

# A Prospective Multicenter Evaluation of 1,583 3i Implants: 1- to 5-year Data

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**Purpose:** The purpose of this prospective multicenter study was to evaluate the efficacy of 3i threaded implants for the treatment of edentulous patients in a 1- to 5-year period. This article reports the total data and global results of 3 threaded designs of 3i implants: self-tapping, ICE, and Osseotite. **Materials and Methods:** A total of 1,583 implants (619 ICE, 545 Osseotite, and 419 self-tapping) were placed between 1995 and 1999 in 528 patients at 13 European clinical centers. The average age of the patients was 53.6 years. Clinical and radiographic evaluations were performed annually for up to 5 years. **Results:** Of the total implants, 707 were placed in the maxilla and 876 in the mandible. A total of 1,162 implants were placed in posterior segments. Forty-eight implants were lost to follow-up and 55 were failures. The most frequent prosthetic indication was the short-span fixed prosthesis (440 cases), followed by 172 single-tooth replacements, 56 long-span prostheses, and 4 overdentures. Radiographic evaluation after 6, 12, and 24 months of implant loading showed, respectively, mean crestal bone loss of  $0.04 \pm 1.3$  mm,  $0.12 \pm 1.6$  mm, and  $0.2 \pm 1.7$  mm. A cumulative survival rate of 96.5% was observed 5 years after implant placement, with 97.2% survival in the maxilla and 95.8% in the mandible. The survival rate was similar in anterior (96.7%) and posterior (96.5%) segments. **Discussion:** A total of 55 failures were reported in this study with 47 early failures and 8 late failures. The rate of late failures is of utmost importance for the restorative dentist. **Conclusion:** This clinical study gives evidence of very high success rates using 3 threaded designs of 3i implants. (INT J ORAL MAXILLOFAC IMPLANTS 2002;17:820-828)

**Key words:** clinical trial, dental implants, dentures, marginal bone level, multicenter study

More than 30 years of evidence involving the clinical use of endosseous implants has shown excellent long-term results.<sup>1-4</sup> Success rates between 65% and 100% have been reported with various implant systems.<sup>5,6</sup> Numerous parameters have been analyzed to evaluate successful treatment: macroscopic and microscopic nature of the implant

surface, material biocompatibility, quality and quantity of the residual bone, surgical protocol, and the conditions of implant loading.<sup>7</sup>

Since introduction of the original Brånemark System implant (Nobel Biocare, Göteborg, Sweden) in the early 1980s, numerous changes have taken place in major implant systems. New implant designs, new prosthetic components, simplification of the armamentarium, and an evolution of surgical and prosthetic protocols have been proposed. The 3i implant system (Implant Innovations, West Palm Beach, FL) has been used since 1988. Many studies have reported between 91% and 98% success rates and therapeutic predictability.<sup>8-14</sup> These results appear to be comparable to scientific clinical reports of other implant systems, including Nobel Biocare, ITI (Straumann Institut, Waldenburg, Switzerland), and AstraTech (Mölnådal, Sweden).<sup>5</sup>

The aim of this prospective study was to evaluate the cumulative survival rates of 1,583 threaded 3i implants placed in 13 European clinical centers over a 1- to 5-year period. This report includes the total

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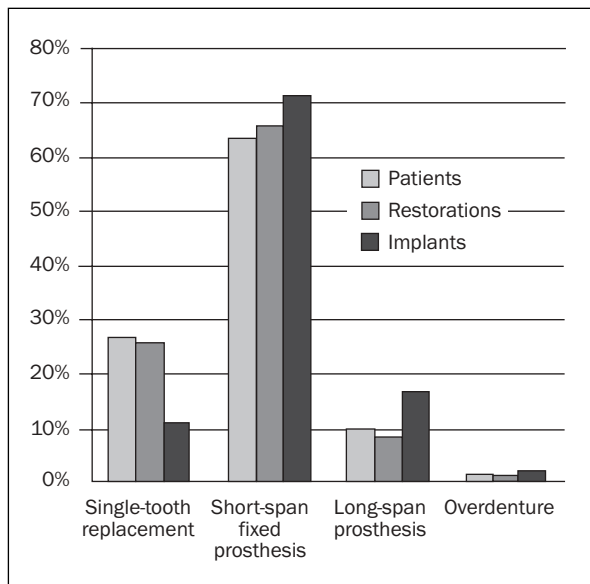
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**Table 1** Evaluation Center Distribution

Center	No. of Patients	No. of Restorations	No. of Implants
1	71	91	181
2	63	80	177
3	73	85	154
4	45	66	202
5	16	17	32
6	18	34	90
7	76	100	246
8	16	18	45
9	59	77	221
10	25	27	58
11	22	25	76
12	21	23	34
13	23	29	67
Total	528	672	1583

data and global results of 3 different threaded type of implants: self-tapping, ICE, and Osseotite.

