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ORIGINAL ARTICLE

Randomized controlled clinical trial on the three-dimensional accuracy of fast-set impression materials

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Abstract
Objectives The use of fast-setting impression materials with different viscosities for the one-stage impression technique demands precise working times when mixing. We examined the effect of varying working time on impression precision in a randomized clinical trial.
Materials and methods Focusing on tooth 46, three impressions were made from each of 96 volunteers, using either a polyether (PE: Impregum Penta H/L DuoSoft Quick, 3 M ESPE) or an addition-curing silicone (AS: Aquasil Ultra LV, Dentsply/DeTrey), one with the manufacturer's recommended working time (used as a reference) and two with altered working times. All stages of the impression-taking were subject to randomization. The three-dimensional precision of the non-standard working time impressions was digitally analyzed compared to the reference impression. Statistical analysis was performed using multivariate models.
Results The mean difference in the position of the lower right first molar (vs. the reference impression) ranged from ±12 μm for PE to +19 and –14 μm for AS. Significantly higher mean values (+62 to −40 μm) were found for AS compared to PE (+21 to −26 μm) in the area of the distal adjacent tooth.
Conclusions Fast-set impression materials offer high precision when used for single tooth restorations as part of a one-stage impression technique, even when the working time (mixing plus application of the light- and heavy-body components) diverges significantly from the manufacturer's recommended protocol.
Clinical relevance Best accuracy was achieved with machine-mixed heavy-body/light-body polyether. Both materials examined met the clinical requirements regarding precision when the teeth were completely syringed with light material.

Keywords Randomized controlled trial · Fast-set impression material · One-stage impression technique · Computer-aided analysis · Polyether · Addition-curing silicone

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Introduction

In the clinic, the coordination of mixing, application, and insertion of one-stage, two-phase impressions (putty-wash impressions) plays a significant role in determining the accuracy of the resultant impression. The importance of delivering the mixed material at the optimal time is emphasized when using fast-set materials because they have a much reduced working time.

Clinical studies substantiate a correlation between the fitting precision of fixed dental restorations and their clinical success, i.e., the survival rate [1–4]. If errors or shape discrepancies occur in this early stage of the manufacturing

process, they are transmitted through all subsequent lab procedures and are mostly irreversible. The internal fitting precision (i.e., marginal fit and inner surface of the restoration) and the occlusal fitting precision depend upon the accuracy of the shape transfer by the impression [5].

Determination of working times for impression materials has mainly been examined in vitro [6, 7]. In most cases of in vitro studies, only individual materials were considered and were applied only at a fixed time. This approach is not comparable to the clinical mode where one or two materials are processed in a chronological order. Furthermore, in the clinic, the recommended working time is often not achieved due to slow filling of the impression tray by the dental assistant or a delay in syringing (e.g., if replacing a displaced retraction cord or if there is residual moisture or contaminants).

In vitro studies encompassing the evaluation of the type of impression tray used, the different impression techniques (mono-phase, one-stage, and two-stage impression methods), and the influence of storage humidity and time with regard to the impression accuracy of a range of chemically and rheologically different impression materials have been published [8–15]. However, the potential of a multitude of clinical factors to affect the ultimate success of the impression remained largely unconsidered [16–18].

The impression accuracy is commonly assessed by analyzing the resulting gypsum models by measuring interarch and crossarch distances as well as the dimensions of steel cones [11, 12, 15, 19] or prepared teeth [10, 13]. In a clinical study of the resulting restorations, it is impossible to assess the influence of the impression or impression accuracy in isolation from the complete process chain. The relative impact of the impression precision in the fitting accuracy of the final restoration cannot be measured separately from other factors such as crown preparation and moisture control. Therefore, it is not possible to determine independently the differences between various impression materials [20].

Dimensional changes affecting the accuracy of the impression or its resulting gypsum model can be assessed by digital measurement using, for example, flash computed tomography [21], cone-beam computed tomography [22], laser digitizing [23, 24], structured light digitizing [25], or mechanical digitizing [26]. Only the latter two investigations made use of the availability of the complete three-dimensional data, whereas other studies used the 3D data only for straight-line segment measurements.

A computer-aided three-dimensional analysis of simulated impressions attempting to simulate the clinical situation more accurately was described by *Persson* et al. [18], but few clinical trials use three-dimensional digital data and computer-aided analysis to assess the accuracy of dental impressions. A method for a clinical trial on dental impression techniques using computers for precision analysis of digital data derived from gypsum models of impressions was first described by Luthardt et al. [16], and found that the impression technique and a subgingivally positioned preparation margin significantly affected impression accuracy. In addition to these factors, a second study found that residual blood at the impression site and the pocket probing depth around a tooth were also significant factors, and that the best reproduction of the preparation line was achieved with a one-stage putty-wash technique together with a double-cord technique for soft-tissue management [27].

A clinical trial with unprepared teeth showed the two-stage putty-wash technique produced standard deviations around the mean of between +27 μm and −24 μm at the lower first molar and near-complete reproduction of the subgingival tooth surface [28]. Furthermore, a very low viscosity wash material (ultra-light) did not improve the accuracy when established cutting procedures were applied to trim the preliminary impression [28]. In a study using prepared teeth, mean discrepancies of ±10 μm were found after taking monophase impressions and producing saw-cut gypsum models, while the two-stage putty-wash technique resulted in significantly higher discrepancies of +13/−14 μm [29].

The aim of the current study was to evaluate how the working time affects the precision of fast-setting impression materials under clinical conditions, especially when diverging from the manufacturer's recommended mixing protocol. The primary objective of this prospective, stratified, clinical, triple-blind evaluated study (RCT) using fast-setting polyether impression materials and fast-setting addition-curing silicones at different working times was to determine the three-dimensional (3D) impression accuracy based on standardized saw-cut master casts.

