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Gingival displacement methods performance prior impression making: A prospective, comparative randomized clinical trial

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Marie Desclos-Theveniau: Methodology, formal analysis, writing – review & editing,

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Anne-Laure Sérandour: Conceptualization, methodology, formal analysis,

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Hugues Colombel: Investigation.

We decided to improve manuscript by considering recommendations and editor's comments. We distinguished changes in the manuscript document by putting them in bright blue font.

We considered the following points:

Comments #1: Page 11 section discussion "Add references"

Author response: We clarified by modifying the sentence "Racestypine solution and Racegel contain aluminum chloride that have been reported to provide hemostasis (manufacturer data)^{3,5}".

Comments #2: Fig. 2 Change models to casts, Remove trademark symbols, Change "the gum" to "gingiva", Change software to software program.

Author response: We did modifications on Figure 2.

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Declarations of interest: All the authors confirm that they have no conflict of interest with regard to the laboratory and this work to report.

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Marie Desclos-Theveniau: Methodology, formal analysis, writing – review & editing; **Hugo Abgrall:** Investigation; **Vincent Bar:** Investigation; **Françoise Basle:** Investigation; **Dominique Basle:** Investigation; **Marie-Joseph Dautel:** Investigation; **Jacques Rubin:** Investigation; **Franck Delanoue:** Investigation; **Etienne Lefrançois:** Formal analysis; **Anne Dautel:** Supervision; **Anne-Laure Sérandour:** Conceptualization, methodology, formal analysis; **Gwenvael Le Guicher:** Conceptualization, methodology, formal analysis; **Hugues Colombel:** Investigation.

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CLINICAL RESEARCH

Gingival displacement before impression making: A prospective, comparative randomized clinical trial

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ABSTRACT

Statement of problem. Gingival displacement is used in prosthodontics to obtain an accurate impression. However, randomized clinical trials to analyze the performance of different gingival displacement products are lacking.

Purpose. The purpose of this prospective, comparative randomized clinical trial was to evaluate the clinical effectiveness of 3 gingival displacement techniques: Racegel cordless, Racegel with a cord, and Racestypine with a cord.

Material and methods. A prospective, multicenter randomized, open label, 3-arm parallel group study was carried out in private dental practices. Patients with prepared teeth with healthy gingiva were recruited to make impressions before and after gingival displacement, which were

digitized. Lateral and vertical gingival displacements were measured with computer-aided 3-dimensional analysis performed by a single operator who was blinded to the technique and the patient. For mean lateral gingival displacement, each gingival displacement method was compared with a required clinical value of 200 μm with the Student *t* test. The comparison of means among the 3 groups was performed using an ANOVA. Periodontal indices were recorded immediately and 7 to 14 days after gingival displacement. The percentages were compared with the chi-squared test or the Fisher exact test ($\alpha=.05$ for all tests).

Results. Eighty-eight participants were enrolled. The mean lateral gingival displacement obtained by Racestypine with a cord ($253 \pm 59 \mu\text{m}$, $P<.001$) and by Racegel with a cord ($247 \pm 61 \mu\text{m}$, $P<.001$) were significantly higher than 200 μm . Lateral displacement observed with Racegel cordless was $207 \pm 57 \mu\text{m}$ ($P=.53$). For vertical gingival displacement, no difference among the 3 techniques was found. The astringent effect of these products was confirmed by the absence of crevicular fluid or bleeding. No periodontal damage was observed immediately or 7 to 14 days after displacement.

Conclusions. The study showed that cord impregnated with Racestypine and Racegel with or without a cord provided a sufficient sulcus opening before impression making in prosthodontics, consistent with the clinical requirements for lateral displacement.

CLINICAL IMPLICATIONS

The lateral gingival displacement with cord impregnated with Racestypine or Racegel with or without a cord was greater than 200 μm , the required clinical displacement value. This study also confirmed the efficacy of these techniques in achieving hemostasis.

The reversible deflection of the marginal gingiva away from the tooth, termed gingival displacement, has been a standard procedure in prosthodontics to obtain an accurate impression, an essential step for a restoration with an acceptable fit. Displacement cords impregnated with astringents or hemostatic agents has been the mechanochemical method used by most dentists.¹ Among the different chemical agents, Racestypine solution (Septodont) is an astringent containing 25% aluminum chloride to decrease the exudation of gingival fluids and to achieve hemostasis.²⁻⁶ The sulcular opening obtained with a saturated cord has been reported to provide increased displacement and decreased bleeding as compared with other displacement techniques.^{7,8} However, excessive force during cord insertion has been reported to induce hemorrhage or to damage the sulcular and junctional epithelium, especially by an inexperienced clinician or in a patient with a thin periodontal biotype.^{4,9-14}

To avoid gingival trauma, cordless systems such as Racegel (Septodont) have also been developed. Racegel is a gel that contains 25% aluminum chloride, oxyquinol, and other ingredients. Its viscosity increases when in contact with the gingival tissues and mechanically displaces the gingiva. It can be either individually injected into the sulcus or placed with a cord. Cordless displacement materials have been reported to be less invasive, less stressful for the patient, and quicker to apply for the clinician.¹⁵⁻¹⁷ The performance of Racegel has been evaluated,¹⁸ but with a different measurement method than the conventional one.^{7,8,19-23} Clinical data on the gingival displacement of this gel are lacking. An assessment is needed of whether gingival displacement in a lateral direction allows sufficient thickness to prevent tearing and distortion upon removal of the impression material.^{2,8,24}

Randomized clinical trials on gingival displacement with a low risk of bias are lacking,^{4,5,16,20,21,25-27} and the authors are unaware of clinical trials on prepared teeth by multiple dentists in private practice to determine the true clinical situation.^{28,29} Most of the studies assessed only the lateral gingival displacement (sulcus width) defined as the horizontal distance between the crest of the gingiva before and after displacement.²¹ A minimum of 200 μm in lateral displacement has been considered necessary for efficient gingival displacement.²⁴ The measurements in these studies were made under a microscope from slice sections of poured casts before and after displacement. This method limited analysis to only one specific tooth site and a unique parameter.^{7,8} Recently, a computer-aided 3-dimensional (3D) analysis system was developed to accurately assess the gingival displacements at multiple locations around the tooth, both in the vertical and horizontal directions.¹⁹⁻²¹ The vertical gingival displacement (sulcus depth) was identified as the vertical distance between the crest of the gingiva before and after displacement.

