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ORIGINAL ARTICLE

Clinical success rates for polyether crown impressions when mixed dynamically and statically

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Abstract The purpose of this study is to compare success rates of dual-viscosity impressions for two types of mixing techniques of the polyether elastomeric impression material. Additionally, influencing parameters on the success rates should be evaluated. The expectation was that there would be no difference between the success rates for the two mixing techniques. Two centres enrolled 290 subjects (727 teeth) into the trial. Patients were randomized for the two types of mixing techniques. One step, dual-viscosity impressions were made with either statically mixed Impregum Soft tray material (SAM) or dynamically mixed Impregum Penta H DuoSoft (DMM). Low viscosity Impregum Garant L DuoSoft was used for both groups. Gingival displacement involved the use of two braided cords. Full-arch trays were used exclusively. Both critical defects and operator errors were assessed for the first impression taken by trained dentists. The primary outcome was impression success. For comparison of the two mixing techniques, the odds ratio for success and the corresponding one-sided 95% confidence interval was calculated by a logistic regression model. To account for the dependence between several teeth within one patient, the method of general estimating equations was used. The overall impression success rate was 35.4%. Both mixing techniques showed equal success rates indicated by an OR of 1.0 and a lower limit of the one-sided 95% confidence interval of 0.71. Using this result to develop the corresponding interval for the difference, it could be shown that the success rate using SAM was at most 8.2% lower than that when using DMM with a probability of 95%. Multivariate logistic regression analysis of other potential influencing factors showed position of finish line (p=0.008, supra compared to mixed), blood coagulation disorder (p=0.021) and the level of training of the clinician (student vs dentist, p=0.008) to

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have an independent influence on the success rate. Dynamic mechanical mixing and the new static mixing of polyether tray material showed nearly equal success rates in the study even though success rates were comparatively low (DMM, 35.3%; SAM, 35.4%).

Keywords Polyether crown impressions · Dual-viscosity impressions · PE polymer

Introduction

Making an impression is a critical step for dentists in the process of creating a laboratory processed restoration. Polyether (PE), introduced in the 1960s, has long been popular among clinicians for providing dimensionally stable impressions [1]. The inherent hydrophilicity of the PE polymer [2] and its accuracy [3] are well established in literature. Additionally, PE has been shown to be reliable in its ability to produce restorations that fit precisely even in challenging clinical situations [4]. Manual mixing of PE is tedious and can result in small voids at the surface of impressions, thus compromising the usefulness of the impression clinically [5]. Thus, automatic mixing devices can be advantageous. In 1985, a static automixing (SAM) system was introduced which could reduce or eliminate voids in low-viscosity vinyl polysiloxane impression materials [6]. However, medium and heavy body polyether impression materials could not be used in these automixing systems up to now, but were available for use with dynamic mechanical mixing systems (DMM) as an alternative to spatula mixing which is known to produce some air voids [5]. For PE, a dynamic mechanical mixing [7] system has been available for some time and capable of producing a thorough homogeneous mix, free of voids [8]. It was also shown that DMM mixing represented a marked improvement over the traditional hand-mixing methods [9]. This DMM technique can be regarded as the "gold standard" for mixing PE tray consistency material and it is well received in many dental offices. However, the DMM machine occupies counter space, is costly and requires access to an electrical outlet.

Recently, a SAM system for PE tray consistency was introduced [10]. In a recent study, the preference of mixing techniques was assessed and it was found that all participant groups preferred DMM mixing to auto or hand mixing [8]. However, the SAM system for polyether might be ideal for dentists who have not yet made the investment in a DMM unit, or who are limited to using a DMM unit in selected operatories [10]. The efficiency of mixing and the clinical application of this new device for PE, however, remain to be evaluated. The assessment of clinical success in impression techniques is challenging and has been addressed in several studies [4, 8]. Johnson et al. [4] proposed in their study dealing with the success rates of polyether and vinyl polysiloxane impressions, an evaluation form to assess the clinical success of impressions taken by students.

