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A randomized clinical trial of a simplified technique for complete denture fabrication: patient perceptions, masticatory efficiency, temporomandibular disorders and quality of dentures

Ensaio clínico randomizado de uma técnica simplificada para confecção de próteses totais: percepções do paciente, eficiência mastigatória, disfunções temporomandibulares e qualidade das próteses

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ABSTRACT

Objective: To evaluate the efficacy of a simplified technique for complete dentures (CD) fabrication focusing on patient-reported outcome measures (PROMs), masticatory efficiency (ME), temporomandibular disorders (TMD), and CD technical quality. **Material and Methods:** Fifty edentulous individuals were allocated into two groups based on the complete denture (CD) fabrication method: traditional (T) or simplified (S). Patients were evaluated at baseline and at a 3-month follow-up, considering quality of life and satisfaction. The technical quality of the CDs and masticatory efficiency were assessed at the 3-month follow-up using a validated instrument and a colorimetric test, respectively. Data were analyzed using McNemar and Mann-Whitney tests for intra-group comparisons and Chi-square, Fisher's Exact, or Wilcoxon tests for inter-group comparisons. **Results:** Forty-two patients completed the study (T = 20, S = 22). At the 3-month follow-up, no significant differences were observed between the groups for masticatory efficiency ($p = 0.131$), CD technical quality ($p = 0.456$), satisfaction ($p = 0.146$), and quality of life ($p = 0.409$). Patient-reported outcome measures (PROMs) improved from baseline to the 3-month follow-up ($p < 0.01$) for both groups. The presence of temporomandibular disorders (TMD) significantly decreased after denture replacement ($p < 0.001$). **Conclusion:** CD fabricated by a simplified technique seems to be time-efficient and as effective as that fabricated by a traditional technique. Insertion of new dentures positively influenced PROMs and TMD presence.

KEYWORDS

Complete denture; Mastication; Patient satisfaction; Quality of life; Temporomandibular disorders.

RESUMO

Objetivo: Avaliar a eficácia de uma técnica simplificada para fabricação de próteses totais (PT) nos desfechos relatados pelo paciente (PROMs), eficiência mastigatória (EM), difunções temporomandibulares (DTM) e qualidade técnica da prótese. **Material e Métodos:** 50 indivíduos edêntulos foram alocados em dois grupos com base no método de fabricação da prótese total (PT): tradicional (T) ou simplificado (S). Os pacientes foram avaliados antes e 3 meses após a instalação das próteses, considerando a qualidade de vida e a satisfação. A qualidade técnica das PTs e a eficiência mastigatória foram avaliadas no seguimento de 3 meses usando um instrumento validado e um teste colorimétrico, respectivamente. Os dados foram analisados usando os testes de McNemar e Mann-Whitney para comparações intra-grupo e os testes Qui-quadrado, Exato de Fisher ou Wilcoxon para comparações entre os grupos. **Resultados:** Quarenta e dois pacientes completaram o estudo (T = 20, S = 22).

3 meses após a instalação das PTs não foram observadas diferenças significativas entre os grupos quanto à eficiência mastigatória (p = 0,131), qualidade técnica das PTs (p = 0,456), satisfação (p = 0,146) e qualidade de vida (p = 0,409). Os desfechos relatados pelos pacientes (PROMs) melhoraram 3 meses após a instalação das próteses (p < 0,01) para ambos os grupos. A presença de disfunções temporomandibulares (DTM) diminuiu significativamente após a substituição das próteses (p < 0,001). **Conclusão:** As PTs fabricadas pela técnica simplificada parecem ser tão eficazes quanto aquelas fabricadas pela técnica tradicional. A inserção de novas PTs influenciou positivamente os PROMs e a presença de DTM.

PALAVRAS-CHAVE

Prótese total; Mastigação; Satisfação do paciente; Qualidade de vida; Disfunções temporomandibulares.

INTRODUCTION

Edentulism, the condition characterized by the loss of all natural teeth, has significant implications for oral health and overall well-being. It is a devastating and irreversible condition and one of the public health burdens for elderly people and effects clearly the practice of primary care [1]. Factors contributing to edentulism include age, socioeconomic status, and access to dental care [2]. There is a notable decline in edentulism in recent years, marking a positive shift in oral health trends worldwide. However, the edentulism is still prevalent and can continue to increase until 2040 [3]. This trend reflects the historical focus of public oral health care for adults on urgent care, which often involves tooth extractions [3,4].

