

Implant stability and bone height changes for immediately loaded single implant-retained mandibular overdentures with locator attachments

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Abstract

Aim: The aim was to evaluate the efficacy of attachment placement on initial stability and bone height changes for immediately loaded single-implants retaining mandibular overdentures.

Methodology: Twenty edentulous patients were recruited for this study; 9 females (45.0%) and, 11 males (55.0%) (age ranged from 59.0 to 70.0 year). Single endosseous implant was inserted in the mandibular midline region. Immediately after surgery; Locator abutment was secured on the implant, and the male housing was connected intraorally using direct pick-up procedure. Marginal bone height measurements and implant stability values were assessed at the time of implant placement (baseline), 2, 4, 6, 8, 12, 24 weeks then every 6-month interval up to 18 months post-implant placement.

Results: The implant stability values decreased markedly from the baseline, during 4 weeks and, then increased gradually until reaching the initial values after 12 weeks followed by continuous increase to study's end ($p < 0.05$). The peri-implant marginal bone level revealed an acceptable range of bone loss with a statistically significant differences between different follow-up times, and it continued to the end of the study ($p < 0.05$).

Conclusions: Retaining an overdenture by immediately loaded single implant could be a successful treatment option for mandibular edentulous arches, especially in people with limited financial resources. The use of Locator attachment seemed to have a favorable effect on implant stability and marginal bone around immediately loaded single implant mandibular overdenture after 18-months of function.

Keywords: Locator attachment, mandibular overdenture, single midline implant, immediate loading protocol

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Introduction

In the past decades, two-implant retained overdenture is considered as the first choice for treatment for patients with edentulous mandibles that were poorly adapted to conventional dentures (1, 2). However, many patients refused this treatment modality due to their fear from surgical procedures (3-5). Moreover, this treatment remains inaccessible for patients with poor socio-economic conditions, and higher surgical risks due to impaired health conditions (6-8).

Current evidence-based studies (7-10) and randomized controlled trials (RCTs) (3, 4, 11, 12) showed that retaining the existing mandibular denture by a single midline implant might be considered as a potential alternative treatment for completely edentulous patients. Cordioli et al. used delayed loading protocol and ball attachment with 100% implant survival rate after 5 years (13).

Single-implant mandibular overdenture (SIMO), when opposed with maxillary denture, exhibited good results in comparison with two-implants-retained denture. This can be clinically interpreted by survival rates, clinical parameters, improved patient's satisfaction and quality of life (4, 5, 9, 12, 14). The favorable bone quality in the symphysis region and, the inferior alveolar neuromuscular bundles, would simplify the surgical procedure, this is an advantage to the clinicians (14). Whilst; the minimally-invasive implant surgery and reduction in costs encourage elder patients who are not willing to undergo bone grafting procedures are advantages to the patients (8, 15, 16).

As the single midline dental implant is located in an excellent host site for oral implantology at thick cortical bone in the symphysis, those implants are showed high success rate for delayed (13, 17) and immediate loading protocols (12, 18). Fortunately; immediate loading concepts could lead to a shorter overall treatment time and the patients could benefit earlier from the advantages provided by the implant-assisted overdenture (3, 19). However, many authors noticed a significant increase in early failures of immediately-loaded implants (6, 20). A recent RCT by Kern et al., concluded that immediate loading of a single implant in the edentulous mandible should be considered only in exceptional cases (3). The authors attributed these failures to implant overload or improper implant positioning (3, 5, 21).

Among the attachment systems used in implant overdentures, ball-type attachments were preferably used in the published SIMO studies, probably due to their better retentive forces (8, 11, 22). On the contrary, several laboratory studies reported that

SIMO-retained with ball attachments could move and slide on the mucosa in various directions that could increase the concentration of stresses around the housing portion of the single implant during function (23, 24). This compromised denture stability might negatively influence the implant stability of the immediately loaded implants, resulting in more implant failures (3, 4, 25).

Consequently, reporting implant failures will be true if certain prerequisites are not fulfilled (9). It was documented that the success of immediately placed implants depends on avoiding any micro-movement and understanding the underlying biologic changes that occur at the bone-implant interface during the healing or remodeling phase (26-28). According to the current knowledge, there is no evidence in the literature stated that the attachment system has any influence on implant success in SIMO treatment with immediate loading protocol (9, 16). It seems that the choice of the most appropriate attachment may be dependent on the professional's preference, and commercial availability (5).

