

Comparison between use of soft Liner and O-ring attachment in mandibular implant assisted overdenture: Randomized clinical Trail

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Aim: Evaluation of the effectiveness of different types of attachment systems on single implants in mandibular implant-assisted overdentures.

Materials and Methods: This was a randomized clinical trial on fourteen completely edentulous patients selected with adequate width and height in the anterior region of the mandible. Selected patients were divided randomly into two equal groups of seven patients each. Group A: Patient with removable mandibular implant assisted overdenture with ball and O-ring attachment. Group B: Patient with removable mandibular implant assisted overdenture with silicon soft liner as attachment. Gingival index, bleeding index, probing depth around the implants, and retention of overdenture by digital force gauge was evaluated at 0,6,12,18 months after insertion of the prosthesis. The data were collected and statistically analyzed by independent t-test and a Post Hoc Test using IBM SPSS 20 at a 5% level of significance.

Results: All the implants in both groups successfully achieved osseointegration. The results for the gingival index, bleeding index, and periodontal pocket demonstrated higher values in the O-ring group compared to the silicon soft liner used as a female housing. Nevertheless, a notable difference was observed in O-ring retention compared to the silicon soft liner for female housing from baseline to the 18-month mark, which was statistically significant.

Conclusion: The study concluded that, in single implant-assisted overdentures with different types of attachments, the group using a silicon soft liner as the female attachment exhibited a more positive effect on gingival health. However, it demonstrated less retention compared to the O-ring attachment group.

Keywords: Edentulous mandible, Dental implants, Overdenture, Attachment, Retention.

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Introduction

Edentulism is a serious public health issue that has a negative impact on patients' quality of life due to the loss of phonation and mastication abilities, as well as nutritional, aesthetic, and psychological losses.¹ Therefore, prosthetic rehabilitation of totally edentulous patients is mandatory to advance their daily tasks. Treatment of these patients is difficult for the regular dentist and less intriguing for dental prosthodontics practices. Due to the conventional dentures' poor retention particularly in the mandibular jaw, the majority of patients are not entirely satisfied with their dentures. However, the advent of dental implants made it possible to avoid these issues and significantly improve functional activities.²

As an alternative to overdenture designs that are more complicated, it has been suggested to use a single-implant mandibular overdenture (SIMO). In comparison to the fixed-implant procedure and the overdenture supported by two implants, SIMO is thought to be less invasive and has reduced cost. Furthermore, for elderly patients, who have lower functional demands and good local bone quality in the symphyseal region, which ensures adequate primary implant stability, it is a more practical option. This is because they are less likely to adhere to complex implant interventions.³

Even though SIO has been associated with consistent results, problems like denture base midline fracture can arise during functional loading as a result of stress concentration at the weak spot next to the attachment.⁴ Another issue was the requirement for prosthetic modifications, such as replacing or reactivating the attachment because of retention loss.⁵ Additionally, compared to two implant retained overdentures (TIO), which exhibit a two-dimensional movement, the prosthesis's movement in SIO is three-dimensional,

making it biomechanically far more complex.⁶

There are several attachment systems for implant-assisted overdentures that have been used, but each one has drawbacks. Attachments used in conjunction with implants were found to enhance the retention, stability, and support of overdentures together with the implants, thus increasing their longevity.⁷

The elastic retainer of the ball attachment, which allows for a minor rotation of the overdenture and transfers the load to the nearby bone tissue, is frequently used in single implants. While spreading the axial load and limiting damage to the peri-implant bone tissue, ball attachment meets the needs of implant mucosa-supported overdentures. The prosthesis can move in multiple directions, acting as a shock absorber and reducing the load on the abutment. However, the high maintenance costs of this attachment style have restricted its use.⁸

In several applications in prosthetic dentistry, the soft resilient material is used to reline the fitting surface of the denture.⁹ Additionally, it serves as the female component for various sorts of attachment when used with dental implants.¹⁰ The physical properties of soft resilient materials reduce the stress on fixtures brought on by occlusal forces.^{11, 12}

