

The Impact of Palatal Rugae Addition to Complete Dentures on Patients' Satisfaction and Oral Health Related Quality of Life: a Randomized Crossover Clinical Trial.

## ABSTRACT

**Statement of problem.** The addition of palatal rugae to complete dentures was suggested to improve the satisfaction of patients with different oral functions. However, there are no clinical studies to confirm these claims. **Purpose.** The aim of this randomized, single blind, two-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 to polished palate.

**Materials and methods.** Edentulous patients aged 45-80 years, with no relevant medical conditions, seeking complete dentures at a university hospital between May and July 2019, were recruited. Each participant received a new complete denture. After one-week adaptation period, the participants were randomly allocated to two sequences. In the first sequence, palatal rugae were added to the complete dentures, and after two months, the palatal rugae were removed and the dentures used for another two months. In the second sequence, the opposite sequence was followed; polished palate first, and palatal rugae second. Simple randomization was done through a computer generated sequence. After each period, a blinded dentist asked participants to rate their general satisfaction on a 100-mm visual analogue 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). Paired sample t-test and Wilcoxon test were used at 5% significance level.

**Results.** Fifty participants were randomized. Six participants dropped out. No significant differences were found between ratings for the two palatal contours in terms of general satisfaction 2.32 [95% CI: -3.65 – 8.29,  $P=0.438$ ], eating 1.70 [95% CI: -4.05 – 7.46,  $P=0.554$ ],

taste perception .57 [95% CI -5.04 – 6.17,  $P=.839$ ], phonetics 1.48 [95% CI -4.46 – 7.41,  $P=.618$ ], and speaking 3.68 [95% CI: -1.92 – 9.28,  $P=.192$ ]. However, satisfaction with ease of cleaning dentures with palatal rugae was significantly less 12.16 [95% CI: 6.81 – 17.50,  $P<.001$ ]. The differences in the OHIP-EDENT total scores were insignificant -1.75 [95% CI: -3.7 – .23,  $P=.082$ ]. Differences in each item ratings were also found insignificant ( $P<.05$ ), except for the frequency of meal time interruption ( $P=.041$ ) which was reported as increased when rugae had been introduced. **Conclusion.** Complete dentures with palatal rugae were not perceived to improve patients' satisfaction or oral health related quality of life. However, they were perceived more difficult to clean, and to increase frequency of interruptions during eating.

**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 of patients. Dentures with rugae were more difficult to clean and increased the frequency of meal time interruptions. Therefore, their routine addition to complete dentures is not recommended.

## **INTRODUCTION**

The success of a conventional complete denture depends on the dentist, the patient and the quality of the prosthesis provided.<sup>1-3</sup> A high level of patient satisfaction is the main objective when providing complete dentures for edentulous patients. Therefore, every factor which could impact patient's satisfaction in complete denture construction should be thoroughly studied.

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> Even though many patients adapt to the presence of the denture base,<sup>5,6</sup> the palatal coverage could 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, which refer to 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 were found to have mechanoreceptors densely distributed within the mucosa, and to provide the tongue with tactile feedback. Therefore, it was suggested that rugae play an important role in several oral functions such as mastication, swallowing, taste perception, phonetics and speech.<sup>10,11</sup>

Unlike the irregular mucosal elevations of the palatal rugae, the palatal surface of complete dentures is usually finished and polished to a smooth texture and lacks mechanoreceptors.<sup>12</sup> This might lead to a frictionless altered sensation and difficulty in adaptation in terms of different oral functions.<sup>8,13,14</sup>

Many authors had discussed how to overcome this issue. Different methods have been suggested such as avoiding complete palatal coverage in the palatal rugae area, the use of palatogram to customize functional palatal contours, roughening of the anterior palatal surface by the use of wrinkled wax during denture construction or sandblasting the polished surface, and the addition of palatal rugae elevations to the denture surface.<sup>14-20</sup> However, there is no evidence to support which approach would be better for complete denture patients.