The self-tapping implant design (commercially pure titanium) was the first generation of self-tapping implants and was followed by a second generation of super-self-tapping implants (ICE, or “Incremental Cutting Edges” implant). This design evolution was aimed at simplifying the surgical protocol and improving primary implant stability.<sup>12</sup> The apical part of the ICE implant has a truncated cone shape, which permits progressive engagement in the bone. The implant apex has 4 open sections with enhanced cutting capacity. In 1995, a new 3i implant (Osseotite) with a hybrid surface (smooth and rough) was proposed. Its original design was intended to meet the requirements of both soft tissues and bone. The coronal part of the implant has a smooth surface, whereas from the third thread to the apex, the surface of the implant is acid-etched (hydrochloric acid/sulfuric acid). This dual-textured finish (smooth and rough) encourages long-term stability of soft tissues at the smooth neck of the implant and favors early osseointegration because of the rough surface texture.<sup>15</sup> This implant presents several advantages: potential increase in the bone-implant surface contact area and forces necessary to dislodge the implant, lack of contamination on the implant, elimination of risk of detachment of surface particles, and optimal healing of bone against the surface.<sup>15-21</sup> The morphology of the Osseotite implant is similar to that of the ICE implant so as to optimize surgical implant placement.

**Fig 1** Distribution of patients, restorations, and implants placed.

## MATERIALS AND METHODS

Between January 1995 and November 1999, a total of 1,583 threaded implants were placed in 528 patients at 13 clinical centers in Europe (Table 1). A total of 528 patients participated in the study: 335 women (63%) and 193 men (37%). The age of the patients at the time of implant placement varied from 16 to 86 years, with a mean age of 53.6 years. The patients enrolled in this multicenter study (different prosthetic indications) were treated with implant-supported fixed restorations or implant-supported overdentures, totalling 672 prosthetic restorations. The most frequent indication was the short-span (2 to 5 units) fixed prosthesis (65.5%) (Fig 1). Three different threaded implants were used in this study: self-tapping, ICE, and Osseotite. Different types of implants were sometimes placed in the same patient. Patient selection excluded all subjects with local or systemic contraindications (eg, untreated periodontitis, local infection, mucosal disease, radiation treatment to head, systemic uncontrolled diseases, heavy smoker, bacterial endocarditis risk, hematologic disorder, alcoholism, or drug abuse). No bone reconstruction was performed during placement of the implants (eg, guided bone regeneration, onlay graft, sinus lift, or osteotomy technique). Bone quality (dense, normal, or soft) was clinically evaluated during surgical preparation (tactile sensation) by each surgeon.

### Treatment Protocol

The surgical protocol for the 3 implant designs was similar up to the point of using the 3-mm drill for standard-diameter implants.<sup>22</sup> In the presence of dense bone, the 3.15-mm drill was used, followed eventually by a tapping for the self-tapping implant.<sup>12</sup> This tapping was rarely necessary for the ICE and the Osseotite implants. For narrow- and wide-diameter implants, the surgical protocol and indications followed have been previously described.<sup>23,24</sup> Prophylactic antibiotic therapy was prescribed as follows: 1 g of amoxicillin 2 hours before surgery, followed by 2 g each day for 6 days for those patients with no prior allergy to penicillin. For patients who were allergic to penicillin, a combination of spiramycin and metronidazole was prescribed. A solution of chlorhexidine (0.12%) as a mouthwash (twice a day) was used 2 hours before the surgery and then resumed 24 hours after surgery and continued for 7 days. Wearing removable prostheses associated with the implant sites was forbidden for 15 days postoperatively. The interior surfaces of all removable prostheses were adjusted and relined with soft acrylic resin to minimize harmful forces on the implants.

