Immediate Loading of Single Implants: A Two-Year Prospective Multicenter Study

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The aim of this prospective multicenter study was to evaluate the outcomes of single implants subjected to immediate functional loading. Inclusion criteria were single-tooth placement in postextraction sockets or fully healed sites, and sufficient bone height and width to place an implant of at least $3.5 \times 10.0 \text{ mm}$. All implants were functionally loaded immediately after placement and followed for 2 years. Outcome measures were implant survival, complications, and peri-implant marginal bone loss (MBL). A total of 57 implants (38 maxilla, 19 mandible) were placed in 46 patients (23 men, 23 women, aged 18–73 years). Of these, 10 implants were placed in postextraction sockets. One implant failed, in a healed site, giving a patient-based overall 2-year survival rate of 97.6%. The incidence of biologic complications was 1.8%; prosthetic complications amounted to 7.5%. The peri-implant MBL was $0.37 \pm 0.22 \text{ mm}$ (healed sites: $0.4 \text{ mm} \pm 0.22$; postextraction sockets: $0.3 \text{ mm} \pm 0.22$). The immediate functional loading of single implants seems to represent a safe and successful procedure. Long-term follow-up studies on a larger sample of patients are needed to confirm these results. Int J Periodontics Restorative Dent 2017;37:69–78. doi: 10.11607/prd.2986

Dental implants are a proven solution for the rehabilitation of partial and total edentulism, and the survival of fixed implant-supported restorations is now very high. For this reason, more patients are asking to be rehabilitated with implants. Implants represent a successful solution even in single-tooth gaps, as demonstrated by a large number of studies and systematic reviews. In recent years, implantology has increasingly advocated the concept of immediate loading, even in the case of rehabilitation with single implants. Immediate loading is defined as the placement of a prosthetic restoration within 48 to 72 hours of implant placement. Among the advantages of immediate loading is an overall reduction of treatment times, with functional, cosmetic, and psychologic benefits for the patient. With this procedure, the fixed prosthetic restoration can be positioned in occlusion (immediate functional loading) or it can be drained by the occlusion (immediate nonfunctional restoration). The difference between these two procedures is the force ideally exerted on the implant by the fixed prosthetic restoration positioned on it. This is not a trivial matter. On one hand, immediate loading is greatly successful in complex rehabilitations that provide for the placement of numerous

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implants splinted between themselves, as shown by numerous clinical studies.\textsuperscript{8,11,12} On the other hand, there is less evidence in the literature regarding the immediate loading of implant-supported single crowns, especially in the posterior region.\textsuperscript{13} The transmission of the load on the implant during the healing period and immediately after placement could lead to micromovements at the interface between the bone and the implant, compromising healing and osseointegration.\textsuperscript{14} Immediate nonfunctional restoration provides for the transmission of a certain amount of loading on the underlying implant.\textsuperscript{8,10} Especially in the posterior area, the forces of chewing and those determined by musculature (eg, those transmitted by the tongue in the mandibular arch) will act in some way on the implant even in the absence of specific occlusal contacts.\textsuperscript{15} However, it is evident that immediate functional loading carries a higher risk, especially in the case of implant-supported single crowns in the posterior area.\textsuperscript{15} Different surgical protocols are now available for the rehabilitation of single-tooth gaps with implants.\textsuperscript{15,16} These include immediate implant treatment (IIT) within 48 hours of extraction of the affected tooth, early implant treatment (EIT) 4 to 8 weeks after extraction, and conventional implant treatment (CIT) performed on complete healing of the surgical site 4 to 6 months after extraction.\textsuperscript{15,16} Although all of these surgical techniques can ensure high success and survival rates, immediate implant treatment in the postextraction site may represent an additional risk factor for implant failure, especially where adequate or satisfactory primary implant stability has not been obtained.\textsuperscript{16,17} To date, few studies have addressed the topic of immediate functional loading with implant-supported single crowns,\textsuperscript{18–25} and even fewer have addressed the issue of single implants placed in postextraction sockets and immediately loaded.\textsuperscript{21,22,25} The purpose of this prospective multicenter study with 2 years follow-up was therefore to assess survival, complications, and peri-implant marginal bone loss (MBL) of single implants placed in healed sites and in postextraction sockets and subjected to immediate functional loading.

