

CLINICAL AND RADIOGRAPHIC EVALUATION OF LOCATOR R-TX ATTACHMENTS FOR TWO IMPLANTS SUPPORTED MANDIBULAR OVERDENTURE USING TWO LOADING PROTOCOLS; A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Purpose: This study was conducted to evaluate clinically and radiographically locator R-TX attachments using two different loading protocols for implant-supported mandibular overdenture.

Material and Methods: Thirty edentulous patients (a total of 60 implants) received two implants interforamenally in the canine area. Patients were divided randomly (using balanced randomization) into two equal groups in accordance with the loading process utilized to attach the mandibular overdenture. Group I (control): Patients received traditional loading protocol with a mandibular implant overdenture retained in place by two RTx locator attachments (after 3 months from implant placement). Group II (study): Patients received early loading protocol with a mandibular implant overdenture retained in place by two RTx locator attachments (at 6th week after implant placement). No implants were lost in the study. After denture placement (T0), six (T6), and twelve (T12) months later, the peri-implant tissue health [Plaque (PL) and (GI) gingival scores, pocket depth (PD) in mm, and crestal bone loss (CBL) in mm] was assessed.

Results: After one year, no statistical significant difference was found in peri-implant tissue health parameters [(PL), (GI), (PD), and (CBL)] at all observation times and between both groups.

Conclusion: Given the sample size limitations on this study, it is possible to reach the following conclusion: RTx locator is a promising attachment system especially when an early loading protocol is planned to be used regarding peri-implant tissue parameters. More randomized clinical studies are needed to confirm the clinical predictability of Rtx locator attachments.

KEYWORDS : Implant Overdenture, Rt-x locator, implant loading protocol

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INTRODUCTION

In cases when more implants cannot be placed, using two implants interforaminally to construct a mandibular implant-supported over dentures can be considered the main treatment modality.^[1] For patients who are completely edentulous, they have offered a potentially viable and extremely profitable treatment solution at a reasonable price. Implant-supported over dentures have been proven by many studies to have high success rates ranging from 94% to 100% in completely edentulous arches.⁽¹⁾⁽²⁾

Several attachment systems, each with advantages and disadvantages, are successful at retaining an implant overdenture in place. Many clinicians have adopted locator attachment, especially in two implant-supported scenarios. Its numerous advantages include self-aligning ability, double retention, rotational action, and integrated guiding planes for accurate insertion. Up to 40 degrees of nonparallel situations can also be utilized with it. Moreover, it can be employed in conditions with reduced interarch space and comes in a variety of colors with various retention values.^(3,4)

Nowadays, a new locator-style abutment has been developed, Locator RTx. The locator RTx Removable Attachment System combines improved design features, system simplicity, and Duratec Coating toughness. The new coating is composed of Titanium carbon nitride which is 32% harder and has 26% greater wear resistance and a 64% reduction in surface roughness. RTX locator exhibits dual engagement on the external surface as claimed by the manufacturer. This feature improves overdenture retention with the absence of a central stud in the retentive inserts (nylon) so, decreasing maintenance visits. It is claimed by the manufacturer to have an increased Pivoting Technology and treats up to 30° angle correction per implant (recommended for implant angle discrepancies up to 60 degrees). Patients can simply align and precisely seat their overdentures because to these characteristics. To

prevent rotational and vertical movement, the denture attachment housing has grooves and flat surfaces.⁽⁵⁾

Conventional loading is usually accompanied by low satisfaction, this is mainly because of the long waiting time for implant Osseo integration. Esthetics and phonation issues with restricted mastication are the main consequences of this waiting. Several techniques, including early and immediate loading, have been used to accelerate the partially or completely edentulous patient's prosthetic recovery. and these have grown in significance as a result of the shorter treatment duration. Early loading protocol begins from two weeks to one month after implant placement.⁽⁶⁾ This will facilitate early use of the mandibular overdenture.⁽⁷⁾ Reductions in the number of visits and lower expenses are accrued, consequently patient satisfaction increases.⁽⁸⁾

Reviewing the literature, limited researches evaluate the clinical outcomes of using R-TX locator attachments in both early loading and conventional loading protocols. This study aims to evaluate peri-implant tissue health parameters around R-TX locator attachments in two different loading protocols: early loading and conventional delayed loading. The study's null hypothesis is that, when using RTx locator attachments, there won't be any difference in peri-implant tissue health parameters between early and conventional loading protocols.

