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Immediate functional loading of single implants: A 1-year interim report of a 5-year prospective multicentre study



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Purpose: The aim of this prospective multicentre study was to evaluate the clinical outcome of immediately loaded single implants.

Materials and methods: Patients were recruited at six clinical centres. Inclusion criteria were single-tooth replacement in fully healed sites or post-extraction sockets with adequate bone height and width, to place an implant of at least 3.5 mm in diameter and 10.0 mm in length. All implants (AnyRidge, MegaGen, Gyeongbuk, South Korea) were functionally loaded immediately after placement. After 3 months, final crowns were delivered. All implants were followed for 1 year. Outcome measures were: implant stability; complications; peri-implant marginal bone level changes; probing pocket depth.

Results: Fifty-seven implants (38 in the maxilla and 19 in the mandible) were placed in 46 patients (23 males, 23 females, aged between 18 to 73 years). Ten implants were placed in post-extraction sockets. Two patients (two implants) withdrew from the study and were classified as drop-outs. At the end of the study, only one implant was lost in a healed site. All the surviving implants were stable, giving an overall 1-year survival rate of 97.7% (patient-based). A few complications (one patient experienced swelling after surgery, two had loosened abutments and another patient had a ceramic crown fracture) were encountered. After 1 year of functional loading, the patients had lost an average of 0.32 mm (± 0.22) of peri-implant marginal bone; the mean probing pocket depth (PPD) was 2.16 mm (± 0.68).

Conclusions: Within its limit (limited number of patients treated and self-evaluation of the outcomes), this study supports the concept that immediate functional loading of single dental implants can be a successful treatment procedure, with satisfactory clinical outcomes.

Conflict-of-interest statement: *MegaGen Implant Co., Gyeongbuk, South Korea, the manufacturer of the implants used in this investigation, partially supported this study by donating the implants and prosthetic components; however, the research data belonged to the authors and by no means did Megagen interfere with the conduct of the study or the publication of the results.*

■ Introduction

Single tooth replacement using dental implants has proven to be a successful treatment procedure¹. This procedure has been well documented in medium to long-term studies^{2,3}, confirming predictable out-

comes. In a recently published meta-analysis, survival of implants supporting single crowns at 5 years amounted to 97.2% (95% CI: 96.3 to 97.9%)¹. Consequently, the placement of a dental implant is a very popular choice to replace missing single teeth¹⁻³.

Traditionally, dental implants have been placed in a two-stage protocol, with a submerged healing period of 3 to 6 months⁴. This load-free healing period, in fact, was considered an essential prerequisite to obtain mineralised bone at the bone-implant interface before second-stage surgery and prosthesis placement^{4,5}. This guideline was based on the initial clinical experience of Branemark and co-workers, who believed that applying forces to the implant during the critical healing period might cause micro-movement at the bone-implant interface, which in turn could result in fibrous encapsulation and eventually implant failure⁴⁻⁶. As a consequence, patients were asked either to wear a removable interim prosthesis or remain partially edentulous for an extended period of time for the osseointegration to take place⁷. However, this long unloaded period can impose hardships on patients for many reasons; most obviously the inconvenience, discomfort and embarrassment of removable prostheses, especially in aesthetically relevant regions^{7,8}.

With increasing demands by patients to overcome the functional and aesthetic problems related to two-stage protocols, clinical and experimental investigations were initiated to evaluate whether healing and osseointegration could be achieved under functional loading⁹ and the concept of immediately loaded implants began to be investigated¹⁰.

To date, immediate loading is defined as placing the implants into functional occlusion within a period of 48 to 72 h after insertion¹⁰. Therefore, implants can be defined as 'immediately loaded' only if they are restored by a functional, fixed prosthesis at the time of the surgery or within 48 to 72 h afterwards⁷; the immediately loaded prosthesis must be in contact with the opposing dentition. In contrast, the fixation of prostheses to implants within the first 48 to 72 h but not in functional occlusion with the opposing dentition, is defined as immediate non-functional loading or immediate provisionalisation/restoration^{11,12}.

Immediate loading of implant-supported prostheses is highly appreciated by patients, because it reduces the overall treatment time, avoids a second-stage operation and offers immediate comfort as there is no need for a temporary removable prosthesis during the healing phase^{11,12}. This finally results in increased patient satisfaction and acceptance of implant therapy⁹⁻¹³.

Although immediate functional loading has been successfully applied in the case of splinted implants placed in mandibles to support prostheses or bar-retained overdentures^{9,14-17}, immediate functional loading of single implants might involve more risk, particularly in posterior regions of the maxilla¹². In fact, it might induce micro-motion and instability of the implant, leading to soft tissue encapsulation instead of direct bone apposition and failure of osseointegration^{9,18}.

To date, reports and clinical studies have confirmed high success rates using immediate provisionalisation/restoration of single unsplinted implants^{8,12,19-21}, but only a few studies have been reported on the immediate functional loading of single titanium implants²²⁻²⁵. In addition there is limited evidence regarding the effect of immediate loading on peri-implant marginal bone and soft tissue responses^{6,9}.

The aim of the present prospective multicentre study was to evaluate the clinical outcome of immediately loaded single tooth implants, placed in healed ridges or in fresh extraction sockets. This study is reported according to the STROBE statement (<http://www.strobe-statement.org/>), which aims to improve the quality of reporting of observational studies in epidemiology.

■ Materials and methods

■ Patient selection

The present investigation was designed as a prospective clinical study based on data from patients recruited and treated for immediately loaded single-tooth implants by six different clinicians (CM, GL, FR, CL, TE, MO) in private practices, under a single protocol and using standardised procedures. Between February 2012 and February 2013, interested patients were selected according to the following inclusion and exclusion criteria.

Inclusion criteria were:

- any partially dentate patient, in need of replacement of a single missing or failing tooth at the time of recruitment
- being at least 18 years old
- in good systemic and oral health

- physically and psychologically able to tolerate conventional surgical and restorative procedures
- having sufficient residual bone to allow the placement of an implant at least 10.0 mm long with a 3.5 mm diameter
- able to sign an informed consent form.