Some reformulation of the PE impression material was necessary for use in the SAM. For instance, the ratio of PE catalyst to base paste was adjusted from 5:1 to 2:1 for SAM cartridge mixing. The reactive components are the same as those used in the polybags of the DMM, but some changes were made to non-reactive components. Triglycerides are very important in providing a unique rheology of PE. The amount of triglycerides in SAM is only about one third of that in DMM. In SAM, a non-reactive polyether type is used as a diluent in the base paste, whereas DMM employs a mixture of low viscous carbohydrates and high molecular weight polymers. In addition, the overall filler load in SAM is nearly twice as high as that in DMM. To improve stability of the set material, a stabilizer has been added to the SAM formulation (information supplied by the manufacturer).

Thus, the purpose of this randomized controlled clinical trial was to compare first impression success rates of dual-viscosity impressions for two types of mixing techniques (DMM versus SAM, see Fig. 1) of the PE tray material using a standardized evaluation form. Additionally, influencing parameters on the success rates were evaluated. The expectation was that there would be no difference between the success rates for the two mixing techniques and that several independent variables have an influence on the success rate.

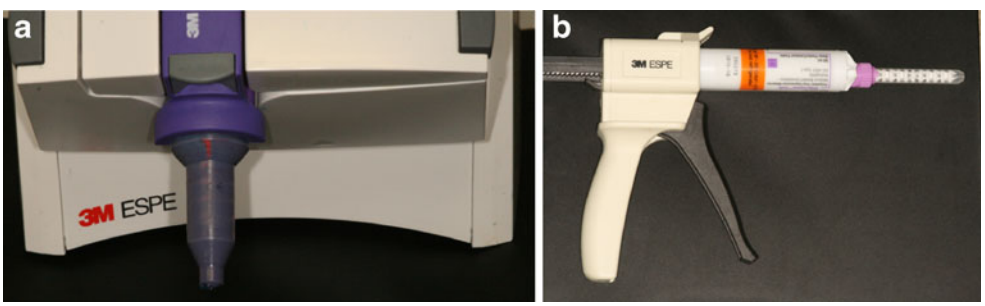

Fig. 1 Dynamic mechanical mixing unit (Pentamix 3, 3M ESPE (**a**)) and hand-dispensed cartridge mixing system (3M ESPE (**b**))

Material and methods

Patients

Two centres participated in the trial, the Department of Prosthetic Dentistry of the University Hospital Heidelberg and the Department of Prosthetic Dentistry of the University Clinic Homburg/Saar. The study was approved by the review board of the University of Heidelberg (S-295/2008) and the ethics committee of the medical society of Saarland. The impressions were made by fourth- and fifth-year dental students and faculty dentists of the Department of Prosthodontics at the University of Heidelberg and of the Department of Prosthodontics at the University of Homburg/Saar. The students received didactic training, followed by practical training which included placement of retraction cords and taking two impressions. All patients signed an informed consent form. The inclusion criteria for the participants were the following: need for at least one crown (full metal crown, metal ceramic crown, all-ceramic crown and telescopic crown); age of subject ≥18 years and a signed consent form. Exclusion criteria were: pregnancy or lactation.

To assess the influence of several parameters on the success rate of the impressions, relevant patient and treatment characteristics were gathered using a case report form. The following were documented as baseline data: gender, age, number of teeth to be prepared, dental arch, the presence of a blood coagulation disorder (which might complicate taking the impression) and the status of the person taking the impression (student vs. dentist). Additionally, the following data with respect to the treatment was gathered: position of the teeth, position of the finish line (supragingival, subgingival, mixed), use of cords with epinephrine, type of tray (standardized or individual tray) and the individual who evaluated the impression.

Randomization

The allocation of the mixing technique to each patient was done by a stratified block randomization, the details of which were not known by the treating dentists. A block randomisation with a variable block length was used to achieve equal group sizes for DDM and SAM for both centres. Furthermore, the randomisation was stratified for the factors “centre” and “number of prepared teeth per patient” which were expected to have an influence on the impression success rate and therefore should be well balanced between both groups (six strata: two centres and three levels for number of teeth: one to two, three to four or five to six teeth). On the basis of the prepared randomization list, sealed numbered envelops were created by an independent person, for each centre and for the different numbers of teeth. For each patient the number of teeth to be prepared was identified and immediately before the impression was taken, the envelope next in sequence with the suitable number of teeth was opened. The mixing technique that was specified on the randomisation sheet was applied.

