Early Loading of Fixture Original Implants with Mandibular Overdentures—A Preliminary Report on a Prospective Study

Nikolai J. Attard, BChD, MSc, PhD[a]/Mark Diacono, BChD, FDSRCPS[b]

Purpose: The aim of this study was to report the short-term clinical- and patient-based results of an early loading protocol using two Fixture Original implants with a mandibular overdenture. ***Materials and Methods:*** Fifteen consecutively treated patients were enrolled in this study. Each patient received 2 implants; one patient received an additional implant during the observation period, yielding a total of 31 implants used in this study. All patients were treated with overdentures supported by a resilient ovoid bar mechanism. Clinically based outcomes were documented throughout the study, while patient-based outcomes were recorded at baseline and at the 1-year follow-up using the Denture Satisfaction and the Oral Health Impact Profile. ***Results:*** Patients were followed for an average of 28.87 ± 5.04 months. The overall success rate was 100% for the implants and 93% for the original prosthetic treatment plan, since an overdenture was converted to a fixed prosthesis for one patient throughout follow-up. The mean bone loss measured during the first year of loading was 0.11 mm (standard deviation: 0.14 mm). Prosthetic maintenance events were mainly related to the acrylic superstructure. Patient-based treatment outcomes showed a statistically significant improvement with the prosthetic treatment and in their quality of life (Wilcoxon signed rank rest, $P < .05$). ***Conclusions:*** This short-term longitudinal study suggests that Fixture Original implants can be loaded early using mandibular overdentures. Additionally, modified prosthetic and surgical protocols led to minimal postinsertion prosthodontic maintenance. The results underscore the effectiveness of the overdenture technique in rectifying patients' complaints with conventional mandibular prostheses. *Int J Prosthodont 2010;23:507–512.*

Dental treatment is considered successful when a patient's oral function, appearance, and self-confidence are restored satisfactorily. Implant treatment for edentulous patients addresses these concerns,[1–3] along with an associated improvement in quality of life.[4,5] Additionally, economic studies have suggested that the mandibular overdenture is more cost-effective than the fixed alternative[6] or complete dentures.[7] Considerable clinical evidence endorses immediate and early loading of implants in the edentulous mandible, although the level of scientific evidence is site- and patient-specific[8] for both fixed[9,10] and overdenture prostheses.[11–18] However, the terminology relating to the various loading protocols remains controversial.[19] Rather than rigidly assigning a specific time frame to a particular loading protocol, it seems more prudent to focus on the impact of "challenging" the implants during the various stages of the healing process. Therefore, loading during the initial phase of bone and soft tissue healing, often referred to as an early loading protocol, tests the healing process directly and can be as challenging as an immediate loading protocol. It has also been suggested that there is no difference in the clinical outcomes for specific patients when using either the immediate or early loading protocols.[8]

The cited benefits for immediate and early loading include a reduction in the number of surgical and prosthodontic procedures, as well as reduced associated clinical time and treatment costs. Indeed, previous studies concluded that although treatment was successful from an implant outcome perspective, the prosthetic success was curtailed due to considerable maintenance.[17,20] Consequently, the authors postulated that modifications in prosthodontic and surgical techniques might lead to greater postinsertion maintenance. Indeed, an economic analysis[20] showed that an early loading protocol did not actually result in a less expensive alternative overall.

[a]*Senior Lecturer, Department of Restorative Dentistry, Faculty of Dental Surgery, University of Malta, The Medical School, Mater Dei Hospital, Malta; The Dental and Implantology Unit, St. James Hospital, Sliema, Malta.*

[b]*Researcher, The Dental and Implantology Unit, St. James Hospital, Sliema, Malta.*

Correspondence to: *Dr Nikolai Attard, The Dental and Implantology Unit, St. James Hospital, G. Borg Olivier Street, Sliema, Malta. Email: njattard@maltanet.net*

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Table 1 Inclusion Criteria

Medically healthy (or a medically controlled condition) to allow a minor oral surgical procedure
No significant psychiatric disorder
No alcohol or drug abuse
Advanced age or compromised general health such that the long surgical and prosthodontic appointments required for a fixed tissue-integrated prosthesis would be too demanding
Mandibular edentulism
Terminal residual mandibular dentition indicated for extractions
Adequate bone dimensions to allow placement of at least two implants in the interforaminal area
Satisfied with removable prosthetics but looking for enhanced retention and stability
Demand realistic treatment outcomes
Cannot afford a fixed tissue-integrated prosthesis
Esthetic demands favor the use of a removable prosthesis
Obtained consent

Therefore, a clinical study was designed to address the treatment outcomes of a surgically and prosthodontically modified early loading protocol of Fixture Original implants (Brånemark Integration) with mandibular overdentures. The preliminary short-term observational outcomes are presented.

