Immediate Occlusal Loading of NanoTite™ PREVAIL® Implants: A Prospective 1-Year Clinical and Radiographic Study

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ABSTRACT

Background: Recently, a new implant surface texture, featuring application of nanometer-scale calcium phosphate has been shown to enhance early bone fixation and formation in preclinical studies and in human histomorphometric studies, which may be beneficial in immediate loading situations.

Aim: The purpose of the present prospective clinical study was to, during 1 year, clinically and radiographically evaluate a nanometer scale surface modified implant placed for immediate loading of fixed prostheses in both maxillary and mandibular regions.

Materials and Methods: Thirty-five out of 38 patients who needed implant treatment and met inclusion criteria agreed to participate in the study and were consecutively enrolled. Surgical implant placement requirements consisted of a final torque of a least 25 Ncm prior to final seating and an implant stability quotient above 55. A total of 102 NanoTite™ PREVAIL® (NTP) implants (BIOMET 3i, Palm Beach Gardens, FL, USA) (66 maxillary and 36 mandibular) were placed by one investigator, and the majority of these were placed in posterior regions (65%) and in soft bone (69%). A total of 44 prosthetic constructions were evaluated consisting of 14 single-tooth restorations, 26 fixed partial dentures, and four complete fixed restorations. All provisional constructions were delivered within 1 hour, and the final constructions placed after 4 months. Implants were monitored for clinical and radiographic outcomes at follow-up examinations scheduled for 3, 6, and 12 months.

Results: Of the 102 study implants, one implant failed. The simple cumulative survival rate value at 1 year was 99.2%. The average marginal bone resorption was 0.37 mm (SD 0.39) during the first year in function. According to the success criteria of Albrektsson and Zarb, success grade 1 was found with 93% of the implants.

Conclusion: Although limited to the short follow-up, immediate loading of NanoTite Prevail implants seems to be a viable option in implant rehabilitation, at least when a good initial fixation is achieved.

KEY WORDS: dental implants, immediate loading, Nanotite, Prevail

INTRODUCTION

During the past 40 years, prosthetic rehabilitation of the edentulous patient with implant-supported bridges has developed into a viable and predictable treatment option. High clinical success rates with the original implant protocols[1] have given clinicians and researchers confidence to further develop and refine the osseointegrated technique and, consequently, implants are used in increasingly more challenging situations and on broader indications.[2–4] A submerged healing period of 3 to 6 months was originally considered a prerequisite for achieving osseointegration of titanium implants.[1] However, during the past decade, this traditional protocol has been challenged. The obvious advantages with immediate implant loading for patients have led to an increased focus on the development and evaluation of such protocols. Recent literature reviews concluded that predictable results can be achieved in the anterior mandible, irrespective of implant type, surface properties,

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and prosthesis design.[5,6] Although good results have been reported for immediate implant loading also in the totally edentulous maxilla and partially edentulous jaws, the limited number of investigations does not allow for a conclusion regarding the long-term predictability of the treatment.

While firm, initial stability is regarded as a perquisite for success when implants are placed with two-stage healing protocols,[7] it may be an even more important factor for immediately loaded cases due to functional and occlusal forces at placement. Initial implant stability is often based on torque resistance measurements at implant placement. An insertion torque value from 30 to 40 Ncm before the implant is finally seated is considered sufficient to indicate stability[3,8], and torque measurements have been shown to reflect bone density.[9] Modified surgical techniques using a combination of thinner drills, osteotomes, tapered implants, and/or wider implants have been studied to enhance primary stability.[10–12] Friberg and colleagues[10] did not demonstrate any correlation between insertion torque and implant failure for two-stage Brånemark® (Nobel Biocare AB, Göteborg, Sweden) implants. A correlation, however, was reported in a recent study on immediately loaded Frialit (DENTSPLY Friadent, Mannheim, Germany) implants for single-tooth replacements.[13]

In a previous study, the primary stability of 905 threaded titanium implants placed according to a protocol aiming at high initial stability was evaluated at the time of implant placement using resonance frequency analysis (RFA).[12] A mean implant stability quotient (ISQ) value of 67.4 was obtained for all sites. Sennerby and Meredith[14] found that Brånemark implants with an ISQ value around 65 did not show an increased stability with time and suggested this to be a safe level for immediate loading. In the study by Östman and colleagues,[12] about 65% of 905 implants had an ISQ value of 65 or higher. Moreover, implants placed in posterior segments were as or even more stable than anteriorly placed implants in both the mandible and the maxilla. Although posterior regions, especially in the maxilla, are considered as more challenging due to the presence of soft bone, the results suggest that sufficient stability can be achieved for immediate loading when using thinner drills and or wider implants.

