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Simplified edentulous treatment: A multicenter randomized control trial to evaluate the timing and clinical outcomes of the technique

ABSTRACT

Statement of problem. The time and cost of traditional complete denture procedures have been questioned in favor of simplified and faster methods. Whether the simplified edentulous treatment (SET) method yields complete dentures with acceptable outcomes is unclear.

Purpose. The purpose of this randomized clinical trial (RCT) was to evaluate the outcomes of 2 techniques in providing complete dentures: the traditional and the SET.

Material and methods. Three Italian academic institutions participated in this single-blind parallel RCT. In total, 64 participants were selected and agreed to join the study. They were allocated randomly to 1 of 2 treatment groups, the traditional and SET: 32 per group, 50% women in each. Treatment was provided by final year predoctoral dental students. The time required for the clinical and laboratory procedures, the number of clinical sessions, and the laboratory returns were recorded. The clinical quality of the dentures and participant satisfaction were evaluated with questionnaires. Differences between treatment group outcomes were analyzed with 2-tailed independent sample *t* tests for clinical and technical timing and clinical and technical steps and Mann–Whitney U-tests for denture quality and participant satisfaction (α=.05).

Results. The clinical time required (-34%, $P<.001$), number of clinical sessions (-34%, $P<.001$), and laboratory returns (-46.5%, $P<.001$) were significantly lower for the SET than the traditional method. The laboratory time required (-10.6%) was not significantly less with the SET method

(*P*=.06). Participant satisfaction (*P*=.816) and prosthodontist ratings of denture quality (*P*=.539) were comparable between the groups. The participants appreciated the reduced number of clinical sessions with SET (*P*=.003).

Conclusions. SET may be considered a reliable method for providing complete dentures in a shorter timeframe while maintaining denture quality and patient satisfaction.

CLINICAL IMPLICATIONS

This study presents findings from a simplified technique for providing complete dentures that requires fewer clinical sessions and retains most traditional theories. This technique could be a successful alternative to the conventional method for patients who require shorter treatment times.

INTRODUCTION

Disagreement prevails about the process of providing complete dentures. Some prosthodontists promote traditional techniques and theories rather than making complete denture more rapidly and less expensively with a simplified edentulous treatment (SET) method.[1,2]

The need for complete denture service will remain for the foreseeable future in many countries. The state of edentulism is decreasing, but the prevalence remains quite high in developing and even some industrialized countries, and the large increase in the elderly population is estimated to counteract diminishing edentulism.[2] Unfortunately, implants do not solve all problems because of factors such as systemic diseases, economic concerns, and lack of access to implant services.[2,3] Thus, the need for teaching complete denture treatment remains,

possibly with simplified programs for predoctoral students and advanced postgraduate programs for those specializing in prosthodontics.[2]

The debate also concerns the need to apply traditional theories and procedures (individual trays and border molding, use of a facebow, clinical arrangement of anterior teeth, occlusal schemes). Carlsson[4] deemed some of the "old truths" to be dogma, opinions based more on beliefs than scientific evidence. Many prosthodontists and many universities still apply traditional stability, retention, and support principles. They advocate precise extension of the denture base, covering of the primary support area, close contact with the mucosa, and respect of the neutral zone in increasing stability and retentive force, giving support to the denture, and, as much as possible, preventing bone ridge resorption.[1] Respecting all of these principles and procedures seems to be time-consuming and expensive (more numerous and longer clinical sessions and laboratory returns).