In the present study, a post-marketing clinical follow-up investigation was conducted to collect the clinical performance and safety data of Racegel and the Racestypine solution. It was a prospective, multicenter randomized, open label, 3-arm parallel group clinical trial (PROBE) design³⁰ that allowed the quantification of lateral and vertical gingival displacements obtained by using 3 gingival displacement techniques: Racestypine solution with a cord, Racegel with a cord, and Racegel cordless. The gingival displacement was measured with conventional impression digitalized and 3D analysis.¹⁹⁻²¹ The satisfaction of participants and clinicians and the changes in the gingival and periodontal tissues were also assessed. The research hypothesis was that the 3 gingival displacement techniques would provide an efficient lateral gingival

displacement before impression making in prosthodontics, consistent with the required clinical value of at least 200 μm .²⁴

MATERIAL AND METHODS

This clinical trial was conducted in accordance with the ethical principles of the Declaration of Helsinki. The investigation was approved by the Ethics Committee in France (committee of protection of persons) and registered at the Clinical Trials Database under the number NCT04861285 (ClinicalTrials.gov). The goal of this study was to determine whether the lateral gingival displacement of 3 methods was at least 200 μm , the required clinical value.²⁴ Sample size was calculated based on a difference of 50 μm from the minimal lateral gingival displacement of 200 μm , with a standard deviation of 70 μm , an alpha risk of 5%, a power of 90%. Therefore, the estimated number of participants needed for each group was 23. To compensate for dropouts and withdrawals or potentially unusable dental impressions, 30 participants were targeted to be enrolled in each group. A computer-generated block randomization list was created. A system of opaque, sealed, and numbered randomization envelopes was used to assign the gingival displacement method. Participants were randomly allocated in a 1:1:1 ratio corresponding to 3 parallel groups: Racegel with a cord, Racegel cordless, and Racestypine with a cord.

Participants were selected according to the inclusion and exclusion criteria summarized in Table 1. Informed consent was obtained for all participants. Recruitment was conducted over 6 months between May and November 2021. The clinical investigation was carried out by 8 dentists (investigators) in 5 private practices. After an initial screening to select and inform participants, 2 interventions were performed at 0 day

(Day 0) and 7 to 14 days after displacement (Day 7 to 14), respectively (Fig. 1). At Day 0, the Silness-Löe plaque index³¹ and gingival biotype³² were evaluated (Fig. 1). Impression before gingival displacement was made with the 2-phase impression technique and polyvinyl siloxane material (Aquasil Light and Aquasil Putty soft; Dentsply Sirona). One of the 3 displacement techniques was then assigned. For Racegel with a cord, a sufficient amount of gel and then 1 of 6 available sizes of cord (Ultrapak knitted non-impregnated; Ultradent Products, Inc) was inserted into the sulcus of the prepared tooth and left in place for 2 minutes. After removing the cord, the sulcus and prepared tooth were rinsed twice and gently dried. For Racegel cordless, sufficient gel was directly applied into the sulcus. After 2 minutes, the gel was rinsed off and the sulcus was gently dried. For Racestypine with a cord, a cord soaked in Racestypine solution was applied into the sulcus for 2 minutes. For the 3 groups, visual inspection was performed to determine bleeding in the sulcus, absence of crevicular fluid, and sufficient sulcus opening. An impression was made after displacement. At the end of the visit, participants also answered a few questions about discomfort and pain intensity during gingival displacement. To assess pain, no local anesthetic was administered to the patient. At day 7 to 14, a second clinical intervention was then planned to determine whether all tissues had returned to normal (Fig. 1).^{33,34} The clinician also responded to a questionnaire.

Impressions before and after gingival displacement were scanned to create 3D casts in STL files, which were then imported to an inspection software program (GOM Inspect software 2019; GOM Metrology) to be superimposed and analyzed blindly to the technique and the patient (Fig. 2).^{35,36} The mean of gingival displacement was obtained from 3 to 6 measurements around the tooth (Fig. 2).²¹

Statistical analyses were made with a software program (JMP, v15.0.0; JMP Statistical Discovery LLC). All analyses were 2-tailed tests ($\alpha=.05$). Descriptive statistics were presented according to the type of data: means and medians for the quantitative variables along with measures of dispersion (standard deviation and range) and frequencies/percentages for the nominal variables. In each group, the mean lateral gingival displacement observed was compared with the required clinical value of 200 μm (expected performance) with the Student *t* test (1 sample). The 95% confidence interval of the mean was also calculated. For continuous variables, comparison of means among the 3 groups was performed by using analysis of variance (ANOVA). The Wilcoxon (1 sample and 2 sample) nonparametric test was used to compare data in the analysis of subgroup gingival biotypes. The percentages were compared with the chi-squared test or the Fisher exact test ($\alpha=.05$ for all tests).

RESULTS

A total of 88 participants was enrolled in this study (Fig. 3). Twenty-nine were allocated to the Racegel with a cord group, 30 to the Racegel cordless group, and 29 to the Racestypine with a cord group. No randomization error, withdrawals, or discontinuations occurred. Distorted impressions that prevented measuring gingival displacements occurred in 8 participants (Fig. 3). No adverse events were reported.

Baseline characteristics of enrolled participants revealed a male/female ratio of 50/50 and a mean age of approximately 55 years (range: 19 to 85 years) for each group (Table 2). For most (67%) participants, the teeth were prepared before Day 0 (Table 2). In 70% of the preparations, the margins were subgingival and juxtagingival in 30% (Table

2). The premolars and molars were the teeth most included in each group, whereas the canines were the teeth less often prepared (Table 2).

A total of 52% of participants had a gingival biotype A1 with a thin and scalloped periodontium, and 36% had a gingival biotype A2 with a thick and scalloped periodontium (Table 2). Gingival biotype B corresponding to a flat and thick periodontium was only found in 11% of participants. Plaque index assessment revealed that 97% of participants had a thin layer of or no gingival plaque (Table 2). The 0 cord size was most often chosen by the clinician (50%; Table 2).

Distributions of mean lateral displacement values per group were illustrated with boxplots (Fig. 4). The cord techniques provided a mean lateral displacement significantly greater than the required clinical value of 200 μm .²⁴ The mean \pm standard deviation lateral displacement was 253 \pm 59 μm for Racestypine with a cord (IC95% [230–275]; $P < .001$) and 247 \pm 61 μm for Racegel with a cord (IC95% [224–271]; $P < .001$). The Racegel cordless technique resulted in lower lateral displacement, with a mean \pm standard deviation of 207 \pm 57 μm (IC95% [185–229]; $P = .53$). The cord techniques allowed an average sulcus opening significantly greater than the cordless procedure (Fig. 4). These results were also compared according to the gingival biotype group for each material. Because of the low participant number with biotype A3 ($n < 10$), only biotypes A1 and A2 were analyzed. The results showed no significant difference in lateral gingival displacement between A1 and A2 gingival biotypes ($P > .05$) (Table 3). For both biotypes, the cord techniques revealed a higher sulcus opening than with Racegel cordless.

The mean \pm standard deviation of vertical gingival displacement was 103 \pm 98 μm (Fig. 5). Although the cord techniques tended to provide a higher vertical displacement (Racestypine: 111

$\pm 84 \mu\text{m}$; Racegel with a cord: $119 \pm 103 \mu\text{m}$) than the cordless method ($82 \pm 104 \mu\text{m}$), there was no significant difference among the 3 techniques ($P=.343$).

The gingival index and the papillary bleeding index were used to determine gingival inflammation. In the 3 groups, most participants had gingival index grade 0, papillary bleeding index grade 0, and no pathologic probing depth (normal probing depth $\leq 3 \text{ mm}$) before gingival displacement at Day 0 and at Day 7 to 14 (Table 4). According to visual inspection by the clinicians, an absence of crevicular fluid (97%) or bleeding (92%) in the sulcus was determined for all groups (Table 4). In the subgroup of participants characterized by minor bleeding before the procedure (papillary bleeding index grade ≥ 1), no bleeding in the sulcus was observed for 100% of participants after Racegel applications and for 75% of participants after Racestypine with a cord (Table 4). At day 7 to 14, no periodontal attachment loss, irreversible gingival recession, or gingival necrosis were identified in the 3 groups (Table 4). Overall, no periodontal damage was identified at day 0 or at day 7 to 14 compared with the initial situation ($P > .05$ for all criteria) (Table 4).

