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Prosthetic Complications and Patient Satisfaction of Bar Versus Locator-Retained Overdentures in Completely Edentulous Patients. A Randomized Clinical Trial

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Research Article

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ABSTRACT

Background: Several types of attachments have been effectively used with removable implant OVDs. They can be classified as non-splinted as locator attachments or splinted as bar attachments.

Aim: The aim of this clinical study was to evaluate implant survival, maintenance requirements and patient satisfaction in fully edentulous patients who received implant overdentures retained by bar or locator attachments

Materials and Methods: A total of 24 completely edentulous patients were selected from the outpatient clinic. Patients were divided into Group (I): 12 patients had received two titanium implant with bar retained overdentures and Group (II): 12 patients had received two titanium implant with locator retained overdentures. The implant survival rate, prosthodontic complications and patient satisfaction for bar retained overdentures and locator retained overdentures were recorded during an 18 months' follow-up period.

Results: No implants were lost during the follow up period. Regarding prosthetic complications, it was recorded 11 times in the bar group and 13 times in the locator group but the difference is below the statistical significance for patient satisfaction, there was no statistical significant difference

Conclusion: No significant difference between bar and locator attachments regarding implant survival, prosthetic complications and patient satisfaction. Further randomized clinical trials are neededg.

INTRODUCTION

Edentulism is believed to affect the quality of life and health outcome of individuals. The conventional treatment plan of completely edentulous patients is removable complete maxillary and mandibular denture. Due to problematic neuromuscular coordination and difficulties in achieving a tight seal with the adjacent soft tissues, over 50% of mandibular dentures had problems with retention and stability and patients always show dissatisfaction with their mandibular complete denture [1].

Mandibular implant-retained overdentures (OVDs) are suggested to overcome those drawbacks and are relatively inexpensive when compared to fixed implant-supported prosthesis [2]. According to the McGill consensus statement, the two-implant-supported mandibular OVDs is considered as the "standard of care for the edentulous patient [3]" OVDs offer good retention and stability, better function and aesthetics and consequently higher patient satisfaction and quality of life [4]. Other advantages are the reduced amount of alveolar ridge resorption and the decreased number of the implants and uncomplicated surgical steps. On the other hand, it is obvious that implant-retained OVDs need regular maintenance and repairs, as implant-retained prosthesis are subjected to biomechanical stresses [5].

Recently, several types of attachments have been effectively used with removable implant OVDs. They can be classified as non-splinted including ball, magnet, telescopic and locator attachments or spinted as bar attachments [6]. The choice of the attachment system depends on the needed amount of retention, jaw anatomy and morphology and financial state of the patient [7].

Bar represents an excellent attachment system that provides greater retention, allowing better force balance by its splinting effect and it can also correct severe unparalellisms. The retention components or clips are interchangeable and can be reactivated. The main disadvantages of bar attachments are the need for a large prosthetic space and the risk of mucosit is due to an insufficient oral hygiene under the bar and the need of clip activation [8-10].

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Since it was introduced in 2001, locater attachment has been widely used in retaining dentures. Locator attachment has self-aligning mechanism, has dual retention and is supplied in different colors according to the retention values [11,12]. This attachment is available in different vertical heights, also they are retentive, resilient, durable, and possess some compensatory built-in angulation. Additionally, it is easily repaired and replaced [13,14].

Controversy exists about biomechanical forces transmitted to solitary and splinted attachments [15,16]. Some studies propose that splinted implants work as a single unit, thus protecting dental implants being overloaded [17,18] and that bar-retained OVDs showed the least maintenance requirements [19,20]. On the contrary other studies revealed that the difference in the deformation between the mandible and bar attachments can cause loss of bone surrounding dental implants, screw loosening and fractures due to concentration of stresses [21,22].

Regarding patient satisfaction, as an outcome measure, with mandibular two-implant overdenture treatment has been comprehensively reported worldwide using different methods of assessment [23]. Results proposed that, dependent on the attachment system used, the level of patient satisfaction is affected by the amount of retention and stability of the implant overdenture.

The purpose of this randomized clinical trial was to evaluate implant survival, maintenance requirements and the oral health-related quality of life in fully edentulous patients who received implant overdentures retained by bar or locator attachments. The null hypothesis was that the implant survival, maintenance requirements and the oral health-related quality of life of implants supporting bar or Locator attachments is not different.

