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

Pär-Olov Östman, DDS, PhD;* Ann Wennerberg, DDS, PhD;† Annika Ekestubbe, DDS, PhD;‡ Tomas Albrektsson, MD, PhD, ODHc†

ABSTRACT

Background: During the last decade, high success rates have been reported for implants placed with immediate loading procedures, especially when bone quality and quantity provide good implant stability. In many of these studies, straight-walled implants with moderately rough surfaces were employed. Tapered implants are becoming increasingly more popular due to standardized drilling protocols and reports of high initial primary stability.

Purpose: The aim of the present prospective, single center clinical study was to evaluate surface topographical analysis and the clinical and radiographic outcomes of the NanoTite™ (BIOMET 3i, Palm Beach Gardens, FL, USA) Tapered Implant when used for immediate loading of fixed prostheses and single-tooth restorations.

Materials and Methods: Forty-two patients who needed implant treatment and met admission criteria agreed to participate in the study and were consecutively enrolled. Surgical implant placement requirements consisted of a final torque of a least 30 Ncm prior to final seating and an implant stability quotient above 55. A total of 139 NanoTite Tapered implants (112 maxillary and 27 mandibular) were placed by one investigator, and the majority of these implants ($n = 77/55\%$) were placed in posterior regions, and in soft bone ($n = 90/65\%$). A total of 57 prosthetic constructions were evaluated consisting of 20 single-tooth restorations, 30 fixed partial dentures, and 7 complete, fixed maxillary restorations. Radiographs were taken at baseline and at 12 months of follow-up.

Results: Of the 139 study implants, one implant failure was declared. The overall cumulative survival rate at 1 year is 99.4%. Mean marginal bone resorption is 1.01 mm (SD 0.85) during the first year of function.

Conclusion: Although limited to the short follow-up, immediate loading of NanoTite Tapered implants seems to be a viable option in implant rehabilitation, when insertion torque of at least 30 Ncm is achieved. Further studies are needed to authenticate the finding of this study.

KEY WORDS: dental implants, immediate loading, NanoTite, tapered

INTRODUCTION

During the last decade, implant treatment has been progressed from the traditional two-stage surgical protocol with long healing times, turned surface and straight wall configuration to accelerated loading protocols using implants designed with macro-, micro-, and nano-surface modification. These new trends not only demand more skill from the treatment team but also benefit from implant components that perform in these challenging biological situations. The tapered implant configuration has grown in popularity and today a larger portion of implants placed has a tapered design.[1,2] One reason for its growing popularity might be the standardized drill protocol and the ability to gain good primary stability.

*Assistant professor, Department of Biomaterials, Institute for Clinical Sciences, Sahlgrenska Academy, Gothenburg University, Gothenburg and Department of Dental Materials, Malmö University, Malmö, Sweden; †professor, Department of Biomaterials, Institute for Clinical Sciences, Sahlgrenska Academy, Gothenburg University, Gothenburg and Department of Dental Materials, Malmö University, Malmö, Sweden, and Department of Prosthodontics, Malmö University Faculty of Odontology, Malmö, Sweden; ‡professor, Department of Oral and Maxillofacial Radiology, Institute of Odontology, The Sahlgrenska Academy at Gothenburg University, Gothenburg, Sweden

Reprint requests: Dr. Pär-Olov Östman, Holmgatan 30, SE-79171 Falun, Sweden; e-mail: po@holmgatan.se

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Good primary stability is one of several factors that seem to have an impact on success when placing implants for immediate loading.[3] Primary stability is based on torque resistance during placement of implants. An insertion torque of 30–40 Ncm before the implant is fully seated seems to be a good indicator that the implant has reached sufficient stability for immediate loading.[4–7] Resonance frequency analysis (RFA) measurement is another method to measure stability and is frequently used to back up the torque value. Studies have shown that an implant stability quotient (ISQ) level of approximately 65 ISQ is a safe value for immediate loading.[8] Findings reported in a previous paper authored by the group showed that the stability in soft bone could not fully be compensated by adaptive drilling protocol and slightly tapered implants.[8] One interesting feature of the tapered implant design is the ability to reach better initial stability even in challenging bone qualities, for example soft bone compared with straight wall configuration.[9]

Implant surface topography may be another important factor for proper integration in challenging situations, such as immediate loading. The minimally rough surface NanoTite™ (BIOMET 3i, Palm Beach Gardens, FL, USA) featuring nanotopography with calcium phosphate nanoparticles added to the dual acid-etched titanium surface was presented in 2007. Histological investigations have shown larger 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[10–12] and in humans.[13,14]

Only limited information is available on short- and long-term outcome of immediately loaded tapered implants, and to the knowledge of the authors, no information on NanoTite Tapered Implants.

