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## Wide-diameter locking-taper implants: a prospective clinical study with 1 to 10-year follow-up

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**KEYWORDS** Complications; Locking-taper implants; Long-term prospective clinical study; Survival; Wide-body implants.

### ABSTRACT

**Aim** Wide-diameter implants (WDIs, diameter  $\geq 4.5$  mm) are increasingly being used in patients with poor bone quality and reduced bone height. The aim of this study was to evaluate the survival rate, peri-implant bone loss, biological and prosthetic complications of wide-diameter (4.8 mm) locking-taper implants used in the restoration of partially and fully edentulous patients.

**Materials and methods** Between January 2002 and December 2011, all patients referred to a private clinic for treatment with WDIs were considered for inclusion in the study. At each annual follow-up session, clinical and radiographic parameters were assessed: the outcome measurements were implant failure, peri-implant bone loss (distance between the implant shoulder and the first visible bone-to-implant contact: DIB), biological and prosthetic complications. The cumulative survival rate (CSR) was assessed using the Kaplan-Meier estimator; Log-rank was applied to evaluate correlations between the study variables. The statistical analysis was performed at the patient and at the implant level.

**Results** A total of 438 WDIs were placed in 411 patients. Four implants failed, for a CSR of 99% (patient-based) and 99.1% (implant-based) at 10-year follow-up. The CSR did not differ significantly with respect to patients' gender, age, smoking or parafunctional habit, implant location, position, length, bone type or prosthetic restoration. A mean DIB of 0.34 mm ( $\pm 0.23$ ), 0.45 mm ( $\pm 0.27$ ) and 0.75 mm ( $\pm 0.33$ ) was shown at the 1-, 5- and 10-year follow-up examination.

**Conclusions** Wide-diameter, locking-taper implants can be a good treatment option for the rehabilitation of partially and fully edentulous patients over the long term.

### INTRODUCTION

Wide-diameter implants (WDIs) are defined as implants with 4.5 mm diameter or more (1,2). They were originally introduced in 1993 as rescue implants, used for immediate replacement of non-osseointegrated or fractured fixtures to allow adequate anchorage in cases of over-enlarged sites, and to expand implant placement in posterior areas with poor bone quality and limited height (3-5). Nowadays, WDIs are the first choice in situations such as fresh extraction sockets, and are increasingly being used for implantation in patients with poor bone quality, reduced bone height and habit of bruxism (6-10).

The use of WDIs may enhance bicortical stability, and increase the surface available for osseointegration (6-11). In fact, WDIs are often used to be placed immediately in extraction sockets because they increase stability by reaching the socket wall (2,10); in addition, they may improve bone-to-implant contact (BIC) due to the increased implant surface area (6-11), which could enhance the osseointegration of implant to bone and establish implant stability (10), compensating for the lack of bone height or density (11). Moreover, their larger surface area enhances connectivity with the surrounding bone and shows an anchorage strength 3- to 6-fold of that of standard diameter implants (12-15). Several experimental studies indicated that WDIs are associated with increased removal torque values and that the load on cortical bone decreases with increasing the implant diameter (12-15). A WDI may better bear the occlusal loading, as compared to a standard (3.75- 4 mm) diameter implant, being biomechanically

more effective in counteracting occlusal forces of the magnitude that may be exerted in the posterior region, particularly in molar areas (12-14). A better distribution of occlusal forces and the possibility to use wider prosthetic components may reduce the risk for mechanical complications, such as abutment screw loosening or fracture (12-15). Despite encouraging data obtained from finite element analysis and animal studies (11-15), early publications on WDIs reported an increased failure rate compared to standard diameter implants (3,5,16-19). More recently, several short-term studies on WDIs have been published, showing favorable survival rates (2,7,8,10). However, there is no abundance of studies evaluating the long-term ( $\geq 10$  years) clinical outcome of WDIs (6,20,21).

More than 20 years ago, locking taper implants have been introduced as an alternative to screw-retained abutment systems (22,23). Locking-taper implants are composed of a fixture and an abutment joined together by a Morse taper connection; this tapered fit implant-abutment connection is able to induce a self-locking mating between the components (22-25). Several studies demonstrated that locking-taper implants can represent a successful treatment modality for the rehabilitation of partially and completely edentulous patients (22-25).

