Randomized trial in split-mouth design to evaluate the effectiveness of manual and machine-aided cleaning of removable partial dentures

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Abstract

Purpose: To evaluate the efficacy of manual and machine-aided cleaning to remove matured plaque from removable partial dentures (RPD). Materials and Methods: A total of 32 patients with bilateral free-end saddle RPDs were included. The plaque was stained, and the RPD was photographed on all sides. One saddle was randomly allocated to manual cleaning, while the other was allocated to no cleaning. The patient manually cleaned the saddle by applying a denture brush and gel. The whole RPD was then cleaned with the aide of a machine using a rotating needle device. After each step, plaque dyeing and photographing were repeated. The plaque proportions (% pixel) were measured using special software. For statistical analysis, mixed models were used to adjust for baseline covariates, including plaque and surfaces, and to cover all time points. Results: The mean plaque area without cleaning at the fitting surface was higher than at the buccal/lingual surfaces (32.8% [95% CI: 28.1% to 36.4%] vs 15.3% [13.1% to 17.4%], respectively). Manual cleaning was not substantially better than no cleaning (4.6% [–0.1% to 9.2%] for the difference at fitting surfaces; disclaiming a substantial difference of > 10%; the difference found was even smaller at buccal/lingual surfaces). Machine-aided cleaning was substantially better than manual cleaning (16.1% [12.0% to 20.2%] for the difference at fitting surfaces and 7.3% [4.6% to 10.0%] at buccal/lingual surfaces). The combination of manual and machine-aided cleaning was not better than machine-aided cleaning alone (–0.2% [–2.6% to 2.1%] difference at fitting surface). Conclusion: Manual cleaning is insufficient in removing matured denture plaque. Machine-aided cleaning is clearly superior to manual cleaning, especially at fitting surfaces. *Int J Prosthodont* 2021. doi: 10.11607/ijp.7280

Introduction

Denture plaque is a dense, non-rinsable layer of food residues, yeasts, microorganisms, and their metabolites that can develop on prosthetic surfaces.¹ Biofilms at dentures can lead to local diseases including prosthetic stomatitis, angular cheilitis, traumatic ulcers, denture irritation hyperplasia, flabby ridges and rarely oral carcinoma.² The most common disease is prosthetic stomatitis, which affects the mucosa in about 50% of wearers of complete or removable partial dentures (RPDs).² Furthermore, dentures may also be a germ reservoir for systemic diseases, e.g. pneumonia.³⁻⁸ Moreover, there are
associations between periodontal diseases and RPD plaque. Rapid reinfection after periodontal therapy is definitely possible if the RPDs of partially edentulous patients are not cleaned along with the professional and the oral hygiene at home. Unexpectedly, the professional cleaning of RPDs is neither part of periodontal therapy according to guidelines, e.g., in Germany nor any comparative study assessed the cleaning of RPDs.

The main causes of denture plaque are insufficient hygiene habits. Removable dentures can be cleaned using mechanical, chemical, or a combination of both methods. Mechanical methods are further subdivided into manual (cleaning brushes and paste or gel) and methods based on ultrasound or lately with rotating needles. Brushing represents the most commonly applied method combining simplicity, rapidity and low cost. However, the effectiveness of brushing is dependent on frequency, technique and aids. Remaining plaque for some time acts as a film for stain deposition and if left, may calcify, which requires more than brushing to remove it. There is also the fact that cleaning the fitting surface is more difficult owing to the roughness compared with the polished denture parts. Therefore, denture wearer with restricted manual capabilities, cognitive impairment, or just insufficient hygiene habits should be accompanied by professional support. A worldwide consensus on denture cleaning recommendations is lacking among dental healthcare professionals. The guideline of the American College of Prosthodontists include a daily cleaning by soaking and brushing with an effective, nonabrasive denture cleanser and an annual cleaning by a dentist or dental professional using ultrasonic cleansers to minimize biofilm accumulation over time.