To reduce clinical and laboratory steps during denture fabrication, simplified techniques for complete denture (CD) fabrication have been developed. These approaches appear to be as effective as traditional approaches while requiring less time and resources [5]. There is no evidence that dentures made using traditional techniques are preferred by patients over those made using simplified techniques [6]. The complete dentures must also provide retention and stability, which may be affected by the manufacturing process [7]. Masticatory ability can also be influenced by technical quality [5]. The degree of residual ridge atrophy and the duration of edentulism may also have an impact on treatment success and may introduce bias when comparing CD fabrication techniques [8-10].

Several variables, including those assessed by professionals and patient-reported outcome measures (PROMs) [11], must be investigated to assess the effectiveness of simplified methods. Patient satisfaction should be taken into account during rehabilitation treatment, especially since it is associated to patients' adaptation, as well as comfort, aesthetics, chewing, and phonetics [6]. The assessment of Oral Health-Related Quality of Life (OHRQoL) has been considered essential in determining an individual's quality of life [12], as oral rehabilitation encompasses psychological and social aspects in addition to physical health [12]. A widely used instrument for assessing OHRQoL in edentulous patients is the OHIP-EDENT [13]. This inventory has demonstrated strong psychometric properties, enabling the evaluation of the impact of oral rehabilitation on both the functional aspects and quality of life of edentulous individuals [14].

Epidemiological studies have reported the presence of Temporomandibular Disorders (TMD) in complete dentures (CD) patients; however, there is no consensus regarding the prevalence of these disorders in these patients [5,15]. Most CD wearers are elderly and the prevalence of TMD in this population is controversial. Authors such as Schmitter et al. [16] claim that elderly patients may exhibit signs and symptoms of TMD, but rarely complain of pain. Literature is still controversial regarding the factors that contribute to the development of TMD in CD wearers [6].

For instance, Sanjeevan et al. [17] in a meta-analysis, compare simplified and traditional CD production techniques and found no differences in patient satisfaction or technical quality. The authors also observed that the simplified technique made less expensive and time efficient CD. However, while some studies support the efficacy of simplified techniques, the limited number of randomized clinical trials using similar clinical methodologies and differences in simplified techniques in the literature did not support the use of such a technique.

Simplified techniques for CD offer significant benefits in terms of cost, time efficiency, and

accessibility. However, they also present trade-offs, particularly concerning customization for patients with anatomical limitations, overall quality, and improvements in PROMs. The propose of this research is evaluate the efficacy of a simplified CD fabrication technique in terms of PROMs, masticatory efficiency, TMD, and CD technical quality. Given that this is an equivalence trial, our expectation was that the simplified technique would demonstrate efficacy comparable to traditional methods while being more cost-effective and time-efficient. The null hypothesis was that there is no difference between the S and T techniques with respect to the parameters analyzed.

MATERIAL AND METHODS

This randomized clinical trial was entered into the clinicaltrials database (identifier: NCT02652403). Each patient provided written informed consent in accordance with the regulations of the local Research Ethics Committee (protocol number: 37098714.5.0000.5292). The sample size calculation was according to prior study Regis et al. [6]. The power test was calculated using Sealed Envelop Ltd software (https://www.sealedenvelope.com/power/continuous-equivalence/) at 80% and the 95% confidence interval and considering a standard deviation of 2.99 from General Ohip-Edent [6] with a minimum sample of 18 patients per group, anticipating possible sample loss, 25 patients' group were adopted.

The sole inclusion criterion was the use of previous dentures (in both jaws) for at least one year, while the exclusion criterion was the presence of pathological changes in the alveolar ridges (such as CD-induced fibrous hyperplasia). A standardized preliminary alginate impression using edentulous metal tray was made for all patients. Subsequently, patients were randomly assigned, using a sealed envelope, to one of two groups: traditional technique, considered the control group (T), or simplified technique (S). Patients were blinded to their assigned study group.

The treatment was carried out by four experienced prosthodontists in accordance with a standardized clinical protocol. The clinical protocol for the traditional technique was similar to previous studies [5,6,12] and the simplified technique consisted of four chair-side and three laboratory steps (as detailed in the Table I). The initial alginate impression was standardized and consistent across groups, and it was made with metal-perforated edentulous impression trays that were wax-lined on the border using soft utility wax (to minimize border over extension). The work casts based on the alginate impression and the arbitrary mount on SAA (using a 15 degrees plan) in the S group were the differences between the traditional and simplified methods [6].