METHOD OF RESEARCH

Patient selection and study design

From February 2020 to August 2021, Thirty patients, ages ranging from 40 to 60 (mean age 50), from the outpatient clinic of the prosthodontics department at the Faculty of Dentistry, Mansoura University, were selected to participate part in the study. The patient's sample was determined using an 80% power in line with the results of an earlier study (9), which revealed no significant difference

in crestal bone loss between early and conventional loading for two implant-supported overdenture using two unsplinted attachment systems (effect size=.70mm and $\alpha=.05$). The power analysis was performed using the G*Power program (version 3.1.5, Kiel, Germany)

The main complaint for all patients involved in this study was insufficient retention and stability of the mandibular dentures. Patients who met the following inclusion criteria were all enrolled: A preoperative cone beam computed tomography confirmed that the mandible had sufficient bone quantity (class III–V according to Cawood and Howell, 2010) to accommodate two implants (4 x 13 mm) in the interforaminal area. Additionally, there was adequate restorative space (12–15 mm, Class I according to Ahuja and Cagna, 2011) for an implant overdenture supported by RTx from the mandibular ridge mucosa to the occlusal plane. The former denture space was measured directly to confirm this. 3) Angel's class I maxillo-mandibular relationship. Systemic diseases that preclude implant placement, radiation therapy to the neck and head region or chemotherapy within the previous three years, bone metabolic disorders such uncontrolled diabetic mellitus, and smoking habits are among the exclusion criteria. Throughout the whole duration of the trial, patients were informed about the course of treatment and the necessity of following up with calls. Furthermore, all patients provided informed consent. The study was approved by the Dental Research Ethics Committee of the Faculty of Dentistry, Mansoura University, and carried out in accordance with CONSORT standards, as shown in Figure 3. (No. A03110220), and was first registered on the clinical trial website on (22/3/2022) under the number (No.NCT05290376). Patients were randomly assigned to one of two groups to ensure comparability between groups; Group I (control): patients were received mandibular implant overdenture using conventional loading protocol (after 3 months from implant placement). Group II

(study): patients were received mandibular implant overdenture using early loading protocol (at 6th week after implant placement). (12) Dental staff members who were blind to the treatment groups randomly assigned and divided the subjects into them.

Surgical and Prosthetic Procedures

For each case, the mandibular canine region's bone height and width were measured using (CBCT). A sealed envelope technique was used to allocate participants randomly to one of two loading protocols at the beginning of the clinical trial. According to the loading protocol used, patients were randomly classified into 2 equal groups: Group I (control): fifteen patients received the prosthesis by conventional loading protocol after three months from implant placement. Group II (study): fifteen patients received the final prosthesis by early loading protocol after six weeks from implant placement.

Conventional dentures were constructed for all patients in both study groups. To construct a radiographic template, all mandibular dentures were duplicated using clear acrylic resin. Multiple holes (1 mm in diameter) were created in various labial, buccal, and lingual polished surfaces to place gutta-percha radio-opaque reference markers, the fitting surface of the mandibular radiographic template at selected implant sites. By subjecting patients to CBCT while they were wearing the radiographic template, a dual scan approach was performed that was guided by gutta-percha radiopaque markers. Then, just CBCT exposure was done to the radiographic template. The images were superimposed over each other to estimate mucosal thickness. After implant planning, the mucosal-borne stereolithographic guide was constructed.

