Original Article

Immediate Functional Loading of Single Implants: a 2-Year Prospective Multicenter Study

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ABSTRACT

Objectives. The aim of this prospective multicentre study with 2 years of follow-up was to evaluate the clinical outcome of single implants subjected to immediate functional loading. Materials and methods. Patients were enrolled in six clinical centers. Criteria for inclusion were single tooth placement in post-extraction sockets or fully healed sites, and sufficient bone height/width to place a fixture of at least 3.5 mm in diameter and 10.0 mm in length. All fixtures (Anyridge®, Gyeonbuk, Megagen, South Korea) were functionally loaded immediately after placement. Final restorations were delivered after a period of 3 months. All implant-supported restorations were followed for 2 years. Outcome measures were: implant survival, complications, peri-implant marginal bone loss (MBL).

Results. A total of 57 fixtures (38 maxilla, 19 mandible) were installed in 46 patients (23 males, 23 females, aged between 18 - 73 years). Ten fixtures were installed in post-extraction sockets. Four patients (four implants) dropped out from the study. At the end of the study, only one fixture 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%, with one patient experiencing swelling after surgery; prosthetic complications amounted to 7.5%, with three loosened abutments and a ceramic crown fracture. Finally, after 2 years of functional loading, the overall peri-implant MBL was 0.37 mm (± 0.22). In the healed site group, a 2-year MBL of 0.4 mm (± 0.22) was reported, while in post-extraction sockets the 2-year MBL amounted to 0.3 mm (± 0.22).

Conclusions. The immediate functional loading of single implants seems to represent a safe and successful procedure. Further, long-term follow-up studies on a larger sample of patients will be needed to confirm the present results.

KEYWORDS

Single implants; Immediate functional loading; Survival; Complications; Marginal bone loss.
1. Introduction

Dental implants are a proven solution for the rehabilitation of partial and total edentulisms, and the survival in the medium and long-term of fixed implant-supported restorations is now very high, as clearly demonstrated in the literature [1-3]. For this reason, more and more patients ask to be rehabilitated with implants, to restore the function and aesthetics that have been compromised by a loss of one or more dental elements.

Even in the case of single-tooth gaps, implants represent a successful solution, as demonstrated by a large number of studies [3-5] and systematic reviews [6,7] in the literature, with higher survival rates in the medium and long term.

In recent years, implantology has increasingly asserted the concept of immediate loading, even in the case of rehabilitation with single implants [7,8].

Immediate loading is defined as the placement of a prosthetic restoration within 48-72 hours of implant placement [7,8]. Among the undeniable advantages of immediate loading, we must include the overall reduction of treatment times, with functional, cosmetic, and psychological benefits for the patient (who will avoid having to keep uncomfortable removable partial dentures during the healing period) [7-9].

Under this procedure, the fixed prosthetic restoration positioned can be in occlusion, and it is called immediate functional loading [9,10], or it can be drained by the occlusion, and it is called immediate non-functional restoration [11,12]. The difference between these two procedures is in the size of the forces ideally exerted on the implant by the fixed prosthetic restoration positioned on it [12]. This is not a trivial matter, particularly in the case of rehabilitation of monoedentulisms with implant-supported single crowns. In fact, if on the one hand immediate loading is greatly successful in complex rehabilitations that provide for the placement of numerous implants splinted between themselves, as shown by numerous clinical studies [10,13,14], on the other hand there is less evidence in the literature regarding the immediate loading of implant-supported single crowns, especially in the posterior regions [15].

In fact, 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 fixture, thus compromising healing and osseointegration [16]. These consequences, originally advanced by the Branemark school, still remain topical, since micro-movements over a certain size can lead to loss of stability and implant failure [16].
In truth, the same procedure of immediate non-functional restoration provides for the transmission of a certain amount of loading on the underlying implant [11,12]. In fact, especially in the posterior areas, the forces of chewing, together with those determined by musculature (e.g. those transmitted by the tongue in the mandibular arch) will act in some way on the fixture, even in the absence of specific occlusal contacts [18]. However, it is evident how immediate functional loading represents per se the procedure characterized by the higher risk, especially in the case of implant-supported single crowns in the posterior areas: in fact, the load will be entirely transmitted to the fixture during all the function’s different phases, including swallowing [17,18].