Impression materials and clinical procedures

The impression technique and materials did not differ from those normally used at both study locations. The material was provided from the manufacturer ensuring that the material came from the same lot. Gingival displacement involved the use of two braided cords (Ultrapak Cord or Ultrapak E Cord, Ultradent Products Inc, South Jordan, Utah; Surgident, Sigma Dental Systems-Emasdi GmbH, Jarplund-Weding, Germany) where the initial smaller cord remained in the sulcus at the time the impression was made [11]. Full-arch trays were used exclusively with either a stock metal (Rim-Lock, Dentsply/Caulk, Milford DE, USA) or custom tray (Light-cured Tray Material, Omnident, Rodgau, Germany). Adhesive was applied to the impression tray per manufacturer’s direction (Polyether Adhesive, 3M ESPE).

A one-step, dual-viscosity impression technique was used where the medium- or heavy-bodied material was placed in the full-arch impression tray while the low viscosity material was injected onto the prepared tooth/teeth. The tray material was dispensed by random assignment either from the DMM device (Pentamix 3, 3M ESPE) or a static automixer (SAM) from cartridges. The colour of the two tray impression materials was identical. The injected low viscosity was the same for both groups: SAM mixed ISO Type 3 Impregum Garant L DuoSoft (3M ESPE). The tray viscosities consisted of either DMM ISO Type 1 Impregum Penta H DuoSoft or SAM ISO Type 2 Impregum Soft (3M ESPE).

Evaluation of the impressions

In order to use the same basis for the evaluation of the success rates for the two impression (mixing) systems, only the first impressions taken were used in this study. Impression trays used for “first impressions” were marked to avoid confusing them with additional impressions made for the same patient when needed.

Six experienced clinicians (all with more than 4 years of experience using PE impression materials), blinded with respect to the impression mixing technique, evaluated the impressions based on criteria modified from that originally developed by Johnson et al. [4]. Both, critical impression

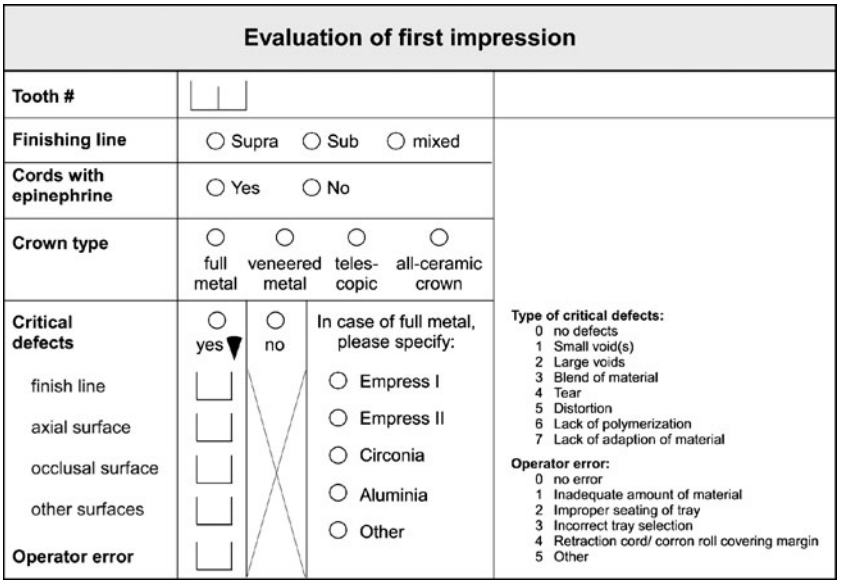

Fig. 2 Data sheet for the evaluation of first impressions (cutout of the case report form, originally in German)

defects and operator errors were assessed (see Fig. 2). When such existed, the raters identified the most severe critical defect in a given impression (e.g. voids, blend of material) and the type of operator error (e.g. improper seating of tray; see Fig. 2). Each impression was rated by one examiner who was not involved in or viewed the patient treatment. If there were one or more critical defects, the location of the most severe critical defect was described. If a critical defect or an operator error was found, the impression was rated "not successful", even when the critical defect was located at one prepared tooth, and the other prepared teeth (if available) had no critical defects. However, in some cases the dentist who treated the patient might have decided to use the impression nevertheless.