There are several clinical trials about denture cleaning methods with brushes, paste, cleaning tablets, ultrasound, and even placebo. The outcome measures can be classified in primary outcomes, e.g. health of denture bearing areas, participants’ satisfaction/preference, and secondary outcomes, e.g. denture plaque coverage area, indicators of halitosis, and microbial counts on abutment teeth, soft tissues, denture base or saliva. There are visual, laboratory, and the planimetric methods to assess plaque. The visual assessment is used in different indexes for evaluating patient compliance and monitoring. The laboratory assessment is being applied in scientific research or for diagnostic purposes, e.g. the molecular method. For computerized planimetric evaluations, the denture plaque is stained.
digital photographs of denture parts, the pixel proportion of the disclosed biofilm to the whole area is measured by special software.\textsuperscript{28,29} This study aimed to evaluate the efficacy of manual and machine-aided cleaning procedures on matured plaque at RPDs by planimetry. We hypothesized that (1) manual cleaning is not substantially better than no cleaning (<10% difference); (2) machine-aided cleaning is substantially better than manual cleaning (>10% difference); (3) manual plus machine-aided cleaning is slightly better than machine-aided cleaning alone (>5% difference); (4) each cleaning method leaves plaque residuals (>5%); and (5) treatments differ in fitting and buccal/lingual surfaces.

**Material and Methods**

**Study design and participants**

The within-person study was designed as a split-mouth randomized controlled trial and reported according to the respective extension of the CONSORT 2010 statement.\textsuperscript{30} The trial is registered at the German clinical trials register (Deutsches Register Klinischer Studien) under DRKS-ID: DRKS00014094 (www.germanctr.de). The ethics committee of the University Medicine XXX approved this study (BB 002/18) and all participants signed an informed consent for the study procedures. Participants were patients of the dental school in XXX, Germany with at least one RPD. The RPDs had to be adapted for at least 2 months and must have two separate free-end saddles with the replacement of at least both 1st molars. The patients were asked to avoid denture cleaning right before the experiment. In-depth denture cleaning by dental professionals had to be at least six months ago. If the participant has two eligible RPDs, only one randomly chosen RPD was included. Exclusion criteria were any mental disorders and poor general health (Class III-IV according to the classification of the American Society of Anesthesiology). To compare two mechanical denture cleaning methods without consideration of any interindividual variability, one saddle was randomly allocated to manual brushing. Thereafter the whole denture was cleaned by machine. The examiner (JG) was a research assistant not involved in the treatment of the patients. The examiner was trained by an experienced dentist (AA) who developed and validated this standard operating procedure for denture plaque assessment.
Questionnaire

The participants were asked to fill out a questionnaire about the wearing time of the denture, denture hygiene habits (methods, aids, daily frequency), and the frequency of professional denture cleaning at the dental school.

RPD preparation and photography process

The procedure of plaque assessment is described in detail elsewhere. Briefly, the RPD was rinsed under running water for 10 seconds to remove any food remains and dried with air. A plaque disclosing agent (Erythrosine 5%) was applied at all RPD surfaces using a foam pellet and left for one minute. Finally, the unbound dye was removed by running water and the RPD was dried by air jet. A plaster plate with an individual silicon key fixed each RPD in the same position during repeated photographing. A split cast magnet connected the plate with a movable base to tilt the RPD anterior, posterior, left, and right (Figure 1). An adjustable reprostand Hama Reprostativ RS 20 held the Canon EOS/450D with an objective MR-14EX Macro Canon ultrasonic 60 mm f/2.8 and Ring flash MR-14EX TTL Macro Lite Flash. The manual settings were ISO 100, exposure 200 and aperture 22. Six images were taken for each RPD: at an angle of 90-degree for the occlusal and fitting surfaces and of 45-degree for front, back, left, and right side (Figure 2).

RPD cleaning and documentation

First, the patient was instructed to brush all surfaces of the saddle for at least 30 seconds by using a special denture cleaning brush and denture cleaning gel (Presh, Kockdental, Wallenhorst, Germany). Afterward, this saddle was stained again and both saddles were photographed. The subsequent mechanical cleaning of the entire partial denture was carried out with the help of a rotating needle device (Sympro, Renfert, Hilzingen, Germany) in a special cleaning agent (Symprofuid) for 20 minutes. A magnet surrounds a tub with the fluid and puts the steel needles in rapid motions. The plaque is removed by numerous collisions of the needles with the denture surface. Finally, both denture saddles were stained and photographed again.