It should be noted that different surgical protocols are now available for the rehabilitation of single edentulisms with implants [17,18]. Among these, it is important to remember immediate implant treatment (IIT), within 48 hours of extraction of the affected tooth, early implant treatment (EIT), 4-8 weeks after extraction, and conventional implant treatment (CIT), performed upon complete healing of the surgical site, 4-6 months after extraction [17,18]. Although all three of these surgical techniques can ensure high success and survival rates, it is intuitive how immediate implant treatment in the post-extraction site may represent an additional risk factor for implant failure, especially where it has not been possible to obtain adequate or satisfactory primary implant stability [18,19].

To date, few studies have addressed the topic of immediate functional loading with implant-supported single crowns [20-24,26,27], and even fewer studies have addressed the issue of single implants placed in post-extraction sockets and immediately loaded [23,24,27]. The purpose of this prospective multicenter study with follow-up at 2 years is therefore to assess survival, complications, and peri-implant marginal bone loss of single implants placed in healed sites and in post-extraction sockets, subjected to immediate functional loading.

2. Materials and methods

2.1 Patient selection

This prospective study is based on data from patients enrolled and subsequently treated with immediately loaded single implants in 6 different dental centers. In all, six surgeons with proven experience (Carlo Mangano, Giuseppe Luongo, Filiep Raes, Carolina Lenzi, Tammaro Eccellente, Michele Ortolani) participated in the study as operators, using the
same predetermined protocol. In the period between February 2012 and February 2013, patients were selected for treatment based on specific criteria of inclusion and exclusion. The inclusion criteria for this study were:
- patients with single-tooth gaps, or with a single, compromised, non-recoverable dental element (due to root fracture, endodontic failure, extensive crown destruction) 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;
- age ≥ 18 years;
- good general and oral health;
- ability to sign an informed consent and willingness to participate in the annual checkups.

The exclusion criteria for this study were:
- chronic periodontitis with advanced loss of bone support (periodontal pocking depths > 6 mm; clinical attachment loss > 4 mm; radiographic evidence of bone loss; increased tooth mobility) [28];
- oral diseases (vesiculobullous diseases, ulcerative diseases, white or red lesions, diseases of the salivary glands, the connective tissue or lymphoid lesions, cystic lesions, benign or malignant tumors of the oral cavity);
- the need to use major regenerative techniques before implant insertion, such as block regeneration with autografts, allografts, or xenografts (regenerative minor procedures including covering exposed implant threads with granulate or buccal grafting and interproximal procedures were instead not included in the exclusion criteria);
- active infections in the compromised tooth to be extracted (pain, pus, fistula);
- severe impairment or damage to one of the four walls of the alveolus following extraction of the affected and non-recoverable tooth;
- lack of teeth and therefore occlusal contacts in the antagonist arch;
- parafunctions (bruxism and clenching);
- uncontrolled diabetes;
- immunocompromised states;
- in cancer treatment or chemotherapy;
- radiotherapy;
- treatment with intravenous amino-bisphosphonates;
- psychiatric disorders;
- abuse of drugs or alcohol.
The diagnosis of parafunction was made as a result of careful anamnesis, physical examination, and electromyography of the masticatory muscles [29]. Instead, 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 [30]. In general, all patients were informed in detail about the planned therapy and the risks related thereto, with particular reference to the protocol of immediate loading on single implants; after being made aware, patients 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 this study was approved by the Local Ethical Committee of the Hospital of Varese.

2.2 Dental implants
The fixtures inserted in this study (AnyRidge®, Gyeonbuk, Megagen, South Korea) were characterized by a tapered design with strong self-cutting threads, to ensure excellent initial stability in the immediate loading protocol (Knifethread®) [23]. These fixtures possessed an internal hexagon and a 5-mm deep conical connection (10°), providing a tight seal and a high mechanical resistance, with built-in platform switching designed to preserve crestal bone and to maintain soft tissue volume. These implants had a novel nano-structured calcium-incorporated surface (Xpeed®) conceived to accelerate the healing processes and to reduce the time for osseointegration [31]. The fixtures were available in different lengths (10.0, 11.5 e 13.0 mm) and diameters (3.5, 4.0 e 4.5 mm).