The aim of the present prospective study was to evaluate the survival rate, peri-implant bone loss, biological and prosthetic complications of wide-diameter (4.8 mm) locking-taper implants used in the rehabilitation of partially and fully edentulous patients over the long term.

## MATERIALS AND METHODS

### Patient selection

Over a 10-year period (January 2002-December 2011) all patients referred to a private clinical center for treatment with dental implants were considered for inclusion in this study. Inclusion criteria were: age  $> 18$  years, fully or partially edentulous patients,  $> 6$  weeks of healing after tooth extraction, placement of wide-diameter (4.8 mm) dental implants, good systemic and oral health, dentition in the opposing jaw to have occlusal contacts. Exclusion criteria were: unsatisfactory oral hygiene, active periodontal infections or other oral disorders, insufficient bone volume to place wide-diameter (4.8 mm) implants, with at least 8 mm in length, bone augmentation procedures with autogenous bone or bone substitutes, uncontrolled diabetes mellitus, severe systemic pathologies that would contraindicate implant placement, coagulation disorders, irradiated bone, psychologic disorders, alcohol or drug abuse. Smoking and bruxism were recorded but were not an exclusion criteria for this study. All patients who smoked were defined as smokers, without considering

the amount of cigarettes; these patients were told that smoking is associated with an increased implant failure rate. Bruxers were patients with a repetitive jaw-muscle activity characterised by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible. Patients' questionnaires, clinical examination and electromyography were used for the diagnosis of bruxism (26).

The study protocol was explained to each participant, and each patient was required to sign an informed consent. The patients agreed to participate in a post-operative control program. The study was carried out in accordance with the principles outlined in the Declaration of Helsinki on experimentation involving human subjects, as revised in 2000, and approved by the Ethical Committee of the University of Insubria, Varese, Italy.

### Implant design and surface characterization

Screw-shaped, wide-diameter (4.8 mm) implants made of grade-5 titanium alloy (Leone Implant System, Florence, Italy) were used. The surface of these implants is blasted with 50 micro-meters  $Al_3O_2$  particles and acid-etched with  $HNO_3$ , after which the average of roughness (i.e., the mean of the peak-valley distance on surface irregularities) is 0.5 micrometers. This implant system uses a Morse taper implant-abutment connection combined with an internal hexagon; the Morse taper has an angle of  $1.5^\circ$ .

### Preoperative study

Before implant placement, an accurate examination of the hard and soft tissues was carried for all patients; the presence of periodontal disease, caries, soft tissue disorders was investigated, and patients received appropriate treatments and oral hygiene instructions. Panoramic radiographs were the basis for the initial investigation; in a few selected cases, cone beam computed tomography (CBCT) scans were used. CBCT datasets were acquired and then transferred to specific implant navigation softwares (Mimics®; Materialise, Leuven, Belgium), where a three-dimensional (3D) reconstruction of the jaws was performed. With these softwares, it was possible to correctly plan the implant position, depth and angulation, by assessing the width of each implant site, the thickness and the density of the cortical plates and the cancellous bone, as well as the ridge morphology. Pre-operative study also included an assessment of the edentulous ridges using casts and diagnostic wax-up.

### Implant placement

After local anesthesia, obtained by infiltration of articaine (4%) containing 1:100.000 adrenaline, a midcrestal incision was made at the site of implant installation. The mesial and distal aspects of the crestal incision were connected to two releasing incisions. A full thickness flap was reflected exposing the alveolar ridge, and

preparation of implant sites was carried out with spiral drills of increasing diameter, under constant irrigation, as previously reported (23,24). The implants were placed in the prepared sites, achieving good primary stability, with the neck located at the bone crest level. Finally, sutures were performed. All patients were prescribed antibiotics, amoxicillin + clavulanic acid 2 g each day for 6 days. Postoperative pain was controlled with 100 mg nimesulide every 12 hours for 2 days. Patients received detailed instructions on oral hygiene, with mouth rinses containing 0,12% chlorhexidine administered for 7 days. Sutures were removed after 8-10 days.