Image analysis
Adobe Photoshop CS5 extended 12 was used for image analysis according to the standard operating procedure. Only the buccal, lingual, and fitting surfaces of each RPD saddle were included in the analysis. At first, the image was duplicated as a so called layer. Then the selection was determined by isolating specific areas in the three RPD surfaces per saddle (Figure 3). Using the Magnetic Lasso Tool, all acrylic resin base areas (with denture teeth buccally and lingually) were successively separated and individually saved as selected layers. After that, the plaque selection was accomplished by using the color range selection. The fuzziness value was set at 10 for all images. Because the plaque was sometimes slightly darker or brighter, some areas or spots had to be selected separately. Each image was evaluated two times and the average was considered the final reading. The pixel number of the selected layer and the pixel number of the plaque selection were captured from the histogram (Figure 3). The percent of plaque on the selected part of the RPD was calculated using the following formula:

\[
\text{Percent of plaque on selected part} = \frac{\text{Pixels of plaque}}{\text{Pixels of selected part}} \times 100
\]

**Statistical analysis**

Owing to the lack of split-mouth studies on cleaning of RPDs, clinical, statistical, and practical aspects were considered to determine design and sample size of this study.\textsuperscript{32} The required minimal number of 30 participants corresponds to previous within-patient studies,\textsuperscript{29, 33, 34} which is a more sensible approach than sample-size calculation.\textsuperscript{32} The split-mouth design is appealing to efficiently estimate the effect of manual cleaning because carry-across effects can be excluded for RPDs with two clearly separate free-end saddles. Even symmetrical prosthesis parts are not needed if side-specific baseline covariates (baseline surface, baseline plaque) are included in the model. To have a substantial cleaning effect the lower limit was set at 10% difference in the plaque area between methods according to our pilot results\textsuperscript{31} and to other studies.\textsuperscript{23, 33, 35} Because we hypothesized that manual cleaning is not substantially better than no cleaning, we chose a corresponding split-mouth design at the first time point. As the machine cannot clean single parts of the RPD, the whole RPD was cleaned by machine only at the second time point. Thus, at the second time point, the design facilitates comparing the effect of the add-on of manual and machine-aided cleaning with that of machine only. In a model over both time points however, the effect of
machine-aided cleaning cannot be statistically separated from that of the second time point. Thus, from this model alone, machine-aided cleaning cannot be compared with manual cleaning. Nevertheless, interpreting the model over both time points together with that from the first time point solves the problem. Moreover, the time gap between manual and machine-aided cleaning was very short, less than ten minutes. Thus, the overall design is well justified to answer the ordered research questions.

Replacing “period” by “side”, the split-mouth design of a single time point was analyzed as cross-over design in the “classical” way, including treatment, sequence, period, and subject effects. The statistical analyses were performed both for untransformed and for log-transformed outcome values to meet the model assumptions. Robust variances were modeled to correct for heteroscedastic residuals of the untransformed outcome values. To adjust for baseline covariates including surface and plaque (which were modeled as restricted cubic splines with three knots) and to analyze both time points, mixed models were used. For log-transformed outcome values, the Kenward-Roger method using the observed information matrix was applied to correct for small-sample inference using Stata software (release 14.2, Stata Corporation, College Station, TX, USA). For a missing value of baseline surface, the mean value of the corresponding sequence and period group was imputed for the missing data point (Table 1). Summary statistics are presented by sequence and period as recommended.