2.3 Case study and planning
Careful evaluation and study of patients' anatomy and prosthetic needs preceded the surgical phase. Essentially, patients were subjected to x-ray examinations by performing peri-apical and panoramic radiographs, with the purpose of preliminary study of the residual bone anatomy, and to assess the compromised element consequently to be extracted. However, these two-dimensional tests allowed information to be obtained regarding the height of the residual bone crest, but did not provide any information about the thickness of the bone crest and its inclination. In order to obtain this information, if deemed necessary, the surgeon could request a cone beam computed tomography (CBCT), for three-dimensional assessment of the surgical site. CBCT was used to obtain information on the height, width, and inclination of the residual bone crest; furthermore, the files
obtained through the CBCT could be imported into specific bone reconstruction software (Invivo Dental 5®, Anatomage, San Jose, CA, USA) for the three-dimensional reconstruction of the crest and the evaluation of every anatomical detail. The preliminary examinations were completed by generic impressions and development of stone casts for diagnostic wax-up, to provide the clinician with a better understanding of the patient’s prosthetic needs.

2.4 Surgical and prosthetic procedures

Two weeks before surgery, patients underwent a professional dental hygiene session, in order to break down the bacteria present in the oral cavity. For the same purpose, beginning two days before surgery, patients were asked to perform 2-3 daily rinses with Chlorhexidine 0.12% based mouthwash (Chlorexidine®; OralB, Boston, MA, USA) 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 (Ubistesin®, 3M Espe, St. Paul, MN, USA).

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. Already at this stage, clinical evaluation of the residual crest's bone quality was made, according to the clinician's judgment [5]. The implant site was then prepared according to this assessment, using the set of helicoidal frees, as suggested by the implant manufacturer. After site preparation, the surgeon positioned the implant of chosen length and diameter. All implants were positioned according to the manufacturer’s recommendations, at crestal level, and their stability 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 to be extracted was gently dislocated with a periotome, and then extracted, taking care not to damage the remaining socket walls, with particular reference to the buccal wall (the compromise of even one of the socket walls determined the exclusion of patients in this study). The post-extraction alveolus was gently curetted in order to remove any present or remaining granulation tissue. The procedure continued with sterile saline irrigation and the integrity of the residual walls of the alveolus was tested again, using a conventional periodontal probe (PCP-UNC 15®Hu-Friedy Manufacturing, Chicago, IL, USA). Once the
integrity of the remaining walls was verified and proven, the procedure continued with the preparation of the implant site. Again, drill selection was based on the receiving site's bone quality. The implants were placed in prepared osteotomies, apically pushed 3-4 mm to the peak of the post-extraction socket. In cases with high aesthetic value, particular attention was paid to placing the implant palatally, avoiding putting it into contact with the buccal wall of the alveolus. The implants were manually placed in a slightly subcrestal position, using a hand ratchet, which 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 (MBCP®; Leone, Florence, Italy).

Immediately after implant placement, a pre-fabricated titanium abutment was prepared, and screwed onto the fixture. This served as a temporary abutment, to support a temporary resin crown. Temporary resin crowns were adapted from preformed shells or obtained from the laboratory; in both cases, they were relined with light-curing flowable resin directly onto the stub. The provisional crowns were finished with care, and polished meticulously, in order 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 screwed, therefore they had a hole in the occlusal surface, which was closed with composite resin. A careful check of occlusion was conducted, using articulating papers (Bausch Articulating Papers®; Bausch Inc., Nashua, NH, USA). Light and distributed occlusal contacts were obtained. An intra-oral peri-apical radiograph was taken. Ice packs were provided. In order to counteract the possible post-operative discomfort, analgesics were prescribed, 100 mg nimesulide every 12 h for 2 days (Aulin®; Roche Pharmaceutical, Basel, Switzerland). Patients were prescribed antibiotics, amoxicillin + clavulanic acid, 2 g each day for 6 days (Augmentin®; GlaxoSmithkline Beecham, Brentford, UK). Finally, mouthrinses with chlorexidine 0.12% (Chlorexidine®; OralB, Boston, MA, USA) were prescribed, 2/3 times a day for 10 days. Patients were asked to avoid hard foods, at least in the first week after implant placement; smokers were asked to avoid smoking for at least 48 hours after surgery. All patients were recalled at 10 days, for a control and for removal of the sutures, where present.

