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Impact of single implant versus two-implant mandibular retained overdentures on retention and success rate in totally edentulous patients. A Randomized Controlled Clinical Trial

A. A. ALSOURORI[1, 2], M. H. MOSTAFA[1,3], A. F. KADDAH[1], A. E. FAYYED[1], M. S. SWEDAN[1], A. Z. AL-ADL[1]

[1] Department of Prosthodontics, Faculty of Oral and Dental Medicine, Cairo University, Cairo, Egypt
[2] Department ofProsthodontics, Faculty of Oral and Dental Medicine, Ibb University, Ibb, Yemen
[3] Assistant Researcher, Fixed and Removable Department, National Research center, Egypt

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ABSTRACT

Aim Purpose of this RCT was to evaluate the denture retention and success rate of totally edentulous patients in single median versus two inter-foraminal implant-supported mandibular over-dentures on.

Material and methods Twenty-four totally edentulous patients were selected in this trial. The eligible patients were allocated randomly into two equivalent groups of 12 participants each. A single-implant (G I) or two inter-foraminal implants (GII) were located in the mandible. Three months later, pick up of the locator attachment wa performed to all implants and denture bases. Assessments of denture retention and success rate of implants were measured at the three, six, and twelve month's follow-up assessments. The study consists of twenty-four totally edentulous patients (14 males and 9 females) with age range of 59.6 years. Thirty six implants were inserted (12 in single-implant and 24 in the two inter-foraminal implants). All patients accomplished the twelve months period of follow-up.

Results Regarding denture retention, the two inter-foraminal implant group (GII) showed statistically significant differences compared to the single-implant group (GI). Concerning success criteria of implants the results revealed insignificant differences between patients in both groups.

Conclusion Single-implant mandibular over-dentures may be recommended as an alternate treatment option for the management of edentulous patients in populations with low economic status.

INTRODUCTION

Complete loss of teeth has adverse effect on the general health and social lifecycle of the patients. So the prosthetic rehabilitation of totally edentulous patients is mandatory to advance their live activities. Treatment of these patients is less interesting a dental prosthodontic practice and challenging for the general dentist. As most patients are not well satisfyed with their conventional denture regarding the retention of the denture especially the mandibular jaw (1). But with the revolution of dental implant it became possible to avoid these problems and greatly enhance the functional activities.

Many authors agree that implant supported overdentures have been presented to be better than conventional dentures (2). Moreover, implant overdentures are considered the best solution for the totally edentulous jaws, for their low cost (economic issue) when compared to fixed restorations (3).

Sufficient evidence is available to supports the suggestion that a two-implant supported mandibular overdenture should be suggested to edentulous patients as a first choice of treatment (4, 5). But, the low economic status of developing countries represents the major obstacle. Hence, the introduction of single-implant concept to stabilize the lower denture was developed as an acceptable alternative to two implant supported mandibular overdenture (6). Single-implant mandibular overdentures concept may be of beneficial effect on geriatric population regarding the health and financial status. Nevertheless, this concept needs well-organized controlled trials to evaluate all aspect of patients oriented and functional outcomes.

Unluckily, available publications on single-implant ovedentures are limited. Few randomized controlled trials exist in the literature comparing single-implant and two inter-foraminal implants mandibular overdentures (7-10).
Geertman et al. in 1996 (11) and Zitzmann and Marinello in 2006 (12) reported that denture retention extremely improves patients' satisfaction of the prostheis. Overall, patients are further pleased with implant-retained prostheses than complete dentures.
Sadig in 2009 (13) conducted an *in vitro* study to estimate the influence of number and position of implants on overdenture retention by calculating forces of dislodgement all through perpendicular direction and also in two horizontal directions. He concluded that cases of implant supported overdentures with locator connector deliver the maximum retention and stability, followed by ball connectors and then magnets.
Abi Nader et al. 2011 (14) evaluated the impact of triggered mastication on stud attachments about retention for two-implants overdentures. They concluded that triggered mastication produced small variations for the ball attachment with no significant effect on its retention force. Nevertheless, triggered mastication produced changes in the Locator nylon part and subsequent reduction in the retention force was produced.
Success of dental implants should be related to peri-implant soft tissues, implant fixtures, and patient's subjective outcomes. The most frequently recorded criteria were mobility, pain, radiolucency, and bone loss around the implant >1.5 mm (15).
Hence, this trial was performed to estimate if the single-implant mandibular overdenture is an optional treatment modality compared to that retained by two inter-foraminal implants mandibular overdentures. The research question stated here was "In totally edentulous patients will the single-implant overdenture result in equivalence of denture retention and implant success rate in comparison with two inter-foraminal implant mandibular overdenture? This study was accomplished following confirmations created in the CONSORT, Statement for reporting RCT.