MATERIALS AND METHODS

This study was a randomized clinical trial (RCT) carry on patients presented on the outpatient clinic in Prosthodontics Department, Faculty of Oral and Dental Medicine, Delta University for Science and Technology, Egypt.

Trial Design

Parallel group, two arms, Randomized Controlled Trial (RCT) with 1:1 allocation ratio.

Selection Criteria

The inclusion criteria were (1) Completely edentulous patients have Angle Class I maxilla-mandibular relationship; (2) age ranged from 50 to 65; (3) there was no recent extraction in Maxillary and mandibular arches; (4) proper bone height to accommodate two implants in the canine region; (5) absence of oral pathological lesions intra-orally such as residual infections and cysts.

The exclusion criteria were (1) past history of head and neck radiation; (2) ridge augmentation or grafting; (3) Absence of any systemic diseases that could affect osseointegration of implants as uncontrolled diabetes, hypertension, and osteoporosis; (4) Heavy smokers exceeding 20 cigarette/ day; (5) para-functional habits such as bruxism or clenching.

Patient Examination

To determine that the patients were meeting the inclusion criteria a preliminary evaluation was done. This evaluation included a medical history form, a clinical assessment, a radio-graphic examination (panorama and cone beam).

Informed Consent

The main aspects and procedure will discuss with participants. If they accept to share in trial, written consent will obtained from them. Arabic versions of consent will prepared for better participant's communication. The trial was accompanied in agreement with the Declaration of Helsinki (2008).

Interventions and Study Procedures

If the patients' old dentures were present, they were checked for proper extension, aesthetic and occlusion. On the other hand, if a new denture is to be constructed, the conventional steps are performed.

Patient Grouping (Randomization Process)

Patients were randomly assigned to one of two parallel groups, in 1:1 ratio, to receive either bar retained overdentures (group 1) or locator retained overdentures (group 2). The method used to generate the random allocation sequence of the participants is a computer-generated list of random numbers using a research randomizer (https://www.randomizer.org/). Allocation was done using simple randomization procedure using sequentially numbered opaque sealed envelopes having [24]. Allocation card (12 for group 1 and 12 for group 2).

Blinding

Single blinded (Data analyst). Operator and patient are not blinded. Only statistician was blind.

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Radiographic Stent Fabrication

Before surgical procedures Pre-operative cone beam computed tomography (i-CAT 17-19, Imaging Sciences International, Hatfield, PA, USA) was made to assess bone quality and quantity of edentulous mandibular ridge. Finished denture was duplicated by mixing cold curing acrylic resin (Acrostone dental company, Egypt.) with barium sulphate powder (Elnasr pharmaceutical chemicals co, Egypt.) in a ratio of 4:1. Two holes were prepared at mandibular canine regions; where implants would be placed. Transparent acrylic resin template was adjusted to be used as a template during surgery.

Surgical and Prosthetic Procedures

Implants installation: The mandibular complete denture was reproduced into Clear acrylic resin and different to be used as a surgical template. After that the implants were placed in the canine region as they are parallel and perpendicular to each other and to the occlusal plane. Each implant was placed according to the two stage surgical protocol. Then the covering screws were threaded into the implants. The post-operative treatment was composed of chlorhexidine 0.2% mouth wash, Anibiotic coverage with amoxacylinClavulinate 625mg (AmoxacillinClavulinic Acid, Galaxo-Smith Kline-Becheem, Great Britain) one tablet/8 hours for one week. Brufen 400mg (Ibuprofen, Knoll AG, Ludwigshafen, Germany) was prescribed as an analgesic and anti-inflammatory used every 8 hours. After seven days the patient was asked to come to remove the sutures. All implants were permitted to integrate for three months before loading. The digital panoramic radiograph was used to check the Osseo integration of the implants. After that, the surgical uncovering of implants was done after verification of osseointegration.

Regarding the locator attachment, the loading procedures were performed as following the white block-out spacer (zest order #8519package) was placed around the head of separately locator abutment. 908a locator cap with black processing male (zestorder #8519 package) was placed into each locator implant abutment with white block-out spacer.

To create adequate space for over denture pick up, the relief was performed to those areas. The denture was adjusted for attachments and tried intraorally to make ensure from complete seating. The auto polymerizing acrylicresin (Acrostone Relining Materials, Egypt) was mixed and placed into the relieved areas over the metal housing oflocator attachment.