After a period of 3 months, the provisional restorations were replaced by the final crowns. Briefly, the final implant impression was made with individual trays using polyether (Impregum®, 3MESPE, Seefeld, Germany) or polyvinylsiloxane (Aquasil Mono®, Dentsply,
York, PA, USA). A pre-fabricated titanium abutment was prepared, finished, and tightened. The final restorations were metal-ceramic or zirconia-ceramic single crowns; these crowns were screwed or cemented, depending on the choice of the prosthodontist. Again, occlusion was carefully checked using standard occluding papers (Bausch Articulating Papers®) on the articulator and intraorally. Again, an intra-oral peri-apical radiograph was taken, to check final restoration seating. Patients were therefore enrolled in a maintenance program with professional oral hygiene sessions every 6 months.

2.5 Outcome variables
The following outcome variables were analyzed, at the time of implant insertion and provisionalization (T0), at the delivery of final restoration (3 months after implant insertion, T1) and after 1- (T2) and 2 years (T3) of functional loading:
- implant survival. The stability of individual implants was checked at delivery of final crowns by applying a reverse torque of 20 N/cm² with a dedicated wrench. Implant stability was checked again after 2 years of loading;
- complications. The complications were divided into biologic and prosthetic complications. Pain/swelling after surgery, peri-implant mucositis and peri-implantitis were enlisted as biologic complications; abutment screw loosening/fracture, ceramic/veneer fractures were enlisted as prosthetic complications. All these complications were registered and managed, where possible, during the control visit; additional appointments were arranged in case of need;
- peri-implant marginal bone loss (MBL). This evaluation was performed as previously described [23]. In brief, intraoral peri-apical radiographs were taken at different times (T0, T1, T2 and T3) for each implant, using a Rinn alignment system (Rinn®; Dentsply, Elgin, IL, USA) with a rigid film-object X-ray source being coupled to a beam-aiming device in order to achieve reproducible exposure geometry. In order to keep the same angulation, 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 x 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; therefore, ratios were calculated to adjust for distortion. At the end, peri-implant marginal bone loss (MBL) was calculated, as modification in the peri-
Implant marginal bone level at different time periods, on the mesial and distal implant side: the average from the mesial and distal calculations was used as the final value.

2.6 Statistical evaluation

Data were collected and analysed by two independent, experienced and calibrated observers, who were not part of the treating team. All data were inserted in specific statistical sheet, created with Excel 2003 (Microsoft Excel®, Microsoft Corporation, Redmond, WA, USA); then, the statistical analysis was conducted. Descriptive statistics were used for the evaluation of patients’ demographics (such as gender, age, smoking habit) and implants’ characteristics/features (implant site, position, length, diameter, bone quality at the recipient site. Absolute and relative frequency distributions were calculated for qualitative variables, means, standard deviations (SD), medians and confidence intervals (CI 95%) were estimated for quantitative variables, such as peri-implant marginal bone loss (MBL). Implant survival was calculated at the patient- and at the implant level; peri-implant marginal bone loss (MBL) was calculated at the patient level.

3. Results

Four patients were excluded from the study (2 for insufficient residual bone, 1 for chronic periodontal disease, and 1 for bruxism). Forty-six patients (23 males, 23 females, aged between 18-73 years, mean 44.5) were eligible for the present study.

The gender, age, and smoking habit of the enrolled patients, with related survival rates, were reported in Table 1. The site, position, length and diameter of the installed implants, together with the quality of the recipient sites and the related survival rates were reported in Table 2. Forty-seven fixtures (82.5%) were installed in healed sites, while 10 (17.5%) were installed 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%) or extensive tooth decay (1 single case; 10%). Most of the immediate implants (8/10: 80%) were installed in the anterior maxilla. In this group, no buccal bone damages occurred, therefore 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.
The final restorations were metal-ceramic (52 cases; 91.2%) or zirconia-ceramic (5 cases; 8.8%) single crowns, screwed or cemented. Four patients (four implants) withdrew from the study. In fact, one patient died, two patients had serious health problems (not related to the dental implant therapy) and were hospitalized, and another patient moved to another country. As these patients could not attend the scheduled 2-year follow-up examination, they were consequently classified as drop-outs, even if they had their implants still in function. At the two-year follow-up, only one implant was lost, in the posterior maxilla (second premolar, healed site) of a 48-year old female smoking patient. The failed fixture (3.5 mm diameter x 10.0 mm length) was installed in type III bone. This implant showed mobility and lack of osseointegration 2 months after surgery, and was consequently removed; all the other implants were stable, giving a patient-based 2-year overall survival rate of 97.6% (Figures 1–4).

