

CLINICAL RESEARCH

# Impact of adding palatal rugae to complete dentures on patient satisfaction and oral health–related quality of life: A randomized crossover clinical trial



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## ABSTRACT

**Statement of problem.** The addition of palatal rugae to complete dentures has been suggested to improve the satisfaction of patients with different oral functions. However, clinical studies to support these claims are lacking.

**Purpose.** The purpose of this randomized, single-blind, 2-period crossover trial was to assess the satisfaction of edentulous patients and their oral health impact profile when provided with complete dentures with palatal rugae compared with a polished palate.

**Material and methods.** Edentulous patients aged 45 to 80 years, with no relevant medical conditions, seeking complete dentures at a university hospital between May and July 2019 were recruited. Each participant received new complete dentures. After a 1-week adaptation period, the participants were randomly allocated to 2 sequences through a computer-generated sequence. In the first sequence, palatal rugae were added to the complete dentures, and after 2 months, the palatal rugae were removed and the dentures used for another 2 months. In the second sequence, the opposite sequence was followed: polished palate first and palatal rugae second. After each period, a blinded dentist asked participants to rate their general satisfaction on a 100-mm visual analog scale (primary outcome) and to rate their satisfaction regarding eating, taste perception, speaking, phonetics, and ease of cleaning. Participants were also asked to fill the 20-item oral health impact profile for edentulous patients (OHIP-EDENT). The paired sample *t* test and the Wilcoxon test were used ( $\alpha=.05$ ).

**Results.** Fifty participants were randomized, of whom 6 dropped out. No significant differences were found between ratings for the 2 palatal contours in terms of general satisfaction 2.32 (95% confidence interval: -3.65 to 8.29,  $P=.438$ ), eating 1.70 (95% confidence interval: -4.05 to 7.46,  $P=.554$ ), taste perception 0.57 (95% confidence interval: -5.04 to 6.17,  $P=.839$ ), phonetics 1.48 (95% confidence interval: -4.46 to 7.41,  $P=.618$ ), or speaking 3.68 (95% confidence interval: -1.92 to 9.28,  $P=.192$ ). However, satisfaction with ease of cleaning dentures with palatal rugae was significantly less 12.16 (95% confidence interval: 6.81 to 17.50,  $P<.001$ ). The differences in the OHIP-EDENT total scores were not significantly different -1.75 (95% confidence interval: -3.7 to 0.23,  $P=.082$ ). Differences in each item ratings were also found to be not significantly different ( $P>.05$ ), except for the frequency of mealtime interruption ( $P=.041$ ), which was reported to increase when rugae had been provided.

**Conclusions.** Complete dentures with palatal rugae were not perceived to improve patient satisfaction or oral health–related quality of life. However, they were perceived to be more difficult to clean and to increase frequency of interruptions during eating. (J Prosthet Dent 2021;126:646-52)

The success of a conventional complete dentures depends on the dentist, the patient, and the quality of the prosthesis provided,<sup>1-3</sup> the goal being a high level of

patient satisfaction. Therefore, each factor that could impact patient satisfaction in complete denture fabrication should be thoroughly studied.

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## Clinical Implications

The addition of palatal rugae to complete dentures required extra laboratory steps and did not improve the satisfaction or oral health-related quality of life for patients. Dentures with rugae were more difficult to clean and increased the frequency of mealtime interruptions. Therefore, their routine addition to complete dentures is not recommended.

In conventional maxillary complete dentures, the palatal area is covered with the denture base to provide the necessary support, retention, and stability.<sup>4</sup> Although many patients adapt to the presence of the denture base,<sup>5,6</sup> palatal coverage can cause discomfort to patients and disturbance to different oral functions, which could reduce their satisfaction and quality of life.<sup>7,8</sup>

Anatomically, the anterior third of the palatal area contains the palatal rugae, asymmetrical and irregular elevations in the palatal mucosa behind the incisive papilla, on both sides of the median palatal raphe.<sup>9</sup> The palatal rugae have mechanoreceptors densely distributed within the mucosa and provide the tongue with tactile feedback. Therefore, they have been reported to play an important role in several oral functions, including mastication, swallowing, taste perception, and speech.<sup>10,11</sup>

Unlike the irregular mucosal elevations of the palatal rugae, the palatal surface of complete dentures is typically polished to a smooth texture,<sup>12</sup> possibly leading to a frictionless sensation and difficulty in adapting to different oral functions.<sup>8,13,14</sup> Therefore, different solutions have been suggested, including avoiding complete palatal coverage in the rugae area, the use of a palatogram to customize functional palatal contours, roughening of the anterior palatal surface with wrinkled wax during denture fabrication, airborne particle abrading the polished surface, and the addition of palatal rugae elevations to the denture surface.<sup>14-20</sup> However, evidence to support which approach would be better for patients is lacking.