Implant surface topography may be an important factor for proper integration in challenging situations. Most papers on immediate loading using dual acid-etched implants describe immediate loading protocol in the totally edentulous mandible[15–18] and/or maxilla[15,18] with a survival rate of 96.9% to 100%. Drago and Lazzara[19] treated 38 partially edentulous patients with single-tooth restoration. In total, 93 dual acid-etched implants were placed. Inclusion criterion was a final torque of at least 30 Ncm. Seventy-seven implants were followed for at least 18 months. The survival rate was 97.4% after an 18-month follow-up. In 2007, an implant surface featuring nanotopography with calcium phosphate (CaP) nanoparticles added to the dual acid-etched titanium surface was presented. The surface topography has previously been characterized, and the result demonstrates a minimally rough surface, that is, an average height deviation (surface roughness parameter Sa) of 0.5 μm.[20] However, the surface enlargement (parameter Sdr) is 40% compared with a totally flat reference plane; thus, the implant surface area is close to the experimental ideal when evaluated with this hybrid parameter.[20] Histological investigations have demonstrated greater bone content percentage and a more rapid fixation of the implant when adding the nanosurface in comparison with dual acid-etched control titanium implants in animals[21–23] and in humans[24,25].

The aim of the present prospective, single-center clinical study was to clinically and radiographically evaluate the outcome of the nanotopography surface when used for immediate loading of fixed prostheses and single-tooth restorations in a patient group with an initial implant stability corresponding to an ISQ value of 55 and a final torque of 25 Ncm.

MATERIALS AND METHODS

Study Patients and Preliminary Inclusion Criteria

The study was conducted at single study center by one investigator, and the basis for patient selection was need for implant-supported prostheses with preliminary inclusion criteria as follows: presence of residual bone sufficient to house at least an 8.5 mm long implant and implant site free from infection. All patients were thoroughly informed about the procedure and gave written consent for inclusion in the study. Exclusion criteria consisted of general contraindications for oral surgery and individuals less than 18 years old. Thirty-eight patients were invited to participate and were

Figure 1 Showing the type of implant used in the study.

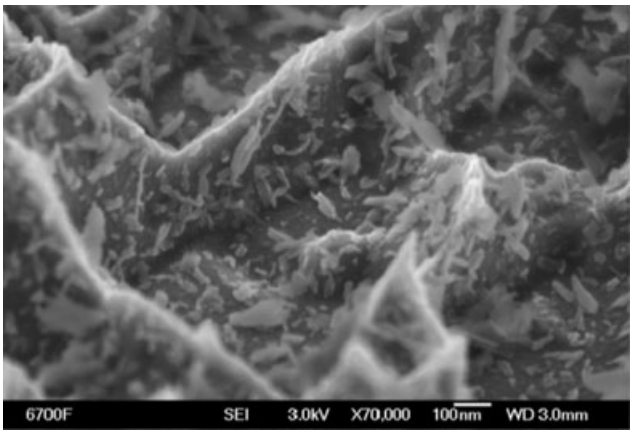

Figure 2 Scanning electron micrograph showing the surface of the implant used in the study. Calcium phosphate (CaP) nanoparticles can be observed on the acid-etched titanium alloy surface. SEI = site evaluation implants.

thoroughly informed about all study procedures and understood that the final decision for enrollment would be based on final inclusion criteria determined at the implant placement surgery.

Study Implants

Threaded titanium alloy implants with an internal connection in lengths of 8.5 to 15 mm and diameters of 4 and 5 mm (Figure 1) (PREVAIL®, BIOMET 3i, Palm Beach Gardens, FL, USA, and with a nanotopography [NanoTite™]) (Figure 2) surface extending from the apex to the top of the collar were used in the study. At the coronal portion of the implant, the diameter expands creating a collar that is 1 mm greater than the body of the implant.