Chlorhexidine digluconate 0.2% mouthwash and antibiotic (Amoxicillin and clavulanic acid) started one day before surgery and then twice/daily for 1 week following surgery. The flapless

surgical protocol was used by the same oral and maxillofacial surgeon for the placement of two implants (4.1×13mm, RES, IMAX, tapered internal, Switzerland). A rubber base interocclusal record was used for fixing the stereolithographic stent to the mucosa, fixation pins were used to secure it to the mandibular bone. The same oral and maxillofacial specialist performed the surgical operations. Implant osteotomies were carried out with the use of an In2Guide universal surgical kit. A minimum force of 35 Ncm was required for implant insertion in order to provide sufficient primary stability.

A chairside silicone-based soft liner was used to reline the mandibular denture after relieving above the implants to act as a cushion and allow for early progressive loading for Group II. For Group I using delayed loading, the implants were covered with the cover screw, after three months, the cover screw was unscrewed, and the healing abutments were inserted for one week for gingival recontouring.

The locator RTx abutment was placed using a 0.050/1.25 mm hex driver and hand tighten. Figure 1A. A direct functional pickup technique was applied by seating the female housing covers with black nylon inserts over the locator abutment. Selection of the final retentive inserts was done (pink for medium retention) and the zero retentive black inserts were replaced. Figure 1B Occlusion was then refined by selective grinding. All patients

were instructed to perform oral hygiene measures such as cleaning the denture after each meal with a medium toothbrush to avoid gingival inflammation and to brush gently around the implants to avoid gingival inflammations and peri implantitis.

Study Outcomes

After the placement of the overdenture (T0), six (T6), and twelve (T12) months later, the peri-implant tissue's health was assessed. Indexes (PL) and (GI) were calculated in accordance to Mombelli et al. (13) Using a periodontal probe, (PD) was calculated as the distance from the gingival edge to the greatest apical depth of the implant sulcus. Each implant's mesial, distal, buccal, and lingual surfaces were examined for all measurements. PD measurements were averaged for each implant.

Radiographic assessment of bone height around the implants was carried out by using standardized digital intraoral periapical radiography. It was carried out at the time of denture insertion T0, T6, and T12 after denture insertion. The long cone paralleling technique was employed to take intraoral radiographs. A long cone technique was obtained for each implant to have standardized intra-oral radiographs (SIR) as described by Elsyad and Shoukour⁽¹⁴⁾ as follows: to ensure that the film-implant and cone-implant distances remain constant after repeated film exposures, a hole above the implant orifice was drilled carefully then the digital

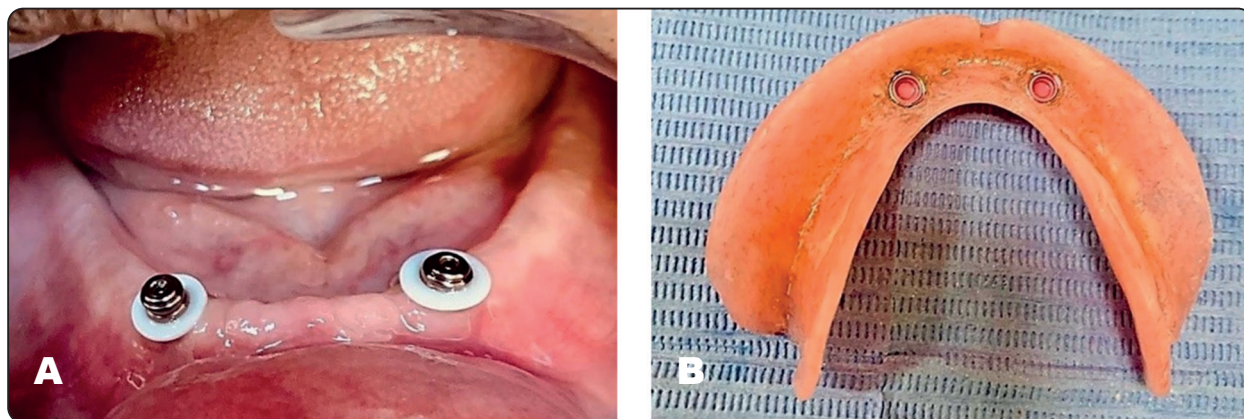


Fig. (1) A). The white block out spacer around each abutment was placed (B). The intaglio surface of mandibular overdenture with the picked up retention insert.