Secondary objectives were the determination of the 'window' within which the working time is clinically optimal (i.e., gives the best possible accuracy) and investigation of whether the kinetics of the polymerization reaction (snap-set behavior) of the polyether material make it advantageous compared to other materials.

The hypothesis was that the 3D impression accuracy is affected by the working time used for fast-set materials and on the type of material employed.

Materials and methods

The study design for a prospective, randomized, triple blind evaluated clinical study (RCT), stratified according to impression tray size, was prepared in accordance with best clinical practice [30–34] and approved by the ethics committee of the Carl Gustav Carus Medical Faculty of the Technical University Dresden (Reference No. EK

180092004). The trial is registered in the International Standard Randomised Controlled Trial Number Register (No. ISRCTN73608522).

Clinical procedure

After concluding the pilot study with eight volunteers, putty-wash impressions (two-phase, one-stage impression technique) were taken of the mandibular teeth of 96 further volunteers using fast-set materials (either polyether (Impregum Penta H/L DuoSoft Quick) or addition-curing polyvinylsiloxane silicone (Aquasil Ultra LV Fast Set); see Table 1 for product details) in a metal stock tray with a distal dam. Eight protocols diverging from the recommended working time were used for these impressions, the most extreme of which approached the period at which the material became completely set. The light material was syringed 40, 50, 60, or 70 s earlier than recommended or was applied 40 s (−40) to 70 s (−70) later than recommended.

Subsequent to a professional tooth cleaning, three impressions were taken per volunteer in randomized order:

(1) using the recommended working time as a reference impression
(2) two impressions using different working times from those recommended by the manufacturer, using the same material as used for the reference impression (polyether or addition-curing silicone). The manufacturer of the polyether material recommended 1 min for processing from the start of mixing (equivalent to entry of the paste into the mixing tip) and a further 3 min in the mouth for setting. The manufacturer of the addition-curing silicone recommended 1 min 10 s for mixing and processing of the heavy-body material and a maximum of 35 s for the intra-oral application of the light-body material (i.e., the tray must be seated within 35 s from the time at which the wash material was applied intraorally). The minimum working time is therefore 1 min 15 s at 22 °C, which is reduced to a maximum intraoral working time of 35 s at 37 °C. The minimum removal time is 3 min (from the start of mix).

Suitable volunteers ranged between 18 and 80 years of age and had a closed dental arch in the quadrant to be examined (lower right mandible) with at least one premolar and two molars with direct proximal contacts. All teeth had to be either healthy or proficiently restored. Patients belonging to one of the following groups were excluded from the study: alcohol or drug addicts; persons incapable of contracting; pregnant women; volunteers whose participation in another study created a conflict of interest to the current study; volunteers suffering from periodontitis (PSI (Periodontal Screening Index) >2) [35], and volunteers with incomplete dental arches (except for third molars or first premolars with gap closure). Volunteers with an existing infectious disease such as hepatitis or HIV were also excluded.

The informed consent of the volunteers was requested at their second appointment so as to allow them sufficient time to consider their participation and undergo any remedial, urgent, or stabilizing dental treatment required (e.g., for caries).

Table 1 Materials used in the clinical trial including manufacturers and LOT numbers

Material	Materials type	Manufacturer	LOT no.	Volunteer no.
Impregum™ Penta™ H DuoSoft Quick base	Heavy-body polyether	3M ESPE, Seefeld, Germany	195971	1 to 60
			205895	61 to 96
Impregum™ Penta™ H DuoSoft Quick catalyst			196002	1 to 60
			206405	61 to 96
Impregum™ L DuoSoft Quick	Light-body polyether	3M ESPE, Seefeld, Germany	174999	1 to 60
			B194744	61 to 96
Aquasil Ultra LV Fast Set Smart Wetting® base	Soft Putty PVS	Dentsply DeTrey, Constance, Germany	403001447	1 to 72
			410000843	73 to 96
Aquasil Ultra LV Fast Set Smart Wetting® catalyst			403001447	1 to 72
			410000843	73 to 96
Aquasil Ultra LV Fast Set Smart Wetting®	Light-body PVS	Dentsply DeTrey, Constance, Germany	405000947	1 to 65
			405040415	66 to 96
esthetic-rock 285® apricot	ISO 6873: 2000, type 4 gypsum, resin fortified		70302042	
			71102047	
			80302040	
			80503040	
			80503049	
			80901044	

Batch numbers of the impression materials used for each volunteer were recorded throughout

The study was stratified by the size of the impression tray. The impression material used for each volunteer was assigned according to a randomization list,[1]—which was also used to assign the different working time protocols and to determine the order in which the three impressions were to be taken; all of this information was recorded on the case report form (CRF). The clinical investigator responsible for the professional cleaning and impression taking received the CRF from the trustee of the randomization list directly before the appointment, and carried out these procedures in accordance with that CRF.

Due to the variations in the procedures (hand mixing vs. machine mixing) and the different coloration of the impression materials, a double-blind study was not possible (Fig. 1).

The unblinded impressions, made anonymously and identifiable only by volunteer number and impression number, were then used to fabricate gypsum models. This process was undertaken in a different building and at a different time than the digitizing and evaluation. All residues of the impression materials were completely removed from the gypsum models before the responsible academic employee blinded and coded them. The model codes were designed not to reveal any information regarding the volunteer or material used. These blinding measures ensured a triple-blind evaluation because the data given to the biometrician for analysis were also blinded. Identification of the impression materials used for each cast took place only after statistical analysis.

Under the recommended mixing protocol, the impression tray was filled first. After a delay of about 15 s, the investigator began to syringe the light-body material around the whole of the lower right first molar crown, and into the fissures of the distal and mesial neighboring teeth. Immediately after being filled, the impression tray was handed to the clinical investigator at the exact moment that intraoral application of the light-body material was completed.