Implant Placement Surgery and Final Inclusion Criteria

Patients were given antibiotics (PECEVE®, Ipex Medical AB, Sweden, 2 grams) and diazepam (Stesolid®, Alpharma, Stockholm, Sweden) (0.3 mg/kg body weight) orally, approximately 1 hour prior to surgery. The surgical site was infiltrated with lidocain-epinephrine (Xylocaine®-Adrenaline 2%, Dentsply Pharmaceutical, York, PA, USA), and a midcrestal incision was performed. After reflection of the mucosal flap, the site and alveolar ridge were carefully evaluated with consideration for both the aesthetic and biomechanical aspects to determine the optimal implant position. Bone quality and quantity were assessed according to Lekholm and Zarb's criteria[26] (Table 1). Implants were placed in underprepared osteotomies to increase initial stability.[12] Selection of the final drill size was based on bone quality. In type 1 bone, the final drill size was 3.25 mm, in type 2 bone 3.0 mm, and in type 3 to 4 bone a 2.75-mm final drill was used (Figure 3). A countersinking technique was utilized in order for the implant to engage as much cortical crestal bone as possible. Insertion torques were measured with a drill unit (Osseocare™ Nobel Biocare AB, Göteborg, Sweden). After seating of the implant, RFA measurements were performed (Osstell Mentor™ Integration Diagnostics AB, Göteborg, Sweden).

At this stage, the decision was made whether to proceed and immediately load the implant or to cancel

TABLE 1 Bone Quality and Quantity. Failure within Bracket

Certain Prevail NanoTite Implants					
Bone Quality	Bone Quantity 1	2	3	4	Number of Implants
A	—	2	5	—	7
B	8	5	23	19 (1)	55 (1)
C	—	14	16	—	30
D	2	—	8	—	10
Total	10	21	52	19	102

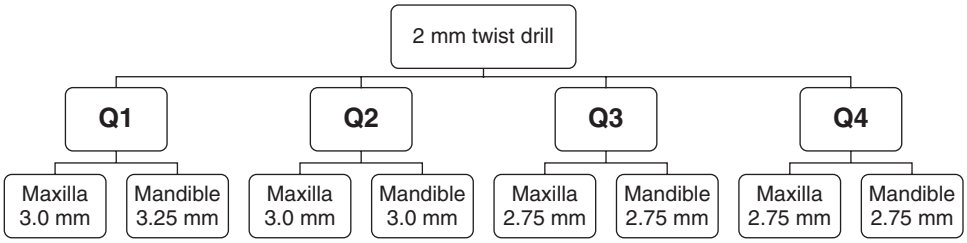

Figure 3 Drill protocol used in the study.

the study protocol and use a two-stage healing approach, dropping the patient from the study. The decision was based on the following final inclusion criteria: a minimum insertion torque of 25 Ncm before the final seating of the implant, and an ISQ above 55 measured with the RFA instrument. Of the original 38 patients who had been invited to participate in the study, 35 patients with 102 implants supporting 44 prosthetic constructions met the final inclusion criteria (Tables 2 and 3). For the first 10 days after implant installation, the patients were prescribed 2 g/day of penicillin V (Kåvepenin®, AstraZeneca, Södertälje, Sweden), mouth rinsing with chlorhexidine (Hexident®, Ipex Medical AB, Solna, Sweden) (0.1% twice per day), and a diet consisting of soft food.

Prosthetic Procedures

Before adaptation and suturing of the mucosal flaps, specially designed components for fabrication of provisional crowns/bridges were placed (PreFormance Posts™ or QuickBridge™ components, BIOMET 3i, Palm Beach Gardens, FL, USA). Cantilevers were allowed in the study but were restricted from exceeding 5 mm.

Fourteen single-tooth replacements were made, and for these, the PreFormance Post was ground to fit into occlusion. All temporary constructions were made chairside. A prefabricated translucent strip crown (Frasaco strip crown, Frasaco GmbH, Tettnang, Germany) was filled with composite resin (CeramX™, Dentsply International, York, PA, USA) and pressed over the PreFormance Post. A rubber dam was used to avoid composite material from entering the pocket and to limit excess material from overfilling the prefabricated crown. After light curing the composite, the occlusal surface and interproximal contours of crown were adjusted outside the mouth. The single-unit crowns were left out of occlusion and free from approximal contacts. Subsequently, the crowns were cemented with temporary cement (Tempbond®, Kerr, Orange, CA, USA), with the rubber dam in place. In Figure 4, a typical single-unit treatment is illustrated.