Indications for tooth extraction and immediate implant placement included: trauma resulting in root fracture; endodontic failure; or a non-restorable crown. Only post-extractive sites with well preserved bony walls were included in the study.

Exclusion criteria were:

- chronic periodontitis with advanced loss of support. Chronic periodontitis with advanced loss of support was defined by periodontal pocketing depths (PPD) >6 mm with clinical attachment loss (CAL) >4 mm, radiographic evidence of bone loss and increased tooth mobility²⁶
- other oral disorders (vesiculo-bullous or ulcerative diseases, red or white lesions, salivary gland diseases, connective tissue or lymphoid lesions, cysts of the oral region, benign or malignant tumours)
- need for major bone augmentation procedures with autogenous bone or bone substitutes prior to implant insertion, to obtain an ideal position for the implant (although a minor augmentation procedure to cover exposed threads or interproximal/buccal grafting owing to hard tissue deficiency was not an exclusion criterion)
- presence of active infection (pus, fistula) around the failing tooth
- loss or damage of the buccal bone crest (>5 mm) after extraction of the failing tooth
- lack of opposite occluding dentition in the area intended for implant placement
- parafunctions (bruxism or clenching)
- uncontrolled diabetes
- immunocompromised status
- radiotherapy in the maxillofacial region
- chemotherapy
- treatment with intravenous amino-bisphosphonates
- psychiatric disorders.

Patient questionnaires, clinical examination, and electromyography were used to diagnose parafunc-

tion²⁷. Any smoking habit was recorded but was not considered as exclusion criteria for this study. Smokers were defined as patients who smoked cigarettes without consideration of the amount. Patients were advised that smoking is associated with an increased risk of implant failure²⁸. Information was given to each patient regarding alternative treatment options, such as more traditional therapies (including fixed partial dentures on natural teeth or implants with two-stage protocol). All participants received thorough explanations about the planned treatment and its potential risks and complications, and signed a written informed consent form prior to being enrolled in the study. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki on clinical research involving human subjects, 1975, as revised in 2000.

■ Implant design and surface characterisation

The implants used in this study (AnyRidge; MegaGen Implant Co., Gyeongbuk, South Korea) are characterised by a tapered design with strong self-cutting threads, to ensure high initial stability in the immediate loading protocol (Fig 1). These implants have an internal hexagon combined with a 5-mm deep conical connection (10 degrees), offering a tight seal and a high mechanical strength, with built-in platform switching designed to maintain crestal bone and to increase soft tissue volume. The implants feature a novel nanostructured calcium-incorporated surface (Xpeed)^{29,30}. The implants for the study were available in lengths of 10 mm, 11.5 mm, 13 mm; the available diameters were 3.5 mm, 4.0 mm and 4.5 mm.

■ Preoperative assessment

Prior to implant placement, each patient was investigated clinically and radiographically. Panoramic radiographs formed the basis for the primary investigation, and were further supplemented with periapical radiographs to more accurately assess the quantity of bone available for implant placement. Cone beam computed tomography (CBCT) scans were used only when it was considered necessary by the treating surgeon, as a final investigation. CBCT datasets were eventually transferred to specific implant navigation



Fig 1 Schematic drawing of the implant (AnyRidge; MegaGen) used in this study. This implant is characterised by a tapered design with strong self-cutting threads, to ensure high initial stability for immediate loading protocol.

software (Invivo Dental 5; Anatomage, San Jose, CA, USA) to perform a three-dimensional reconstruction of the maxillary bones. With this navigation software it was possible to correctly assess the width of each implant site, the thickness and the density of the cortical plates and the cancellous bone, as well as the ridge angulations. The ridge anatomy was assessed using casts and diagnostic wax up, to provide the clinician with a better understanding of the patient's prosthetic needs.

■ Surgical and prosthetic procedures

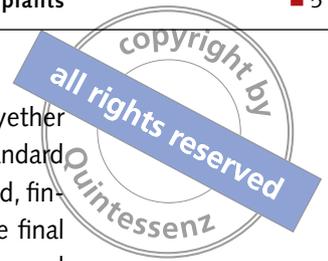
All patients received professional oral hygiene treatment prior to implant insertion and were instructed to rinse with a chlorhexidine mouthwash 0.12% (Chlorexidine; OralB, Boston, MA, USA) for 1 min, twice a day, starting 2 days before the intervention. Patients were treated under local anaesthesia using articaine with adrenaline 1:100000 (Ubistesin; 3M ESPE, St. Paul, MN, USA).

For healed ridges, minimal crestal incision was performed to access the sites. After reflection of a full thickness flap, osteotomies were initiated with a 2.0 mm drill to the desired depth. Bone quality was evaluated by radiographic assessment, according to the criteria of the Lekholm and Zarb index, and at drilling, according to the clinician's judgment³¹. The preparation of the implant sites was performed as suggested by the implant manufacturer. Surgeons were free to choose implant lengths (10.0, 11.5 and 13.0 mm) and diameters (3.5, 4.0 and 4.5 mm), according to clinical indications. All implants were inserted according to the manufacturer's recommendations, at crestal level, and their stability was determined clinically as the absolute absence of axial or rotational movement by the removal of the implant driver without use of the stabilising wrench.

For extraction sockets, a flapless approach was utilised. The failing teeth were extracted following careful luxation of the root with a periosteal elevator, as atraumatically as possible, attempting to preserve the buccal alveolar bone. Sockets were debrided from any remains of granulation tissue by an excavator and irrigated by sterile saline. Subsequently, a careful examination of the extraction socket was performed by means of a conventional periodontal probe (PCP-UNC 15; Hu-Friedy Manufacturing,

Chicago, IL, USA), to verify the integrity of the four walls. If this was not the case, and a buccal bone loss or damage (>5 mm) was present after extraction, the patient was excluded from the study and the implant was placed by means of a conventional protocol, including, in most instances, flap elevation and simultaneous guide bone regeneration. Again, selection of the final drill size was based on bone quality, and profuse saline irrigation was used throughout the drilling procedure. In general, to increase primary stability, implants were placed in underprepared osteotomies, and socket preparation was deepened beyond the alveolar apex, to engage the apical bone. There was not a threshold for insertion torque; the surgeons were free to decide the type of preparation and consequently the insertion torque, based on their clinical experience. In aesthetically-sensitive cases, the osteotomies were directed through the palatal aspect of the socket, so that the implant was well stabilised in the remaining alveolar bone without contacting the intact buccal plate. Special attention was paid to ensure the correct three-dimensional position of the implant³². The implants were manually seated in the proper position, slightly subcrestally, using a hand ratchet, which gave a rough estimate of the maximum insertion torque obtained. Afterwards any discrepancies between the buccal bone and the implant surface were filled with biphasic calcium phosphate granules (MBCP; Biomatlante, Vigneux de Bretagne, France).