In contrast, under the non-optimal working time regimes, the light material was mixed and syringed either too early or too late compared to the filling of the tray. The time deviations used (40, 50, 60, or 70 s early and 40 or 70 s late) were determined in pretests.

Recordings of voice commands by the clinical investigator and assistants (e.g., “heavy mixing ready—now” or “application ready—now”) were analyzed later (using freeware ALC Record (Automatic Level Control Record) and Winamp 5.06, Windows media player equalizer) to determine whether the mixing and processing protocol had been followed correctly.

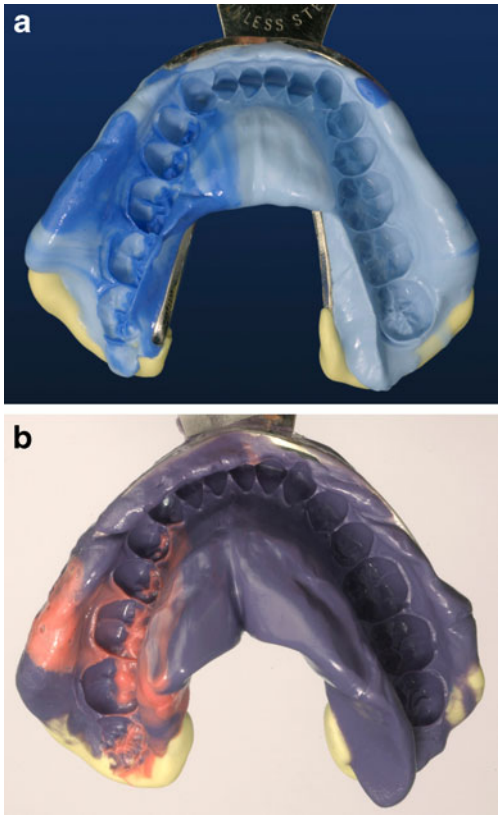

Fig. 1 Impression taken with fast-set addition-curing silicone (**a**) and fast-set polyether (**b**) in a metal stock tray with distal dam

Immediately after removing the impressions from the mouth, their clinical acceptability was rated according to a classification of “Romeo” for error-free impressions, “Sierra” for impressions with slight errors but clinically acceptable, and “Viktor” for clinically unacceptable impressions. All reference impressions that were not considered as “Sierra” or “Romeo” had to be repeated.

If the saw-cut model contained errors, all data for the corresponding volunteer was completely omitted from the trial. In such cases, the randomization list was revisited and that impression regimen was repeated with a new volunteer.

Pilot study

Eight working time protocols designed to diverge from the recommended protocol were run completely within the scope of the pilot study, with three impressions taken from each of eight volunteers. The pilot study took place in midsummer in a non-air-conditioned room, which affected the setting properties of the materials. For the main study, we therefore maintained the impression materials at 21 °C (conditioning cabinet WK2976, Liebherr-International

[1] The list was prepared by the Institute for Medical Informatics and Biometrics at the Dresden University of Technology, Germany (Director at that time: Prof. Dr. med. Hildebrand Kunath) and kept by an academic employee of the Department of Prosthodontics, who was involved neither in the clinical procedure nor in the evaluation of results.

Deutschland, Biberach an der Riss, Germany) prior to use to guarantee uniformity of results.

Model fabrication

Digitization and evaluation of the models were always carried out by a second clinical investigator who had had no role in the taking of impressions, eliminating the possibility that the clinical investigator may recognize certain anatomical features and create an association with the impression material used.

After a period of 4 h to ensure adequate material resilience, the impressions were poured out with type 4 gypsum (esthetic-rock® 285, for details see Table 1) and saw-cut models fabricated with the Zeiser II system (today: Giroform system, Amann Girrbach Dental, Pforzheim, Germany).

After at least 12 h (but not more than 72 h) from pouring, the reference tooth (lower right first molar) and its mesial and distal neighbors in all models were measured with a non-contact optical digitizing system (DigiSCAN, Amann Girrbach, Pforzheim, Germany).

Analysis of the three-dimensional reproduction precision

The reference tooth and its adjacent teeth were positioned (angled) in the digitizing system so as to achieve maximum measuring accuracy. The data measured were reduced by suitable filter methods to a point cloud with highly accurate measuring points [16]. A CAD surface model was generated for the reference model, to which all subsequent, 'altered working time' protocol impressions were aligned (i.e., appeared in an identical coordinate system). This is a prerequisite for 3D analysis (Surfacer 10.6, SDRC Imageware, Neu Isenburg, Germany). The 3D analysis of the accuracy of impressions taken using the 'altered working time' protocols was made separately, each in comparison to the reference impression. The accuracy of the alignment was assessed using root mean square error (RMS). The 3D differences for the individual tooth (46) and for the complete model (molar plus adjacent teeth: 45, 46, and 47) were calculated (Fig. 2).

Statistical analysis

An equivalence design was chosen to analyze the time-related processing tolerance at an intended minimum power of 80 % and a two-sided significance level of $\alpha=0.05$. The test factors were arranged in a tri-periodic, incomplete, balanced, non-orthogonal block plan of size 2×24. The primary objectives were the differences between the two impression materials (polyether and addition-curing silicone) and the discrepancy between reference and comparative impressions regarding the direction as well as the strength.

