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Effectiveness of immediately loaded single-implant mandibular overdentures versus mandibular complete dentures: A 1-year follow-up of a randomized clinical trial

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ABSTRACT

Objective: This randomized clinical trial (RCT) aimed to assess the 1-year effectiveness of single-implant mandibular overdentures (SIMO) compared to conventional complete dentures (CCD).
Methods: In the first phase of the study, participants received new maxillary and mandibular CCDs. Then, they were randomly allocated to one of the study groups (CCD or SIMO). Participants in SIMO group received an external hexagon implant in the mandibular midline, with the immediate connection of an O-Ring/ball attachment. Oral health-related quality of life (OHIP-EDENT) and patient satisfaction in both groups were assessed before allocation and at 6- and 12-month follow-up visits. Both intention-to-treat (ITT) and per-protocol approaches were used for analyses. Statistical analyses were performed using the Wilcoxon Signed Ranks test and the Generalized Estimating Equations.
Results: Eighty-four participants (CCD n = 42; SIMO n = 42) were included, out of which 70 completed the 12-month follow-up (CCD n = 34; SIMO n = 36). ITT analysis showed no changes for the CCD group in the longitudinal assessment compared to baseline. Participants in SIMO group had a significant improvement in OHIP-EDENT scores and satisfaction with the mandibular denture. No changes for the maxillary denture were observed in either groups. Similar results were found when per-protocol analysis was performed.
Conclusions: SIMO treatment resulted in a significant improvement in patient perceived outcomes compared to the CCD. SIMO may be considered as an alternative treatment modality for patients with poorly adapted and/or unstable mandibular dentures (ClinicalTrials.gov NCT03463174).
Clinical relevance: The immediately loaded single-implant mandibular overdenture markedly improved patient satisfaction and oral health-related quality of life of conventional denture wearers after a 12-month follow-up.

1. Introduction

Within the last decades, we are witnessing a noticeable increase in life expectancy worldwide. The proportion of individuals over 60 years compared to population of all ages, has increased from 9.2% in 1990 to 11.7% in 2013 and it is expected to reach 21.1% by 2050 [1]. This trend can be attributed to greater access to health care, as well as innovations in medicine and related fields. As a result, the growth of the elderly population has been shaping health care policies, since this group requires specific care that includes particularities and challenges [2].

Despite the advances in oral health care of elderly patients and the use and popularization of dental implants as an effective component in oral rehabilitation, this population still faces difficulties on treatment access, which is mainly precluded by financial constraints. In addition, the prevalence of complete tooth loss (edentulism) is still considerable among this age group and it is suggested that this situation will not change in a near future, especially in low-income countries [3].

The minimum standard of care recommended for rehabilitation of the edentulous patient is a maxillary conventional complete denture over a 2-implant mandibular overdenture [4,5]. However, this may not be financially feasible for some patients. In general, patients that cannot afford 2-implant overdentures end up having conventional complete dentures (CCD) with all its shortcomings, considering this may be the

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only available option in most settings.

The single-implant mandibular overdenture (SIMO) has been proposed as a viable alternative to the 2-implant overdenture, and is considered technically easier to perform, less invasive and less costly [6]. The meta-analysis by Elawady et al. [7] suggested that SIMO performed superior to 2-implant overdentures in terms of marginal bone loss and number of implant failures. However, this conclusion should be interpreted with caution due to the limited number of studies that were included in the review, different loading protocols and the short follow-up periods [7]. Other studies also suggest that patient-reported outcomes such as patient satisfaction and oral health-related quality of life did not present significant differences between patients treated with mandibular overdentures retained either by one or two implants [8].

To date, the comparative effectiveness of the SIMO and the CCD has only been assessed by single-group prospective studies [9]. Our group was the first to conduct a randomized clinical trial to investigate the incremental effect of stabilizing a mandibular denture with a single implant. Considering that the CCD still remains the most common treatment option worldwide [10], the relevance of studies addressing cost-effective alternatives to this conventional treatment is more palpable than ever. Thus, the aim of this study was to assess the 1-year comparative effectiveness of two treatment alternatives for the edentulous mandible: CCD versus SIMO.

2. Material and methods

This report was produced according to the Consolidated Standards of Reporting Trials (CONSORT Statement) [11]. The study was designed as a 2-arm parallel groups randomized controlled trial. The local ethics committee approved the study protocol (No. 020/2012), which was registered at the database ClinicalTrials.gov (identifier NCT03463174). All participants were treated at the Faculty of Dentistry of the Federal University of Goias, Goiania, Goias, Brazil. Participants were rendered all treatments free of charge. All subjects signed a written informed consent after the explanation of the study methods and procedures.

