

Masticatory performance of different impression methods for complete denture fabrication: A randomized controlled trial



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ABSTRACT

Objectives: To compare the effect of conventional complete dentures fabricated using two different impression methods on masticatory performance and factors relating to masticatory performance in a randomized controlled trial.

Methods: A crossover randomized controlled trial was performed with edentulous patients requiring maxillomandibular complete dentures. Mandibular complete dentures were fabricated using two different methods. The conventional method (C) used a custom tray border molded with an impression compound and a silicone. The simplified method (S) used a stock tray and an alginate. Participants were randomly divided into the two groups. In the C–S group, the conventional method was used first, followed by the simplified method; the order was reversed in the S–C group. Adjustments were performed four times. The wash out period was 1 month. Masticatory performance as assessed by the mixing of a color-changeable chewing gum (mixing ability). Maximum occlusal force, occlusal contact area, and perceived chewing ability were assessed for each group.

Results: Twenty-seven patients underwent randomization and 24 participants completed the trial. With regard to occlusal contact area, the conventional method showed significantly larger occlusal contact area than the simplified method. No significant differences were observed between the two methods regarding mixing ability, maximum occlusal force, and perceived chewing ability.

Conclusions: This study showed that complete dentures fabricated with the conventional method had a significantly larger occlusal contact area than those made using the simplified method.

Clinical Significance: Complete dentures fabricated with the conventional method, comprising a preliminary impression using alginate in a stock tray followed by a final impression using silicone impression material in a border molded custom tray, resulted in fewer post-insertion adjustments than the simplified method, potentially contributing to earlier stability of new dentures.

1. Introduction

The prevalence of edentulism among the elderly aged ≥ 65 years is decreasing across much of the industrialized world, including Japan, but increasing in developing countries [1]. However, because the elderly population continues to increase, the need for restoration of edentulous arches is likely to remain substantial [2]. In Japan, the first choice for restoration of edentulous arches is still complete dentures. However, most researchers have reported that edentulous individuals show the highest degree of impairment in both patient-reported outcomes, such as patient satisfaction and oral health related quality of life

[3–5], and laboratory-based outcomes, such as masticatory performance [6–10].

Masticatory performance in edentulous individuals is poor compared with that in those with complete dentition [3]. Poorer masticatory performance accounts for lower maximum bite force, which leads to difficulties in chewing a number of food types [6], particularly fresh fruit and raw vegetables, and other hard and chewy foods [7]. This consequently leads to illnesses such as obesity, diabetes, cardiovascular disease, and some cancers [1,2]. Moreover, inadequate nutrient intake due to tooth loss is associated with weight loss, which is a factor in frailty [5]; therefore, edentulous individuals are also at risk of

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becoming frail. Consequently, it is essential for edentulous individuals to be provided with complete dentures that are appropriately fabricated.

Complete denture fabrication includes several stages. Among these stages, many practitioners have been reported to simplify the impression procedure [11]. A one-step impression is a single alginate impression as the definitive impression whereas a two-step impression involves two dental impressions as a traditional and academic procedure. The preliminary impression involves an alginate impression, and a final impression that uses individual trays for border molding and greater precision impression materials such as silicone.

A few reports based on randomized controlled trials have assessed the effect of conventional impression methods for complete denture fabrication on masticatory performance. Kawai et al. [12] and Cunha et al. [13] compared the conventional method, which included making two impressions using a facebow and a semi-adjustable articulator, and a simplified method comprising a single impression without a facebow and a semi-adjustable articulator with standard settings. According to the results of these studies, there was no significant difference in masticatory function measured by objective tests and patient self-assessments between the two methods. Omar et al. compared conventional methods with simplified methods using the same conventional methods for four groups at the clinical phase and omitting selected steps during the laboratory phase for three groups [14]. There was no significant difference in masticatory ability measured by patient self-assessments among the four groups. In addition, in a systematic review, Paulino et al. reported no significant difference in masticatory function between the conventional method and a simplified method [15]. To date, no study has compared masticatory function between complete denture fabrication impression methods.