Following implant placement, a pre-fabricated titanium abutment, which would serve as provisional abutment, was prepared with a high-speed bur to the proper retentive and resistant form. This provisional abutment was hand-tightened onto the implant with finger pressure (approximately 15 to 20 N/cm²). All implants were restored with provisional crowns. These were delivered immediately after surgery, if fabricated chairside with the help of single shell crowns or clear vacuum-formed templates, and relined with light-curing flowable resin composite directly to the provisional abutment. They were delivered within 6 h, if fabricated by the laboratory after taking an impression. The provisional crowns were carefully contoured and polished to provide correct emergence profiles (slightly flat or concave in interproximal and palatal sides, and slightly convex in the buccal aspect to support the



soft tissues), adaptation to the gingival tissues, scalloped gingival architecture, and appropriate support to the interdental papillae. All temporary restorations were screw-retained, with a hole created in the direction of the long axis of the implant to fit the abutment and the prosthetic screw. The occlusion was checked with articulating papers (Bausch Articulating Papers; Bausch, Nashua, NH, USA). All temporary crowns were adjusted with light occlusal marks, so that the occlusal surfaces were in slight static contact with the opposite dentition but with no contact in lateral movements. In the healed ridge group, the flap was adapted to the emergence profile and sutured; in the extraction sockets group, the contours of the temporary restorations were designed to mimic the original tooth form, sealing the socket and maintaining clot formation subgingivally. This kind of morphology provided support for the labial gingiva. Finally, the provisional crown was screwed to the implant, and the occlusal hole was closed with teflon flowable resin composite. A periapical radiograph was made to evaluate implant placement, ensure proper abutment placement, and ascertain the fit of the provisional restoration.

■ Postoperative treatment

Ice packs were provided postoperatively. The patients were given anti-inflammatory and analgesic medication, consisting of 100 mg nimesulide (Aulin; Roche Pharmaceutical, Basel, Switzerland) every 12 h for 2 days. All patients received oral antibiotics, amoxicillin and clavulanic acid, 2 g each day for 6 days (Augmentin; Glaxo-Smithkline Beecham, Brentford, UK). Chlorhexidine 0.12% mouthrinses were prescribed for 2 weeks to enhance plaque control. Patients were instructed to eat a soft diet for 7 days and maintain daily hygiene after surgery. Smokers were told to avoid smoking for 48 h postoperatively. Patients were then observed after 2 weeks for a postoperative control and sutures were removed (if present).

■ Final restorative phase

After 3 months, the provisional restoration was replaced by a final restoration. Briefly, the final implant impression was made with individual trays using polyvinylsiloxane (Aquasil Monophase; Dent-

sply International, York, PA, USA) or polyether (Impregum; 3M ESPE, Seefeld, Germany). A standard pre-fabricated titanium abutment was prepared, finished and tightened to 25 N/cm² torque. The final restorations comprised metal-ceramic crowns and zirconium-ceramic crowns, depending on patient requirements, which were screwed to the implants. The occlusion was checked using standard occluding papers (Bausch Articulating Papers). All final restorations were carefully evaluated for proper occlusion, and protrusion and laterotrusion were assessed on the articulator and also intraorally. The restorations needed to have occlusal surfaces similar to those of natural teeth, with occlusal contacts in maximum intercuspation and with functional contacts during lateral and protrusive excursions. Finally, an intraoral radiograph was made to check final restoration seating. Patients were included in a maintenance program to achieve optimal hard and soft tissue healing, which comprised professional oral hygiene every 6 months.

■ Outcome measures

Patient examinations and measurements were performed by each investigator in his/her dental office at the time of implant placement and provisionalisation (T0), at the delivery of definitive restoration (3 months after implant placement, T1) and after 1 year of functional loading (T2), and the following outcome measures were recorded:

- *Implant stability.* The stability of individual implants was measured at the delivery of definitive crowns by applying a reverse torque of 20 N/cm² with a dedicated wrench. Implant stability was then re-assessed at the 1-year follow-up control using the metal handles of two dental mirrors.
- *Complications.* Complications included pain or swelling after surgery, soft tissue inflammation and peri-implant infection with fistula formation, pain, suppuration or exudation, discomfort on occlusion, prosthetic complications (screw or abutment loosening, screw or abutment fracture, ceramic or veneer fractures). All complications were carefully registered, and if possible, managed during the follow-up visit; additional appointments were arranged if needed.

Table 1 Distribution of the patients treated and the implants inserted in the study, with related clinical outcomes, for each clinical centre.

