JOURNAL of
OSSEOINTEGRATION

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Immediate occlusal loading of Tapered Internal Laser-Lok® implants in partial arch rehabilitations: a 24-months clinical and radiographic study

TO CITE THIS ARTICLE
Grande M, Ceccherini A, Serra M, Bava L, Farronato D, Iorio Siciliano V, Guarnieri R. Immediate occlusal loading of Tapered Internal Laser-Lok implants in partial arch rehabilitations: a 24-months clinical and radiographic study. J Osseointegr 2013;5(2):53-60.

KEYWORDS Crestal bone loss; Immediate functional loading; Laser-Lok® microtextured collar surface.

ABSTRACT

Aim The purpose of this 2 year prospective clinical study was to clinically and radiographically evaluate an implant with laser microtextured collar surface placed for immediate loading of fixed prostheses in cases of partial posterior maxillary and/or mandibular edentulism.

Materials and methods Thirty-five partially edentulous patients who needed implant treatment and met inclusion criterias were consecutively enrolled at different study-centers in Italy. A total of 107 Tapered Internal Laser-Lok® implants (49 maxillary and 58 mandibular) were placed and immediately loaded. All provisional constructions were delivered within 1 hour, and the final constructions placed after 4 months. A total of 107 Tapered Internal Laser-Lok implants (49 maxillary and 58 mandibular) were placed and immediately loaded. All provisional restorations were delivered within 1 hour, and the final prosthesis placed after 4 months. A total of 32 prosthetic restorations, consisting of 10 two- units, 12 three-units, and 10 four-units fixed partial dentures were evaluated. Clinical and radiographic outcomes were monitored at follow-up examinations scheduled 6, 12, 24 months after implants placement.

Results Five implants were lost after loading (3 implants in a two-unit maxillary restorations, 1 implant in a two-unit mandibular restorations, and 1 implant in three-unit maxillary restorations)giving a survival rate of 95.4% after 24 months. Mean crestal bone loss at 6, 12, and 24 months after implant insertion was 0.42 +/- 1.1 mm, 0.52 +/- 0.9 mm, and 0.66 +/- 1.3 mm, respectively.

Conclusion Although limited bytheshort follow-up, immediate function with Tapered Internal Laser-Lok® implants seems to be a viable option to treat partially edentulous patients.

INTRODUCTION

During the past decade, techniques of immediate and early loading of dental implants have gradually gained popularity (1). The rehabilitation of partially edentulous patients with immediately loaded standard diameter implants, in cases where suitable bone volume and quality is present, has been described by many authors (2-11). Various definitions for immediate or early implant loading can be found in the scientific literature (12). When the applied load is reduced, it may also be correct to use the term "immediate/early function" rather than "immediate/early loading" (13). Different publications have shown that with attention to specific factors, implant survival with immediate restoration in partially edentulous segments was comparable to the results of conventional protocols (14, 15). Factors that influence the outcomes of implant immediate loading can be divided into 4 categories (15) as follows.

- Surgery-related factors, pertaining to primary implant stability and a non-traumatic surgical technique.
- Host-related factors, pertaining to bone quantity and quality (density) and proper bone healing environment.
- Implant-related factors, pertaining to the influence of macro- (thread) and micro- (surface coating) structure of the implant.
- Occlusion-related factors, pertaining to the importance of occlusal forces and prosthetic design.

Implant primary stability has been identified by many authors as one of most important clinical factors influencing success of immediate loading (15-18), because transmission of micro-movements to the implant body can cause crestal bone loss or failure of osseointegration. The literature data (19) suggest that the critical micro-movements threshold above which fibrous encapsulation prevails over osseointegration, lies somewhere between 50 and 150 µ.

Beside from bone density, primary stability seems to be related to the surgical technique (underpreparation of the site) and particularly to the geometry of the implant. Experimental data (20) reporting the initial implant stability by the insertion torque and the resonance frequency, showed that the positioning of slightly tapered fixture in a cylindrical site gives a greater stability compared to cylindrical implants. Furthermore, clinical studies documented that tapered implant's survival rate in soft bone was higher than the one obtained with cylindrical implants (21, 22).

