Long-Term Results of Immediately Loaded Fast Bone Regeneration–Coated Implants Placed in Fresh Extraction Sites in the Upper Jaw

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Recently, many authors have investigated the results of immediately loaded implants in fresh extraction sites, reporting favorable success rates, but only a few studies have included a long-term follow-up in the maxilla with analysis of clinical and radiographic data. The aim of this study was to evaluate the predictability of the immediate loading protocol with fast bone regeneration (FBR)-coated implants placed in postextractive sites in the maxilla, considering the success rate after at least 5 years of follow-up. Moreover, the clinical and radiographic results are evaluated in terms of soft tissue conditions and crestal bone loss values. One hundred fifty-eight implants were inserted following dental extraction in 70 consecutively operated patients. Each implant was immediately prosthesized. The data were collected before surgical planning, at the time of insertion, and after 3 and 5 years of occlusal loading. Specific success criteria were used to assess the success rate of immediately loaded postextraction implants. Clinical and radiographic examinations were used to determine long-term results. After a 5-year follow-up, 2 implants were lost, with a cumulative success rate of 98.7%. The radiographic and clinical data revealed well-maintained hard and soft tissues, with acceptable long-term results. The use of immediately loaded FBR-coated implants in fresh extraction sockets is shown to be a predictable technique if implants are inserted in selected cases and positioned with great care, following thorough preoperative analysis.

**Key Words:** immediate loading, bioactive surfaces, FBR-coated implants, postextractive sites

**INTRODUCTION**

The predictability of implant osseointegration was once considered possible only thanks to a thorough prosthetic and surgical protocol. In order to obtain optimal implant osseointegration, Branemark’s original guidelines recommend the insertion of a submerged implant 4 months after extraction. This procedure avoids functional stress during the healing process (6 months in the maxilla and 3–4 months in the mandible), limits potential infections, and prevents epithelial growth in the artificial alveolus.1,2 The validity of the 2-phase process is confirmed by its increasingly widespread use and by the results achieved over a total follow-up...
period of more than 30 years. Many studies have demonstrated that the use of osseointegrated dental implants yields substantial long-term success rates in the treatment of edentulism and mono-edentulism.\(^2,3\)

Whereas osseointegration in the mandible requires a shorter time period because of better quality, the ossointegration process in the upper jaw requires a longer time gap between primary stability (insertion stability) and secondary stability (osseointegration stability) because of its poor bone quality.

Precisely for this reason, research in implantology over the years has always sought to find solutions capable of improving the osseointegration process: greater and faster osseointegration of implants makes it possible to reduce the hard tissue healing period and to perform early or immediate loading.\(^5\)

Analysis of the theoretical basis of immediate loading of implants enables us to understand how to overcome this obstacle. In this connection, the main consideration is the possibility of using a functional load as osteogenetic induction during the bone healing phase.\(^6\) According to Wolff’s law, “Bone architecture is modified with load, and bone density is proportional to mechanical solicitation.” Jaw bones undergo endosseous solicitations, which generate an internal positive stimulus (natural teeth and endosseous implants), and extrasosseous solicitations, which generate an external compressive stimulus (mucous membrane–supported prostheses).\(^7\)

However, immediate and early loading have been found to induce micromotions at the bone-implant interface that may lead to fibrous encapsulation instead of direct bone apposition.\(^8\) Implant surface characteristics can influence the bone response during the healing period in the presence of these micromovements. Consequently, implant surfaces can play a significant role in the immediate loading protocol.\(^5,9,10\)

The possibility of transmitting “positive” micromovements to the bone, preserving the implant from “negative” micromovements (ie, those reaching 2000–4000 microstrains over the bone tolerance threshold) is an essential condition for obtaining osseointegration, particularly in immediate loading.\(^8,11\)

Since immediate loading offers the chance of drastically reducing the time elapsing between insertion and functional prosthesization of implants, with a view to improving the patient’s quality of life, many authors have focused on the immediate and early loading of implants. “Immediate loading” means the application of loads and forces to the implants after placement, while “early loading” means the application of loads and forces to the implants after a time gap that is less than the waiting times of the standard protocol.\(^12\) The most important feature of an immediate loading protocol is that it allows clinicians to treat edentulous patients and immediately replace extracted teeth with an implant-supported prosthesis, which gives the patient a considerable advantage, consisting in the absence of the stress of psychologic trauma due to tooth loss, since the latter is immediately replaced.\(^13\)

It is important to emphasize that the healing times of Branemark’s protocol were established empirically, starting from experimental studies on implants with machine-processed smooth surfaces.\(^8\)

Implant surfaces have undergone a series of evolutions over the years. As mentioned previously, it is well known, in fact, that surface characteristics influence the feedback of healing bone tissues.\(^11,14\)

Initially, rough surfaces were created to improve implant performance in conditions of low bone density (type IV), where machine-processed implants obtained much lower success rates than when used in the case of higher bone density (type III, II, I).\(^15\)

New types of implant surfaces have been developed to improve the quality of osseointegration and the quantity of bone contact at the interface level.\(^16\) Additive
kinds of treatment, such as titanium plasma spray (TPS) or hydroxyapatite (HA) coatings were the initial proposals made.