With regard to biological complications, one female patient (one fixture installed in a healed site of the posterior mandible) experienced pain and swelling after surgery: this was managed by prescribing analgesic medication, and no further complications were reported for this implant. At the end of the study, the incidence of biologic complications was 1.8%. Prosthetic complications were more frequent, and amounted to 7.5%. In fact, three patients had their abutments loosened (2 of them 3 months after surgery, and the other 1 year after surgery, respectively). Two of the loosened abutments were in the posterior mandible of two male patients, while the other one was in the anterior maxilla of a female patient. All these abutments were re-inserted and screwed in again; however, these mechanical complications were enlisted as prosthetic complications. In addition, a veneer fracture occurred in a metal-ceramic definitive crown, in the posterior maxilla of a male patient; the damaged restoration was removed, and a new crown was fabricated and provided. Finally, the peri-implant marginal bone loss (MBL) as calculated at the 1- and 2-year examinations, was reported in Table 3.

4. Discussion

Up to now, few studies are available in the literature on immediate functional loading of single implants [20-24,26,27]; the major part of these studies deals with implants placed in the anterior maxilla [24-27], where functional loads are reduced, and a few studies examine
the immediate loading of implants placed in post-extraction sockets [23,24,27]. A recent randomized, controlled trial compared the survival and success of single implants in immediate functional loading placed with the flapless method, with those of delayed loading implants, positioned after raising a surgical flap [20]. The implants were placed in the maxilla and mandible of partially edentulous patients. At the end of the study, the immediate functional loading did not compromise the rate of survival and success of the implants, and allowed reduction in the times and costs of therapy, in addition to patients' discomfort [20]. 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 [21]. In a prospective study with follow-up after 5 years, with the immediate functional loading of 40 implant-supported single crowns in the posterior mandible (molar) placed in 33 patients, the cumulative success reported was 95%, with only two implant failures [22]. However, the posterior mandible is characterized by a higher bone quality, and generally allows a better primary stabilization of the implant after placement with respect to the posterior maxilla [32]. Excellent results have been reported following the placement of single implants with immediate loading in the anterior maxilla [24,26,27]. In a study involving 70 patients treated with single implants placed in healed sites (45 implants) and in post-extraction sockets (25 implants), one year after loading all implants were functional and x-rays confirmed successful osseointegration [24]. Similar excellent results were reported in a clinical study where the placement of single implants subjected to immediate functional loading in aesthetic areas had a survival rate of 96.1% at 3 years, and minimal peri-implant marginal bone loss [26]. 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 and respectively subjected to immediate, early, or delayed loading [25]. In this review, in fact, no significant difference were found in the survival of implants subjected to different load conditions, with an overall survival rate greater than 95% [25]. A recent clinical study with follow-up at 5 years has finally compared the peri-implant marginal bone loss of single implants placed in healed sites and post-extraction sockets of the anterior maxilla [27]. In this study, the mean marginal bone loss 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; the mean marginal bone loss was 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 [27]. Loss of marginal bone was more pronounced in implants inserted in healed ridges (p < 0.041).
compared to fresh surgical extraction sockets \( (p < 0.540) \) [27].

All these results seem to be in agreement with those of our present clinical work with follow-up at 2 years, where 57 single implants (38 in the maxilla and 19 in the mandible, 47 in healed sites and 10 in post-extraction sites) 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% (patient-based). All other implants were functioning, with a very low incidence of biological complications (1.8%) with one patient experiencing swelling after surgery; the incidence of prosthetic complications was slightly higher (7.5%) with three loosened abutments and a ceramic crown fracture. Finally, after 2 years of functional loading, the overall peri-implant marginal bone loss was 0.37 mm (± 0.22). In the healed site group, a 2-year marginal bone loss of 0.4 mm (± 0.22) was reported, while in post-extraction sockets the 2-year marginal bone loss amounted to 0.3 mm (± 0.22).