Locator attachment had widespread and international use as a low-profile attachment for free-standing implants supporting overdentures (22). The use of a low-profile attachment may develop more favorable stress distribution in the peri-implant area, with less damage to the osseointegrating implants and overdentures (3, 29). It offers several advantages including; dual retention, self-aligning, compensation for a misaligned implant, and availability of different levels of retentive forces obtained from the nylon male inserts (11, 22, 30).

Although good clinical results have been reported for immediate loading on ball attachments, (3, 5, 6, 12, 15, 18-20) studies available for reliable data on immediately loaded locator attachments are limited in the literature (11). Therefore, the aim of this study was to assess primarily the influence of locator attachment on the initial stability and bone height changes for immediately loaded SIMO. A secondary goals were to find an interaction between changes in the implant stability quotient (ISQ) and other factors including; age, gender, and marginal bone loss.

Materials and Methods

Patient Selection

Twenty edentulous patients with newly inserted conventional complete dentures {9 female (45.0%) and, 11 male (55.0%) (age of 63.75±3.38 years ranged from

59.0 to 70.0 years). All participating subjects signed a specific written informed consent form and, the study was approved from the Faculty's Ethics Committee for Human Clinical Research. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Eligibility of complete denture wearers for possible inclusion in the study was decided prior to screening. Patients expressed interests in participating in this cohort study were selected from Department of Removable Prosthodontics. They had been edentulous for at least 12 months before participation. Patients had wearing technically acceptable new complete dentures in terms of function, esthetics and had constructed with lingualized balanced occlusion, (31) They had worn their dentures for at least one month, as adaptation period, and still complaining from poor denture retention to the mandible.

Patients with poor oral hygiene, compromised health condition, parafunctional habits, uncontrolled diabetes, history of irradiation to head and neck, alcohol intake, drug abuse or, psychological disorders were also excluded. Also, Subjects were excluded from the study if they reported smoking habit of more than 10 cigarettes per day.

For all patients, preoperative radiographic analysis by using panoramic x-ray (Soredex, Helsinki, Finland) was performed with radiopaque reference marker in the mandibular denture to determine the least alveolar bone height of 15mm (Type II) according to McGarry et al. (32). Generally, a sufficient residual bone in the mandibular midline region was available for receiving single implant of 13 mm in length and diameter of 4 mm in the anterior native bone (IS-II implant system, Neobiotech Inc.USA).

Surgical Design and Positioning of Implants

Midcrestal incision was cut under local anesthesia (2% lidocaine with 1:100,000 epinephrine), to allow appropriate visualization of lingual cortical bone after elevation of a full-thickness flap. Bone reduction was performed, if needed, to provide a bony platform that allows placement of the proposed implant without bone augmentation. The pilot drill was directed toward the crestal bone of the mandibular symphysis guided by the midline of the maxillary denture.

Osteotomy procedures for implant placement followed the guidelines recommended by the manufacturer (IS Full kit v.5, Neobiotech Inc.USA). The surgical implant machine (Surgical XT, NSK, and Japan) was adjusted for 1200 rpm sequential drilling speed and

45 Ncm torque. A torque wrench was used to manually measure the implant insertion torque of at least 45 Ncm. The smart peg transducer was directly mounted onto the fixture to assess initial implant stability using the resonance frequency analysis (RFA) (Osstell ISQ, Gothenburg, Sweden) (Fig. 1). Implants with low initial stability ISO < 56 were submerged and the patients were excluded from the study and then, they were planned for delaying the load after 3-month healing period according to West and Oates (26). The transducer was replaced by Locator abutment (Locators; Zest Anchors LLC) that was secured on the implant using hand torque controller at 20 Ncm, and then the flap was sutured for primary closure.