Materials and Methods

The study group consisted of 15 patients (12 women, 3 men; average age: 62.47 ± 7.93 years) seeking private treatment at the Dental and Implantology Unit, St. James Hospital, Malta. Enrollment in the study commenced in the fall of 2005 and the most recent recall visits were in the spring of 2009, with an average follow-up period of 28.87 ± 5.04 months (range: 26 to 38 months).

During the initial consultation, patients were provided with the necessary information on implant treatment, as well as the specifics of the modified protocol. Patients were provided with an information package and encouraged to participate in the study. Inclusion criteria are described in Table 1. The treatment protocol was approved by the ethics board at St. James Hospital.

Prior to treatment, patients were assessed by both authors using an appropriate combination of medical questionnaires and clinical and radiographic examinations. A conventional protocol for fabrication of new complete dentures was followed up to the try-in stage of treatment. Once the patients approved the dentures, they proceeded to the surgical intervention.

Surgeries were completed under local anesthesia, intravenous sedation, and antibiotic coverage. The incisions performed to gain access to the bone crest were conservative, typically either a punch approach or elevation of the soft tissues in the predetermined implant sites to exclude extensive stripping of the mucoperiosteum. In a limited number of patients who required crestal bone reduction, a conventional crestal incision was made between the mental foramina.

All patients were treated with 2 Fixture Original implants in the mandibular interforaminal area at least 20 mm apart to allow fabrication of a bar superstructure (Figs 1 and 2). In one patient, an additional implant was inserted later in the follow-up period; this was placed in the center of the mandible to support a fixed prosthesis, since the overdenture protocol did not meet her expectations. All implants were 3.9-mm diameter, and their average length was 12.97 ± 1.78 mm (range: 10 to 15 mm). The mean insertion torque for the implants was 46.00 ± 4.71 Ncm.

Prosthetic treatment proceeded immediately after surgery, with the connection and torquing of the multiunit abutments to 20 Ncm with a standardized manual torque. A pickup impression of the implants was performed using modified trial dentures (Fig 3). These prostheses had the anterior teeth removed and a window opened to allow placement of impression copings.

The trial denture was then hollowed out and relined with a soft liner in direct contact with the abutments. Patients were advised to follow a soft diet and to wear their prostheses continuously until the next appointment.

The trial denture and pickup impression were sent to the dental laboratory. A prefabricated ovoid bar (Cendres + Métaux) was soldered to gold cylinders, and the prosthesis was returned to the clinic an average 8.06 ± 3.67 days after surgery (Fig 4). Patients were reviewed at 3-, 6-, and 12-month intervals and annually thereafter.

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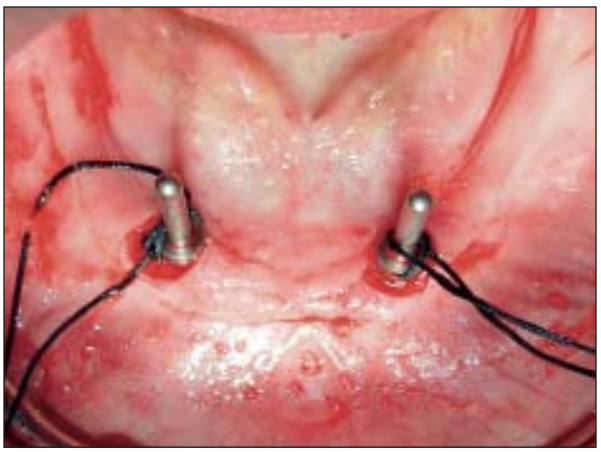

Fig 1 Two implants were placed surgically. A flat ridge crest permitted a "punch" exposure rather than a full flap one.

Fig 2 The mandibular denture was used as a surgical guide for implant positioning.

Fig 3 Pickup impression of the implants with a modified try-in denture.

Fig 4 An ovoid bar was inserted within 1 week.