The denture was placed into its position in the oral cavity. The patient was asked to close into centric position, with maintaining accurate relationship with the opposing arch. The denture was removed and eliminates the white spacer after acrylic resin curing.

The locator male removal tool was used (attached to the locator core tool, zest order #8393) to eliminate the black processing male from the metal denture cap. The locator male seating tool (contained in locator core tool, zest order #8393) was used to place a locator replacement male into the metal denture cap. The replacement male was settled securely into place.

Regarding the bar attachment, the permanent transmucosal titanium abutments (Transmucosal Octa abutment, DENTIS-Korea) were fastened over the implant fixtures and torqued to 35 Ncm using torque ratchet. Secondary impression was performed with rubber base (Putty and light consistency addition silicone, elite HD+, Zhermack, Italy) using open tray impression technique. Master casts were verified for accuracy using an acrylic verification jig. The verification jig was tried intraoral and if it was not passively seated it was sectioned and reassembled using duralay resin (Duralay. Low shrink self-cure acrylic resin. Reliance Dental Manufacturing Company-Chicago- USA) then a new cast was constructed. After finishing laboratory procedures for custom made bar attachment the bar was screwed intraorally and new impressions were performed.

A new maxillary complete denture and an implant-retained mandibular overdenture were then constructed. Record blocks were fabricated and jaw relations were recorded. Shallow cusp acrylic resin teeth (Vitapans, Vita Zahnfabrik, Bad Sackingen, Germany) were used and the functional masticatory concept was a bilateral balanced occlusion. Trial dentures were verified intraorally for esthetics and function.

Dentures were processed in the usual manner and retentive clips (Yellow, Medium retention, Rhein 83) were picked up intraorally using self-cure acrylic resin.

Post-insertion Maintenance

The first follow up visit was done Patients after 30 days for. Then one visit every 6 months with a total follow up period of 18 months. The prosthodontic complications for bar retained overdentures and locator retained overdentures were recorded during the 18 months follow-up period. A record of all required corrections and repairs was done. The maintenance was recorded for each over denture in the form of an adjustment or a repair. The repair means adding or replacing a new material or teeth while adjustment indicates modifications without addition to the present over denture like correction of occlusal discrepancies and tightening of loosened abutment screws.

Patient Satisfaction and Quality of Oral Health Measurements

All subjects were inquired to complete aquestionnaire recording six aspects of patient satisfaction by using a 100 mm visual analog scale (VAS). The scales extended from completely satisfied to completely dissatisfied. The patients used the scales to express their personal opinions of six factors: general comfort, retention, chewing, speech, esthetics, and pain.

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Data Collection and Analysis

Regarding implant survival and prosthetic complications, the relative risk between both groups was calculated. Additionally, 95% confidence intervals were stated. Chi-square test was used for categorical variables and Fisher's Exact for correction of chi-square when more than 20% of the cells have expected count less than 5. The significance level was set at P ≤0.05. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows. Regarding the patient satisfaction, the mean and standard deviation values were calculated for each group. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests and showed non-parametric (not normal) distribution. Mann Whitney-U test was used to compare between independent samples.

RESULTS

No implants were lost during the follow up period. The survival rate was 100%. Concerning prosthetic complications, in the bar group; necessity of relining, occlusal adjustments, loss of retention, fracture of denture base and remake of the prosthesis occurred in one denture. Screw loosening occurred in 4 events affecting 2 abutments. Dislodged attachment took place in 2 events. While in the locator group necessity of relining and occlusal adjustments occurred in one denture, Screw loosening and attachment fracture occurred twice. Dislodged attachment happened in 4 events and loss of retention was in 3 events.. No additional prosthetic complications were recorded during the follow-up period. Comparing the total prosthetic complications in both groups, it was recorded 11 times in the bar group and 13 times in the locator group as shown in **Table 1 and Figure 1.** The relative risk is 0.9215 but the difference is below the statistical significance.

As for patient satisfaction, there was no statistical significant difference in satisfaction scores between bar and locator attachments where (p=0.068). As shown in **Table 2 and Figures 2-4**, the highest mean score of satisfaction was found in bar attachment while the least mean score of satisfaction was found in locator attachment.

Table 1: Comparison between the two studied groups according to the prosthetic complications.