The addition of replicated palatal rugae to complete dentures has been advocated, with different techniques and variations for this process reported.<sup>21-28</sup> However, others have discouraged the addition of palatal rugae as it could increase the thickness of the palate and have a negative impact on speech.<sup>12,29</sup>

Most of these studies focused on clinical outcomes rather than patient-reported outcomes, and patient-reported outcomes regarding their dental prostheses have been reported to differ from the evaluation of dentists.<sup>30,31</sup> As a result, the importance of patient-

reported outcome measures was emphasized, and multiple measures, such as the visual analog scale (VAS) and the Oral Health Impact Profile for Edentulous Patients (OHIP-EDENT), were developed.<sup>32-35</sup> The OHIP-EDENT is a modified short version of the comprehensive Oral Health Impact Profile (OHIP) measure, which was developed as a condition specific measure for edentulous patients.<sup>35,36</sup>

The authors are unaware of studies evaluating the impact of adding palatal rugae to complete dentures on patient-reported outcomes. Therefore, the purpose of this randomized crossover clinical trial was to compare patient satisfaction with their complete dentures, with and without the addition of palatal rugae, and to compare its impact on their oral health-related quality of life. The null hypothesis was that no statistically significant difference in patient-rated general satisfaction would be found between complete dentures with palatal rugae and complete dentures with a polished palate after 2 months of using each type.

## MATERIAL AND METHODS

The present study was designed as a randomized, single-blind, 2-period, crossover clinical trial. No changes were made to the protocol after the commencement of the study. The study was conducted in accordance with the World Medical Declaration of Helsinki and conformed to the COSORT statement for randomized clinical trials.<sup>37</sup> The protocol was reviewed and approved by the dean-ship of academic research at the university hospital (IRB number: 5/11/392) and registered at [ClinicalTrials.gov](https://www.clinicaltrials.gov) (ID: 10/2019/27400).

The study population was completely edentulous patients in need of conventional complete dentures. The inclusion criteria are listed in [Table 1](#). The study was conducted at the prosthodontics department at the university hospital. Each participant received new complete dentures and was followed up for 1 week to make any necessary adjustments until no further problems were reported. The complete dentures were fabricated by consultants in prosthodontics. The laboratory procedures throughout the study were performed by 1 senior dental technician.

Eligible participants as per the inclusion criteria were randomized with 1:1 allocation ratio, without restrictions, into 2 sequences. A computer-generated sequence provided by the statistician was used. In the first sequence, participants started with complete dentures with added palatal rugae and then received the same dentures but with a polished palate. In the second sequence, participants received the same intervention but in the opposite order: started with polished palate and then with added palatal rugae. Review appointments were conducted after 2 months of using each palatal contour.

At the first review appointment and after data collection, the complete dentures were obtained from the participants by a consultant in prosthodontics who was not in the room during the data collection process. The dentures were then modified in the hospital laboratory by the senior dental technician. The modifications included either removal of the palatal rugae to obtain a polished palate or the addition of acrylic resin palatal rugae. The modified dentures were delivered during the same appointment by the same consultant.

A modification of the method described by Gitto et al<sup>22</sup> was used for the replication and addition of the participants palatal rugae. During the denture fabrication process, a duplicate of the maxillary casts poured in Type III dental stone (Microstone; Whip Mix Corp) for each participant was stored in the dental laboratory. Putty and light-body polyvinyl siloxane impression material (Zhermack Elite HD+; Zhermack) were adapted on the palatal area of the duplicated cast to obtain a silicone index of the rugae area. Autopolymerizing acrylic resin (Jet Denture Repair; Lang Dental Manufacturing Co) was then added in small quantities to the index to record the details of the rugae area. Once polymerized, the acrylic resin rugae duplicate was trimmed to size as marked on the cast.

The existing rugae area was roughened and thinned by using an acrylic bur (H251EA; Komet USA), minimizing the increase in palatal base thickness. The rugae duplicate was adapted and attached to the roughened denture palatal area with autopolymerizing acrylic resin. The incisive papillae, labial frenum, and midline were used as a guide for proper orientation. The palatal area was then polished to remove rough borders. To remove the palatal rugae from the denture surface, the rugae area was polished in the laboratory until smooth. Attention was given to minimize the reduction of the palatal base thickness.