### Prosthetic procedures

A two stage technique was used and the implants were left submerged during the healing period, ranging from 3 months in the mandible to 4 months in the maxilla. The prosthetic rehabilitations were single crowns (SCs), fixed partial prostheses (FPPs), fixed full-arches (FFAs) and overdentures (ODs). Second-stage surgery was conducted to be able to access the submerged implants and healing abutments were placed. The flap was adjusted to the healing abutment and sutured in position. Two weeks after the second surgery, in all fixed restoration protocols (SCs, FPPs, and FFAs), the abutments were connected and provisional acrylic restorations were provided. These restorations remained in situ for 3 months, in order to monitor the implants' stability under load and to obtain good soft-tissue healing around the implants; after this period, definitive ceramo-metallic restorations were provided, cemented with temporary cement.

All the restorations were carefully evaluated for proper occlusion, and protrusion and laterotrusion were assessed on the articulator and intraorally. Finally, in patients with implant-supported overdentures (ODs), the prosthodontic procedure was achieved as previously described (27). Patients wore provisional complete dentures, relined with a tissue conditioner, for a 3-month period; after that, second-stage surgery was then conducted to gain access to the underlying implants, and the healing abutments were inserted. Two weeks later, the healing abutments were removed, pick-up impression posts were placed at the implant level and an impression was taken; a master cast was poured, and a rigid gold bar was fabricated. The fixtures were elongated with pre-fabricated abutments to the top of which gold copings were screwed. The splinting superstructures for the implants consisted of an egg-shaped Dolder gold bar, with or without extensions. All these bars were supported by 3-4 fixtures. All ODs had a horseshoe design and were fabricated with acrylic resin with a metal framework. Retention of the superstructure was ensured by several pre-fabricated gold clips. The ODs were carefully evaluated for proper occlusion and protrusion and laterotrusion were assessed on the articulator and intraorally.

### Follow-up examinations

The patients were enrolled in an annual recall program. During each annual follow-up visit, the clinical assessment of implants, peri-implant tissues and prostheses were performed by a surgeon and a prosthodontist, who were not directly involved in the study. The outcome measurements were as follows.

- › Implant failure. Failure to osseointegrate with implant mobility, persistent peri-implant infections with pain/suppuration, progressive marginal bone loss due to mechanical overload and implant body fracture were the conditions for which implant removal was indicated (28). The implant failures were divided into early (before the abutment connection) and late (after the abutment connection) failures.
- › Peri-implant bone loss. Intraoral periapical radiographs were taken for each implant, using a Rinn alignment system with a rigid film-object x-ray source coupled to a beam-aiming device to achieve reproducible exposure geometry (29). Customized positioners, made of polyvinyl-siloxane, were used for precise repositioning of the radiographic template. Radiographs were taken immediately after implant placement and at each annual follow-up session, with the aim to: evaluate the presence/ absence of continuous peri-implant radiolucencies; measure the distance between the implant shoulder and the first visible bone-to-implant contact (DIB) in mm, at the mesial and distal site of each implant (29). For the latter, measurements were made by means of an ocular grid; the following equation: "rx implant length : true implant length = rx DIB : true DIB" was used to correct potential distortions in the radiograph, and to establish with precision the amount of vertical bone loss at the mesial and distal site of the implant (29). A mean DIB value was obtained from the mesial and distal measurement at each radiograph. In the present study, modifications in the distance from the implant shoulder to the first visible bone-to-implant contact (DIB) were measured on periapical radiographs which were taken immediately after installation and at the 1-, 5- and 10-year follow-up examination.
- › Complications, which were divided into two types:
  - a) biological complications, including the disturbances in the function of the implant characterized by a biological process affecting the supporting tissues and structures (pain or swelling after surgery, soft tissue inflammation and peri-implant infection with fistula formation, pain, suppuration or exudation, discomfort on occlusion). The threshold to define a peri-implantitis was set at a probing pocket depth  $\geq 6$  mm and bleeding on probing or pus secretion;
  - b) prosthetic complications, related to implant components (mechanical complications, such as loosening or fracture of abutment) or prostheses (technical complications, such as loss of retention

or porcelain fracture) for fixed restorations, and anchorage structure (broken bars, or loose, lost, or broken bar retainers) or prostheses (repairs of fractured prostheses or overdenture teeth) for removable restorations.