Data Collection

Patient demographics, health, and dental-related parameters were recorded (Table 2). Patient satisfaction was measured using the Denture Satisfaction Scale questionnaire, and oral health–related quality of life outcomes were determined using the short version of the Oral Health Impact Profile questionnaire (OHIP),[21] both collected at baseline prior to consenting to the study and at the 1-year follow-up visit.

Surgery-related parameters, including bone quality and quantity,[22] were also recorded. Osseointegration was determined by testing the implants for mobility and pain with a standardized torque wrench set at 20 Ncm. At baseline (insertion of the gold bar) and during the first annual visit, digitized periapical radiographs (DenOptix Dental Imaging System, Gendex) were taken using the long cone technique placed at a distance of 10 cm from the cone of the x-ray unit (Oralix AC System, Gendex). The radiographs were calibrated using the VixWin software (Gendex) calibration function, and the distance was measured from the shoulder of the implant, adjacent to the abutment, to the crest of the lowest plate of bone visible. Oral hygiene was observed and recorded as described previously.[17] The number and nature of clinical visits, along with the types and number of prosthodontic maintenance or complication issues, were recorded.

Statistical Analysis

Statistical analysis was completed using the SPSS statistical package (version 10, SPSS). The outcomes were implant success, maintenance outcomes, and number of visits. The Denture Satisfaction questionnaire and OHIP scores obtained at various stages were compared using the Wilcoxon signed rank test. Statistical significance for all tests was set at $P < .05$.

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Table 2 Descriptive Variables at the Patient Level

	Males (n = 3)*	Females (n = 12)*
Occupation		
Gainfully employed	2	7
Retired	1	—
Housewife	—	5
Health		
Healthy	—	2 (4)
Medically controlled condition	3 (6)	10 (21)
Smoking		
Smoker	2 (4)	1 (2)
Nonsmoker	1 (2)	11 (23)
Tooth loss		
Periodontal disease	2	10
Caries	1	2
Edentulous period		
0–1 y	2	3
1–10 y	1	8
> 10 y	—	1
Opposing dentition		
Complete dentures	3	11
Natural dentition or implant-supported prosthesis	—	1
Mandibular jawbone status		
Extraction, immediate implant placement, and loading	1 (2)	1 (2)
Healed jawbone	2 (4)	11 (23)
Surgical technique		
Full flap	1 (2)	3 (7)
Punch/minimal incision surgery	2 (4)	9 (18)
Crestal reduction		
None	2 (4)	10 (20)
Ridge reduction	1 (2)	2 (5)
Bicortical stabilization		
None	1 (2)	5 (11)
Achieved	2 (4)	7 (14)
Oral hygiene post–implant treatment		
Good	2 (4)	11 (22)
Poor	1 (2)	1 (3)
Jaw quality		
Type 1 and 4	—	—
Type 2 and 3	3 (6)	12 (25)
Jaw quantity		
Quantity A-B	2 (4)	6 (12)
Quantity C-D	1 (2)	2 (5)
Quantity E	—	4 (8)

*Numbers in brackets indicate the number of implants.

Table 3 Prosthodontic Maintenance at the Patient Level

Type of prosthodontic maintenance	Early loading
Clinical visits: 1-year (days)	
Presurgical visits including consults	4.00 ± 2.24
Postinsertion adjustments	2.80 ± 1.82
Complication visits	1.67 ± 1.10
Days prior to loading	8.06 ± 3.67
Denture easing	8
Damaged framework screws	—
Damaged abutment screws	—
Nonpassive retentive clip	4
Fractured denture teeth	—
Fractured overdenture	1
Fractured opposing denture	—
Loose framework	1
Laboratory reline of:	
Opposing denture only	2
Overdenture only	2
Remake of implant prostheses	—
Remake of new opposing denture	—
Conversion of overdenture to fixed prosthesis	1

Results

The implant success rate throughout the follow-up period was 100%. None of the surgical parameters had a direct impact on implant success. The mean bone loss measured during the first year of loading was 0.11 mm (standard deviation: 0.14 mm), and none of the independent variables had a statistically significant impact on bone level. The overall success rate of the original prosthetic treatment plan was 93%, since one patient had her overdenture converted to a fixed prosthesis. The patient variables are presented in Table 2. The prosthodontic maintenance was mainly related to the acrylic superstructure and included easing and relining of the dentures for two patients. Four patients had a nonpassive clip assembly on insertion that necessitated retaking of the impressions (Table 3). The patient-based treatment outcomes are presented in Table 4. A statistically significant reduction in the respective scores was observed with both questionnaires, which suggested an improvement, resulting from the denture treatment, as well as an increase in quality of life.