Clinical centre	Number of patients treated	Number of implants inserted	Drop-outs	Implant failures	Complications
1	10	11	1	1	1
2	12	14	1	–	1
3	6	10	–	–	1
4	5	5	–	–	–
5	7	9	–	–	1
6	6	8	–	–	–
	46	57	2	1	4

- *Radiographic peri-implant marginal bone changes*^{33,34}. To perform this evaluation, intraoral periapical radiographs were taken 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. Radiographs were taken at the baseline (immediately after implant placement, T0), at the delivery of definitive restoration (T1) and after 1 year of functional loading (T2). The radiographs had the same angulation: the film holder was customised by means of polyvinylsiloxane polymerised on the occlusal surfaces of the adjacent non-restored teeth. Mesial and distal marginal bone levels of all implants were determined at baseline (T0) and recall evaluations (T1, T2) with the aid of an ocular grid (magnification: 4.5×). Reference points for the linear measurements were the coronal margin of the implant collar and the most coronal point of bone-to-implant contact. To account for variability, the implant dimension (length) was measured and compared with the documentation dimensions; and ratios were calculated to adjust for distortion^{33,34}. After that, crestal bone changes were measured as modifications in the peri-implant marginal bone level at different time periods, on the mesial and distal implant side; then, the average from the mesial and distal calculations was used as the final value. All the bone level changes were measured by an independent calibrated observer, who was not part of the treating team.
- *Probing pocket depth (PPD)*. Probing depth was defined as the linear distance from the free mucosal margin to the base of the pocket (apical termination of the junctional epithelium) and was meas-

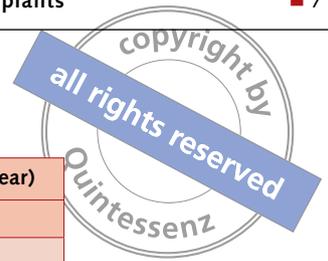
ured using a light probing force (approximately 25 g) to the nearest mm with a conventional periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing, Chicago, IL, USA) at four sites per implant (mesially, mid-buccally, distally, and mid-lingually).

■ Statistical analysis

Data analysis was performed by an independent investigator who was not directly involved in the study. Databases were created with Excel 2003 (Microsoft Excel; Microsoft Corporation, Redmond, WA, USA) and used for the analysis. Descriptive statistics were used for patient demographics (gender, age, smoking) and distribution of implants (site, position, length, diameter, bone type). Absolute and relative frequency distributions were calculated for qualitative variables, and means and standard deviations (SD) were estimated for quantitative variables such as peri-implant bone resorption. Implant survival was calculated at the patient and at the implant level; peri-implant bone resorption and probing pocket depth were calculated at the patient level.

■ Results

Patients were recruited and treated in six different private practices located in Italy. One experienced surgeon at each centre, having extensive experience in the treatment of patients with immediate loading procedures, performed all of the operations. Four patients could not be included in the study (2 patients had insufficient residual bone to allow the placement of an implant at least 10 mm long with a 3.5 mm diameter; 1 patient had chronic periodontal disease;

**Table 2** Distribution of the patients by gender, age, smoking habit, and related survival rates (patient-based).

	N° of patients	Drop-outs	Failures	Survival rate (1 year)
Gender				
Males	23 (50%)	2	–	100%
Females	23 (50%)	–	1	95.7%
Age (years)				
16–25	7 (15.2%)	–	–	100%
26–35	6 (13.0%)	–	–	100%
36–45	7 (15.2%)	–	–	100%
46–55	13 (28.2%)	–	1	92.4%
56–65	9 (19.5%)	1	–	100%
>65	4 (8.7%)	1	–	100%
Smoking habit				
Smokers	17 (37.0%)	–	1	94.2%
Non-smokers	29 (63.0%)	2	–	100%

Table 3 Distribution of the implants by site, position, diameter, length, bone type and related survival rates (implant-based).

	N° of implants	Drop-outs	Failures	Survival rate (1 year)
Site				
Maxilla	38 (66.7%)	–	1	97.4%
Mandible	19 (33.3%)	2	–	100%
Position				
Incisors	9 (15.8%)	–	–	100%
Cuspids	3 (5.2%)	–	–	100%
Premolars	31 (54.4%)	–	1	96.8%
Molars	14 (24.6%)	2	–	100%
Diameter				
3.5 mm	25 (43.9%)	–	1	96.0%
4.0 mm	21 (36.8%)	1	–	100%
4.5 mm	11 (19.3%)	1	–	100%
Length				
10.0 mm	30 (52.7%)	–	1	96.7%
11.5 mm	21 (36.8%)	2	–	100%
13.0 mm	6 (10.5%)	–	–	100%
Bone type				
Type II	18 (31.6%)	1	–	100%
Type III	31 (54.4%)	–	1	96.8%
Type IV	8 (14.0%)	1	–	100%

1 patient was a bruxist). In total, 46 patients (23 males and 23 females; aged between 18 to 73 years, mean age 44.5 years) were eligible for the present study. The number of patients treated and distribution of implants inserted in the study, for each clinical centre, and the related outcomes are reported in Table 1.

The distribution of the patients by gender, age, smoking habit, and the related survival rates (patient-based) are reported in Table 2. The distribution of the implants by site, position, diameter, length, bone type and the related survival rates (implant-based) were reported in Table 3. Forty-seven implants (82.5%)

