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Clinical Paper
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Randomized study on the effect of single-implant versus two-implant retained overdentures on implant loss and muscle activity: a 12-month follow-up report

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Abstract. The objective was to evaluate and compare single- and two-implant retained overdentures for the rehabilitation of the edentulous mandible. Fifty-six edentulous subjects were eligible for inclusion. Using a random sampling system, a single implant or two implants were placed in the mandible. After 3 months, locator attachments were connected to the implants and the denture delivered with the retentive components incorporated in the denture base. Implant failure and muscle activity were evaluated at the 3-, 6-, and 12-month follow-up examinations. The study sample comprised 56 patients (32 male, 24 female), with a mean age of 58.2 years. A total of 84 implants were placed (28 in the single-implant group and 56 in the two-implant group). All patients completed the 12 months of follow-up. No significant differences were found between subjects in the two groups with respect to implant failure. With regard to improvements in muscle activity, the two-implant group showed statistically significant but perhaps not clinically important differences. Single-implant mandibular overdentures may be suggested as an alternative treatment modality for the rehabilitation of edentulous patients who cannot afford the cost of a two-implant overdenture.

Key words: dental implants; muscle activity; overdentures; single-implant overdenture.

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The classical treatment plan for the edentulous patient is a conventional complete denture. However, this treatment is associated with several complications, in particular related to stability and retention, leading to a constant fear of denture loosening during different jaw movements. These problems occur more frequently with the lower denture[1,2].

With the advent of dental implants for the retention and/or support of removable prostheses, the functional deficiencies associated with conventional dentures have improved greatly[3–5]. Nonetheless, the optimal number of implants required to retain a mandibular overdenture is still under evaluation.

As a consensus, many investigators agree that the basic restoration for the edentulous mandible should be an implant-retained overdenture with two implants placed in the anterior mandible[6,7]. However, the costs of this standard treatment could be outside the financial capacity of several compromised edentulous patients. This problem is of great concern in developing countries.

From this standpoint, the concept of a single implant to retain the mandibular overdenture represents a possible alternative treatment option for the edentulous mandible, especially for those with a low socio-economic status. The single-implant overdenture modality might also prove beneficial in elderly patients for reasons related to economic factors[8–12]. However, this treatment concept needs to be investigated thoroughly through well-designed clinical trials covering a wide range of functional, prosthodontic, and patient-oriented outcome measures before it can be recommended as a reliable protocol[13].

Unfortunately, up-to-date published data on single-implant overdentures are scarce and most have been derived from case reports and in vitro studies. There are only two randomized clinical trials in the literature comparing the single-implant versus two-implant overdenture in regard to implant failure, prosthetic maintenance, and patient satisfaction[14,15]. Both trials showed more implant failures in the two-implant groups. These two trials used immediate and early loading protocols and experienced a large number of dropouts, particularly in the single-implant group, making their conclusions questionable.

The masticatory muscles exert higher activity in patients with conventional complete dentures compared to dentate patients, due to the effort required to stabilize and retain the prosthesis in addition to masticatory function[16]. Several trials have shown that the two-implant supported overdenture improves masseter and temporalis muscle activity[17,18].

Electromyography (EMG) is described as a research tool for evaluating the electrical activity of muscle function. Records from EMG systems have been used to evaluate muscular activity during mastication and command mandibular movements. EMG is frequently used for the assessment of masticatory muscle function both quantitatively and qualitatively and also for assessing the role of individual muscles and their contributions to oral function[19].

The aim of this randomized clinical study was to evaluate whether the single-implant overdenture is a valid alternative treatment to the overdenture retained by two implants using a conventional loading protocol. The question addressed here was: ''In the completely edentulous patient, is the single-implant overdenture as effective as that retained by two implants in regard to implant failure and muscle activity?"

This trial was performed following the recommendations made in the CONSORT statement for reporting randomized clinical trials[20].

Materials and methods

Trial design and registry

The study was designed to be a parallel randomized controlled trial. The study protocol was approved by the Evidence-based Dentistry Committee, Prosthodontic Department Board and Ethics Committee of the Faculty of Oral and Dental Medicine, Cairo University. The study protocol has been registered in the Pan African Clinical Trial Registry (PACTR) under registration number PACTR201411000592156.

Participants

Sample size calculation

A total of 56 patients was required to be 80% certain that the limits of a two-sided 95% confidence interval (CI) would exclude a difference in EMG record means of more than 20 μV (28 patients in each group).

Selection criteria

Fifty-six completely edentulous patients were recruited from the outpatient clinic of the Prosthodontics Department, Faculty of Oral and Dental Medicine, Cairo University during the period March 2013 to August 2014.

The inclusion criteria for this study encompassed patients who were (1) completely edentulous with the ability to provide informed consent; (2) aged from 55 to 65 years; (3) free from any systemic disease that could affect implant osseointegration, such as diabetes mellitus or osteoporosis; (4) free from any oral pathological lesions in the oral cavity, such as cysts, remaining root, or residual infection; (5) free from any temporomandibular disorders (TMD) or muscular disorders.

The following patients were excluded: smokers, those with severe mandibular bone resorption, those with a history of bruxism or clenching, those with a skeletal class II or class III relationship, and those undergoing any medical treatment that could affect muscular activity, such as diazepam.

Patient examination

An initial evaluation was conducted to determine whether the patient met the study inclusion criteria. This evaluation consisted of a medical history questionnaire, a clinical examination, and radiographic assessment. The baseline characteristics of the study subjects are shown in Table 1.

Informed consent

All patients were requested to sign an informed consent form; this was translated into the Arabic language to be understood by the patients. The trial was conducted in

Table 1. Baseline characteristics of the study subjects.

	Single-implant OD group ($n = 28$)	Two-implant OD group ($n = 28$)
Age (years), mean	59	57.4
Sex, *n*		
Male	15	17
Female	13	11
Edentulous period (mandible) (years), mean	5.4	5.3
Bone height in the symphyseal area (mm), mean (SD)	16.3 (2.6)	15.8 (4.1)

OD, overdenture; SD, standard deviation.