# Influence of Laser-Lok Surface on Immediate Functional Loading of Implants in Single-Tooth Replacement: A 2-Year Prospective Clinical Study

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University of Naples Federico II
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# Influence of Laser-Lok Surface on Immediate Functional Loading of Implants in Single-Tooth Replacement: A 2-Year Prospective Clinical Study

*Davide Farronato, DDS, PhD, PD[1]/Francesco Mangano, DDS[2]*
*Francesco Briguglio, DDS[3]/Vincenzo Iorio-Siciliano, DDS, PhD[4]*
*Francesco Riccitiello, MDS[5]/Renzo Guarnieri, MD, DDS[1]*

*The purpose of this study was to evaluate the influence of a Laser-Lok microtexturing surface on clinical attachment level and crestal bone remodeling around immediately functionally loaded implants in single-tooth replacement. Seventy-seven patients were included in a prospective, randomized study and divided into two groups. Group 1 (control) consisted of non-Laser-Lok type implants (n = 39), while in group 2 (test), Laser-Lok type implants were used (n = 39). Crestal bone loss (CBL) and clinical parameters including clinical attachment level (CAL), Plaque Index (PI), and bleeding on probing were recorded at baseline examinations and at 6, 12, and 24 months after loading with the final restoration. One implant was lost in the control group and one in the test group, giving a total survival rate of 96.1% after 2 years. PI and BOP outcomes were similar for both implant types without statistical differences. A mean CAL loss of 1.10 ± 0.51 mm was observed during the first 2 years in group 1, while the mean CAL loss observed in group 2 was 0.56 ± 0.33 mm. Radiographically, group 1 implants showed a mean crestal bone loss of 1.07 ± 0.30 mm compared with 0.49 ± 0.34 mm for group 2. The type of implant did not influence the survival rate, whereas Laser-Lok implants resulted in greater CAL and in shallower radiographic peri-implant CBL than non-Laser-Lok implants.*
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[1]Assistant Professor, Department of Biomaterial Sciences, Insubria University, Varese, Italy.
[2]Private Practice, Gravedona, Como, Italy.
[3]Assistant Professor, Istituto Policattedra di Odontostomatologia University of Messina, Messina, Italy.
[4]Assistant Professor, Department of Periodontology, University of Napoli Federico II, Napoli, Italy.
[5]Professor, Department of Restorative Dentistry, University of Napoli Federico II, Napoli, Italy.
[6]Freelance Researcher, SCS Scientific Consulting Services, Rome, Italy.

Correspondence to: Dr Renzo Guarnieri, SCS Scientific Consulting Services, via Paolo Emilio, Rome 00144, Italy; email: guarnierirenzo@gmail.com



The use of osseointegrated implants to support prosthetic reconstructions has become a common treatment modality for partially and completely edentulous patients. Even in cases of single-tooth replacement, implant therapy was demonstrated in long-term prospective studies to be a predictable and successful treatment procedure.[1–6] The presented data were based on treatment methods in which the implants were left unloaded for different periods of time (between 3 and 6 months) to provide osseointegration. High clinical success rates with the original treatment protocol have given clinicians and researchers confidence to further develop and refine the osseointegrated technique, and a trend toward shorter treatment periods to allow immediate or early loading of implants has been advocated.[7–17] Accordingly, in the past decade, immediate and early loading of dental implants are techniques that are gradually gaining popularity, and several consensus conferences have been held on the topic.[18–21] The existing literature provides definitions for immediate loading, early loading, and immediate nonocclusal loading that sometimes differ. Immediate loading usually refers to the placement of a restoration in functional contact at the time of implant placement.[19] Early loading is usually defined as the placement of a restoration after an adequate healing time, shorter than that of the original Branemark protocol.[22] Immediate nonocclusal loading refers to the placement of a restoration that is not in functional contact at the time of implant placement.[19] However, as in single-tooth replacement, because the applied load is often reduced or even absent, the use of the term "immediate/early function" has been proposed rather than "immediate/early loading."[19]