All participating raters were trained before the start of the trial. The training was performed in a 3-h session first using close up images of defective and acceptable impressions and then evaluation of several original impressions. The data form and criteria for critical defects were presented and discussed during this training. Two raters from Homburg/Saar and four raters from Heidelberg were trained during this session.

Sample size

Since no information about the correlation among the teeth within one patient was available before the start of the trial, a sample size calculation was carried out assuming only one study tooth per patient keeping in mind that the final analysis with more than one tooth per patient would augment the precision of the result. We assumed a length of 0.33 for the distance from the lower limit of the one-sided 95% confidence interval to the estimator of the odds ratio for the success rates of the impressions. Based on the expectation of an equal success rate of approximately 60% for both groups, this corresponds to a one-sided 95% confidence interval for the difference of the success rates with a width of 10% from the lower limited to the estimator. These assumptions resulted in a needed sample size of 138 patients per group (nQuery Advisor 6.1).

Statistical analysis

The main objective of the trial was the comparative assessment of the success rates for first impressions for the two types of mixing technique.

As similar success rates were expected, the primary analysis was performed in two analysis populations in analogy to non-inferiority trials. Results obtained by intention-to-treat-analysis only, might have been misleading in terms of a higher chance of overlooking an existing difference. Therefore, a "per protocol" analysis of the primary endpoint was added to verify the results only for subjects (or teeth) which were treated and documented in high concordance with the procedures defined in the protocol (Fig. 3).

The two analysis populations were as follows: the full-analysis-set (FAS) included all patients with a valid informed consent and a documented primary endpoint (successful impression or critical defect). The analysis of the FAS was conducted according to the intention-to-treat principle where each patient was analysed as randomized. The per protocol set included all patients of the FAS who were treated as randomized and whose documentation of the primary endpoint and corresponding secondary endpoints (type of defect) were completed for all assessed teeth

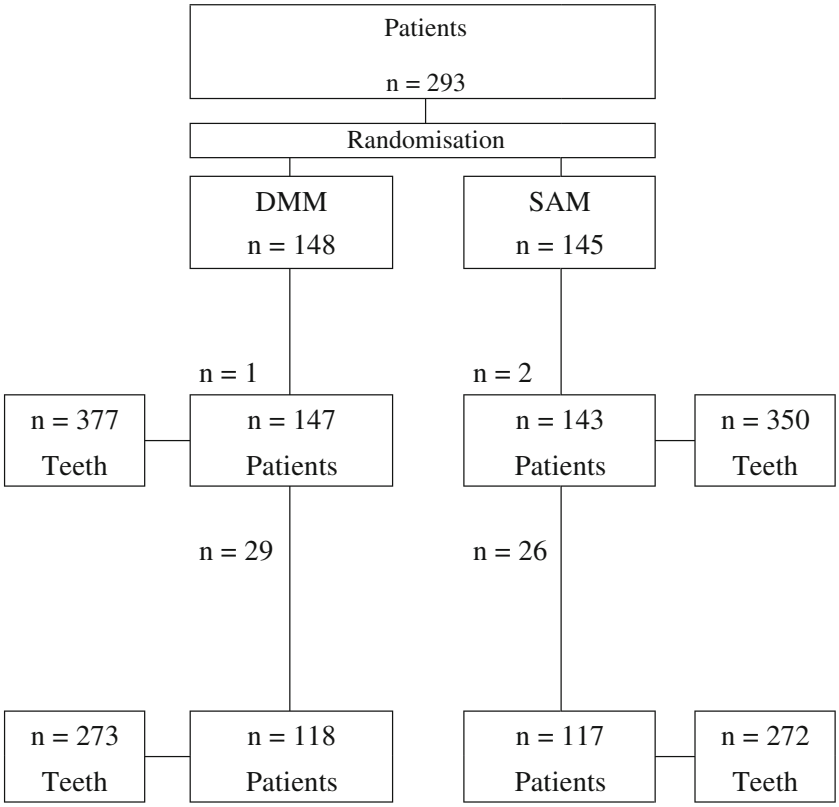

Fig. 3 Flow chart showing the reasons for exclusion of analyses sets and the resulting numbers of patients (and prepared teeth) analysed. A number of 293 patients were included into the trial and randomly assigned to the mixing techniques SAM or DMM. Three patients had to be excluded from the full analysis set due to missing ability to give informed consent for the trial or missing documentation of the primary endpoint. Additionally, 29 (DMM) and/or 26 (SAM) patients, respectively, were excluded from the per protocol set