Results

Out of 38 participants, 6 had to be excluded because of an unnoticed defect of the ring flash. The remaining 20 men and 12 women aged between 53–89 years (mean age of 70.4 ± 8.1 years) had 19 double crown-retained, 10 clasp-retained and 3 bar-retained RPDs with two posterior free-end saddles. All saddle surfaces consisted of hard acrylic resin and showed one or more acrylic denture teeth. The duration of denture use was between 2 -6 months in 2 participants, between 6 months and 2 years in 7 participants, and more than 2 years in 23 participants. All participants brushed their dentures daily, namely either 3 times (n=4), 2 times (n=21) or once a day (n=7) by using a toothbrush (n=23) or a denture brush (n=9) with dentifrice (n= 21), a special denture cleaning paste (n=10) or a dish detergent (n=1). Less than half of the participants (n=14, 44%) used commercial denture cleaning tablets daily and two participants
used ultrasonic cleansers. Half of the participants reported on denture cleaning by a dentist or dental professional that was performed annually (n=4), twice a year (n=5) or on demand (n=7).

A total of 20 lower and 12 upper RPDs were analyzed (Figure 4). None of the RPD had an adverse event, e.g. broken RPD, partial loss of RPD material. Some RPD images could not be measured for technical errors and subsequent poor picture quality (Figure 4, Table 1). The percentage of plaque at the fitting surfaces of both RPD sides together ranged between 7.9 and 76.1 with a median of 33.1. The percentage of plaque at the polished surfaces was lower without relevant differences between buccal and lingual (0 – 40.5, median 11.8 versus 0 – 42.5, median 13.2, respectively). Only in one RPD, the polished surfaces of both saddles showed no plaque.

Baseline surface and plaque differed by side (Table 1). Summary statistics by sequence and period in table 1 allow reproducing some of the treatment effects in table 2. The sequence no/manual and the period left imply no treatment because left corresponds to the first period after transforming the split-mouth design into the cross-over design. Likewise, no/manual and right imply treatment; manual/no and left imply treatment; manual/no and right imply no treatment. The treatment effect in fitting surfaces at the first time point can then be calculated from the means in table 1 as=((32.0 – 34.3) + (22.4 – 33.2))/2 = -6.55 or, more exactly based on software, -6.54 ≈ -6.5 as in table 2 (except for the reversed sign). The same calculation is useful to evaluate imbalances in baseline plaque.

The final results of the mixed models for the untransformed (Table 2) and log-transformed (Table 3) outcome values were broadly similar. The confidence intervals for the treatment contrast comparing manual with no cleaning do not exceed 10% if baseline covariates are included as seen in tables 2 and 3. Thus, the effect of manual cleaning is not substantial. This is supported by the narrow confidence intervals for the treatment contrast comparing the add-on (manual and machine-aided cleaning) with machine-aided cleaning only. From the model of the first time point and that of both time points, it can be concluded that the machine-aided cleaning is superior to manual cleaning, which is more pronounced in fitting surfaces than in buccal or lingual ones (Figure 5).
Discussion

Brushing with a gel had a small cleaning effect on matured denture plaque as only < 10% was removed. Machine-aided cleaning was clearly superior to manual cleaning. The plaque reduction by machine averaged about 10% at the polished surfaces and 20% at the fitting surfaces. The additive effect of machine plus manual cleaning compared with the machine alone was negligible (< 5%). However, machine-aided cleaning also leaves some biofilm residues with most of them at the fitting surfaces. Not only the initial but also the post-cleaning plaque coverage at the fitting surface was markedly higher than at the polished outer denture surfaces.

Some aspects of this study merit consideration. First, only the treatment effect of the rotating needles on the plaque amount was compared with one-time brushing of the denture saddle. Possible side effects of the steel needles on denture teeth, acrylic resin, or inner surfaces of secondary crowns were not evaluated. Especially electroplated fine gold for secondary crowns could be deformed by the needles. Second, this is the first split-mouth study to compare two cleaning modalities on dentures. A replication of this design would be desirable to exclude possible unnoticed systematic faults. Third, the number of participants was at the lower border in comparison to other studies. However, by using a within-person design it can be reasonably assumed that “the stage of the condition (plaque) is similar in the sites to be randomized” and the number of individuals required for recruitment can be decreased since the interindividual variability can be neglected. Fourth, for our design it was not possible to consider a standardized biofilm formation time without cleaning prior to the procedure except on the day of the appointment. Anyhow, professional denture cleaning belongs either to the past namely at least six months or not at all. Thus, our study set-up reflects rather the clinical reality (effectiveness trial) than a study under ideal circumstances (efficacy trial).