Participants were left with their modified complete dentures for another 2-month period. They were then recalled for a second review appointment, where data collection was repeated in the same manner.

During the review appointments, participants rated their general satisfaction with the different palatal contours on a horizontal 100-mm VAS.<sup>34,38</sup> In addition, they rated their satisfaction regarding eating, taste perception, speaking, phonetics, and ease of cleaning. The questions were phrased as "With respect to eating, how satisfied are you with your upper denture?"<sup>39</sup> The anchor words were "Completely dissatisfied" and "Completely satisfied." The participants were asked to draw a vertical line that best represented their response.

In addition, participants filled out an Arabic translation of the OHIP-EDENT questionnaire.<sup>35,40,41</sup> The OHIP-EDENT consists of 7 domains and 20 items, which included functional limitation, physical pain, psychological

**Table 1.** Inclusion criteria

Inclusion Criteria
Patients seeking new conventional complete dentures for first time or as replacement of their previous complete dentures.
Patients aged 45-80 y.
Patients who had been completely edentulous for at least 3 mo.
Patients without severe underlying medical conditions, neuromuscular dysfunction, auditory problems, mental conditions, oral pathology, xerostomia, or tied tongue condition.
Patients who signed consent form.

discomfort, physical disability, psychological disability, social disability, and handicap. Each item was scored on a 1 to 5 scale: 1 = "never," 2 = "hardly ever," 3 = "occasional," 4 = "fairly often," and 5 = "very often." The sum of the scores was computed, yielding a total score ranging from 20 to 100, where 20 represents the best possible score and 100 represents the worst possible score. The 100-mm VAS and OHIP-EDENT measure were both validated and verified.<sup>35,42</sup> They were administered by 1 trained dentist, who did not participate in providing the treatment.

The primary outcome measure was the difference in general satisfaction between the 2 palatal contours as rated on the 100-mm VAS. The secondary outcome measures were the difference in satisfaction ratings for eating, taste perception, speech, phonetics, and ease of cleaning. It also included the difference in OHIP-EDENT total score and separate item ratings.

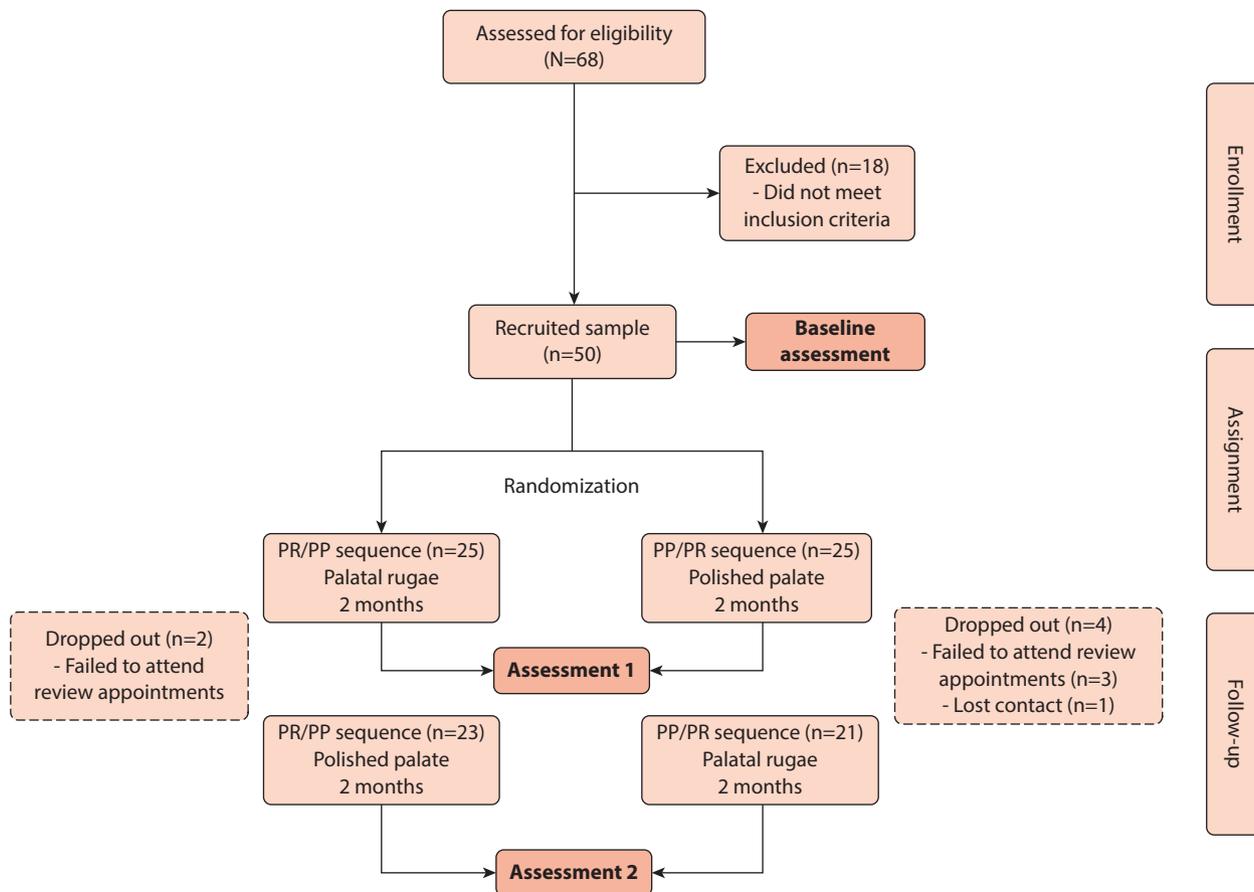
A total of 40 participants were needed to detect a difference of 10 mm on the 100-mm VAS with 90% power ( $\alpha=.05$ ). The sample size calculation assumed that the standard deviation of the difference for the response variables would be 19. To compensate for a potential 20% of dropouts, the number of participants was increased to 50.