film holder (CMOS Schick sensor) is modified. A large screw on the impression coping attached the holder to the implant. Radiographs were taken using a direct digital imaging system. The same dental x-ray machine was used for each exposure, and the same exposure parameters, exposure duration, and distance between the film sensor and guiding ring were all used. After the radiograph was digitised, the image was enlarged ten times. Lines and reference points were then interactively marked on the screen with Scanora lite version 3.2.6. The distance between point (A) and point (B) indicated CBL in mm (AB line) Figure 2. The subtraction of the AB line length in mm of T0 from the AB line length of each T6 and T12 at the mesial and distal surface of each implant gave the CBL. The CBL of the 2-implant surfaces was averaged.

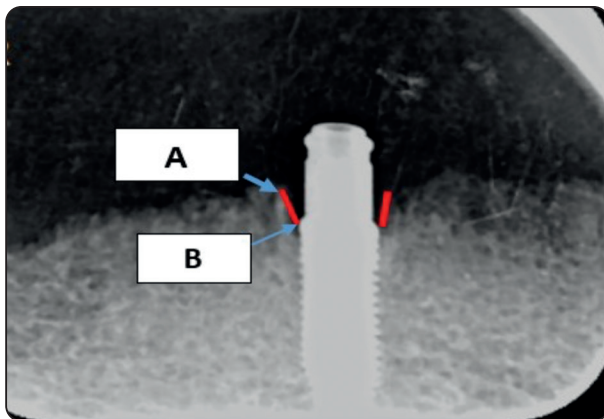


Fig. (2) AB line represent the peri-implant alveolar bone height measurements

Statistical Analysis

A comparison of PL, GI, PD, and CBL between observation times was done using the Friedman test. For comparisons between pairs, the Wilcoxon signed ranks test was employed. Using the Mann-Whitney test, these parameters were compared between the two groups. A P-values below .05 were considered as significant. The SPSS statistical program for social science, version 25 (SPSS Inc.), was used for data analysis.

RESULTS

There were no implant failures. For the whole study period, no dropouts were noted (12 months). Figure 3 displays the flowchart. If retention loss occurred, retentive caps replacements (n=5 in the conventional loading group and n=6 in the early loading group) were carried out.

The comparison of clinical and radiographic outcomes between groups and observation times are shown in Tables 1, 2, and 3, respectively. Plaque scores significantly increased with time in both groups, as confirmed by the Friedman test and the Wilcoxon signed ranks test for pairwise comparisons. No significant difference is found in plaque scores between GI and GII at all observation times as verified by Mann Whitney test.

Table 1 displays a comparison of gingival scores among the groups. No statistically significant difference was found in gingival scores at all observation times between both groups. Gingival scores increased significantly with the advance of time in both groups as verified by Friedman test followed by Wilcoxon signed ranks test for pairwise comparisons. GII is higher in gingival scores at T12 than GI, however, the difference is not statistically significant ($P > .005$).

Table 2 presents a comparison of pocket depth between groups. With time, pocket depth in both groups increased significantly, as confirmed by the Friedman test and the Wilcoxon signed ranks test for pairwise comparisons. G (II) recorded higher pocket depth than G (I) only at T12, however, the difference is not statistically significant ($P > .005$). Gingival scores did not differ statistically significantly between the two groups at any time during the observation time.