Static and dynamic occlusion were evaluated, using standard occluding papers; all prosthetic complications were carefully registered, and if possible, managed during the follow-up visit; additional appointments were arranged if needed.

### Statistical analysis

Data collection and analyses were performed by two independent examiners (a surgeon and a prosthodontist) who were not directly involved in the treatment of patients. Data were tabulated and analysed by means of Microsoft Excel Software 2003. A descriptive analysis was performed for patient demographics, distribution of implants, radiographic bone loss, biologic and prosthetic complications. Absolute and relative frequency distributions were calculated for qualitative variables, and means, standard deviations (SD), median, range and confidence intervals (CI: 95%) were calculated for quantitative variables. Implant failure was the principal variable of the study, and implant survival rates were calculated using Kaplan-Meier survival curves (30). Each implant was followed from the date of placement to either the date of failure or the date of last follow-up. The cumulative survival rate (CSR) was estimated both by a patient-based and an implant-based analysis. In the implant-based analysis each inserted implant was considered as the analysis unit. In the patient-based analysis, each patient was considered as the analysis unit: in case of multiple indications for implant therapy (with the same patient receiving more than one implant), the patient was classified as a failure even in the event of a single implant loss. Variables including gender, age at surgery, smoking habit (smokers or non-smokers); parafunctional habits (bruxists or non-bruxists) were analyzed at the patient-level. Variables including implant location (mandible or maxilla), implant position (incisors, cuspids, premolars or molars), implant length (8.0, 10.0, 12.0 or 14.0 mm), type of prosthetic restoration (SCs, FPPs, FFAs or ODs) and bone type (type I, II, III or IV) were analysed at the implant-level. Bone quality was ascertained clinically by tactile evaluation at the time of implant placement, during drilling, according to the clinician's judgment and by radiographic assessment according to the criteria of Lekholm and Zarb index (31). In particular, following the withdrawal of an osteotomy reamer, an assessment of the bone in the reamer flutes was conducted in terms of quality and appearance. Bone quality was classified as type I if the bone was compact, cortical and nearly bloodless. Type II bone was red and filled the flutes of the reamer. If no bone remained in the flutes, the bone quality was classified as type IV. If the findings were

intermediate between those described for types II and IV, the bone was categorized as type III. Log-rank test was used to evaluate the correlations between the study variables. Data analysis was performed with a statistical software package (SPSS 17.0, SPSS Inc, Chicago, IL, USA). The level of significance was set at 0.05.

## RESULTS

### Patient population and implant-supported restorations

In total, 411 patients (235 males and 176 females; aged between 24–73 years, mean  $47.6 \pm 9.0$ ) were enrolled in the present study. Among these patients, 58 (14.1%) were smokers and 29 (7.0%) were bruxists. The average follow-up time was  $6.1 \pm 2.7$  years. Twenty-one patients had multiple indications for implant therapy. A total of 438 WDIs were placed. One-hundred and ninety-one implants (43.6%) were inserted in the maxilla, while 247 implants (56.4%) were inserted in the mandible. With regard to the position of the installed implants, 12 (2.8%) were incisors, 18 (4.1%) were cuspids, 134 (30.5%) were premolars and 274 (62.6%) were molars. The detailed distribution of the implants according to the position is reported in figure 1.

Regarding bone quality, most of the implants were inserted in posterior areas of lower density, with 232 implants (53.0%) placed in bone type III, and 121 implants (27.7%) placed in bone type IV; only 80 implants (18.2%) and 5 implants (1.1%) were placed in bone type II and I, respectively. The most frequently used implant length was 12 mm, with 195 implants (44.5%), followed by 10 mm, with 135 implants (30.9%); 54 implants (12.3%) were 8 mm and 14 mm long. Finally, the most frequent indication was the restoration of single-tooth

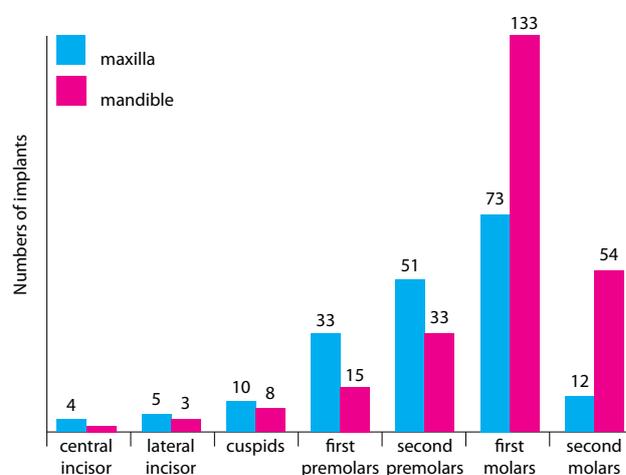


FIG. 1 Implant distribution by location.