The post dam was created arbitrarily, by marking the work cast, for the S group and during

Table I - Chair-side and laboratory steps of the two methods

Step		Traditional	Simplified
1	Chair-side	Preliminary alginate impression (edentulous metal trays)	Final alginate impression (edentulous metal trays)
2	Laboratory	Primary casts and custom trays fabrication (auto polymerizing acrylic)	Work casts and occlusal rims fabrication
3	Chair-side	Secondary impression (impression compounds and Zinc oxide–eugenol paste)	Jaw registration (vertical dimension and centric relation), teeth shade selection and casts arbitrarily mount on SAA (using a 15 degrees plan)
4	Laboratory	Work casts and occlusal rims fabrication	Teeth set-up (33-degree teeth and mutually protected occlusion)
5	Chair-side	Jaw registration (vertical dimension and centric relation), teeth shade selection and casts mount on SAA using face-bow	Teeth try-in
6	Laboratory	Teeth set-up (33-degree teeth and mutually protected occlusion)	Laboratorial finishing process
7	Chair-side	Teeth try-in	Denture insertion
8	Laboratory	Laboratorial finishing process	
9	Chair-side	Denture insertion	

SAA: semi adjustable articulator.

the custom tray adjustment, before the secondary impression, for the T group. The denture insertion appointment was conducted similarly for both groups. Before insertion, professionals checked the surface polish and border design of the dentures. After inserting the CDs, they assessed border extension and fit, retention, stability, and occlusal contacts. If the patient reported any discomfort or if any occlusal disharmony was observed, the professional performed the necessary adjustments followed by a polishing procedure.

Patients completed a general information inventory at the baseline (gender, age, and years of use of the previous CD). A calibrated examiner performed a clinical evaluation of mandibular residual ridge height, which was classified according to prognosis: high and medium (better prognosis), or low residual ridge height (worst prognosis). The follow-up appointments were scheduled for 24 hours, 7, 14, and 30 days, and 3 months after the CD insertion. However, additional follow-up appointments could be scheduled if necessary, for instance, if the patient had any complaints.

PROMs and TMD presence were assessed at baseline, while patients wore their previous CD. PROMs were evaluated by a satisfaction inventory [6] and using the Portuguese version of OHIP-Edent [13]. Ohip-Edent questions were grouped into subclasses [6,18]. All subclasses were comprised of 5 questions, with scores ranging from 0 to 10 points, except for the psychological discomfort and disability subclasses, with 4 four questions and scores ranging from 0 to 8 points. The presence of TMD was assessed by the Portuguese version of RDC/TMD [19] and all TMD patients were classified based on TMD origin (myogenous or arthrogenous or myogenous and arthrogenous).

Masticatory efficiency was assessed using mastication capsules in combination with a colorimetric method, as described previously by Santos et al. [20]. All patients were properly seated in chairs and instructed to chew the capsule for 20 seconds. A spectrophotometer (Ultrospec 2100 pro UV / Visible Spectrophotometer, GE Healthcare, New York, USA) was used to measure the concentration of the staining intensity of the fuchsin solution, which was expressed as absorbance (abs).

The CD quality was assessed using the Sato et al. [7] instrument, which evaluates: anterior teeth arrangement, interocclusal distance, stability of mandibular denture, occlusion, articulation, retention of mandibular denture, and border extension of mandibular denture. Each item was assigned a conversion number (0-18) based on the scores assigned (1-3). The general quality of the prosthesis score ranges from 0 to 100, and 100 indicate better quality and 0, poor quality.

Examiners calibrated and blinded for patients group collected data. The same examiner assessed PROMs and the presence of TMD at baseline and three months later. Masticatory efficiency and CD quality were only assessed after a three-month follow-up, to assess patients after the adaptation period.

Statistical analysis

SPSS software (Statistical Package for Social Sciences) for Windows, version 20.0, was used to analyze the data. Baseline data were compared using the Mann-Whitney, Pearson's chi-square or Fisher's exact tests. The TMD diagnosis was compared before and after the CD insertion using the Pearson Chi-square test. The TMD origin was evaluated using the Mann-Whitney, Pearson's Chi-square, and Fisher's Exact tests. The satisfaction analysis used the Chi-square test, Fisher's Exact test (for inter-group comparison), and the McNemar test (for intra-group ratings). For OHIP analysis, the Mann-Whitney test (for inter-group comparison) and the Wilcoxon test (for intra-group evaluations) were used. The Mann-Whitney test was used to evaluate masticatory efficiency and denture quality. A 5% significance level was used.

