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EVALUATION OF TWO DIFFERENT ATTACHMENT SYSTEMS IN MANDIBULAR OVERDENTURES RETAINED WITH TWO INCLINED IMPLANTS

(A RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: Selection of the proper overdenture attachment system can be challenging for the prosthodontist if there is a lack of implant parallelism.

OBJECTIVES: The study aimed to radiographically assess the influence of two distinct attachment systems on marginal bone loss (MBL) around a pair of 30-degree divergent implants retaining mandibular overdentures.

MATERIALS AND METHODS: The study involved 22 fully edentulous patients who underwent a prospective randomized controlled trial (RCT). In this trial, each patient received a pair of implants tilted at a 15° angle from the vertical axis, bilaterally placed in the canine regions using a minimally invasive flapless surgical technique. The participants were evenly divided into two groups: Group N (n = 11), which received mandibular overdentures with angled Novaloc attachments, and Group L (n=11), which received mandibular overdentures with Locator attachments. The evaluation of MBL was conducted at three time points: baseline (prosthetic loading), 3 months, and 12 months after prosthetic loading.

RESULTS: By the end of 12 months, the mean values of MBL did not exceed 1.5 mm in both groups. The mean values of MBL were greater in group N than in group L with a statistically significant difference ($P < .001$).

CONCLUSION: The Locator attachment may be viewed as superior to the angled Novaloc attachments when it comes to peri-implant bone loss around 15° distally inclined implants used to retain mandibular complete overdentures. Nevertheless, the bone loss with angled Novaloc attachments remains within clinically acceptable limits.

KEYWORDS: Overdenture, Inclined implants, Novaloc, Locator, Attachment.

RUNNING TITLE: Evaluation of two attachment systems in mandibular overdentures.

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INTRODUCTION

Edentulous patients often face well-documented issues, including masticatory impairment, primarily because of the inadequate retention and stability of their complete dentures (1). Bone resorption may result in functional restrictions and discomfort, particularly in the mandible (2). Research suggests that using implant-supported removable prostheses for treating edentulous patients can produce a dependable and successful solution for addressing the functional limitations linked to conventional dentures (3,4). The McGill Consensus Statement (5) and the York Consensus Statement (6) offer substantial evidence endorsing the idea that a two-implant mandibular overdentures has to be the preferred approach for managing edentulous patients.

While it is ideal for implant placement for overdenture to be both parallel to one another and aligned with the prosthesis insertion path, while also being perpendicular to the occlusal plane (7), practical constraints like bones quality, anatomical structures, and clinical considerations often lead to some deviation from the desired insertion path (8,9). The placement of implants with a higher inclination may occur with less skilled surgeons (10). As a result, placing two implants bilaterally in the canine position within a curved edentulous arch can cause them to diverge in the frontal planes (11). From a clinical perspective, a facial concavity may make this distal implant inclination issue obvious While computer-assisted implant placement may eliminate the need for bone grafting and flap elevation, it remains inaccessible to elderly individuals facing economic constraints and limited financial resources (12,13).

Lack of implant parallelism can make it difficult for a dentist to choose the right overdenture attachment system (14). If the implants are slanted, an optimal attachment system should provide substantial and consistent retentive force while exerting minimal lateral force on the implant (15).

The widely employed conventional ball attachment allows angulation adjustments of only up to 20˚, making it the most commonly utilized system. To correct tilted implants, alternative prosthetic methods, like employing a Locator attachment instead of ball patrices or employing a splint with a bar, were suggested (10,16).

The bar design will increase costs, increase the risk of gingival hyperplasia, and reduce tongue space in the presence of tapered arches (17). While the Locator attachment can handle a divergence of up to 40 degrees between implants, concerns such as frequent wear and inadequate retention have been observed (14,15,18-20).

To tackle this concern, the market is witnessing a rise in systems featuring angled abutments. One example is the Novaloc Retentive System developed for hybrid dentures (Insitut Straumann AG, Basel, Switzerland). This system, introduced in 2016, includes a 15° angled abutment alongside straight abutments. It relies on mechanical retention through a polyetheretherketone (PEEK) matrix on a cylindrical patrix, which might offer superior wear resistance compared to the nylon found in alternative attachment system. These abutments additionally treated with a surface made of amorphous diamond-like carbon, which decreases roughness and improves the durability of the attachment components. The Novaloc attachment occupies minimal space, with the female part measuring just 2.3 mm in height and 5.5 mm in diameter. Consequently, it ranks among the smallest applicable attachment accessible. In vitro studies have been carried out to assess the enduring retention of PEEK matrices versus the conventional Locator system, yielding encouraging outcomes (21-23). Nonetheless, it is worth noting that increased abutment angulation imposes greater stress on the surrounding bone, as demonstrated by photoelastic stress evaluations, finite element analyses, and strain-gauge investigations (24,25).