Stage 2 surgery was performed 4 months after bone healing in the mandible and after 6 months in the maxilla. Implant integration was evaluated by digital assessment to determine the presence or absence of implant mobility at the time of abutment connection, radiographic examination of the implant-bone interface, peri-implant probing, and patient-reported symptomatology. Mucosal healing of 6 to 8 weeks was advocated before beginning prosthetic rehabilitation. Final abutment selection was based on individual requirements to accommodate the prosthetic treatment planning.

### Implant Evaluation

Clinical and radiographic evaluations were performed after 6 months of loading and annually thereafter. An implant was considered as "not followed" if a patient could not be followed. Fixed prostheses (cemented or screw-retained) were not removed during evaluations if all clinical and radiographic parameters were satisfactory. Supra-implant removable prostheses were removed to clinically test implant mobility, examine the prosthetic attachments, and evaluate the peri-implant mucosa. Plaque control was recorded at every follow-up appointment and classified clinically as good, fair, or poor. Probing depth was measured at each implant to the nearest 0.5 mm with a periodontal probe (data not reported).

Radiographically, stability of the bone level surrounding the implant, the absence of radiolucent zones, and the adaptation of the various implant components were compared to baseline conditions after 6 months of prosthetic loading and then once per year. Crestal bone level changes were registered as modifications in the distance from the implant-abutment interface to the level of the bone on the mesial and distal implant aspects. Baseline radiographs were obtained at the time of prosthesis connection. Crestal bone level changes were evaluated in periapical radiographs. Each evaluation included 4 measurements per tooth site: apical-mesial, coronal-mesial, apical-distal, and coronal-distal. The mean of the values was calculated and served as the bone level measure to evaluate crestal bone loss. Each radiograph was mounted and labeled with study number, study center, patient number, case number, radiograph date, and tooth number of the implanted sites.

A team of 6 radiographic evaluators was selected from a group of individuals trained in reading radiographs with experience in treating dental patients. First, the team manager evaluated a standard set of radiographs, identified as the radiographic subset. Thirty radiographs were carefully measured by the team manager for parameters that will be described later in detail. The recorded values became the standard for qualifying subsequent prospective evaluators. To qualify as an evaluator for scoring study radiographs, the prospective evaluator had to record measurements that were within  $\pm 10\%$  of the standard values for the 30 radiographs after a training session outlining standard operating procedures. When a prospective evaluator's results exceeded the 10% limitation, the procedures used by the evaluator to measure radiographic variables were reviewed to determine the nature of individual or systematic errors in measurement. Following this review, the prospective evaluator was given a second opportunity to score the standard radiographic subset. No radiographic evaluator failed to qualify after the second evaluation of the radiographic subset on the basis of the established guidelines. A standardized Radiographic Evaluation Form was used by all examiners. Measurement materials included a fluorescent light box, a standard 3 $\times$  magnifying lens, and a Mitutoyo Digmatic Caliper 573-225-50 (Tokyo, Japan). The caliper number for this specific caliper used for evaluation was recorded on each data form. Evaluators requiring eyewear for proper vision (20/20) were wearing such at the time of radiographic evaluation.

### Criteria for Implant Survival

- Absence of mobility.<sup>25</sup> Any mobile implant was removed. Mobility of implants was tested directly during the initial functional placement and during the clinical evaluations with those patients who received a supra-implant removable prosthesis. For the other patients, stability was considered adequate in the absence of prosthetic mobility (cemented or screw-retained) and any signs of pathology around the implant.
- Absence of painful symptoms or paresthesia.<sup>25</sup> Any acute symptom that was treated and under control was not considered as failure, but rather a complication.
- Absence of peri-implant radiolucency areas during radiographic evaluation.<sup>25</sup>
- Absence of progressive marginal bone loss.<sup>25</sup> An initial bone loss of up to 3 mm that stabilized with time (without peri-implant treatment) was not considered to be a failure. An implant with bone loss greater than 3 mm (higher than the third thread) and stabilized with time was considered a surviving implant.