RESULTS

Fifty patients were selected and randomly assigned to one of two groups: T (N=25) or S (N=25). There were 44 females (88%) and 6 males (12%). The participants' ages ranged from 50 to 92 years, and their previous CD use ranged from 1 to 30 years. At the baseline, there were no statistical differences between the groups (Table II). At the 3-month follow-up, 8 participants dropped out of the study for various reasons (Figure 1). As a result, the final sample included 42 patients (38 females and 4 males) with an average age of 65.96 ± 9.35 years.

Table II - Baseline characteristics of the sample

	Group		Overall	*p*
	T	S		
Age (years)	64 (57.5-72)	65 (61.5-75)	65 (58.75-72)	0.225
Gender				
Female	22 (88%)	22 (88%)	44 (88%)	-
Male	3 (12%)	3 (12%)	6 (12%)	
Use of previous CD (years)				
Maxillary	6 (3-13.5)	9 (4.5-10)	8 (4-12)	0.430
Mandibular	7 (3-15)	8 (4-10)	8 (4-12)	0.992
Height of the mandibular residual ridge				
High / medium	7 (28%)	6 (24%)	13 (26%)	0.500*
Low	18 (72%)	19 (76%)	37 (74%)	

T: Traditional, S: Simplified. Median (interquartile range) for age, and previous use of last complete denture (CD). Other variables in absolute values (%). Mann- Whitney test, Chi Square test*. (-) Tests not applicable. Significant difference, p<0.05.