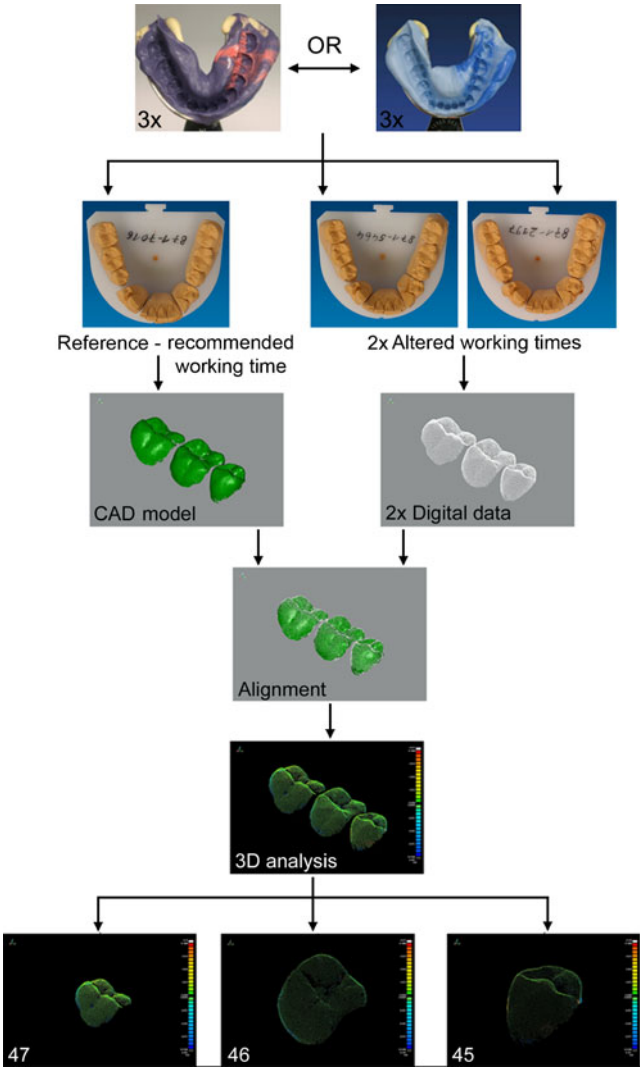

Fig. 2 Computer-aided analysis of three-dimensional impression accuracy

As the plan for both impression materials was applied independently, the tests for material differences were only possible inter-individually.

Recruitment and randomization continued until two completely filled blocks were available for both materials. The complete test plan was repeated twice so that a total of 96 volunteers were included.

The effects were tested by an analysis of variance using generalized estimating equations (GEE, SAS procedure GENMOD, SAS Institute, Heidelberg, Germany). Special contrast tests were adjusted by the Bonferroni method.

Results

All 24 impressions and the resultant saw-cut models of the pilot study were usable and were assessed by descriptive

statistics only, preserving the continuous data blinding for the main study. In the scope of the main study, all 288 impressions and gypsum models were usable.

3D analysis of the impression accuracy (pilot and main study)

The RMS error of the alignment of reference and comparison models ranged from 14.7 to 29.3 μm (mean ± SD=18.9± 2.7 μm), with a median of 18.3 μm.

Results for the mean 3D discrepancies of tooth 46 and its adjacent premolar (45) and molar (47) are shown in Table 2 and Fig. 3. For the first molar, 192 comparative impressions were made (two per volunteer for comparison with the corresponding reference cast), of which 18 exhibited mean positive or negative discrepancies beyond a range of ±20 μm. Of these discrepancies, 14 were with the addition-curing silicone (14.6 % of the impressions were not clinically acceptable) and only four were with the polyether (4.2 % not clinically acceptable).

Table 2 Mean three-dimensional discrepancies per material (addition-curing silicone or polyether) and tooth (45, 46, 47)

Tooth		Impression material	
		Polyether	Addition-curing silicone
45	Positive mean [μm]	17.7	19.4
	Standard deviation	14.3	19.4
	Positive minimum [μm]	7.7	7.6
	Positive maximum [μm]	94.7	143.5
	Negative mean [μm]	−17.5	−17.8
	Standard deviation	16.5	12.2
	Negative minimum [μm]	−7.9	−8.8
	Negative maximum [μm]	−107.2	−101.4
46	Positive mean [μm]	11.7	18.6
	Standard deviation	3.6	30.4
	Positive minimum [μm]	8.1	8.2
	Positive maximum [μm]	26.9	207.6
	Negative mean [μm]	−11.5	−13.6
	Standard deviation	2.6	7.9
	Negative minimum [μm]	−8.7	−7.9
	Negative maximum [μm]	−25.2	−55.5
47	Positive mean [μm]	21.2	62.8
	Standard deviation	11.8	136.5
	Positive minimum [μm]	9.1	8.2
	Positive maximum [μm]	88.1	1,013.6
	Negative mean [μm]	−26.2	−40.4
	Standard deviation	38.2	37.9
	Negative minimum [μm]	−8.3	−8.5
	Negative maximum [μm]	−275.6	191.7

Determination of the optimal working time

We were able to obtain impressions from all materials in all time regimens, even those that diverged from the recommended working time by over a minute. A time offset of ±70 s between intraoral application of the light-body material and filling of the tray, at a mixing/processing time of approximately 40 s, generally resulted in clinically acceptable impressions.

Influence of the working time regimen

We found no direct correlation between the different working time protocols and the 3D precision of the resultant impression (Fig. 4). Thus, we were able to reject the hypothesis that, for fast-set materials, the 3D impression accuracy is dependent on the working time. The red hyperbola in Fig. 4 shows the expected (hypothetical) distribution of the discrepancies. The dotted hyperbola in the right panel suggests an emerging trend: divergence by 60 s or more seemed to result in somewhat higher 3D discrepancies. The slight right-shift of the curve compared to the predicted course suggests that early intraoral application by syringe has less effect on the final impression accuracy than early filling of the tray. It should be noted that both of these trends occurred only with the polyether material.