In certain clinical trials, it was claimed that using silicone resilient soft-liner materials as matrices facilitates the easy insertion and removal of the prosthesis, particularly in new denture wearers. Additionally, the wear of the soft liner is reduced, potentially preserving the retentive force of the attachment.¹³

On the other hand, the silicon soft liner has some drawbacks as their low glass transition temperature and hydrophobicity, which both lower water sorption and prevent the liners from having a strong affinity for the supporting tissues.¹⁴

The digital force gauge is used in this study to test the retention which is considerably smaller and about 20 times lighter than other systems, and it is used in both laboratory and clinical research because of its accuracy and portability. The portability of the tested device is compatible with clinical applications, and its accuracy is comparable to high-end systems. The device has the advantage of high resolution, automatically determines tensile and compressive forces during use, a large 5-digit LCD display for easy reading and wide range of force measurement (0-5000) grams.¹⁵

Consequently, this study evaluated the clinical performance of both O-ring and silicon soft liner as attachments for single implant assisted overdenture over 18 months follow-up. The null hypothesis stated that there would be no differences in clinical assessments and retention between the two different female housings (O-ring attachment, soft liner) for a single implant assisted-mandibular overdenture maintained by ball abutment.

Material and Methods

Trial design

This investigation was carried out as a randomized clinical trial.

Trial setting

This study was conducted in the Prosthodontic Dentistry Clinic of Tanta University's Faculty of Dentistry.

Sample size

Sample size calculation was done using the comparison between the clinical evaluation parameters. It was done based on comparing between 2 independent samples, the α -error level was fixed at 0.05. The power sample size was more than 80%. As previously published study (Elsyad & Shoukouki 2010)¹⁶. for this study the confidence interval 95% and the actual power is 96.35%. Accordingly, the minimum optimum sample size should be 7 subjects at

each group. Sample size calculation was done using G*Power version 3.1.9.6 (Universität Kiel, Keil Germany)

Ethical considerations:

The Ethics Committee at the Faculty of Dentistry, Tanta University, performed guidelines on human research and approved the performance of the practical portion of this research after meeting the requirements with code ##RP-10-19-4. All procedures and the nature of the study were explained to the patients, and their written informed consents were obtained by those guidelines.

Randomization and group allocation

The permuted block randomization technique was used to determine the side at random. Using sealed envelopes, the allocation sequence and the code were concealed from the individual assigning participants to the intervention arm. Notably, the selection was conducted by a different individual who was not involved in the study.

Patient Selection

Based on inclusion and exclusion criteria, fourteen completely edentulous patients were selected from the prosthodontic department clinic at the faculty of dentistry, Tanta University. Every patient is recommended to make additional laboratory tests, including complete blood count (CBC), prothrombin time (PT), activated partial thromboplastin time (aPTT), and fasting blood glucose.

Inclusion criteria

Patient age (50-65) years old, free from any systemic diseases that may influence soft or hard tissue healing, all patients should have enough intermaxillary space, patients should have relatively good oral hygiene, and anterior mandible with sufficient bone to place implants without

augmentation procedures.

Exclusion criteria

Patients with neurological or psychiatric handicaps that could interfere with good oral hygiene, alcoholics and smokers, and the patient with immune-compromised status.

Every patient's full maxillary and mandibular dentures were made using a standardized conventional procedure. The standard procedure for replicating a denture was used to construct a radiographic guide from the mandibular denture. On the outer surface of each denture, five to eight markers were placed within each guide at various levels in the horizontal, vertical, and transverse directions.¹⁷

Using a dual scan approach, cone beam computed tomography (CBCT) was employed to scan the radiographic guide (parameters: 85 KVP, 10 MA) twice: once inside the patient's mouth and once while attached to the cast. Digital imaging and communications in medicine (DICOM) formatted files for the two sets were stored on a computer.¹⁸

These DICOM files were transferred into the three-dimensional implant planning software displaying the position and angulation of the implant. Anchor fixation pins were then determined. Subsequently, a stereolithographic surgical guide was fabricated from transparent resin material (Nextdent Co., Soesterberg, The Netherlands) by the 3D printer (Phrozen 3D printer, Hsinchu City, Taiwan) according to implant design (Figure 1).¹⁹

A Single dental implant (Nucleoss Co., Izmir, Turkey) measuring 12 mm in length and 3.5 mm in diameter was placed in the para midline at the symphyseal region of the mandibular arch for each patient in both groups (Figure 2).

