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ORIGINAL RESEARCH

Three-year Prospective Evaluation of Immediately Loaded Mandibular Implant Overdentures retained with Locator Attachments

Ayman Al-Dharrab

ABSTRACT

Introduction: Immediate implant-loading protocol has progressed because of various clinical advantages offered by this treatment approach. However, available studies on edentulous patients are still few compared to those in which delayed implant-loading protocol was applied.

Aim: This prospective study was to evaluate the implant survival rate and the peri-implant tissue response in a group of patients who received two unsplinted immediately loaded dental implants in the mandibular anterior region to retain a complete overdenture using locator attachments.

Materials and methods: A total of 24 edentulous patients with a mean age of 63.4 years were involved in this study following certain inclusion criteria. All patients received a new set of complete dentures before implant positioning. Two *Prima Connex* tapered implants were put in the interforaminal area of the mandible with a flapless surgical procedure, and the prefabricated dentures were immediately retained with a zest locator attachment. Clinical and radiographic records of the patients were reviewed immediately after placement of the implant, at 3 months, and at 1, 2, and 3 years following fixture installation. The obtained data were analyzed using paired samples t-test and the Wilcoxon signed-rank test at 0.05 significance level.

Results: At 3 years, all implants had osseointegrated with a 100% survival rate. In addition, the total mean marginal bone change was −0.89 ± 0.14 mm, and the mean periotest value was −7.631 ± 0.921.

Conclusion: Results of this study propose that immediate loading of mandibular implant overdentures that are retained with locator attachments was a feasible treatment alternative for this particular group of patients.

Department of Oral and Maxillofacial Prosthodontics, Faculty of Dentistry, King Abdulaziz University, Jeddah, Kingdom of Saudi Arabia

Corresponding Author: Ayman Al-Dharrab, Department of Oral and Maxillofacial Prosthodontics, Faculty of Dentistry, King Abdulaziz University, Jeddah, Kingdom of Saudi Arabia, Phone: +96626403316, e-mail: aaldharab@kau.edu.sa

Clinical significance: Immediate implant- loading of mandibular implant overdentures that are retained with locator attachments is a reliable treatment option

Keywords: Immediate implant loading, Implant survival rate, Locator attachments, Overdenture.

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INTRODUCTION

The percentage of edentulous patients is high in many societies, and this had been attributed utmost to the prevalence of caries and periodontal diseases. Different records have shown that nondisease factors, such as environmental, biological, and socioeconomic factors play significant roles in the etiopathogenesis of edentulism.[1,2] Regardless of the optimistic expectation for a steady decline in the frequency of total edentulism in forthcoming decades with improved dental care, it continues to exist as an utmost global health problem because of the associated disabilities. Current reports reveal that 30.5% of individuals above the age of 65 years are edentulous in one jaw, with at least 22.6% having both jaws edentulous.[3,4] The unremitting tooth loss not only adversely affects dietary intake, nutritional status, and phonetics, but also compromises general health. Furthermore, edentulism is an independent risk factor for significant weight loss and is associated with both systemic and chronic diseases.[4,5-7] Consequently, rehabilitation of edentulous patients with complete dentures has long been the prevailing standard of care. However, a long-term success of this therapy is often unpredictable because of the progressive alveolar resorption associated