HA coating confers osteoconductive and osteoinductive qualities on the implant, allowing the formation of a strong chemical connection with bone. Buser et al\textsuperscript{15} showed that HA-coated implants are capable of adhering faster and more efficiently to bone tissue.

The implant surfaces also underwent some subtractive kinds of treatment. One of these is sanding; more recently, acid etching, combined with other treatments, was introduced as a technique for treating implant surfaces.\textsuperscript{16,17}

Many authors have demonstrated the ability of modified surfaces to improve osseointegration compared with machined surfaces.\textsuperscript{15,18,19} Moreover, a growing body of data demonstrates that when implants with a bioactive surface are positioned in post-extractive sites with sufficient primary stability, they can be immediately loaded with high success rates.\textsuperscript{20,21}

In the present study, fast bone regeneration (FBR)-coated TPS implants were used to enhance the primary stability. FBR coating is a fully resorbable calcium phosphate (CaP) coating made of brushite, which is obtained by electrochemical deposition on TPS implants.\textsuperscript{22}

The aim of the study was to check the success rate of these FBR-coated implants, which were immediately loaded in fresh extraction sockets of the maxilla, after a long-term follow-up. The study aimed also to consider the crestal bone loss and soft tissue conditions associated with an immediate loading protocol using this kind of implant.

\textbf{Materials and Methods}

\textbf{Patients}

All patients were referred and treated between 2001 and 2003 at the Department of Morphological and Biomedical Sciences, Section of Dentistry and Maxillofacial Surgery, University of Verona, for partial or complete implant-supported rehabilitation in the upper jaw.

A sample of 90 operated patients was selected for this study, but only 70 patients were included on the basis of the inclusion and exclusion criteria. All patients signed an informed consent form before implant rehabilitation.

Each patient in this sample underwent radiographic examinations, such as periapical X rays, orthopantomography (OPT), and CT scans, to evaluate the residual bone volumes and assess implant success and bone resorption over a follow-up period of at least 5 years (Figure 1).

The inclusion criteria for the analysis were:

- one or more dental elements to be replaced with immediately loaded postextraction implants situated exclusively in the upper jaw, due to traumas, radicular fractures, radicular resorption, failure of periodontal and endodontic therapies, deep destructive caries, or nonprosthetically restorable crowns;
- absence of systemic pathologies (eg, diabetes);
- good oral hygiene; and
- adequate bone volume to guarantee the insertion of 3.25 mm $\times$ 8.5 mm short implants without requiring bone grafts.

The exclusion criteria were:

- active infection around the tooth to be replaced;
- risk factors such as alcohol or drug addiction, diabetes, past or ongoing radiotherapy in the facial-cervical region, or any other medical, physical, or psychological reason capable of influencing the surgical procedure or the subsequent prosthetic treatment and the requested follow-up;
- bruxism, parafunctions, or lack of a stable posterior occlusion;
perforation or loss of vestibular bone of the alveolar process due to the extraction of the dental element or the preimplant osteotomy; impossibility of obtaining primary stability of the implant at the time of immediate insertion of the implant; extreme bone atrophy; and a thin biotype with a narrow zone (<2 mm) of keratinized mucosa.

Implant system

FBR-coated implants (Pitt-Easy, Oraltronics, Bremen, Germany) were used. They have a surface coated with platelet-like bonded CaP crystals, which endows them with a high submerging capacity and a marked capillary effect that facilitates osteogenetic bonding.

The FBR surface consists of 100% calcium phosphate, which is additionally applied through electrochemical deposition on the tried-and-tested fine granular V-TPS surface in a 15–20 μm bioactive layer, inducing formation of brushite (Ca/P = 1.1).

Surgical procedures and prosthetic rehabilitation

The surgical protocol included the flapless atraumatic avulsion of the tooth, the complete removal of the fibrotic-inflammatory component present in the alveolar socket, the preparation of the implant site, the placement of the implant fixture, and the immediate loading of a provisional prosthesis (Figures 2 and 3).