Visual assessment of the impressions and of the gypsum models

The polyether was observed more frequently to develop miniscule ‘air-blows’ or bubbles that, although not affecting the clinical acceptability, often resulted in a categorization of “Sierra” rather than “Romeo”. For the addition-curing silicone material, the 3D precision of the impressions rated “Romeo” was significantly higher than for those rated “Sierra”; in contrast, polyether impressions rated “Sierra” were of equal precision to those rated “Romeo”. Impressions rated “Viktor” (i.e., not clinically acceptable) unsurprisingly exhibited the highest 3D discrepancies (Fig. 5).

Addition-curing silicone impressions were more frequently rated “Romeo” than those in polyether. The latter were mostly rated “Sierra” (Fig. 6). For impressions rated “Romeo” or “Sierra”, the proportion of impressions that exhibited discrepancies within a range of ±20 μm at tooth 46 was 87.1 % for silicones, and 95.5 % for polyethers. At the mesial neighbor (45) and distal neighbor (47), the proportion of impressions within this accuracy range was 66.7 and 27.0 %, respectively, for the silicone impressions and 75.5 and 42.3 %, respectively, for polyethers.

Within the scope of this study, five cases were omitted from the analysis due to visible flaws in the saw-cut

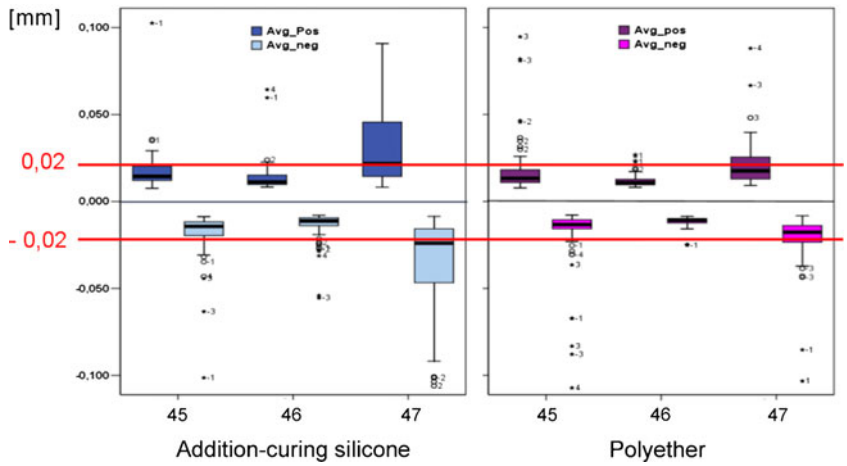

Fig. 3 Three-dimensional discrepancies per material and tooth. The *parallel lines* mark a range of ±0.02 mm (±20 μm). *Circles* denote close outliers; *asterisks* denote extreme outliers

reference model. In these cases, new impressions were taken from different volunteers.

Statistical analysis

Statistical assessment revealed a significant difference between the two impression materials for the mean positive (p=0.030) and mean negative (p=0.011) discrepancies. No significant period and/or surplus effects were found, i.e., no indication of adjustment and/or learning effects or after-effects. Contrary to the pessimistic power estimate, the data from periods 2 and 3 could be used without bias where the power was 80 %.

Discussion

The present study design is not suitable for determining absolute differences. The comparison is always related to the reference impression made using manufacturer-recommended working times, which requires exceptional quality from this impression. The same applies to the precision of the gypsum saw-cut models. Because measurements on uncut casts are known to result in a high incidence of discrepancies [10, 12, 13], and only saw-cut models can compensate for the gypsum expansion that occurs during setting, saw-cut models are strongly preferred for this type of study. Our use of digital characterization of the 3D differences in the gypsum saw-cut models can be considered to be an established and robust technique given its successful application in several similar clinical trials [16, 18, 27–29].

Statistically speaking, it is only possible within this study protocol to obtain an inter-individual evaluation because only one of the two materials can be used per patient and yet the severity and direction of the discrepancies are compared between individuals. It is thus impossible to rule out adjustment and/or learning effects.

For the successful implementation of the study, utmost importance was attached to the compliance with the different

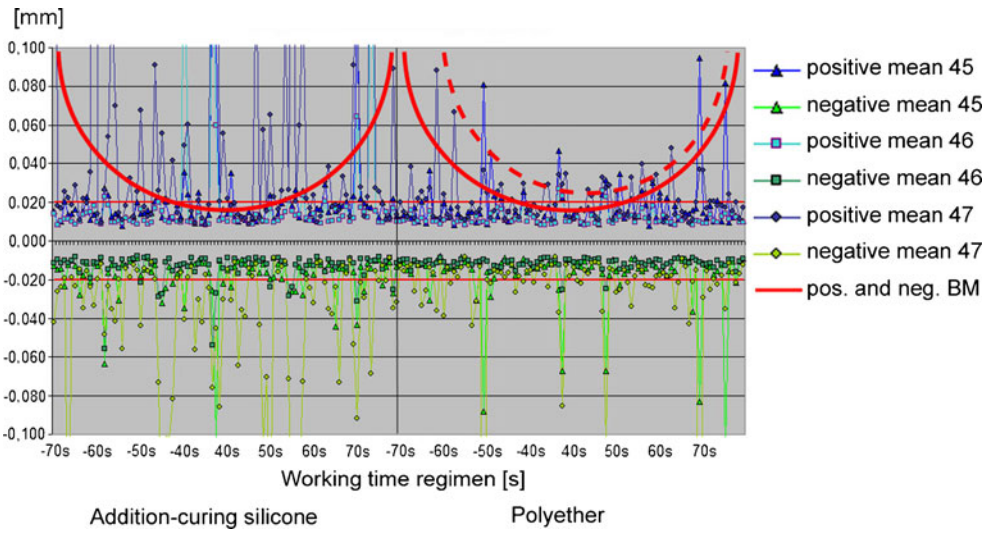

Fig. 4 The *X*-axis indicates the working time regimen used (e.g., −70 s=tray filled 70 s too early; +70 s=tray filled 70 s after syringing). The *left half* of the diagram shows mean discrepancies in the 3D position of the analysis point compared to the same point on the reference model when impressions were made using addition-curing silicone. The *right half* shows the equivalent discrepancies in impressions taken using polyether. The benchmark (BM) was set to ±20 μm. For outliers >0.1 mm, please refer to Fig. 5