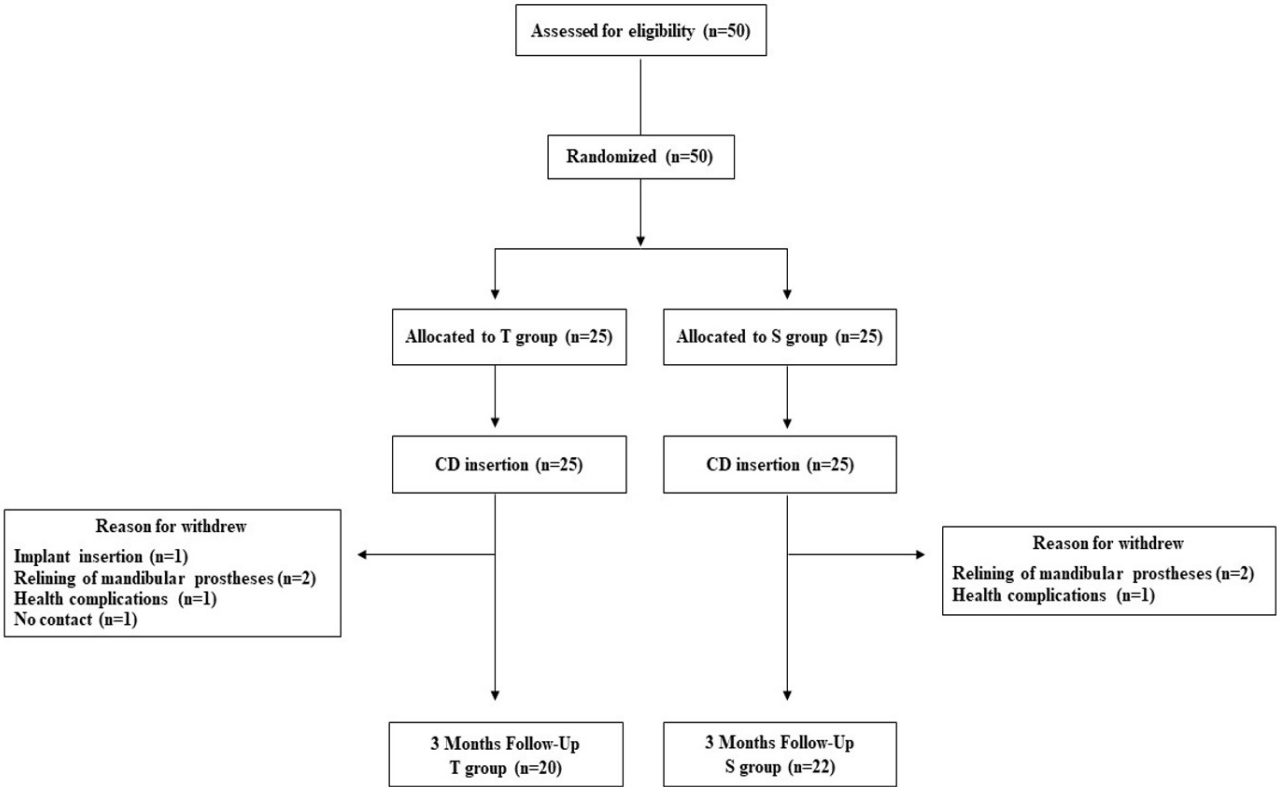

Figure 1 - Study flow diagram.

The level of adjustment required for the CD at the insertion appointment was similar for both groups. On average, patients in the S group needed 2.4 additional follow-up appointments, while patients in the T group needed 2.9 (p = 0.568).

PROMs evaluation revealed no statistically significant differences between groups at baseline (p=0.662) and 3-month follow-up for or general OHIP-Endent (p=0.409). Same result was observed in for general satisfaction baseline (p=0.381) and 3-month follow-up (p=0.146). The intragroup (from baseline to 3-month follow up) analysis revealed significant differences in OHIP-Edent, p<0.01 for both groups and in satisfaction for the majority of the assessed aspects (p<0.05), but not for "pain-maxillary arch," (p= 0.500) "adaptation-maxillary arch," (p=0.500) and "retention maxillary arch" (p=0.125) for the S group.

At baseline, the RDC/TMD identified 28 (56%) TMD patients (myogenous = 1, arthrogenous = 19, and myogenous and arthrogenous = 8). At the 3-month follow-up, 23 TMD patients were evaluated, 11 (45.8%) showed improvements (5 patients classified as non-TMD and 6 improving from myogenous and arthrogenous to myogenous or arthrogenous) and 12 (54.2%) remaining stable. No patient worsened, and all patients who did not have TMD at baseline remained so at the 3-month follow-up. At 3 months of follow-up, the inter-group analysis of TMD diagnosis revealed no difference between groups (p=0.530). For the entire sample, there was a significant difference (p=0.001) in the presence of TMD before and after CD insertion.

The mean masticatory efficiency of the patients was 0.055 ± 0.029 abs and the average score for the CD quality for both groups was 83.19 ± 11.07, with no statistical differences between groups (p>0.05). The entire sample was then evaluated according to the fabrication technique (T or S) and height of the mandibular residual ridge (High / medium or low) with regard to masticatory efficiency and CD quality. No difference was observed for masticatory efficiency (p=0 >0.05) in both assessments. For CD quality, regarding the fabrication technique, there was no difference (p= 0.456), however there was a significant statistical difference in view of the height of the mandibular residual ridge (p = 0.009), and the CD quality was greater for high/medium edentulous ridges (Table III).

DISCUSSION

The present randomized clinical trial evaluated a simplified technique for complete denture (CD) fabrication, focusing on patient-reported outcome measures (PROMs), masticatory efficiency (ME), temporomandibular disorders (TMD), and CD technical quality. The results indicated no significant differences between the fabrication techniques concerning the analyzed variables, leading to the acceptance of the null hypothesis. Additionally, the study demonstrated that PROMs may improve after suitable CD replacement, irrespective of the fabrication technique. These findings are consistent with previous studies by Kawai et al. [21], Regis et al. [6], Komagamine et al. [12] and Tôrres et al. [22].

Although the CD quality was not assessed at the baseline, the authors believe that the improvement in PROMs is attributed to the new CD's aesthetic and functional reestablishment. The previous CD was used, by the majority of the sample, for more than 5 years. This prolonged use may result in poor adaptation, CD wear, and changes in the vertical dimension, all of which are known to have a negative impact on CD retention, chewing, and phonetics, resulting in higher levels of dissatisfaction [23] and reduced OHRQoL.

Despite the fact that the majority of the patients were diagnosed with TMD at the baseline, none of them had TMD as their primary complaint. The presence of TMD was similar in both groups at the 3-month follow-up, but some individuals showed an improvement after CD replacement. Abdelnabi et al. [24] and Goiato et al. [25] found similar results. These results may be related to the restoration of vertical dimension and centric relation, yielding mandibular and muscles stability and driving to the decrease of TMD signs and symptoms [24,25].