While there have been reports of employing the Novaloc attachment for correcting inclined implants in the fabrication of overdentures (26), there is a dearth of clinical research assessing the impact of Novaloc attachments systems on the efficacy of inclined implants that retain mandibular overdenture. Consequently, this research aimed to radiographically compare 30-degree divergent dual implants supporting mandibular overdentures with angled Novaloc and Locator attachment systems, focusing on Marginal Bone Loss (MBL). The null hypothesis posited that there would be no significant disparity between the two attachment systems.

MATERIAL AND METHODS

This study, a prospective, double-blinded, balanced, randomized controlled clinical trial with a parallel-group design, was undertaken after obtaining approval from the ethical scientific research committee of the Faculty of Dentistry, Alexandria University, Alexandria, Egypt (International number: IORG 0008839) and the implant's research committee. Furthermore, it is registered on www.ClinicalTrials.gov (ID: NCT05695612) and adhered to the good clinical practice guidelines and principles for clinical research as outlined in the Declaration of Helsinki.

Patient selection

This research involved twenty-two fully edentulous patients with age ranged from 40 to 65 years chosen from the Prosthodontic department at the Faculty of Dentistry, Alexandria University. The sample size was determined using MedCalc Statistical Software version 19.0.5, based on a study comparing retention force between Novaloc and Locator attachment systems (23). We set a significance level of 95% and a power of 90%. An online software program, Research Randomizer (http://www.randomizer.org), was used to generate a random allocation sequence (27). The allocation was concealed within opaque envelopes, which were opened by the clinician during prosthetic loading appointments. Both the participants and the statistician were kept unaware of the attachment type being assessed.

Every edentulous participant selected was dissatisfied with the traditional mandibular denture. All patients possessed sufficient bone for implant placement, with a minimum diameter of 3.5 mm and a length of 10.0 mm, along with adequate inter-ridge space. All subjects in this research had an ample zone of keratinized mucosa. Individuals with systemic illnesses and those unwilling to undergo implant overdenture treatment were excluded. The study included only motivated, cooperative patients who provided informed consent. We adhered to the 2010 CONSORT checklist for this randomized trial (Fig. 1) to ensure adherence to proper guidelines.

Prosthetic phase I (Construction of Conventional Complete Denture):

Complete maxillary and mandibular dentures were created for each patient using a standardized traditional technique.

Construction of surgical guide

A dual scan technique was employed in creating CAD/CAM surgical guides. Flowable composite resin (Filtek Bulk Fill; 3M ESPE) was applied randomly to both the facial and lingual aspects of the mandibular acrylic dentures to determine the optimal implant sites. Scanning was carried out for both the denture while worn by the patient and for the denture alone using cone beam computed tomography (CBCT) (3D Accuitomo J Morita, Kyoto, Japan). To stabilize the denture and opposing dentition during the CBCT scanning process, an occlusal index (Zetaplus; Zhermack Spa, Badia Polesine, Italy) was utilized. The 3D implants planning software (Blue Sky Plan; Blue Sky Bio LLC) allowed for virtual planning of the implant location and angulation. The plan included placing two implants in the canine areas, each with a diameter of at least 3.5 mm and a length of 10.0 mm, featuring 15° distal inclinations to the vertical axis to achieve a 30° interimplant divergence (Fig. 2). After completing the computer-based planning, this plan was exported as an "STL" file and sent to the printer's software (Form2, Formlabs Inc., Somerville, MA, USA) for fabricating surgical guides using clear acrylic resin (Dental SG Resin; Formlabs).

Surgical procedures

Phase I surgical procedure: Prior to the surgery, patients received a prophylactic antibiotic treatment (2 g amoxicillin oral tablet) and were directed to rinse with a 0.2% chlorhexidine gluconate mouthwash. Afterward, 2% mepivacaine HCL, combined with 1:20,000 levonordephrine for local anesthesia, was administered. Surgical templates were secured onto the ridge using an occlusal index, followed by the fixation screws (Fig. 3). Once the surgical guides were correctly positioned, two root form dental implants (Neodent Implants, Curitiba, Brazil) were placed using the guided surgical kit (Neodent, Curitiba, Brazil) and following the recommended drill sequence from the manufacturer (Fig. 4). Cover screws were affixed to each implant, and patients refrained from wearing their mandibular dentures for 2 weeks after surgery to prevent implant loading. Each patient was given a 3-month healing period to ensure optimal osseointegration.