Twenty-six partially edentulous (64 implants) and four fully edentulous maxillae cases (24 implants) were included in the study (see Table 2). An alginate impression of both jaws had been taken prior to surgery for partial restorations. For cases presenting with full dentures, impressions were taken of the existing removable dentures. Occlusal records were also registered for each case. A translucent vacuum template was constructed from a 2.5-mm thick thermoformed material (Ergoflex 95 ERKOFLEX®95, ethyl-veny-acetate, Erkodent®, Pfalzgrafenweiler, Germany) by the same dental laboratory for all cases.

The translucent templates were mounted on articulators by technicians to confirm that the temporary

TABLE 2 Number of Prosthetic Construction and Implants

Site	No. of Prosthetic Construction	No. of Implants
Total maxilla	4	24
Partial maxilla	13	35
Partial mandible	13	29
Single maxilla	7	7
Single mandible	7	7
Total	44	102

TABLE 3 Implant Length of Included Implants

Implant Length (mm)	Number
15	32
13	37
11.5	11
10	17
8.5	5
Total	102

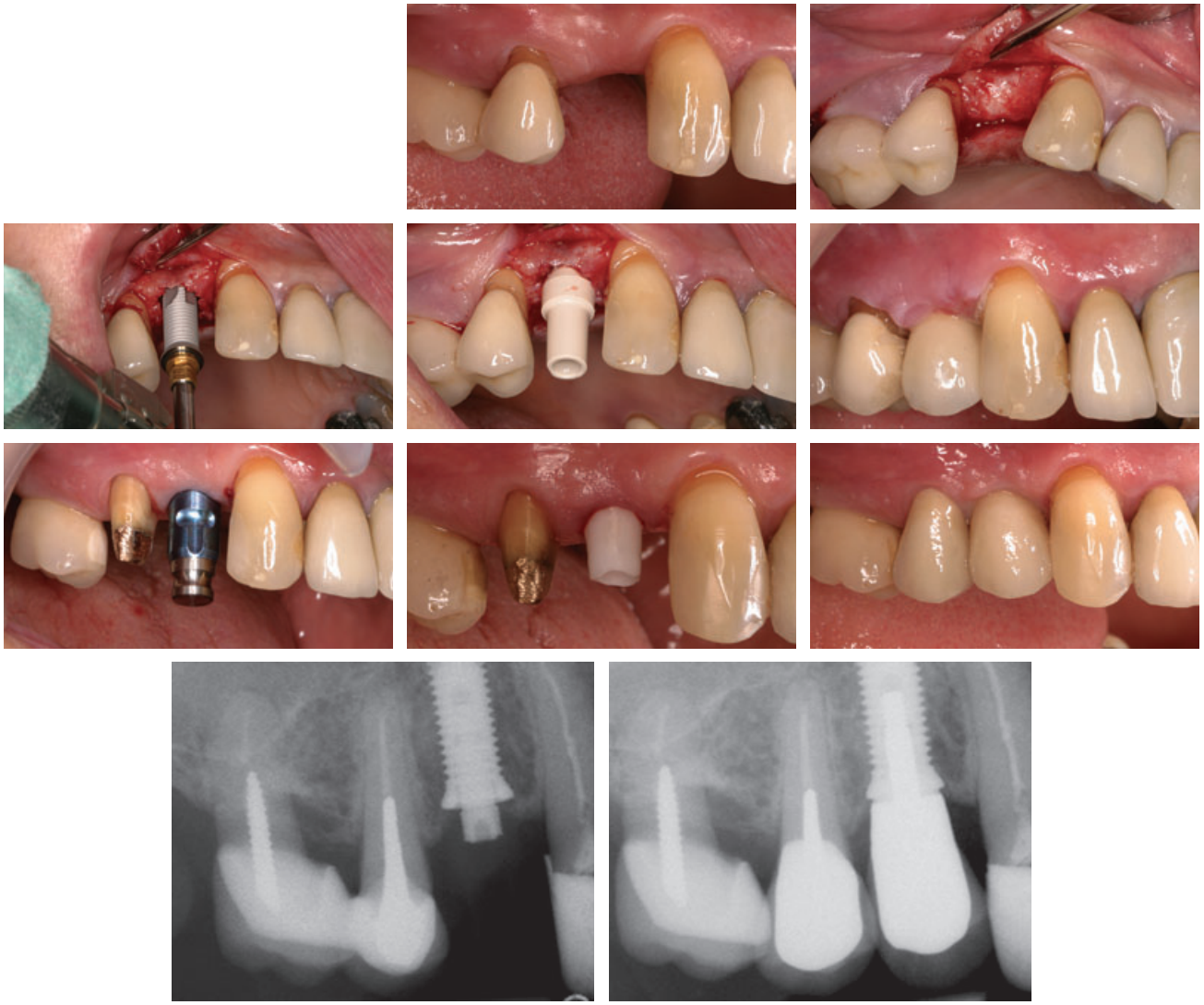

Figure 4 A typical single-unit treatment is illustrated.