with prolonged edentulism, particularly in the mandible. Besides, discomfort, reduced masticatory efficiency, speech difficulties, compromised esthetics, and frequent denture fracture may lead patients to ask for alternative therapy.[7-9] Since the advent of endosseous implants, the therapeutic possibilities for edentulous patients have dramatically improved.[7] Osseointegrated implants used as anchors for overdenture have become a widespread and predictable treatment method for the edentulous jaw as they not only handle many of the problems associated with conventional denture therapy, but also do so with better function, esthetics, and physical health[10-13] There are a number of implants used to retain or support an overdenture in current literature.[10-17] Many years ago, Naert et al[18] suggested positioning a third fixture in the nearness of the mandibular midline if suspicion emerges during surgery with regard to the success of the osseointegration of one of the other two. However, with the improved quality of surgical and prosthodontic procedures, the technique has proceeded toward the use of two interforaminal implants, which are considered to sufficiently support the mandibular overdenture in an edentulous patient.[19] According to the York consensus statement, the mandibular two-implant overdenture should be advised as a first-choice therapeutic option for edentulous patients.[20] Since a long time, it has advocated that a two-stage surgical procedure for load-free and submerged healing is a prerequisite to enclose predictable osseointegration.[21] Challenges facing patients and clinicians are inconvenience, discomfort, and anxiety that are related with the waiting period. Consequently, implant loading later after placement was attempted and has gained popularity among clinicians. The concept of immediately loading implants in fully edentulous patients gives patients many profits, including improved comfort during healing and the ability to eat postplacement. This path also may decrease the number of patient visits as compared with the conventional approach of implant placement and healing over a 3- to 4-months healing period.[22-24] For many years, dental implants have shown varying degrees of success when loaded immediately on implant placement. As clinicians' understanding of biological and mechanical factors involved in immediate occlusal loading has developed, the success of these procedures has increased mainly as a treatment option for the restoration of the edentulous mandible.[25-27] However, before being embraced as a useful innovative step and becoming part of regular treatment, immediate loading protocols need to be endorsed with a significant number of clinical cases, extended follow-ups, and a clear definition of limitations. Combinations of factors affect the amount of stress transferred to the developing implant interface and, hence, may affect the risk of immediate occlusal loading for implant prostheses. These factors include systemic condition of the patient, bone quality and quantity, cantilever forces, occlusal load direction, and position of implant.[26,27] Nkenke et al[28] found that immediate loading does not affect the bone mineral apposition rate when compared with unloaded implants if all conditions are under control. After 4 months of placement of implant, the bone-to-implant contact was 77.8% for the loaded and 78.0% for the unloaded implants. Although numerous studies have reported promising success rate for the delayed loading of dental implants that retain mandibular overdentures, similar evidence using immediate loading protocol is still limited. The aim of this prospective study was to evaluate the implant survival rate and the peri-implant tissue response of immediately loaded mandibular implant overdentures retained with locator attachments.

MATERIALS AND METHODS

Patient Selection

This study was conducted at the Faculty of Dentistry of King Abdul-Aziz University, Kingdom of Saudi Arabia, between January 2010 and July 2015. A total of 24patients (10 men and 14 women) between the ages of 55 and 74 years with mean age of 63.4 years were enrolled from those admitted to the specialty clinics of the oral and maxillofacial prosthodontics department. To be included, patients had to be completely edentulous for at least 12 months; have enough bone at the anterior region of the mandible to accommodate an implant length of at least 13 mm and diameter of 4.1 mm; have the commitment to accept the implant overdenture treatment option; have the manual dexterity necessary to place and remove an implant overdenture and to provide adequate oral hygiene around the implants; be compliant with oral health-care instructions; have an acceptable maxilla–mandibular relationship and a normal range of mandibular motion with no deviation; have sufficient interridge space; and be presented with no obvious mucosal lesions or pathological changes in either maxilla or mandible. Exclusion criteria dictated that the patient did not have a history of drug/alcohol abuse, smoking,[29] head and neck radiation,[30,31] psychiatric problems, or a health condition that would otherwise preclude the implant therapy. Patients who did not show primary implant stability following implant placement were also excluded from participation in this study.

Clinical Procedures

All patients underwent adequate presurgical diagnostics and treatment planning procedures to determine whether they were qualified for implant therapy and to

ensure a prosthetically driven implant placement.[32] About 2 weeks before the implant surgery, conventional complete maxillary and mandibular dentures with a bilateral balanced occlusal scheme[33] were fabricated, placed, and adjusted. Following the administration of local anesthetic, two PrimaConnex-tapered implants (Prima, Keystone Dental, Burlington, Massachusetts) were installed in the anterior region of the mandible through a flapless procedure. The final implant tightening had a torque resistance of 35 to 45 Ncm (manufacturer recommendation). The proper PrimaConnex zest locator abutment (Zest Anchors, LLC, Escondido, California) was threaded into the implant and torque to 30 Ncm, ensuring 1.5 mm of height above the mucosa. A carbide bur was used to create a recess in the denture base to accommodate the abutment and attachment assembly (metal denture cap and the nylon locator replacement male). The attachment assembly was picked up through direct chair-side procedures using an autopolymerizing acrylic resin (Fig. 1). During resin polymerization, the patient was required to keep their dentures in centric occlusion using moderate pressure so that the denture base was in intimate contact to the supporting tissues. A white block-out spacer was placed over the head of each locator abutment to protect the surgical site from exposure to excess acrylic resin and monomer and block out the area immediately surrounding the abutment. The space created allowed the full resilient function of the pivoting metal denture cap over the locator replacement male. In this study, a light retention replacement male (3.0 Ib pink nylon) was used. The patient was then instructed on how to insert and remove the denture several times. Prescriptions for postoperative antibiotics (Amoxicillin 500 mg, SPIMACO, Kingdom of Saudi Arabia) and a nonsteroidal anti-inflammatory drug (Ibuprofen 400 mg, Riyadh Pharma, Kingdom of Saudi Arabia) were given to each patient for 6 days postoperatively. The patients were advised to avoid chewing food over the surgical site and to remain on a liquid diet for the first 2 weeks and a soft diet for the remainder of the implant healing phase.[34] The patients were also instructed to remove the overdenture every other day to clean it and the surgical site. An oral rinse (0.2% chlorhexidine digluconate, Corsodyl, GlaxoSmithKline, UK) was used twice a day for the first 2 weeks after implant placement. A postoperative examination was performed 1 week following the procedure.