The consultants who provided the treatment were unaware of the allocation sequence. The dentist (M.A.) who collected the data was blind to the palatal contour type for each participant. Blinding of the participants was not possible.

Statistical analyses were conducted by using a statistical software package (IBM SPSS Statistics, v22.0; IBM Corp).<sup>43</sup> The data were inspected for normality using a histogram and Q-Q plot. In addition, the z-scores of skewness revealed values significantly less than 1.96, indicating the VAS data were normally distributed.<sup>44</sup> Therefore, the paired-sample *t* test was used to compare between VAS ratings at the 2 different time points. The OHIP-EDENT scores had a non-normal distribution; therefore, the Wilcoxon signed-rank test was used, as it is the standard statistical test for ordinal paired data ( $\alpha=.05$ ).

## RESULTS

A total of 68 participants were assessed for eligibility between May and July 2019; of whom, 50 met the



**Figure 1.** Study flowchart. PP, polished palate; PR, palatal rugae.

inclusion criteria and signed a consent form. A flow diagram of the participants adapted from the CONSORT statement is presented in Figure 1.<sup>37</sup>

The sample consisted of 38 men (76%), and 12 women (24%). The mean age was 62.3 years (standard deviation=7.3, range: 45 to 79 years). First-time complete dentures wearers were 14 (28%), and those with previous complete denture wearing experience were 36 (72%). The median duration of edentulism was 37 months (interquartile range [IQR]=11.5 to 96, range: 3 to 408).

Table 2 presents analyses of within-participant differences of VAS ratings for different palatal contours. No significant differences were detected according to the paired sample *t* test, except for satisfaction with ease of cleaning, which was significantly less for dentures with palatal rugae ( $P<.001$ ).

The difference in the OHIP-EDENT total scores for dentures with a polished palate (median=32.5, IQR=25 to 45.75) compared with dentures with palatal rugae (median=36.5, IQR=24 to 46) was not significantly different according to the Wilcoxon signed rank test ( $P=.126$ ). Table 3 shows the median values of all OHIP-EDENT item responses, and *P* values from the Wilcoxon signed rank test for the difference between 2 different palatal

contours. Only 1 item, mealtime interruptions, revealed significant difference, which increased when complete dentures with palatal rugae were used ( $P=.041$ ).

## DISCUSSION

The authors are unaware of a previous clinical trial to assess the effect of adding palatal rugae to complete dentures on patient satisfaction. No significant differences in satisfaction ratings were found when compared with the polished palate. Therefore, the null hypothesis was accepted. The only exceptions were related to ease of cleaning the dentures and mealtime interruptions, where rugae addition had a negative impact.