MATERIALS AND METHODS

Trial design and setting

The study was designed to be a Randomized Clinical Trial (RCT), parallel group with 1:1 allocation ratio. Twenty-four totally edentulous patients (14 males and 9 females) with mean age of 59.6 years were selected from the outpatient clinic of Prosthodontics Department, Faculty of dentistry, Cairo University, from June to December 2015. The patients were randomly assigned to either one of the following groups.

- Study group (Group 1): each patient received single-implant-retained mandibular overdenture.
- Control group (Group 2): each patient received two inter-foraminal implants-retained mandibular overdenture.

Trial registration

The study protocol was approved by Evidence-based Dentistry Committee, Prosthodontics Department Board and Ethics Committee of Faculty of Oral and Dental Medicine, Cairo University. The study protocol registered on the Pan African Clinical Trial Registry (PACTR) with a registration number (PACTR201507001169125).

Participants (Sample size calculation)

A total of 24 patients were required to be 80% sure that the limits of a two-sided 95% confidence interval would exclude a difference in means of more than 10 (12 patients in each group).

Eligibility criteria

Inclusion criteria

1. Totally edentulous patients.
2. Adult patients with age range 40-70 years.
3. Patients suffering from mandibular conventional denture complaints related to retention or stability due to bone resorption.
4. Cooperative patients and willing to follow the instructions.
5. Patients should be free from Temporomandibular disorders (TMD) or muscular disorders.

Exclusion criteria

1. Patients with TMJ disorders, as it interferes with the prosthetic outcomes.
2. Medically compromised patients, as it will affect the implants surgical placement.
3. Smoking patients, because it affects the healing process.
4. Uncooperative patients, because they would not return for follow-up.
5. Patients submitted to surgical operation in the maxillofacial region, because it interferes with the prosthesis.

Patient examination

An initial evaluation was done 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).

Patient consent form

Diagnostic results, proposed treatment and alternatives were discussed with patients for this study. Explanatory consultation, treatment duration, prosthodontic restoration and possible complications as well as risks were all written in a consent form. The patients were fully informed about the possible consequences of the proposed research and signed a special written consent form designed for this purpose.
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 accordance with the Declaration of Helsinki (2008).

	Variables				
	Age (years), mean	Gender, n		Edentulous period (mandible) (years), mean	Bone height in the symphyseal area (mm), mean (SD)
Groups		M	F		
Single-implant OD group (n = 12)	59	8	4	6.2	16.3 (2.6)
Two-implant OD group (n = 12)	57.4	6	6	6.1	15.8 (4.1)

TAB. 1 Baseline characteristics of the study subjects.

Interventions and study procedures
A conventional complete denture was fabricated for all patients following the traditional steps, before they were divided into the two groups.

Patient grouping (randomization process)
With regard to random sequence generation, after complete denture construction, the 24 patients were assigned randomly to two identical groups, each containing 12 patients, using a research randomizer (https://www.randomizer.org/).

Blinding
Apparently, neither the participants nor care providers could be blinded as to the number of implants placed, but care providers were directed to avoid commenting about treatment possibilities to subjects. The denture retention was assessed by an independent assessor who was not aware of the type of intervention. The statistician was blinded.