\section*{Materials and methods}

\subsection*{Patient selection}

This prospective study is based on data from patients treated with immediately loaded single implants in six different dental centers, under the same protocol. In the period between February 2012 and February 2013, patients were selected for treatment based on the following inclusion criteria: patients with single-tooth gaps or with a single, compromised, nonrecoverable dental element to be replaced with an implant; enough bone to place an implant of at least 10.0 mm in length and 3.5 mm in diameter; aged \( \geq 18 \) years; good general and oral health; ability to sign an informed consent; and willingness to participate in annual checkups. The exclusion criteria were chronic periodontitis with advanced loss of bone support,\textsuperscript{26} oral diseases; need for major regenerative techniques before implant placement (minor procedures including covering exposed implant threads with granulate or buccal grafting and interproximal procedures were not exclusion criteria); active infections in the tooth to be extracted (eg, pain, pus, fistula); severe impairment/damage to one of the four walls of the alveolus following extraction; lack of occlusal contacts in the antagonist arch; parafunction (ie, bruxism/clenching); uncontrolled diabetes; immunocompromised states; chemotherapy; radiotherapy; treatment with intravenous amino-bisphosphonates; psychiatric disorders; and abuse of drugs/alcohol. The diagnosis of parafunction was made as a result of careful anamnesis, physical examination, and electromyography of the masticatory muscles.\textsuperscript{27} Smoking was not considered an exclusion criterion for this study; however, patients enrolled in the study were informed in detail about the risks associated with cigarette smoking, which in several studies has been identified as a risk factor for implant failure.\textsuperscript{28} All patients were informed in detail about the planned therapy and the related risks and signed an informed consent to treatment. This study was conducted in compliance with the principles set out in the Declaration of Helsinki for clinical research on humans in 1975 (revision of 2000) and was approved by the Local Ethical Committee of the Hospital of Varese (protocol number 0034086).
Dental implants

The implants inserted in this study (AnyRidge, Megagen) were characterized by a tapered design with self-cutting threads (KnifeThread, Megagen). These implants possessed an internal hexagon and a 5-mm-deep conical connection (10 degrees) with built-in platform switching. These implants had a nanostructured calcium-incorporated surface (Xspeed, Megagen) and were available in different lengths (10.0, 11.5, and 13.0 mm) and diameters (3.5, 4.0, and 4.5 mm).

Case study and planning

Patients were subjected to periapical and panoramic radiographs for preliminary study of the residual bone anatomy and to assess the compromised element to be extracted. Where needed, the surgeon could request a cone beam computed tomography (CBCT) scan for three-dimensional (3D) assessment of the surgical site. The files obtained through CBCT were imported into 3D software for reconstruction of the crest and evaluation of every anatomical detail. The preliminary examinations were completed with generic impressions and development of stone casts for diagnostic wax-up.

Surgical and prosthetic procedures

Two days before surgery, patients were asked to rinse two to three times daily with chlorhexidine 0.12% mouthrinse for a total time of 1 minute. The same procedure was repeated 15 minutes before surgery. The surgery was performed under local anesthesia obtained by infiltration with articaine with adrenaline 1:100,000. In the case of single-tooth-gap patients, the surgical procedure involved the execution of a crestal incision possibly connected to two short incisions of vestibular relaxation. The mucoperiosteal flap was raised, and the surgeon proceeded with the osteotomy, starting with a 2.0-mm-diameter pilot drill, to the desired depth. The bone quality of the residual crest was assessed according to the clinician’s judgment and the implant site was prepared accordingly. The surgeon then positioned the implant of chosen length and diameter at crestal level. The stability of the implants was determined clinically as the absence of axial or rotational movement by the removal of the implant driver, without use of the stabilizing wrench. In patients with severely compromised dental elements, which called for extraction and immediate implant treatment, the procedure was performed with the flapless approach. The tooth was gently extracted, with care taken not to damage the remaining socket walls, particularly the buccal wall (the compromise of even one socket wall excluded patients from this study). The postextraction alveolus was curetted to remove any remaining granulation tissue. The integrity of the residual walls of the alveolus was verified, and the procedure continued with the preparation of the implant site.