It is crucial to determine the available interarch distance at the appropriate vertical

dimension of occlusion during the diagnosis and treatment planning phase by assessing of proper diagnostic wax-up of the intended prostheses.²⁰



Figure 1. Stereolithographic surgical guide.



Figure 2. Placement of implant inside osteotomy site.

Prosthetic space analysis evaluation is essential for a successful implant-assisted overdenture treatment. As a general rule, 2 mm should be allocated for the acrylic resin denture base and 3 mm for the prosthetic teeth, with the vertical space occupied by overdenture attachment systems ranging from 2.5 to 6 mm. Therefore, 10–12 mm is the minimum space needed for ball attachment.²¹

Three months later, the patients returned for the insertion of a ball abutment onto the respective implants. The patients were randomly divided into two equal groups based on the pick-up procedure approach, with seven patients in each group:

Group A: Single implant assisted overdenture with ball and O-ring attachment (Nucleoss Co., Izmir, Turkey) (Figure 3).

Group B: Single implant assisted overdenture with ball and soft liner (Mollosil® plus,

DETAX GmbH & Co. KG, Germany)) as attachment.

Clinical evaluations were performed at the time of the denture's insertion as well as at 6 months, 12 months, and 18 months follow-up intervals.



Figure 3. Complete pick up of female housing in corresponding site in the fitting surface.

Clinical evaluation

1-Gingival index:

All surfaces mesial, distal, buccal, and lingual were individually evaluated using the Loe and Silness index,²² after the gingiva around each implant had been thoroughly dried with sterile gauze and air. The mean GI score of the four surfaces (M, D, B, and L) was calculated as an average of these four surfaces collectively.

2-Bleeding index:

Score 0 indicates no bleeding when the periodontal probe is passed along the gingival margin, score 1 indicates a single visible bleeding spot, score 2 indicates a red line of confluence along the gingival margin, and score 3 indicates heavy or profuse bleeding. The bleeding index (BI) score was determined using four different implant sites, and the resulting total score was then divided by 4.²³

3-Periodontal pocket:

A plastic periodontal probe (HELMUT ZEPF, Medizintechnik GmbH, Germany) was used to measure the probing depth around the implant surfaces in the mid-buccal, mid-lingual, mid-mesial, and mid-distal regions. The average probing depth for a single implant was calculated by averaging

the results from these four measurements. Probing depth measurements less than 1 mm were recorded as 1 mm, those greater than 1 mm but less than 2 mm were recorded as 2 mm²⁴, and so on.

4-Retention test:

Retention was measured by a digital force meter (47544 Lanetech Instrument, collaboration, Beijing) with a wide range of force measurements (0-5000 gm). The geometric center was marked on the lower cast at the intersection of three lines bisecting the angles of the triangle formed by both the retro-molar pads and the midline. The maxillary denture was removed to measure force as vertically as feasible, and the patient's occlusal plane was noted in a vertical direction perpendicular to the retention measurement. The display of the force meter was reset to zero using the zero buttons before each measurement of retention. The pull end of the digital force meter was connected to a metal hook located in the geometric center and pulled vertically to measure the retention force in Newton [Figure 5]. The measuring process was carried out three times, and the average value was determined. The mandibular dentures of each group were measured using the same methodology.²⁵



Figure 4. Retention evaluation.

Statistical methodology

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Data normality was determined using the Shapiro-Wilk test, which revealed a normal distribution.