Comparison of VBL between observation times as verified by the Friedman test followed by Wilcoxon signed ranks test for pair-wise comparisons demonstrated that CBL significantly increased from T6 to T12 for both groups at all sites as presented in table 3. No statistically significant difference was found in CBL scores at all observation times between both groups.

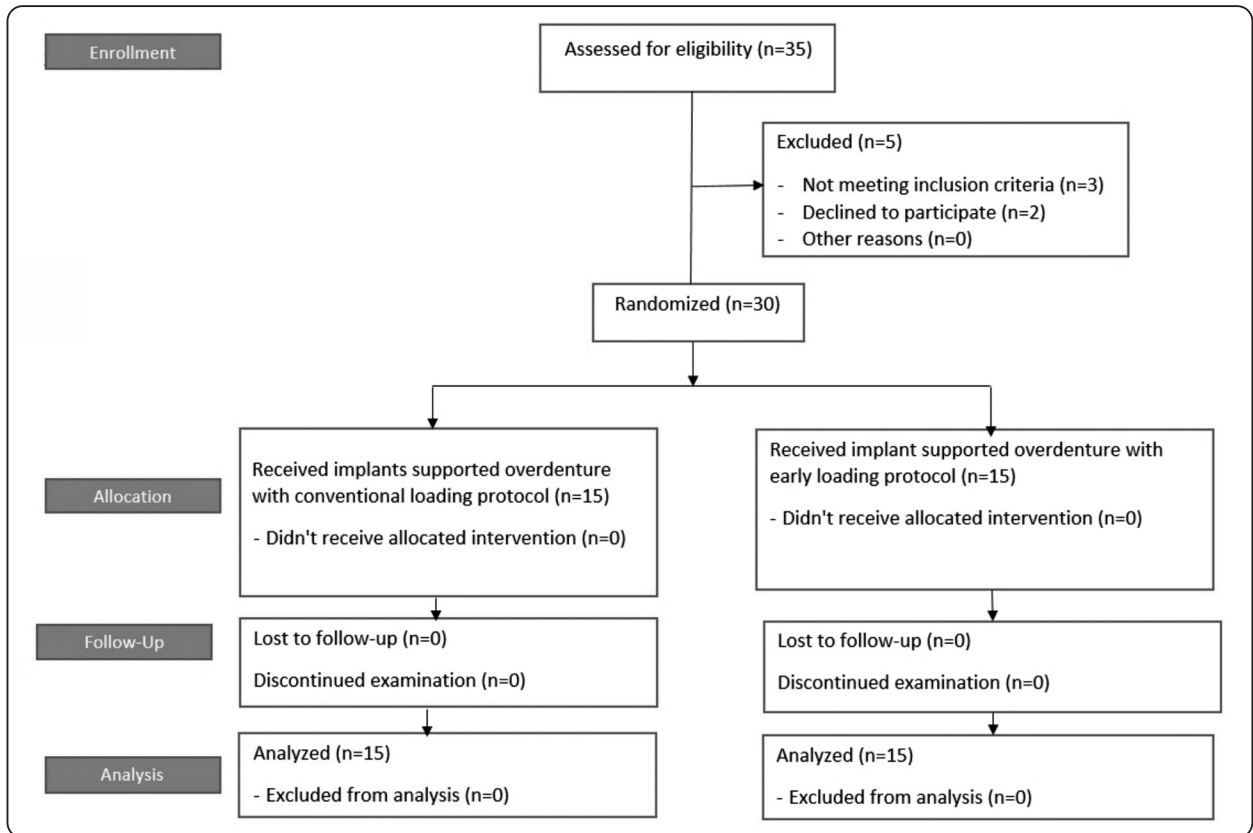


Fig. (3) CONSORT Flowchart

TABLE (1) Comparison of plaque and gingival scores between groups

GROUP	PL-T0M	PL-T0D	PL-T0B	PL-T0L	PL-T6M	PL-T6D	PL-T6B	PL-T6L	PL-T12M	PL-T12D	PL-T12B	PL-T12L	P (Freidmann)
	Median(min-max)				Median(min-max)				Median(min-max)				
GI (delayed loading)	.00 (0-0)	.00 (0-0)	.00 (0-0)	.00 (0-0)	1.00 (1-1)	1.00 (0-1)	1.00 (0-1)	1.00 (1-1)	2.00 (1-2)	2.00 (1-2)	2.00 (1-2)	2.00 (1-2)	.000*
GII (early loading)	.00 (0-0)	.00 (0-0)	.00 (0-0)	.00 (0-0)	1.00 (1-1)	1.00 (0-1)	1.00 (0-1)	1.00 (1-1)	2.00 (1-2)	2.00 (1-2)	2.00 (1-2)	2.00 (1-2)	.000*
Mann Whitney	1	1.	1.	1	1.	1.	1.	1	.79	.79	.27	.69	
GROUP	GI-T0M	GI-T0D	GI-T0B	GI-T0L	GI-T6M	GI-T6D	GI-T6B	GI-T6L	GI-T12M	GI-T12D	GI-T12B	GI-T12L	P (Freidmann)
	Median(min-max)				Median(min-max)				Median(min-max)				
GI (delayed loading)	.00 (0-0)	.00 (0-0)	.00 (0-0)	.00 (0-0)	1.00 (1-2)	1.00 (1-2)	1.00 (0-1)	1.00 (1-2)	2.00 (1-2)	2.00 (1-2)	1.00 (1-2)	2.00 (1-2)	.000*
GII (early loading)	.00 (0-0)	.00 (0-0)	.00 (0-0)	.00 (0-0)	1.00 (1-2)	1.00 (1-2)	1.00 (0-1)	1.00 (1-2)	2.00(1-2)	2.00 (1-2)	1.50 (1-2)	2.00 (1-2)	.000*
Mann Whitney	1.000	1.000	1.000	1.000	.741	.741	.767	.741	.069	.069	.798	.082	

TABLE (2) Comparison of pocket depth between groups and between observation time

Group	PD_T0	PD_T6	PD_T12	P