constructions fit into the templates. Protemp™ 3 Garant (3M ESPE, St. Paul, MN, USA) was injected into the template; the template was seated and allowed to set for 4 minutes. For fixed bridges, the temporary prostheses were removed from the QuickBridge titanium interface and for single-tooth restorations from PreFormance Posts, and subsequently trimmed outside the mouth. Careful adjustments of occlusion and articulation were performed to minimize lateral forces, for example, light centric occlusion contacts and no contacts in lateral movements. In Figure 5, a typical multi-unite treatment is illustrated.

Three to 4 months after implant placement, a visit was scheduled to take a new impression from which to build a master cast to fabricate the permanent fixed restoration.

Follow-up Evaluations

All patients participating in the study agreed to be enrolled in a strict and individually designed maintenance care program focusing on the following: (1) oral hygiene; (2) stability of fixed restorations; (3) soft tissue health; and (4) function of the dentition. Post-treatment follow-up examinations were scheduled for 3, 6, and 12 months. Implant stability was assessed with RFA in ISQ units at the 6-month visit when the temporary prosthesis was removed. Patients' oral hygienes were treated and maintained on an individual basis.

Marginal Bone Resorption

The marginal bone levels were evaluated from digital periapical radiographs by a radiologist. Periapical

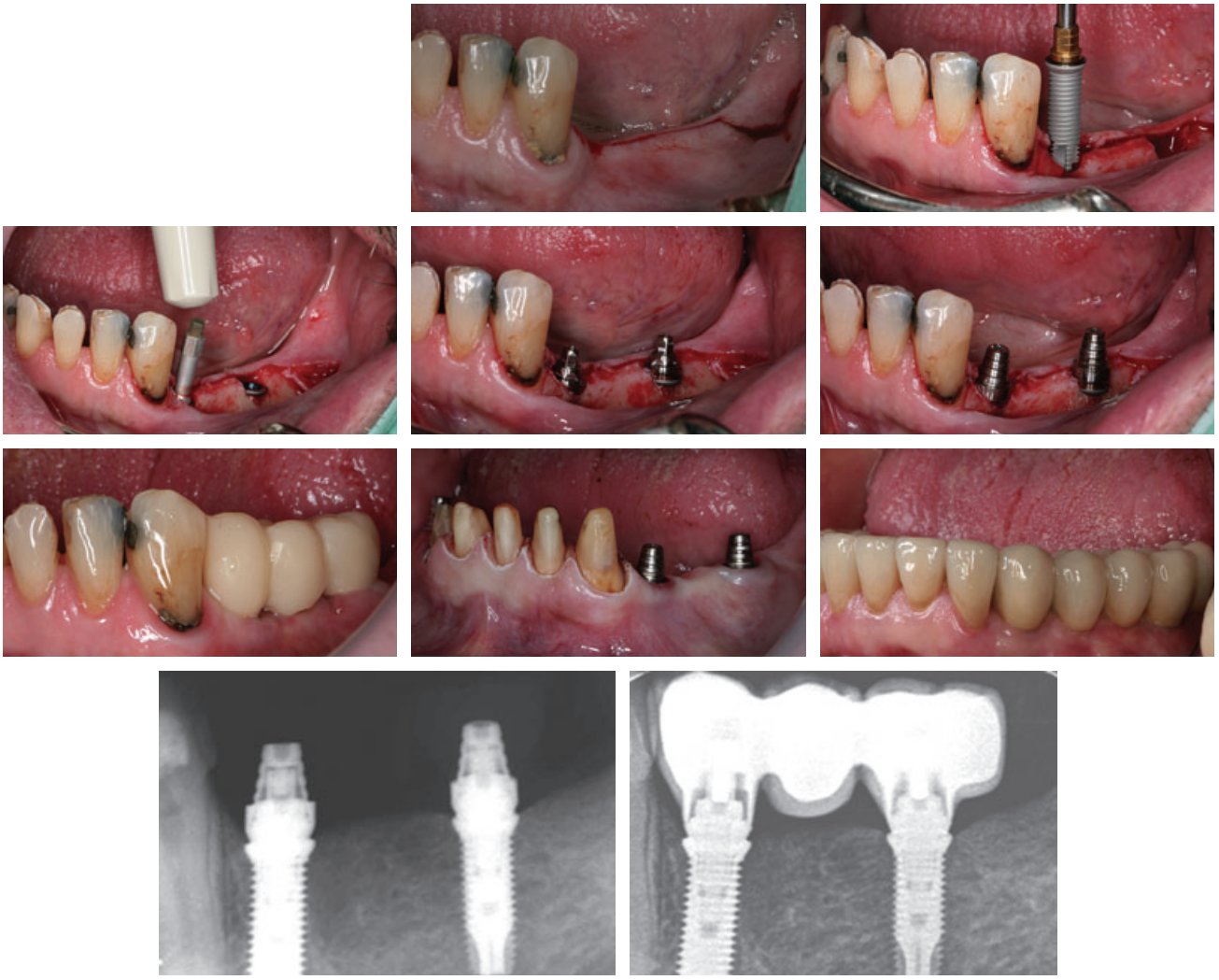

Figure 5 A typical multi-unit treatment is illustrated.

radiographs were exposed after implant surgery to establish baseline, at 6 months and at 1 year of function. For the radiograph procedures, a silicone index material was fixated to the upper dentition and a radiograph holder was constructed for each patient. This technique ensured that the same position of the radiograph film could be reproduced at each visit and the angle of the radiograph would not deviate despite changes to the occlusal surface when the provisional fixed partial denture (FPD) was replaced with the permanent restoration. Crestal bone loss was determined by measuring the distance from the implant/abutment junction (IAJ) on the mesial and distal aspects to the level of the margin of the crestal bone. Bone loss was presented as the mean values for distal and mesial changes from baseline for each implant and each time point.

Success Rating