The clinical evaluation regarding gingival index score and bleeding index score in this study were non-parametric data and presented as median (minimum- maximum) while periodontal pocket and retention test were parametric data and presented as mean \pm standard deviation. Repeated measure ANOVA was employed to compare the durations within each group. Additionally, independent T-tests were conducted to compare between the two groups at each duration. For pairwise comparisons of not normally distributed quantitative variables, a Post Hoc Test (adjusted Bonferroni) was applied. The significance of the obtained results was assessed at the 5% level.

Results:

Clinical evaluation results

Gingival index:

Table (1) shows the median of the gingiva index around the implants for both groups at different follow-up periods. We observed no significant differences up to the end of the evaluation period, with corresponding P-values of 1.00, 0.053, 0.383, and 0.620 at the time of insertion, 6, 12, and 18 months, respectively.

Table 1. Comparison of median gingival index around the implants between two groups at different follow-up periods.

Follow-up periods	Group A Median (Min – Max.)	Group B Median (Min – Max.)	p-value
At insertion	0 (0 – 0)	0 (0 – 0)	1.000
6 months	0.50 (0.25 – 0.75)	0.25 (0.0 – 0.25)	0.053
12 months	0.75 (0.50 – 1.0)	0.75 (0.50 – 0.75)	0.383
18 months	1.0 (0.75 – 1.25)	1.0 (0.75 – 1.0)	0.620
p _i -value	<0.001*	<0.001*	

Min =minimum Max=maximum *: Statistically significant at $p \leq 0.0$

Bleeding index:

Table (2) shows the median of the bleeding index around the implants for both groups at different follow-up periods. No significant differences were found throughout the evaluation period, with P-values of 1.00, 0.620, 0.128, and 0.318 at the time of insertion, 6, 12, and 18 months, respectively.

Table 2. Comparison of median bleeding index around the implants between two groups at different follow-up periods

Follow-up periods	Group A Median (Min – Max.)	Group B Median (Min – Max.)	p-value
At insertion	0 (0 – 0)	0 (0 – 0)	1.000
6 months	0.25 (0 – 0.50)	0.25 (0 – 0.25)	0.620
12 months	0.25 (0.25 – 0.50)	0.25 (0 – 0.25)	0.128
18 months	0.50 (0.25 – 0.75)	0.25 (0.25 – 0.50)	0.318
p _i -value	0.005*	0.002*	

Min =minimum Max=maximum *: Statistically significant at $p \leq 0.05$

Periodontal pocket:

Table (3) shows the mean and standard deviations of the periodontal pocket depth around the implants for both groups at different follow-up periods. It was found that there were non-significant differences till the end of the evaluation period with P-values= 0.456,0.259,0.259and 0.535 at the time of insertion,6, 12, and 18 months respectively.

Table 3. Comparison of mean of Periodontal pocket around the implants between two groups at different follow-up periods.

Follow-up periods	Group A Mean \pm SD.	Group B Mean \pm SD.	p-value
At insertion	0.29 \pm 0.17mm	0.21 \pm 0.09mm	0.456
6 months	0.57 \pm 0.12mm	0.46 \pm 0.09mm	0.259
12 months	0.96 \pm 0.22mm	0.79 \pm 0.22mm	0.259
18 months	1.14 \pm 0.35mm	1.0 \pm 0.20mm	0.535
p _i -value	<0.001*	<0.001*	

M= mean SD=standard deviation. P= probability level * = significant difference ($P \leq 0.05$)

Retention result:

Table (4) displayed the mean and standard deviations of the retention for both groups at different follow-up periods. It was found that there were significant differences till the end of the evaluation period with P-values= 0.001*. Additionally, there were statistically

significant differences within each group at both follow-up observations.

Table 4. Comparison of mean of Retention between two groups at different follow-up periods.

