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A randomized controlled trial of the different impression methods for the complete denture fabrication: Patient reported outcomes

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ABSTRACT

Objectives: To compare the effect of conventional complete dentures (CD) fabricated using two different impression methods on patient-reported outcomes in a randomized controlled trial (RCT).

Methods: A cross-over RCT was performed with edentulous patients, required maxillomandibular CDs. Mandibular CDs were fabricated using two different methods. The conventional method used a custom tray border moulded with impression compound and a silicone. The simplified used a stock tray and an alginate. Participants were randomly divided into two groups. The C-S group had the conventional method used first, followed by the simplified. The S-C group was in the reverse order. Adjustment was performed four times. A wash out period was set for 1 month. The primary outcome was general patient satisfaction, measured using visual analogue scales, and the secondary outcome was oral health-related quality of life, measured using the Japanese version of the Oral Health Impact Profile for edentulous (OHIP-EDENT-J) questionnaire scores.

Results: Twenty-four participants completed the trial. With regard to general patient satisfaction, the conventional method was significantly more acceptable than the simplified. No significant differences were observed between the two methods in the OHIP-EDENT-J scores.

Conclusions: This study showed CDs fabricated with a conventional method were significantly more highly rated for general patient satisfaction than a simplified.

Clinical significance: CDs, fabricated with the conventional method that included a preliminary impression made using alginate in a stock tray and subsequently a final impression made using silicone in a border moulded custom tray resulted in higher general patient satisfaction.

Trial registration: UMIN000009875.

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1. Introduction

Complete dentures (CD) are the most common treatment for edentulous patients[1,2]; however, many patients find them unsatisfactory due to discomfort and difficulties in chewing.[3,4] The greatest problems are associated with the mandibular dentures due to anatomical conditions, so getting favourable results is difficult even if the dentures are made by experienced prosthodontists.[2,5] Currently, educators at dental schools advocate the use of the conventional impression method for CD fabrication, which involves two dental impressions: the preliminary and the final impressions. Despite this advice, dental literature reports that many general practitioners use a single alginate impression as the definitive impression for CD fabrication because of deficits in the knowledge of the technique, time, and cost.[6]

There have been three comparative studies regarding differences in impression methods for CD fabrication with the patient-reported outcome as the primary outcome, which have provided high quality evidence based on randomized controlled trials (RCT).[7–9] These studies, except that conducted by Omar et al.,[9] compared a conventional method, which included making the impressions twice using a facebow and a semi-adjustable articulator, and a simplified method, which included making a single impression without a facebow and using a semi-adjustable articulator with standard settings. The studies of Kawai et al.[7] and Regis et al.[8] used the same protocols; however, both used different tools to measure the primary outcome. No significant differences were observed in participant ratings for general satisfaction between the two groups in the study conducted by Kawai et al.[7] and in the influence on oral health-related quality of life (OHRQoL) in the study conducted by Regis et al.[8] Omar et al.[9] conducted a four-armed double-blind randomized trial to compare conventional methods with simplified methods using the same conventional method for all groups at the clinical phase and omitting selected steps during the laboratory phase for three groups. No significant differences were observed among the four groups in participant ratings for general patient satisfaction. Thus, no previous studies have concluded better values for neither conventional nor simplified methods. The inability to demonstrate a difference should not lead to the assumption of equivalence. It suggests that lack of evidence is not an evidence of equivalence. In their systematic review comparing conventional and simplified methods for the fabrication of CDs, Paulino et al.[10] revealed no differences in participant ratings for general satisfaction and OHRQoL between two groups and reported that the evidence for the efficacy of either remained unclear. However, these studies, except that conducted by Omar et al.,[9] included in the systematic review did not compare impression methods only.[10] Moreover, even if the study conducted by Omar et al.[9] was considered, to-date there has been neither any significant evidence for the need of a final impression (using silicone impression materials in border moulded custom trays) nor any evaluation of how the inclusion of a final impression influences CD fabrication when compared with only using a single impression with alginate.[10]

The aim of this study was to consider the efficiency of making a final impression for the mandible in the conventional method in a randomized crossover controlled clinical trial. Therefore, this study focused only on impression methods and other conditions were left unchanged. For the purpose of this study, a simplified method meant only using a single alginate impression and a conventional method meant making a final impression with a silicone impression in border moulded custom trays for CD fabrication. The null hypothesis was that there would be no difference in patient-reported outcomes between the simplified method and the conventional method groups.

2. Material and methods

This paper reports results from a single centre, single blind randomized controlled crossover clinical trial. The trial protocol was approved by the Ethics Committee of the Faculty of Dentistry, Tokyo Medical and Dental University (TMDU) under the register number 946 and published in the University hospital Medical Information Network (UMIN) Center (UMIN-CTR Clinical Trial, Unique trial Number: UMIN000009875).

2.1. *Participants*

The participants were patients who were edentulous in both arches, currently using dentures, and requiring a new pair of CDs. The participants were recruited by telephone from patients who had travelled to Dental Hospital TMDU earlier. Inclusion criteria were as follows: ability to independently travel to the clinic for prosthodontics of TMDU Hospital Faculty, adequate understanding of written and spoken Japanese, and the ability to understand and respond to a questionnaire. Exclusion criteria were as follows: dementia, no current use of dentures, existing psychiatric conditions. All participants gave informed consent, signed a letter of consent, and underwent a preliminary examination. This examination included a panoramic radiographic survey.

2.2. *Interventions*

Fig. 1 shows a flow diagram of the conventional and simplified methods for CD fabrication. The clinical steps for both methods were the same. 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). We did not use the alginate laminated double impression technique, and only a single impression with alginate was made. The border of the denture was outlined on the study model, which was fabricated after the preliminary impression was poured by referring to anatomical landmarks; subsequently, custom trays were fabricated with autopolymerizing resin (Ostron II, GC Corporation, Tokyo, Japan). Then, a final impression was made using this custom tray border moulded with red and green stick two impression compounds (Kerr Impression Compound, Kerr Corporation, Orange, CA, USA) consisting of materials with different softening temperatures and silicone impression materials (Exadenture, GC Corporation, Tokyo, Japan). For the simplified method, the master