Fig. 1: Metal denture cap with pink locator replacement male

Patient Evaluation

Patients were recalled regularly for evaluation up to 3 years after implant surgery. The evaluations were made instantly after implant placement (baseline evaluation); at 3 months and at 1, 2, and 3 years after implant placement. The following variables were recorded.

Implant Survival

The survival and success rate of the implants were defined based on the criteria originally proposed by Alberktsson et al[35] and included the following points: (a) an individual, unattached implant was immobile when tested clinically, (b) vertical bone loss ranges between 0.4 and 1.4 mm following the implant's 1st year of service, (c) a radiograph did not show any proof of peri-implant radiolucency, and (d) individual implant performance characterized by absence of signs and symptoms, such as infection, pain, paresthesia, or neuropathies. Accordingly, an implant failure was considered if there was a significant marginal bone loss, peri-implant radiolucency, mobility, pain, and/or discomfort.

Implant Mobility

A periotest (Medizintechnik Gulden, Modautal, Germany)[36-38] was used to evaluate implant stability at the time of the implant placement and subsequently at 1, 2, and 3 years after implant placement. The locator abutment was utilized as the tapping surface for the periotest instrument. Measurements were repeated three times per implant, and the mean value was calculated. A periotest value (PTV) ranging between 0 and –8 denoted a good osseointegration.

Marginal Bone Level Change

Marginal bone levels on the mesial and distal aspects of the implants were measured using sequential periapical radiographs and the long-cone paralleling technique with a commercial Rinn XCP holder (Dentsply, USA) and a polyvinyl siloxane bite (Regisil, Dentsply Caulk, USA) to standardize the angulation and position of the film to the X-ray beam during serial evaluations. Measurements were made from a predefined reference

point to the first implant-to-bone contact at either side of the implants, and a mean value per implant was calculated. The junction between the implant machined collar bevel and the microrough surface was used as the reference line.[39,40] The distance between the reference line and the most coronal implant–bone contact point was measured to the nearest 0.1 mm using Kodac R4 dental software. The value was positive when the implant–bone contact point was more coronal than the reference line and negative when the contact point was more apical to the reference line. Marginal bone levels were then compared between each follow-up time interval and the changes calculated.

Modified Plaque Index

The presence of plaque, as an indicator of the oral hygiene status of individual patients at different time intervals, was assessed at the labial, mesiolabial, distolabial, lingual, mesiolingual, and distolingual surfaces of each implant abutment according to the modified plaque index (MPI)[41] by running a probe across the surface supragingivally (0 = no plaque detected, 1 = plaque only recognized, 2 = plaque can be visually seen with unaided vision, 3 = abundance of soft matter) at 3 months and 1, 2, and 3 years after implant placement. The mean MPI for each patient was calculated by dividing the sum of MPI scores per abutment by six. The patient's oral hygiene status was classified as good (mean MPI ≤ 1), fair (mean MPI >1 and ≤ 2), or poor (mean MPI > 2).

RESULTS

Implant Survival

All 48 implants were immobile, and none had lost osseointegration after 3 years from immediate functional loading. This was consistent to an overall implant survival of 100%.