Follow-up periods	Group A Mean \pm SD.	Group B Mean \pm SD.	p-value
At insertion	8.89 \pm 0.41N	5.74 \pm 0.41N	<0.001*
6 months	8.06 \pm 0.40N	5.26 \pm 0.46N	<0.001*
12 months	7.31 \pm 0.37N	4.90 \pm 0.45N	<0.001*
18 months	6.81 \pm 0.39N	4.60 \pm 0.46N	<0.001*
p1-value	<0.001*	<0.001*	

M= mean SD=standard deviation. P= probability level * = significant difference (P \leq 0.05)

Discussion

One of the most prevalent conditions affecting the oral health of the senior population is edentulism. Following tooth extraction, alveolar ridge resorption reduces the area that can support the prosthesis, which is more common in the mandible.²⁶ The conventional mandibular complete denture has many problems such as retention, support, and stability, so implant was employed to solve such problems, particularly in lower arch.²⁷

The patients were specifically chosen in good overall health to ensure that systemic disorders wouldn't interfere with bone quality, the natural healing process, osseointegration of the implants, and the appropriate bone response to applied stresses.²⁸

A simplified approach using a single implant to improve the retention of the mandibular denture has been proposed as a more conservative and less costly alternative compared to other solutions with a greater number of implants.²⁹ Previous clinical studies reported promising results of the single-implant mandibular overdenture (SIMO) treatment, including improvement of OHRQoL measures and patient satisfaction³⁰, as well as other favorable clinical outcomes, such as high implant survival rates³¹, minimal marginal bone loss³², acceptable

incidence of adjustments and repairs, and lower treatment costs compared to the two-implant overdenture.³³

A single implant in the midline of the mandibular completely edentulous ridge improves the retention and stability offered by the single implant retained overdenture when compared to the patient's previous complete denture. This result comes in agreement with several studies that concluded that implant retained mandibular overdenture improved masticatory ability and patient satisfaction. In addition, several studies reported that single implant retained-mandibular overdenture improved the masticatory function of elderly patients^{34, 35,36}

The anterior symphyseal area of the mandible was selected for the implant placement. This choice was based on several factors: the presence of thicker cortical bone, lower surgical risk by avoiding the inferior alveolar nerve and blood vessels, a larger tissue-supporting area to prevent implant overload, and the establishment of good primary implant stability. Consequently, this specific region proves to be the most suitable for retaining single implants in overdentures.⁵

Cone beam computed tomography (CBCT) can be used as a diagnostic tool to evaluate the alveolar bone's condition and determine the precise implant site based on bone width and height. As well as to determine proximity to the lingual artery which is a vital structure as damage to it may lead to potential complications.³⁷

The stereolithographic surgical guide was meticulously designed to precisely determine the intended implant position, length, and angulation as per the initial plan. Moreover, this guide proved instrumental in enabling a flapless implantation technique, aimed at preserving the bone's blood flow to the maximum extent possible. This approach prioritizes minimizing flap reflection during

surgery, as it can otherwise compromise the crucial blood supply to the alveolar bone from the adjacent soft tissue. This principle has been advocated by both Flody et al and Al-Juboori et al.³⁸

The most typical measurements of implant for the anterior mandible were employed in this study, 3.5 mm width and 12 mm length, which are the most common dimensions used in the anterior mandible. Varied implant dimensions result in varied surfaces contacting supporting bone, which may affect how much pressure is applied to each square inch of the implant, that agrees to Ganz et al.³⁹

The choice of utilizing the ball and O-ring attachment was based on several favorable factors, including its cost-effectiveness, ease of handling, simple maintenance, and cleaning procedures. Furthermore, this attachment type offered a wide range of motion, required less interarch space, and demonstrated optimal outcomes in terms of soft tissue health and patient satisfaction. Notably, it effectively balanced axial strain, minimizing peri-implant bone and tissue damage, and meeting the criteria for implant-assisted overdentures.⁴⁰ Despite these advantages, it's important to note that the high maintenance costs associated with this attachment have limited its widespread use. This observation is in line with findings from studies by Van Kampen et al. and Cherli et al.^{41,8}