There are few studies on immediate functional loading of implants used for single-tooth replacement[17,20–27]; however, published data demonstrated that immediate functional loading of implants placed with conventional placement technique and with sufficient primary stability may be considered a valid treatment alternative in single-tooth replacement. The possibility of rehabilitating the function and esthetics of a patient in a very short period is without any doubt one of the main reasons why immediate functional loading is performed, and new implant surfaces are continually proposed in an effort to improve hard and soft tissue integration, which may be beneficial in immediate loading situations.[28–32] The aim of this study was to evaluate the outcome of immediate functional loading of implants in single-tooth replacement using two different BioHorizons Tapered Internal implants. Both implants have the same design and the same surface treated with resorbable blast media, with the exception that the Laser-Lok implant has a dual bio-affinity collar consisting of two types of laser microtexturing grooves (8 and 12 μm).

## Method and materials

This randomized clinical trial was approved by the Institutional Review Board of the University of Naples, Naples, Italy (Prot. 7413). All patients considered for inclusion in the study were examined and treated between January 2008 and December 2011 in four Italian dental clinics, all having extensive experience in implant treatment. Treatments were performed in accordance with the Helsinki Declaration, and all patients were informed that two different implants were employed and gave their informed consent. The study group was formed from 78 implants that were placed in 77 patients (36 men and 42 women; mean age: 49.3 years; range: 45 to 65 years) referred for implant therapy who required single-tooth rehabilitation in the middle to anterior area of the maxilla and the middle to anterior area of the mandible. The implant sites were randomly allocated to one of the following treatment groups. In group 1 (control), BioHorizons Tapered Internal non-Laser-Lok type (n = 39) implants were used, while in group 2 (test) BioHorizons Tapered Internal Laser-Lok type (n= 39) implants were used. A randomization protocol was produced from a computer-generated list for the distribution of subjects into the two treatment groups. Minimization was used for the age variable (≤ 30 years, > 31 ≤ 60 years, > 60 years). The preoperative assessments included clinical and radiographic examinations using intraoral radiographs and sometimes orthopantomography and/or computed tomography scans.

Patients were selected according to the following criteria: *(1)* no contraindications for treatment, such as systemic diseases (eg, diabetes), pregnancy, regular use of prescription medications, or consumption of recreational drugs; *(2)* single tooth loss with neighboring teeth in normal occlusion; recipient sites for implants that had healed for ≥ 3 months following tooth extraction; *(3)* teeth adjacent to the implant area (mesially and distally) be present and free of overhanging or insufficient restoration margins and/or caries (restorations and caries lesions were repaired during the initial professional oral hygienic therapy); *(4)* available bone for at least 9-mm-long and 3.8-mm-wide implants; and *(5)* a minimal peak insertion torque of 35 Ncm.

Bruxism, the presence of a deep bite in the superior central incisors, and periodontal disease were considered only as risk factors. Patients with periodontitis were treated before implant surgery.

The exclusion criteria were *(1)* noncompensated diseases; *(2)* poor oral hygiene; and *(3)* patients smoking > 10 cigarettes a day. Patients

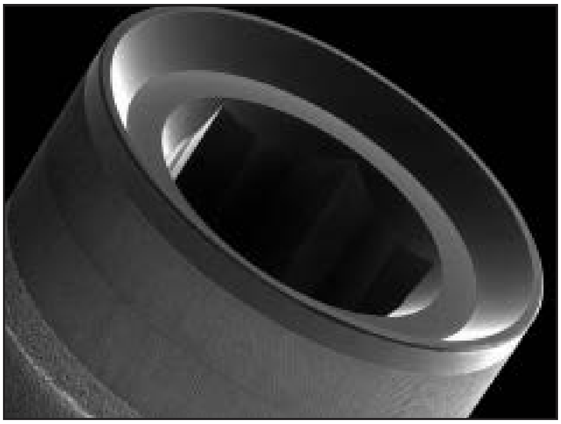

**Fig 1** *Laser-Lok Tapered Internal implant collar composed of a 0.3-mm turned surface, 0.7-mm microgroove with an 8 mm microgrooved pitch, and 0.8-mm microgroove with a 12 mm microgrooved pitch.*

**Fig 2** *Orthopantomography of the patient who received two implants (a Laser-Lok in the maxillary right first premolar and a non-Laser-Lok in the maxillary left first premolar).*

received detailed information on the two types of implants and a full description of the surgical procedures and possible risks of immediate loading.

