this will mask the temperature effect. In contrast, PE, which was only slightly sensitive to the diverging mixing protocols, exhibited a statistically significant but not clinically relevant influence of room temperature. All mean deviations were well within the benchmark of ± 20 µm; nonetheless, the results suggest an optimal temperature of 18°C to 22°C.

In this highly standardized clinical trial with only one experienced dentist taking all impressions (HR), the success rate was 97.9% for AS material and 89.6% for PE material. These results are in accordance with those of other clinical trials.[25–28] PE was more prone to small voids, especially in the depth of the sulcus. The subjective inspection may have negatively influenced the success rate of the PE impressions, although a significant influence could not be found in the 3D analysis of the subgingival surface reproduction. A Romeo or Sierra rating was associated with increasing mean deviations for AS impressions. The mean deviations for PE did not show such a corresponding rise; rather, constantly smaller differences were found independent of the respective subjective rating. AS impressions rated Victor were clearly outside the benchmark of ± 40 µm for clinical acceptability.

The statistically significant influence of the individual tooth, with the smallest deviations at the first molar and larger deviations at the neighboring teeth, could also be a result of differences in flowability.[12,23] The fast-setting PE was less susceptible to violations of the recommended mixing protocol than AS. In a previous study using shark fin testing, PE impression materials showed a greater fin height at the start (≥ 25 mm), a drop to the initial height found for AS after about 2 minutes (approximately 15 mm), and a further drop to a height of 1 mm or less after 2.5 minutes.[12] The fin height of the AS material dropped to 1 mm or less 30 seconds before the PE material.[12] These findings may explain the higher sensitivity of AS to violations of the recommended mixing protocol.

The hypothesis that there is a difference in the reproduction of subgingival tooth surfaces based on the fast-setting material used was rejected. The hypothesis regarding the influence of diverging mixing protocols can be accepted only for AS impressions.

Conclusions

The fast-setting polyether used in this study proved to be fairly tolerant of violations of the recommended mixing protocol. For the addition-curing silicone, filling the trays too early with heavy-body material led to significant changes regarding the accuracy of the reproduced subgingival tooth surfaces. For the two fast-setting materials, no divergences from the recommended mixing protocol of less than 2 minutes led to impression failure. Based on these results, the following recommendations can be made:

- In contrast to common recommendations, every tooth requiring high-precision reproduction must be completely syringed with light-body material. Filling only the central fissure will lead to reduced precision.
- The time frame supplied by the manufacturer can be used in full when using fast-setting impression materials.
- Diverging from the recommended mixing protocol does not necessarily result in impression failure. However, the addition-curing silicone used in this study is more sensitive to a tray filled too early with heavy-body material.
- Completely covering a molar with light-body material using an automix syringe takes approximately 10 seconds. Thus, the fast-setting materials examined in this study can be used not only for single-tooth restorations but also for impressions capturing an entire quadrant.

Acknowledgments

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