Participants reported that the Racegel cordless technique was significantly less painful than the procedures with a cord ($P=.002$) (Table 5). In this group, 93% of participants felt no pain during gingival displacement compared with 59% and 69% in Racegel with a cord and Racestypine with a cord, respectively. In the cord techniques, pain was equally experienced as low or moderate (approximately 20% of participants for each level of pain). For the 3 groups, only 16 participants answered that they did feel discomfort (Table 5). The discomfort was related to product taste ($n=11/16$) and pain ($n=5/16$).

For the cord techniques, clinicians found the sulcus opening sufficient and the margins correctly recorded on the impression (Table 6). In the Racegel cordless group, they were less satisfied with the sulcus opening, the time to reach sufficient sulcus opening, and overall satisfaction. They noted that only two-thirds of participants had sufficient gingival displacement, and that the cervical margins of the prepared tooth were accurately recorded in 80% of the impressions (Table 6). However, they reported that the Racegel cordless procedure was easier to use than the cord techniques.

DISCUSSION

This randomized trial evaluated the clinical effectiveness of 3 gingival displacement techniques: Racegel cordless, Racegel with a cord, and Racestypine with a cord. The blinded gingival displacement measurements revealed that the research hypothesis that the 3 gingival displacement techniques would provide an efficient lateral gingival displacement before impression making in prosthodontics, consistent with the required clinical value of at least 200 μm ,²⁴ was accepted. The mean lateral gingival displacement generated by Racegel cordless ($207 \pm 57 \mu\text{m}$), Racegel with a cord ($253 \pm 59 \mu\text{m}$), and Racestypine with a cord ($247 \pm 61 \mu\text{m}$) were greater than 200 μm . These values corresponded to the clinical sulcular opening sufficient to record the cervical margins of the prepared tooth without causing material impression distortion.²⁴ The cord techniques had significantly greater gingival displacements than the cordless group. Similar data were also reported in previous studies, one of which included Racegel.^{7,8,18}

No significant difference in lateral gingival displacement between thick biotype A1 and thin biotype A2 was observed in the present study. In addition, regardless of the biotype, the cord

techniques revealed a higher sulcus opening than the Racegel cordless procedure. The current results were not consistent with a systematic review that reported that lateral gingival displacement with a cord was more effective for patients with a thick gingival biotype.⁸ They suggested that mechanical pressure exerted by a cord could produce more displacement forces on a dense and fibrotic tissue with a large zone of attachment.

Only 2 recent studies have assessed displacement in the vertical direction.^{20,21} As found in the present trial, they reported that vertical gingival displacement was less than lateral displacement. The cord techniques tended to provide increased vertical displacement than Racegel cordless, but the differences were not statistically significant. In a recent study that compared a cord technique with 3M Astringent Retraction Paste, similar data were also identified.²¹

Racestyptine solution and Racegel contain aluminum chloride that have been reported to provide hemostasis (manufacturer data).^{3,5} In the present study, after cord or Racegel removal, no bleeding or crevicular fluid was observed in the sulcus. For participants with gingival papilla bleeding before displacement, bleeding in the sulcus was absent after displacement for all participants enrolled in both Racegel groups and for 75% of those in the Racestyptine with a cord group. These results demonstrated an improved ability of Racegel to achieve hemostasis. The changes of gingival and periodontal indices were compared with the baseline data to examine the effects of methods upon periodontal tissue. No periodontal damages immediately at day 0 and at day 7 to 14 were detected compared with the initial situation. Periodontal indices have also been reported to be not significantly affected by different methods in previous studies.^{5,16,27} The cord techniques have been reported to cause transient gingival

inflammation after 1 day, which was reported to clinically reverse itself in 2 weeks.^{4,9,11-13} An in vitro study reported that Racegel cordless generated lower pressure than cord techniques¹⁴ and others have determined that paste or gel systems are less traumatic for gingival tissue.^{8,26}

The satisfaction of participants and clinicians was also evaluated in the present study. The cordless method was significantly less painful for participants than the cord techniques ($P=.002$), consistent with previous studies.^{8,15,17} The clinicians found that the displacements achieved with cord techniques were sufficient and that the margins were visible in the sulcus and correctly recorded in the impression. Although the Racegel cordless was more straightforward to use, it was deemed less satisfactory for opening the sulcus. These data were consistent with those of other studies.^{8,16,17}

The present trial can be considered as having a low risk of bias. The involvement of dentists in private practices reflected the real-world situation in contrast with single-center studies conducted in hospitals or academic institutions.^{28,29} This multicenter practice-based study allowed the inclusion of significant participants from 19 to 85 years and a mean age of approximately 55 for all groups. Moreover, the number of teeth in each group was sufficient and well distributed.^{7,8} Most teeth included were premolars and molars, the most restored permanent teeth.³⁷ According to recent systematic reviews, the lack of consensus on criteria and methodology for evaluating clinical performance makes comparison of studies difficult.^{7,8}

Limitations of the study involved clinical conditions that may have influenced gingival displacement, including clinical accessibility, restricted number of dentists, adverse effects during tooth preparation, and patient compliance. This trial was based on recruited participants with a healthy gingival condition. In clinical reality, gingival displacement is frequently performed on patients with gingival disease. The authors are

aware of only 2 recent studies that assessed the gingival displacement of cord and paste methods for participant mild gingivitis,^{20,21} where gingivitis was reported to worsen the performance of cords, unlike paste. Further investigations could analyze the performance of these materials with mild gingivitis.

CONCLUSIONS

Based on the findings of this prospective and comparative clinical trial, the following conclusions were drawn:

1. For the 3 techniques, the lateral gingival displacement was greater than the required clinical value of 200 μm . The cord methods revealed higher sulcus opening than the Racegel cordless technique.
2. No significant differences in vertical gingival displacement were found among the 3 methods.
3. The efficacy of these techniques was confirmed in achieving hemostasis.

PATIENT CONSENT

Informed consent was obtained for all participants.

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CRedit authorship contribution statement

Marie Desclos-Theveniau: Methodology, formal analysis, writing – review & editing; **Hugo Abgrall:** Investigation; **Vincent Bar:** Investigation; **Françoise Basle:** Investigation; **Dominique Basle:** Investigation; **Marie-Joseph Dautel:** Investigation; **Jacques Rubin:** Investigation; **Franck Delanoue:** Investigation; **Etienne Lefrançois:** Formal analysis; **Anne Dautel:** Supervision; **Anne-Laure Sérandour:** Conceptualization, methodology, formal analysis; **Gwenvael Le Guicher:** Conceptualization, methodology, formal analysis; **Hugues Colombel:** Investigation.