Bone quantity and bone quality are also important determinants with a major influence on immediate loading protocols (23). Traditionally, a good quality bone is a dense, cortical bone which allows fixture primary stability preventing micro-movements due to its strength and elevated mineral component (24). Torque measurements have been shown to reflect bone density (25, 26), and the clinical assessment of stability is often based on torque resistance measurements at the time of implant placement. An insertion torque value from 30 to 40 Ncm before the implant is finally seated is considered a sufficient value indicating the required stability for success (27-31).

Although implant surface characteristics do not seem to play an important role in primary stability achievement nor influence it, it is essential for the acceleration of the osseointegration process (20, 21, 32). It is generally acknowledged that rough surface implants usually have better success rates when compared to smooth surface fixtures (33). Due to this, in recent years, implant manufacturers have progressively abandoned smooth surface machined implants for rough/treated surfaces. However, it has been noticed that when the microstructure (or surface coating) of an implant was assessed in relation to immediate implant loading, neither animal nor human studies have shown significant differences in implant success regardless of which type of surface coating was used (34-36).

The majority of studies showed that occlusal disorder is a contraindication for immediate loading (37-39)and “maximum interocclusal contact without any lateral contact” is the recommended occlusal scheme which an immediate loaded implant restoration should receive (33).

Prosthetic design and surgical planning are other factors of great importance in immediate loading protocol. Several studies showed that adequate implant position, parallelism among fixtures, and splinting of the implants in case of multiple implant restorations can decrease the risk of overloading to each implant because of the greater surface area and better biomechanical distribution of the applied forces (40-42).

Using the principles of tissue engineering, recently some strategies have been developed, in an effort to improve hard and soft tissue integration and to prevent crestal bone loss which may be beneficial in immediate loading. Laser-microtexturing of surfaces is one of them. Tissue culture studies have demonstrated osteoblast and fibroblast cellular attachment to laser-microgrooved surfaces (43,44), as well as histological studies have proved connective tissue fibers attachment to Laser-Lok® microtexturing surface of implants and abutments (45, 46). The first clinical data presented (47, 48) show that implants with laser-microtexuted collar surface reduced crestal bone loss and probing depth (PD) when compared to machined-collar-implants; however the biological and clinical impact of this novel kind of laser microtxtured implant collar surface has not yet been thoroughly investigated, especially using different protocols.

The purpose of the present study was to clinically evaluate the outcome of immediate functional loading of BioHorizons Laser-Lok® tapered internal implants in cases of partial posterior maxillary and/or mandibular edentulism, and to evaluate radiographically the influence of Laser-Lok® microtextured implant surface on crestal bone loss (CBL).

MATERIALS AND METHODS

This multicentric prospective clinical study was private-practice based. All patients considered for inclusion in the study were examined and treated between January 2008 and December 2011 in several private dental practices in Italy all having extensive experience in the implant treatment. All patients signed a written informed consent form and were selected according to the following criteria.

- No contraindications for treatment, such as systemic diseases (e.g., diabetes), pregnancy, regular use of prescription medications or consumption of recreational drugs.
- Need for rehabilitation with implant-supported prosthesis (two to four units) in a partially unilateral edentulous mandible or maxilla.
- Adequate amount of bone height for placement of an implant with a minimum length of 9 mm in an optimal prosthetic position.
- Healed bone sites free from infection (at least 5 months following extraction).
- Sufficient primary stability (minimal insertion torque of 35 Ncm.
- Minimal ISQ value of 60 (Osstell™, Osstell AB, Gothenburg, Sweden).
- Signed informed consent to participate and to follow a maintenance and observation program for 24

FIG. 1 BioHorizons Laser-Lok® Tapered Internal Implant (on the left magnification X 700).

