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**A 1-year parallel-group randomized clinical trial comparing patient-reported outcomes between mandibular complete denture and early loaded single-implant overdenture**

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# **A 1-year parallel-group randomized clinical trial comparing patient-reported outcomes between mandibular complete denture and early loaded single-implant overdenture**

## **Abstract**

**Purpose:** To assess the effectiveness of converting a conventional mandibular denture (CMD) into a single-implant mandibular overdenture (SIMO). **Material and methods:** Edentulous subjects received a new set of CMD and were randomly assigned to CMD or SIMO groups. For SIMO patients, a midline early-loaded implant was inserted and incorporated into the CMD after three weeks. Patient satisfaction and oral health-related quality of life were assessed at baseline and up to 1-year. Regression models were constructed using Generalized Estimating Equations. **Results:** After 12 months, 32 patients were assessed (CMD: n=17; SIMO: n=15). Significant improvement was observed for the SIMO group when compared to baseline measures. **Conclusion:** SIMO may be considered an effective alternative for patients unsatisfied with their CMDs. (ClinicalTrials.gov NCT02710357)

**Keywords:** Edentulous patient; complete denture; mandibular overdenture; patient satisfaction; oral health-related quality of life.

## **Introduction**

The single-implant mandibular overdenture (SIMO) has gained visibility as an alternative for edentulous patients. Preliminary data derived from single-group

prospective studies suggested marked improvement when a midline implant is incorporated into a mandibular denture [1]. It also seems to have similar effectiveness compared to the mandibular overdenture retained by two implants [2]. However, there is scarce evidence from randomized clinical trials that compared the effectiveness of conventional mandibular dentures (CMD) to the SIMO treatment, which are essential to improve the level of evidence and support the use of SIMO treatment on a regular basis.

Thus, this study aimed to compare the effectiveness of the SIMO versus CMD after a 12-month follow-up period, focusing on patient-reported outcome measures.

## **Material and methods**

This study was designed as a parallel two-group randomized clinical trial. A full description of methods was published previously [3]. Briefly, edentulous individuals were screened according to specific inclusion/exclusion criteria. Then, participants were randomized to the two study groups, and new conventional complete dentures were provided for all. After a minimum 3-month adaptation period, a baseline assessment was carried out, and participants were randomly allocated to CMD or SIMO groups. For the CMD group, outcomes were subsequently assessed 6 and 12 months after allocation. For the SIMO group, a Standard Plus SLActive® regular neck implant (Straumann, Switzerland) was placed in the symphyseal region of the mandible and after a 3-week healing period, the overdenture retention was provided using a 3.4 mm retentive titanium anchor abutment and the corresponding elliptical matrix (Straumann,

Switzerland). Outcomes were assessed 6 and 12 months after incorporating the retention system.

Oral health-related quality of life (OHRQoL) and patient satisfaction were assessed as outcomes. The Brazilian version of the OHIP-Edent instrument was used to assess OHRQoL. Patient satisfaction with the maxillary and with the mandibular dentures was measured separately, and a 10-cm uninterrupted Visual Analog Scale was used to assess their self-ratings for general satisfaction, comfort, stability, aesthetics, ability to speak, and ability to chew. In addition to the item scores, a mean summary was obtained as a measure of patient satisfaction with the maxillary and mandibular dentures.

Preliminary data analysis included descriptive statistics and bivariate comparison tests. Further, Generalized Estimating Equation (GEE) was used to fit a regression model for the longitudinal data, aiming to investigate whether there exist significant group differences in temporal trends of the repeated-measure outcomes. IBM-SPSS 24.0 software was used for statistical analysis.

## **Results**

The patient flowchart is detailed in Figure 1. Overall mean age was 64.0 ( $\pm 9.3$ ) years, 65.6% women. Groups were similar at baseline regarding sex, age and measured outcomes ( $p > 0.05$ ). Thirty-two participants completed the 6 and 12-month follow-ups (CMD group:  $n = 17$  and SIMO group:  $n = 15$ ).

Distributions of the outcome measures according to the treatment groups are depicted in Figure 2. Non-parametric Friedman test revealed that OHIP-Edent

scores remained unchanged for CMD group ( $p=0.314$ ) and significantly reduced for SIMO ( $p=0.003$ ). Patient satisfaction with the mandibular denture increase after 12 months for SIMO ( $p=0.002$ ) and had a slight non-significant decrease for CMD ( $p=0.051$ ). Patient report of satisfaction with the maxillary denture did not change for CMD ( $p=0.229$ ) and increased after 12 months for SIMO ( $p=0.030$ ).

Table 1 summarizes the results of GEE analysis. Regression models reveal that treatment groups differ with respect to change in OHIP-Edent and satisfaction with the mandibular denture from baseline to post-intervention periods. In addition, the estimated differences in slopes indicate that the responses are improving significantly over time for the SIMO group than for the CMD group.