Again, drill selection was based on the bone quality of the receiving site. The implants were placed in prepared osteotomies, apically pushed 3 to 4 mm to the peak of the postextraction socket. In cases with high esthetic needs, particular attention was paid to placing the implant palatally and avoiding contact with the buccal wall of the alveolus. The implants were manually placed in a slightly subcrestal position, using a hand ratchet. This gave a rough estimate of the maximum insertion torque obtained, after which any spaces between the buccal bone wall and the implant body were filled with hydroxyapatite/beta-tricalcium phosphates granules.

Immediately after implant placement, a prefabricated titanium abutment was prepared and screwed onto the implant. Temporary resin crowns were adapted from preformed shells or obtained from the laboratory; in both cases, they were relined with light-curing flowable resin. The provisional crowns were finished and polished meticulously to obtain the desired emergence profiles. In the healed ridge group, the flap was adapted to the emergence profile and sutured; in the extraction sockets group, the temporary restorations sealed the socket and maintained clot formation subgingivally. The provisional restorations were screw retained; each had a hole in the occlusal surface, which was closed with composite resin. A careful check of occlusion was conducted using articulating papers. Distributed occlusal contacts were obtained, and in all cases articulating papers were firmly held.
by the occluding teeth. An intraoral periapical radiograph was taken.

Ice packs were provided and analgesics were prescribed (100 mg nimesulide every 12 hours for 2 days). Patients were prescribed antibiotics (amoxicillin + clavulanic acid, 2 g per day for 6 days) and asked to avoid hard foods, at least in the first weeks after implant placement. All patients were recalled at 10 days, for a control and for removal of sutures, where present. After 3 months, the provisional restorations were replaced with the final metal-ceramic or zirconia-ceramic crowns; these were screwed or cemented, depending on the choice of the prosthodontist. Occlusion was carefully checked and an intraoral periapical radiograph was taken to check final restoration seating. Patients were thereafter enrolled in a maintenance program with professional oral hygiene sessions every 6 months.

Outcome variables

The following outcome variables were analyzed at the time of implant insertion and provisionalization (T₀), at delivery of the final restoration (3 months after implant insertion, T₁) and after 1 (T₂) and 2 years (T₃) of functional loading:

- **Complications.** Pain/swelling after surgery, peri-implant mucositis, and peri-implantitis were enlisted as biologic complications; abutment screw loosening/fracture and ceramic/veneer fractures were enlisted as prosthetic complications.
- **Peri-implant MBL.**²¹ Intraoral periapical radiographs were taken at different times (T₀, T₁, T₂, and T₃) for each implant, using a Rinn alignment system with a rigid film-object X-ray source coupled to a beam-aiming device to achieve reproducible exposure geometry. Customized film holders were fabricated, with polymerized polyvinyl siloxane on the occlusal surfaces of the adjacent teeth. Mesial and distal marginal bone levels of all implants were measured at different times (T₀, T₁, T₂, and T₃); an ocular grid (×4.5 magnification) was used for all measurements. The coronal margin of the implant neck and the most coronal bone-to-implant contact point were used as references for the linear measurements. To account for variability, the implant length was measured and compared with the documentation dimensions. Ratios were calculated to adjust for distortion. At the end, peri-implant MBL was calculated as modification in the peri-implant marginal bone level at different times on the mesial and distal implant sides. The average mesial and distal calculations were averaged to obtain the final value.

**Statistical evaluation**

Data were collected and analyzed by two independent, experienced observers who were not part of the treating team. All data were entered into a specific statistical sheet, where the analysis was conducted. Descriptive statistics were used for the evaluation of patient demographics (sex, age, smoking habit) and implant characteristics/features (site, position, length, diameter, bone quality at the recipient site). Absolute and relative frequency distributions were calculated for qualitative variables, means, standard deviations, and medians, and 95% confidence intervals (CI) were estimated for quantitative variables such as peri-implant MBL. Implant survival was calculated at the patient and implant levels; peri-implant MBL was calculated at the patient level.