Shorter and less expensive, but still satisfactory, treatment options should be defined and chosen for elderly people with contraindicating pathologies, chronic diseases, or significant social and economic disadvantages. Decreased mobility and dependence on others means reduced freedom of movement, especially for those living in rural areas where public transport options may be limited.[3,5,6]

Scientific reports suggest that a simplified fabrication method can replace the traditional method and still provide satisfactory and high-quality dentures.[2,5,7] In a recent review, 3 methods were identified: the normal simplified techniques (1 impression, no border molding, no facebow transfer, arrangement of anterior teeth in the laboratory), the 1-step denture (1 appointment, 1 hour), and the simplified edentulous treatment (SET) method.[1] However, the authors are unaware of standardization of the normal simplified method, or adequate evidence that such simplified

techniques are really comparable with the traditional.[1,7,8] The SET technique was conceived in an attempt to achieve the goals of reducing the number of clinical steps while still respecting the traditional principles of complete denture treatment.[9-11]

Therefore, the purpose of this clinical trial was to evaluate the outcomes of 2 techniques in providing complete dentures: the traditional and SET. The primary outcome was the clinical time needed to provide the dentures. Secondary outcomes were the time needed in the dental laboratory, the number of clinical sessions, laboratory returns, patient satisfaction, and the clinical quality of the dentures.

MATERIAL AND METHODS

Two techniques for making complete dentures were evaluated. The following outcomes were recorded: time for clinical and laboratory procedures, number of clinical sessions and laboratory returns, clinical quality of the dentures, and patient satisfaction. The hypothesis was that no between-group differences in clinical and laboratory timing, the number of clinical sessions, and the number of laboratory returns and no between-group difference in patient satisfaction and denture quality would be found.

Three academic institutions participated in this parallel randomized controlled single-blind clinical trial: the Universities of Turin, Ferrara, and Siena (Italy). The study protocol and consent form were approved by an institutional review board and ethics committee (CE UNIFE, protocol number 9/2010).

Individuals who had been completely edentulous for at least 2 years, who were wearing previous dentures, and who required new maxillary and mandibular complete dentures were invited to participate. Exclusion criteria were the presence of temporomandibular disorders,

xerostomia, orofacial motor disorders, systemic diseases with oral manifestations, and psychological or psychiatric conditions that could influence the response to treatment. The participants were recruited, considering the exclusion criteria, among those referred consecutively at the 3 institutions.

Those who met the criteria, accepted the conditions of the study, and provided informed consent were randomly assigned to the traditional (TRAD) or SET (SET) group. The TRAD group received complete denture treatment following traditional clinical procedures. The SET group received complete denture treatment following the clinical procedures proposed in the SET method. A blinded research assistant assigned participants to the groups using computer-generated random numbers (JMP; SAS), balanced for the similar characteristics considered relevant to the outcomes analyzed (age and sex). Blinding of the clinicians to treatment allocation was not possible; however, the participants were not told to which group they had been assigned (single blind).

To estimate the sample size, a between-group difference of 20% in clinical time was considered clinically meaningful. Consequently, 27 participants per group (total n=54) would be required for 80% power with a 2-sided α=.05, assuming that the data would be normally distributed.

The participants were treated in the 3 institutions involved in the study. Students in the final year of predoctoral dental education who had passed a qualifying examination for clinical practice in prosthodontics provided care, supervised by faculty members, from participant enrollment to the end of the prosthetic treatment.

Traditional and SET procedures differed in the way clinical data were recorded: impressions, maxillomandibular relationships, and the selection and arrangement of anterior

teeth were combined in a single clinical step in the SET procedure (Table 1). In the traditional group, the definitive impression was made with a custom tray, fabricated from a cast made from preliminary alginate impression, and a border was molded with a modeling plastic impression compound (Impression Compound; Kerr Corp) and a polysulfide impression material (Permlastic, Light Body; Kerr Corp). Maxillomandibular relationships were established by clinically adapting maxillary and mandibular wax occlusion rims fabricated on definitive casts according to functional and esthetic parameters. In the next step, an individualized clinical arrangement of the maxillary anterior teeth was performed at the dental chair. Posterior teeth were arranged in the laboratory.