Implant Mobility

Immediately after fixture installation, all implants showed a good primary stability with a mean periotest score of −6.10 ± 0.753. On the upcoming evaluation stages, the PTVs were increased, however, with no detectable mobility (PTV < −8), which indicated stable and osseointegrated implants. The mean PTV recorded at 1, 2, and 3 years subsequent to implant placement were −6.98 ± 0.723, −7.54 ± 0.440, and −7.631 ± 0.921 respectively. The Wilcoxon signed-ranks test revealed a significant difference between the mean PTV recorded at the follow-up stages and that recorded immediately after implant placement or baseline stage (p > 0.05); however, there was no significant difference between the PTVs recorded at 1, 2, and 3 years follow-up (Table 1).

Table 1: Wilcoxon signed ranks test of PTVs

Interval (years)	*Mean PTV*	*1 year*	*2 years*	*3 years*
Baseline	−6.10 ± 0.753	0.001*	0.002*	0.001*
1	−6.98 ± 0.723		0.134	0.115
2	−7.54 ± 0.440			0.123
3	7.631 ± 0.921			

*p < 0.05, clinically significant

Marginal Bone Level Change

The mean overall marginal bone levels recorded immediately after implant placement and at 1, 2, and 3 years were 0.20 ± 0.052, −0.42 ± 0.23, −0.61 ± 0.27, and −0.69 ± 0.11 mm respectively. The mean annual marginal bone loss after 1, 2, and 3 years were −0.62 ± 0.13, −0.81 ± 0.20, and −0.89±0.14 mm respectively (Table 2). The paired samples t-test showed significant differences in marginal bone levels recorded immediately following functional loading of implants (baseline) and the succeeding evaluation stages (p > 0.05; Table 2). Moreover, significant differences were further found between the mean annual marginal bone levels recorded after 1, 2, and 3 years of immediate functional loading of implants (p > 0.05).

Modified Plaque Index

The frequency distribution of mean MPI recorded at the subsequent patient's evaluation appointments is shown in Table 3. After 3 months of wearing the implant-retained mandibular overdentures, 13 of 24 patients presented with an MPI score > 2, which denoted poor oral hygiene condition. After 1 year of prosthesis use, 4 patients presented with an MPI score <1, which denoted good oral

Table 2: Paired samples t-test comparing means of implant marginal bone level changes at different time intervals

Observation stage (years)	*Overall implant marginal bone levels*	*Overall marginal bone level change at different time intervals*		
		1 year	*2 years*	*3 years*
Baseline	0.20 ± 0.052	−0.62 ± 0.13 (p = 0.000*)	−0.81 ± 0.20 (p = 0.000*)	−0.89 ± 0.14 (p = 0.000*)
1	−0.42 ± 0.23		−0.19 ± 0.09 (p = 0.000*)	−0.27 ± 0.23 (p = 0.000*)
2	−0.61 ± 0.27			−0.08 ± 0.06 (p = 0.000*)
3	−0.69 ± 0.11			

*p < 0.05, clinically significant

Table 3: Mean MPI scores at different observation stages

Patient no	Observation period											
	3 months			1 year			2 years			3 years		
	G	F	P	G	F	P	G	F	P	G	F	P
1		1.9			1.6			1.8			1.4	
2			2.4		1.8			2.6			2.0	
3			2.7		1.9			1.9			1.9	
4	0.9				1.6			1.8			1.8	
5		1.9			1.8			1.8			1.6	
6			2.2			2.6		2.0			1.9	
7	0.9			0.8			0.8			0.8		
8			2.7			2.1		1.9			1.9	
9			2.6		1.9			1.9			1.8	
10		1.9			1.9			1.8			1.7	
11			2.1			2.3			2.1			2.2
12	0.5			0.8			0.9				1.3	
13			2.4		1.8		0.9				1.2	
14			2.2			2.1			2.2			2.1
15		1.3			1.5			1.3			1.3	
16			2.7		1.9			1.9			1.9	
17		1.7			1.3			1.6			1.3	
18			2.2			2.1		1.8			1.7	
19		1.7			1.5			1.7			1.4	
20			2.5	0.9				1.3			1.1	
21			2.1		1.2		0.8			0.9		
22	0.5			0.9			0.9			0.9		
23			2.4			2.2		1.7			1.6	
24		1.8			1.3			1.5			1.3	

G: Good oral hygiene; F: Fair; P: Poor

hygiene. Furthermore, 14 patients presented with an MPI score > 1, but < 2, and the remaining 6 patients had poor oral hygiene. After 2 years, 2 patients maintained poor oral hygiene, while fair oral hygiene was evident in 17 patients and only 5 patients had good oral hygiene. At the end of the study, 18 patients had an MPI > 1, but < 2 and only 2 patients had poor oral hygiene.