In procedures with immediate functional loading, success essentially depends on the degree of primary implant stabilization, the presence of controlled load conditions, and by the macro- and micro-topographical characteristics of the implant used [7-9,12,19,23]. The primary stability, defined as the biometric stability achieved immediately after implant insertion by the mechanical locking of the implant to the bone [19], is of course essential. An 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 also the shape and surface of the implant [19].

A good trick for maximizing the implant’s primary stability is to under-preparare the surgical site, using burs with a diameter that is smaller than the implant’s diameter: this applies particularly in the case of post-extraction sockets, where stabilization is often achieved through an apical fixation of a few millimeters [17-19,23]. Certainly, the use of an aggressive fixture with a certain degree of taper may help to obtain a valid primary stabilization [23]. In our present study, we followed a strict surgical protocol, placing implants in under-prepared osteotomies, particularly in the case of poor bone quality (bone types III- IV) and in fresh extraction sockets. Moreover, the macro-topographical features of the fixture used in this study are designed to provide high insertion torque, with threads of increasing dimensions 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 the immediate functional loading, particularly in areas characterized by poor bone quality [23]. The receiving bone site is in fact fundamental: primary stabilization is simpler in the anterior areas of the jaw bones, where the bone
density is higher, and is more difficult in the posterior areas, and particularly in the posterior maxilla [32]. 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 [7,9,15,18,32]. In fact, certain micro-movements at the interface between the bone and the implant, beyond a certain critical threshold, can lead to the loosening of the fixture, resulting in fibrous encapsulation and failure [7,9,16-19,23]. In our present study, most of the implants (26; 45.7%) were placed in the posterior maxilla; however, only one failure was reported. This excellent result was probably related to the controlled loading protocol used in the study. In fact, after placement, all provisional single crowns were adjusted with light occlusal marks, so that the occlusal surfaces were in slight static contact with the opposite dentition, with no contact in lateral movements, as previously reported. Last but not least, in procedures with immediate functional loading, it is of fundamental importance to use implants with specific micro-topography and surface characteristics, capable of stimulating the apposition of new bone and promoting and accelerating the healing phenomena [7,9,16-19,23,25-28,33-35]. In the present study, we used implants with a novel nano-structured calcium-incorporated surface, which is highly osteoconductive [23,31,33-35] and may promote bone healing; this peculiar micro-topographical feature, combined with the shape of the implant body, designed for critical bone conditions and high insertion torques, may have minimized the risk of failure associated with immediate functional loading.

5. 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 biological complications, and rather limited peri-implant marginal bone loss (MBL) (0.37 ± 0.22 mm). Complications of a prosthetic nature were more represented, with a slightly higher incidence (7.5%), though not dissimilar from what is reported in the literature for implant-supported single crowns [6]. This study has its limitations, such as the small number of patients treated and the low number of implants inserted; for this reason, further studies will be needed to confirm the results obtained here.
6. Acknowledgments
The authors report no conflicts of interest relating to the preparation of this scientific work.

7. References


8. Tables

Tab. 1. Distribution of the patients by gender, age, smoking habit, with the related survival rate (patient-based).

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<td></td>
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<tr>
<td><em>Smokers</em></td>
<td>17 (37.0%)</td>
<td>1</td>
<td>1</td>
<td>92.3%</td>
</tr>
<tr>
<td><em>Non smokers</em></td>
<td>29 (63.0%)</td>
<td>3</td>
<td>-</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>All patients</em></td>
<td>46</td>
<td>4</td>
<td>1</td>
<td>97.6%</td>
</tr>
</tbody>
</table>
Tab. 2. Distribution of the implants by site, position, length, diameter, bone type, with related survival rate (implant-based).