Radiographic stent fabrication
The finished mandibular complete dentures were duplicated to construct a radiopaque barium sulfate acrylic resin stent. After verification of the stent in the patient mouth, 2 mm channels were drilled through the stent at the at estimated implant position. During Cone Beam Computed Tomography (CBCT) imaging, the patient was instructed to wear his/her stent and upper complete denture to stabilize the stent during imaging process.

Conversion of radiographic stent into surgical stent
After complete radiographic imaging the modifications to the radiographic stent were made by drilling three channels of 2 mm at midline and canine areas bilaterally in each stent. Then stent was checked intraorally for stability and comfort.

Surgical procedure

Implant selection
Dentis® (DENTIS Implant system, Korea) 3.7 mm diameter and 10 mm length implant was chosen to be inserted in the proposed sites: midline in the study group and canine region bilaterally in the control group.

Incision and flap elevation
After administration of anesthesia a crestal incision was made with two vertical releasing incisions in the bilateral canine area for patients of group 2. For patients of group 1, the crestal incision was made in the anterior midline area.
A full thickness mucoperiosteal flap was reflected using a sharp mucoperiosteal elevator. Any crestal bone irregularity was adjusted with a bone file.

Implant installation
The stent was placed, bone was marked for positioning of the implants with twisted guiding drill and the osteotomy was done using the sequence of the drill. Drilling of the osteotomy site was performed with surgical drills (Dentis Surgical Kit; Dentis Co., Ltd, Korea) in a sequential manner following the manufacturer's directions. Osteotomy was performed with three drills at increased diameter. A parallel pin was placed and the stent was repositioned to ensure proper alignment of the osteotomy site. The drilling process was performed under copious irrigation with sterile saline. The drilling speed was adjusted at 1300 rpm using the microcomputer of the motor system. After drilling with the final drill, a root-form self-tapping implant (Dentis Implant System; Dentis Co., Ltd, Korea - 3.7 mm, length 10 mm) was then carried by its fixture mount and inserted manually into its position in the prepared site till manual tightening met resistance. Then the fixture mount was removed and further tightening using a ratchet by threading the implant in place in a clockwise direction until its top flushes with the bone surface. After that the implants were covered by covering screws (Fig. 1). The flap was properly repositioned and sutured using 000 black silk with interrupted stitches.

Postoperative instructions
Postoperative instructions were provided in written to the patients, who were instructed to apply ice packs for the first 24 hours, follow the antibiotic regimen for five days and eat soft diet for the first 8 weeks. The patients were not allowed to wear their complete denture for 2 weeks after surgery. The denture was then relieved in the implant area and a soft liner (Acrostone; Acrostone Relining Materials, Egypt) was applied during denture wearing throughout the healing period.

Second-stage surgery

Second-stage surgery was performed after 3 months. The surgical stent was used to determine the position of the implant with the aid of a periodontal probe after the application of infiltration anaesthesia. A minimal crestal incision was made to uncover the dental implant. The cover screw was removed. Healing abutments were placed for 2 weeks. After that, the locator attachment of appropriate height (Kerator overdenture attachment made for Dentis; Kerator, New York, USA) was used according to the peri-implant mucosal height. The selected locator attachments were unpacked and the female part had been carefully held and threaded into the implant internal hex (fixture) using a locator hand torque to tighten locator abutment, further torque was achieved using torque wrench up to 35 N.

Prosthetic pick up procedure

After the verification of the dentures intraorally the pick-up was performed. The male parts of the attachments, the nylon caps with their metal housings (the housing-cap assembly), were snapped onto the locator abutments. The locator cap attachments were picked up intraorally using cold-curing resin (Rebaron self-curing acrylic; GC Corporation, Tokyo, Japan). Occlusion and the adaptation on the residual ridges was then checked and adjusted if necessary and the patient discharged. No limitations to chewing function were given (Fig. 2).

Evaluation of denture retention

The relative geometric center of the lower denture was recognized first. A wrought wire, 1 mm in diameter was bent at its center and adjusted to run 2 cm above the occlusal plane from one retro-molar pad groove of one side to that of the other side. A second wrought wire, 1 mm in diameter was adjusted to extend from the groove at the lingual flange upwards to be 2 cm above the occlusal plane and the other end was shaped to form a c-shaped loop around the first wire. The lower denture was then inserted inside the patient's mouth to check tongue freedom, loop position and denture stability.