DISCUSSION

It has long been stated that one of the prerequisites of the early protocols to permit osseointegration of dental implants is to avoid any occlusal loading following implant surgery. However, the necessity for this load-free period was mainly formulated based on clinical practice.[42,43] It is, therefore, just to question whether this healing period is essential to permit osseointegration, or if under specific circumstances, this period can be reduced without threatening the osseointegration and long-term results. In particular, it should be displayed if any kind of motion transferred to the implants during the early phases of integration can compromise the long-term results. The concept of immediate loading, whereby implants with sufficient primary stability are occlusally loaded with the prefabricated prosthesis at the same clinical visit, is appealing to both dentist and patient. Recently, the use of immediately loaded implants became more agreeable as a standard protocol for completely edentulous lower jaw and/or partially edentulous upper jaw cases, mainly in the anterior region, after it was one of the cornerstones of the early protocols to avoid any occlusal loading of the implants for at least 3 months. This technique could potentially provide immediate function and esthetics to the patient.[44] However, it is yet unknown how predictable this approach is. A 3- to 8-year prospective study[45] has been conducted on 328 implants placed in the anterior region of the mandible and were immediately loaded with implant-retained overdentures. The total success rate of implants was 97.6%, which was considered similar to that obtained in the case of delayed loading, after osseointegration has occurred. In addition, studies[46,47] based on histologic and histomorphometric evaluations of immediately loaded implants recovered from humans have also shown a high degree of bone-to-implant contact percentages. This study reported the preliminary data from 48 immediately loaded implants placed in the interforaminal area of edentulous mandibles of 24 patients (2 implants for each patient) to retain over-denture prostheses with a success rate of 100%. The difference in success rate reported in different reports justifies the need for additional evidence regarding the immediate

loading protocol. In case of immediate loading, it may be hypothesized that the number of implants placed and their distribution might influence the survival rate of the implant-retained overdentures. However, in this study, only two implants were placed to retain the overdenture prosthesis as no evidence is reported in the literature that lesser numbers of implants are sufficient to offer stability to withstand the mechanical demands of immediate loading. Similarly, there are no data in the literature that demonstrate that a higher number of implants can improve implant survival.[48]

The surgical placement of dental implants has endured changes since the beginning of placement of root-form implants. Using the Branemark protocol firstly, an incision in the mucosa or the mucobuccal fold was made, and a flap was then reflected to expose the underlying bone. The implants were placed and the flap was sutured back in place.[49,50] The PrimaConnex tapered implants used in this study offered an advantage of being placed without the need of a soft tissue flap. With a flapless approach, surgical trauma was minimal, in order that postoperative pain, swelling, and discomfort related to soft tissue trauma were also greatly minimized. After a 10-year clinical retrospective analysis regarding the flapless technique, Campelo and Camara[51] believed that this surgical approach decreases the amount of bone loss caused by reflecting soft tissue flaps. Nevertheless, since flapless implant placement is generally a "blind" surgical technique, care was taken to avoid perforations when placing the implants. An implant length of at least 13 mm was placed, as a minimum acceptable implant length of 10 mm was considered viable by some authors when immediate loading protocol is to be attempted.[52,53] Care was also taken to ensure primary stability of implants before being immediately loaded. The primary stability is a crucial factor that determines the long-term success of dental implants. High success rates with immediate loading of dental implants have been reported in several studies.[47,54] This was attributed to high primary stability. Others studies[46,47] have also preferred insertion torque as a determinant of implant stability (torque values of 32, 35, 40 Ncm and higher have been chosen as thresholds for immediate loading), which was further fulfilled in this study. In this study to gauge the primary stability, the periotest was used as a dependable method. This method has been shown to be helpful in determining the implant stability in both conventional and immediate loading of dental implants.[36-38] The results obtained by Dilek et al[55] found that immediate loading of osseointegrated implants can only occur if their PTVs were between the range of −8 and +9, in agreement also with the findings obtained by Abboud et al[56] who reported that PTVs of −4 are indicative of a successful protocol. However, other studies have given an even narrower range for periotest (−4 to −2 and −4 to +2).[57] In this study, all implants consistently produced PTVs between −6.10 ± 0.753 and −7.631 ± 0.921 along the subsequent observation stages. These findings indicate that all implants remained stable from the time of placement to 3 years following implant placement.