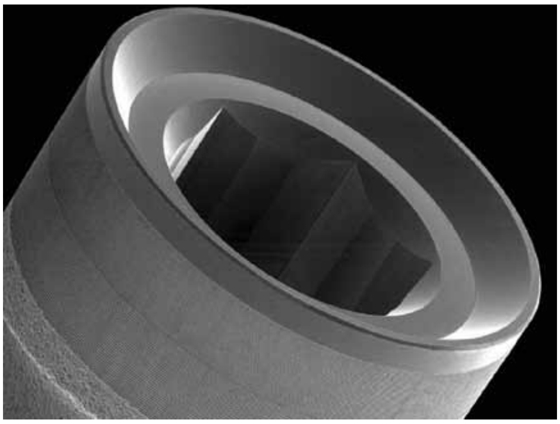

FIG. 2 BioHorizons Laser-Lok® Tapered Internal implant collar comprised of a 0.3 mm turned surface, a 0.7 mm microgrooves with an 8µ pitch, and a 0.8 mm microgrooves with a 12µ pitch.

DIAMETER MM	LENGTH MM	MANDIBLE	MAXILLA	TOTAL NUMBER
3.8	9	4	2	6
3.8	10.5	6	4	10
3.8	12	8	6	14
3.8	15	7	5	12
4.6	9	12	8	20
4.6	10.5	8	14	22
4.6	12	7	8	15
4.6	15	6	2	8

TABLE 1 Length and Diameter of 107 Inserted Implants.

BONE QUALITY	BONE QUANTITY				TOTAL NUMBER
	1	2	3	4	
A	-	2	5	2	9
B	8	10	18	13	49
C	-	13	15(1)	7 (1)	35 (2)
D	1	6 (1)	3	4 (2)	14 (3)
TOTAL	9	31	41	26	107

TABLE 2 Bone Quality and Quantity (failure within the brackets).

months which included postoperative radiographs.

Exclusion criteria were non compensated diseases, poor oral hygiene, severe maxilla-mandibular space discrepancies as well as presence of a "deep bite" and parafunctional habits (bruxism and clenching).

Periodontal status was assessed by a comprehensive periodontal examination, and patients with periodontitis were treated before implant surgery. A complete pre-surgical evaluation was performed for all patients, including a wax-up and fabrication of a surgical stent. All splinted provisional restorations were fabricated in the dental laboratory based on the wax-up. Each case was evaluated by examining diagnostic casts for the maxilla-mandibular relationship, intraoral radiographs or panoramic radiographs, and computed tomography scans. Demographic data, medical and dental health history, and smoking status were obtained by questionnaire.

BioHorizons Laser-Lok® Tapered Internal implants (Birmingam, AL, USA) were used in the study (Fig. 1). This implant is characterized by a positive tolerance, signified by a tapered geometry. It has a modified surface treated with resorbable blast media (roughness between 0.72 and 1.34 µ) and a dual bio-affinity collar with an implant neck consisting of two types of microgrooves. The implant neck is comprised of a 0.3 mm turned surface, a 0.7 mm microgrooves with an 8µm pitch, and a 0.8mm microgrooves with a 12 µm pitch (Fig. 2). A total of 107 implants with lengths of 9 to 15 mm and a diameter of 3,8 to 4,6 mm were inserted: 49 in maxillary posterior area and 58 in the posterior mandible (Table 1).

Surgical Treatment

Patients were given 2 g of amoxicillin (Zimox®, Pfizer, Italy Srl) before implant surgery. Under local anesthesia, the implant sites were exposed via a midcrestal incision followed by a releasing distal incision. A full thickness flap was elevated and the positions of the implants were marked with a round bur. Then, the receiving

FIG. 3

FIG. 4

FIG. 5

FIG. 6

FIG. 3-6 Example of three units mandibular restorations
FIG. 3 Implant placement and temporary abutments. FIG.4 Immediate temporary prosthesis made of acrylic with a metal reinforcement.
FIG. 5 Soft tissue healing 4 months after implants placement. FIG. 6 Final prosthesis made of porcelain casted on golden alloy.