Retention measurement procedure

The wired-lower denture was inserted into the patient's mouth. The patients were seated in upright position so that the floor of the mouth parallel to the floor and his head is well supported (Fig. 3). Retention was measured by digital force gauge (Extech's Model 475055 Digital Force Gauge FLIR Commercial Systems, Inc.) that measures tension or compression (pull/push) to 980 Newton.

The reading, at which the lower denture detached, was recorded. The procedure was repeated five times. The highest and lowest readings were excluded and the mean of the other three readings was analyzed. The lower denture was then removed from the patient. The wires were removed. The grooves were re-filled with self-cured acrylic resin. These areas were then refinished and

FIG. 1A

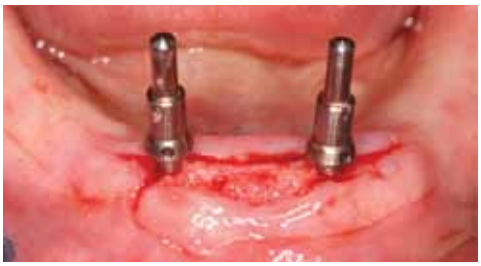

FIG. 1B

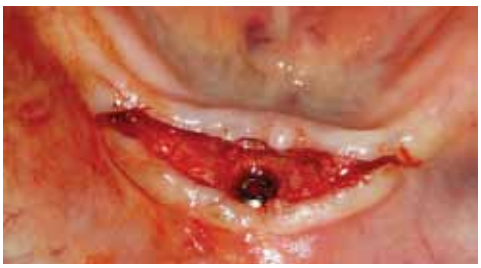

FIG. 1C

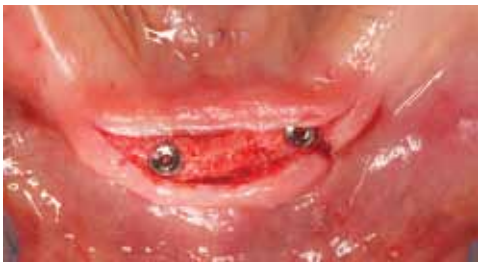

FIG. 1D

FIG. 1 Surgical procedure.

FIG. 2A

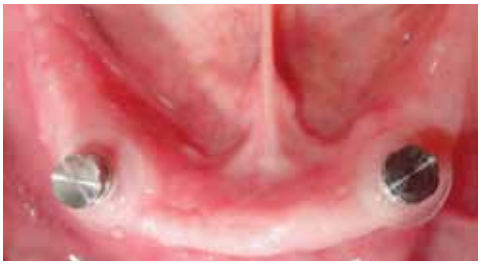

FIG. 2B

FIG. 2 Locator attachment.

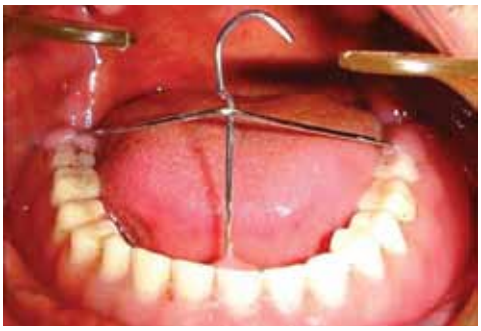

FIG. 3A

FIG. 3B

FIG. 3 Retention measurement.

repolished. Previous steps were repeated after three, six and twelve months after implant loading.

Success rate evaluation

Implant success was characterized by implant immobility when tested clinically, radiographically no evidence of peri-implant radiolucency or marginal bone loss range 1.5–2 mm in the first year and individual implant performance characterized by absence of persistent and/or irreversible signs and symptoms of pain or infections.

RESULTS

The study sample comprised 24 totally edentulous patients (14 males and 10 females) with average age of 59.6 years. In total 36 implants were placed: 12 in the study group (Group 1) and 24 in the control group (Group 2). All participants completed one year follow-up (Fig. 4). No implant loss was detected in any group, resulting in a general success rate of 100% at the end of follow-up period.