**Results**

A total of 46 patients (23 men and 23 women; aged 18–73 years, mean age: 44.5 years) were eligible for the present study. The sex, age, and smoking habits of the enrolled patients, with related survival rates, are reported in Table 1. The site, position, length, and diameter of the placed implants, together with the quality of the recipient sites and the related survival rates, are reported in Table 2. A total of 47 implants
(82.5%) were placed in healed sites, while 10 (17.5%) were placed in fresh extraction sockets. The reasons for extraction of the teeth substituted with immediate implants were root fracture (7 cases; 70%), endodontic failure (2 cases; 20%), and extensive tooth decay (1 case; 10%).

Most of the immediate implants (8/10; 80%) were installed in the anterior maxilla. No buccal bone damage occurred in this group, so no patients were excluded for this. No major augmentation procedures were needed, but minor augmentation to cover exposed threads and/or interproximal/buccal grafting owing to hard tissue deficiency was performed after installation of 15 implants (26.3%).

The final restorations were screwed or cemented metal-ceramic (52 cases; 91.2%) or zirconia-ceramic (5 cases; 8.8%) single crowns. A total of 4 patients (4 implants) withdrew from the study and were consequently classified as dropouts, even if their implants were still in function.

At the 2-year follow-up, one implant was lost, in the posterior maxilla (second premolar, healed site) of a 48-year-old woman with a smoking habit. The failed implant (3.5-mm diameter × 10.0-mm length) was installed in type 3 bone. This implant showed mobility and lack of osseointegration 2 months after surgery and was removed; all the other implants were stable, giving a patient-based 2-year overall survival rate of 97.6% (Figs 1 and 2).

With regard to biologic complications, one patient experienced pain and swelling after surgery. This was managed by prescribing an-
amounted to 7.5%. Three patients had their abutments loosened, two in the posterior mandible and one in the anterior maxilla. All these abutments were inserted and screwed in again; however, these mechanical complications were recorded as prosthetic complications. In addition, a veneer fracture occurred in a metal-ceramic definitive crown. The damaged restoration was removed, and a new crown was fabricated and provided. Finally, the peri-implant MBL as calculated at the 1- and 2-year examinations is reported in Table 3.

**Discussion**

Few studies are available in the literature on immediate functional loading of single implants.\(^{18-22,24,25}\) For the most part, the studies that do exist deal with implants placed in the anterior maxilla,\(^{22-25}\) where functional loads are reduced. Only a few studies examine the immediate loading of implants placed in postextraction sockets.\(^{21,22,25}\) A recent randomized controlled trial compared the survival and success rates of single implants in immediate functional loading placed with the flapless method with those of delayed loading implants positioned after raising a surgical flap.\(^{18}\) At the end of this study, the immediate functional loading
had not compromised the survival and success rates of the implants.\textsuperscript{18} These results were confirmed by a subsequent clinical trial with 4 years of follow-up, where flapless placement of single implants with immediate functional loading determined high survival and success rates in the posterior areas of the maxilla and mandible.\textsuperscript{19} In a prospective study on the immediate functional loading of 40 implant-supported single crowns in the posterior mandible of

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MBL = marginal bone loss.
33 patients with follow-up after 5 years, the cumulative success rate reported was 95% with only 2 implant failures.20

Excellent results have been reported following the placement of single implants with immediate loading in the anterior maxilla.22,24,25 In a study involving 70 patients treated with single implants placed in healed sites (45 implants) and in postextraction sockets (25 implants), 1 year after loading all implants were successfully osseointegrated.22 Similar excellent results were reported in a clinical study where the placement of single implants subjected to immediate functional loading in esthetic areas had a survival rate of 96.1% at 3 years and minimal peri-implant marginal bone loss.24 This is in agreement with what was reported in a previous meta-analysis of the literature relating to single implants positioned in the anterior maxilla, where no significant differences were found in the survival of implants subjected to different load conditions.23