<table>
<thead>
<tr>
<th></th>
<th>Nº of implants</th>
<th>Drop-outs</th>
<th>Failures</th>
<th>Survival rate (2-years)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Site</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxilla</td>
<td>38 (66.7%)</td>
<td>2</td>
<td>1</td>
<td>97.2%</td>
</tr>
<tr>
<td>Mandible</td>
<td>19 (33.3%)</td>
<td>2</td>
<td>-</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Position</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incisors</td>
<td>9 (15.8%)</td>
<td>-</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>Cuspids</td>
<td>3 (5.2%)</td>
<td>-</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>Premolars</td>
<td>31 (54.4%)</td>
<td>2</td>
<td>1</td>
<td>96.5%</td>
</tr>
<tr>
<td>Molars</td>
<td>14 (24.6%)</td>
<td>2</td>
<td>-</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Length</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 mm</td>
<td>30 (52.7%)</td>
<td>1</td>
<td>1</td>
<td>96.5%</td>
</tr>
<tr>
<td>11.5 mm</td>
<td>21 (36.8%)</td>
<td>2</td>
<td>-</td>
<td>100%</td>
</tr>
<tr>
<td>13 mm</td>
<td>6 (10.5%)</td>
<td>1</td>
<td>-</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Diameter</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.5 mm</td>
<td>25 (43.9%)</td>
<td>1</td>
<td>1</td>
<td>95.8%</td>
</tr>
<tr>
<td>4.0 mm</td>
<td>21 (36.8%)</td>
<td>2</td>
<td>-</td>
<td>100%</td>
</tr>
<tr>
<td>4.5 mm</td>
<td>11 (19.3%)</td>
<td>1</td>
<td>-</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Bone quality</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type II bone</td>
<td>18 (31.6%)</td>
<td>1</td>
<td>-</td>
<td>100%</td>
</tr>
<tr>
<td>Type III bone</td>
<td>31 (54.4%)</td>
<td>2</td>
<td>1</td>
<td>96.5%</td>
</tr>
<tr>
<td>Type IV bone</td>
<td>8 (14.0%)</td>
<td>1</td>
<td>-</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All implants</td>
<td>57</td>
<td>4</td>
<td>1</td>
<td>98.1%</td>
</tr>
</tbody>
</table>
Table 3. Peri-implant marginal bone loss (MBL) between groups at different time periods (patient-level), in mm.

<table>
<thead>
<tr>
<th></th>
<th>Baseline- 3 months</th>
<th>Baseline- 1 year</th>
<th>Baseline-2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N; mean (SD); median; CI95%</td>
<td>N; mean (SD); median; CI95%</td>
<td>N; mean (SD); median; CI95%</td>
</tr>
<tr>
<td>Healed sites</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>35</td>
<td>33</td>
<td>31</td>
</tr>
<tr>
<td>0.23 (± 0.18)</td>
<td>0.36 (± 0.21)</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>0.2</td>
<td>0.4</td>
<td>0.33- 0.47</td>
<td></td>
</tr>
<tr>
<td>0.18- 0.28</td>
<td>0.29- 0.43</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extraction sockets</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>0.2 (± 0.18)</td>
<td>0.22 (± 0.20)</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>0.25</td>
<td>0.25</td>
<td>0.35</td>
<td></td>
</tr>
<tr>
<td>0.09- 0.31</td>
<td>0.10- 0.34</td>
<td>0.17- 0.43</td>
<td></td>
</tr>
<tr>
<td>All sites</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>45</td>
<td>43</td>
<td>41</td>
</tr>
<tr>
<td>0.22 (± 0.17)</td>
<td>0.33 (± 0.22)</td>
<td>0.37</td>
<td></td>
</tr>
<tr>
<td>0.2</td>
<td>0.4</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>0.18- 0.26</td>
<td>0.27- 0.39</td>
<td>0.31- 0.43</td>
<td></td>
</tr>
</tbody>
</table>
9. Figures

Figure 1. Immediate implant placement in the anterior maxilla (right cuspid):

a- extraction of the non-recoverable root;
b- placement of the implant in the fresh post-extraction socket;
c- the implant in position with the provisional abutment, 24 hours after surgery;
d- the provisional restoration is positioned within 48 hours of implant placement.
Figure 2. Immediate implant placement in the anterior maxilla (right cuspid):
 a- 3 months after implant placement, the final metal-ceramic crown is delivered;
b- radiographic control at the delivery of final metal-ceramic crown;
c- 2-year clinical control;
d- 2-year radiographic control.
Figure 3. Conventional implant placement in the posterior mandible (first left molar):
   a- placement of the implant in the healed ridge;
   b- the provisional abutment in position;
   c- the implant in position with the provisional restoration, immediately after implant placement;
   d- the provisional restoration in position immediately after implant placement.
Figure 4. Conventional implant placement in the posterior mandible (first left molar):
a- 3 months after implant placement, the final metal-ceramic crown is delivered;
b- radiographic control at the delivery of final metal-ceramic crown;
c- 2-year clinical control;
d- 2-year radiographic control.