For each patient, diagnostic casts were made and mounted on a semiadjustable articulator using a facebow and bite registration. Occlusal analysis was performed, diagnostic wax-ups were prepared on the articulated casts, and restorative treatment needs were determined. Demographic data, medical and dental health history, and smoking status were obtained through the use of a questionnaire. Periodontal status was determined by a comprehensive periodontal examination. All patients demonstrated good oral hygiene and compliance (probing depth [PD]: 1.8 ± 0.7 mm; bleeding on probing [BOP]: 4%; Plaque Index [PI]: 6%).

### *Implants*

Two different BioHorizons Tapered Internal implants were used. Both implants have the same design and the same surface treated with resorbable blast media (roughness between 0.72 and 1.34 μm), with the exception that the Laser-Lok implant has a dual bio-affinity collar with an implant neck consisting of two types of microgrooves. The implant neck comprises a 0.3-mm turned surface, a 0.7-mm microgroove with an 8-μm pitch, and a 0.8-mm microgroove with a 12-μm pitch (Fig 1).

### *Surgery*

Implants were placed using a one-stage surgical approach (Fig 2). Surgical access was carried out using a full-thickness flap at the level of keratinized mucosa to minimally extend the release incision to expose the crest and vestibular limit of the bone. Site preparation was performed, and final implant positioning was carried out using a torque driver (Precise Adjustable Torque Wrench, BioHorizons). Inclusion criterion was a final torque of at least 35 Ncm. The receiving sites were prepared with cylindrical burs of increasing diameter, according to the manufacturer's recommendations. Bone quality and quantity were assessed according to Lekholm and Zarb criteria.[33] In the presence of soft bone (type 3 to 4), an underpreparation technique was performed using a specifically thinner final bur. In type 3 to 4 bone, a 3.2-mm drill and 3.7-mm final drill were used for implants of 3.8-mm and 4.6-mm diameter, respectively.

**Fig 3** *Example of single-unit treatment with Laser-Lok implant in maxillary right first premolar. The patient was unhappy with the esthetics of the partial denture and wanted separated teeth. Therefore, the old denture was replaced with a single crown.*

*Implant loading*

After the complete positioning of the implants, sterile impression transfers were connected and the flaps were sutured where needed. Impressions were taken with an open tray using Impregum NF (3M ESPE) and the jaw relationship was recorded. The provisional acrylic resin crowns were fabricated the same day and cemented with temporary cement (TempBond, Kerr). The crowns were not in contact both in centric occlusion and in lateral guidance with a minimum free space of 1 mm to the opposing teeth. The occlusion marking paper of 0.2-mm-thickness was not kept by the occlusion at the level of the implant. A fixed final prosthesis made of porcelain casted on gold alloy or zirconia was made after 4 to 6 months (66 after 4 months, 7 after 6 months, and 5 after 5 months). A patient treated with a Laser-Lok implant in the maxillary right second premolar and a nonLaser-Lok implant in the maxillary left first premolar is shown in Figs 3 to 5.

*Medication and postoperative care*

Patients scheduled for surgery were prescribed an analgesic (ibuprofen 600 mg immediately after the surgical intervention and after 8 hours), a systemic antibiotic (amoxicillin plus clavulanic acid 1 g twice daily for 7 days), and a chlorhexidine digluconate solution 0.12% rinse (twice daily for 1 minute). Sutures were left in place for 10 days. During the healing period, patients received oral hygiene instructions and debridement, if necessary, at monthly appointments with the dental hygienist. At the time of definitive crown placement, patients were enrolled in a maintenance program consisting of semiannual follow-up appointments. At the follow-up visits, oral hygiene instructions were given and debridement and polishing were performed. BOP, PI, and clinical attachment level (CAL) were recorded on four surfaces of each implant. CAL, defined as the distance in millimeters between the deepest point of the peri-implant pocket and the coronal margin of the implant, was estimated by the use of a periodontal probe (PCP-UNC 15, Hu-Friedy).