Periapical X rays and OPT, and eventually a CT dental scan, were used to evaluate the residual bone volume and to plan the placement of the immediately loaded postextraction implants.

The pharmacologic protocol comprised the following: antibiotic therapy (amoxicillin plus clavulanic acid, 1 gram every 12 hours, starting 24 hours before surgery to be continued 5 days after intervention); oral hygiene with a 1.2% chlorhexidine mouthwash (daily use for 7 days before and after intervention); and painkillers if needed.

Regarding the positioning of the fixtures and the realization of the prosthetic handmade products, a series of concepts based on biomechanical principles must be borne in mind, aimed at optimal positioning of the implants and management of the hard and soft tissues.23–25

In premaxillary and premolar areas, the preparation of the implant site, because of the limited amount of bone available in the apicocoronal direction, was inclined palatally by around 15°–20° in relation to the alveolar axis, in order to obtain optimal primary stability. In molar areas, the implant site was centered on the alveolar axis,
preparing it also with hand osteotomes to compact residual bone.

- For a 3-unit prosthesis, at least 3 implants are used, with an alignment waste of the implant in the central position measuring 2–3 mm in the buccolingual direction. In the tripod configuration thus obtained, the relationship with the flexing forces is essentially axial, and the solicitations are minimized.

- If the possibility of inserting only 2 implants exists, the latter should be located as terminal supports, eliminating possible cantilevers.

- As far as single implant supports are concerned, we perform the centering of the occlusal contacts and reduce the inclination of the cuspids.

- In order to place the head of the implant and obtain optimal support, a slight inclination of the implant can be used, maintaining the head aligned with the occlusal forces acting on the prosthetic restoration. This step does not cause any additional flexion of the implant, but only a slight increase in bone solicitation. Problems can occur when the prosthetic reconstruction is not aligned with the head of the implant: this introduces a moment that flexes on the implant. In this case, the damage is not due to the inclination but to the long lever on which the occlusal force is applied.

- Extreme caution is called for when using a single implant to replace a perfectly functioning molar. This situation can easily generate an increase in flexion overload. Considering the high level of potential solicitation, the occlusion should be centered and mild, and ≥4 mm implants should be preferred.

- It may be difficult to control the occlusal forces in the event of reduced periodontal tissue support around contiguous teeth, which could force the implants to absorb a larger amount of the axial load. In such cases, the treatment plan should be implemented with due caution.

- In patients with parafunctional habits, the loading stresses on the implant components or on bone are increased. Thus, in such situations, an optimal implant support, the minimization of the occlusal contacts, and the elimination of cantilevers need to be obtained.

- Adequate accuracy of adaptation between prosthesis, abutment, and adequately installed junction screws are important factors for obtaining the most reliable mechanical resistance of the component. Passivity of the implant-prosthetic set must always be obtained.

- Loosening or fracture of the screws must be considered as overload risk factors and make immediate evaluation and correction of the cause mandatory to avoid further complications.

Implants supporting single crowns were placed in nonocclusion, conferring a nonfunctional load on them, ie, equal to 10 kg/cm² for up to 30 minutes per day. The same criterion was used in the case of short bridges supported by 2 implants. Bridges supported by 3 implants or more, on the other hand, were placed in occlusion, where the occlusal surface was thoroughly modeled, so that it presented reduced contact areas with little or no laterality or protrusion in order to reduce the dislocating vectorial components.

Regarding the provisionalization of the complete cross-arch blockages, the teeth were all placed in occlusion immediately, according to the ability of the structure of the arch to transform the dislocating forces into axial forces.

The modeling of the prosthetic restorations of single elements involved wide centric, slightly accentuated angles, milder slopes, and smaller grinding rather cutting cuspids, provided with considerable junctions “protected” by correct interproximal contact with the adjacent elements.
All of the implants were prosthesis with provisional resin crowns realized on the basis of presurgical impressions, subsequently lowered in acrylic resin, and bonded with provisional cement (Temp Bond, Kerr, GmbH, Karlsruhe, Germany) with titanium abutment. Extreme caution was observed to avoid any centric or eccentric contact on provisional crowns.

**Follow-up protocol**

Results were assessed in clinical and radiographic examinations at the time of surgery, at 10 days, at 1, 3, and 6 months, then at 1 year, and at yearly intervals until the end of the fifth year. In a number of cases, the follow-up period was over 5 years (Figures 4–11).

The lack of follow-up data on some patients due to relocation, health, or other problems did not lead to exclusion from the final analysis, provided results of periapical X rays or OPT were available at 5 years.