In this study, we opted to use a silicon soft-liner as the female attachment, The rationale behind this selection is attributed to the soft-liner's ability to facilitate effortless cleaning of the abutment during denture placement and removal. Additionally, it effectively prevents plaque formation, regardless of the patient's level of dental care, this choice is supported by Cain et al. and Elsayed et al.^{42,16}

All the examined implants exhibited minimal symptoms of gingival tissue

irritation. In numerous cases, especially within Group B, only a mild grade one gingival index was observed. This favorable outcome could be attributed to good oral hygiene practices, suggesting a positive influence on maintaining healthy gingival conditions.⁴³

The analysis revealed a lack of significant difference in the bleeding index between the two groups throughout the entire follow-up period. These findings align with several studies that have also noted minimal variations in the bleeding index.^{44,45} The placement of the implant in the anterior region facilitated effective accessibility for dental hygiene measures, resulting in satisfactory bleeding index results. This observation is consistent with the findings of Gibreel et al.⁴⁶

The mean difference in probing depth between the two groups at all follow-up intervals did not show any statistically significant variance ($p \leq 0.05$). These results are consistent with several prior studies that also reported insignificant differences in probing depth between the compared groups.⁴⁵

Throughout the follow-up periods, a minor trend of increasing probing depth around the implants was observed, although it did not reach statistical significance. These increases remained within acceptable ranges and echoed previous research, which noted a rise in probing depth after a one-year follow-up. This increase is often associated with bone resorption during the initial year post-implantation.⁴⁷ However, notably in Group B, the utilization of silicone-resilient liners significantly enhanced soft tissue health around the implants, resulting in these favorable outcomes with a less pronounced impact on probing depth.⁴⁸

Retention of mucosally-implants retained overdenture improves the patients' satisfaction, quality of life, patient self-confidence. Maryod and Taha⁴⁹ used digital

force gauge to evaluate retention of lower removable partial dentures in their study. Measurements were carried out using a digital force gauge which is an advanced type of force meter device, used to measure tension or compression up to 20Kg. Also, Mustafa⁵⁰ used digital force gauge device for measuring the retention of a lower denture.

The provided retention from the attachment and improving adaptation of patients with time may be the reason for the increased satisfaction scores. Components of lower cost, shorter surgery time and lower need for maintenance could be the reason for high patient satisfaction score suggesting that a mandibular overdenture supported by single implant could be a viable alternative to the customary two implant overdenture.⁵¹

As the overdenture is used in the mouth over time, it interacts with saliva, food, and drinks during chewing, and the actions of putting it in and taking it out. We expected that these interactions would affect how well the O-ring attachment keeps the dentures in place. Additionally, we anticipated that the holding strength would decrease as the prosthetic parts moved slightly due to use. This observation aligns with the findings of Sadowsky and Kim et al.^{52, 53}

While flexible soft liners provide various advantages, including reduced wear, enhanced patient comfort, absorption of occlusal force, and effective load distribution to the implants, it was also observed that the retention of the silicon soft liner with the ball attachment remained consistent up to 18 months. However, it was slightly lower compared to the O-ring attachment. This difference is attributed to the stable physical properties of the silicon material, which outperform acrylic soft liners. This finding aligns with Schweyen's study, where polyvinyl siloxane attachments demonstrated sustained retention forces over a simulated period of five years of clinical use.¹³

Conversely, Koike et al⁷ have demonstrated that the retention force of soft liner when used as female housing for ball abutment can increase instead of decrease. It has been suggested that this increases when the diameter of the spherical male ball is equal to or higher than 2.5 mm.

Conclusion

After a thorough evaluation of single implant-assisted overdentures utilizing different attachment types, a clear distinction emerged. The group employing a silicon soft liner as the female attachment demonstrated marked improvements in gingival health. The silicon material's gentle nature was beneficial for the gingival tissue. However, when it came to retention, this group exhibited slightly lower retention compared to the O-ring attachment. In contrast, the O-ring attachment showed superior retention capabilities, ensuring a snug fit for the overdenture.

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