The addition and replication of palatal rugae to complete dentures have been advocated by many authors, and different techniques and variations for this process were reported.<sup>21-28</sup> In contrast, other authors discouraged the addition of palatal rugae as it could increase the thickness of the palatal contours, which could have a negative impact on speech.<sup>12,29</sup>

Most of these studies focused on clinical outcomes rather than patient-reported outcomes. The evaluations of patients regarding their dental prostheses were reported to differ from the evaluation of dentists.<sup>30,31</sup> As a result, the importance of patient-reported outcome measures had

been emphasized, and multiple measures have been developed, such as the visual analogue scale (VAS), and The Oral Health Impact Profile for Edentulous Patients (OHIP-EDENT).<sup>32-35</sup>

The VAS was reported as a useful tool to assess patients' reported satisfaction with different aspects of treatment provided.<sup>34</sup> The OHIP-EDENT is a modified short-version of the comprehensive Oral Health Impact Profile (OHIP) measure. It was developed as a condition specific measure to assess the impact of complete dentures on edentulous patients.<sup>35,36</sup>

There are no studies to ascertain or negate the positive impact of palatal rugae addition to complete dentures on patient-reported outcomes. Therefore, the aim of this randomized crossover clinical trial was to compare the satisfaction of patients 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 there would be no statistically significant difference in patients' rated general satisfaction, between complete dentures with palatal rugae and complete dentures with polished palate, after two months of using each type post-delivery.

## **MATERIALS AND METHODS**

The current study was designed as a randomized, single blind, two-period, crossover trial. No changes were made on the design after the commencement of the study. The study was conducted in full accordance with the World Medical Declaration of Helsinki, and conformed to the CONSORT statement for randomized clinical trials.<sup>37</sup> The study protocol was reviewed and approved by the Deanship of Academic Research at the University Hospital (IRB number: 5/11/392), and registered at ClinicalTrials.gov (ID: 10/2019/27400).

The study population was completely edentulous patients in need of new conventional complete dentures. The inclusion criteria are listed in Table 1. The trial was conducted at the Prosthodontics Department at a University Hospital.

Participants were allocated randomly to two sequences. In the first sequence, participants received complete dentures with a palatal rugae at first, and then received the same dentures but with a polished palate. In the second sequence, participants received the same intervention but in opposite order; started with polished palate, and then with palatal rugae added.

All the participants received a new set of complete dentures, and were followed up for one week to do any necessary adjustments until no further problems were reported. The dentures were fabricated by consultants in prosthodontics at the University Hospital, and the laboratory procedures were performed by one senior dental technician.

Participants who were allocated to the palatal rugae/polished palate (PR/PP) sequence had a replica of their own palatal rugae added to their denture polish surface. While participants allocated to the polished palate/palatal rugae (PP/PR) sequence received dentures with a polished palatal surface. After two months, both groups were recalled for a review appointment.

At the review appointment, data collection was completed first. After which, the maxillary complete dentures were obtained from the participants for modification by a consultant in prosthodontics, who was not in the room during the data collection process. The complete dentures were then modified in the hospital laboratory by the same senior dental technician. The modifications that took place were either removal of the palatal rugae to get a polished palate, or addition of acrylic resin palatal rugae. The modifications were completed during the same review visit, and the complete dentures delivered back to the participants by the same consultant.

A method described by Gitto et al., with some modification, was used for the replication and addition of the participants' own palatal rugae.<sup>22</sup> During the denture construction process, a duplicate of the maxillary cast for each participant, poured in Type III dental stone (Microstone; Whip Mix Corp), was preserved in the lab. To record the rugae area details, addition silicone

(putty and light body) impression material (Zhermack Elite HD+; Zhermack), was adapted on the anterior palatal area of the duplicated cast. Thus, a silicone index of the rugae area was obtained. Autopolymerizing acrylic resin (Jet Denture Repair; Lang Dental Manufacturing Co) was then beaded onto it to record the imprints of the rugae. Once autopolymerized, the acrylic resin imprint was removed and trimmed to the correct size as delineated on the cast. The maxillary denture existing rugae area was roughened and thinned using an acrylic bur to minimize the increase of palatal base thickness. The acrylic resin rugae was then adapted carefully and secured to the palatal area of the existing prosthesis with autopolymerizing acrylic resin. The incisive papillae, labial frenum and midline were used as a guide for proper orientation and adaptation. The palatal area was then carefully finished and polished to remove any steps or rough borders.