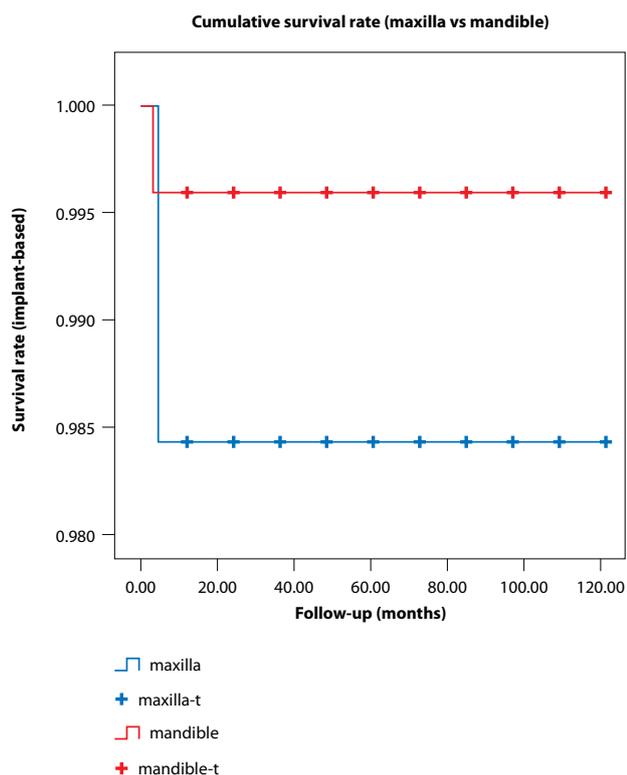


FIG. 2 Survival rate with Kaplan Meier estimates.

gaps (235 implants, 53.7%), whereas the least frequent indication was the treatment of fully edentulous patients with ODs (21 implants, 4.8%); a total of 132 implants (30.1%) were installed to support FPPs, while 50 implants (11.4%) were used to support FFAs.

**Implant survival**

Four implants failed and were removed, in 4 different patients. Eleven of the 411 patients were classified as drop-outs, since they did not participate in the post-operative control program in full. At the end of the study, an overall CSR of 99.0% (patient-based) and 99.1% (implant-based) were achieved at 10-year follow-up, with 434 implants still in function. In the maxilla, the CSR was 98.4%, with 3 implants failed and removed. In the mandible, the CSR was 99.6%, with one implant failure (Fig. 2). With regard to the position of the failed implants, 2 were premolars (1 maxilla, 1 mandible) and 2 were molars (2 maxilla). All implants were lost within the healing period (3-4 months after surgery), before the abutment connection. For this reason, they were classified as "early failures", showing implant mobility due to lack of osseointegration, before functional loading, with no signs of peri-implant infection. No implants failed after the abutment connection, or after prosthetic loading, so that no "late failures" were found. The details of the failed implants are recorded in table 1. The survival rate did not differ significantly with respect to patients' gender, age, smoking or parafunctional habit, implant location, position, length, bone type or prosthetic restoration. The

FAILURES	1	2	3	4
<b>PATIENT DETAILS</b>				
Gender	Female	Male	Male	Male
Age	54	46	52	57
Smoking	No	No	Yes	No
Bruxism	No	No	No	No
<b>IMPLANT DETAILS</b>				
Location	Mandible	Maxilla	Maxilla	Maxilla
Position	Premolar	Premolar	Molar	Molar
Bone type	Type III	Type IV	Type IV	Type IV
Length	14.0 mm	10.0 mm	12.0 mm	8.0 mm
Restoration	FPP	SC	SC	FPP
<b>FAILURE DETAILS</b>				
Time of failure	3 months	4 months	4 months	4 months
Failure reason	Implant mobility-lack of osseointegration			

TABLE 1 Details of the failed implants.