Implant success was evaluated using a Four-Field table according to Albrektsson and Zarb[27] using the following categories:

1. Success – An implant meeting with success criteria. Criteria for success according to Albrektsson and colleagues[28] and Albrektsson and Zarb[22] include absence of implant mobility and absence of pain and neuropathy. Originally, 1 mm of bone loss from the lower corner of the implant head was acceptable during the first year and less than 0.2 mm annually thereafter. Slightly less strict criteria were used in the present study since implants were individually tested for mobility only after 3 months and not later. Success grade 1 was defined as an implant with no clinical and radiographic signs of pathology

TABLE 4 Life-Table of Certain Prevail NanoTite Implants

Interval (months)	Implants in Interval	Failures	CSR (%)
0–6	102	1	99.2
6–12	101	0	99.2
12–18	81	0	99.2
18–24	20	0	—

CSR = cumulative survival rate.

showing less than 1 mm of bone resorption at 1 year of follow-up. Success grade 2 was defined as an implant with no clinical and radiographic signs of pathology showing less than 2 mm of bone resorption at 1 year of follow-up.

2. Survival – An implant still in the bone that does not meet with or has not been tested for success criteria.
3. Unaccounted for – An implant in a patient who dropped out of the study for any reason.
4. Failure – An implant removed for any reason.

RESULTS

Clinical Observations

Few complications were observed during the 1-year follow-up. One provisional FPD showed temporary mobility due to loosening of the prosthetic screw. Two provisional single crowns fractured and had to be rebuilt.

Implant Survival

One implant of the 102 implants showed rotational mobility after 3 months at the visit scheduled for impression for a three-unit permanent bridge. The failed implant showed no radiographic signs of loss of integration. The implant was located in the anterior maxilla, in quality 4 bone. The two other implants placed in this case were successful; therefore, no surgical intervention was necessary. The overall cumulative survival rate for implants in the study was 99.2% after 1 year (Table 4). Based on radiographs and clinical examinations, success grade 1 was applicable for 93%, for survived 6%, for unaccounted 0%, and for failed 1% (Table 5).

RFA

RFAs were performed for all 102 study implants and the ISQ units scored at implant placement. Units ranged from 55 to 87 and the mean value was 73.4 (SD 8).