We designed a randomized crossover controlled clinical trial to compare a simplified method, only using a single alginate impression, and the conventional method, involving a final impression with a silicone impression in border-molded custom trays, for complete denture fabrication. In a previous study, we reported the effect of the conventional method on patient satisfaction as the primary analysis [16]. Therefore, as a secondary analysis, the aim of this study was to report on masticatory function, measured by both an objective test and self-assessment, occlusal contact area, and maximum occlusal force, which are related to masticatory performance. The null hypothesis was that there would be no difference in masticatory function measured by both an objective test and self-assessment, occlusal contact area, and maximum occlusal force between the simplified and conventional methods.

2. Materials and methods

This study was a single blind randomized controlled crossover clinical trial. The detailed information of this study's protocol has been reported in a previous publication [16]. The trial protocol was approved by the Ethics Committee of the Faculty of Dentistry, Tokyo Medical and Dental University (TMDU) (No.: 946) and published in the University Hospital Medical Information Network Center (Unique Trial Number: UMIN00009875).

2.1. Participants

Participants comprised patients who were edentulous in both arches, currently using dentures, and requiring a new pair of complete dentures. They were recruited via telephone after having travelled to the Dental Hospital of TMDU. Inclusion criteria were as follows: ability to independently travel to the prosthodontics clinic of TMDU Hospital Faculty, adequate understanding of written and spoken Japanese, and the ability to understand and respond to a questionnaire. Exclusion criteria comprised: dementia, not currently using dentures, and existing psychiatric conditions. All participants provided informed consent, signed a letter of consent, and underwent a preliminary examination.

This examination was a panoramic radiographic survey.

2.2. Interventions

The clinical steps for both methods have been described in a previous report [16]. First, a preliminary impression was obtained using alginate impression materials (Aroma Fine Plus, GC Corporation, Tokyo, Japan) in a metal edentulous impression tray (Schreinemakers metal edentulous impression trays, Clan Dental Products, Maarheeze, Netherlands). The border of the denture was outlined on the study model, which was fabricated after the preliminary impression, and pouring by referring to anatomical landmarks; subsequently, custom trays were fabricated with an autopolymerizing resin (Ostron II, GC Corporation, Tokyo, Japan). Following this, a final impression was made using the custom tray border molded with two red and green stick impression compounds (Kerr Impression Compound, Kerr Corporation, Orange, CA, USA) and silicone impression materials (Exadenture, GC Corporation, Tokyo, Japan). For the simplified method, the master casts were made from the preliminary impression as the definitive impression only for the mandible while for the conventional method, the master casts were made from the final impression. The clinician then determined the border of the denture on the cast by referring to anatomical landmarks for the simplified methods. To implement a blinded protocol, the mandibular final impressions were not used for denture fabrication and were simply dummy impressions in the simplified method.

After the impressions were made, all procedures for both the methods were the same: making maxillomandibular relation records, mounting in an average-value articulator (Gysi Simplex OU-H3, COMATSU, Saitama, Japan), denture fittings, and the delivery of the dentures. After denture delivery, adjustments, including modification of the denture base, elimination of pressure spots in the denture base, and occlusal adjustments, were conducted four times every week from the initial delivery. After adjustments, assessments were performed. The number of adjustments was determined to be four in this study [17,18]. Participants did not receive further adjustments. Following assessments, a wash out period was set for 1 month, and participants were instructed to use their old dentures, on which adjustments were made using Tissue Conditioners (Tissue Conditioner II, Shofu Inc., Kyoto, Japan) throughout this period. The second phase for new complete denture fabrication was then started using the alternate fabrication method. During new complete denture fabrication, participants used their old dentures. They were also instructed to not use the dentures from the first phase. Two dentists with 10 to 12 years of experience conducted all clinical procedures. Another two personnel conducted the laboratory steps.

2.3. Outcomes

Study outcomes included mixing ability, maximum occlusal force, occlusal contact area, and perceived chewing ability. An independent researcher applied the following outcomes assessments 1 month after the denture delivery in both the first and second phases.

2.3.1. Mixing ability

A color-changeable chewing gum (Masticatory Performance Evaluating Gum Xylitol; Lotte Co., Ltd., Tokyo, Japan) was used as the test item. Participants were instructed to chew the gum 60 times freely, at a rhythm of chewing once per second. The chewed gum was flattened to a thickness of 1.5 mm in polyethylene films by compression between two glass plates, and then L^* , a^* , and b^* values were measured with a colorimeter (CR-13; Konica-Minolta Sensing, Tokyo, Japan) using the CIECLB color system at the following five points; the center, and approximately 3 mm above, below, and to the right and left of the center. ΔE values were calculated from the mean of L^* , a^* , and b^* values of the five points following the method followed in previous reports [19,20].