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Table 4 OHIP and Denture Satisfaction Scores (Mean ± SD)

	Baseline	1-y recall	*P**
OHIP scores			
Global	73.50 ± 21.43	29.00 ± 7.01	.002
Functional-related	43.83 ± 12.55	16.50 ± 3.26	.002
Psychosocial-related	29.67 ± 10.47	12.50 ± 4.54	.002
Denture satisfaction scores			
Maxillary denture	15.67 ± 7.02	7.33 ± 2.90	.008
Mandibular denture	21.42 ± 3.06	6.25 ± 1.60	.002
Functional variables	7.25 ± 2.18	2.58 ± 0.67	.003
Global	44.33 ± 10.76	16.17 ± 4.11	.002

OHIP = Oral Health Impact Profile; SD = standard deviation.
*Wilcoxon signed ranks test.

Discussion

This clinical report's limitations are acknowledged. The study had a small patient sample size and lacked a control group. However, preliminary observations suggest a high predictability for the mandibular overdenture technique supported with two Fixture Original implants placed in the mandibular interforaminal area. Indeed, the implant success rate of the implants was 100%, and the bone loss during the first year of loading was 0.11 ± 0.14 mm, a figure comparable to other implant systems.[12,13,15,17,18,23,24]

The notion of successful osseointegration is broader than the exclusive success of implants per se. Other parameters such as prosthetic maintenance, with the underlying concomitant impacts on economic outcomes and patient satisfaction, should also be addressed.

Attard et al[17] reported that although implant success outcomes were highly predictable, an economic evaluation[20] of the technique as a whole indicated that the early loading approach was more expensive than the conventional protocol. It was felt that the prosthodontic protocol required modifications, specifically postponing the processing of the dentures after the implant position was picked up in the impression. In addition, it was postulated that the surgical technique might have led to a high percentage of patients requiring relining of the overdenture's anterior housing area. In a previous study,[17] the surgical approach consisted of raising a full flap exposing the labial and lingual walls of the anterior mandible completely. In contrast, in this study, a very conservative technique was used, whereby a punch or localized incision was performed in the implant site without unnecessarily stripping the periosteum. A full flap was performed only in patients requiring ridge reduction or extraction to accommodate the implants.

A conservative surgical approach precluded extensive soft tissue remodeling. Various authors have noted changes in the soft tissues after an adequate healing period, sometimes necessitating relining of the overdentures or changing the abutment height. This was noted for both overdenture prostheses[13,15] and fixed prostheses.[9,25] On the other hand, in studies that placed healing abutments during the healing process, only minor complications were reported, such as loosening of the healing abutments or replacement with longer ones.[11,26] Packer et al[26] noted that only half of the definitive abutments placed in that study were the same length as the healing abutment, underscoring how hard it is to predict the eventual form of the soft tissues at the crest of the ridge and floor of the mouth.

This report suggests that a very conservative surgical approach, along with the fabrication of dentures after a pickup impression, might have led to a minimal need for additional prosthodontic intervention after prosthesis insertion. These favorable results also have a direct economic impact for both the patient and clinician. This underscores the notion that a loading protocol should be customized accordingly for each individual patient rather than sticking to a predetermined modus operandi.

Various authors have reported that modifications to the surgical protocol may improve success outcomes.[19] Interestingly, in the current study, none of these modifications impacted the results, even though the implant used had a machined surface. This outcome is likely to result from the favorable bone anatomy encountered in the anterior mandible rather than to the implant itself.

The improvement in both the Denture Satisfaction and OHIP scores confirms that the overdenture is an effective method in rectifying patients' functional complaints with conventional mandibular prostheses

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and improving their quality of life. In this study, data were not collected right after insertion of the overdentures, since it has been shown that the improvement in both scores is immediate and sustained during the first year and up to 5 years of longitudinal observation.[18]

Conclusion

This short-term prospective study suggests that Fixture Original implants can be loaded early with mandibular overdentures. This study is limited by the number of recruited patients and the short observation period, but it seems prudent to suggest that the conservative surgical approach and modified prosthodontic protocol employed led to minimal postinsertion maintenance needs. This outcome underscores the effectiveness of the overdenture approach in rectifying patients' complaints with conventional mandibular prostheses.

Acknowledgment

The authors wish to thank Brånemark Integration for providing a research grant to conduct this study.

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