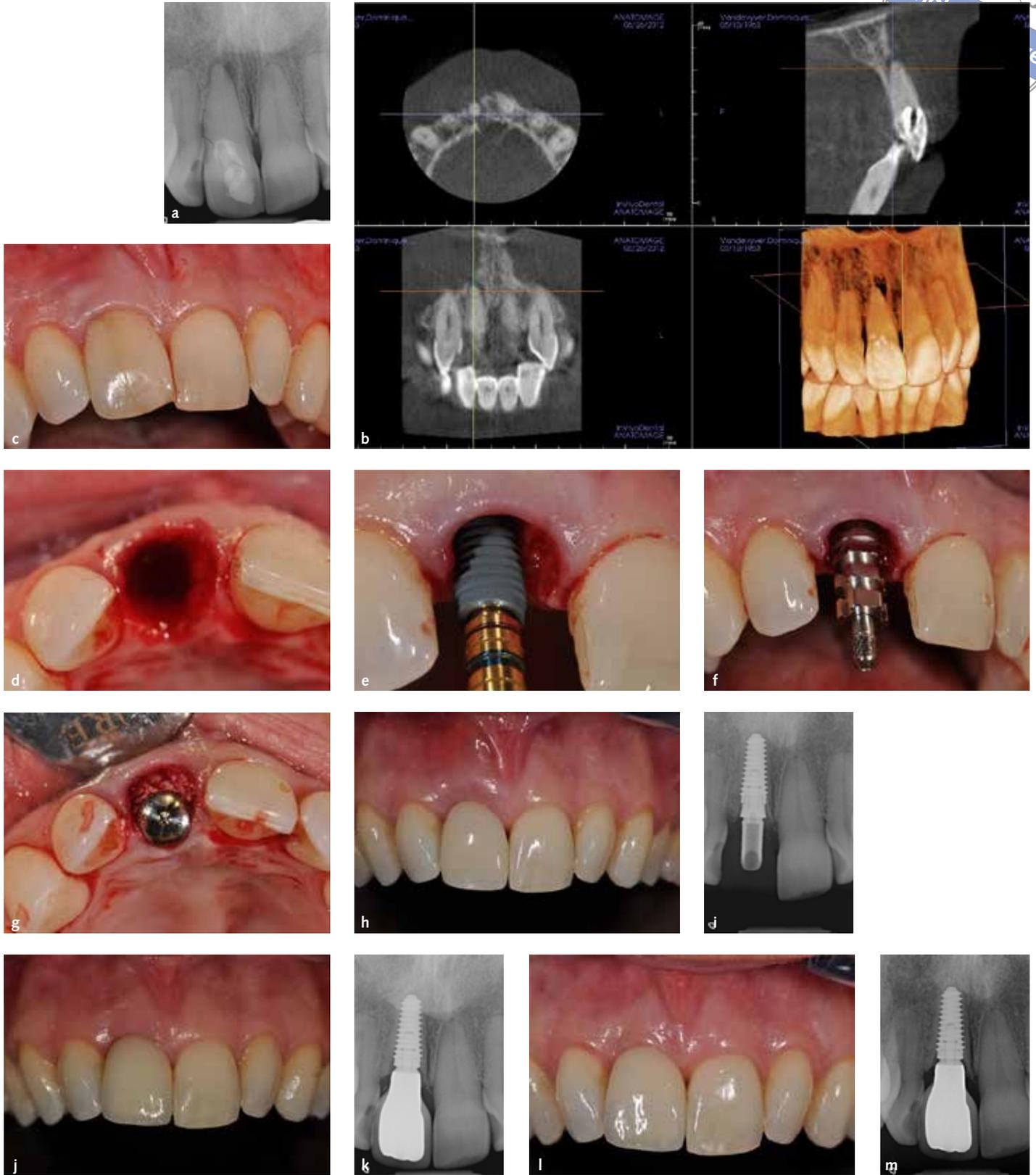
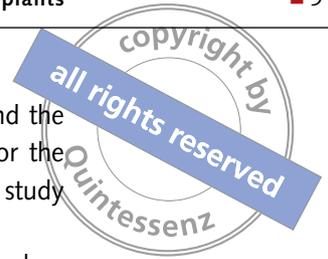


Fig 2 Representative case of a post-extractive implant: (a) periapical radiograph of a patient with a fractured central incisor; (b) 3D reconstruction of the fractured central incisor and the maxillary bone with Invivo Dental 5 software (Anatomage); (c) clinical view of the fractured central incisor; (d) the socket after tooth extraction; (e) implant placement; (f) transfer for impression in position immediately after implant placement; (g) healing abutment in position with biomaterial filling the gap between the implant and the buccal bone; (h) the delivery of the temporary restoration 6 h after surgery; (i) periapical radiograph of the implant with temporary restoration in position; (j) 3 months after surgery, the final restoration is placed; (k) periapical radiograph of the final restoration in position; (l) the final restoration after 1 year of loading; (m) periapical radiograph of the final restoration after 1 year of loading.



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 consisted of trauma resulting in root fracture (7 cases; 70%), endodontic failure (2 cases, 20%) or extensive tooth decay with non-restorable crown (1 single case; 10%). The majority of the implants placed in fresh extraction sockets (8/10: 80%) were in the anterior maxilla. No patients in the extraction socket group were excluded because of buccal bone damage.

When placing 15 implants (26.3%), minor augmentation procedures to cover exposed threads or interproximal/buccal grafting owing to hard tissue deficiency were performed. No patients needed major augmentation procedures. The definitive restorations were meta-ceramic (52 cases; 91.2%) or zirconium-ceramic (5 cases; 8.8%) single crowns, cemented or screwed to the implants. Two patients (two implants) withdrew from the study, and were classified as drop-outs. In fact, they had serious health problems (not related to the dental implant therapy) and they were hospitalised, so that they could not come to the scheduled 1-year follow-up examination. However, these two patients had their implants in function when hospitalised.

At the end of the study, only one implant was lost, in a healed site (second premolar) of the posterior maxilla of a 48-year old female patient who was a smoker and the failed implant (3.5 mm diameter × 10.0 mm length) was placed in type III bone. This implant was lost within the healing period (2 months after surgery), before the delivery of the definitive metal-ceramic restoration, as it showed mobility due to lack of osseointegration; all the surviving implants were stable (Figs 2 and 3), giving a 1-year overall survival rate of 97.7% (patient-based).

One female patient (one implant placed in a healed site of the posterior mandible) experienced pain and swelling after surgery. However, the pain was managed by giving anti-inflammatory and analgesic medication, and no further complications were reported for this implant. Two provisional abutments became loose, 3 months after surgery, in the posterior mandible of two male patients. These abutments were re-inserted and screwed in again. In addition, a ceramic fracture occurred in a metal-ceramic definitive crown, in the posterior maxilla of a male patient.

In this case, the final crown was removed and the clinician had to provide a new restoration for the patient. The complications encountered in this study are summarised in Table 4.

The changes in peri-implant marginal bone levels, as calculated at the 3- and 12-month examination, are reported in Table 5.

The mean probing pocket depth (PPD) values, as registered at the 3- and 12-month examination, are reported in Table 6.