Phase II surgical procedure: The second stage of surgical procedure occurred three months after the initial implantation. A surgical guide was employed to reposition the implant locations with infiltration anesthesia. A precise tissue punch was utilized to incise the mucosa covering the implants, following which the cover screws were unscrewed using a screwdriver. Stock healing abutments were affixed to the implants, screwed into place, and left for a two-week period to facilitate proper gingival healing.

Prosthetic Phase II: (connecting the attachments to the existing Mandibular Complete Denture): After two weeks of placement of the healing abutments, they were removed and the proper 15° angled Novaloc and conventional Locator abutments were selected and screwed on the implants in group N and group L (Fig. 5), respectively according to the prosthetic platform and the tissue height. Block-out spacers were positioned over each abutment. For group N, a matrix housing with a white processing insert was positioned on each Novaloc abutment, and for group L, a matrix housing with a black processing insert was placed on each Locator abutment. In order to ascertain the alignment of the metal housings in relation to the prosthetic's tissue-bearing surface, the denture was inserted into the patient's mouth, and the metal housings were designated using an indelible pencil. The regions above the housings were adjusted using an acrylic bur until the denture could be comfortably positioned without touching the metal housings. Minor relief holes were created at the upper part of the lingual flanges to facilitate the overflow of surplus acrylic.

A mixture of auto-polymerizing acrylic resin, was prepared and used to fill the spaces using a plastic filling tool. The denture was then positioned into the oral cavity, and the patient was directed into centric occlusion, leaving it in place for 5 minutes to enable polymerization to take place. Subsequently, the denture was taken out, and the spacers were disposed of, along with any excess acrylic resin around the metal housings and the lingual vent-holes. Finally, the denture underwent polishing prior to switching to the final male retentive insert.

For each patient in group N, the processing Inserts were removed by using Novaloc processing insert removal instrument and the final Novaloc retention inserts were placed in the metal housings by using Novaloc retention insert instrument. Based on the authors' previous laboratory and clinical experience with comparable attachments (22,23), they commonly use the "medium" insert, weighing 1,200 grams and colored yellow, in practical clinical settings. So it was chosen as the final insert in group N in the current study

For each patient in group L, the Locator male removal tool was utilized to extract the processing Inserts, and the Locator core tool was used to position the final Locator retention inserts into the metal housings. Based on previous laboratory study (23) that selected the (orange) insert to be compared with (yellow) Novaloc insert in case of 15° implant angulation, the "light retention" (0.91 kg, orange) strength insert was selected to be close the Novaloc system and final overdentures were inserted into the patients' oral cavity.

Radiographic Evaluations:

CBCT scans (3DAccuitomo 170; J. Morita Corp) underwent assessment for MBL by a sole examiner during prosthetic loading (baseline), as well as at 3 and 12-month intervals. The Digital Imaging and Communications in Medicine (DICOM) files were exported and analyzed through dental imaging software (OnDemand3D version 1.0.9.3223; Cybermed). To align coronal and sagittal images with the implant axis, they were rotated accordingly (28,29). The horizontal image was also adjusted to ensure precise alignment with the implant center using crosshairs. Bone height was determined by measuring the distance from the implant platform to the bone's height in millimeters using the software's ruler measuring tool (Fig. 6). MBL was computed by subtracting the bone heights measured at 3 and 12 months from those measured at the baseline. For each implant, MBL was calculated mesially, labially, distally, and palatally, and a mean was then expressed.

Statistical Analysis:

Normality was assessed for all variables employing descriptive statistics, plots (histogram and boxplots), and Shapiro Wilk normality test. All variables displayed a normal distribution. Consequently, means and standard deviation (SD) were computed, enabling the utilization of parametric tests. For comparisons between the two study groups, we conducted an independent samples t-test, calculating mean disparities along with 95% confidence intervals (CIs). For intra-group comparisons, a paired samples t-test (3 months vs. 12 months) was used. Percent change was determined using the following formula: $\frac{value\ at\ 12\ months - value\ at\ 3\ months}{value\ at\ 3\ months} \times 100$.

Significance level was set at p value <0.05. Data were analyzed using IBM SPSS for Windows (Version 26.0).