as specified in the protocol. Analyses other than the primary analysis were only based on the FAS.

For the primary comparison of the two mixing techniques, the odds ratio for success (SAM in relation to DMM) and the corresponding one-sided left limited 95% confidence interval as well as the two-sided 95% confidence interval were calculated. A logistic regression model was used which included mixing technique, number of prepared teeth and attending dentist as fixed factors. To account for the dependence between several teeth within one patient, the method of general estimating equations (GEE) was used.

Furthermore, an exploratory analysis was done to identify other possibly influencing parameters on the success rates. Therefore, we evaluated the influence of the factors of position of tooth, dental arch, position of finish line, use of cords with epinephrine, type impression tray, blood coagulation disorder, type of clinician and evaluator using a univariate as well as a multivariate logistic regression model.

Additionally, descriptive statistical analyses were performed in order to show the distribution of baseline and treatment parameters in both groups. The distributions of continuous data were given as mean and standard deviation or as median, interquartile range and range. Categorical data were described by absolute and relative frequencies. For comparison of distributions of continuous or ordinal variables between both groups, the Mann–Whitney *U* test was used and for comparisons of dichotomous data, the Chi-square test was employed. All statistical tests were carried out as two sided. Statistical analysis was performed using SAS Version 9.1 for Windows.

Results

In total, 290 patients involving 727 teeth prepared for crowns were recruited for the present trial between December 2008 and January 2010. Regarding types of crowns placed, 6.5% were complete gold, 39.1% metal ceramic, 22.9% ceramic and 31.4% telescopic crowns.

In total, there were 147 impressions using DMM (64 in females and 83 in males) and 143 impressions using SAM (70 in females and 73 in males). There were no significant differences with respect to the patient and

Table 1 Comparison of baseline and treatment parameters for DMM and SAM referring to the number of patients

	DMM (N=147)	SAM (N=143)	Total (N=290)	p value
Age	58.5±12.8	57.3±12.1	57.8±12.5	0.303
Gender				
Female	64 (43.5%)	70 (49.0%)	134 (46.2%)	0.355
Male	83 (56.5%)	73 (51.0%)	156 (53.8%)	
Blood coagulation disorder				
No	140 (95.2%)	137 (95.8%)	277 (95.5%)	0.816
Yes	7 (4.8%)	6 (4.2%)	13 (4.5%)	
Number of prepared teeth				
1	42 (28.6%)	41 (28.7%)	83 (28.6%)	0.965
2	43 (29.3%)	43 (30.1%)	86 (29.7%)	
3	25 (17.0%)	27 (18.9%)	52 (17.9%)	
4	22 (15.0%)	21 (14.7%)	43 (14.8%)	
5	9 (6.1%)	7 (4.9%)	16 (5.5%)	
6	5 (3.4%)	4 (2.8%)	9 (3.1%)	
14	1 (0.7%)	0 (0.0%)	1 (0.3%)	
Impression tray				
Stock metal	125 (85.6%)	117 (81.8%)	242 (83.7%)	0.382
Custom	21 (14.4%)	26 (18.2%)	47 (16.3%)	
Centre				
Heidelberg	120 (81.6%)	117 (81.8%)	237 (81.7 %)	0.967
Homburg	27 (18.4%)	26 (18.2 %)	53 (18.3 %)	
Operator				
Student	80 (54.4%)	72 (50.3%)	152 (52.4%)	0.488
Dentist	67 (45.6%)	71 (49.7%)	138 (47.6%)	
Evaluator				
1	40 (27.2%)	28 (19.6%)	68 (23.4%)	0.079
2	32 (21.8%)	20 (14.0%)	52 (17.8%)	
3	25 (17.0%)	31 (21.7%)	56 (19.3%)	
4	23 (15.6%)	38 (26.6%)	61 (21.0%)	
5	3 (2.0%)	5 (3.5%)	8 (2.8%)	
6	24 (16.3%)	21 (14.7%)	45 (15.5%)	