TABLES

Table 1. Criteria for participant recruitment

Inclusion criteria	Exclusion criteria
Men or women (age ≥ 18 years)	Use of gingival displacement to prepare tooth
No cognitive or psychological deficits	Known allergy to aluminum, aluminum salts or to one of compounds of formula of Raceptysine solution or Racegel or to one of impression material compounds
Prepared tooth that required complete coverage crown or fixed partial denture	Uncontrolled systemic disease
Healthy gingiva: probing depth ≤ 3 mm, attached gingival > 2 mm, gingival index ≤ 1 , plaque index < 3 ^{31,33}	Clinical follow-up expected to be difficult (unable to go to final visit 7 to 14 days after gingival displacement)
No mechanical trauma during tooth preparation which could produce gingival irritation or inflammation	Simultaneous participation in another interventional clinical investigation or trial
	Vulnerable participants referred to in articles L.1121-5 to 8 and L.1122-1-2 of the French Public Health Code and Article 66 of the Regulations (EU) 2017/745 on Medical Devices (including pregnant, breastfeeding, deprived of their liberty).

Table 2. Baseline characteristics of trial participants

		Racegel with cord <i>n</i> =29	Racegel cordless <i>n</i> =30	Racestyptine with cord <i>n</i> =29
Sex	Women	44.8%	56.7%	48.3%
	Men	55.2%	43.3%	51.7%
Mean age (years \pm standard deviation)		58.3 \pm 18.2	54.6 \pm 17.4	51.7 \pm 17.2
Tooth prepared	Incisor	18.5%	10.0%	13.8%
	Canine	0.0%	0.0%	10.3%
	Premolar	44.4%	30.0%	24.1%
	First or second molar	33.3%	60.0%	51.7%
	Third molar	3.7%	0.0%	0.0%
Gingival biotype	A1	55.2%	53.3%	48.3%
	A2	34.5%	33.3%	41.4%
	B	10.3%	13.3%	10.3%
Plaque Index	Grade 0	72.4%	76.7%	75.9%
	Grade 1	27.6%	16.7%	20.7%
	Grade 2	0.0%	6.7%	3.5%
Tooth preparation at Day 0		31.0%	36.7%	34.5%
Margin placement	Subgingival	65.5%	66.7%	79.3%
	Juxtagingival	34.5%	33.3%	29.5%
Cord size	000	17.2%		24.1%
	00	27.6%		31.0%
	0	55.2%		44.8%

Table 3. Influence of gingival biotype (biotype A1 versus biotype A2) on lateral gingival displacement for each technique³²

	Racegel with cord <i>n</i> =25	Racegel cordless <i>n</i> =28	Racestyptine with cord <i>n</i> =27
Gingival Number of participants (<i>n</i>)	14	15	13
biotype Mean \pm standard deviation lateral gingival	0.254 \pm 0.057	0.191 \pm 0.064	0.262 \pm 0.061
A1 displacement (mm)			
Median [IQR]	0.242 [0.210-0.288]	0.199 [0.176-0.221]	0.247 [0.228-0.284]
Comparison Group versus 0.2 mm <i>P</i> *	.001	.626	.002
Gingival Number of participants (<i>n</i>)	8	9	12
biotype Mean \pm standard deviation lateral gingival	0.246 \pm 0.076	0.215 \pm 0.046	0.248 \pm 0.062
A2 displacement (mm)			
Median [IQR]	0.267 [0.158-0.317]	0.194 [0.180-0.243]	0.234 [0.207-0.300]
Comparison Group versus 0.2 mm <i>P</i> *	.102	.547	.012
Comparison A1 versus A2 <i>P</i> *	1	.512	.514

IQR, interquartile range. *Wilcoxon test.

Table 4. Periodontal control assessment before and after gingival displacement at 0 day (Day 0) and 7 to 14 days after displacement (Day 7 to 14)

		Racegel with cord <i>n</i> =29	Racegel cordless <i>n</i> =30	Racestypine with cord <i>n</i> =29
Gingival index Day 0 (before gingival displacement)	Grade 0	69.0%	80.0%	69.0%
	Grade 1	24.1%	13.3%	24.1%
	Grade 2	6.9%	6.7%	2.9%
Gingival index Day 0 (after gingival displacement)	Grade 0	69.0%	75.9%	69.0%
	Grade 1	27.6%	24.1%	31.0%
	Grade 2	3.4%	0.0%	0.0%
Gingival index Day 7 to 14 (end of study)	Grade 0	82.1%	86.2%	82.8%
	Grade 1	17.9%	10.3%	13.8%
	Grade 2	0.0%	3.4%	3.4%
Papillary bleeding index Day 0 (before gingival displacement)	Grade 0	58.6%	80.0%	72.4%
	Grade 1	31.0%	16.7%	24.1%
	Grade 2	10.3%	3.3%	3.5%
Papillary bleeding index Day 0 (after gingival displacement)	Grade 0	69.0%	79.3%	72.4%
	Grade 1	31.0%	20.7%	20.7%
	Grade 2	0.0%	0.0%	3.5%
Papillary bleeding index Day 7 to 14 (end of study)	Grade 0	71.4%	86.2%	72.4%
	Grade 1	28.6%	10.3%	24.1%
	Grade 2	0.0%	3.4%	3.4%
Probing depth Day 0 (before gingival displacement)	≤3mm	100%	100%	100%
	>3mm	0%	0%	0%
Probing depth Day 0 (after gingival displacement)	≤3mm	100%	100%	100%
	>3mm	0%	0%	0%
Probing depth Day 7 to 14 (end of study)	≤3mm	100%	100%	100%
	>3mm	0%	0%	0%
Dried out sulcus Day 0 (after gingival displacement)	Yes	96.6%	96.7%	96.6%
	No	3.4%	3.3%	3.4%
Bleeding in the sulcus Day 0 (after gingival displacement)	Yes	6.9%	10%	6.9%
	No	93.1%	90%	93.1%
Gingival epithelium necrosis Day 7 to 14 (end of study)	Yes	0%	0%	0%
	No	100%	100%	100%
Periodontal attachment loss Day 7 to 14 (end of study)	Yes	0%	0%	0%
	No	100%	100%	100%
Irreversible gingival recession Day 7 to 14 (end of study)	Yes	0%	0%	0%
	No	100%	100%	100%

Table 5. Assessment of patient comfort for each group of gingival displacement technique

		Racegel with cord <i>n</i> =29	Racegel cordless <i>n</i> =30	Racestyptine with cord <i>n</i> =29
Pain during gingival displacement	• No	58.6%	93.3%	69.3%
	• Low	24.1%	6.7%	17.0%
	• Moderate	17.2%	0.0%	13.6%
Comparison between 3 groups <i>P</i> *		.003		
Comparison with cord versus cordless <i>P</i> †		.002		
Feeling discomfort	• Yes	13.8%	10.0%	18.2%
	• No	86.2%	90.0%	81.8%
Comparison between 3 groups <i>P</i> *		.084		
Comparison with cord versus cordless <i>P</i> †		.152		

*Fisher exact test, †Chi-squared test.