	N° OF PATIENTS	FAILURES	KAPLAN-MEIER (%)	LOG-RANK
<b>PATIENTS GENDER</b>				
Males	235	3	98.7	0.473
Females	176	1	99.4	
<b>PATIENTS AGE</b>				
24-34	18	0	100	0.675
35-44	108	0	100	
45-54	175	3	98.3	
55-64	100	1	99.0	
65-	10	0	100	
<b>SMOKING</b>				
Smokers	58	1	98.3	0.532
Non-smokers	353	3	99.2	
<b>BRUXISM</b>				
Bruxists	29	0	100	0.581
Non-bruxists	382	4	99.0	

TABLE 2 Patient-based analysis.



evaluation of the influence of different patient-related and implant-related variables on implant survival is reported in table 2 and table 3, respectively.

**Peri-implant bone loss**

The mean distance between the implant shoulder and the first visible bone-to-implant contact (DIB) was

	N° OF IMPLANTS	FAILURES	KAPLAN-MEIER (%)	LOG-RANK
<b>IMPLANT POSITION</b>				
Maxilla	191	3	98.4	0.206
Mandible	247	1	99.6	
<b>IMPLANT LOCATION</b>				
Incisors	12	-	100.0	0.931
Cuspids	18	-	100.0	
Premolars	134	2	98.5	
Molars	274	2	99.3	
<b>IMPLANT LENGTH</b>				
8.0 mm	54	1	98.1	0.877
10.0 mm	135	1	99.3	
12.0 mm	195	1	99.5	
14.0 mm	54	1	98.1	
<b>BONE QUALITY</b>				
Type I	5	-	100.0	0.054
Type II	80	-	100.0	
Type III	232	1	99.6	
Type IV	121	3	97.5	
<b>Type of restoration</b>				
SCs	235	2	99.1	0.686
FPPs	132	2	98.5	
FFAs	50	-	100.0	
ODs	21	-	100.0	

TABLE 3 Implant-based analysis.

YEAR	MEAN	SD	MEDIAN	CI (95%)
1	0.34	0.23	0.4	0.32-0.36
5	0.45	0.27	0.4	0.43-0.47
10	0.75	0.33	0.7	0.66-0.84

TABLE 4 Peri-implant bone loss (in mm).

0.34 mm ( $\pm$  0.23), 0.45 mm ( $\pm$  0.27) and 0.75 mm ( $\pm$  0.33) at the 1-, 5- and 10-year follow-up examination, respectively (Tab. 4; Fig. 3, 4).

**Complications**

After surgery, 4 patients treated with a single implant experienced severe swelling and pain; three months after, one of these patients experienced implant failure. Two implants were diagnosed with peri-implantitis, showing suppuration/exudation, bleeding on probing and a probing pocket depth  $\geq$  6 mm, 6 years after placement; however, these implants were successfully treated and no further biological complications were reported. In total, the overall incidence of biological complications was 1.3%.

With regard to prosthetic complications with fixed restorations (SCs, FPPs and FFAs: 417 surviving implants), all complications were technical in nature (loss of retention, porcelain fracture). In fact, the most frequent complication was loss of retention, which occurred in 16



FIG. 3A



FIG. 4A



FIG. 3B



FIG. 4B



FIG. 3C



FIG. 4C

FIG. 3 A Periapical radiographs of a WDI placed in the maxilla: 1-year follow-up. B. Periapical radiographs of a WDI placed in the maxilla: 5-year follow-up. C. Periapical radiographs of a WDI placed in the maxilla: 10-year follow-up.