The stability of the two implant-retained overdentures greatly dependent on tissue supports from the residual ridge because two implants cannot supply enough support and retention for the entire arch. With continuous residual ridge decrease, the stability and chewing efficiency may be compromised owing to the lack of resistance to lateral and rotational forces. The quality of the overdentures, particularly, the addition of a balanced occlusion scheme is important in patients lacking alveolar tissue supports.[33] Thus, care was taken to correct the occlusion and provide balanced contacts in all directions to prevent harmful lateral and rotational forces during function.

Different types of attachments can be used to retain the mandibular implant overdentures. Attachments as bar-clip retainers, stud, or ball-cap attachments and magnetic attachments can be used. Stud or ball-cap attachments, like the locator attachment that was used in this study, use a spring mechanism to absorb the functional loads, which allows even distributions of axil forces and tolerates slight rotation of the denture. Such type of attachment design has the merit of minimizing lateral load on the implant fixture that promotes bone health.[32,58] Some authors[59,60] found that the use of a locator attachment may be a better option than the magnetic attachment type, as it provides superior retentive force. Furthermore, the locator attachment type can regulate the retentive forces through the choice of varying color-coded nylon housings. Although increased retention quality of the implant overdenture is advantageous in most clinical situations, it may prove to be questionable for elderly patients to easily remove and insert the denture for cleaning and maintenance. Consequently, a locator attachment with lower retentive force was used in this study. Implant mobility and considerable peri-implant bone loss are typically accepted criteria for designating an implant as failed. The relationship of the marginal gingival condition and peri-implant probing for implant survival remains a debatable issue.[32] Thus, evaluation of the implants in this study made according to the standard of success suggested by Albrektsson et al[35] was considered sufficient. The results of this study after 3-year follow-up have shown that it is possible to maintain a high implant survival rate (100%) over a longer period of time, which corresponded to the long-term results achieved by Büttel et al.[61] The 100% implant survival rate reported in this

study is most likely a result of adequate primary stability, careful patient selection, proper surgical planning and execution, a balanced occlusal scheme, proper tissue adaptation of the prostheses, and adequate patient compliance with instructions and postoperative care in conjunction with the microrough titanium surface implant.

Observing marginal bone loss around dental implants is considered as the most important basis in determining the success of implants. This basis is generally accepted as a dependable indicator of bone response to the surgical procedure and the upcoming occlusal loading. Early recommendations included a projected 1.0 mm of marginal bone loss during the 1st year of function and 0.2 mm annually thereafter.[35] A subsequent publication[62] extended the "permissible" marginal bone loss during the 1st year to 1.5 mm and added the descriptor "average," which reflected the considerations that implant success should be determined on an entire-mouth basis and not by each implant as an independent unit. In this study, the recorded mean marginal bone loss during the 1st year of immediate loading was −0.62 ± 0.13 mm, and the mean marginal bone loss up to the 3-year follow-up was <0.2 mm annually. Consequently, the survived implants in this study were successfully osseointegrated. Furthermore, the results of marginal bone loss evaluation in the existing study seem to be comparable with those previously reported in studies conducted on immediately loaded implant-retained mandibular overdentures. Castellon et al[63] reported a range of 0 to 2.5 mm of marginal bone loss after 2 years of immediate loading of mandibular implant-retained overdentures.

The effect of oral hygiene on the success of dental implant is always controversial. The agreement is that the collection of plaque could produce a negative mucosal reaction. Inflammation of the peri-implant tissues is commonly encountered with implant-retained overdentures due to plaque accumulation.[32] This is usually the result of the inability of patients to access certain areas of the implant abutment or suprastructure. Over the course of 36 months of this study, most patients gradually improved their oral hygiene at the 1st year of denture use as manifested by lower plaque index scores. However, some patients were unable to sustain the same level of oral hygiene and relapses were seen during the 2nd and 3rd years. Frequent recall visits were scheduled to reinforce and motivate the patient's oral hygiene.

CONCLUSION

Within the limitations of this study, it was possible to conclude that when using strict patient selection together with both surgical and prosthetic protocols, the immediately loaded implant overdenture, i.e., retained with a locator attachment can be a safe and reliable option for the treatment of edentulous mandible.

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