Table 6. Assessment of clinician satisfaction for each gingival displacement technique

		Racegel with cord	Racegel cordless	Racestyptine with cord
How satisfied are you with the ease of use and application of the product/material?	<ul style="list-style-type: none"> • Not satisfied • Satisfied 	14.3% 85.7%	28.6% 71.5%	16.7% 83.3%
How satisfied are you with the tissue displacement and the depth of the sulcus (access to the preparation limits)?	<ul style="list-style-type: none"> • Not satisfied • Satisfied 	14.3% 85.7%	71.5% 28.6%	0% 100%
How satisfied are you with the time it takes to achieve satisfactory displacement?	<ul style="list-style-type: none"> • Not satisfied • Satisfied 	28.6% 71.4%	57.2% 42.9%	16.7% 83.3%
What is your overall satisfaction with this product?	<ul style="list-style-type: none"> • Not satisfied • Satisfied 	28.6% 71.4%	71.5% 28.6%	16.7% 83.3%

FIGURES

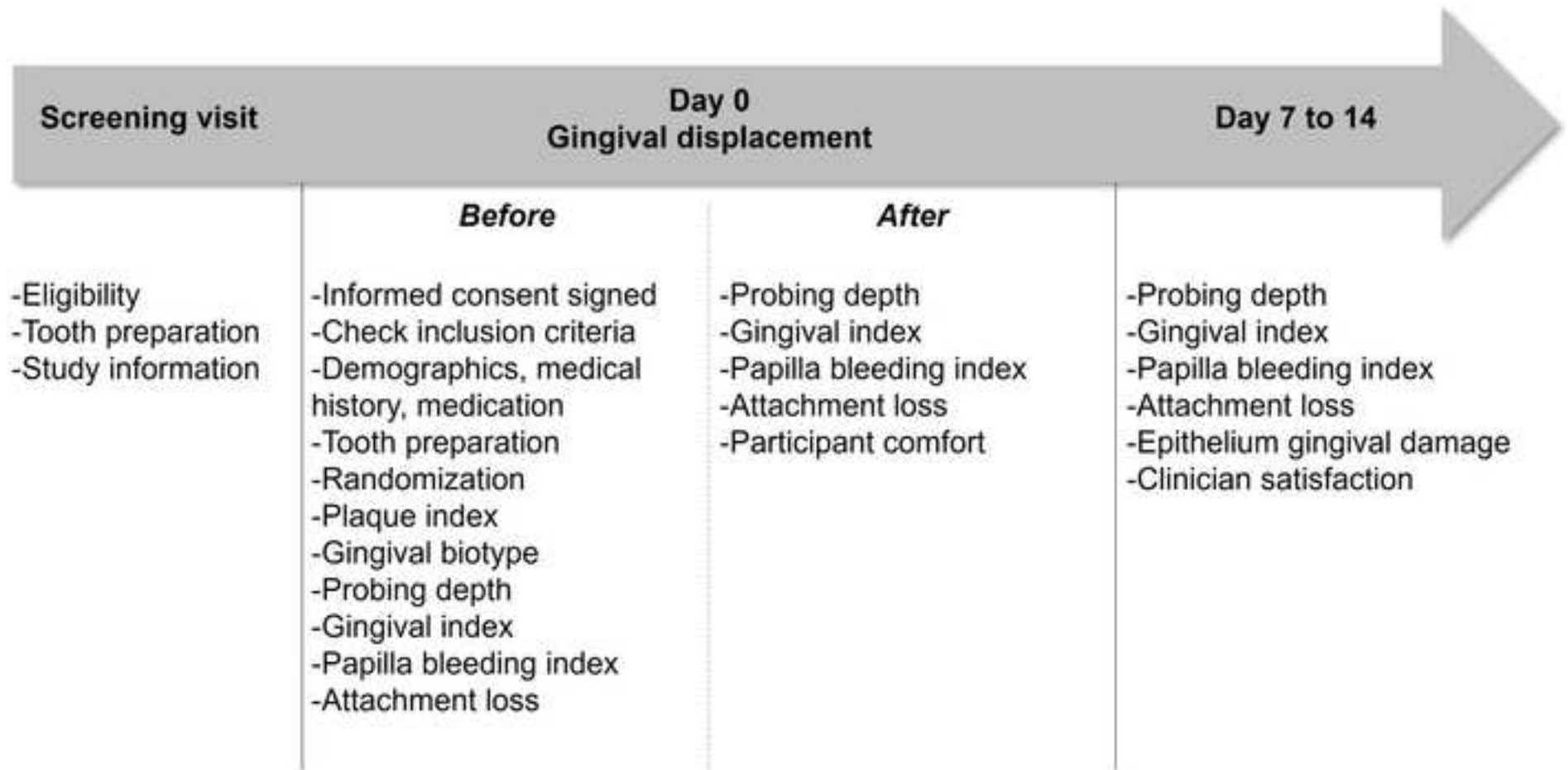
Figure 1. Study schedule. Day 0, day of gingival displacement intervention; Day 7 to 14, follow-up between 7 and 14 days after displacement.

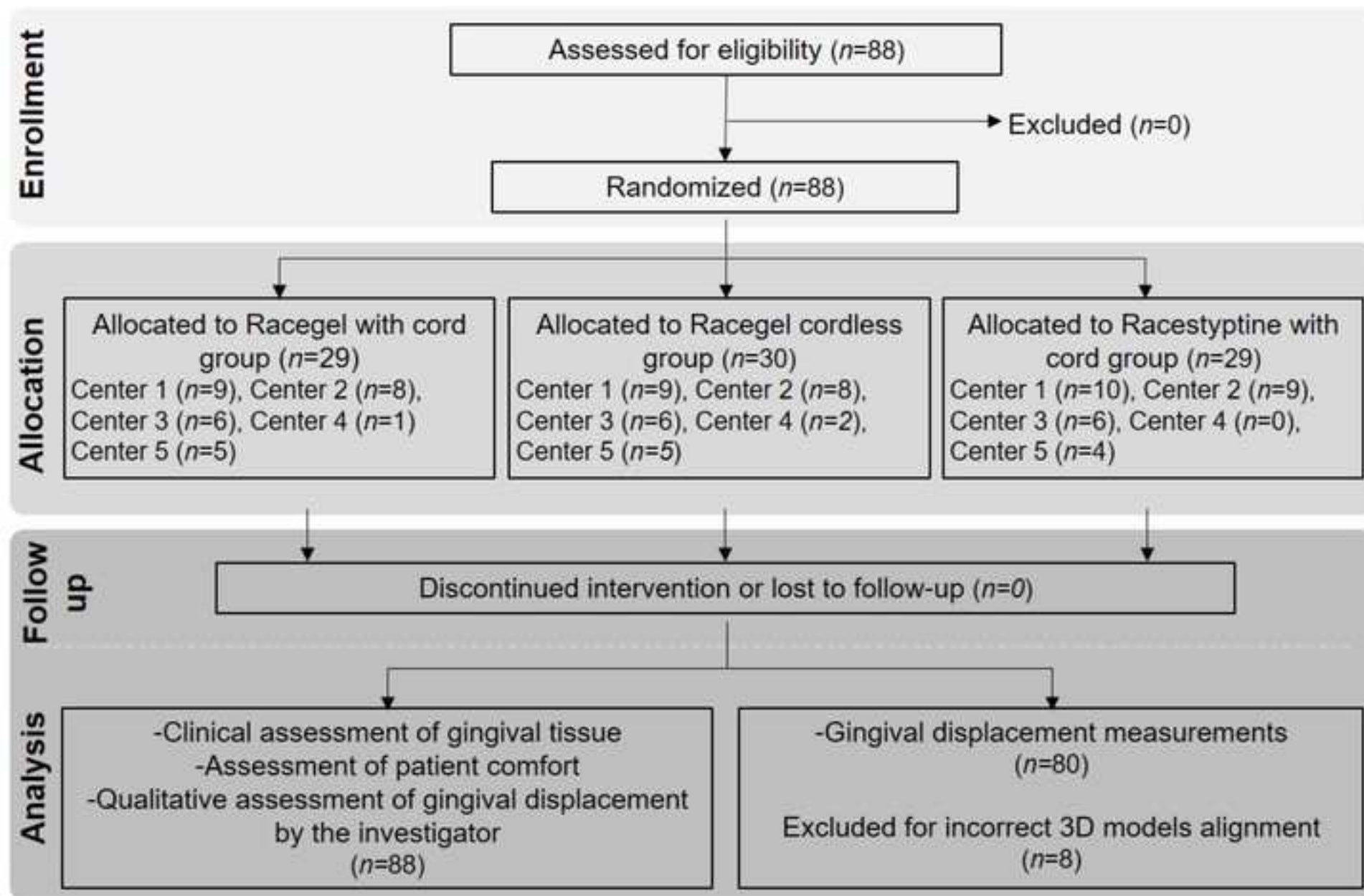
Figure 2. Gingival displacement measurement. STL, standard tessellation language; 3D, 3-dimensional.