Type of complication	Bar group (events)	Locator group (events)	Relative risk	95% CI	Significance level P-value
Necessity of relining	1	1	1	0.0704 to 14.2087	1
Occlusal adjustments	1	1	1	0.0704 to 14.2087	1
Dislodged attachment	2	4	0.8571	0.1807 to 4.0663	0.8461
Loss of retention	1	3	3	0.3612 to 24.9196	0.3091
Fracture of denture base	1	0	0.3333	0.0149 to 7.4511	0.4883
Screw loosening of abutments	4	2	0.5385	0.1075 to 2.6973	0.4514
Remake of the prosthesis	1	0	0.3333	0.0149 to 7.4511	0.4883
Attachment fracture	0	2	2.4074	0.1243 to 46.6188	0.5612
Total prosthetic complications	11	13	0.9623	0.4483 to 2.0659	0.9215

CI: confidence interval; Statistical significance at p-value ≤ 0.05.

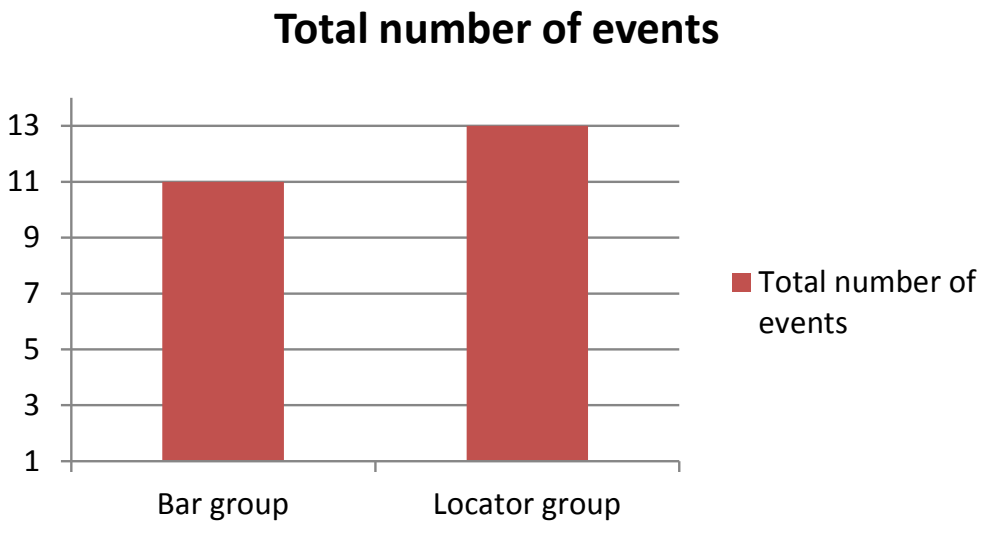

Figure 1. Bar chart representing total prosthetic complications in both groups.

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Table 2: The mean, standard deviation (SD) values of satisfaction scores of both groups.

Variables	Satisfaction scores	
	Mean	SD
Bar attachment	18.8	1.3
Locator attachment	17.2	0.84
P-value	0.068ns	

Figure 2. Bar chart representing the mean of scores of satisfaction in both groups.

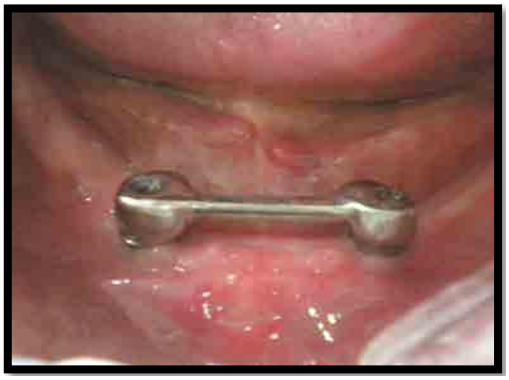

Figure 3. Bar attachment in place.

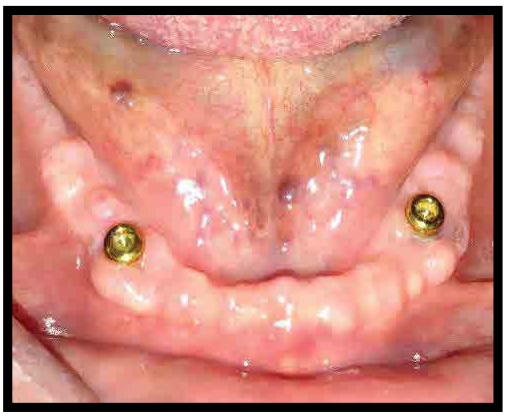

Figure 4. Locator attachment in place.