	M (min-max)	M (min-max)	M (min-max)	
G (I)	.31(.00-0.75)	1.01(0.5-1.5)	1.64 (1.2-2.12)	.000*
G (II)	0.16 (0.0-0.50)	0.72 (0.0-1.4)	1.99 (1.60-2.30)	.000*
	0.20	0.061	0.004*	

TABLE (3) Comparison of CBL between groups and between observation times

Group	VBL_T0	VBL_T6	VBL_T12	P
	M(min-max)	M(min-max)	M(min-max)	
G (I)	0.68(.00-1.9)	1.26(0.45-2.75)	2.16(1.80-2.87)	.000*
G (II)	0.94 (.00-2.07)	1.51(0.80-2.32)	2.09(1.60-2.65)	.000*
	0.36	0.36	0.59	

DISCUSSION

When more implants cannot be inserted, rehabilitation with mandibular implant-supported overdentures using two implants may be the main treatment option. ⁽¹⁵⁾ Although the limitation in the study regarding the number of patients and study intervals, the null hypothesis in our clinical study was accepted that there was no significant difference between early loading and conventional loading groups regarding plaque index, gingival index probing depth, and CBL parameters. In this study medium retention was selected for locator attachments as reported by Nejatidanesh, et al that a minimum retentive force of 4 N is sufficiently needed for a single individual unsplinted attachment and a retentive force of 20 N has been proposed for overdenture supported with two implants. ⁽¹⁶⁾

When comparing the plaque index between the two groups; it revealed insignificant differences during all follow-up periods. These results are similar to the study by Ilser Turkyilmaz et al ⁽¹⁷⁾ who reported that no significant differences in peri-implant soft tissue parameters (PI, PD, BI, GI) were observed between the early loaded group and

conventional loaded group although this study used ball abutment as the attachment instead of the RTx locator attachment in our study.