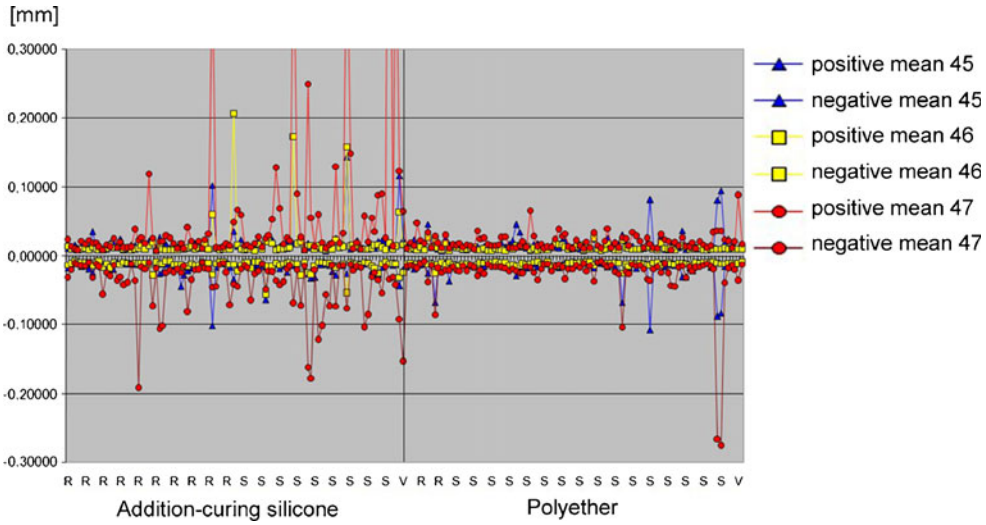

Fig. 5 Clinical impression assessment: *R*=Romeo, *S*=Sierra, *V*=Viktor. The *left side* of the diagram shows the 3D discrepancies in recorded tooth position compared to the reference model in impressions made in addition-curing silicone; the *right side* shows the equivalent results for impressions made in polyether. Discrepancies are sorted from Romeo (*R*) to Viktor (*V*) (*left to right*) for each material. The *Y*-axis scale (±0.3 mm) allows inclusion of most of the extreme outliers

working time protocols because any overlap may disguise time-dependent differences in impression accuracy. The clinical investigator and assistant were required to practice together for these sequences prior to the start of the study. The assessment of the audio data confirmed that the prescribed time intervals were adhered to exactly throughout the study.

Residual blood or moisture around the prepared tooth could precipitate a clinical situation where the tray is filled too early (equivalent in our study to light material being applied 40 s (−40) to 70 s (−70) later than recommended) as application of the filled tray would be delayed while the tooth was re-dried and cleaned before syringing light-body impression material. This is a common occurrence in prosthodontic treatment. A dropped or otherwise contaminated tray or heavy-body impression material, or a lack of preparation/coordination on the part of the dental assistant (equivalent in our study to light material being applied 40, 50, 60, or 70 s earlier than recommended compared to the filling of the tray) are less frequent occurrences and therefore arguably less clinically relevant.

The influence of such clinical factors lead to the mean positive and negative discrepancies sometimes exceeding the results of in vitro studies into putty-wash impressions using the same polyether material [25]. The mean positive and negative discrepancies from the reference model ranged from 11.8 to 12.4 μm in in vitro situations, in agreement with values obtained in vitro by two-dimensional link tests on the same material [19] and below those for other elastomeric impression materials tested in vitro [15]. The silicone material, however, gave significantly higher discrepancies from the reference model, especially in the case of longer links (e.g., across the palate from molar to molar, or from

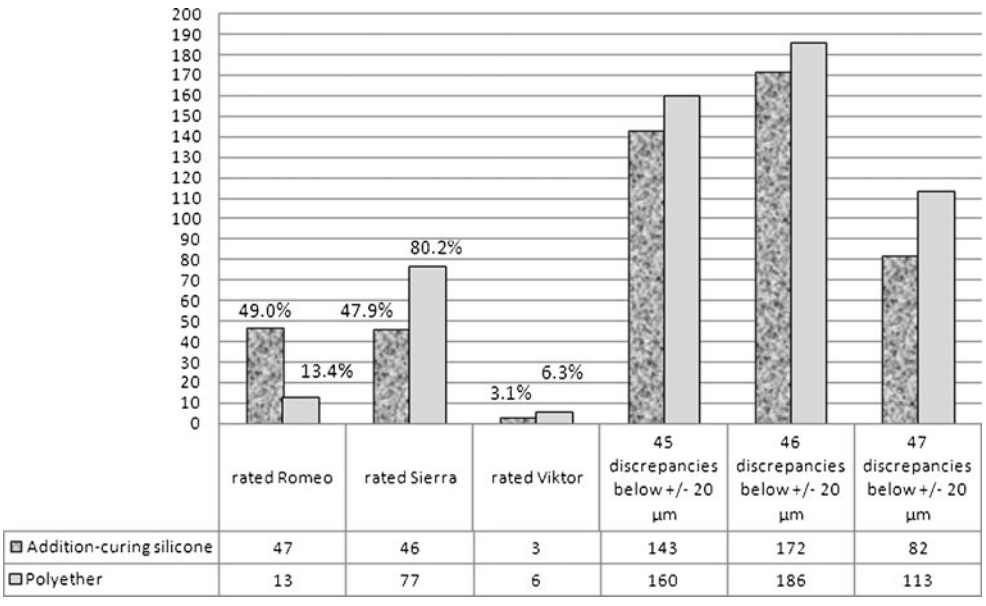

Fig. 6 Number and proportion (%) of different clinical impression ratings and the number of Romeo/Sierra impressions (out of 192) in which the positive and negative discrepancies per tooth/material were within the range of ±20 μm