## **Discussion**

Findings of this study provide confirmatory evidence that use of a single midline implant to retain a mandibular denture significantly improved patient-reported outcome measures (PROMs), such as OHRQoL and satisfaction with the dentures compared to the conventional treatment. One strength of this study was the use of PROMs as a way to measure treatment effects, which represent relevant aspects that should be included as an integral part of clinical care.

Nevertheless, even when exempted from financial charges patient adherence to overdentures seems to be dependent on other factors such as patient's perception of the need for stabilization of the CMD, the amount of information about the treatment they have, as well as previous experiences reported from others. A study on elderly participants who refused 2-implant overdentures

highlighted patient's fear/anxiety and the appropriateness of the procedure in an elderly person as the main reasons for implant treatment refusal [4]. However, age alone should not be a limiting factor for dental implant therapy in elderly patients, since robust evidence have been reported in terms of high implant survival rates, clinically acceptable marginal bone loss changes and minimal complications [5].

Finally, conventional complete dentures remain as an important part of oral health care in many clinical settings. Nevertheless, simplified interventions with implants such as SIMO may potentially increase implant utilization for a number of patients with lower access to implants, due to economic constrains or the need of less invasive procedures.

### **Acknowledgements**

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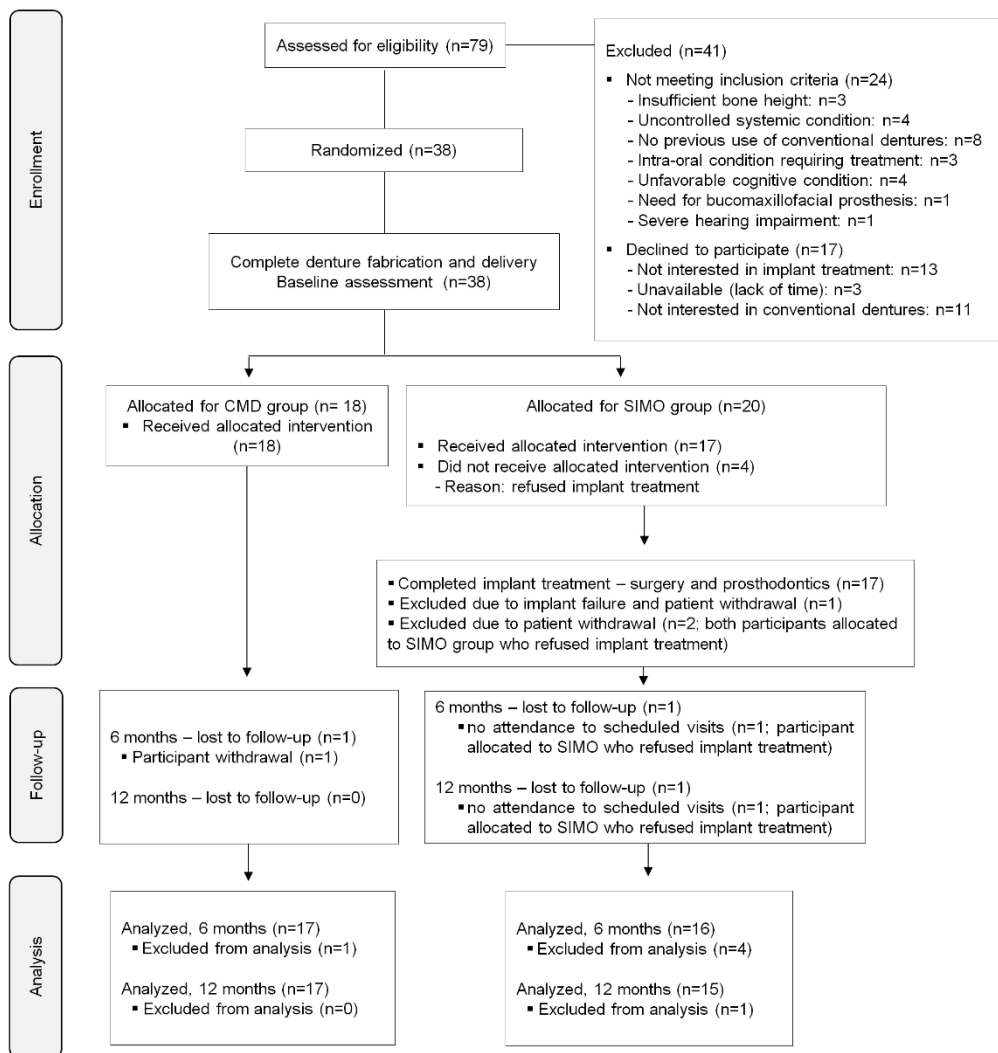


Figure 1. Flowchart of the study.

