Tooth loss causes advanced resorption of alveolar ridges, which leads to chewing impairment and functional dislodgment, primarily of the mandibular complete denture (CD). Dental implants have been proposed to improve stability in association with a mandibular CD, characterizing implant-supported overdentures. According to the McGill consensus, the first-choice treatment for the edentulous mandible should be the insertion of a two-implant overdenture (TIO). Despite all possible benefits that TIOs could deliver, it is necessary to consider the oral and general health of elderly people to indicate this therapy. In addition, it is important to provide low-cost treatment options with high effectiveness for low-income elderly patients, especially considering the growth in life expectancy around the world. Therefore, the concept of mandibular single-implant overdentures (SIOs) was proposed as an effective alternative to the TIO for replacement of the conventional CD, aiming to enhance daily activities, social abilities, and oral health satisfaction of elderly people.

SIOs can increase chewing efficiency and masticatory performance when compared to conventional CDs, as the use of dental implants improves prosthesis retention and stability. Some authors evaluated the bite force of elderly patients with conventional complete dentures (CDs) and single-implant overdentures (SIOs). The purpose of this study was to compare maximum bite force, masseter thickness, and oral health–related quality of life (OHRQoL) in elderly patients rehabilitated with conventional complete dentures (CDs) and single-implant overdentures (SIOs). A paired design was conducted, and 12 elderly patients were selected. Initially, a set of new CDs was manufactured and placed. After a 2-month adaptation period, the mandibular CD was transformed into an SIO by inserting one osseointegrated implant into the symphysis region. All variables were evaluated 2 months after both treatments (CD and SIO). Maximum bite force was evaluated using pressure sensors, while masseter thickness was obtained via ultrasound during muscle contraction and relaxation. The Oral Health Impact Profile for edentulous people (OHIP-Edent) was used to measure OHRQoL. Data were analyzed using Student t test and Wilcoxon test. Pearson coefficient of correlation between bite force and masseter thickness was calculated. Values for maximum bite force and masseter thickness during contraction increased significantly after SIO use (P < .001), indicating an improvement in muscle function. Considering OHRQoL, the general score and the domains functional limitation and physical pain were reduced (P < .05), indicating better perception of OHRQoL, with SIO use. Moreover, masseter thickness during contraction was moderately correlated with bite force (r = 0.480; P = .018). Using SIO increased the maximum bite force and masseter thickness of elderly patients, leading to an improved OHRQoL.

**Purpose:** To compare maximum bite force, masseter thickness, and oral health–related quality of life (OHRQoL) in elderly patients rehabilitated with conventional complete dentures (CDs) and single-implant overdentures (SIOs).

**Materials and Methods:** A paired design was conducted, and 12 elderly patients were selected. Initially, a set of new CDs was manufactured and placed. After a 2-month adaptation period, the mandibular CD was transformed into an SIO by inserting one osseointegrated implant into the symphysis region. All variables were evaluated 2 months after both treatments (CD and SIO). Maximum bite force was evaluated using pressure sensors, while masseter thickness was obtained via ultrasound during muscle contraction and relaxation. The Oral Health Impact Profile for edentulous people (OHIP-Edent) was used to measure OHRQoL. Data were analyzed using Student t test and Wilcoxon test. Pearson coefficient of correlation between bite force and masseter thickness was calculated. Values for maximum bite force and masseter thickness during contraction increased significantly after SIO use (P < .001), indicating an improvement in muscle function. Considering OHRQoL, the general score and the domains functional limitation and physical pain were reduced (P < .05), indicating better perception of OHRQoL, with SIO use. Moreover, masseter thickness during contraction was moderately correlated with bite force (r = 0.480; P = .018).

**Conclusion:** Using SIO increased the maximum bite force and masseter thickness of elderly patients, leading to an improved OHRQoL.
CDs and TIOs and found an increase of 120% when wearing TIOs, showing the positive effect of implants on masticatory function. Considering SIOs, only a single pilot study has proven that inserting one implant into the symphysis area would improve bite force. However, the absence of a standardized protocol for manufacture of the previous CDs could compromise their findings. Thus, considering that an enhanced masticatory function would lead to nutritional improvement, further studies on SIO rehabilitation are important to extend elderly longevity as well as quality of life.