FIG. 4 A Periapical radiographs of a WDI placed in the mandible: 1-year follow-up. B. Periapical radiographs of a WDI placed in the mandible: 5-year follow-up. C. Periapical radiographs of a WDI placed in the mandible: 10-year follow-up.

implants during the observation period (3.8%); moreover, 7 (1.6%) porcelain fractures occurred. No mechanical complications (loosening or fracture of abutment) were reported. In total, the overall incidence of prosthetic complications for fixed restorations was 5.5%. With removable prostheses (ODs: 21 surviving implants), all the complications were related to the weakness of the anchorage components used for connecting the bar to the denture. In fact, no complications related to implant components (loosening or fracture of abutment) were reported. In total, 9 clip loosening and 4 clip fractures were recorded; in addition, in 3 patients, acrylic resin or tooth fractures were encountered. All these prosthetic complications were managed during the follow-up visit where possible; additional appointments were arranged when major repairs were needed.

## DISCUSSION

The initial experience with machined-surface WDIs showed lower success rates than those reported for standard-sized implants (3,5,16). In 1993, Langer and co-workers introduced a new 5 mm diameter implant and recommended its use as rescue implant for immediate replacement of non-osseointegrated or fractured regular implants (3). Due to the larger surface area, this WDI was also recommended for use in areas of compromised bone quality and quantity. Unfortunately, a high overall implant failure rate of 13% to 25% was described for WDIs in this 3-year follow-up study (3). In 1998, Aparicio and Orozco reported a cumulative success rate of 97.2% for WDIs in the maxilla and 83.4% in the mandible, with a mean post-loading follow-up of 33 months (5). Extremely low survival rate (82%) of WDIs have also been described by Ivanoff and associates: reporting on the influence of variations in Brånemark implant diameter in a 3- to 5-year retrospective clinical study, the authors found the highest implant failure rate (18%) for 5 mm diameter implants, compared with 3% for 4 mm wide implants and 5% for the 3.75 mm diameter implants (13,16). However, only 10% of the WDIs used in this study had a length >10 mm, as the implants studied were predominantly short wide-body implants (6 to 8 mm long) (6, 16). Eckert and colleagues also found statistically higher failure rates for WDIs in both maxilla (29%) and mandible (19%); according to the authors, a critical bone volume was needed for osseointegration, which was sometimes hampered by WDIs (17). Similar results were reported in a retrospective study by Shin and colleagues, with survival rates of 80.41% and 96.8% for wide- and regular-body implants, respectively (18); in 2004, Hultin-Mordenfeld and co-workers reported a higher implant failure rate with WDIs, with better results in the mandible (94.5%) than the maxilla (78.3%) (19). Although initially higher failure rates for WDIs were

reported, recently improved surgical procedures, new implant design and surface configurations have demonstrated that wide implant body and lower survival rates are not related (6-10,20,21,29,32).

In a retrospective study on 131 WDIs with a mean loading time of 17 months, Khayat and colleagues found an overall survival rate of 95% (7). Similar results were reported by Friberg and colleagues, with a loss rate of 4.5% for WDIs (5 mm) and no differences in survival rates between 5 mm, 4 mm and 3.75 mm implants (32). In a retrospective study on 168 hydroxyapatite (HA)-coated WDIs placed in posterior areas with reduced bone height, Griffin and Cheung reported a survival rate of 100% after 35 months of loading (33). More recently, several studies have reported failure rates of less than 5% up to 5 years of function (20,21). However, the long-term ( $\geq 10$  years) observation on WDIs is still missing, and details of survival, success and complications of this treatment modality in the long-term are still unknown. In our present prospective study on 438 WDIs placed in 411 patients, an overall CSR of 99% (patient-based) and 99.1% (implant-based) was achieved at 10-year follow-up. Four implants failed; all these implants were lost within the healing period (before functional loading) and were classified as "early failures", showing implant mobility due to lack of osseointegration, with no signs of peri-implant infection. These results are in accordance with those of previous studies, in which a prevalence of early failures was reported (7,20,21,32,33). The CSR of WDIs was compared in terms of different subgroups, and it did not differ significantly with respect to patients' gender, age, smoking or parafunctional habit, implant location, position, length, bone type or prosthetic restoration. With respect to the patient-based analysis, one implant failure due to lack of osseointegration was found among smoking patients in our study, giving a CSR of 98.3% for smokers. Smoking is a well-documented risk factor for implant failure (34), however no statistically significant difference in survival rate was found between smokers and non-smokers in this study ( $p=0.532$ ). Bruxists had a very high 10-year CSR (100%). This result could suggest that the use of WDIs may be helpful in case of parafunctional habits; it should be noted, however, that the number of bruxists in the present study was low (29). With regard to the implant-based analysis, in the present study, the CSR of WDIs in the mandible (99.6%) was shown to be slightly higher than in the maxilla (98.4%). The higher bone density of the mandible was probably the reason for the better outcomes, as previously reported (19). In the present study, a lower CSR (97.5%) was found in regions with poor bone quality (type IV;  $p=0.054$ ), with 3 implants failed in the posterior maxilla. Bone in the posterior jaw region is more commonly type III or type IV, especially in the maxilla: according to the literature, implants in poorer quality bone have a higher failure rate (2,35).