The p values refer to the comparison of DMM versus SAM for each factor separately

treatment characteristics between SAM and DMM, but the distribution of the evaluators showed a moderate imbalance for three of the six evaluators (Table 1). Furthermore, the comparison of baseline parameters referring to the number of teeth prepared showed significant differences for dental arch and position of the finish line (Table 2).

The impression success rates were equal in both groups with 35.3% for DMM and 35.4% for SAM (full analysis set, Tables 3 and 4). The odds ratio was OR= 1.0 (one-sided 95% confidence interval, [0.71, ∞]). The corresponding one-sided 95% confidence interval for the difference in absolute success rates was [−8.2%; ∞]. Thus, with a probability of 95%, the success rate when using the SAM is at most 8.2% lower than the success rate with DMM. The analysis confined to patients who were treated as randomized and whose documentation was complete and in complete accordance with the protocol (per protocol set), yielded similar results and the same conclusion (Table 3). The most common critical defect was located on the preparation finish line (98.2%).

Univariate analyses of further potential influencing factors showed position of finish line (p=0.014, supra compared to mixed), use of cords with epinephrine (p< 0.001), type of full-arch impression tray (p=0.017), blood coagulation disorder (p=0.012), the experience of the person who took the impression (dentist, student, p< 0.001) as well as the evaluators 1 to 5 (p<0.001 to 0.009 when compared to evaluator 6); all to have an influence on the success rate (Table 4). Despite examiner training before the start of the trial, there was variation among evaluators regarding the success or alternately defect rate (Table 1). Among the six evaluators, the mean impression defect rate was 65% with a high for evaluator 2 of 83% and with a low of 38% for evaluator 6. With the exception of cords with epinephrine and impression tray, these factors also showed a relevant influence when analysed within the multivariate model. Thus, the position of finish

Table 2 Comparison of baseline parameters for DMM and SAM referring to number of prepared teeth

	DMM (N=377)	SAM (N=350)	Total (N=727)	p value
Position of the teeth				
Anterior	143 (37.9%)	145 (41.4%)	288 (39.6%)	0.335
Posterior	234 (62.1%)	205 (58.6%)	439 (60.4%)	
Jaw				
Maxilla	200 (53.1%)	231 (66.0%)	431 (59.3%)	<0.001
Mandible	177 (46.9%)	119 (34.0%)	296 (40.7%)	
Position of the finish line				
Supra	47 (12.9%)	28 (8.1%)	75 (10.6%)	0.019
Sub	171 (47.0%)	195 (56.4%)	366 (51.5%)	
Mixed	146 (40.1%)	123 (35.5%)	269 (37.9%)	
Missing data	13	4	17	
Use of cords with epinephrine				
No	241 (66.6%)	228 (66.5%)	469 (66.5%)	0.977
Yes	121 (33.4%)	115 (33.5%)	236 (33.5%)	
Missing data	15	7	22	

The p values refer to the comparison of DMM versus SAM for each factor separately

line (p=0.008, supra compared to mixed), blood coagulation disorder (p=0.021) and dentist versus student (p=0.008) had an independent influence on the success rate even when adjusted for all covariates in the multivariate model. For patients without a blood coagulation disorder, the chance to get a successful impression is better by a factor of 4.48 (Table 4). In contrast, the number of teeth prepared, the position of the tooth (anterior or posterior) and the dental arch seemed to have only a minor or no influence.

Discussion

The primary aim of this clinical trial was to compare the first impression success rate for two types of mixing techniques (DMM versus SAM) of the PE tray material. Both mixing techniques showed equal success rates in the study since the confidence interval indicates that the success rate of the SAM technique in relation to the DMM techniques could differ by no more than 8%. Though success rates varied among evaluators, no interaction could be observed between the evaluator and the mixing techniques within the multivariate analysis thus did not detract from the overall result of the comparability of both mixing techniques. However, several variables had an independent influence on the success rate.