DISCUSSION

The present study compared the bar and Locator attachment system regarding implant survival, prosthetic complications, and patient satisfaction.

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No implants were lost during the follow up period, with a survival rate of 100%. This is similar to a study (24) in which 36 patients were treated, each with two implants and a locator attachment, and compared immediate and delayed loading. Twelve months after overdenture insertion, two implants had failed in the immediate loading group, resulting in survival of 100% for delayed loading and 94.5% for immediate loading. Another study found that there was no statistically significant difference between the ball, bar and locator group regarding the implant failure (p=0,339) [25]. It was stated that the bone quality and quantity and the morphology of the arch affects the implant survival rate more than the type of the attachment.

It was reported that the need for relining ranges from 6.5% to 18% during 0.5-1.5 years follow up [26]. It was declared that resilient attachments can result in undesirable forces to the tissues supporting the denture which can cause bone resorption which makes relining necessary [27]. In addition, the tissues supporting the denture are subjected to change and atrophy eventually, which is another cause of necessity for relining. In the present study, necessity of relining occurred once in each group this is similar to a study comparing three types of attachments (ball, bar and locator) where the necessity for relining was detected in 10 patients, but more significant in ball attachments (p=0.30) as it was needed in 8 dentures and once in the bar and locator group [28]. The author claimed that the difference between locator attachments and ball attachments may be attributed to the dissimilar resilience mechanisms of the two types of attachments [29].

Screw loosening of the abutments took place 4 times in the bar group and two times in the locator group. Several factors may cause screw complications: inadequate preload on the screws, overtightening of the screws which can lead to stripping and/or screw deformation, and/or occlusal overload due to parafunction, occlusal interferences, or exceedingly long cantilevers [30].

Fracture of the denture base occurred once in the bar group only and the denture were renewed, while fracture of attachments occurred twice in the locator group. Fracture of the denture base, attachments and the fracture of implants are due to biomechanical stress [31]. It was reported the frequency of the overdenture prosthetic fracture is 12% [32].In a study comparing ball, bar and locator attachments, 3 overdentures (2 in ball, 1 in bar group) were renewed as a result of the denture base fracture related to biomechanical stresses.

Loss of retention was observed once in the bar group and three times in the locator group. In addition dislodged attachment occurred twice in the bar group and 4 times in the locator group. Loss of retention can be due to fatigue and wear of the material. Several clinical studies showed that 3-dimensional loads take place frequently during function. A slight rocking occurs when food is chewed on free end denture bases leading to plastic deformation of the matrice, causing a reduction of retention or dislodgement of the clip. A study 6 evaluating bar and locator attachments demonstrated that retentive values of the locator attachments are reduced significantly after multiple pulls. Another study recorded no problem of retention associated with the Locator system when compared to ball and bar designs.

Up to our knowledge there are no recent papers comparing bar retained mandibular implant over denture with locator regarding patient satisfaction. Therefore, the results of previous studies comparing splinted and un splinted attachments can be considered to explain this result.

It is obvious within the literature that the use of implants to retain prosthesis in contrast to a conventional prosthesis has been shown to progress patient satisfaction and oral health-related quality of life outcome measures [33].

A previous studyconcluded that most of the patients expressed the same level of satisfaction for oral function restoration [34]. Regarding general patient satisfaction, no significant differences detected between splinted and unsplinted implants [35].

Another study showed that the retention and stability improved compared to a complete denture that the patients used before, they felt a somewhat higher satisfaction with an implant overdenture [36]

A study comparing ball-socket- and bar-clip-retained two-implant mandibular overdentures observed that there was no difference in satisfaction between the studied groups [37]. In addition, another study found out that there were no differences between ball and locator attachment for any items of satisfaction assessed and neither attachment had a significant patient preference [38]. The current literature would propose that there is no strong evidence for the superiority of one system over the others regarding patient satisfaction [39].

CONCLUSION

It is concluded that there was no significant difference between bar and locator attachments regarding implant survival, prosthetic complications and patient satisfaction. However, the locator group needed more services and showed less patient satisfaction but this was below the level of significance. Further randomized clinical trials are needed to confirm our results.

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