sites were prepared with cylindrical burs of increasing diameter, according to the recommendations of the manufacture. In the presence of very soft bone, an under-preparation technique was used with a specific smaller final bur prepared by the manufacturer for each implant diameter. Bone quality and quantity were assessed according to Lekholm and Zarb's criteria (49) (Table 2).All surgical procedures were performed with the aid of a custom-made surgical stent. Every effort was made to maintain parallelism between the implants and the adjacent dentition. To obtain adequate primary stability, the implants had to achieve an initial torque value of at least 35 Ncm, which was facilitated by the tapered shape of the implants. After the final implant positioning, sterile impression coping were connected and the flaps were sutured. Impressions were taken with an open tray technique using Impregum NF® (ESPE, Seefeld, Germany). Following this, a provisional abutment was positioned (Fig. 3) on the implant, and a transducer was fixed on the abutment in order to analyze the resonance frequency (RFA). The implant stability (expressed in ISQ) measurements had to be above 60 (Ostell, Integration Diagnostic) to confirm primary stability. The ISQ stability values are determined by the rigidity of the implant/tissues interface and by the distance between the transducer and the first bone contact. Several studies have confirmed the correlation between the measurements with the resonance frequency and the

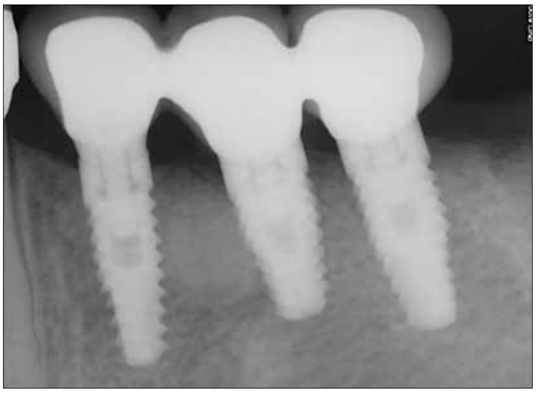

FIG. 7 Radiographs taken at 24 months follow-up (T3).

PARAMETERS	N	SUCCESS (%)	FAILURE (%)	EXPLANTATION
Implant	107	95.4	4.6	5
Gender				
Male	52	94.3	5.7	3
Female	55	96.4	3.6	2
Smokers				
Yes	67	94.1	5.9	4
No	40	97.7	2.3	1
Region				
Mandible	58	98.1	1.9	1
Maxilla	49	91.9	8.1	4

TABLE 3 Implant Success and Failure Rates.

	MANDIBLE	MAXILLA	TOTAL
Two units	5	6	11
Three units	6	5	11
Four units	7	6	13

TABLE 4 Prosthesis distribution according to the number of units.

rigidity of the implant in the bone tissue (50, 51), and a lower ISQ limit of 60 has been suggested for immediate implant loading (52).

Subsequently, a bite registration was taken in centric relation with occlusion waxes. The impressions were sent to the laboratory for the manufacturing of the temporary prosthesis. The patients were treated with a postsurgical antibiotic therapy (amoxicillin, Zimox®, Pfizer, Italy Srl), 1 g twice a day for 6 days, starting just before surgery, an anti-inflammatory therapy (nimesulide, Aulin®, Roche, Milan, Italy), twice a day for 4 days, and they were instructed to rinse with 0,2% solution of chlorexidine, twice a day for 10 days. Oral hygiene was limited to brushing around the implants with a soft toothbrush for the first 2 weeks. Thereafter, conventional brushing and flossing were re-established. Within 1 hour following surgery a temporary metal reinforced acrylic resin restoration was delivered and cemented with a temporary cement (Temp Bond, Kerr Co., Orange, CA, USA). No distal extensions were incorporated and a flattened cusp occlusal scheme was used as well as a platform switching design applied to the abutment (Fig. 4). Occlusion was in centric, with light contacts, possibly avoiding lateral and protrusion contacts. Occlusion marking paper had to leave lighter marks on the implant prosthesis compared to those of the adjacent teeth. After 4 to 6 months from implant placement (T1) (Fig. 5), provisional abutments and abutment screws were removed to assess implant stability by RFA. Final impressions were made directly on the abutments and a fixed final prosthesis made of porcelain casted on golden alloy was made and delivered (Fig. 6).