For the SET group, the first impression was made using the MIT (Multilayer Impression Tray; Major Dental).[9] The MIT is a light-polymerizing 1.2-mm-thick composite resin layer with a 4-mm soft wax layer, separated by a polyvinyl chloride (PVC) film. It was adapted in the patient's mouth before polymerization for fabricating maxillary and mandibular baseplates, which were used both for supporting occlusion rims and for making the impressions once the border had been molded (Figs. 1-3). A maxillary rim was fabricated on the baseplate by adapting a roll of light-polymerizing resin (Lightcure Tray; Major Dental) using a so-called bone resorption compensating curve (BRCC - Compensating Curve; Major Dental).[9] This was adapted until the occlusal plane was oriented 3-dimensionally, the neutral zone and lip support were correct, and the esthetic and phonetic goals achieved; it was then polymerized (Fig. 4). Definitive impressions were made with polysulfide impression material. The selection and initial arrangement of maxillary anterior teeth was achieved using adhesive paper teeth (Paper Teeth; Major Dental) on the maxillary rim.[9] For all participants, the treatment plan considered the recording of maxillomandibular relationships by inviting and assisting the participant to close

and swallow. The definitive block contained all of the information necessary for the technician to prepare the clinical evaluation and definitive prostheses (Fig. 5).

For each participant, the following outcomes were recorded by operators on a specific research data sheet: time in minutes spent in clinical procedures, time in minutes spent in laboratory procedures, number of clinical sessions, and number of laboratory returns. At delivery, the clinical quality of the dentures was assessed using a questionnaire completed by a blinded expert operator. At 6 months after delivery, patient satisfaction was assessed using a specific questionnaire completed by the participants.[12,13] They were also asked to judge their treatment in a questionnaire.

Differences between treatment group outcomes were analyzed according to type of data. Two-tailed independent sample *t* tests were used for clinical and laboratory time and clinical and laboratory steps, and the Mann–Whitney U-test was used for denture quality and patient satisfaction (α=.05).

RESULTS

In total, 64 participants, aged between 48 and 93 years, were recruited for the study. They were randomly allocated into 2 groups: 32 per group, 50% women in each group (Table 2). All the participants remained in the same groups and were analyzed; there was no drop out.

The clinical time required (-34%, P<.001), number of clinic sessions (-34%, P<.001), and number of laboratory returns (-46.5%, P<.001) were significantly lower in the SET than in the traditional method. The expected between-group difference of 20% was exceeded. The laboratory time required (-10.6%) was not significantly less with the SET method (P=.06) (Table 3). The quality of the dentures, evaluated with the questionnaire, was comparable in the 2 groups

(P=.539). Satisfaction was also comparable in the 2 groups (P=.816). Participants were asked specific questions regarding satisfaction with their treatment (Table 4). The SET group significantly appreciated the reduced number of clinical sessions (P=.003).

DISCUSSION

The results of the present study confirmed the initial hypothesis: SET was a less time-consuming technique, with comparable levels of patient satisfaction and denture quality. One of the evaluated parameters, the time needed in the dental laboratory for fabricating the denture, did not reflect the initial hypothesis; the SET technique required less time in the laboratory, although the difference was not significant. The number of laboratory returns was also significantly different between groups. Transferring the prosthetic work back and forth between the laboratory and clinic is time-consuming and costly. Laboratory returns can be reduced to 1, depending on the patient and the operator. Technicians have, in fact, after 1 clinical session, all the necessary information for fabricating the definitive dentures: impressions, rims, esthetics, and maxillomandibular recordings. The main satisfaction score was comparable between groups, whereas the satisfaction score regarding treatments showed that satisfaction with the timing of SET was significantly higher.

The accelerated treatment protocol for complete denture prosthodontics has been controversial.[2-7] The concern is that a faster and less expensive method would not respect some traditional concerns and cannot be indicated for patient who nay require more a complex treatment regimen. Abbreviations of the techniques traditionally taught in the dental schools should yield an acceptable complete denture service for the straightforward patient with edentulism, while other patients may require more complex treatment regimen.[14] The SET

technique was not conceived as an abbreviation in the sense that it skips steps, but it condenses all the traditional steps into the same clinical session by using new materials and devices. Therefore, in the opinion of the authors, this technique may be proposed as an alternative and faster method, even for patients with more complex needs.