**Fig 4** *Example of single-unit treatment with non-Laser-Lok implant in the maxillary left first premolar.*

**Fig 5** (a) *Before treatment,* (b) *after treatment.*

Measurements were recorded at the time of definitive crown placement (baseline [BSL]) and at 6- (T1), 12- (T2), and 24-month (T3) examinations.

*Radiographic examination*

For each patient, periapical radiographs (Ultra-speed A, Eastman Kodak) by means of a 65 kV dental x-ray unit equipped with a long-cone (Oralix 65 S, Gendex Dental Systems) were exposed after implant surgery at BSL, T1, T2, and T3. For the radiographic procedures,

**Table 1 Implant success and failure rates among 78 patients**

| Parameter | n | Success (%) | Failure (n) |
|---|---|---|---|
| Implant type | | | |
| Laser-Lok | 39 | 96.1 | 1 |
| Non-Laser-Lok | 39 | 96.1 | 1 |
| Sex | | | |
| Male | 36 | 96.4 | 1 |
| Female | 42 | 95.8 | 1 |
| Smoker | | | |
| No | 50 | 94.9 | 2 |
| Yes | 28 | 100 | 0 |
| Arch | | | |
| Maxilla | 42 | 95.8 | 1 |
| Mandible | 36 | 96.4 | 1 |
| Site | | | |
| Maxillary incisor | 14 | 100 | 0 |
| Maxillary canine | 16 | 98.4 | 1 |
| Maxillary premolar | 12 | 100 | 0 |
| Mandibular incisor | 15 | 100 | 0 |
| Mandibular canine | 11 | 100 | 0 |
| Mandibular premolar | 12 | 89.8 | 1 |
| Total | 78 | 96.1 | 2 |

a silicone index material was fixed to the maxilla and a radiograph holder was constructed for each patient. This technique ensured that the same position of the radiograph film could be reproduced at each visit and the angle of the radiograph would not deviate despite changes to the occlusal surface when the provisional fixed partial denture was replaced with the permanent restoration. The radiographs were then digitalized using a dedicated scanner (HP 3000) with a resolution of 2,048 × 3,072 and converted into JPG files. A software package (AutoCAD 2000) was used to calibrate the image at a 1:1 ratio, referring to the implant length and diameter, and to take measurements. The distance from the connection of the implants to the first bone-to-implant contact was measured parallel to the major axis of the implant. The delta between the measured lengths at T1, T2, T3 and the BLS length defines the CBL as the mean between the two sides of the implant.

*Success rating*

Success criteria according to Albrektsson and colleagues[34] were applied, including the absence of implant mobility and absence of pain and neuropathy. Failure was defined as the removal of an implant for any reason.

*Data analysis*

The Kolmogorov-Smirnov test was used to detect significant deviation outcomes from the normal distribution. Nonparametric methods were used to investigate to what degree age, sex, smoking, arch, region, or implant type influenced CAL and CBL measurements from BSL to T3. Changes in CAL and CBL were similarly evaluated. All statistical tests were two-sided, and the level of significance was set at 0.05%. The statistical analysis was performed using statistical software (SPSS for Windows, IBM).

## Results

This study reported on the longitudinal observation of 78 implants divided into two groups: 39 implants in group 1 and 39 in group 2. Forty-two implants were placed in the maxilla (22 Laser-Lok and 20 non-Laser-Lok) and 36 were placed in the mandible (17 Laser-Lok and 19 non-Laser-Lok) (Tables 1 to 3).

Two implants (3.9% of total implants placed) were lost and not included. The implant failures presented with a sudden onset of pain, suppuration of exudates, and mobility. The two groups showed no significant difference in implant failures (group 2: 3.9% versus group 1: 3.9%; $\chi^2$ test; $P > .05$).