In the study design, we balanced practical, theoretical, and ethical issues. For ethical reasons, each patient should benefit from the expected strong effect by machine cleaning. For practical reasons, it was of special interest that the effect of the manual cleaning was estimated precisely enough. Moreover, whereas each patient performed the manual cleaning, the dental student performed the machine cleaning. Therefore, both groups got the machine cleaning only at the second time point, which is theoretically suboptimal. However, given that the precise estimating of the manual cleaning resulted in merely
moderate effects, discounting of the strong effects by machine cleaning does not appear to be well justified. This is supported by the short time period between the first and second time point. Following the E9 guideline, the outcome was chosen for practical reasons as well and corresponds to a surrogate variable rather than a direct assessment of the clinical benefit as done by measuring, for example, mucositis of the denture bearing area, periodontal diseases, or caries. The strong associations of accumulated denture biofilm and the incidence of localized stomatitis are proven and plausible from biological view. Furthermore, denture biofilm may have other possible effects, i.e. source for systemic diseases. Following the E10 guideline, the common standard therapy (brushing) was included and examined both as an itself and an add-on. Ultrasonic cleaning as one other effective form of machine-aided procedures can only be compared with the rotating needles device in other study designs, i.e. parallel arm or cross-over trials and should be the matter of future research.

Carry-across effects from one side to another can be excluded because only partial prostheses were included and the canines defined a clear limit for the picture analysis. Potential carry-over effects from the first time point (manual treatment or no treatment) to the second time point (machine treatment) is a minor issue given the large effects of machine treatment. Furthermore, a cross-over study may have the main disadvantage that a new biofilm formation after the first treatment would need some months to reach a comparable quality of the denture plaque. In other within-patient studies various cleaning methods were compared after a short wash-out period and only the cleaning effect of young biofilms was analyzed. Most of the participants in the present study wore their dentures 2 years or more.

Despite the anamnestic hygiene habits, i.e. all participants brushed their RPDs, among them 78% at least twice a day and nearly half used cleanser tablets, every surface of the saddles except the polished parts of one RPD showed plaque at baseline. Similar results were obtained in a study from Wales. Only 18.3% of RPDs that were cleaned twice a day according to the self-statements of their wearers showed a good cleanliness. Even repeated denture brushing per day should be combined with the daily use of a chemical cleaning method according to various studies.

The high plaque amount at the fitting surface may have several reasons. First, the rough acrylic base encourages biofilm formations by the retention of food components. Second, the rinsing effect of the saliva under the saddle is lacking. Third, the cleaning effect of the denture brush is diminished not only
due to the roughness but also due to the molding of denture parts covering the alveolar ridges.\textsuperscript{23} One-time brushing using a special gel removed only about one-fifth of the stained plaque deposit both at the polished and at the rough fitting surfaces. Thus, our outcome is contrary to the results from other studies in which manual cleaning with a toothbrush and various denture pastes was more effective with significant reduction of the plaque area or amount, by up to half.\textsuperscript{12, 23, 33-35} However, in the aforementioned studies, the surfaces of complete dentures were initially cleaned in depth and thereafter brushed three times a day after the meal, throughout seven days. Hereby, only newly formed biofilms were repeatedly removed. After machine-aided cleaning, only the surfaces of one RPD were free from plaque and all other surfaces had on average one-third the residue of the original plaque. According to other studies all authors reported about the reduction and not about the elimination of the biofilm area, plaque amount, bacterial or Candida counts.\textsuperscript{11, 12} Entirely residue-free surfaces of years-long worn dentures can seemingly not be achieved by using any cleaning method. Hence, newly incorporated dentures should be carefully cleaned, ideally from day one. Hardly any patient is capable of this and the ability for sufficient cleaning decreased in old age, especially among nursing home residents.\textsuperscript{19, 45} Older and dirty dentures should be initially, and thereafter at least annually cleaned by dental healthcare professionals.\textsuperscript{10, 20, 21} An effective cleaning machine might be useful for this purpose. The rotating needle device of the present study is easy to handle and can be applied without specialist knowledge. It could not only be used in dental offices but also geriatric care institutions. Whether this device is efficient over time, and without side effects for the dentures, should be further evaluated.