■ Discussion

In our present study based on 57 implants placed in 46 patients, only one implant was lost, in the posterior maxilla of a smoker. This implant was lost within the healing period (2 months after surgery), before the delivery of the definitive metal-ceramic restoration, as it showed mobility due to lack of osseointegration. All the other implants were stable at the 1-year follow-up control, with no soft tissue inflammation or peri-implant infection as confirmed by mean probing depths parameters, and by the absence of pain or discomfort on function, fistula formation, suppuration or exudation, or continuous peri-implant radiolucency. After 1 year of functional loading, patients had lost an average of 0.32 mm (± 0.22) of peri-implant marginal bone. Finally, only two abutments became loose during the follow-up period, before the delivery of the definitive restorations in the posterior mandible. These abutments were re-inserted, tightened and no further loosening occurred in the study. In fact, the implants used in the present study feature a 5-mm deep conical connection, providing a secure internal prosthetic interface with a built-in platform switch occurring at the bone level. These features may also have positive effects on the hard and soft tissue preservation with time, as previously reported^{2,15,31,32,34}.

In a 3-year randomised controlled trial, Cannizzaro and co-workers compared the efficacy of immediate functionally loaded implants placed with a flapless procedure versus implants placed after flap elevation and conventional load-free healing, in both arches of partially edentulous patients²². The authors concluded that implants can be successfully placed flaplessly and loaded immediately without compromis-



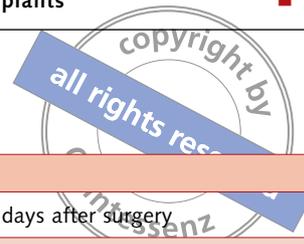
Fig 3 Representative case of an implant placed in the healed alveolar ridge: (a) periapical radiograph of a patient missing an mandibular first molar; (b) clinical view of the ridge; (c) preparation of the implant site; (d) implant placement; (e) temporary restoration in position; (f) periapical radiograph of the implant with temporary restoration in position; (g) healthy tissues before the delivery of the final prosthetic restoration, 3 months after surgery; (h) the final restoration is placed; (i) periapical radiograph of the final restoration; (k) the final restoration after 1 year of loading; (l) periapical radiograph of the final restoration after 1 year of loading.

ing success rates. The immediate loading additionally decreased treatment time and patient discomfort²².

In a 5-year follow-up prospective multicentre study on the immediate occlusal loading of 40 single mandibular molars placed in 33 patients, Calandriello et al reported a satisfactory cumulative success rate of 95.0%, with only two implant failures²³. The mandible, however, with better bone in relation to quality, quantity, and axial loading, is considered ideal for immediate functional loading compared with the maxilla^{6,9,11}.

More recently, Di Alberti and co-workers have documented satisfactory outcomes with immediately loaded single implants placed in the anterior maxilla²⁵. In their study, 70 patients were treated with single implants, placed in healed sites (45 implants) or fresh extraction sockets (25 implants); after 1 year of functional loading all implants were in function, with radiographs showing complete osseointegration²⁵.

These results are in accordance with a previous meta-analysis of treatment outcomes of single-tooth

**Table 4** Details of complications encountered during the study.

Gender	Age (years)	Smoke	Site	Position	Length	Diameter	Complication
Female	46	no	mandible	molar	10.0 mm	4.5 mm	Pain and swelling, 2–3 days after surgery
Male	35	yes	mandible	premolar	11.5 mm	4.0 mm	Abutment screw loosening, 3 months after surgery
Male	66	no	mandible	molar	10.0 mm	4.5 mm	Abutment screw loosening, 3 months after surgery
Male	58	no	maxilla	molar	10.0 mm	4.0 mm	Porcelain fracture, 6 months after surgery

Table 5 Detailed data of changes in peri-implant marginal bone levels between groups at different time periods (patient-level) in mm.

	Baseline – 3 months	Baseline – 12 months
	N; mean (SD); median; CI 95%	N; mean (SD); median; CI 95%
Healed ridges	35; 0.25 (± 0.17); 0.3; 0.20–0.30	33; 0.35 (± 0.22); 0.4; 0.28–0.42
Extraction sockets	10; 0.20 (± 0.18); 0.25; 0.09–0.31	10; 0.22 (± 0.20); 0.25; 0.10–0.34
All sites	45; 0.22 (± 0.17); 0.2; 0.18–0.26	43; 0.32 (± 0.22); 0.4; 0.26–0.38

Table 6 Probing pocket depth (PPD) values as registered at the 3- and 12-month examination, in all sites (patient-level), in mm.

	3 months	12 months
	N; mean (SD); median; CI 95%	N; mean (SD); median; CI 95%
Healed ridges	35; 2.24 (± 0.50); 2; 2.16–2.32	33; 2.23 (± 0.65); 2; 2.12–2.34
Extraction sockets	10; 2.20 (± 0.99); 3; 1.90–2.50	10; 1.95 (± 0.74); 2; 1.75–2.15
All sites	45; 2.23 (± 0.64); 2; 2.14–2.32	43; 2.16 (± 0.68); 2; 2.06–2.26

implants placed in the anterior maxilla and treated with immediate, early, and conventional loading protocols, where an overall implant survival rate of 95.5% was reported, with no discernible difference between the different loading protocols³⁵.

Finally, Cannizzaro and co-workers have reported that flapless-placed and immediately loaded 6.5 mm-long single implants can be clinically successful up to 4 years after loading, in both arches²⁴. The results of these previous investigations seem to be in accordance with those of our present study^{22-25,35}.

With immediate functional loading, predictable results are believed to depend on optimal initial implant stability, controlled loading conditions, and technological advances in the texture of implant surface^{7,23,35}.

Primary stability is defined as the biometric stability achieved immediately after implant insertion by the mechanical locking of the implant to the bone³⁶. It depends on the surgical protocol followed, on the operator's skills, on the shape and material of the

implant, and on the bone density at the recipient site³⁶. To maximise initial stability, it has been recommended that the recipient bed should be prepared in a slightly smaller size than the implant diameter; at the same time, the use of a fixture with specific macroscopical features may be helpful²¹. In our present study, a strict surgical protocol has been followed: in soft bone (types III and IV) and in fresh extraction sockets, implants were placed in under-prepared osteotomies. In addition, the threads of the implant used in this study were designed to provide high insertion torque, by increasing their dimensions toward the coronal end of the implant. This specific macrotopographical feature may allow for axial and radial bone compression during implant insertion, and it may be particularly useful in areas of poor bone quality, providing the increased primary stability that is necessary for immediate loading. The current literature has conclusively demonstrated a strong correlation with bone density and jaw as well as location: it is well-known that the quality of bone

is poorer in the posterior maxilla, in the context of achieving primary implant stability^{5-9,11,18,23}.