molar to central incisor) [19]. These results are supported by the present study where the silicone showed the highest and most significantly different discrepancies in the area of the distal neighboring tooth (Fig. 3). The loss of hydrophilic properties over time after mixing, especially beyond a timeline of 50 s, offers a possible explanation for the lower precision of the addition-curing silicone [22]. However, no statistically significant time-dependence was observed between the different working time protocols and the 3D precision of the impressions. Based on results gained in in vitro studies and with additional tolerance built in for the challenges of impression-taking under clinical conditions, impressions with 3D discrepancies within a range of ±20 μm can be considered as clinically acceptable [25, 28].

In contrast to the mesial and distal adjacent teeth, which were only covered occlusally, the lower right first molar was completely syringed with light material. At this tooth, both materials (silicone and polyether) comfortably met the requirements for clinical acceptability. Comparing the two materials, the polyether impressions gave a reproduction precision within the defined clinical benchmark even though the premolar and second molar were not completely covered with light material. This positive effect probably resulted from the high flowability of the polyether tray material [11]. When using a heavy-body tray material like the addition-curing silicone used in this trial, it is crucial (for the accuracy of the impression) to cover the teeth to be restored completely with the light-body material. This correlation between the amount of filler and the resultant impression accuracy has been found in vitro previously for another addition-curing silicone [36].

Robustness of the setting behavior/temperature influences

Regarding the snap-set behavior of the polyether [37], this study did not show a statistically significant advantage compared to the addition-curing silicone. Since the pilot study showed that the ambient temperature significantly influenced the setting speed of the materials, the impression materials were stored in a conditioning cabinet at 21 °C for the main study and were removed only when needed. At temperatures below 20 °C, the light-body silicone material set more slowly, and the impression required up to 90 s longer to set in the mouth to preclude the light material detaching from the heavy-body material upon removal. The setting behavior of the polyether material was less affected by lower room temperatures (approximately 18 °C), meaning that the setting time in the mouth did not need altering. A discrepancy between the working time according to ISO, the manufacturer's recommended working time, and the operator-assessed working time was found in in vitro tests of other impression materials [7]. In impressions taken with the silicone material, the 3D discrepancies tended to increase slightly, albeit not significantly.

When materials were hand-mixed, the hand temperature of the operator had a perceptible influence on the setting speed (delayed setting with very cold hands, faster setting with warm hands). Furthermore, hand-mixing impression materials may cause air entrapment during spatulation, which can cause voids in the impression [38]. Thus, machine mixing offers a clear advantage in producing uniform and reproducible impression quality.

Although the silicone impressions were more frequently assessed clinically as of "Romeo" standard, this does not necessarily imply better 3D precision. However, the incidence of 3D discrepancies did increase in impressions rated "Sierra". Nevertheless, polyether impressions rated "Sierra" and "Romeo" both provided excellent dimensional stability, in contrast to the widely scattered 3D discrepancies seen with silicone impressions (Fig. 5, Table 2). Interestingly, although we expected the maximally delayed working time protocol to result in severe discrepancies, we found no direct time-dependence in the incidence or severity of 3D discrepancies.

Conclusion

While not all relevant factors can be included or controlled for in two-dimensional in vitro studies, it is possible to assess the precision of an impression material using a clinical volunteer study followed by a three-dimensional evaluation. The present study showed that the two fast-setting impression materials examined in this study are sufficiently adaptable that the working time can be altered significantly without causing any loss in precision. We also found that, for the polyether material, early application of the light-body material into the mouth had less effect on impression accuracy than premature filling of the impression tray.

Within the scope of this study, the machine-mixed heavy-body/light-body polyether offered a significantly higher precision in the distal area of the mandible. Regardless of the statistically significant differences, both materials meet the clinical requirements regarding precision when a tooth is completely syringed with light material. When heavy-body tray materials are used, all relevant areas should be completely covered with light material in order to maximize precision.