The crossover design and the provision of 1 set of complete dentures for each participant minimized confounding factors involved in complete denture fabrication. It was not possible to blind participants, as the participants would have noticed the changes made to the palatal area<sup>45</sup> when they removed their dentures to clean them.

A limit on the minimum duration of edentulism was necessary because significant ridge remodeling occurs during the first few months and can impact the fit of any denture provided.<sup>46</sup> A 2-month duration was considered

**Table 2.** Within-participant comparison for VAS ratings for dentures with polished palate compared with dentures with palatal rugae using paired-sample *t* test

OHIP-EDENT Item	PP		PR		VAS Ratings (PP-PR)			
	M	SD	M	SD	M Difference	95% CI	SD	P
General satisfaction	79.43	17.13	77.11	20.55	2.32	-3.65 to 8.29	19.64	.438
Eating	75.70	19.08	74.00	18.98	1.70	-4.05 to 7.46	18.93	.554
Taste perception	78.16	24.43	77.59	25.38	0.57	-5.04 to 6.17	18.44	.839
Speaking	77.48	21.64	73.80	22.43	3.68	-1.92 to 9.28	18.42	.192
Phonetics	74.93	21.95	73.45	22.86	1.48	-4.46 to 7.41	19.52	.618
Ease of cleaning	89.43	11.90	77.27	18.57	12.16	6.81-17.50	17.57	<.001*

CI, confidence interval; M, mean; OHIP-EDENT, Oral Health Impact Profile for Edentulous Patients; PP, polished palate; PR, palatal rugae; SD, standard deviation; VAS, visual analog scale.  
\*Statistically significant ( $P < .05$ ).

sufficient to eliminate any carryover effect, as 2 to 4 weeks are generally required to achieve adaption in complete dentures wearers.<sup>4</sup>

The negative impacts of palatal coverage compared with no coverage have been reported.<sup>7,8,10,11</sup> Although avoiding palatal coverage is possible in implant retained overdentures, it is not recommended in conventional complete dentures. One study suggested keeping the rugae area exposed in complete dentures to improve tactile sensation. They found that if the exposure area was small, acceptable levels of retention could be maintained.<sup>15</sup> However, the sample consisted of dentate participants, and its generalizability to edentulous patients was not assessed.

Examining the impact of different palatal contours on edentulous patients is important.<sup>47</sup> Steas<sup>13</sup> reported improved taste perception after the addition of palatal rugae to complete dentures. This was based on feedback from 12 patients who complained of taste sensation loss when using their dentures. The author suggested the addition of rugae led to improved food texture perception, which was possibly interpreted as improved taste perception. In addition, palatal rugae provide the tongue with a surface to push and lock against. This will stretch the tongue microvilli away from each other, which can lead to better taste sensation.<sup>23</sup>

One study reported no differences in duration for food size and shape perception between different palatal contours, including smooth palate, wrinkled palate, population average rugae pattern, and individual replicated rugae. The only exception was for the population average rugae pattern, which caused increased duration for food perception.<sup>19</sup>

No significant differences in satisfaction ratings for eating and taste perception were found in the present study. However, 1 item in the OHIP-EDENT measure, mealtime interruptions, was perceived worse when complete dentures with palatal rugae were used. This could be from food retention in the acrylic resin rugae.

Similarly, speech and phonetics ratings were not significantly affected by different palatal contours. This was in contrast with others who reported improved speech adaptation with rugae addition.<sup>14,21</sup> A study

**Table 3.** Median values of OHIP-EDENT item responses and *P* values from Wilcoxon signed-rank test for difference between 2 different palatal contours

OHIP-EDENT Item	Median PP	Median PR	P (PP vs PR)
Difficulty in chewing any foods?	2	2	.134
Food catching in your dentures?	2	2	.600
Dentures not fitting properly?	2	2	.205
Painful aching in your mouth?	2	2	.433
Uncomfortable to eat any foods?	2	2	.205
Sore spots in your mouth?	2	2	.375
Uncomfortable dentures?	2	2	.083
Worried by dental problems?	1	2	.054
Self-conscious because of dentures?	1	1	.480
Unclear speech	2	2	.330
Avoid eating some foods?	2	2	1.000
Unable to eat?	1	1	.739
Interrupt meals?	2	2	.041*
Upset with dentures?	1	2	.168
Bit embarrassed?	1	1	1.000
Avoided going out?	1	1	.317
Less tolerant of partner or family	1	1	.317
Irritable with other people?	1	1	.317
Avoid other people's company?	1	1	1.000
Feel life in general was less satisfying?	1	1	.131