Although it was the intention to consider as many confounding variables as possible, there could be other variables that might have an influence on the success rate too. Prior to the start of the study, a sample size calculation was performed and it appeared to be necessary to include more than one study site to achieve the required sample within a reasonable period of time. Thus, the study was performed at two sites. However, this approach is challenging and it could not be guaranteed that marginal differences in the clinical procedure have occurred. Although all first impressions were evaluated by trained dentists, the influence of the evaluator on the success rate could not be eliminated. However, the observed different defect rates among evaluators occurred for both mixing techniques and in both study locations. Thus this finding seems to be acceptable.

Table 3 Odds ratios (OR) and corresponding one-sided and two-sided confidence intervals for successful impressions for SAM in relation to DMM calculated for the full analysis set and for the per protocol set

	No.	OR	Lower limit of one-sided 95% CI	Two-sided 95 % CI	p value
Full analysis data set (FAS)					
Primary analysis	727	1.00	0.71	0.67–1.50	0.99
With further covariates	688	0.99	0.71	0.66–1.50	0.98
Per protocol data set (PP)					
Primary analysis	545	1.02	0.71	0.66–1.58	0.91
With further covariates	515	0.95	0.65	0.60–1.50	0.84

The primary analysis was based on a GEE model including the patient as a cluster and mixing technique, number of teeth and operator as fixed factors according to the protocol. In addition, results are shown for the multivariate analysis using a GEE model including all further covariates as given in Table 4

Table 4 Analysis of possible influencing factors on success of impressions

	Successful impression	Impression with critical defect	*p* value (univariate logistic regression)	*p* value (multivariate logistic regression)	OR (multivariate logistic regression)
Mixing technique					
DMM	133 (35.3%)	244 (64.7%)	0.966	0.982	1.00
SAM	124 (35.4%)	226 (64.6%)			
Number of prepared teeth					
1	28 (33.7%)	55 (66.3%)	0.486	0.933	0.97
2	68 (39.5%)	104 (60.5%)	0.403	0.348	1.39
3	50 (32.5%)	104 (67.5%)	0.732	0.967	1.02
4	55 (32.0%)	117 (68.0%)	0.743	0.601	0.84
≥5	56 (38.4%)	90 (61.6%)			
Position of tooth					
Anterior	107 (37.2%)	181 (62.8%)	0.410	0.577	1.12
Posterior	150 (34.2%)	289 (65.8%)			
Jaw					
Maxilla	151 (35.0%)	280 (65.0%)	0.830	0.959	1.01
Mandible	106 (35.8%)	190 (64.2%)			
Position of finish line					
Supra	38 (50.7%)	37 (49.3%)	0.014	0.008	2.46
Sub	118 (32.2%)	248 (67.8%)	0.475	0.055	0.62
Mixed	94 (34.9%)	175 (65.1%)			
Missing data	7	10			
Cords with epinephrine					
No	127 (27.1%)	342 (72.9%)	<0.001	0.079	0.53
Yes	125 (53.0%)	111 (47.0%)			
Missing data	5	17			
Impression tray					
Stock metal	194 (33.1%)	392 (66.9%)	0.017	0.289	0.74
Custom	61 (43.9%)	78 (56.1%)			
Missing data	2	0			
Blood coagulation disorder					
No	251 (36.4%)	439 (63.6%)	0.012	0.021	4.48
Yes	6 (16.2%)	31 (83.8%)			
Operator					
Student	110 (28.1%)	282 (71.9%)	<0.001	0.008	0.46
Dentist	147 (43.9%)	188 (56.1%)			
Evaluator					
1	69 (34.0%)	134 (66.0%)	<0.001	0.184	0.53
2	20 (16.8%)	99 (83.2%)	<0.001	0.001	0.20
3	53 (42.1%)	73 (57.9%)	0.002	0.113	0.48
4	34 (25.0%)	102 (75.0%)	<0.001	0.066	0.41
5	11 (35.5%)	20 (64.5%)	0.009	0.009	0.23
6	70 (62.5%)	42 (37.5%)			

Absolute and relative frequency of successful impressions and impressions with critical defects with respect to the specific factor; *p* values received from a univariate or multivariate logistic regression using GEE and odds ratio (OR) from multivariate analysis, too. The results presented were obtained by analyses based on the full analysis set and included all prepared teeth. *p* values and OR given refer to the last category of the respective factor

It should be kept in mind that the present study assessed the clinical success rate and not the accuracy or dimensional stability of the materials, which could be done in a laboratory study.