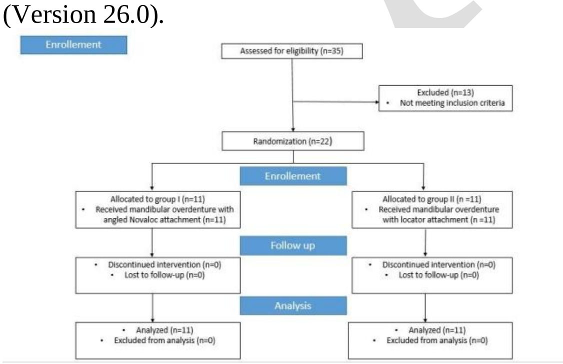

Figure (1): Flow-chart diagram of study.

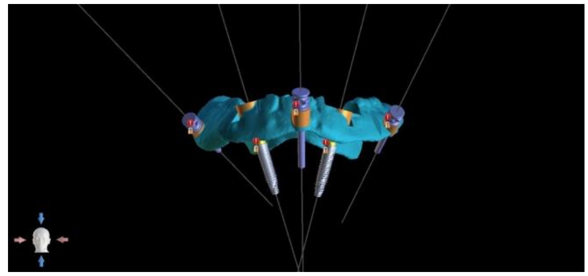

Figure (2): Virtual Planning of implants with 30° interimplant divergence.

Figure (3): Surgical guide secured onto the ridge using an occlusal index and the fixation screws.

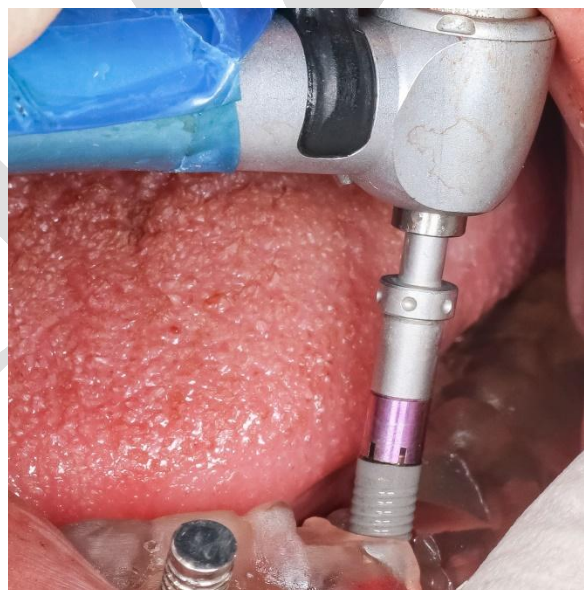

Figure (4): The implant insertion into the osteotomy the through the surgical guide.

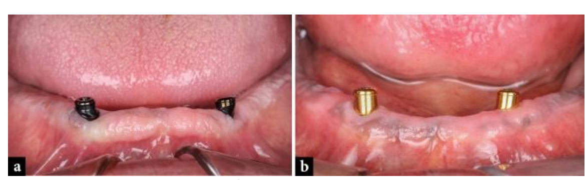

Figure (5): (a) 15° angled Novaloc attachments screwed into the implants in group (N); (b) locator attachments screwed into the implants in group (L).

Figure (6): Measurements of marginal bone loss.

RESULTS

Twenty-two participants who met the inclusion criteria were randomly assigned to two equal groups using permuted block randomization with variable block size. Group N received mandibular overdentures with angled Novaloc attachments, while group L received mandibular overdentures with locator attachments. Among the participants, 14 (63.6 %) were men and 8 (36.4 %) were women, with an average age of 56 years. The 44 implants remained clinically stable and symptom-free. Follow-up evaluations revealed stable prostheses without complications. MBL was investigated at three time points: baseline, 3 months, and 12 months after prosthetic loading.

Table 1 presents the MBL comparison between the two groups over the 12-month follow-up period. Group N exhibited higher mean MBL values compared to Group L at both the 3-month and 12-month follow-ups, and these differences were statistically significant ($P < .001$). While both groups showed a statistically significant increase in mean MBL over the 12-month period, the percent change from baseline had no significant difference among the two groups ($P = .45$).

Table (1): Bone changes in the two study groups across time.

	Group N	Group L	Mean difference (95% CI)	η_p^2	P value 1
	Mean ±SD				
3 months	0.62 ±0.04	0.54 ±0.08	0.09 (0.05, 0.13)	0.31	<.001*
12 months	1.21 ±0.07	1.06 ±0.10	0.16 (0.10, 0.21)	0.46	<.001*
Difference	0.59 ±0.05	0.52 ±0.09	0.07 (0.02, 0.12)	0.19	.004
Percent change	95.66 ±10.07	100.57 ±28.16	-4.91 (-18.01, 8.19)	0.01	.45
P value 2	<.001*	<.001*			

SD: Standard deviation, CI: Confidence interval, η_p^2: partial eta squared (effect size)
P value 1: Independent samples t-test was used.
P value 2: Paired samples t-test was used.
*statistically significant at p value <.05

DISCUSSION

Regarding the findings of the present study, group N experienced a notable peri-implant bone loss increase compared to group L during various follow-up intervals, leading to rejecting the null hypothesis.