Implant survival was determined after clinical and radiographic evaluations. Implants that satisfied all the criteria were classified as surviving implants because the individual stability of the majority of the implants was not tested at each annual clinical evaluation. Fixed prostheses were not removed at a follow-up appointment if all clinical and radiographic parameters were satisfactory. Implants not satisfying all criteria were considered failures. Patients unable to participate in follow-up examinations, regardless of cause, were considered lost to follow-up. Early failures occurred before prosthesis placement and late failures occurred after prosthesis placement.

### RESULTS

A total of 1,583 threaded implants were placed from 1995 to 1999 in 528 patients at 13 clinical centers. At the time of last data collection, 48 implants (22 in the maxilla and 26 in the mandible) placed in 17 patients had been lost to follow-up (patients did not attend the scheduled recall visits or changed residence). The most frequently used implant was the ICE, with 619 (39.1%) placed implants, followed by 545 (34.4%) Osseotite implants, and 419 self-tapping implants (26.5%). Of the total number of implants, 876 (55.3%) were placed in the mandible and 707 (44.7%) in the maxilla. In addition, 1,162 (73.4%) implants were placed in posterior seg-

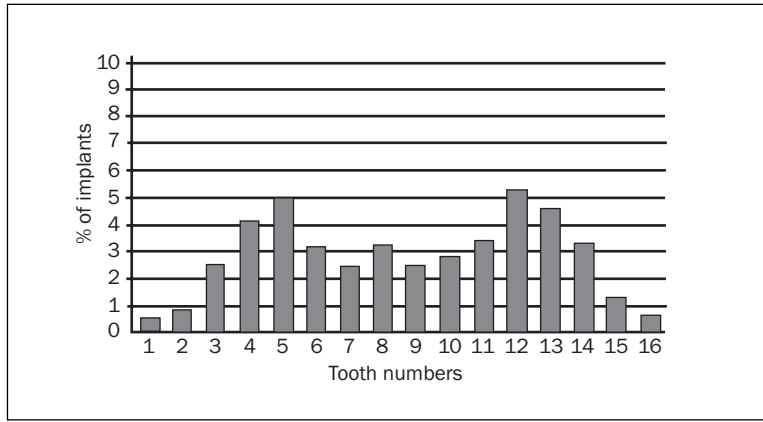
ments, 62.7% in the mandible, and 37.3% in the maxilla. The detailed proportion of placed implants is listed in Figs 2a and 2b. The most frequent implant site placement in the maxilla was the premolar area (18.7%), and in the mandible, the most common site was the molar region (29.6%).

The most frequently used implant diameter was the 3.75 mm (52.9%), followed respectively by the 4.0-mm (23.2%) and the 5.0-mm implant (20.8%) (Fig 3a). The 10-mm-long and 13-mm-long implants were the most frequently used lengths (Fig 3b).

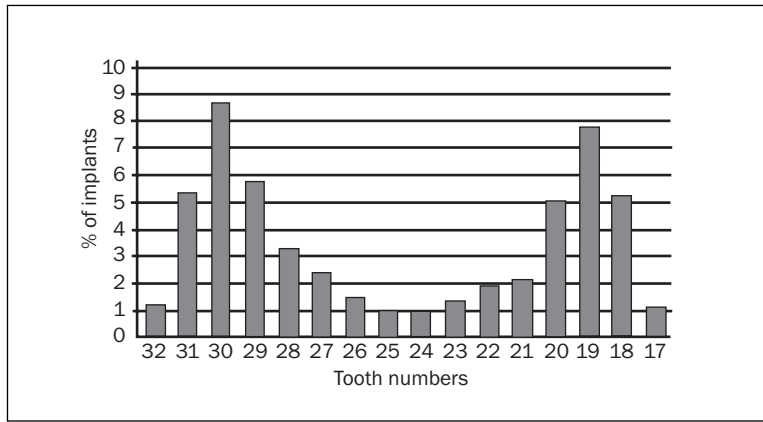
With regard to bone quality, 11% of the implants were placed in dense bone, 66% were placed in normal bone, and 23% were placed in soft bone (as evaluated during surgical preparation) (Fig 4). Prosthetic treatment included the placement of 172 single-tooth replacements, 440 short-span fixed prostheses (2 to 5 units), 56 long-span prostheses, and 4 overdentures. The majority of restorations (98.6%) were fixed prostheses.