The locking-taper implant system used in the present study is composed of a fixture and an abutment joined together by a self-locking connection by means of a Morse taper guided by an internal hexagon. The Morse taper has an angle of 1.5°, and is able to induce a self-locking mating between the parts, thus giving a higher implant-abutment mechanical stability (22-25,36). Recent researches have shown that the use of locking taper implants can effectively reduce the incidence of prosthetic complications at the implant-abutment interface, by resisting eccentric loading complexes and bending moments, ensuring excellent mechanical stability (22-25,36,37). In our present study, no technical complications related to implant components (loosening or fracture of abutment) were reported, both for fixed and for removable restorations. This seems to confirm previous results obtained with locking-taper implants (22-25). In addition, WDIs create a wider base, giving the opportunity to use wider and stronger prosthetic components: this may help to reduce the risk of technical complications and increase the ability of implants to tolerate occlusal forces of the magnitude that are present in posterior areas (9,20,21). The distribution of stress toward surrounding bone and the control of biomechanical loads are thought to be critical for long-term maintenance of implant-bone interface (15): a dental implant serves as a load-bearing device that not only sustains masticatory forces, but also transfers loads to peri-implant bone (15). It has been postulated that among the factors that affect the load transfer at the bone-implant interface is implant geometry, diameter and the surface area of implant integrated into the bone (11,12,15). From this point of view, it could be helpful to design the implant with a geometry that will minimize the peak bone stress caused by loading (11).

In our present study on wide-diameter, locking-taper implants, a minimal marginal bone loss between implant installation and the 10 years' follow-up visit was reported, with a mean DIB of 0.34 mm ( $\pm$  0.23), 0.45 mm ( $\pm$  0.27) and 0.75 mm ( $\pm$  0.33) at the 1-, 5- and 10-year follow-up session, respectively. Finally, the locking-taper implant-abutment connection may provide an excellent seal against bacterial penetration (38). It is noteworthy that all implants with screw-type connections show a microgap of variable dimensions (40-100 micrometers) at the implant-abutment interface (39,40). As this microgap is colonized by micro-organisms, capable of penetrating into the inner portion of the implant, the bacterial leakage and persistent colonization may lead to chemotactic stimuli which initiate and sustain recruitment of inflammatory cells (39,40). Eventually this could result in inflammation of the peri-implant tissues and bone loss (39,40). The Morse taper connection reduces microgap dimensions (1-3 micrometers) at the implant-abutment interface, providing an excellent biological seal, preventing microbial infiltration (38). This

may reduce the level of soft tissue inflammation, ensuring long-term bone crest stability (38, 41, 42).

## CONCLUSION

Initially introduced as rescue implants, WDIs have increasingly been used for implantation in fresh extraction sites or in patients with insufficient bone height, poor bone quality or habit of bruxism. Early studies on WDIs have reported an increased failure rate; however, those unsatisfactory results were probably related to older implant design, machined surfaces, the learning curve for the surgical technique required and the traumatic effect on the bone from the wide drills used during the osteotomy preparation. Nowadays, new implant designs and surface configurations, modified drilling techniques and adapted surgical protocols have contributed to the enhanced performance of WDIs. Our present study suggests that the use of locking-taper WDIs can be a predictable treatment modality and may provide benefits for long-term maintenance of various implant-supported prosthetic restorations. Locking-taper WDIs can yield reliable long-term outcomes, with high 10-year survival (patient-based: 99%; implant-based: 99.1%) rates and few biological and prosthetic complications. However, further long-term researches should be performed on locking-taper WDIs, such as randomized controlled trials, in order to obtain definitive evidence.

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