Since the fabrication technique seems not to influence the masticatory efficiency, variables such as age, gender, duration of edentulism, residual ridge, and previous experiences can affect it [8]. Koshino et al. [8] found a significant correlation between the basal area of the mandibular residual ridge with masticatory ability. However, no statistical correlation was

Table III - Patients' masticatory efficiency, in abs and complete denture quality

	n	Masticatory efficiency	*p*	CD quality	*p*
Technique					
Traditional	20	0.046 (0.031-0.056)	0.131	83 (77-96)	0.456
Simplified	22	0.056 (0.038-0.078)		84 (73.75-89.75)	
Height of the mandibular residual ridge					
High / medium	12	0.055 (0.032-0.079)	0.449	88.5 (81.5-95)	0.009*
Low	30	0.049 (0.033-0.062)		80.5 (72.5-86)	

Median (interquartile range). Sample size (n) in absolute values. Mann- Whitney test. Significant difference, p<0.05.

found between masticatory efficiency and other variables in our study. This could be explaining by factors such as harmful previous experience or patients' expectations [9].

Border molding procedures are thought to be necessary for adequate CD retention, stability, and support [26] however, in our study, the omission of this step did not impact the overall quality of the CD or the retention and stability of the mandibular CD. These findings are supported by the literature [6,21,27,28].

Reabsorbed ridges can have a detrimental effect on the impression process [8] In our study, the mandibular residual ridge's reduced height led to a significant decrease in the quality of the CD. Ribeiro et al. [10] found similar results to ours when they investigated whether the shape of the jaw was related to CD retention and stability. Evaluating only patients with severely resorbed mandible Albuquerque et al. [29,30] compare one- vs two-step impression procedures for complete denture fabrication and did not observe differences between techniques in relation to PROMs, quality of the prostheses and chewing. As such, careful execution of preliminary impressions, taking into account the anatomy of the residual ridge, seems to produce CD with comparable technical quality to the traditional technique.

A recent meta-analysis has observed that complete dentures produced using the simplified method exhibit significantly lower costs and reduced manufacturing time compared to those produced through traditional methods [17]. Consequently, the findings from this clinical trial are promising and hold particular significance for public health dental systems. The 2010 Brazilian oral health survey (SBBrasil 2010) highlighted a considerable demand for prosthetic rehabilitation, particularly among the elderly population. Despite this, the number of dentures fabricated remains insufficient in meeting the treatment needs of the population.

Studies using simplified complete denture (CD) techniques involving digital dentures [31,32] have demonstrated that CDs fabricated through these methods are as effective as those produced using traditional methods in terms of patient-reported outcome measures (PROMs). Moreover, digital dentures reduce production time and cost, and provide a more efficient means of storing and retrieving patient records. However, there are disadvantages to this technology, including the significant investment required for equipment and training, and potentially limited levels of customization compared to traditional methods.

Reducing the number of visits to CD fabrication results in a positive response of patent's satisfaction [33]. Employ a simplified technique for fabricating complete dentures in in specialized dental centers could enable the rehabilitation of a greater number of patients with more efficient utilization of financial resources [34,35]. Moreover, streamlining clinical sessions has the potential to enhance patient adherence to treatment, particularly among individuals with limited mobility [35,36]. The short follow-up period of our study should be considered as a limitation. Future research should focus on longer-term follow-up to confirm our findings and also explore the integration of advanced digital technologies in simplified CD fabrication techniques to enhance clinical outcomes and PROMs.

CONCLUSION

Within the limitations of this current study, it was concluded that complete dentures fabricated by a simplified technique seems to be time-efficient and as effective as that fabricated by a traditional technique. The insertion of new dentures positively influenced PROMs and TMD presence.

Author's Contributions

ALBP: Investigation, Formal Analysis, Writing – Original Draft Preparation. MRP: Investigation, Formal Analysis, Writing – Original Draft Preparation. AGRCO: Supervision, Formal Analysis. AFPC: Supervision, Funding Acquisition. WMJ: Funding Acquisition. PSC: Conceptualization, Writing – Review & Editing, Project Administration, Supervision, Funding Acquisition.

Conflict of Interest

No conflicts of interest declared concerning the publication of this article.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of: Federal University of Rio Grande do Norte Research Ethical Comitee.

The approval code for this study is: 7098714.5.0000.5292.

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