Another age-related concern is the decline in muscle function associated with loss of muscle mass. In this sense, previous studies reporting prosthetic rehabilitation with a TIO or a removable partial prosthesis retained by implants have revealed increased masseter muscle thickness and maximum bite force after wearing implant-supported prostheses for 2 months. Recently, other authors verified the importance of mandibular CD use in terms of masseter thickness and masticatory function improvements in edentulous elderly patients. However, the literature lacks reports on the impact of prosthetic rehabilitation with an SIO on the masticatory muscles of edentulous elderly patients.

Considering the advantages of SIOs for elderly people with resorbed residual ridges and health problems that contraindicate invasive procedures, the aim of this study was to evaluate the maximum bite force, masseter thickness, and oral health–related quality of life (OHRQoL) of elderly people rehabilitated with SIOs processed with a low-profile abutment and reinforced by a metallic framework. The null hypothesis was that SIOs would not improve outcomes when compared to conventional CDs.

MATERIALS AND METHODS

Experimental Design
This paired clinical trial was designed to evaluate the maximum bite force, masseter thickness, and OHRQoL in completely edentulous geriatric patients after two different prosthetic treatments. First, conventional maxillary and mandibular CDs were manufactured using conventional techniques and delivered to all subjects. After 2 months of use of the new conventional CDs, outcome variables were evaluated. Subsequently, one external hexagon implant (Titamax Cortical, Neodent) with 11-mm length and 3.75-mm width was inserted in the mandibular symphysis region of each volunteer and remained covered during the osseointegration process. Three months later, a small incision in the mandibular symphysis region was performed in order to access the implant platform, and a low-profile attachment was adapted (Equator, Neodent). Then, the new CD was relieved in the denture base, and the conversion into an SIO occurred when the matrix was intraorally captured using self-curing acrylic resin. Variables were remeasured after 2 months of use of the SIO. All prosthetic treatments were performed by a single specialized dentist (C.F.A.) and the same dental technician.

The study protocol was submitted and approved by the Ethics Committee of Piracicaba Dental School, University of Campinas (#087/2015), and registered in the Brazilian Registry of Clinical Trials (ReBEC RBR-3kgttj). Study participation was voluntary, and procedures required no cost to the patients. All subjects provided written informed consent, which complies with the 1964 Helsinki Declaration and its amendments.

Participants
Completely edentulous elderly patients who had participated in a previous study that measured masticatory efficiency, self-reported masticatory ability, and satisfaction with the SIO were allocated for this study. To be included, the elderly patients had to (1) present mandibular residual ridges classified as Type III or IV according to the Classification System for Complete Edentulism from the American College of Prosthodontics; (2) display adequate bone volume and height in the anterior mandibular region that allowed implant insertion with no need for major bone augmentation procedures; and (3) display a regular salivary flow rate, measured by chewing a 0.02-mm–thick piece of plastic paraffin film (Parafilm M, Bemis) for 5 minutes.

Elderly patients with parafunctional behavior, oro-facial pain, or cognitive limitations were excluded. The Mini-Mental State Examination was applied directly to each subject to verify cognition and attest the subject’s ability to answer questionnaires appropriately. Its scores can range from 0 to 30 points, with lower scores indicating greater cognitive impairment. A cut-off point of 20 was established according to Folstein et al in order to quantitatively estimate severe cognitive changes. Subjects were excluded if they had scores below the cut-off point. Volunteers presenting systemic conditions controlled by routine medication, such as hypertension and diabetes mellitus, were included. In contrast, those presenting systemic or neurologic diseases that would contraindicate implant surgery or physical limitations that may prevent variable evaluations were excluded. Details about the participants of this study have been previously described.

Sample size calculation, based on a previous study, indicated that 12 participants would yield an 80% power ($\beta = 0.8$) at $\alpha = .05$. Since the present study is part of a major investigation on SIO rehabilitation, the sample size was estimated considering a difference of 0.5 points in masticatory performance values. It was increased by 10% to compensate for patient dropout, resulting in a total sample size of 12.
Prosthetic Treatment
Elderly participants first received new conventional maxillary and mandibular CDs, which were processed in acrylic resin according to conventional techniques. In addition, a metallic framework (cobalt-chromium) was included in the anterior region of the mandibular CD to promote a better force distribution throughout the entire mandibular prosthesis, preventing early fracture. All prostheses were installed in the patient’s mouth and adjusted using a bilateral balanced occlusion scheme. Additional adjustments were performed according to individual necessities until the patients presented no complaints. Patients wore the CD for a 2-month period of adaptation before the baseline assessment.