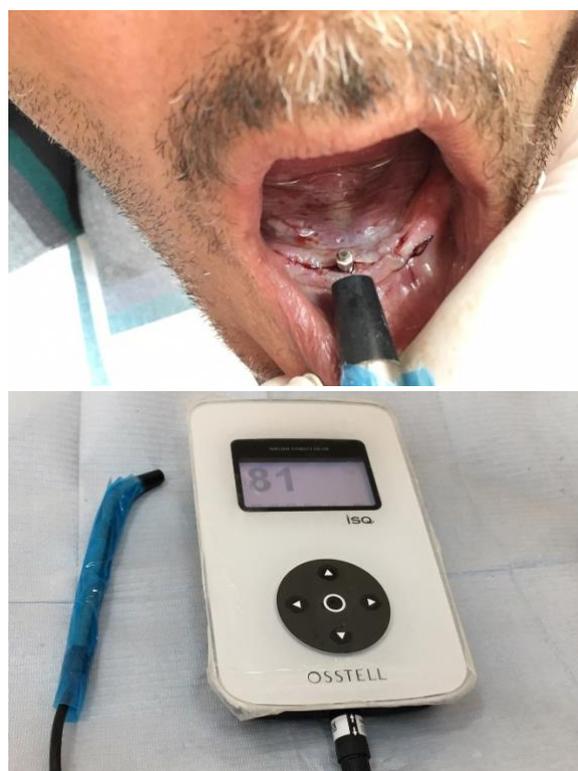


Figure 1. Resonance frequency analysis.

Prosthodontic Treatment

Spacer rings were placed over the head of the Locator abutments to block the undercut areas under the housing. Additionally, a circular portion of sterile rubber dam sheet was adapted on the abutment during the pickup procedure. The retentive element of metal housing with extra-light retentive nylon insert (blue color, 6.7 N) was snapped on the abutment. The intaglio surface of the existing mandibular denture, at the area of Locator abutment, was relieved without any direct contact between them. The housing was connected intraorally using autopolymerized acrylic resin (Repair Material, Dentsply, York, Pa) through direct pick-up procedure (Fig. 2). The excess

polymerized acrylic resin contacting the Locator abutment was trimmed to avoid transfer any additional stresses to the implants during function. Occlusion and denture base adaptation were then checked and adjusted before dismissing the patient. The prosthodontist E.A.A. placed all the implants and did all the subsequent denture adjustments.

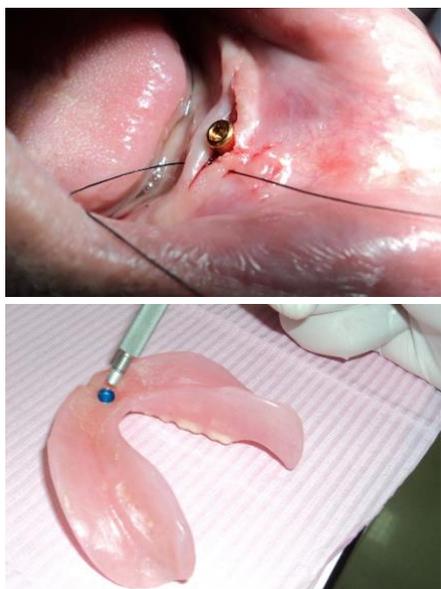


Figure 2. Immediate loading with direct pick-up procedure.

After implant placement, each patient received an antibiotic regimen consisting of 500 mg of amoxicillin 3 times a day and, if needed, 400 mg of Ibuprofen 4 times a day for pain control. The subjects were instructed in oral hygiene measures around the implants. Patients were instructed not to remove the denture for 7 days. The patients were limited to a soft diet for 6 weeks and they were asked to rinse with 0.2% chlorhexidine solution twice a day for one minute. All patients were scheduled for follow-up visits and suture removal after 2 weeks. Each patient was commanded to leave the denture out at night. Marginal bone height measurements and ISQ values were recorded at the time of implant placement (baseline), 2, 4, 6, 8, 12, 24 weeks then every 6-month up to 18 months post-implant placement.

Radiographic Evaluation of Bone Height Changes:

A series of digital periapical radiographs were obtained using an individual acrylic template and long-cone paralleling technique by using a film-aiming device (Fig. 3). After isolating the denture with petroleum jelly, an autopolymerized acrylic dough was adapted to the occlusal surface of the denture involving two guiding metal pins according to Abdel-khalek, (33).

The acrylic template covered the mandibular incisal edges and extended to the first premolar cusp tips bilaterally to ensure reproducibility.

Radiographic measurements were made directly on the radiograph by one examiner to the nearest 0.01 mm using software (Corel Draw v12.iso, Corel Corporation, Ottawa, Canada) at 400x magnification using the implant shoulder as a reference for evaluation of marginal bone level of implants. The distance from the implant shoulder to the most coronal implant-bone contact points left and right to the median implant was measured and recorded. The mean of measured data was calculated for each implant.