In the present study, exclusion criteria were applied, and patients with relevant comorbidities were excluded because predoctoral final-year students in their clinical practice rotation were chosen as operators. Testing the technique as applied by nonexpert operators revealed weak points in the procedures. Expert operators can provide complete dentures in straightforward patients with the SET technique in a single session of 75 minutes. Students needed more time for both the traditional and SET techniques; thus, the findings here should be considered not for their absolute values but for differences between the groups. A trial with complex patients and expert operators would give further and useful data for a comprehensive evaluation of the technique.

Patients with anatomic defects,[15] elders, and patients with difficulties in reaching dental facilities may benefit more from the technique. Furthermore, the SET clinical evaluation block can be used in a digital workflow (CAD-CAM, 3D printing technologies) in that it offers "impressions that record the shape of both the intaglio and cameo surfaces of complete denture bases while also identifying muscular and phonetic locations suitable for the placement of prosthetic teeth," as required for digital denture design.[16]

CONCLUSIONS

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

1. In the study population, SET allowed the provision of dentures in a shorter timeframe.

2. Subjective patient satisfaction with objective denture quality were comparable.

3. SET may be considered an acceptable alternative method for providing complete dentures.

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TABLES

Table 1. Description of techniques

Traditional procedure	SET procedure
1. Preliminary impression	1. Definitive impression, recording of maxillomandibular relationships, selection and arrangement of anterior teeth
2. Definitive impression	2. Definitive clinical evaluation
3. Recording of maxillomandibular relationships	3. Delivery
4. Anterior tooth arrangement	
5. Definitive clinical evaluation	
6. Delivery	

Table 2. Baseline characteristics of groups

	Age ±SD	**Male/Female**
SET (n=32)	71.34 ±10.7	16 (50%)
TRAD (n=32)	70.34 ±10.0	16 (50%)

Table 3. Outcomes of parameters evaluated

	Clinic time (min)	Laboratory time (min)	Number of clinic appointments	Number of laboratory returns	Quality questionnaire score (/100)	Satisfaction questionnaire score (/100)
SET						
MEAN VALUE	363.5	582.92	5.63	2.41	83.8	81.43
SD	97.4	164.88	1.62	0.56	9	7.72
CI	33.75	57.13	0.56	0.19	3.12	2.67
TRAD						
MEAN VALUE	551.22	652.08	8.53	4.5	85	80
SD	184.69	173.03	1.76	0.98	6.38	12.23
CI	63.99	59.95	0.61	0.34	2.21	4.24
P	<.001	.060	<.001	<.001	.539	.816

Table 4. Treatment satisfaction

	Overall (/100)	Number of appointments (/100)	Duration of sessions (/100)	Mean value
SET				
MEAN VALUE	81	95	88	88
SD	1.16	0.40	0.67	0.74
CI	0.40	0.14	0.23	0.26
TRADITIONAL				
MEAN VALUE	88	82	87	85
SD	0.76	0.89	0.67	0.77
CI	0.26	0.31	0.23	0.26
P	.310	.003	.850	.370

FIGURES

Figure 1. Adaptation of multilayer impression tray.

Figure 2. Excess material removed with scissors.

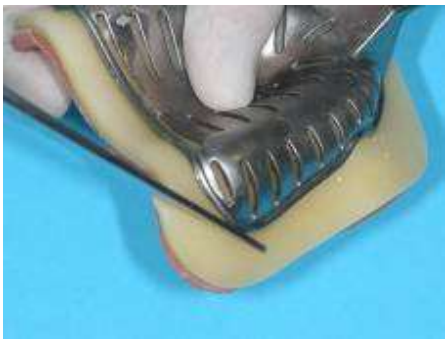

Figure 3. First impressions made with the multilayer impression tray.

Figure 4. Compensating curve and unpolymerized resin roll used to determine occlusal plane height, position, and orientation in three-dimensions.

Figure 5. Maxillary and mandibular impression, occlusal record, position of anterior and posterior teeth, and esthetics (approximated with paper teeth).