Retention of lower mandibular implant retained overdentures in Newton (N) was registered by digital force gauge.

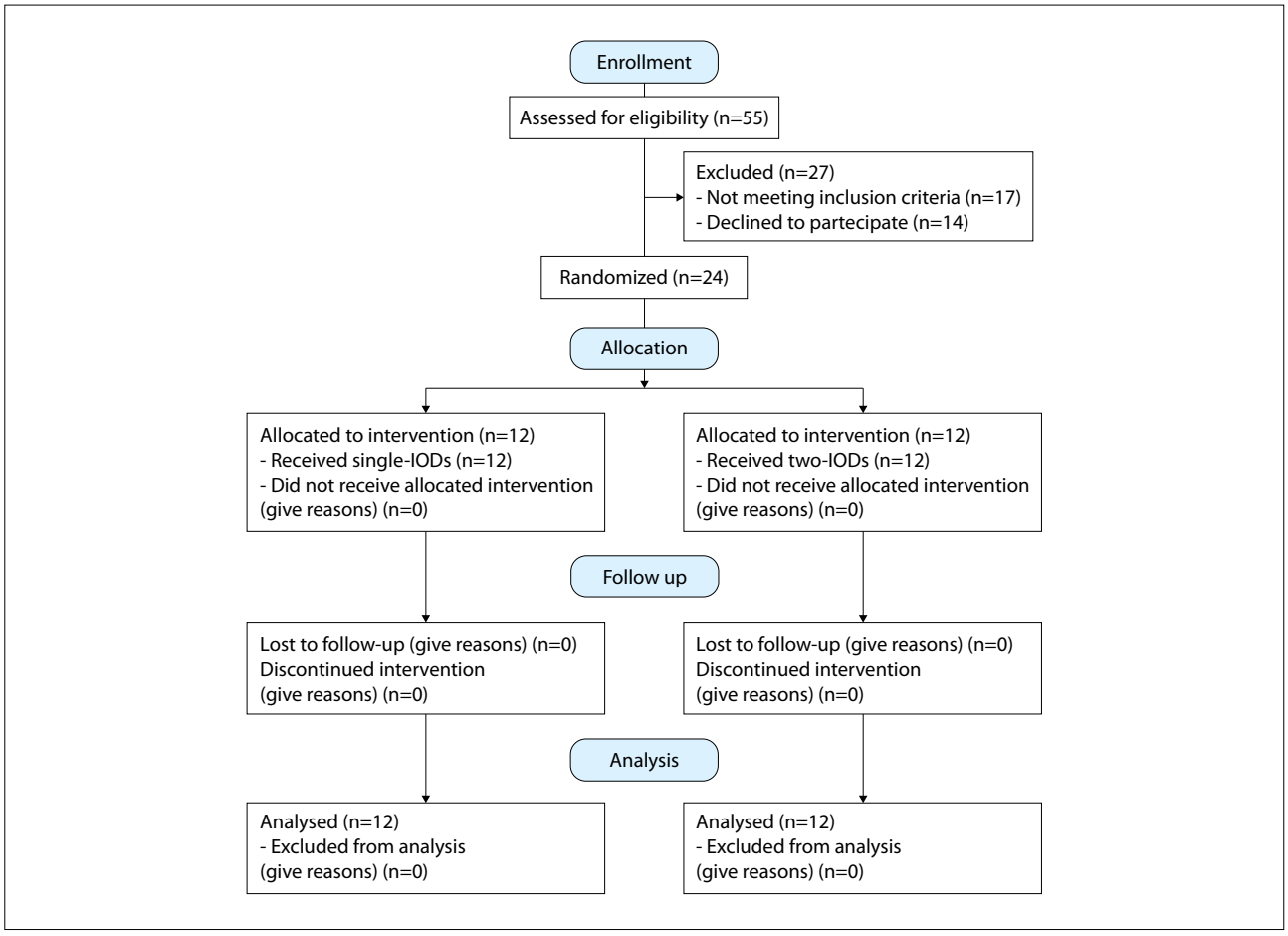

FIG. 4 CONSORT flow diagram.