Figure 3. Standard radiographic technique and measurements.

Assessment of Implant Stability

Each visit required the removal of the abutment and the smart peg was directly mounted onto the fixture. The hand-held probe was perpendicularly directed onto the peg transducer labially, lingually, mesially, and distally. The recorded readings were averaged, and the mean value was calculated.

Statistical Analysis

Data were tabulated and statistically analyzed using the Statistical Package for Social Sciences (SPSS) version 20 (SPSS IBM Inc., England). Quantitative data were described as mean and standard deviation after testing normality by Kolmogorov-Smirnov test. All tests used in the study were 2-tailed. Student t-test was used for comparison between two variables. Repeated measures ANOVA test was used to compare parametric variable at different times of measurements (from baseline till 18 months) with Post Hoc LSD test to detect within group comparison. Percent of change in ISQ was calculated using the following formula (difference in values from baseline / baseline) x 100. Pearson correlation coefficient used for parametric correlation between continuous variables. P value ≤ 0.05 was considered to be statistically significant.

Results

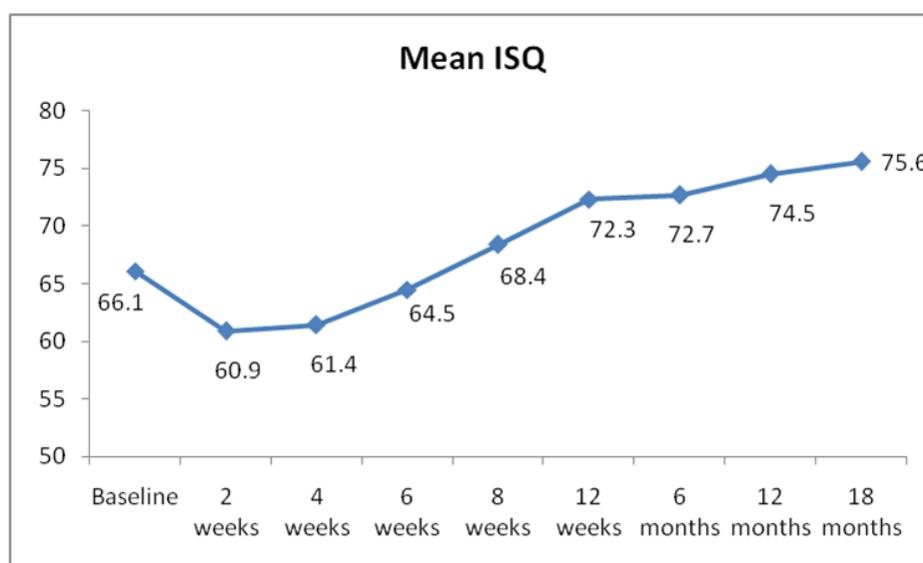
Graphic 1 and Table 1, illustrated the ISQ values which decreased markedly after the next 4 weeks (61.4 ± 5.1) from the baseline (66.1 ± 7.4). The ISQ values increased gradually until reaching the initial values after 3 months (12 ws.) with slight continuous increase until the end of the study (75.6 ± 5.9). There was a statistically significant difference in ISQ changes for implants from baseline to first 3 months (12 ws), 12 and 18 months respectively ($p < 0.01$).

Starting from the baseline, percent of change in ISQ showed a statistically significant increase ($P = 0.003$) between first 12 weeks ($-0.09 \pm 0.07\%$) and 12 months ($-0.13 \pm 0.06\%$) from the initial ISQ value. However, there was no statistically significant difference ($P = 0.08$) in percent of change in ISQ between 12 months and 18 months ($-0.15 \pm 0.08\%$).

When comparing mean ISQ at different times from baseline (initial ISQ); there was a statistically significant difference between different follow-up times up to 12 months ($P < 0.001$). Therefore, there was no statistically significant difference between 12 and 18 months from the baseline (Table 2).

Regarding peri-implant marginal bone level (MBL); comparing the mean bone height changes at different time points from baseline (implant placement) revealed a statistically significant difference between different follow-up times and it continued to the end of the study ($P < 0.001$). The first 12 months (0.52 ± 0.14 mm) showed the majority of MBL changes, as shown in Table 2.