TABLE 5 Implant Success Using a Four-Field Table According to Albrektsson and Zarb

Success Grade 1	Unaccounted for
93%	0%
Survival	Failure
6%	1%

Marginal Bone Resorption

Crestal bone loss after 1 year was determined from digital radiographs, averaged from distal and mesial measurements for each implant. At baseline implant placement, the mean crestal bone level was 0.19 mm (SD 0.3) below the IAJ, and after 1 year of loading, the level was 0.56 mm (SD 0.37) from the IAJ. The average bone loss for 102 surviving implants was calculated to be 0.37 mm (SD 0.39) after 1 year of follow-up (Table 6). Six (6%) implants showed more than 1 mm of bone loss, and no implants showed more than 2 mm of bone loss after 1 year.

DISCUSSION

This consecutive prospective clinical study of immediately loaded NanoTite Prevail implants was successful as only one of 102 implants was lost during the follow-up time. One factor contributing to the good results is probably the modified drill protocol aiming for high primary stability, by using thinner final twist drills depending on bone quality. From the authors' point of view, when changing from a two-stage procedure to an immediate-loading protocol, the drill protocol cannot

TABLE 6 Marginal Bone Resorption at 1 Year Follow-up

	NanoTite Prevail	
	(m + d)/2	(%)
Number	101	
Mean value (SD)	0.37 (0.39)	
<0	9	9
0	17	17
0.1–1.0	69	68
1.1–2.0	6	6
2.1–3.0	0	0
>3.0	0	0
Total	101	100

be standardized but needs to be modified according to bone quality. This surgical technique was previously evaluated in a study in which the primary stability of 905 Brånemark implants was evaluated with RFA.[12] The influence on the primary stability of factors related to the patient, implant, and surgical technique was statistically analyzed. It was concluded that good primary stability could be achieved in all jaw regions, and if a lower ISQ limit of 60 was used for immediate loading, 85% of the implants could have been considered for immediate loading. In the present study, an ISQ of 55 was required for inclusion in the study. Thirty-eight patients (105 implants) were invited to participate in the study. Out of these patients, 35 patients with (102) (97%) implants met with the final inclusion criteria and were subsequently immediately loaded. The reason for such a high number of patients meeting with the inclusion criteria of an ISQ above 55 may relate to the macroanatomy of the Prevail implant with its large coronal flange that engage the marginal cortical bone. As most of the stress on an implant is in this region, the macroanatomy of the Prevail implant might be suitable for immediate loading.

All multi-unit constructions in this study were splinted with a chair/side technique,[29] placed in light centric occlusion. By splinting, the implants work as a group rather than as single units, thereby compensating for lateral forces and eliminating the risk that the patient grinds only on the most superior implant. All 14 single restorations were placed in nonocclusional loading, and care was taken to avoid any lateral forces.

Another reason for the good result might be the surface modification on the implant used. Observations from biomechanical studies indicate that the nanotopography surface effects take place early in the healing process, which may facilitate endosseous implant integration during early healing stages after implant placement. A rabbit model shows that at 2 weeks, bullet-shaped implants with the same surface as used in the present study placed in tibias required forces 189% greater to detach the implants from tibias in comparison to noncoated control implants.[21] This suggests that the effects are occurring during the time when de novo bone formation is most susceptible to micromotion and other forces that may impede osseous fixation mechanisms and prior to substantive mineralization of the bone matrix. Nishimura and colleagues 2007[23] demonstrate the early fixation properties of the same nanosurface in a rat push-in model, with the mechanical withstanding loads increasing by 76% after 2 weeks. Further fixation studies corroborate these findings, demonstrating disruption forces for nanosurfaced implants at 9 days in a rat model to be more than 450% greater compared to noncoated control implants.[17]

Histological and histomorphometric outcomes of nanotopography implants placed in humans in comparison with the dual-etched surfaces also demonstrate significant effects. Using a previously described model[24,25], Orsini and colleagues 2007[25] placed custom 2 mm × 10 mm site evaluation implants (SEI) in posterior maxillas of 15 patients and measured bone-implant contact (BIC) after 2 months of healing. The results show an increase of 70% BIC on the nanosurface in comparison with the control surface and were statistically significant ($p < .05$). Further human histomorphometric investigations using a similar protocol measured a 194% increase in BIC on SEI at 4 weeks and a 148% increase at 8 weeks on the nanosurface in comparison to control surfaces.[24] The results of these preclinical and human histomorphometric studies indicate that the effect of the nanosurface occur early in bone healing. This fact might have had an influence on the clinical outcomes of the immediate loading cases presented here.

CONCLUSION

Although limited to the short follow-up, immediate loading of NanoTite Prevail implants seems to be a viable option in implant rehabilitation when following a protocol based on primary stability criteria.

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