The number of chewing cycles (N) was calculated with the equation and defined as the evaluation value.

2.3.2. Occlusal contact area and maximum occlusal force

Occlusal contact area was measured using pressure-sensitive films and a pre-calibrated scanning device (Dental Prescale/Occluzer, GC Corp., Tokyo, Japan). Before the measurement, participants were seated comfortably on a dental chair with the Frank-fort horizontal plane parallel to the floor. They were then asked to bite the film for 3 s with maximum bite force. Only one measurement was taken. Occlusal contact area and maximum occlusal force were obtained with scanning and analyzed by the scanning device [21].

2.3.3. Perceived chewing ability

Twenty food items were assessed for the participants' perceived ability to bite and chew food using a four-point rating scale [22]. The ratio of number of food items that a participant answered "can chew well" to, which represents the highest rating for the 20 food items, was calculated to provide a percentage score for self-perceived chewing ability.

2.4. Sample size estimation, randomization, and blinding

Sample size estimation was described in a previous report [16]. Allocation to the C–S and S–C groups was performed based on the classification system for complete edentulism of the American College of Prosthodontists (ACP) with stratified randomization [23]. The C–S group used the conventional method first, followed by the simplified method. The S–C group went through the procedures in the reverse order. None of the clinicians or participants were provided information about the methods or the order of allocation. Blinding of the clinicians, laboratory workers, and the researcher who performed assessments and analysis of outcomes was impossible because they could view the master casts. Blinding of participants was possible as they were not provided information about the order of fabrication or the method that was used first (simplified or conventional). The number of clinical appointments was the same between the conventional method and the simplified method groups due to the inclusion of the mandibular final dummy impressions in the simplified method.

2.5. Statistical analysis

Participant baseline characteristics were compared between the two groups. The differences were analyzed according to age using an independent sample two-sided t-test, according to sex by using the Chi-square test, and according to ACP classification system using the Mann-Whitney test. Differences in mixing ability test, maximum occlusal force, occlusal contact area, and perceived chewing ability between the simplified method and the conventional method were analyzed using the Wilcoxon signed-rank test. Analyses were performed using the statistical software JMP ver. 13 (SAS Institute, NC, USA) at a significance level of 0.05.

3. Results

3.1. Participants

Participants were recruited from August 2013, and the trial was completed in October 2014. Twenty-seven patients who met the criteria underwent randomization. Fig. 1 presents a flow diagram of each step of the process through the randomized controlled trial. By the end of the trial, three participants had withdrawn due to disease. Therefore, the outcomes of 24 participants who completed all parts of this trial were analyzed. Table 1 shows a comparison of baseline characteristics between Group C–S and Group S–C. Half of the participants were classified as ACP class III. No significant differences in baseline

characteristics were observed between the two groups.

3.2. Outcomes

Table 2 shows the median, lower quartile, and upper quartile values for mixing ability, occlusal contact area, and maximum occlusal force of each group. There was no significant difference in mixing ability between the two groups ($p = 0.357$). There was significant difference in occlusal contact area with a larger score in the conventional method ($p = 0.005$). Fig. 2 shows an example of occlusal contact area analyzed by the scanning device. There was no significant difference in maximum occlusal force between the two groups ($p = 0.076$). Table 3 shows the median, lower quartile, and upper quartile values for the perceived chewing ability of each group. There was no significant difference between the two groups ($p = 0.378$).

4. Discussion

To the best of our knowledge, no previous study has compared masticatory function and other factors related to masticatory function between complete denture fabrication impression methods. This is the first study to assess the difference in masticatory performance measured by mixing ability, occlusal contact area, maximum occlusal force, and perceived chewing ability, between the conventional and simplified impression methods for complete denture fabrication. In the present study, the null hypothesis concerning occlusal contact area was rejected because a significantly larger occlusal contact area was observed by using the conventional method compared with the simplified method. The reason might be that a more appropriate impression by the conventional method could lead to more accurate subsequent procedures in each stage such as jaw relation recording and occlusal adjustment. This is because the wax occlusal rims with the autopolymerizing resin bases made from impressions in the conventional method might provide good stability and make it easy to make maxillomandibular relation records. This would consequently provide new dentures of which jaw relation is improved with easier post-insertion adjustments than the simplified method [16].