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

References

1. Karlsson S (1986) A clinical evaluation of fixed bridges, 10 years following insertion. J Oral Rehabil 13(5):423–432
2. Sorensen SE, Larsen IB, Jorgensen KD (1986) Gingival and alveolar bone reaction to marginal fit of subgingival crown margins. Scand J Dent Res 94(2):109–114
3. Boulton JL, Gage JP, Vincent PF, Basford KE (1996) A laboratory study of dimensional changes for three elastomeric impression materials using custom and stock trays. Aust Dent J 41(6):398–404
4. Nissan J, Laufer BZ, Brosh T, Assif D (2000) Accuracy of three polyvinyl siloxane putty-wash impression techniques. J Prosthet Dent 83(2):161–165
5. Samet N, Shohat M, Livny A, Weiss E (2005) A clinical evaluation of fixed partial denture impressions. J Prosthet Dent 94(2):112–117
6. Balkenhol M, Haunschild S, Erbe C, Wostmann B (2010) Influence of prolonged setting time on permanent deformation of elastomeric impression materials. J Prosthet Dent 103(5):288–294
7. Balkenhol M, Kanehira M, Finger WJ, Wostmann B (2007) Working time of elastomeric impression materials: relevance of rheological tests. Am J Dent 20(6):347–352
8. Abuasi HA, Wassell RW (1994) Comparison of a range of addition silicone putty-wash impression materials used in the one-stage technique. Eur J Prosthodont Restor Dent 2(3):117–122
9. Corso M, Abanomy A, Di Canzio J, Zurakowski D, Morgano SM (1998) The effect of temperature changes on the dimensional stability of polyvinyl siloxane and polyether impression materials. J Prosthet Dent 79(6):626–631
10. Al-Bakri IA, Hussey D, Al-Omari WM (2007) The dimensional accuracy of four impression techniques with the use of addition silicone impression materials. J Clin Dent 18(2):29–33
11. Balkenhol M, Ferger P, Wostmann B (2007) Dimensional accuracy of 2-stage putty-wash impressions: influence of impression trays and viscosity. Int J Prosthodont 20(6):573–575
12. Caputi S, Varvara G (2008) Dimensional accuracy of resultant casts made by a monophase, one-step and two-step, and a novel two-step putty/light-body impression technique: an in vitro study. J Prosthet Dent 99(4):274–281
13. Faria AC, Rodrigues RC, Macedo AP, Mattos Mda G, Ribeiro RF (2008) Accuracy of stone casts obtained by different impression materials. Braz Oral Res 22(4):293–298
14. Kanehira M, Finger WJ, Endo T (2006) Volatilization of components from and water absorption of polyether impressions. J Dent 34(2):134–138
15. Stober T, Johnson GH, Schmitter M (2010) Accuracy of the newly formulated vinyl siloxanether elastomeric impression material. J Prosthet Dent 103(4):228–239
16. Luthardt RG, Koch R, Rudolph H, Walter MH (2006) Qualitative computer aided evaluation of dental impressions in vivo. Dent Mater 22(1):69–76
17. Balkenhol M, Wostmann B, Kanehira M, Finger WJ (2007) Shark fin test and impression quality: a correlation analysis. J Dent 35 (5):409–415
18. Persson AS, Oden A, Andersson M, Sandborgh-Englund G (2009) Digitization of simulated clinical dental impressions: virtual three-dimensional analysis of exactness. Dent Mater 25(7):929–936
19. Wadhwani CP, Johnson GH, Lepe X, Raigrodski AJ (2005) Accuracy of newly formulated fast-setting elastomeric impression materials. J Prosthet Dent 93(6):530–539
20. Wostmann B, Blosser T, Gouentenoudis M, Balkenhol M, Ferger P (2005) Influence of margin design on the fit of high-precious alloy restorations in patients. J Dent 33(7):611–618
21. Tarawneh FM, Panos PG, Athanasiou AE (2008) Three-dimensional assessment of dental casts' occlusal surfaces using two impression materials. J Oral Rehabil 35(11):821–826
22. White AJ, Fallis DW, Vandewalle KS (2010) Analysis of intra-arch and interarch measurements from digital models with 2 impression materials and a modeling process based on cone-beam computed tomography. Am J Orthod Dentofacial Orthop 137(4):456 e451–459, discussion 456-457
23. DeLong R, Heinzen M, Hodges JS, Ko CC, Douglas WH (2003) Accuracy of a system for creating 3D computer models of dental arches. J Dent Res 82(6):438–442
24. Brosky ME, Pesun IJ, Lowder PD, Delong R, Hodges JS (2002) Laser digitization of casts to determine the effect of tray selection and cast formation technique on accuracy. J Prosthet Dent 87 (2):204–209
25. Rudolph H, Quaas S, Luthardt R (2008) Precision of duplicate dies made with different impression making procedures. Dent Mater 25 (5):e27–e28. doi:10.1016/j.dental.2009.01.052
26. Persson AS, Andersson M, Oden A, Sandborgh-Englund G (2008) Computer aided analysis of digitized dental stone replicas by dental CAD/CAM technology. Dent Mater 24(8):1123–1130
27. Luthardt RG, Walter MH, Weber A, Koch R, Rudolph H (2008) Clinical parameters influencing the accuracy of 1- and 2-stage impressions: a randomized controlled trial. Int J Prosthodont 21 (4):322–327
28. Haim M, Luthardt RG, Rudolph H, Koch R, Walter MH, Quaas S (2009) Randomized controlled clinical study on the accuracy of two-stage putty-and-wash impression materials. Int J Prosthodont 22(3):296–302
29. Luthardt RG, Walter MH, Quaas S, Koch R, Rudolph H (2010) Comparison of the three-dimensional correctness of impression techniques: a randomized controlled trial. Quintessence Int 41 (10):845–853
30. GCP "Good Clinical Practice". Investigators' handbook (1991) Rostrum Publications, Romford Essex, UK
31. International Organization for Standardization (2003) Clinical investigation of medical devices for human subjects—Part 1: general requirements, Part 2: clinical investigation plans. DIN EN ISO 14155: Part 1 and 2
32. Comission E (2001) 2001/20/EC—Directive 2001/20/EC OF the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. Off J Eur Communities L 121:34–44
33. Moher D, Schulz KF, Altman D (2001) The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. JAMA 285(15):1987–1991
34. World Medical Association Declaration of Helsinki (2001) Ethical principles for medical research involving human subjects. Bull World Health Organ 79(4):373–374
35. Diamanti-Kipioti A, Papapanou PN, Moraitaki-Tsami A, Lindhe J, Mitsis F (1993) Comparative estimation of periodontal conditions by means of different index systems. J Clin Periodontol 20(9):656–661
36. Chen SY, Liang WM, Chen FN (2004) Factors affecting the accuracy of elastometric impression materials. J Dent 32(8):603–609
37. McCabe JF, Arikawa H (1998) Rheological properties of elastomeric impression materials before and during setting. J Dent Res 77 (11):1874–1880
38. Di Felice R, Scotti R, Belser UC (2002) The influence of the mixing technique on the content of voids in two polyether impression materials. Schweiz Monatsschr Zahnmed 112(1):12–16