Radiographic Examinations

Intraoral radiographs were taken after implant insertion at baseline and then after 6 (T1), 12 (T2), and 24 (T3) months using a paralleling technique (Dentsply RINN, Elgin, IL, USA) for all radiographs (Fig. 7). Each radiograph was performed using a radiographic personalized stent for each patient, and examined by an independent radiologist. Radiographs were then digitalized using a dedicated scanner (HP 3000) with a resolution of 2,048 X 3,072 lines and converted into JPG files. A software package (AutoCAD 2000) was used to measure crestal bone loss (CBL). The program calculated vertical lines lengths, which represented CBL as the distance from the top of the implants to the crestal bone. Afterwards, CBL was calculated as the difference between follow-up and baseline value.

Implant Success Criteria

The following conditions were considered for implant success and recorded by a calibrated investigator for each implant: absence of fixture mobility, absence of peri-implant radiopacity/radiolucency at radiographic assessment, bone loss lower than 1.5 mm at 12 months radiographic exam, absence of suppuration, pain, infection and paresthesia. Failure was defined as removal of an implant due to any reasons.

Calibration of examiners

Examiners were calibrated by measuring the same 20 implants after 1 week, achieving an intraexamination reliability of 90% (data not shown). Examiners were recalibrated once after 6 months by measuring the same 10 implants following the initial protocol.

RESULTS

Five out of 107 implants were diagnosed as failed, giving a survival rate of 95.4% after 24 months, and were not included in the final study group (Tables 2 and 3). The failure occurred from 4 to 12 weeks after placement and interested 4 implants in the maxilla and 1 implant in the mandible. A total of 32 fixed partial dentures supported by 2 to 4 implants were fabricated (Table 4). Three failed implant were located in quality 4 bone, and 2 in quality 3 bone (Table 2). Three implants were

IMPLANT	SITE	LENGTH (MM)	DIAMETER (MM)	INSERTION TORQUE (NCM)	ISQ	N. OF UNITS	TIME AFTER SURGERY AND PROVISIONALISATION (WK)
1	15	12	3.8	35	80	2	6
2	26	10.5	4.6	35	78	2	4
3	16	10.5	4.6	35	84	2	8
4	46	12	4.6	35	81	2	5
5	17	12	3.8	35	75	3	12

TABLE 5 Characteristics of failed implants.

	MANDIBLE	MAXILLA	TOTAL
T1 (n=102)	0.43± 0.9	0.45 ± 1.3	0.43 ± 1.1
T2 (n= 91)	0.51 ± 0.8	0.53 ± 1,0	0.52 ± 0.9
T3 (n=75)	0.68 ± 1.5	0.64 ± 1.1	0.66 ± 1.3
n= number of sample			

TABLE 6 Mean Crestal Bone Loss (mm).

lost in a two-unit maxillary restoration, 1 implant was lost in a two-unit mandibular restoration, and 1 implant was lost in a three-unit maxillary restoration (Table 5). All the failed implants were successfully replaced with another implant after 4 months of healing, and loaded with delayed loading protocol. RFA showed an average ISQ of 72.8±3.2 at placement and 70.5±4.1 at T1. A marginal bone remodeling of 0.42mm±1.1 mm, 0.52 mm±0.9 mm, and 0.66 mm±1.3 mm was observed at T1, T2, and T3 respectively (Table 6). No statistical differences were observed for implant length, mesial or distal bone levels, or the insertion torque values measured.

DISCUSSION

The present study confirms the results from previous clinical investigations that good outcomes can be obtained with immediate loading of implants positioned in the posterior upper and lower partial edentulous areas (14, 15). Immediate loading protocols offer obvious advantages for the patient, such as a momentary reduction of oral handicap and decreased surgery and chair time, since abutment connection surgery is not needed. In accordance with data from the literature (14-15), in the present study we have used screw implants with tapered design, rough surface, and with a minimum insertion torque value of 35 Ncm. Furthermore, a baseline resonance frequency threshold value of 60 ISQ was set as a minimum stability value in order to perform immediate function.