A fixture was considered successful if it met the success criteria proposed by Albrektsson and Zarb and universally accepted:

- each implant, individually tested, must be clinically immobile;
- no peri-implant radiotransparencies must be detectable radiographically;
- vertical bone loss must remain inferior to 0.2 mm per year, after 12 months of prosthetic load;
- the implant must cause neither signs nor symptoms of pain, infection, neuropathy,
paresthesia nor violation of the mandibular canal; and
• in this context, the success rate must be at least 85% after a 5-year observation and at least 80% after a 10-year observation period.

Since a periapical X ray was available for all patients at 5 years’ follow-up, the marginal bone level was assessed mesially and distally by identifying the lowest observed point of crestal bone intimate contact with the implant, using a \( \times 2.5 \) magnifying glass.

Soft tissue conditions were evaluated and divided into 4 groups: (1) the interdental papilla occupies the entire embrasure space apical to the interdental contact point/area without vestibular recession; (2) the tip of the interdental papilla is located below the interdental contact point/area, without vestibular recession; (3) the vestibular recession of the implant is less than 1 mm, independent of the position of the papilla; and (4) the vestibular recession of the implant is more than 1 mm, independent of the position of the papilla.

**Results**

The results are based on 158 implants, which were inserted in 70 patients in postextractive sites of the upper jaw and were assessed after a long-term follow-up of at least 5 years. Of these implants, 112 were inserted in the anterior zone (from 14 to 24) and 46 in the posterior zone (from 15 to 17 and from 25 to 27). The diameter was 3.25 mm in 5.1%, 3.75 mm in 78.5%, 4 mm in 13.9%, and 4.90 mm in 2.5%. The length was 10 mm in 19.0%, 12 mm in 51.9%, 14 mm in 27.8%, and 16 mm in 13.9%.

The prosthetic load was realized after a maximum of 4 days: 60.8% were positioned immediately, 6.3% after 1 day, 29.1% after 2 days, and 3.8% after 3 days. Single crowns were used to restore 19.0% of the implants (16.5% anterior and 2.5% posterior areas). Bridges were used to restore 44.3% (24.1% anterior and 20.2% posterior areas), and full-arch prostheses were used to restore 36.7% (29.1% anterior and 7.6% posterior areas).

Osseointegration failed in only 2 implants: the first was lost after 23 days in site 1.3, and the second after 26 days in site 1.5. After a follow-up period of 5 years, 2 implants had been lost, yielding a success rate of 98.7% for immediately loaded post-extraction implants.

The radiographs taken at implant placement and after at least 5 years’ functioning revealed a mean marginal bone loss of 1.2 ± 0.2 mm (range: 0.0–2.5 mm). Most implants (n = 117; 74.1%) showed bone resorption ranging from 0.1 to 1.5 mm; 10 implants (6.3%) had no bone resorption; and only 31 implants (19.6%) experienced bone loss between 1.5 and 2.5 mm at 5-years of follow-up. None of the osseointegrated implants showed a marginal bone loss more than 2.5 mm (Table). The distribution of the
158 implants, in terms of mean marginal bone loss can be seen in Figure 12.

The soft tissue conditions were well maintained in 87 implants (55.1%), which showed no vestibular recession and a papilla entirely or partially occupying the embrasure space; 60 implants (38.0%) had a vestibular recession less than 1 mm, which is not always noticeable by the patients; and only 11 implants (6.9%) had a vestibular recession measuring more than 1 mm. The distribution of the 158 implants in terms of soft tissue conditions in the 4 groups is presented in Figure 13.

**DISCUSSION**

The implant osseointegration process is based on the ability of the bone to invade the irregularities of the implant surface and create a bonding capable of bearing mechanical solicitations.  

The roughness of the implant surface is regarded as an important factor among those capable of inducing optimal neo-apposition of bone around the implants. The results of numerous studies on the various relationships between different superficial conformations and the in vivo and in vitro biocompatibility of a number of biomaterials normally used in dentistry and orthopedics suggested the possibility that a rough surface may induce a local cellular response compared with a smooth surface. Thus, the chemical nature of biomaterials may play a decisive role in the definition of the biological response.

The ideal biological affinity existing between bone and hydroxyapatite surfaces has already been widely documented in the literature, which demonstrates a reduction of thickness of the proteoglycan layer located between bone and surface, from 65 nm (=650 Ångström) for the turned titanium surface to 20 nm (=200 Ångström) for the hydroxyapatite surface.