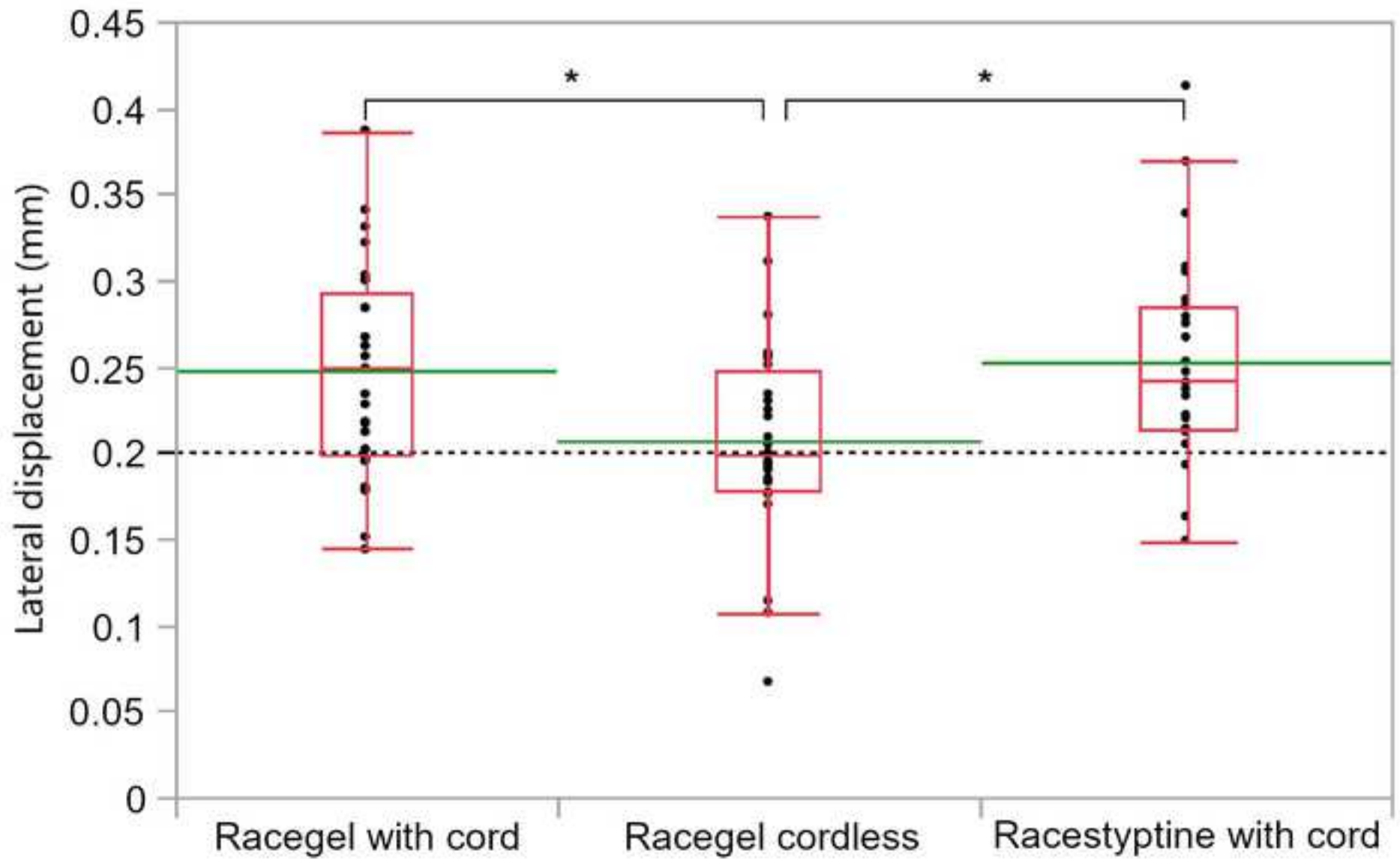
Figure 3. CONSORT diagram showing flow of participants through clinical trial.

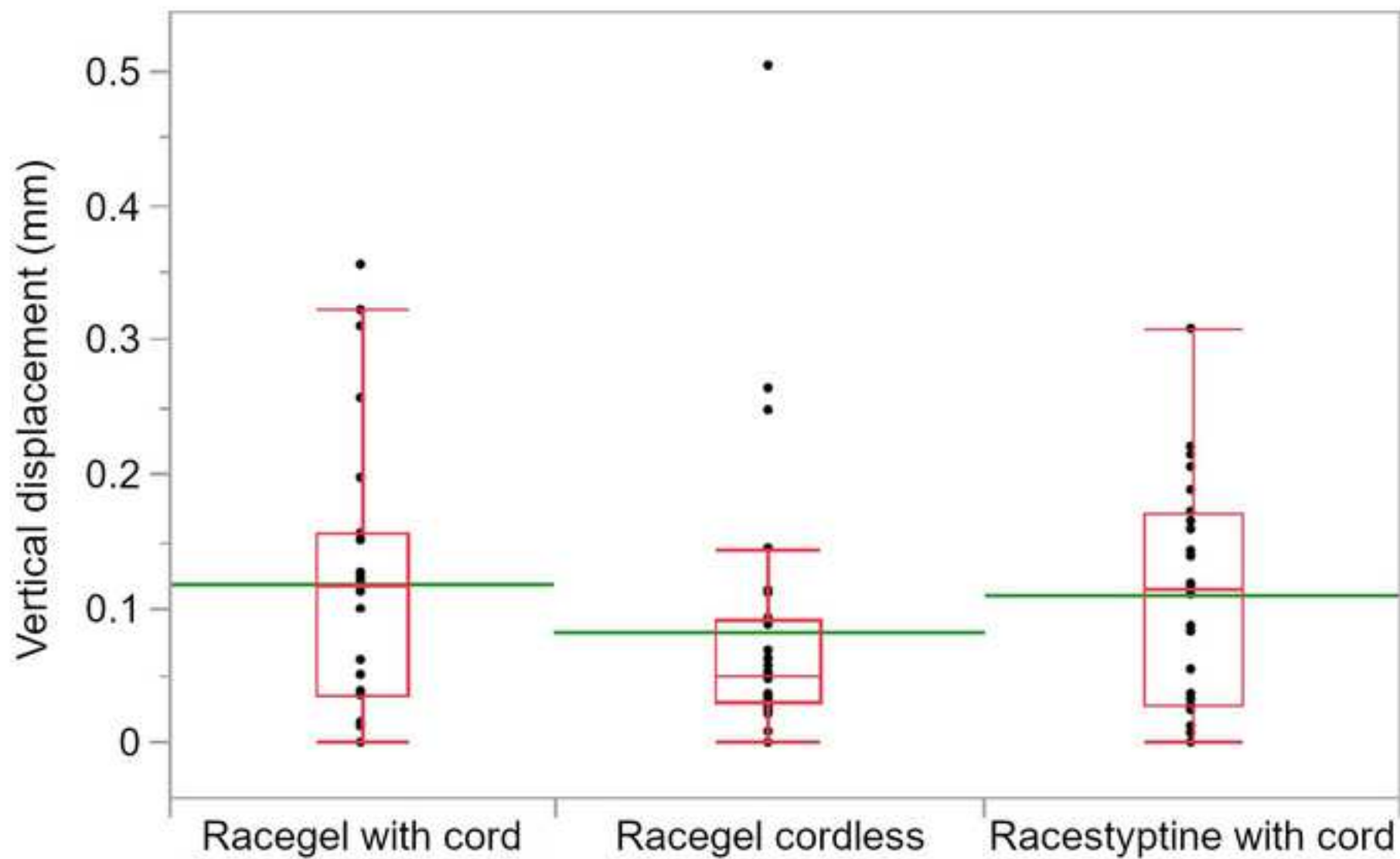
Figure 4. Lateral gingival displacement for each technique. *Green lines*: mean values; *Red lines*: median values; *Dotted line*: 0.2 mm as required clinical displacement value. * significant differences between techniques ($P < .05$).