Due to new neuromuscular adjustments within the masticatory system, patients adapt to the new occlusion over the first few weeks after insertion of new dentures and adaptation is a continuous process. Therefore, occlusal contact points increase with time [24]. In the present study, post-insertion denture adjustments including occlusal adjustments were performed four times during a 1-month period for both groups. Therefore, the difference in the number of occlusal contact points between the groups could increase soon after new denture insertion compared with the difference after four denture adjustments. It is therefore suggested that complete dentures fabricated by the conventional method might already have larger occlusal contact points soon after new denture insertion and may require less post-insertion adjustments than the simplified method. Indeed, an increase in occlusal contact points alone does not lead to an ideal occlusion and stability of dentures, but is believed to be one of the indexes of denture stability. Therefore, the conventional method might contribute to the stability of new dentures at an earlier period, and thereby affect cost-effectiveness [25] and patient satisfaction [16].

In the present study, Dental Prescale pressure-sensitive films, mounted and measured in a central position, were implemented for measurement of maximum occlusal force, which avoided inaccurate measurements caused by denture slipping that can occur with unilateral biting or bilateral biting away from center position. There was no significant difference in maximum occlusal force between the two methods. The mucosal settling, effecting contact to the denture bearing tissues might contribute to the changes in occlusal force [26]. It is therefore likely that the difference in the impression methods did not influence mucosal setting that might cause change in occlusal force, but contributed to an increase in occlusal contact area.

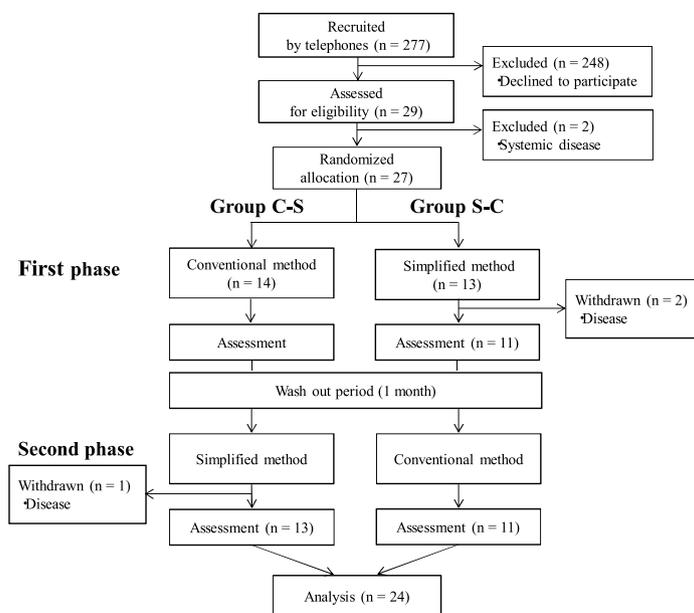


Fig. 1. Flow diagram of each step of the randomized clinical trial.

Table 1
Baseline characteristics of participants.

	Group		Total	p value
	C-S (n = 13)	S-C (n = 11)	(n = 24)	
>		>		
Age (years) [†]	76.2 ± 4.3	71.4 ± 13.3	74.0 ± 9.6	0.22 ^a
Gender (%)				0.97 ^b
Female	7 (54%)	6 (55%)	13 (54%)	
Male	6 (46%)	5 (45%)	11 (46%)	
American College of Prosthodontists classification (%)				0.85 ^c
I	1 (8%)	1 (9%)	2 (8%)	
II	3 (23%)	2 (18%)	5 (21%)	
III	7 (54%)	6 (55%)	13 (54%)	
IV	2 (15%)	2 (18%)	4 (17%)	

[†] Mean ± standard deviation.

^a t-test.

^b Chi-square test.

^c Mann-Whitney test.

Table 2
Median values (lower quartile, upper quartile) of mixing ability, occlusal area, and maximum occlusal force.