**Table 2 CAL outcomes (mean ± SD)**

| | CAL (mm)* | | | |
|---|---|---|---|---|
| | BSL | T1 | T2 | T3 |
| Non-Laser-Lok | 0.63 ± 0.31 | 0.78 ± 0.26 | 0.99 ± 0.27 | 1.10 ± 0.30 |
| Laser-Lok | 0.34 ± 0.21 | 0.44 ± 0.38 | 0.54 ± 0.32 | 0.56 ± 0.33 |

CAL = clinical attachment level; BSL = baseline; T1 = 6 months after loading; T2 = 12 months after loading; T3 = 24 months after loading.
*$t$ = 3.4675, $P$ = .0133; the difference between the observed means is significant ($P$ < .05).

**Table 3 CBL outcomes (mean ± SD)**

| | CBL (mm)* | | | |
|---|---|---|---|---|
| | BSL | T1 | T2 | T3 |
| Non-Laser-Lok | 0.39 ± 0.17 | 0.80 ± 0.31 | 1.02 ± 0.29 | 1.07 ± 0.30 |
| Laser-Lok | 0.19 ± 0.13 | 0.36 ± 0.20 | 0.41 ± 0.27 | 0.49 ± 0.34 |

CBL = crestal bone loss; BSL = baseline; T1 = 6 months after loading; T2 = 12 months after loading; T3 = 24 months after loading.
*$t$ = 2.7338, $P$ = .0340; the difference between the observed means is significant ($P$ < .05).

The variables sex, age, smoking, arch, and position showed no significant influence on implant removal ($\chi^2$ test; $P$ > .05) (Table 1).

Univariate statistical analysis showed no significant effects of age (Spearman correlation; R < 0.2; $P$ > .05), sex, smoking, arch, or position (*U* test; $P$ > .05) on CAL and CBL outcomes or for CAL and CBL change between different time examinations. A general comparison of CAL outcomes (Table 2) for BSL to T3 instead showed a significant change ($P$ < .05), with a CAL for group 1 (1.10 ± 0.51 mm) significantly higher than in group 2 (0.56 ± 0.33 mm) over the total observation period. CAL loss at BSL was 0.34 ± 0.21 mm for group 2 and 0.63 ± 0.31 mm for group 1. A CAL loss of 0.44 ± 0.38 mm was observed at T1 for group 2, and for group 1 was 0.78 ± 0.26 mm; at T2 and T3, a CAL loss was of 0.54 ± 0.32 mm and 0.56 ± 0.33 mm for group 2, and 0.99 ± 0.27 mm and 1.10 ± 0.30 mm for group 1, respectively, was detected. Radiographic results of CBL are summarized in Table 3. At BSL, T1, T2, and T3, group 2 had a mean CBL of 0.19 ± 0.13 mm, 0.36 ± 0.20 mm, 0.41 ± 0.27 mm, and 0.49 ± 0.34 mm, respectively, compared to 0.39 ± 0.17 mm, 0.80 ± 0.31mm, 1.02 ± 0.29 mm, and 1.07 ± 0.30 mm, respectively, for group 1. Results showed a significant statistical correlation between the two groups ($P$ < .05). Univariate analysis of %BOP and %PI at each examination, as well as changes between examinations, demonstrated no significant influence of age, sex, smoking, implant type, arch, or region (*U* test; $P$ > .05).