Subsequently, the elderly patients received one implant in the mandibular midline region. The correct implant position and inclination were established using a surgical guide, and a conventional two-step implant protocol was used. Details of the surgical procedures have been described previously. When necessary, the mandibular CDs were adjusted with resilient soft lining material (Soft Confort, Dencril) and used for 3 months during implant osseointegration.

Subsequent to osseointegration, implants were exposed and patients received low-profile abutments (Neodent) according to the manufacturer's instructions. The CD acrylic base was relined, and the matrix was directly captured in the mouth using self-curing acrylic resin (Vipi Flash, Vipi), converting the CD into an SIO. In order to maintain the previously determined vertical dimension of occlusion, a digital caliper was used to measure the facial height before and after the capture of the matrix. If necessary, slight occlusal adjustments were performed. Variables were reevaluated after using the SIO for 2 months.

Maximum Bite Force
The maximum bite force was measured with a bite force transducer (Quantum X MX840A, Hottinger Baldwin Messtechnik) and pressure sensors (18.28-mm diameter, 0.45-mm thickness; FSR 402, Interlink Electronics). Two sensors were placed in the bilateral first molar regions, and signals were recorded and analyzed by Catman Easy software (version 1.0; Hottinger Baldwin Messtechnik). In order to avoid distortion during clenching and contact with saliva, the sensors were sheltered on both sides with rubber and metal discs and covered with a thin layer of plastic film, yielding a total thickness of 5.6 mm. Subjects were requested to occlude with maximum force for 7 seconds, and the procedure was repeated after a 5-minute rest period. The maximum bite force was considered to be the highest obtained measurement, recorded in Newtons (N).

Masticator Thickness
Masticator thickness was obtained from ultrasound images using the JustVision 200 device (Toshiba), at a frequency of 8 Hz. A single calibrated researcher (C.F.A.) performed all tests in a darkened room. Participants were instructed to sit upright, maintaining their heads in a natural position with the Frankfurt plane parallel to the ground. In order to obtain the correct location of the masseter sites, muscles were identified by palpation in the region between the zygomatic arch and the gonial angle. A line was marked with a dermatographic pencil in order to standardize the placement of the transducer for each measurement.

To avoid tissue compression, a light pressure was applied against the cheek with the transducer, which was covered with gel and positioned perpendicular to the muscle. Identification of muscular structures in ultrasound images consists of recognizing the outer fascia of the masseter muscle (narrow white line) and the adjacent surface of the mandibular ramus (intensive white line). The darker area between the lines is considered the masseter thickness.

Measurements were made with the masseter muscle in the resting position (vertical resting dimension) and with maximum voluntary clenching on both sides of the face. Two measurements were performed for each muscle activity, with a 5-minute interval in between. The final muscle thickness was considered to be the mean value of both measures.

Oral Health–Related Quality of Life
The Oral Health Impact Profile for edentulous patients (OHIP-Edent) questionnaire was used to assess OHRQoL. The OHIP-Edent consists of 19 questions with 7 domains: functional limitations; physical pain; psychologic discomfort; physical disability; psychologic disability; social disability; and handicaps. The questions address masticatory capacity, eating pleasure, level of comfort and assuredness while wearing the prosthesis, and relationship problems, among others. This tool detects the impact of oral health on the quality of life of patients using new prostheses.

Participants were instructed to rate the frequency of each OHIP-Edent item on a 3-point Likert-like scale (2 = almost always; 1 = sometimes; and 0 = never). Thus, the sum of all 19 items can range from 0 to 38. Lower scores represent a satisfactory perception of an individual’s oral conditions, and, therefore, higher satisfaction and better quality of life.

Statistical Analysis
Data distributions were assessed using Shapiro-Wilk tests. Paired Student t test was applied for bite force, masseter thickness, and certain OHIP-Edent domains (functional limitations, physical pain, and handicaps).
The overall score of OHRQoL ($P < .01$), as well as those related to the functional limitation ($P = .046$) and physical pain ($P < .01$) domains, were also improved after SIO insertion (Table 1). In addition, a moderate correlation was found between bite force and masseter thickness during contraction ($r = 0.480$, $P = .018$).