The mean bone level was calculated from periapical radiographs and compared with the baseline radiograph (prosthesis connection). After 6, 12, and 24 months of prosthesis loading, the mean bone loss was  $0.04 \pm 1.3$  mm,  $0.12 \pm 1.6$  mm, and  $0.2 \pm 1.7$  mm, respectively.

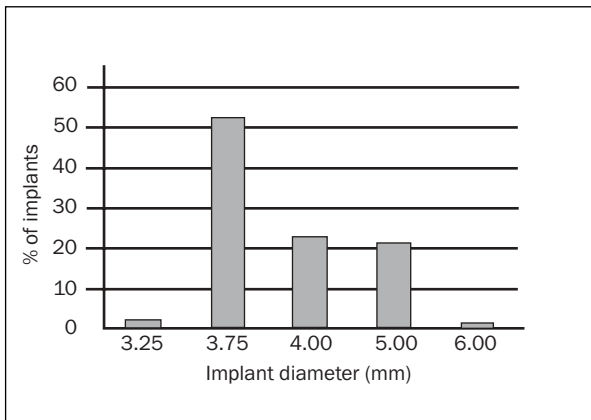
The final analysis included 1,583 implants (707 maxillary and 876 mandibular implants). All surviving implants (1,480) were examined for up to 5 years after implant placement. Forty-eight implants were not followed. Fifty-five implants were classified as failures: 10 in the anterior maxilla, 15 in the posterior maxilla, 4 in the anterior mandible, and 26 in the posterior mandible; 47 (early) prior to or at stage 2 surgery and 8 (late) after loading. Among the 55 failures, 40 implants did not integrate, 9 demonstrated persistent infection, 2 violated the mandibular canal, 2 revealed a continuous radiolucency, and 2 other failures did not have any apparent etiology. A survival rate of 96.5% was noted 1 to 5 years after implant placement (Table 2). The survival rate was 97.2% in the maxilla and 95.8% in the mandible. The survival rate was similar in both anterior (96.7%) and posterior (96.5%) segments. Early failures were more common (85.5%) than late failures (14.5%). According to implant diameter, the majority of failures occurred with 3.75-mm-diameter implants (29/828). However, the absolute number of 3.75-mm-diameter implants placed was greater than any other diameter implant. In fact, if the percent of implant loss was considered for each implant diameter, the outcome is quite different. The failure rate was 3.5% for 3.75-mm-diameter, 6% for 3.25-mm-diameter, 2% for 4.0-mm-diameter, 3.6% for 5.0-mm-diameter, and 25% for 6.0-mm-diameter implants. The greatest



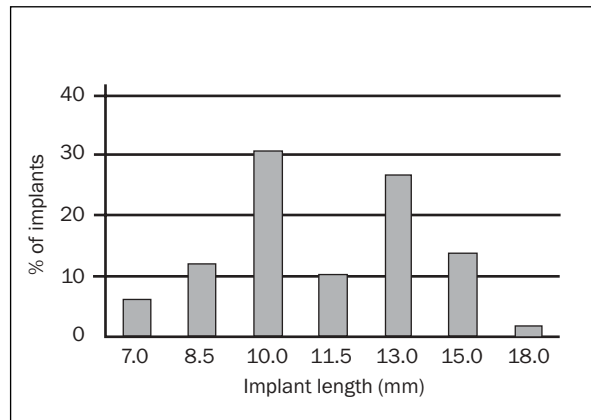
**Fig 2a** Distribution (%) of maxillary implants by tooth site (Universal system).



**Fig 2b** Distribution (%) of mandibular implants by tooth site (Universal system).



**Fig 3a** Distribution of implants placed by diameter.



**Fig 3b** Distribution of implants placed by length.



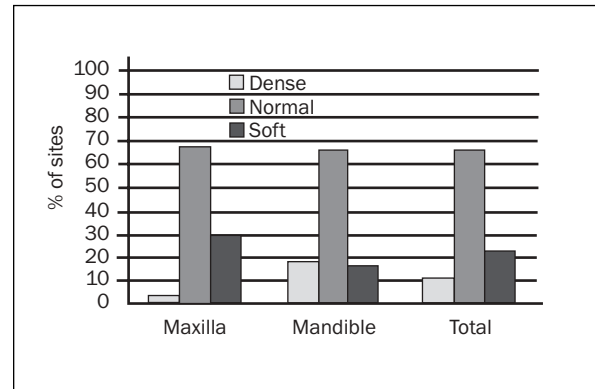
risk for implant failure was in the 6.0-mm-diameter group. Survival rates of 95.7% (33 failures) and 97.3% (22 failures), respectively, were obtained with short and long implants (Table 3).