2.1. Study sample

The target population consisted of fully edentulous patients referred for treatment from the local public health system. No age restrictions were considered for enrollment. To be included, the potential participants were required to have favorable general health and the need to be rehabilitated with a new set of complete dentures. Participants should have agreed to be randomly assigned to one of the two study groups and be able to comprehend and answer the data collection instruments.

Exclusion criteria comprised of general health conditions that could contraindicate implant surgery (such as uncontrolled type II diabetes mellitus or uncontrolled cardiovascular conditions). Those without a minimum mandibular ridge height and volume in the midline region to receive an implant of at least 3.75 mm × 9.0 mm were also excluded from the study. For all participants, a digital panoramic radiograph was used to assess bone availability and, in borderline cases, a digital lateral cephalometric radiograph was also used. Individuals presenting evident signs of cognitive impairment and/or oral conditions requiring additional treatments, such as oral lesions and temporomandibular disorders, and those unable to attend to the scheduled appointments and future follow-up visits were excluded. All excluded subjects were referred to regular prosthodontic care at the university clinic.

For sample size estimation, a more conservative approach was adopted, with an *a priori* minimum power of 0.90 (type II error rate – $\beta = 0.10$) and a two-sided 0.05 significance level (type I error rate). The primary outcome "satisfaction with the mandibular denture", measured in a 0–100 continuous scale, was used to estimate the smallest difference between the treatments, assuming 20 points as the minimum clinically important difference between groups (concerning the difference in before-after changes in each treatment group), and a 25% maximum common standard deviation for the entire sample. Considering these assumptions, a total sample of 72 participants was estimated. In order to reduce the impact of possible losses on the study power throughout the trial, a 10% increase in the final sample resulted in a minimum sample size of 80 participants, 40 in each treatment group.

2.2. Interventions

We fabricated new conventional complete dentures for all participants. The fabrication protocol consisted of preliminary impressions with alginate and stock trays, final impressions with custom trays and zinc-oxide eugenol paste, occlusal registration, mounting in a semi-adjustable articulator set in average configuration, try-in visits to assess aesthetics and occlusion, delivery of the dentures, and post-insertion visits for adjustments. All the prosthodontic clinical procedures were performed by three experienced prosthodontists. The laboratory phases were performed at a single commercial dental laboratory and all the dentures were processed using the same techniques and materials.

After a minimum period of 3-months following the complete dentures delivery, participants were randomly assigned to the study groups (CCD or SIMO) in sets of different sizes by means of a computer-based random number generator. Block randomization, allocation ratio of 1:1, and stratification by gender were employed in order to prevent an imbalance between groups. The generated sequence was concealed in opaque, consecutively numbered envelopes for each block and an independent collaborator managed all the process and was responsible to inform participants about their assigned groups. The treatment group was only revealed after the baseline assessment in an attempt to minimize selection bias.

All participants in CCD group received reinforced instructions on maintenance care, and were informed about the subsequent follow-up appointments.

For the SIMO group, a 3.75 mm diameter external hexagon implant (Titamax TI cortical – Neodent, Brazil) was surgically placed in the mandibular midline according to the implant system instructions. After local anesthesia and crestal incision, the positioning of the bone perforation and drilling was performed and verified using an alignment pin with the maxillary denture in position. Two primary implant stability parameters guided the use of conventional or immediate implant loading: the final insertion torque and the implant stability quotient (ISQ). In cases of insertion torque higher than 30 N·cm and ISQ higher than 60, immediate loading protocol was adopted. When any of these conditions were not achieved, a healing abutment was placed and conventional loading was only implemented after 3 months. Relining with a soft material was performed in order to minimize direct pressure over the implant site and to improve denture fitting during the healing period.

The attachment system used for overdenture retention was a nitrite-coated titanium ball attachment and a nylon matrix (O'ring) (Neodent, Curitiba, Paraná, Brazil). The height of the ball attachment was selected in order for the platform to be at least 1 mm above the gingival margin (Fig. 1). The matrix was incorporated into the denture using self-curing acrylic resin (Duralay, Reliance Dental, USA) with a 3–5 min period for curing before removal. The participant was asked to keep the dentures firmly occluded in the habitual position during this procedure. The excess material was trimmed and the area was polished when needed. All participants have received postoperative care and oral hygiene instructions. In addition, the SIMO patients received instructions on how to insert and remove the overdenture. A follow-up appointment was scheduled after 1 week for suture removal and any needed adjustments.

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