The survival rate of 95.4% found in the present study is in agreement with the data reported in the literature, which show a cumulative failure rate of implant supported fixed dental prostheses of 4.4% in a short time follow-up (53). Most of the lost implants in the present study were two unit prostheses. According with our results, a higher risk of implant failure in two-unit fixed partial prostheses compared to three/four-unit fixed partial prostheses is reported also by Margossian and coworkers (54). This outcome suggests that the number of units in a prosthesis may positively impact implant stability during bone healing. In fact prostheses might work as an external rigid fixation device that splints the implants together and therefore reduces micro-movements. This concept is today also supported by a recent literature review (55), which emphasizes that in immediate implant loading protocols, splinted prostheses showed a higher success rate (94.7%) than those of implants restored with non splinted restorations (88.4%), regardless of implant design.

Another factor contributing to the good results of the present study is probably the modified site preparation protocol aiming for high primary stability, by using smaller final twist drills depending on bone quality. The modified surgical technique that we performed had been previously evaluated by Ostman and coworkers (52) in a study in which the primary stability of 905 implants was evaluated with RFA. Based on the results of the study, the authors suggested that when an immediate loading protocol is applied the drilling surgical technique cannot be standardized but needs to be modified according to the bone quality found.

Marginal bone loss represents an important indicator for peri-implant health, and its level is considered a determining factor in the evaluation of survival quality (and thus of primary outcome), since peri-implant bone loss may induce pocket formation. This could be unfavorable for the long term health of the peri-implant tissues (56). The values generally accepted as a reasonable guideline for crestal bone loss since the late 80's is -1.5 mm for the first year post-loading of the implants and -0.2 mm of additional loss for each following year (57, 58). It must also be emphasized that data present in the literature (59) show that once immediately loaded or restored, implants integrated successfully presented a peri-implant tissue reaction comparable with those of the conventionally loaded implants. No evidence suggested that peri-implant mucosal complications could be directly attributed to immediate loading or restoration protocols. The precise mechanisms of crestal bone resorption around dental implants is not yet completely known. Bone loss may result from implant design, bone density, surgical trauma at implant insertion or at second-stage surgery, occlusal overload, apical migration of crevicular epithelium in an attempt to isolate bacterial-induced infection or to establish a biological width, blood supply interruption, or development of a pathogenic bacterial biofilm (60-64). Previously histological experimental studies highlighted that Laser-Lok® microtextured collar implant surface primarily influence cortical bone remodeling around the implant neck (46). Using a standard loading protocol with Laser-Lok® implants, Botos and coworkers (48) reported a mean crestal bone loss at 1 year of 0,42 mm, while at 3 years Shapoff (68) and Pecora and coworkers (47) reported a mean crestal bone loss of 0,46 mm, and of 0,59 mm, respectively. Results of our study are in agreement with these data, showing a mean crestal bone loss of 0.66 mm±1.3 mm after two years of function, but support also the hypothesis that Laser-Lok® microtextured collar may lead to a decreased amount of initial crestalbone loss also when implants are immediately loaded. Today there is histologic evidence of a mechanical attachment of connective tissue fibers to Laser-Lok® microtexturing surface of implants placed both in native bone (46) and in fresh extraction sites (65). It has been suggested that this direct connective tissue attachment might serve as a physiological barrier to the apical migration of the junctional epithelium, and prevent crestal bone resorption (46). However, to confirm this ipothesys further histological researches are needed, especially comparing Laser-Lok® implants in different loading conditions. While the present study did not demonstrate histologic evidence of a connective tissue attachment to the collar of immediate loaded implants, within the limits of the investigation it is possible conclude that immediate functional loading of Laser-Lok® Tapered Internal implant in partially edentulous arches leads to a short term treatment outcome that seems to be not less favourable than conventional loading, and with no adverse peri-implant consequences after 24 months of function in highly motivated patients with excellent oral hygiene. However, it is correct to remember that the concept of immediate loading should be performed according to a specified protocol with attention to adequate primary implant stability, careful patient instruction, the use of a resilient acrylic resin for the fabrication of the temporary restoration, the exclusion of parafunctional/bruxist patients and, the immediate splinting of the implants.

Acknowledgment

This study has been supported by a grant from Classimplant, Rome, Italy.

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