The present study showed that there were no relevant differences between the two mixing techniques with respect to clinical success. Although this result seems not to be surprising at the first glance, the reformulation and the

effectiveness of mixing of the tray material could have had an influence on the clinical success. For instance, operator errors could have been higher using the hand-dispensed cartridge mixing system. However, both the handling of the cartridge system and the clinical performance of the newly formulated material seems to be acceptable compared to the gold-standard of machine mixing.

Furthermore, variables which have an independent influence on impression success have been identified. Luthardt et al. [12] assessed the clinical parameters influencing the accuracy of one- and two-stage impressions and found the presence of blood as an important factor. The present study showed that the presence of a blood coagulation disorder negatively affects the success rate for impressions. Thus, the absence of blood appears be essential for the success and the accuracy of the impression. Additionally, the present study showed that the use of retraction cords with epinephrine tended to have a positive effect on the success rate. Kombuloglu et al. [13] found that epinephrine-impregnated cord systems were clinically successful, thus consistent with the results of the present study and found that these cords were more effective than nonmedicated cords. Weir et al. [14] assessed the effectiveness of mechanical–chemical tissue displacement methods and confirm the results of the present study with respect to the usage of cords with epinephrine.

Moreover, the degree of experience/education was shown to have an influence on clinical success rates. Johnson et al. [4] assessed the success rates for polyether and vinyl polysiloxane impressions using a standardized evaluation form and found that 50% of the PE impressions using full-arch trays were successful. In the present study, the success rate was lower in both operating groups (student, dentist). However, the results for dentists in the present study are comparable to the results of Johnson et al. (43.9% versus 50%), especially considering that 166 out of 191 impressions in the cited study involved a single prepared tooth whereas only 29% of the impressions in the present study were of a single prepared tooth. Additionally, it could be speculated that the lower success rate in the students of the present study compared to the students in the study of Johnson et al. [4] could be a result of the different experience levels. In the present study, the students had average experience with impressioning, whereas in the study of Johnson et al. the students had extensive experience. Additionally, it has to be taken into consideration that in the present study, about 90% of the teeth were prepared completely or partially subgingival and consequently the impression was challenging [15, 16]. In this context it has to be taken into consideration that in the aforementioned study, most of the critical defects of impressions were observed on the finish line which is confirmed by the present study. This area is examined by clinicians first since this area is thought to be the most important for clinical success [17]. Thus, the raters might have tended to categorize defects at this location more often as "critical defects" than at other locations.

A reason for the lower success rate in the present study in general could be that the clinical situation for making impressions is challenging in the dental school environment since many patients who seek dental treatment have neglected dental care for some time and present with significant loss of tooth structure [4].

The finding that both mixing techniques under examination did not show different success rates might be of interest to practitioners who wish to use static automixing with PE material. Additionally, the present study demonstrated that several factors have an influence on the success rates. This may also be important to many dental practitioners since the selection of the most suitable displacement cord is essential in everyday practice. Future studies could focus on the assessment of other variables which might have an additional influence on the success rate of dental impressions.

Conclusions

Within the limitations of this clinical trial, the following could be concluded: dynamic mechanical mixing and the new static mixing of polyether tray impression material showed nearly equal success (DMM, 35.3%; SAM, 35.4%) with a confidence interval indicating that static automixing could be no more than 8% less successful than dynamic mechanical mixing (one-sided 95% confidence interval, [−8.2%; ∞]). Also, the position of finish line (p=0.008, supra compared to mixed), blood coagulation disorder (p=0.021) and the experience of the clinician who took the impression (dentist, student; p=0.008) had an independent influence on the success rate even when adjusted for all covariates in the multivariate model.

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

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