The extended durability of implants overdentures over extended time periods has been documented in the literature, establishing the baseline care standard for edentulous patients, addressing common issues associated with traditional complete dentures (30-35). This research examined how two distinct attachment systems impacted MBL around 30-degree divergent dual implants retaining mandibular overdentures. All implants employed in the two groups demonstrated effective osseointegration during the follow-up periods, as indicated by (1) the lack of any grievances like pain or discomfort at the implant locations, (2) the absence of infection or discharge at implant locations, and (3) the absence of radiolucencies at the junctions of implants and bones. The results align entirely with implants success criteria discussed by Buser et al. (32) and Smith & Zarb (33). Strict inclusion and exclusion criteria may be responsible for the high implant success rate reported in the present research. However, by the end of this research, two patients from group L presented with a poorly retained mandibular overdenture, this was due to worn out nylon caps which were replaced. This occurrence corroborates Hahnel et al's assertion that nylon inserts and Locator abutments exhibit noticeable signs of wear and tear in clinical usage (18).

In the present study, computer-generated treatments plan and surgical guides construction were employed to promote consistent implant positioning and alignment while minimizing operator-related variations (34). Additionally, they streamlined flapless implant placement, thereby reducing the potential for complications.

In this study, CBCT was employed to evaluate peri-implant because it offers a comprehensive 3D assessment of bone height both mesiodistally and buccolingually. Conversely, traditional periapical radiography, being limited to two dimensions, can solely gauge mesial and distal bones heights, neglecting the significance of tracking buccal and lingual bonse resorption. Another advantage of CBCT is its capacity to circumvent patients discomfort and oral trauma associated with the positioning of periapical radiography film holders, particularly in cases with elevated floor of the mouth and atrophied mandibular ridges. Furthermore, CBCT, along with its software, enables precise measurements without the need for magnification (35,36). Several authors have recommended the utilization of CBCT for assessing implant alveolar bone changes, citing its satisfactory accuracy (28,29).

In this RCT, both groups experienced a statistically significant rise in MBL. Nevertheless, this increase did not surpass 1.5 mm over one year of loading, aligning with findings from a systematic review. This review reported that MBL was at its peak in the initial year following implants positioning and ranging from 0.22 ± 0.55 mm to 2.5 ± 2.7 mm (37).

MBL values were significantly higher when using angled Novaloc attachments compared to locator attachments at various follow-up periods. This aligns with Taha et al.'s research (38) which examined stress distributed around two narrow-diameter titanium-zirconium implants supporting mandibular overdentures. They used the novel Novaloc attachment system and compared it to the traditional locator attachment through 3D finite element analysis. The study found that locator attachments tend to exert slightly less stress on the bones and implants complex. This difference is related to the cushioning impact of the locator attachment's nylon cap, that absorbs induced stresses, while the Novaloc attachment's rigid PEEK matrix tends to transmit these stresses to the attachment implant complex.

The higher significant MBL in group N may be also attributed to the use of 15° angled abutments which may transmit more stresses on implant-bone interface. These findings are consistent with other studies involving photoelastic stress evaluations, finite element analyses, and strain-gauge investigations on angled abutments, which all indicate that increased abutment angulation results in greater stress on the surrounding bone (24,25,39).

Nonetheless, Ghazaly & Nassif. (40) contradicted these findings. They conducted a study comparing micro-strain around tilted implant and axial implant, following the all-on-four concept, linked to two distinct attachments designs. They discovered no variance in micro-strain around tilted implant, whether linked to OT-equator or angled abutment. The differing outcomes might be attributed to several factors: Firstly, this study was in vitro, in contrast to our present clinical research. Secondly, the number of implants used in this study was four, whereas we employed two in our investigation. Lastly, this study compared OT-equator and angled abutment, while our clinical study focused on the comparison between angled Novaloc and locator abutment.

CONCLUSIONS

In this one-year randomized clinical trial, these findings were made within the study limitations:

1. Peri-implant bone loss with Locator or angled Novaloc attachment systems on inclined implants remained within acceptable clinical limits.
2. When retaining mandibular overdentures with 30-degree divergent two implants, the Locator attachment appeared more favorable than the angled Novaloc attachment.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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