Figure 5. Vertical gingival displacement for each technique. *Green lines*: mean values; *Red lines*: median values.









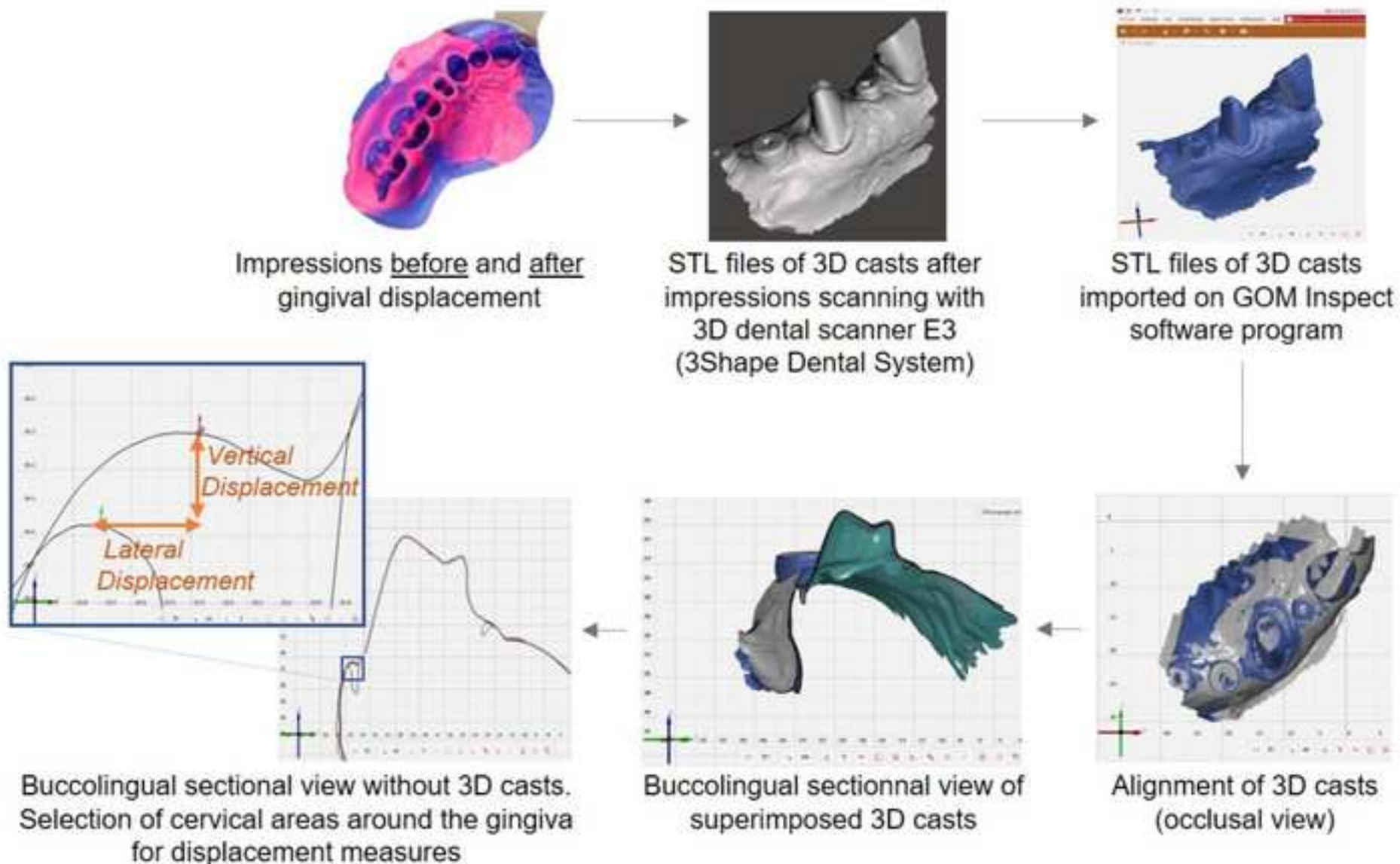


Table 1. Criteria for participant recruitment.

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • men or women (age ≥ 18 years), • no cognitive or psychological deficits, • prepared tooth that required full coverage crown or bridge, • healthy gingiva: probing depth ≤ 3 mm, attached gingival > 2 mm, gingival index ≤ 1, plaque index < 3,^{31,32,33} • no mechanical trauma during tooth preparation that could produce gingival irritation and inflammation. 	<ul style="list-style-type: none"> • use of gingival displacement to prepare tooth, • known allergy to aluminum, aluminum salts or to one of the compounds of the formula of Racesptysine solution or Racegel or to one of the impression material compounds, • participant with an uncontrolled systemic disease, • clinical follow-up expected to be difficult (unable to go to the final visit 7 to 14 days after gingival displacement), • simultaneous participation in another interventional clinical investigation or trial, • vulnerable participants referred to in articles L.1121-5 to 8 and L.1122-1-2 of the French Public Health Code and Article 66 of the Regulations (EU) 2017/745 on Medical Devices (pregnant, breastfeeding women, persons deprived of their liberty, ...).

Table 2. Baseline characteristics of trial patients.