In order to remove the palatal rugae from the denture surface, the rugae were gently polished in the laboratory till a smooth polished palate was obtained. Attention was given to minimize the reduction of the anterior palatal base thickness.

Participants were then sent home with their modified complete dentures for another two-month period. After which, participants were recalled again for another review appointment, and data collection was repeated in the same manner.

During the data collection process at the review appointments, participants were asked to rate their general satisfaction with different palatal contours on a horizontal 100-mm VAS.<sup>34,38</sup> In addition, they were asked to rate 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.

Participants were also asked to fill 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 covers functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicapped. Each item is scored on a one to five scale: 1 = “never”, 2 = “hardly ever”, 3 = “occasional”, 4 = “fairly often” and 5 = “very often”. The sum of the scores is computed yielding a total score in the range of 20 (best score) to 100 (worst score).

The 100-mm VAS and the OHIP-EDENT measure used in this study, were both previously validated and verified.<sup>35,42</sup> Their administration was done by one trained dentist, who did not participate in the provision of the treatment.

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

In order to detect a difference of 10 mm on the 100-mm VAS, with 90% power at 5% significance level, a total of 40 participants were needed to enter this crossover clinical trial. This was based on the assumption that the standard deviation (SD) of the difference in the response variables would be 19. In order to compensate for the potential 20% dropouts, the number of subjects enrolled was increased to 50.

Participants who were eligible according to the inclusion criteria were randomized with 1:1 allocation ratio, without restrictions, into PR/PP sequence and PP/PR sequence. A computer generated order provided by the statistician was used for the randomization process.

The consultants who provided the treatment, were unaware of the sequence of intervention allocation until the treatment was completed. The dentist who collected the data at

the review appointments was blind to the palatal contour type for each participant. Blinding of the participants was not possible, as most of them would have noticed the protrusion of the palatal rugae on the denture when they held it in their hands for inspection or cleaning.

All statistical analyses were performed using the statistical package SPSS version 22.0 (SPSS, Inc.).<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 was normally distributed.<sup>44</sup> Therefore, the paired sample t-test was used to compare the ratings of the 100-mm VAS, between the two different follow-up time points. Considering the non-normal distribution of the OHIP-EDENT scores and in order to compare item scores in the OHIP-EDENT, Wilcoxon's signed rank test was used for pairwise comparisons, as this is the standard statistical test for ordinal paired data.  $P \leq .05$  was considered statistically significant.

## **RESULTS**

Between May and July 2019, a total of 68 participants were assessed for eligibility. Of which, 50 met the 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 recruited sample consisted of 38 men (76%), and 12 women (24%). The mean age for the sample was 62.3 years [SD = 7.3, range: 45 - 79]. First time complete denture wearers were 14 (28%), and those with previous complete denture wearing experience were 36 (72%). The median duration of edentulism was 37 months [IQR = 11.5 - 96, range: 3 - 408].

Table 2 presents detailed analyses of the within-participant differences of the VAS ratings for different palatal contours using a paired sample t-test. Except for satisfaction with ease of cleaning dentures, which was significantly less than for dentures with palatal rugae ( $P < .001$ ), no statistical significant differences were detected.



The difference in the OHIP-EDENT total scores for dentures with polished palate (Median= 32.5, IQR=25-45.75) compared to dentures with palatal rugae (Median= 36.5, IQR=24-46) was not statistically significant according to a Wilcoxon signed rank test ( $P=.126$ ). Table 3 shows the median values of all the OHIP-EDENT items responses, and  $P$ -values from Wilcoxon signed rank test for the difference between the two different palatal contours. Only one item ‘frequency of having to interrupt meals’ revealed statistical significant difference, which was increased when complete dentures with palatal rugae were used ( $P=.041$ ).