The study revealed no correlation between the change in MBL and ISQ values at 3 months (12w) and 18m as there was no statistically significant difference between two dependent variables ($p = 0.59$, $p = 0.36$ respectively). In addition, Table 3 showed no association of gender/age with initial ISQ values ($p = 0.9$, $p = 0.79$ respectively). Nevertheless, there was a strong positive correlation between the change in ISQ and initial ISQ values at 3 months (12w) and 18m ($r = 0.798$, $r = 0.772$ respectively).



Graphic 1. The illustration of the ISQ values

Table 1. Changes in ISQ values for implants from baseline to 12w, 12 and 18 months.

	Baseline	12 weeks	12 months	18 months
ISQ Mean ± SD	66.1±7.4	72.3±5.6	74.5±5.7	75.6±5.9
Mean difference		-6.2 ± 4.4	-8.4 ± 3.7	-9.5 ± 4.7
		P<0.001*	P<0.001*	P<0.001*

ISQ: implant stability quotient SD: standard deviation

*: statistically significant at probability of error ≤0.05

Table 2. Comparisons of different time points from the baseline for the recorded ISQ values and marginal bone loss in mm.

Study parameter	Baseline	2 weeks	4 weeks	6 weeks	8 weeks	12 weeks	6 months	12 months	18 months	Repeated measures ANOVA
ISQ (Mean ±SD)	66.1 ±7.4	60.9 ±4.4 ^A	61.4 ±5.1 ^A	64.5 ±6.0	68.4 ±5.6	72.3 ±5.6 ^B	72.7 ±6.8 ^B	74.5 ±5.7 ^C	75.6 ±5.9 ^C	F=94.9 P<0.001*
Marginal Bone Loss (Mean ±SD)	-	0.02 ±0.01	0.03 ±0.01	0.04 ±0.01	0.05 ±0.02	0.07 ±0.01	0.18 ±0.05	0.52 ±0.14	0.73 ±0.2	F=165.8 P<0.001*

ISQ: implant stability quotient SD: standard deviation

*: statistically significant at probability of error ≤0.05

Similar superscripted letters in same row denote non-significant difference between groups by post Hoc LSD

Table 3. Association of gender/age with Initial ISQ values.

Initial ISQ	Gender		Test of significance	Age (years)		Test of significance
	Male N=11	Female N=9		59-64 N=10	65-70 N=10	
Mean	66.18±8.1	65.89±6.8	t=0.08	66.5±8.3	65.6±6.6	t=0.27
±SD			p=0.9			p=0.79

t: Student t-test

ISQ: implant stability quotient SD: standard deviation

*: statistically significant at probability of error ≤0.05

Discussion

Different clinical investigations were conducted on using mandibular single midline implant to retain an existing mandibular denture over a short- to midterm

observation period (9, 16). Most of these studies used different ball designs as the attachment of choice with delayed loading protocol.

The present study used (RFA) method that would allow the possibility of clinical monitoring of

immediately loaded implants to predict failure during the healing phase (22, 27). Moreover, standard radiographs are the most widely used diagnostic aid as a measure of successful osseointegration, considering accurate bone-level changes around implants (11, 33).

The present study showed 100% success rate according to the success criteria postulated by Papaspyridakos et al (15). The findings of this study confirmed high success rates of immediately loaded implants when the treatment fulfills the prerequisites (25-27). Comparing the current findings to literature's data was not possible because of lack of similar studies. Alsabeeha et al. (11) reported 0.23 mm MBL for locator attachment group after 1-year for early loaded SIMO that had been lower in comparison to the present study (0.52 mm), however, they reported 91.7% implant success. These results may be attributed to variation in the implant surfaces, diameter, length loading, and the method of incorporating the respective matrices into the intaglio surface of the dentures. Moreover, Alsabeeha et al. (11) believed in the successful osseointegration could not be precluded by rotation of an implant during healing.

All implants used in the current study were inserted with ISQ values higher than 56. In implant cases with low initial stability $ISO < 56$, the prosthetic loading was postponed for 3 months to avoid the risk of implant failure (21). Moreover; standard implants long (>10 mm) in the mandibular anterior region showed the highest success rates in previous studies of immediate loading (21, 26).

Extra-light retention (blue insert) was used in the study to reduce damaging effect of the Locator attachment on the healing implant. In contrary, Alsabeeha et al. (11) preferred the use of ball designs with large diameter in SIMO instead of Locator attachment because they concerned the amount of retention.