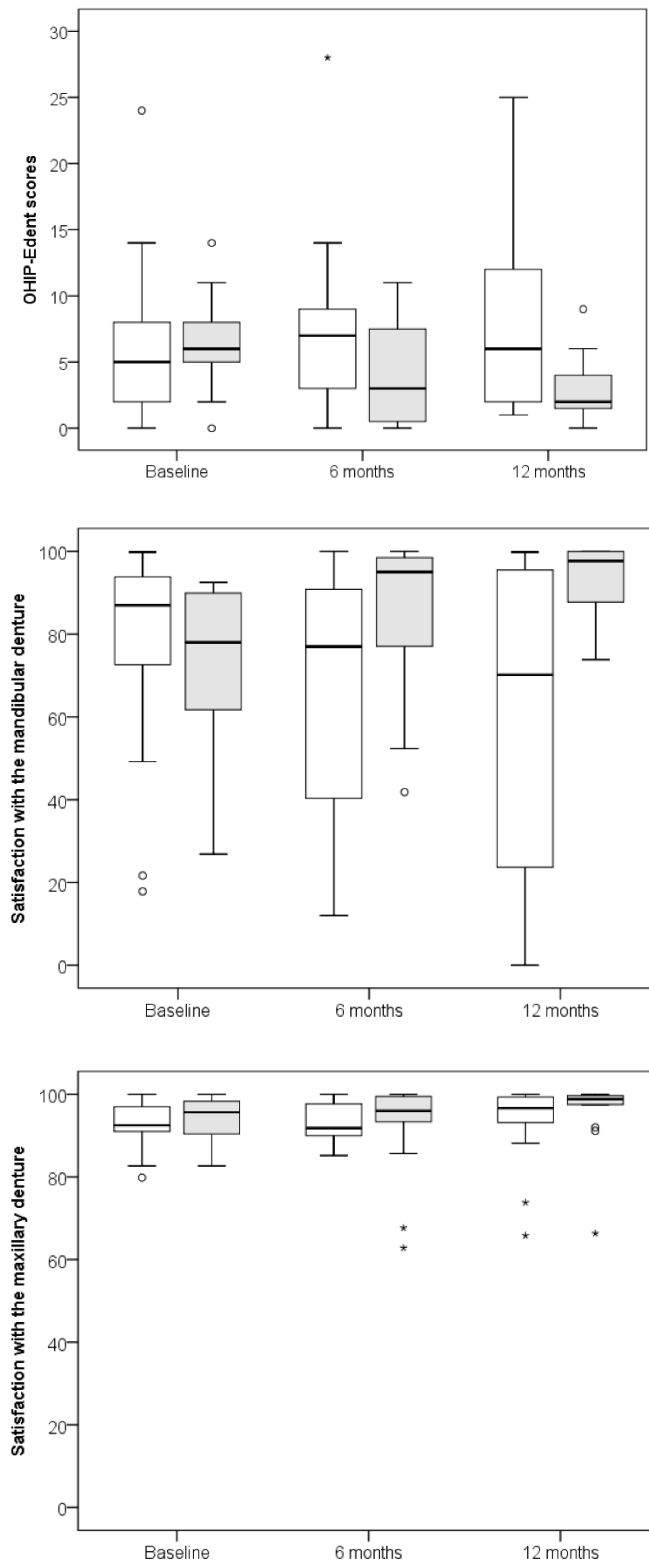


Figure 2. Changes over time in OHIP-Edent scores (2a) and satisfaction with the mandibular (2b) and maxillary denture (2c). CMD: conventional mandibular denture group. SIMO: single-implant mandibular overdenture group. The characters \* and ° represent cases considered as outliers.

Table 1. Intervention effects of predictors on patient-reported outcomes, using Generalized Estimating Equations (GEE). Parameter estimates are regression coefficients (and standard errors – SE).

Predictors	Factors and interactions	OHIP-Edent (Model 1)		Satisfaction with the mandibular denture (Model 2)		Satisfaction with the maxillary denture (Model 3)	
		B (SE)	p	B (SE)	p	B (SE)	p
Intercept		6.1 (1.5)	<0.001	75.9 (6.0)	<0.001	92.9 (1.4)	<0.001
Groups	CMD	<i>Ref</i>		<i>Ref</i>		<i>Ref</i>	
	SIMO	0.2 (1.7)	0.904	-2.3 (7.6)	0.759	1.0 (1.9)	0.621
Time periods	Baseline	<i>Ref</i>		<i>Ref</i>		<i>Ref</i>	
	6 months	1.2 (1.2)	0.316	-10.8 (7.6)	0.035	0.5 (1.4)	0.756
	12 months	2.2 (1.5)	0.152	-14.0 (7.6)	0.065	0.5 (2.7)	0.854
Interaction	CMD ( <i>Ref</i> ) vs SIMO – Baseline	<i>Ref</i>		<i>Ref</i>		<i>Ref</i>	
	CMD ( <i>Ref</i> ) vs SIMO – 6 months	-3.5 (1.5)	<b>0.023</b>	22.1 (7.7)	<b>0.004</b>	-2.0 (3.2)	0.548
	CMD ( <i>Ref</i> ) vs SIMO – 12 months	-5.4 (1.6)	<b>0.001</b>	33.9 (9.0)	<b>&lt;0.001</b>	1.5 (3.3)	0.640

CMD – Conventional mandibular denture; SIMO – Single-implant mandibular overdenture