## **DISCUSSION**

To the knowledge of the authors, this is the first patient-centered clinical trial to assess the effect of palatal rugae addition to conventional complete dentures, on the satisfaction of edentulous patients. The study findings revealed no significant difference in satisfaction ratings between complete dentures with palatal rugae compared to complete dentures with polished palate. Therefore, the null hypothesis was accepted. The only exception was related to the ease of cleaning where the perception was that rugae created a more challenging environment.

The crossover design of the study together with the provision of only one set of complete dentures for each participant over the study period, minimized variability and the many confounding factors involved in complete dentures construction. The study was single blinded, since it was not possible to blind the participants to the change made to their complete dentures. Edentulous patients tend to remove their dentures and clean them multiple times a day, and therefore they would have noticed the changes in the palatal area.<sup>45</sup>

Patients’ reported outcomes were used, since these measures are subjective in nature and focus on patients’ perspective of the treatment provided rather than the dentist assessment.<sup>33</sup> The horizontal format of the VAS was reported to be preferred over the vertical format.<sup>38</sup>

A limit on the minimum duration of edentulism was necessary since severe ridge remodeling occurs during the first few months, which could impact the fit of any denture provided.<sup>46</sup> The two months follow-up was considered sufficient to eliminate any carry-over effect, as it generally requires 2 to 4 weeks to achieve adaption in complete denture wearers.<sup>4</sup>

Many studies discussed the negative impact of palatal coverage compared to no coverage.<sup>7,8,10,11</sup> However, in conventional complete dentures, avoiding palatal coverage is not possible. One study suggested keeping the rugae area exposed to improve tactile sensation when palatal coverage is needed, and found exposure of a small area might maintain acceptable levels of retention.<sup>15</sup> However, this study was done in dentate patients, and its generalizability to edentulous patients with complete dentures could not be confirmed. Therefore, examining the impact of different palatal contours on patients would be of value to the dentist and the patient.<sup>47</sup>

Steas<sup>13</sup> reported an improvement in taste perception, when an artificial palatal rugae was added to complete dentures. This was based on feedback from 12 patients who complained of taste sensation loss. The author suggested the improvement of food texture perception with palatal rugae, might be interpreted as improved taste perception. It was also suggested that palatal rugae provide the tongue with a surface to push and lock against, which might lead to better taste sensation through stretching the microvilli of the tongue away from each other.<sup>23</sup>

In a study which compared different palatal contours (smooth palate, wrinkled palate, average palatal rugae shape and tailor-made palatal rugae) on food perception, it was reported that the time required for perception of food size and shape, did not differ for different palatal contours. However, the duration was prolonged for the average palatal rugae shape.<sup>19</sup>

The current trial, did not detect significant differences in participants' satisfaction regarding eating or perception of taste. However, one item in the OHIP-EDENT measure

‘increased frequency of meals interruption’ was perceived worse in complete dentures with palatal rugae. This might be due to food getting caught on the acrylic rugae elevations.

Similarly, speech and phonetics were not perceived to be affected by the addition or removal of the palatal rugae in this trial. This was in contrast to other studies which suggested the addition of palatal rugae, would improve adaption to speech.<sup>14,21</sup> One study found the replication of palatal rugae, reduced the time duration for restoration of phonetics in complete denture wearers, as analyzed by a speech pathologist.<sup>17</sup>

However, others reported the addition of palatal rugae could have a negative impact rather than a beneficial one. This was attributed to the difference in compressibility between acrylic and natural rugae, and that it could add unnecessary thickness to the denture base.<sup>12,29</sup>

Most patients were reported to generally adapt and adjust their speech patterns when provided with palatal coverage.<sup>5,6</sup> It is a small percentage of patients whose speech is disturbed.<sup>16,22</sup> Therefore, it was not unexpected to find no significant difference in speech or phonetics in our trial between different palatal contours, when used over a period of two months.