## DISCUSSION

Different parameters for presenting a proper clinical report were analyzed recently by Albrektsson and Zarb.<sup>26</sup> These authors proposed that an accurate detailed report include: a multicenter evaluation with at least 2 independent centers with a minimum number of about 50 implants in each center; prospective rather than retrospective design, continuing for at least 5 years; reporting of the frequency of patient recall, dropout information, implant design, duration of follow-up, marginal bone stability, and the mode of presentation of data; and finally, the use of specific criteria to classify implants as successful, surviving, unaccounted for, and failures. The present prospective multicenter study in a 1- to 5-year period attempted to fulfill all these parameters. A cumulative implant survival rate of 96.5% was observed for 1,583 threaded 3i implants placed in 528 patients (completely and partially edentulous patients). This cumulative survival rate is similar to those reported

in some studies that have evaluated the predictability of an implant system.<sup>5,6</sup> However, it is very difficult to compare different studies because success criteria, patient selection, and the parameters of clinical reporting and presentation of data vary considerably.

Among the 55 failures reported in this study, early failures (before prosthetic loading) were more common (n = 47) than late failures (n = 8). The rate of late implant failures is of utmost importance for the restorative dentist.



**Fig 4** Implant distribution by bone quality. (Bone quality was clinically evaluated during surgical preparation by each surgeon based on tactile sensation during drilling.)

**Table 2** Cumulative Survival Rate

Interval (mo)	Implants at start of interval	Failed implants	Lost to follow-up	Interval survival rate	Cumulative survival rate
1 to 12	1583	45	7	97.1%	97.1%
12 to 24	1531	10	7	99.3%	96.5%
24 to 36	1459	0	25	100.0%	96.5%
36 to 48	959	0	1	100.0%	96.5%
48 to 60	289	0	8	100.0%	96.5%

**Table 3** Implants Placed (Failed) by Length and Diameter

Implant length (mm)	Implant diameter*					Total placed (failed)
	3.25 mm	3.75 mm	4.00 mm	5.00 mm	6.00 mm	
7.0	0 (0)	15 (1)	14 (0)	65 (3)	2 (0)	96 (4)
8.5	2 (1)	61 (1)	45 (3)	76 (4)	5 (2)	189 (11)
10.0	6 (1)	246 (12)	113 (2)	112 (1)	4 (2)	481 (18)
11.5	2 (0)	79 (2)	44 (0)	29 (2)	4 (0)	158 (4)
13.0	13 (0)	244 (4)	106 (2)	54 (2)	1 (0)	418 (8)
15.0	7 (0)	166 (9)	36 (1)	4 (0)	1 (0)	214 (10)
18.0	3 (0)	17 (0)	7 (0)	0 (0)	0 (0)	27 (0)
Total placed (failed)	33 (2)	828 (29)	365 (8)	340 (12)	17 (4)	1583 (55)

\*No. placed; no. failed shown in parentheses.

The maxillary survival rate obtained in the present evaluation (97.2%) was better than those observed in several long-term clinical studies.<sup>4,27-31</sup> In fact, the first longitudinal studies with the Brånemark System showed lower cumulative implant success or survival rates in the maxilla. Albrektsson and coworkers,<sup>27</sup> in a retrospective (5- to 8-year) multicenter study of 8,139 Brånemark System implants, reported a success rate of 84.9% in completely edentulous maxillae. Adell and associates<sup>4</sup> presented the results of 4,636 implants placed in 759 completely edentulous jaws of 700 patients with an observation period of up to 15 years. Survival implant rates in the maxilla were 89% at 5 years, 82% at 10 years, and 78% at 15 years. Olsson and colleagues<sup>31</sup> published the results of 563 implants (288 MK II [Nobel Biocare] as test implants and 275 standard implants as controls) placed in 103 patients. A total of 200 implants were placed in the maxilla. Three-year cumulative survival rates were 87.9% and 86.8% for test and control implants in maxilla. Friberg and coworkers,<sup>30</sup> in a clinical evaluation of early failures in 4,641 consecutively placed implants (1,729 in maxillary sites), concluded that jaw shape and bone quality seemed to be the 2 most important factors for early implant failure in the maxilla. Implant survival rates from 50% to 88% in low-density bone have been reported in the scientific literature.<sup>2,32-35</sup>