		Racegel with cord <i>n</i> =29	Racegel cordless <i>n</i> =30	Racestyptine with cord <i>n</i> =29
Sex	• Women	44.8%	56.7%	48.3%
	• Men	55.2%	43.3%	51.7%
Mean age (years \pm SD)		58.3 \pm 18.2	54.6 \pm 17.4	51.7 \pm 17.2
Tooth prepared	• Incisor	18.5%	10.0%	13.8%
	• Canine	0.0%	0.0%	10.3%
	• Premolar	44.4%	30.0%	24.1%
	• Molar	33.3%	60.0%	51.7%
	• Wisdom	3.7%	0.0%	0.0%
Gingival biotype	• A1	55.2%	53.3%	48.3%
	• A2	34.5%	33.3%	41.4%
	• B	10.3%	13.3%	10.3%
Plaque Index	• Grade 0	72.4%	76.7%	75.9%
	• Grade 1	27.6%	16.7%	20.7%
	• Grade 2	0.0%	6.7%	3.5%
Tooth preparation at Day 0		31.0%	36.7%	34.5%
Margin placement	• Subgingival	65.5%	66.7%	79.3%
	• Juxtagingival	34.5%	33.3%	29.5%
Cord size	• 000	17.2%		24.1%
	• 00	27.6%		31.0%
	• 0	55.2%		44.8%

Table 3. Influence of gingival biotype (biotype A1 *versus* biotype A2) on lateral gingival displacement for each technique.³²

	Racegel with cord <i>n</i> =25	Racegel cordless <i>n</i> =28	Racestypine with cord <i>n</i> =27
Gingival • Number of participants (<i>n</i>)	14	15	13
biotype • Lateral gingival displacement (mm ±SD)	0.254 ±0.057	0.191 ±0.064	0.262 ±0.061
A1 • Median [IQR]	0.242 [0.210-0.288]	0.199 [0.176-0.221]	0.247 [0.228-0.284]
Comparison Group <i>versus</i> 0.2 mm <i>P</i> *	.001	.626	.002
Gingival • Number of patients (<i>n</i>)	8	9	12
biotype • Lateral gingival displacement (mm ±SD)	0.246 ±0.076	0.215 ±0.046	0.248 ±0.062
A2 • Median [IQR]	0.267 [0.158-0.317]	0.194 [0.180-0.243]	0.234 [0.207-0.300]
Comparison Group <i>versus</i> 0.2 mm <i>P</i> *	.102	.547	.012
Comparison A1 <i>versus</i> A2 <i>P</i> *	1	.512	.514

IQR, interquartile range; SD, standard deviation. *Wilcoxon test.

Table 4. Periodontal control assessment before and after gingival displacement at 0 day (Day 0) and 7 to 14 days after displacement (Day 7 to 14).

		Racegel with cord <i>n</i> =29	Racegel cordless <i>n</i> =30	Racestyptine with cord <i>n</i> =29
Gingival index Day 0 (before gingival displacement)	<ul style="list-style-type: none"> • Grade 0 • Grade 1 • Grade 2 	69.0% 24.1% 6.9%	80.0% 13.3% 6.7%	69.0% 24.1% 2.9%
Gingival index Day 0 (after gingival displacement)	<ul style="list-style-type: none"> • Grade 0 • Grade 1 • Grade 2 	69.0% 27.6% 3.4%	75.9% 24.1% 0.0%	69.0% 31.0% 0.0%
Gingival index Day 7 to 14 (end of study)	<ul style="list-style-type: none"> • Grade 0 • Grade 1 • Grade 2 	82.1% 17.9% 0.0%	86.2% 10.3% 3.4%	82.8% 13.8% 3.4%
Papillary bleeding index Day 0 (before gingival displacement)	<ul style="list-style-type: none"> • Grade 0 • Grade 1 • Grade 2 	58.6% 31.0% 10.3%	80.0% 16.7% 3.3%	72.4% 24.1% 3.5%
Papillary bleeding index Day 0 (after gingival displacement)	<ul style="list-style-type: none"> • Grade 0 • Grade 1 • Grade 2 	69.0% 31.0% 0.0%	79.3% 20.7% 0.0%	72.4% 20.7% 3.5%
Papillary bleeding index Day 7 to 14 (end of study)	<ul style="list-style-type: none"> • Grade 0 • Grade 1 • Grade 2 	71.4% 28.6% 0.0%	86.2% 10.3% 3.4%	72.4% 24.1% 3.4%
Probing depth Day 0 (before gingival displacement)	<ul style="list-style-type: none"> • ≤3mm • >3mm 	100% 0%	100% 0%	100% 0%
Probing depth Day 0 (after gingival displacement)	<ul style="list-style-type: none"> • ≤3mm • >3mm 	100% 0%	100% 0%	100% 0%
Probing depth Day 7 to 14 (end of study)	<ul style="list-style-type: none"> • ≤3mm • >3mm 	100% 0%	100% 0%	100% 0%
Dried out sulcus Day 0 (after gingival displacement)	<ul style="list-style-type: none"> • Yes • No 	96.6% 3.4%	96.7% 3.3%	96.6% 3.4%
Bleeding in the sulcus Day 0 (after gingival displacement)	<ul style="list-style-type: none"> • Yes • No 	6.9% 93.1%	10% 90%	6.9% 93.1%
Gingival epithelium necrosis Day 7 to 14 (end of study)	<ul style="list-style-type: none"> • Yes • No 	0% 100%	0% 100%	0% 100%
Periodontal attachment loss Day 7 to 14 (end of study)	<ul style="list-style-type: none"> • Yes • No 	0% 100%	0% 100%	0% 100%
Irreversible gingival recession Day 7 to 14 (end of study)	<ul style="list-style-type: none"> • Yes • No 	0% 100%	0% 100%	0% 100%

Table 5. Assessment of patient comfort for each group of gingival displacement technique.

		Racegel with cord <i>n</i> =29	Racegel cordless <i>n</i> =30	Racestyptine with cord <i>n</i> =29
Pain during gingival displacement	• No	58.6%	93.3%	69.3%
	• Low	24.1%	6.7%	17.0%
	• Moderate	17.2%	0.0%	13.6%
Comparison between 3 groups <i>P</i> *		.003		
Comparison with cord vs cordless <i>P</i> †		.002		
Feeling discomfort	• Yes	13.8%	10.0%	18.2%
	• No	86.2%	90.0%	81.8%
Comparison between 3 groups <i>P</i> *		.084		
Comparison with cord vs cordless <i>P</i> †		.152		

*Fisher's exact test, †Chi-squared test.

Table 6. Assessment of dentist satisfaction for each gingival displacement technique.

		Racegel with cord	Racegel cordless	Racestypine with cord
How satisfied are you with the ease of use and application of the product/material?	• Not satisfied	14.3%	28.6%	16.7%
	• Satisfied	85.7%	71.5%	83.3%
How satisfied are you with the tissue displacement and the depth of the sulcus (access to the preparation limits)?	• Not satisfied	14.3%	71.5%	0%
	• Satisfied	85.7%	28.6%	100%
How satisfied are you with the time it takes to achieve satisfactory displacement?	• Not satisfied	28.6%	57.2%	16.7%
	• Satisfied	71.4%	42.9%	83.3%
What is your overall satisfaction with this product?	• Not satisfied	28.6%	71.5%	16.7%
	• Satisfied	71.4%	28.6%	83.3%

Gingival displacement methods performance prior impression making: A prospective, comparative randomized clinical trial

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Declaration of Competing Interest

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