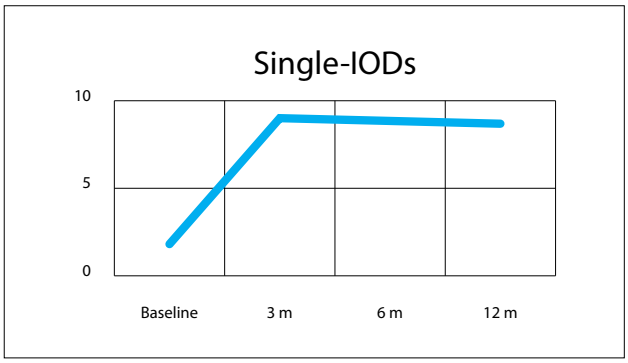

FIG. 5A

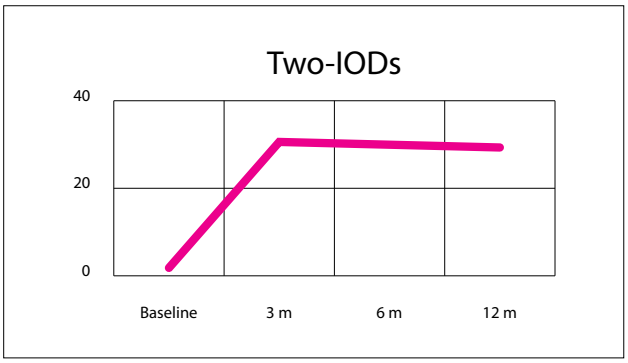

FIG. 5B

FIG. 5 Linear charts showing the effect of time on the retention of single-implant and two-implant overdentures.

Influence of time on denture retention in the two groups
The impact of time on denture retention for the participants with single implant and two inter-foraminal implant overdentures are shown in Figure 5. There was increased retention during the follow-up period, with a statistically significant difference from the baseline recording ($P < 0.05$).

Association between the two groups concerning denture retention
The impact of the implants number on denture retention is shown in Table 2. Both treatments modalities greatly improved the retention of lower dentures with no statistically difference between groups at baseline. However, there were more retention recorded at three, six and 12 months follow-up periods in the two implant group when compared to single- implant group (Fig. 6).

Follow-up periods	Single implant overdentures		Two-implant overdentures		P value
	Mean	SD	Mean	SD	
Baseline	1.8	0.41	1.8	0.39	0.96
3 m	9.1	3.15	31.4	2.69	<0.0001*
6 m	9.08	2.92	29.9	2.79	<0.0001*
12 m	8.7	2.86	28.5	3.22	<0.0001*
SD= standard deviation P value <0.05 show statistically significant					

TAB. 2 Association between retention of single and two- implant overdentures groups.

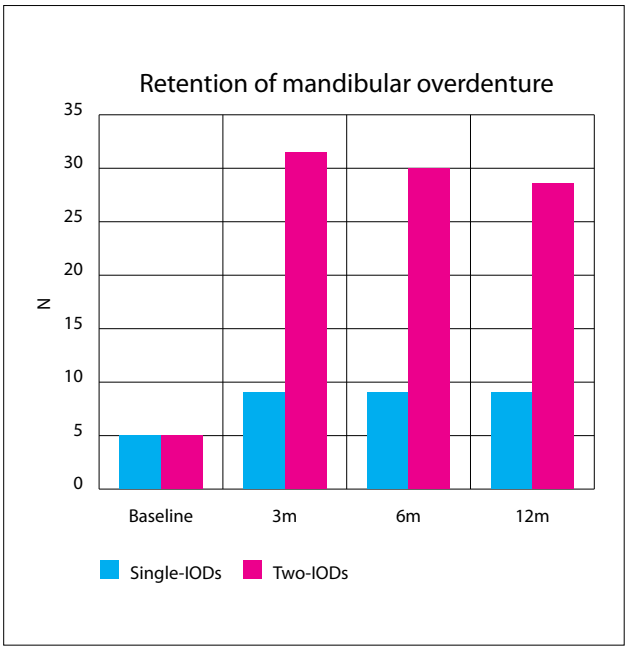

FIG. 6 Bar chart showing the comparison between single and two- implant overdentures groups regarding retention of mandibular overdenture.