In both groups, the plaque scores significantly increased with the advance of time. It could be the resiliency of the locator, which permit movement of the denture accompanied by accumulation of food particles and plaque under the denture. ⁽¹⁸⁾ One more clarification may be the increased patient age which is accompanied by decreased awareness. This has an effect on the patients' dental hygiene practices. ⁽¹⁹⁾

A significant increase in gingival scores was observed as time passed on in both groups. This was similar to a study by M. A. Elsyad et al ⁽²⁰⁾ who reported that in both study groups, GI dramatically increased as time passed on (immediate, conventional loading). Moreover, a parallel observation was reported by Alsabeeha et al ⁽²¹⁾. They observed out that, particularly for elderly people with decreased manual dexterity, the recess of female abutments with locator attachments is thought to serve as a shelter for the accumulation of food and plaque.

However, a different study ⁽²²⁾ discovered a negligible increase in these variables when Locator attachments were applied. The reason for the differences in results might be because of the strict oral hygiene measures patients were exposed to in these studies whereas majority of patients examined in this study had insufficient care for their oral hygiene.

Probing depth significantly increased with the progress of time in both groups. Similarly, studies by Elsyad MA et al ⁽¹⁹⁾ revealed that PD significantly increased with advance of time at all measured sites in both groups of the study (immediate loaded and delayed loaded). In contrast, Turkyilmaz et al. ⁽²³⁾ and Liao et al. ⁽²⁴⁾ demonstrated an insignificant increase in these parameters with the progress of time. The increased PD in both groups could be related to increased peri-implant bone resorption. Comparing probing depth between groups; G(II) recorded a higher probing depth than G (I) only at T12, however, the difference is not statistically significant ($P > .005$). This matched the results of a study by Vygandas Rutkunas et al ⁽⁴⁾ who reported that PD values were not statistically different between conventional and early-loading groups, though the early-loading group showed a slight characteristic increase in PD.

CBL significantly increased with the advance of time from T6 to T12 for both groups at all sites. Similar to studies by Elsyad et al ⁽¹⁹⁾ and Holweg-majert et al ⁽²⁵⁾. The fast bone response to healing and rearrangement under functional stressors may be the cause of the increased CBL over time. This increase in CBL may be the result of bone adapting to withstand occlusal stresses and maturing following fixture placement. Moreover, the increase in CBL may be attributed to the retentive force of Rtx locator attachments which are more than conventional locators as mentioned by ⁽²⁶⁾. The author stated that the R-Tx inserts have more retention when comparing limited range inserts of the R-Tx with standard Locator inserts.

No significant difference was found in CBL between both groups; this may be due to the usage of RTx locator attachment which provides more resilience and decreases functional stress on fixtures as reported in a study by Michael D. Scherer ⁽²⁷⁾ reported that RTx locator has greater flexibility, this permits the denture to move slightly on the soft tissues, decreasing the forces dispersed upon the dental implant and the nylon insert. This is in contrast to a study by Ma et al ⁽⁹⁾ who reported that, compared to implants loaded 12 weeks (delayed loaded) after implantation, CBL was statistically significantly higher (p -value < 0.05) for implants loaded 2 weeks (early loaded) after insertion. The explanation of this result could be that CBL seen with a two-week loading protocol can be attributed to loading implants prematurely with subsequent more marginal bone loss, especially during the early remodeling period.

CONCLUSION

Within the confines of this study's sample size limitation, it could be concluded that RTx locator is a promising attachment system especially when an early loading protocol is planned to be used regarding peri-implant tissue parameters. More randomized clinical studies are needed to confirm the clinical predictability of RT-x locator attachments.

Data availability:

The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

Conflict of Interest

The authors declare no conflict of interest. All authors have viewed and agreed to the manuscript submission

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