Several reasons could explain the better recent results obtained in the maxilla compared to the earlier studies. In the early years of osseointegration, clinicians were not aware of the importance of achieving optimal primary implant stability in soft bone and its impact on osseointegration.<sup>30,36</sup> A new protocol with a specific technical skill may often be associated with a learning curve (surgical experience). It has been shown that inexperienced surgeons profit from a learning curve and initially have a higher rate of implant failures than experienced surgeons.<sup>37,38</sup> Only 10-mm-long and 7-mm-long standard implants with a 3.75-mm or 4.0-mm diameter were reportedly used in the first clinical evaluations.<sup>6</sup> Recently, as a result of surgical and technologic innovations (implant surface texture), new therapeutic proposals have been aimed at achieving better implant integration in the maxilla.<sup>39</sup> In the present study, different implant lengths (7, 8.5, 10, 11.5, 13, 15, and 18 mm) and diameters (3.25, 3.75, 4.0, 5.0, and 6.0 mm) were utilized. Newer implant designs facilitate initial implant anchorage as a result of better adaptation of the implant to the surgical site.

Different publications on 3i implants have reported satisfactory results and therapeutic viabil-

ity.<sup>8,11-14,21,40</sup> In 1996, Lazzara and coworkers<sup>8</sup> published results of a retrospective multicenter study of 1,969 implants placed in 653 patients during a 5-year period with a follow-up from 6 to 60 months. The success rates for 1,277 screw-type implants were 97% in the mandible (710 implants) and 93.8% in the maxilla (567 implants). Davarpanah and associates<sup>12</sup> reported on 614 machined-surface screw-type commercially pure titanium implants (277 self-tapping and 337 ICE) in another multicenter prospective clinical evaluation. The authors reported the therapeutic success and marginal bone level stability after 3 years of prosthetic loading. For the self-tapping implants, survival rates of 92.9% and 91.6% were noted, respectively, after 1 and 3 years of prosthetic loading. Survival rates of 95.4% and 93.8% were obtained with the ICE implant for the same periods. The marginal bone level was at the first thread for 95.1% of the implants. Overall survival rates of 94.3% and 92.9% were reported after 1 and 3 years of prosthetic loading.

Recently, Testori and colleagues<sup>13</sup> reported a cumulative implant success rate of 98.7% for 485 Osseotite implants placed in 181 patients after 4 years of loading. The cumulative success rates in the posterior mandible and maxilla were 99.4% and 98.4%, respectively, for a total of 355 implants placed in posterior segments (73.2%). In that prospective multicenter evaluation, all implant failures (n = 6) occurred prior to restorative loading. Davarpanah and coworkers,<sup>21</sup> in a prospective multicenter study (5 centers), reported a cumulative success rate for 413 Osseotite implants placed in 142 patients. A cumulative success rate of 95.3% was obtained after 3 years of prosthetic loading. The marginal bone level was at the first thread for 91.4% of the implants. Including the survival implants, the cumulative implant survival rate after a 3-year loading period was 96%.

In the present study, the baseline (non-standardized) radiographs were taken at the time of functional loading (placement of prostheses). Under the reported measurement conditioning, changes in marginal bone height and the pattern of tissue stability obtained appeared to correspond to the marginal bone level success criteria proposed by Albrektsson and coworkers.<sup>25</sup>

Results of the present study support the efficacy of the 3i threaded implant in the treatment of partially and completely edentulous patients. The cumulative implant survival rate (96.5%) obtained in a 1- to 5-year period after implant placement is comparable to other implant systems with similar clinical situations over the same time frame.

## CONCLUSION

In the present prospective multicenter study, a global cumulative survival implant rate of 96.5% was observed for the treatment of patients with completely or partially edentulous jaws. This survival rate in a 1- to 5-year follow-up experience demonstrated that 3i threaded dental implants can achieve predictable osseointegration in both jaws in this patient population.

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