## Discussion

Several animal studies have shown that the bone-to-implant contact of implants with immediate functional loading is comparable with that of implants loaded conventionally.[35–39] Histologic studies in humans have confirmed these experimental results in both the mandible and maxilla.[40–44] Bone density (bone quantity, bone quality) and implant stability have been considered important determinants with a major influence on immediate loading protocols.[45–48] Primary implant stability is dependent upon bone density, but also on the technique and accuracy of the osteotomy preparation as well as implant design and surface.[49,50] The clinical assessment of primary stability is often based on insertion torque measurements, and torques of 30 to 40 Ncm may ensure that sufficient stability has been achieved.[51–55] Primary stability, defined as the mechanical anchorage of the implant in the bone bed upon insertion, tends to decrease during the first weeks following the positioning and is progressively replaced by an anchorage of biologic type, tied to the implant surface and defined as secondary stability.[49,56] Secondary stability depends on bone formation and remodeling at the implant-bone interface and is influenced by the implant surface and the wound healing time. New implant designs and surfaces have been proposed in an effort to enhance primary and secondary stability, which may be beneficial in immediate loading situations.[28–32] To facilitate adequate primary stability, a screw implant design has been shown to have a higher mechanical retention as well as greater ability to transfer compressive forces.[50,57] While the surface does not seem to have any particular influence on primary stability, it may influence secondary stability in a determining way, accelerating the osseointegration process.[28–32,57,58] As suggested by the aforementioned literature, data for the present study used screw implants with tapered design, a rough surface, and an insertion torque value of at least 35 Ncm. Results demonstrated no significant difference between the 2-year survival rates of the two types of implants. Similar survival rates were found for both groups (group 1: 96.1%; group 2: 96.1%) and were not influenced by arch, region, age, sex, or smoking habits. These data are in agreement with previous studies[17,23–27] that demonstrated similar survival rates for implants used for single tooth replacement with early/immediate functional loading. In the present study, an interesting result emerges from the comparison of the results of the CAL and CBL. A mean CAL loss of 1.10 ± 0.51 mm was observed during the first 2 years in the group 1, while the mean CAL loss observed in group 2 was 0.56 ± 0.33 mm. Moreover, group 2 implants showed a mean CBL of 0.49 ± 0.34 mm compared with 1.07 ± 0.30 mm for group 1. In a previous study using a standard protocol with Laser-Lok implants loaded after a healing period of 4 to 6 months, Botos and coworkers[57] reported a mean crestal bone loss of 0.42 mm at 1 year, while Shapoff and coworkers[58] and Pecora and coworkers[59] reported a mean crestal bone loss at 3 years of 0.46 mm and 0.59 mm, respectively. In the study by Pecora and coworkers,[59] implants with a laser microtextured collar surface were numerically superior to control implants with a machined collar surface in terms of crestal bone loss at each month after month 1, and this difference increased numerically at each successive visit. Results of the present study confirm these data, showing that at baseline, group 2 implants had a reduced CAL and CBL compared with group 1 implants that remained reduced throughout the follow-up period. The results also support the hypothesis that a Laser-Lok microtextured collar may lead to a decreased amount of CAL and CBL when implants are immediately loaded. The impact and additional value of a microtextured implant collar on peri-implant bone level is currently unclear. However, in vitro studies have investigated the effect of a microgrooved surface with features in the range of 2 to 12 microgrooves with respect to attachment, spreading, orientation, and growth of fibroblast and osteoblast precursors.[60,61] Surfaces with 12 microgrooves showed the best potential for inhibition of fibroblast cell type growth relative to osteoblast cell type growth, while surfaces with 8 microgrooves showed the most effective inhibition of cell migration across the grooves. Two configurations (8-μm and 12-μm feature sizes) of laser micromachined surfaces were then applied to the collars of experimental dental implants, with the microchannels oriented circumferentially around the collar, and tested in animals.[63] These surface were found to attach to fibrous tissue and prevent epithelial downgrowth. Human histologic studies[62,63] also confirmed the results observed in the animal model, and today there is histologic evidence of a mechanical attachment of connective tissue fibers to Laser-Lok microtexturing surface of implants placed in both native bone[63] and in fresh extraction sockets.[65] It has been suggested that this direct connective tissue attachment might serve as a physiologic barrier to the apical migration of the junctional epithelium, preventing crestal bone resorption and preserving the coronal level of bone.[65] However, to confirm this hypothesis, further histologic research is 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 a Laser-Lok implant subjected to immediate loading, there is statistically significant evidence of smaller CBL and greater CAL in group 2 compared with group 1. Within the limits of the present study, clinical and radiographic evaluations suggest that immediate/early function with BioHorizons Tapered Internal implants is a reliable option in single-tooth replacement. Furthermore, it appears that in an immediate/early functional implant loading protocol, a Laser-Lok microtextured surface on an implant collar may mitigate or eliminate the negative sequelae connected with peri-implant bone loss.

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