The success of FBR-coated implants at 5 years is probably due to the coating. The so-called FBR coating is a bioactive layer, which could be totally resorbable in 6–12 weeks. The main component of the FBR surface is brushite, a precursor of hydroxyapatite. Since brushite is unstable

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<td>Group 1</td>
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**Figures 12 and 13.** Figure 12. Distribution of 158 implants in terms of mean marginal bone loss after at least 5 years of follow-up. Figure 13. Distribution of 158 implants in terms of soft tissue conditions after at least 5 years of follow-up in the 4 groups.
when pH values exceed 6.9, the coating is resorbed in about 6 weeks; thus, in contact with tissue fluids, it is resorbed and transformed to hydroxyapatite. Once the FBR coating has been resorbed, the newly formed bone will be in contact with the roughness of the TPS surface.\(^{22,31}\)

Since bioactive coatings are believed to increase micromovement tolerance, it has been hypothesized that the FBR coating could be perfectly suited to increasing the predictability of immediate loading protocols.\(^{10,11,32}\)

FBR coatings present advantages over hydroxyapatite and constitute a kind of evolution: the CaP coating of implants, obtained in electrochemical deposition on TPS surfaces, presents a totally resorbable 20-\(\mu\)m thick crystalline surface; moreover, it not only adapts to the morphology and roughness of the TPS surfaces, it also presents a substantial capillary effect that allows it to bond with the blood and thus stabilize the coagulum.\(^{22,30}\)

The clinical interest in this kind of implant in the upper jaw is mainly linked to bone density, which is certainly poor in posterior areas, even if it may be satisfactory in the premaxilla, thus making the application of immediate loading postextraction protocols difficult. The results obtained in this study demonstrate the primary importance of patient selection, of occlusal evaluation, and of the modified surface for the purposes of reducing the failure rate. To reduce the risk of osseointegration failure with immediately loaded implants, the results obtained reveal the significance of the microscopic and macroscopic characteristics of the implants: the roughness of the TPS surface, associated with the bioactive properties of the CaP coating, makes it possible to increase the osseointegration process.\(^{10,22,30,33,34}\) In this connection, Esposito et al\(^{35}\) stated in 2005 that there was little evidence of a difference in outcomes between patients treated with smooth or rough surface implants. They also claim there is no evidence to show that any given implant type yields higher success rates over time. It is worth noting that the authors of this review did not take CaP-coated or bioactive implants into account.

Since 1998, when Wöhle\(^{36}\) first reported 14 consecutive cases in which an immediate implant placement procedure was used for single-tooth restoration in the esthetic zone with immediate provisionalization, numerous authors have investigated the possibility of using immediately loaded implants in fresh extraction sites in the upper jaw, reporting high success rates, comparable to those achieved with other protocols.\(^{37–40}\)

However, the majority of articles on immediate loading of postextraction implants describe only a short-term follow-up, ranging from 1 to 3 years.\(^{36–38}\) With regard to the immediate loading of implants placed in maxillary fresh extraction sockets, very few reports are available with a follow-up exceeding 3 years.\(^{39,40}\)

Degidi et al\(^{39}\) established that the success rates of immediately loaded implants in postextractive sites were not significantly different from those in healed sites. Furthermore, Crespi et al\(^{37}\) reported that immediate and delayed loading of postextraction implants in the upper jaw showed no statistically significant differences in success rates.

In comparison with similar studies, the results of the present analysis demonstrate the predictability of the use of FBR-coated implants as immediately loaded and postextraction implants: after a long-term follow-up, the overall success rate was 98.7%.

The study lacks any evaluation of differences between FBR coating and TPS surfaces: comparison with other TPS-related studies, whether including biological analysis or otherwise, demonstrates greater osteoactivity and osseointegration with FBR compared to TPS.\(^{41,42}\)

The data discussed above, in conjunction with the findings reported in the present...
Immediate Loading of FBR-Coated Implants at 5 Years

study, suggest that FBR-coated implants can be used in immediate loading with similar or better outcomes than those obtained with already clinically successful implants such as TPS-surfaced implants. The analysis of crestal bone loss indicates that this type of implant permits good maintenance of bone levels also after 5 years of loading. This condition ensures adequate support for the soft tissues, both marginal and interproximal, with a favorable esthetic result in the long term.

We can conclude that the use of immediately loaded FBR-coated Pitt-Easy implants in postextractive sites in the upper jaw constitutes a predictable technique, which enables acceptable results to be achieved from both the functional and esthetic points of view, after a long-term follow-up of 5 or more years.

ABBREVIATIONS

CaP: calcium phosphate
FBR: fast bone regeneration
HA: hydroxyapatite
OPT: orthopantomography
TPS: titanium plasma spray

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