DISCUSSION

This trial was planned to examine the assumption that there is non-inferiority of the retention force and implant success for single implants group compared to that of two-implant supported overdentures. This trial, of parallel groups design, was accepted by Ethical Committee, Evidence-based Dentistry Committee and Prosthodontics Department Board of Faculty of Dentistry, Cairo University, Egypt.
This study has been planned, performed and reported, intentionally using the best presented methodology, according to principles of evidence-based medicine. The cardinal goal was to explore the impact of single versus two-implant mandibular overdentures concerning their clinical retention force performances.
To the best of our knowledge no randomized controlled trials have been published evaluating denture retention in patients rehabilitated with single versus two inter-foraminal implant overdentures.
In this study the mandibular overdenture retention

had greater values at time of insertion, and decreased gradually in the following three, six and 12 months. This could be attributed to wearing of plastic cap of locator attachment. Both groups demonstrated a reduction in retention over time. In the two groups, the lowest denture retention was noted in both groups at time of conventional denture insertion owing to the fact that dentures lack sufficient retention. The benefit of implants with attachments significantly increases denture retention as a direct result of improved support and stability.

Assessing the two groups throughout the whole study period, the results of this study displayed a statistically significant difference between single and two-implant overdentures groups for mandibular denture retention.

The loss of retentive forces over time is expected. it has been endorsed to wear of attachment parts, which may be related to deformation that occurs through prosthesis removal and insertion according to Alsabeeha et al. (2009) (16). Similarly, Kleis et al. in 2010 (17) clarified that there is association between the plastic part wear and retention loss when they compared the locator with two conventional designs, where the locator group displayed 75.5% retention loss. The retention forces increased at the time of pickup of the denture and stabilized in the following 3 months then decreased after one year due to wearing of plastic of locator. This is in harmony with the results of Williams et al. in 2007 (18), that observed in an *in vitro* study on a model with a Harder bar and three clips that the retention force reduced owing to regular denture setting and removing but it stabilized afterwards.

This opinion confirms well the clinical experience that retention loss is simply compensated through activation or replacement of the matrix (19-21).

Overall results in the present study displayed that the retention in the two implant group was higher when compared to that of single implant group. This is explained by the increased number of implants.

Subsequently after the one year follow-up, no implant loss occurred in both groups. The results in the current study show that in the overall success rate there are no statistically significant differences between patients in both groups, demonstrating that the use of single-implant to retain a mandibular overdenture might be regarded as a substitute to the two inter-foraminal implant overdentures. This finding is in agreement with a previous study performed by Kronstrom et al. in 2017 (9). The single-implant overdenture could be used as a solution for edentulous patients especially for the geriatric ones and those belonging to a low economic status. But these results are preliminary one-year outcomes. Proper assessment of implant success or failure rate requires longer follow-up periods. Furthermore, this method may show an economical advantage for the healthcare policy makers, particularly for elderly patients who require less invasive solutions.

CONCLUSION

Considering the limitation of this study, the following conclusions can be drawn.

1. Better retention of two-implant retained mandibular overdenture was statistically significant than the single-implant overdentures groups.
2. Single-implant mandibular overdentures increase the retention of totally edentulous patients.
3. Success rate of implant mandibular overdentures are high in both single and two- implant overdentures.

Consequently, Single-implant mandibular overdentures may be considered as a treatment modality for rehabilitations in the edentulous mandible, particularly for geriatric patients and those with low economic level.

Recommendation

Larger well-conducted RCTs with long follow up periods are recommended including a wide range of functional, prosthodontic, and patient-oriented outcome measures.

Ethical approval

This study was approved by the Ethics Committee of the Faculty of Oral and Dental Medicine, Cairo University.

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