When immediately loaded, single implants in the posterior maxilla might be more susceptible to micro-motion, fibrous encapsulation and failure¹⁸⁻²³. In our present study, however, most of the implants (26; 45.7%) were placed in the maxillary posterior region and only one implant failure was reported. These results were probably related to the loading protocol used in the study, where after placement, all temporary crowns were adjusted with light occlusal marks, so that the occlusal surfaces were in slight static contact with the opposite dentition but with no contact in lateral movements, as previously reported²⁴.

In addition, a higher surface roughness of implants has been associated with an increased osteogenic response, compared with implants with smooth surfaces^{6,7,9,11,36-39}. The implants used in the present study have a nanostructured calcium-incorporated surface, which is osteoconductive and may promote bone healing^{28,29}; this microtopographical feature, combined with the geometry of the implant body, specially designed for critical bone conditions and high insertion torques, may have minimised the risk of failure of immediately loaded single implants^{28,29}.

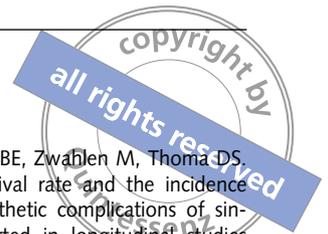
The present study seems to support the hypothesis that the immediate loading of single implants is a predictable treatment procedure, with good survival rates (97.7%, patient-based) and a low incidence of complications. However, this study has its limits: the limited number of patients treated and implants inserted; short follow-up time; self-evaluation of the outcome measures; and further, long-term follow-up studies on a larger sample of patients are needed to confirm these results. At present, immediate functional loading remains a procedure that should be conducted by experienced operators.

■ Conclusions

Within its limit (limited number of treated patients and implants inserted, short follow-up time and self-evaluation of the outcome measure), this study supports the concept that immediate functional loading of dental implants can be a successful treatment procedure. Further, long-term follow-up studies are needed to verify these results.

■ References

- Jung RE, Zembic A, Pjetursson BE, Zwahlen M, Thoma DS. Systematic review of the survival rate and the incidence of biological, technical and esthetic complications of single crowns on implants reported in longitudinal studies with a mean follow-up of 5 years. *Clin Oral Implants Res* 2012;23:2–21.
- Mangano C, Mangano F, Piattelli A, Iezzi G, Mangano A, LaColla L. Prospective clinical evaluation of 307 single tooth Morse taper connection implants: a multicenter study. *Int J Oral Maxillofac Implants* 2010;25:394–400.
- Dierens M, Vandeweghe S, Kisch J, Nilner K, De Bruyn H. Long-term follow-up of turned single implants placed in periodontally healthy patients after 16–22 years: radiographic and peri-implant outcome. *Clin Oral Implants Res* 2012;23:197–204.
- Branemark PI, Hansson BO, Adell R, Breine U, Landstrom J, Hallen O, Ohman A. Osseointegrated implants in the treatment of the edentulous jaws. Experience from a 10-year period. *Scand J Plast Reconstr Surg* 1977;16:1–132.
- Malchiodi L, Cucchi A, Ghensi P, Nocini PF. Evaluation of the esthetic results of 64 non-functional immediately loaded postextraction implants in the maxilla: correlation between interproximal alveolar crest and soft tissues at 3 years of follow-up. *Clin Implant Dent Relat Res* 2013; 15:130–142.
- Suarez F, Chan HL, Monje A, Galindo-Moreno P, Wang HL. Effect of the timing of restoration on implant marginal bone loss: a systematic review. *J Periodontol* 2013;84: 159–169.
- Ghoul WE, Chidiac JJ. Prosthetic requirements for immediate implant loading: a review. *J Prosthodont* 2012;21:141–154.
- Balshi TJ, Wolfinger GJ, Wulc D, Balshi SF. A prospective analysis of immediate provisionalization of single implants. *J Prosthodont* 2011;20:10–15.
- Esposito M, Grusovin MG, Maghaireh H, Worthington HV. Interventions for replacing missing teeth: different times for loading dental implants. *Cochrane Database Syst Rev* 2013 Mar 28;3:CD003878.
- Boedeker D, Dyer J, Kraut R. Clinical outcome of immediately loaded maxillary implants: a 2-year retrospective study. *J Oral Maxillofac Surg* 2011;69:1335–1343.
- Strub JR, Jurdzik BA, Tuna T. Prognosis of immediately loaded implants and their restorations: a systematic literature review. *J Oral Rehabil* 2012;39:704–717.
- den Hartog L, Raghoobar GM, Stellingsma K, Vissink A, Meijer HJ. Immediate non-occlusal loading of single implants in the aesthetic zone: a randomized clinical trial. *J Clin Periodontol* 2011;38:186–194.
- Raes F, Cooper LF, Tarrida LG, Vandromme H, de Bruyn H. A case-control study assessing oral-health-related quality of life after immediately loaded single implants in healed alveolar ridges or extraction sockets. *Clin Oral Implants Res* 2012;23:602–608.
- Chiapasco M, Abati S, Romeo E, Vogel G. Implant-retained mandibular overdentures with Branemark System MKII implants: a prospective comparative study between delayed and immediate loading. *Int J Oral Maxillofac Implants* 2001;16 537–546.
- Mangano C, Mangano F, Shibli J, Ricci M, Sammons R, Figliuzzi M. Morse taper connection implants supporting “planned” maxillary and mandibular bar-retained overdentures. A 5-year prospective multicenter study” *Clin Oral Implants Res* 2011;22:1117–1124.
- Francetti L, Agliardi E, Testori T, Romeo D, Taschieri S, Del Fabbro M. Immediate rehabilitation of the mandible with fixed full prosthesis supported by axial and tilted implants: interim results of a single cohort prospective study. *Clin Implant Dent Relat Res* 2008;10:255–263.