A recent clinical study with follow-up at 5 years finally compared the peri-implant MBL of single implants placed in healed sites and postextraction sockets of the anterior maxilla.25 In this study, the mean MBL after implant placement was 0.26 ± 0.161 mm for 1 year, 0.26 ± 0.171 mm for 3 years, and 0.21 ± 0.185 mm for 5 years in extraction sockets and 0.26 ± 0.176 mm for 1 year, 0.21 ± 0.175 mm for 3 years, and 0.19 ± 0.172 mm for 5 years in the healed ridges group.25 Loss of marginal bone was more pronounced in implants inserted in healed ridges (P < .041) compared with fresh surgical extraction sockets (P < .540).25

All these results seem to be in agreement with those of the present study with follow-up at 2 years, where 57 single implants were placed in 46 patients and subjected to immediate functional loading. At the end of the study, only one implant was lost, in a healed site, for an overall survival rate of 97.6%. All other implants were in function, with a very low incidence of biologic complications (1.8%); the incidence of prosthetic complications was slightly higher (7.5%). After 2 years of functional loading, the overall peri-implant MBL was 0.37 ± 0.22 mm. In the healed site group, a 2-year MBL of 0.4 ± 0.22 mm was reported, while in postextraction sockets the 2-year MBL amounted to 0.3 ± 0.22 mm. These results seem to suggest that there are no differences in the survival and success rates of immediately loaded single implants placed in healed sites and postextraction sites; however, it must be pointed out that in the present study only 10 implants were placed in postextraction sites.

In procedures with immediate functional loading, success essentially depends on the degree of primary implant stabilization, the presence of controlled load conditions, and the macro and microtopographic characteristics of the implant.5–7,10,17,21 Primary stability, defined as the biometric stability achieved immediately after implant insertion by the mechanical locking of the implant to the bone,17 is essential. Adequate primary stabilization of the implant depends on the surgical protocol used, the experience and skill of the surgeon, the density of the receiving bone site, and the shape and surface of the implant.17 A good trick for maximizing primary stability is to underprepare the surgical site. This particularly applies in the case of postextraction sockets, where stabilization is often achieved through an apical fixation of a few millimeters.15–17,21 Use of an aggressive implant with a certain degree of taper may help to obtain a valid primary stabilization.21 In the present study, a strict surgical protocol was followed in which implants were placed in underprepared osteotomies, particularly in cases where bone quality was poor (types 3 and 4 bone) and in fresh extraction sockets. Moreover, the macrotopographic features of the implant used in this study were designed to provide high insertion torque, with threads of increasing dimension toward the coronal end of the implant. This feature may allow for axial and radial bone compression during implant insertion, providing an increased primary stability that is useful in immediate functional loading, particularly in areas of poor bone quality.21 The receiving bone site is fundamental: primary stabilization is simpler in the anterior areas, where the bone density is higher, and more difficult in the posterior areas, particularly in the posterior maxilla.4,30 In the posterior maxilla, a single implant is more difficult to stabilize and therefore more susceptible to failure in the event of immediate functional loading.5,7,13,16,30 In fact, certain micromovements, beyond a critical threshold, can lead to fibrous
encapsulation of the implant, and subsequent failure. In the present study, most of the implants (26; 45.7%) were placed in the posterior maxilla; however, only one failure was reported.

Last but not least, in procedures with immediate functional loading, it is of fundamental importance to use implants with specific microtopography and surface characteristics capable of stimulating the apposition of new bone and promoting bone healing, were used. This peculiar microtopographic feature, combined with an implant body designed for critical bone conditions and high insertion torques, may have minimized the risk of failure associated with immediate functional loading.

Conclusions

This prospective clinical study with follow-up at 2 years seems to validate the hypothesis that immediate functional loading of single implants could represent a safe and effective procedure, characterized by high survival rates (97.6%), low incidence of biologic complications, and rather limited peri-implant MBL (0.37 ± 0.22 mm). Complications of a prosthetic nature occurred at a slightly higher incidence (7.5%). This study has limitations, such as the small number of patients treated and the low number of implants inserted; further studies are needed to confirm the results obtained here.

Acknowledgments

The authors reported no conflicts of interest relating to the preparation of this scientific work.

References


25. Berberi AN, Sabbagh JM, Aboushelib MN, Noujeim ZF, Salameh ZA. A 5-year comparison of marginal bone level following immediate loading of single-tooth implants placed in healed alveolar ridges and extraction sockets in the maxilla. Front Physiol 2014;31:29.