Conclusions

Both initial and post-treatment, the fitting surface showed remarkably more plaque than the polished outer surfaces. One-time brushing of a RPD saddle is insufficient in removing matured denture plaque from polished and fitting surfaces. Machine-aided cleaning is clearly superior to manual cleaning, especially on fitting surfaces. If manual and machine treatment were successively conducted, the cleaning effect was similar to the effect of the machine exclusively. Comparable studies are required to verify the present results.

Acknowledgments
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References
### Table 1 Baseline and outcome characteristics by sequence and period for the split-mouth study presented as cross-over design

<table>
<thead>
<tr>
<th>Surfc.</th>
<th>Left/right related sequence</th>
<th>Period (left ≠ first period)</th>
<th>Cleaning</th>
<th>Group</th>
<th>Baseline surface (time point zero)</th>
<th>Baseline plaque (time point zero)</th>
<th>Plaque at 1(^{st}) time point</th>
<th>Plaque at 2(^{nd}) time point</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Median (1(^{st}) quartile; 3(^{rd}) quartile)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N</td>
<td>Pixel</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Fit.</td>
<td>no/manual</td>
<td>left</td>
<td>no</td>
<td>B</td>
<td>15</td>
<td>3379 (2217; 3685)</td>
<td>15</td>
<td>38.7 (21.8; 56.8)</td>
</tr>
<tr>
<td>Fit.</td>
<td>no/manual</td>
<td>right</td>
<td>yes</td>
<td>B</td>
<td>15</td>
<td>3397 (2075; 4715)</td>
<td>15</td>
<td>37.7 (27.2; 49.7)</td>
</tr>
<tr>
<td>Fit.</td>
<td>manual/no</td>
<td>left</td>
<td>yes</td>
<td>A</td>
<td>16</td>
<td>3593 (3000; 3966)</td>
<td>16</td>
<td>28.1 (14.3; 42.8)</td>
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<tr>
<td>Fit.</td>
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<td>right</td>
<td>no</td>
<td>A</td>
<td>16</td>
<td>3559 (3009; 4541)</td>
<td>16</td>
<td>34.8 (25.5; 43.8)</td>
</tr>
<tr>
<td>Bu.</td>
<td>no/manual</td>
<td>left</td>
<td>no</td>
<td>B</td>
<td>15</td>
<td>8027 (5544; 9438)</td>
<td>15</td>
<td>17.2 (8.6; 27.9)</td>
</tr>
<tr>
<td>Bu.</td>
<td>no/manual</td>
<td>right</td>
<td>yes</td>
<td>B</td>
<td>15</td>
<td>9076 (5864; 11,791)</td>
<td>15</td>
<td>15.9 (7.4; 40.6)</td>
</tr>
<tr>
<td>Bu.</td>
<td>manual/no</td>
<td>left</td>
<td>yes</td>
<td>A</td>
<td>17</td>
<td>9610 (7847; 11,695)</td>
<td>17</td>
<td>8.0 (4.4; 12.8)</td>
</tr>
<tr>
<td>Bu.</td>
<td>manual/no</td>
<td>right</td>
<td>no</td>
<td>A</td>
<td>17</td>
<td>8544 (7403; 10,593)</td>
<td>17</td>
<td>9.2 (4.3; 14.6)</td>
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<tr>
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<td>no/manual</td>
<td>left</td>
<td>no</td>
<td>B</td>
<td>15</td>
<td>5706 (4455; 7940)</td>
<td>15</td>
<td>19.4 (13.6; 29.3)</td>
</tr>
<tr>
<td>Lin.</td>
<td>no/manual</td>
<td>right</td>
<td>yes</td>
<td>B</td>
<td>15</td>
<td>6931 (4710; 8912)</td>
<td>15</td>
<td>22.8 (9.1; 31.3)</td>
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<tr>
<td>Lin.</td>
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<td>yes</td>
<td>A</td>
<td>17</td>
<td>7572 (6606; 8793)</td>
<td>17</td>
<td>6.4 (5.9; 10.1)</td>
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<tr>
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<td>right</td>
<td>no</td>
<td>A</td>
<td>17</td>
<td>6842 (6198; 8612)</td>
<td>17</td>
<td>8.4 (4.5; 10.9)</td>
</tr>
</tbody>
</table>

**Mean (standard deviation)**, but not the quartiles, are related to two imputed baseline values; hence differences in N (for a total of two imputed values).