OHIP-EDENT, Oral Health Impact Profile for Edentulous Patients; PP, Polished palate; PR, Palatal rugae. 1 = Never; 2 = Hardly ever; 3 = Occasionally; 4 = Fairly often; 5 = Very often. \*Statistically significant ( $P < .05$ ).

reported that the addition of replicated palatal rugae reduced the duration for restoration of phonetics, as analyzed by a speech pathologist.<sup>17</sup> However, others reported rugae addition to have a negative impact on speech,<sup>12,29</sup> attributed to the difference in compressibility between acrylic and natural rugae and the added thickness to the denture base. In the present study, the reduction of the anterior palatal area before the addition of the rugae avoided increasing the palate thickness.

In a small percentage of patients, providing palatal coverage leads to speech impairment.<sup>16,22</sup> However, most patients adapt and adjust their speech patterns.<sup>5,6</sup> Therefore, significant differences were not expected in satisfaction ratings for speech and phonetics between the

different palatal contours when used over a 2-month period.

Different methods of adding palatal rugae to complete dentures have been described.<sup>21-27</sup> Whether one method is better than the others is unclear. One study found adding a duplicate of the individual's own palatal rugae to dentures improved food perception compared with adding the populations average rugae pattern.<sup>19</sup> The method used in the present study avoided the need to fabricate new dentures.<sup>22</sup> However, it involved the use of autopolymerizing acrylic resin as opposed to heat-polymerized acrylic resin with better physical properties.<sup>45</sup>

Participants reported less satisfaction when cleaning dentures with palatal rugae. The rugae irregularities possibly made the cleaning process more difficult. In addition, the reduced color stability and increased discoloration of autopolymerizing acrylic resin was possibly perceived as lack of cleanness. To support these assumptions, the use of heat-polymerized acrylic resin is recommended for future studies.

Experienced and first-time complete dentures wearers were included in the present study, which could have impacted the results. Elderly participants who had been used to a polished palate for years may have had difficulty adapting to irregular palatal rugae.<sup>48,49</sup> Therefore, the authors recommend that future studies be limited to experienced complete dentures wearers or to first-time dentures wearers.

## CONCLUSIONS

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

1. The addition of palatal rugae did not improve the satisfaction of participants with their conventional complete dentures or their satisfaction with eating, taste perception, speech, and phonetics.
2. It made the denture cleaning process more difficult and increased mealtime interruptions.
3. The overall oral health impact profile was not affected.
4. The routine addition of palatal rugae to conventional complete dentures is not recommended.

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## Noteworthy Abstracts of the Current Literature

### Effectiveness of disinfectant liquid soaps in the reduction of *candida spp* present in complete dentures: A crossover randomized clinical trial

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**Purpose.** To evaluate the effectiveness of liquid disinfectant soaps for the reduction of microorganisms present on maxillary complete dentures.

**Material and methods.** The selected patients (N=28) were randomly divided into four groups (n=7), and each group underwent all four disinfection treatments in a different order. The disinfection treatments evaluated were: 0.5% sodium hypochlorite (positive control); Dettol liquid soap; Lifebuoy liquid soap; and phosphate-buffered saline solution (negative control). The patients were instructed to immerse their maxillary dentures in the disinfectant solution for 8 hours (overnight) for 7 days, with the solutions in a randomized sequence with a washout period of 1 week between solutions. Biofilm samples of the dental prostheses were obtained before and after each treatment with a sterile swab, and the microbiologic material was diluted and plated in selective media for *Candida spp*. Colony-forming unit count (CFU/mL) was performed in each group. One-way ANOVA with Welch correction was used for analysis, with Games-Howell post hoc test with a significance level of .05.

**Results.** A 3-log reduction in microorganisms was considered effective compared to baseline. The highest incidence observed was for *Candida albicans*, which presented with a frequency between 66% and 92%, followed by *C tropicalis*, with a frequency between 7% and 33%, in all experimental groups. Sodium hypochlorite was able to reduce more than 3 log<sub>10</sub> of microorganisms for all patients, showing high antifungal effectiveness for both *C albicans* and *C tropicalis* species. Regarding the experimental groups, both liquid soaps (Dettol and Lifebuoy) were effective in reducing the two types of microorganisms.

**Conclusions.** Liquid soaps were effective at reducing biofilm and may be an alternative for disinfection of removable partial dentures or complete dentures.

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