DISCUSSION

This clinical study showed that maximum bite force, masseter thickness during contraction, and the OHRQoL of elderly people were greatly improved after SIO use when compared to conventional CD use. Thus, the null hypothesis was rejected.

The bite force values increased by a factor of 1.75 times after SIO therapy. This finding is in accordance with a previous study, which found significantly higher bite force after attaching a conventional CD to a single midline implant. Moreover, the same study reported no differences between SIO and TIO, providing evidence that the former is a suitable option to improve mastication in edentulous elderly patients. Several studies have confirmed the improvement in bite force...
after implant placement, regardless of the number of implants. Considering that the present sample was comprised of elderly patients with a resorbed residual ridge, a condition responsible for reducing denture stability and retention, improvement in bite force after anchoring CDs in dental implants was expected. Likewise, wearing an implant-supported denture can also prevent the progression of alveolar bone resorption.

Another possible explanation for the higher bite force achieved after using an SIO can be related to psychologic aspects, since elderly people might feel encouraged to exert higher biting forces when their dentures are supported by implants. Moreover, pain or discomfort in the mucosa overlying the mandibular ridge anatomical structures, such as the mylohyoid ridge and genial tubercles, could limit the bite forces exerted when wearing conventional CDs.

Increased masseter thickness during contraction while wearing the SIO was also observed. Despite the absence of studies evaluating masseter thickness in elderly patients rehabilitated with SIOs, previous research considering TIOs and implant-supported removable dental prostheses achieved similar results, even though different prosthetic approaches have been adopted. The process of aging is responsible for reduction of fiber diameter, sarcoplasm deterioration, and replacement of muscle mass by adipose tissue. Considering that elderly people with CDs usually compensate for deficits in masticatory ability by changing to a softer diet, this reduced functional demand may result in a low percentage and small size of muscle fibers, which characterizes muscle atrophy. Thus, after receiving implant-supported dentures, it could be suggested that higher retention, stability, and maximum bite force allow larger intake of raw and fibrous food, which requires a more vigorous action of the masticatory muscles; explaining the masseter thickness enlargement and its positive correlation with bite force.

The total overall OHRQoL score, as well as its functional limitation and physical pain domains, was also improved after SIO insertion. It can be hypothesized that due to better retention and stability of the mandibular prosthesis provided by the implant, subjects had better function with less discomfort, thereby positively affecting their quality of life. These findings agree with the findings of certain authors who also reported an improvement in quality of life after SIO therapy. Kronstrom et al evaluated a non-elderly population using TIOs and SIOs and found that satisfaction scores remained high after 36 months of using both types of overdentures. Therefore, it can be suggested that regardless of the number of implants, overdentures improve quality of life for edentulous patients.

The null hypothesis was accepted when considering the remaining domains of the OHIP-Edent, which was contrary to expectations. However, the absence of differences in the psychologic and social domains could be explained by the fact that the maxillary CD was the same in both evaluations. Wearing worn CDs may alter occlusal face height, which could impair facial appearance, speaking, and, consequently, social relations. Nevertheless, as all elderly patients had received a new maxillary CD, they were satisfied with their dentures and already achieved low scores in the first assessment, indicating a positive OHRQoL that remained constant after inserting the SIO.

It is important to emphasize that a longer follow-up period is important to evaluate adaptation of elderly patients to the SIO (including the need for maintenance), which could alter their OHRQoL. Previous studies evaluating this outcome have shown denture fracture to be the most prevalent complication of this therapy. However, the use of a metal framework can be considered to prevent this complication and should be evaluated in further studies. It would also be relevant to confirm muscle behavior over time, especially during rest. As such, the short follow-up and absence of a control group using conventional CDs for the entirety of the study to verify the time effect could be considered limitations of this study. However, 2 months were sufficient to allow habitation of elderly patients to the new condition and identification of differences in all evaluated outcomes.

CONCLUSIONS

Compared to a conventional CD, an SIO increased bite force, masseter thickness during clenching, and OHRQoL in elderly people. Thus, it can be suggested as a less invasive treatment option for such patients.

ACKNOWLEDGMENTS

This study was supported by the São Paulo Research Foundation (FAPESP) - Brazil (grant number 2015/21704-1). This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES) - Finance Code 001.

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