The current study paid the attention to the appropriate extension of the denture base, peripheral seal, and occlusal harmony to avoid excessive rotational movement and augment denture retention (5, 23). In this sense, participants in the current study had residual bone height ranging from 15 to 20 mm that could provide horizontal stabilization against prosthesis rotation (16).

Regardless the attachment used, the survival rate of SIMO at the endpoint of the current study was within results published in other investigations. Liddelow and Henry (6) reported 100% survival rate after three-year observation period for all implants loaded immediately at the day of implant placement. The present results could be compared to 82% implant survival rate in the studies published by Kronström et al. who observed that immediately loaded implants failed within the first

twelve months (18, 20). The slightly higher implant failure rate occurred in Kronström et al. (18,20) studies may be attributed to implant overloading by laboratory inaccuracies, as the researchers did not intra-orally relate the implant components to the denture.

In a similar way, a recent two-years RCT, (3) reported two failed implants (one after 2 months and the other after 21 months) out of 38 immediate loaded implants retaining SIMO. From the authors' point of view, the implant loss could be attributed to smoking and use of short implants (9 -11 mm in length).

All implants met the criteria for success in terms of radiographic bone loss, indicating that the bone remodeling can compensate for forces within the physiologic tolerable limits. These results were in agreement with studies done by Cordioli et al. (13) and Kronstrom et al (20). The total mucosal support of SIMO and use of multidirectional retentive element may be responsible for diminished mechanical overloading of the implant (11, 13, 29).

The study results showed an acceptable ISQ thresholds (66.1 ± 7.4) that were suggested for immediate loading (21). The present findings revealed that ISQ values decreased markedly from the baseline during the first 4 weeks and followed by gradual increase afterwards. This could explain that primary stability comes from mechanical engagement of the implant with cortical bone whereas, the secondary stability is the eventual outcome from regeneration and remodeling of the bone around the implant (27). The study observed that the most pronounced decrease in ISQ values occurred 2 weeks after implant placement which in agreement with Simunek et al. (34).

The significant difference in ISQ changes from the baseline to first 3 months (12ws) or 12 months could result from the stiffness of bone itself and bone density as well as the ratio of cortical and cancellous bone that may affect RFA (27). These results agreed with Nedir et al. (21) who considered the reduction in implant stability through the first 12 weeks of healing is a common event. During the healing process, primary bone contact decreases and secondary bone contact increases depending on the changes in bone density (28). This explains the insignificant difference in ISQ between 12 and 18 months from the baseline that might indicate a stable state of implants represented by ISQ range of 73-75 (11).

The present study found no correlation between the change in marginal bone level and ISQ values at different time points of the follow-up. These observations didn't coincide with histomorphologic studies that reported high correlation of RFA value to the bone-implant contact at early bone healing (27, 28).

The current study revealed no association of gender/age with initial ISQ values. This may be attributed to the old age of participated patients and/or restricting inclusion criteria on those cases with good bone quality and higher primary implant stability. The study found strong correlation between the change in ISQ and initial ISQ values at different times of follow-up. As the bone remodeling is variable, the high initial stability does not necessarily mean the secondary stability will also be the same (21, 27). The variability of the survival rate of SIMO could be attributed to host related factors, implant systems, retentive elements, surgical approaches, and loading protocols (3, 9).

The current study had a number of limitations such as the short follow-up period and the small number of participants. The use of specific implant design and attachment system is another limitation in this study. The performances of different ball and stud designs across the studies are difficult to compare because of the various retention mechanisms (5). Another limitation in this study is the lack of a comparable clinical success of implants inserted with the delayed loading approach (3). Radiographic follow-up of severely resorbed mandibles could be difficult because of the possible superimposition of the genial tubercles over the marginal bone or may result in clinical problems associated with film placement that directly impinged on the lingual frenum (6). The current investigation was performed on locator attachment that differs from other studies in the literature and may provide more opportunity for future analysis. The current study reported data of only 18 months follow-up with a 100% success rate; therefore, research proposals are currently prepared for investigating patient-reported outcomes, prosthetic complications, and implant success after longer period of function.

Conclusions

Within the limits of the present study, it could be concluded that:

- Immediately loaded single implant with locator attachment inserted in the median region of the mandible could be a successful treatment option for edentulous arches, especially in people with limited financial resources.
- The use of Locator attachment seemed to have a favorable effect on implant stability and marginal bone around immediately loaded SIMO after 18-months of function.
- Further long-term clinical studies had been suggested to confirm these results.

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