17. Rocci A, Rocci M, Rocci C, Scoccia A, Gargari M, Martignoni M, Gottlow J, Sennerby L. Immediate loading of Brånemark system TiUnite and machined-surface implants in the posterior mandible, part II: a randomized open-ended 9-year follow-up clinical trial. *Int J Oral Maxillofac Implants* 2013; 28:891–895.
18. Lioubavina-Hack N, Lang NP, Karring T. Significance of primary stability for osseointegration of dental implants. *Clin Oral Implants Res* 2006; 17: 244–250.
19. Felice P, Soardi E, Piattelli M, Pistilli R, Jacotti M, Esposito M. Immediate non-occlusal loading of immediate post-extractive versus delayed placement of single implants in preserved sockets of the anterior maxilla: 4-month post-loading results from a pragmatic multicentre randomised controlled trial. *Eur J Oral Implantol* 2011;4: 329–344.
20. Meloni SM, De Riu G, Pisano M, De Riu N, Tullio A. Immediate versus delayed loading of single mandibular molars. One-year results from a randomised controlled trial. *Eur J Oral Implantol* 2012;5:345–353.
21. Hartlev J, Kohberg P, Ahlmann S, Gotfredsen E, Andersen NT, Isidor F, Schou S. Immediate placement and provisionalization of single-tooth implants involving a definitive individual abutment: a clinical and radiographic retrospective study. *Clin Oral Implants Res* 2013;24: 652–658.
22. Cannizzaro G, Leone M, Consolo U, Ferri V, Esposito M. Immediate functional loading of implants placed with flapless surgery versus conventional implants in partially edentulous patients: a 3-year randomized controlled clinical trial. *Int J Oral Maxillofac Implants* 2008;23:867–875.
23. Calandriello R, Tomatis M. Immediate occlusal loading of single lower molars using Brånemark System® Wide Platform TiUnite™ implants: a 5-year follow-up report of a prospective clinical multicenter study. *Clin Implant Dent Relat Res* 2011;13:311–318.
24. Cannizzaro G, Felice P, Leone M, Ferri V, Viola P, Esposito M. Immediate versus early loading of 6.5 mm-long flapless-placed single implants: a 4-year after loading report of a split-mouth randomised controlled trial. *Eur J Oral Implantol* 2012;5:111–121.
25. Di Alberti L, Donnini F, Di Alberti C, Camerino M, Sgarabella N, Lo Muzio L. Clinical and radiologic evaluation of 70 immediately loaded single implants in the maxillary esthetic zone: preliminary results after 1 year of functional loading. *Int J Oral Maxillofac Implants* 2012;27:181–186.
26. Parameters on chronic periodontitis with advanced loss of periodontal support. *American Academy of Periodontology. J Periodontol* 2000;71:856–858.
27. Lobbezoo F, Ahlberg J, Glaros AG, Kato T, Koyano K, Lavigne GJ, de Leeuw R, Manfredini D, Svensson P, Winocur E. Bruxism defined and graded: an international consensus. *J Oral Rehabil* 2013;40:2–4.
28. d'Avila S, dos Reis LD, Piattelli A, Aguiar KC, de Faveri M, Borges FL, Iezzi G, Oliveira NT, de G Cardoso LA, Shibli JA. Impact of smoking on human bone apposition at different dental implant surfaces: a histologic study in type IV bone. *J Oral Implantol* 2010;36:85–90.
29. Esposito M, Grusovin MG, Pellegrino G, Soardi E, Felice P. Safety and effectiveness of maxillary early loaded titanium implants with a novel nanostructured calcium-incorporated surface (Xpeed): 1-year results from a pilot multicenter randomised controlled trial. *Eur J Oral Implantol* 2012;5: 241–249.
30. Lee SY, Yang DJ, Yeo S, An HW, Ryoo KH, Park KB. The cytocompatibility and osseointegration of the Ti implants with Xpeed surfaces. *Clin Oral Implants Res* 2012;23: 1283–1289.
31. Lekholm U, Zarb GA. Patient selection and preparation. In: Branemark PI, Zarb GA, Albrektsson T (eds). *Tissue-Integrated Prosthesis: Osseointegration in Clinical Dentistry*. Chicago, IL: Quintessence, 1985: 199–208.
32. Mangano F, Mangano C, Ricci M, Sammons RL, Shibli JA, Piattelli A. Single-tooth Morse taper connection implants placed in fresh extraction sockets of the anterior maxilla: an aesthetic evaluation. *Clin Oral Implants Res* 2012;23:1302–1307.
33. Heckmann SM, Schrott A, Graef F, Wichmann MG, Weber HP. Mandibular two implants telescopic overdentures. 10-year clinical and radiographical results. *Clin Oral Implants Res* 2004;15:560–569.
34. Mangano C, Mangano F, Piattelli A, Iezzi G, Mangano A, La Colla L, Mangano A. Single tooth Morse taper connection implants after 1-year of functional loading. *Eur J Oral Implantol* 2008;1:305–315.
35. den Hartog L, Slater JJ, Vissink A, Meijer HJ, Raghoobar GM. Treatment outcome of immediate, early and conventional single-tooth implants in the aesthetic zone: A systematic review to survival, bone level, soft-tissue, aesthetics and patient satisfaction. *J Clin Periodontol* 2008;35: 1073–1086.
36. Javed F, Almas K, Crespi R, Romanos GE. Implant surface morphology and primary stability: is there a connection? *Implant Dent* 2011;20:40–46.
37. Sato R, Matsuzaka K, Kokubu E, Inoue T. Immediate loading after implant placement following tooth extraction up-regulates cellular activity in the dog mandible. *Clin Oral Implants Res* 2011;22:1372–1378.
38. Donati M, Botticelli D, La Scala V, Tomasi C, Berglundh T. Effect of immediate functional loading on osseointegration of implants used for single tooth replacement. A human histological study. *Clin Oral Implants Res* 2013; 24:738–745.
39. Raes F, Cosyn J, de Bruyn H. Clinical, aesthetic, and patient-related outcome of immediately loaded single implants in the anterior maxilla: a prospective study in extraction sockets, healed ridges, and grafted sites. *Clin Implant Dent Relat Res* 2013;15:819–835.