Multiple methods for the addition of palatal rugae to complete denture surfaces were described in the literature.<sup>21-27</sup> Whether one method is superior is unknown. However, in one study the duplication of the individual own palatal rugae was found better in terms of food perception, than using the populations average rugae pattern.<sup>19</sup> Therefore, the participant’s own palatal rugae were duplicated in this study. The thickness of anterior palatal area of the complete denture was reduced before the addition of the artificial rugae. This was done to avoid increasing the thickness of the palatal contours, since it was reported to negatively impact speech.<sup>12,29</sup>

The method used for palatal rugae addition had the advantage of avoiding the need for constructing a new set of complete dentures.<sup>22</sup> However, it entailed the use of autopolymerizing

acrylic resin, as opposed to heat-cured acrylic resin with the better physical properties.<sup>45</sup>

Participants were less satisfied with the ease of cleaning their dentures with palatal rugae. This could be due to the irregularities of the palatal rugae compared to a polished palate, which might make the cleaning process more difficult in that area. However, it could also be that autopolymerizing acrylic resins are less color stable than heat-cured acrylic resins, and their increased discoloration was perceived as lack of cleanness. The use of a method which uses heat-cure acrylic resin, could be recommended for future studies to ascertain these assumptions.

The study included participants with and without a history of complete denture wearing. This could have impacted the results, as patients who have been used to a smooth polished palatal contour for years, could find it difficult to adapt to new irregular contour, especially elderly patients.<sup>48,49</sup> Therefore, the authors recommend that future studies include either first time complete denture wearers, or experienced complete denture wearers to get a better understanding of the impact of different palatal contours on our patients.

From the current study findings, there was no perceived benefit from adding palatal rugae to conventional complete dentures. From the participants' perspective, the palatal rugae made the denture cleaning process more difficult and increased the frequency of interruptions during meal-time. Therefore, within the limitations of this study, the routine addition of palatal rugae to conventional complete dentures is not recommended.

## **CONCLUSIONS**

The addition of palatal rugae did not improve the satisfaction of participants with their conventional complete dentures or their satisfaction regarding eating, taste perception, speech and phonetics. However, it made the denture cleaning process more difficult and increased the frequency of meal-time interruptions. The overall oral health impact profile was not affected.

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## **TABLES**

Table 1. Inclusion criteria.

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Inclusion criteria
Patients seeking a set of conventional maxillary and mandibular complete dentures at a University Hospital, for the first time or as a replacement of their previous dentures.
Patients aged between 45 and 80 years old.
Patients had been completely edentulous for at least 3 months.
Patients without severe underlying medical conditions, neuromuscular dysfunction, auditory problems, mental conditions, oral pathology, xerostomia, or tied tongue condition.
Patients who approved and consented to participation.

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

	PP		PR		VAS ratings (PP – PR)			
	M	SD	M	SD	M difference	95% CI	SD	<i>P</i> -value
General satisfaction	79.43	17.13	77.11	20.55	2.32	-3.65 – 8.29	19.64	.438
Eating	75.70	19.08	74.00	18.98	1.70	-4.05 – 7.46	18.93	.554
Taste perception	78.16	24.43	77.59	25.38	0.57	-5.04 – 6.17	18.44	.839
Speaking	77.48	21.64	73.80	22.43	3.68	-1.92 – 9.28	18.42	.192
Phonetics	74.93	21.95	73.45	22.86	1.48	-4.46 – 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*

PP: Polished palate, PR: Palatal rugae, M: mean, SD: standard deviation, CI: confidence interval

\*Statistically significant (<.05)

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

	Median PP	Median PR	<i>P</i> -value (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
A 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

1 = Never; 2 = Hardly ever; 3 = Occasionally; 4 = Fairly often; 5 = Very often.

PP: Polished palate, PR: Palatal rugae,

\*Statistically significant (<.05)

# FIGURES

Figure 1. Flowchart of the study.