Surfc.: surface  Fit.: fitting  Bu.: buccal  Li.: lingual
Table 2 Margins and treatment effects for plaque as the primary outcome (95% CI); the untransformed outcome values estimate the mean

<table>
<thead>
<tr>
<th>Surface</th>
<th>Time points used</th>
<th>Model</th>
<th>(N_{\text{sub}})</th>
<th>(N_{\text{obs}})</th>
<th>Margins</th>
<th>Treatment contrasts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Fitting</td>
<td>1 Classical</td>
<td>32</td>
<td>33.2</td>
<td>27.1</td>
<td>(21.4 – 32.7)</td>
<td>6.1</td>
</tr>
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<td></td>
<td></td>
<td>64</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fitting</td>
<td>0, 1 Mixed</td>
<td>32</td>
<td>32.3</td>
<td>27.9</td>
<td>(24.6 – 31.2)</td>
<td>11.3</td>
</tr>
<tr>
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<td></td>
<td>64</td>
<td></td>
<td></td>
<td></td>
<td>10.8</td>
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<tr>
<td>Fitting</td>
<td>2 Classical</td>
<td>30</td>
<td>33.2</td>
<td>27.1</td>
<td>(25.2 – 31.2)</td>
<td>11.3</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td>10.9</td>
</tr>
<tr>
<td>Fitting</td>
<td>0, 2 Mixed</td>
<td>30</td>
<td>10.9</td>
<td>11.2</td>
<td>(7.6 – 14.3)</td>
<td>11.3</td>
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<tr>
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Add-on: effect by manual plus machine-aided cleaning at the first and second time point, respectively

\(N_{\text{sub}}\): Number of subjects \(N_{\text{obs}}\): Number of observations
Table 3 Margins and treatment effects for plaque as the primary outcome (95% CI); outcome values were log-transformed and then the predicted transformed values were transformed back, thereby estimating the median of the outcome given the predictors

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| Buccal/ | lingual Add-on: effect by manual plus machine-aided cleaning at the first and second time point, respectively

| Nsub: Number of subjects | Nobs: Number of observations |
Figure legends

Figure 1  Test set-up and a denture after fixation at the silicone key on the 45 ° tilted base

Figure 2  Photographs of the stained buccal surface (right saddle), simultaneously of the lingual surfaces (left saddle) and the whole fitting surface

Figure 3  Buccal selection area of denture teeth and acrylic base (left); the respective plaque selection (right) and the histograms for the pixel number of the whole area and the area with plaque

Figure 4  Flowchart of the study participants

Figure 5  Illustration of the solitary treatment effect for denture brushing versus machine cleaning
Figures

Figure 1
Figure 2
Figure 3
Assessed for eligibility (n=38)

Enrolled (n=38)

Randomization

Allocation (n=38)

Received allocated interventions (n=38)

Baseline T₀

1st time point T₁
(T₀ + 10 min)

Group A (manual left /no treatment right) (n=19)

Group B (manual right/no treatment left) (n=19)

2nd time point T₂
(T₀ + 10 min)

Group A (machine for both sides) (n=19)

Group B (machine for both sides) (n=19)

Picture analysis 30 days after last patient (T₀ + 30 d)

Excluded (n=6)
Data loss due to a technical error of the camera

Group A (n=17)
except for fitting surface at T₀ and T₂ and for buccal surface of left side and lingual surface of right side at T₂ (each n=16 because of technical error of the camera)

Group B (n=15)
except for fitting surface at T₂ and for buccal surface of right side and lingual surface of left side at T₂ (each n=14 because of technical error of the camera)

Figure 4
Figure 5