	Comparison between groups		
	Conventional method (n = 24)	Simplified method (n = 24)	p value
Mixing ability	76.15 (50.48, 92.9)	73.5 (58.25, 104.28)	0.357
Occlusal contact area	3.95 (2.98, 6.1)	2.75 (1.25, 4.63)	0.005 [*]
Maximum occlusal force	166.55 (95.88, 251.08)	122.15 (45.4, 209.03)	0.076

* Significant difference (p < 0.05).

A previous study by Cunha et al. reported no difference in masticatory performance measured by a type of comminution test using capsules coating fuchsine beads [13]. For edentulous individuals, mixing ability tests appear to be more appropriate than comminution

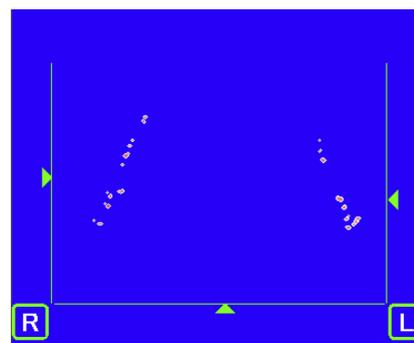


Fig. 2. An example of occlusal contact area analyzed by the scanning device.

Table 3
Median values (lower quartile, upper quartile) of perceived chewing ability.

	Conventional method (n = 24)	Simplified method (n = 24)	p value
Perceived chewing ability	57.5 (45, 78.75)	57.5 (32.5, 73.75)	0.378

tests [27], which was the reason why color-changeable chewing gum was used in the present study. It was reported that mixing ability among dentate individuals measured by a color-changeable chewing gum was associated with occlusal contact area in a previous study [28]. Moreover, in the present study, there was significant difference in occlusal contact area with a larger area in the conventional method compared with the simplified method. Therefore, it was expected that a greater mixing ability would be shown in the conventional method; however, there were no significant difference in mixing ability between the two methods. Certainly, the adaptation period, which participants need for adaptation to new dentures regarding masticatory performance, might have been too short (1 month) in the present study; however, there might be other factors affecting mixing ability in addition to occlusal contact area. Moreover, a difference in impression methods for complete denture fabrication alone might not significantly affect mixing ability. This may be why there was no significant difference in mixing ability detected between the two methods.

Similarly, there was no significant difference in perceived chewing ability measured by the food intake questionnaire between the two methods, which agreed with the results of a previous study that used a questionnaire with a 100 mm visual analogue scale [12]. There are two possible reasons for this finding. First, the evaluation period from the insertion of new dentures might have been too short for the participants to try eating various foods. Second, food intake counselling was not provided in this study; therefore, the participants might not have changed foods regardless of the complete denture fabrication method. Several previous studies have highlighted that most patients are unaware of the need to change their food choice even if their present dietary conditions are inadequate [29–32].

This study had some limitations. First, most denture wearers considered their self-assessed masticatory ability to be better than their objective masticatory performance due to optimistic bias [33], which was the reason why the objective tests, such as mixing ability test, occlusal contact area, and occlusal force were implemented in the present study. However, the evaluation period from the completion of denture adjustment was only 1 month; therefore, the adaptation period for new dentures might have been too short. If denture adjustment was made until each participant was satisfied, any significant difference in outcomes between the methods could not be detected. Therefore, the number of adjustments was determined to be four in this study. Second, due to the cross-over design of the clinical study, it was impossible to follow-up in the long-term. Instead, we minimized the influence of confounding factors among the participants. Third, participants' conditions of residual ridge included both mild resorption and severe resorption, ununified. Therefore, future studies with only severe residual ridge resorption need to be conducted in the future.

5. Conclusion

Under the limitations of this study, there was no significant difference in mixing ability measured by a color-changeable chewing gum, maximum occlusal force, or perceived chewing ability between the conventional method and simplified method. However, complete dentures fabricated by the conventional method provided a larger contact area than the simplified method early after delivery of new dentures, potentially contributing to earlier stability of new dentures. This has great significance for both patients and dentists due to the shorter adaptation period of new dentures and reduced number of post-insertion denture adjustments.

Conflicts of interest

The authors declare there is no Conflict of Interests in this work.

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