The aim of the present prospective, single center clinical study was to evaluate surface topographical analysis and the clinical and radiographic outcomes of the NanoTite Tapered Implant when used for immediate loading of fixed prostheses and single-tooth restorations.

MATERIALS AND METHODS

Study Patients and Preliminary Inclusion Criteria

The clinical work was conducted at a single study center by one investigator. Preliminary inclusion criteria were as follows: presence of residual bone sufficient to house at least an 8.5 × 4Ø mm long implant, implant site free from infection, and the patient willing to sign a consent form. Exclusion criteria consisted of general contraindications for oral surgery and individuals less than 18 years old. All patients included in the study had to sign a written consent form. They were 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. The study was conducted in full accordance with ethical principles, including the World Medical Association Declaration of Helsinki.

Study Implants

Study implants are the NanoTite™ Tapered Certain® Dental Implant system (BIOMET 3i, Palm Beach Gardens, FL, USA) (Figure 1) with the NanoTite surface modification extending from the apex to the collar (Figure 2). The 1.25 mm collar has a polished surface. Implants are titanium alloy, with an internal connection, and the threads widen laterally while extending to the apical end with spiral incremental cutting edges, by that being self-tapping.

Surface Topographical Analysis of Implant Samples

Three NanoTite Tapered Certain implants manufactured from titanium alloy and with a diameter of 4 mm

Figure 1 The NanoTite Tapered Certain Dental Implants with the NanoTite surface modification extending from the apex to the collar. The 1.25 mm collar has polished neck. Implants are titanium alloy, with threads that widen laterally while extending to the apical end with spiral incremental cutting edges.

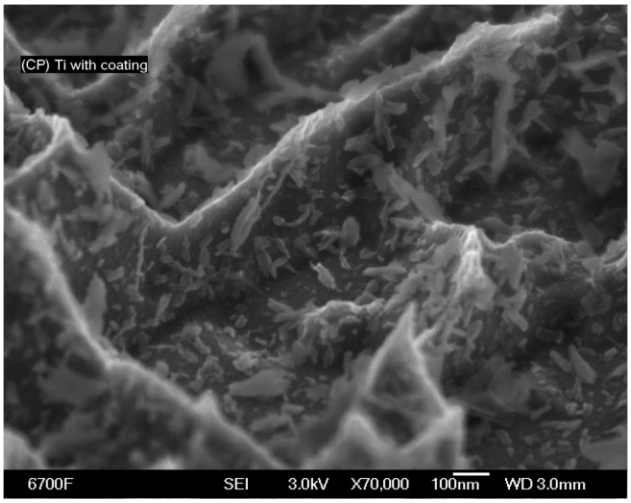

Figure 2 The NanoTite-surfaced implant featuring a nanotopography created by Discrete Crystalline Deposition™ of calcium phosphate (CaP) nanoparticles added to the dual acid-etched Osseotite surface.

were measured on the neck portion and on the acid-etched portion of the implants. Nine measurements were performed on the etched part and three measurements on the turned neck part of each evaluated implant. The measuring equipment was an interferometer (MicroXam, Phase shift, Arizona, USA), ×50 magnification with a zoom of 0.6 resulting in a measuring area of 260 × 260 µm. Three different parameters are presented in this study: Sa = average height deviation, a height descriptive parameter; Sds = density of summits, a spatial parameter ; and Sdr = developed surface area, a hybrid parameter which includes information from spatial as well as height distribution of the surface irregularities.

Implant Placement Surgery and Final Inclusion Criteria

Patients were administered Fenoximetylpenicillin, 2 grams (Kåvepenin® antibiotic, MEDA AB, Solna, Sweden, orally and Diazepam, 0.3 mg/kg body weight, Stesolid®, Alpharma, Stockholm, Sweden) orally approximately 1 hour prior to surgery. The surgical site was infiltrated with Lidocaine HCl 2% with epinephrine 1:100.000 (Xylocaine Adrenaline, Dentsply Pharmaceutical, York, PA, USA) and a mid-crestal 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. If installation followed immediately after extraction (10 implants), no flap was reflected. Bone quality and quantity were assessed according to Lekholm and Zarb's[15] criteria (Table 1). Implants were placed according to a diagnostic drill protocol, meaning that selection of the final Quad Shaping Drill size was based on bone quality to increase initial stability.[6] In Type 1 and 2 bone, the final drill size was 4.0 mm; in Type 3 and 4 bone, the final diameter of the osteotomy was reduced (Figure 3). No countersinking was used. Insertion torques was measured with an elcoMED drill unit (W&H Dentalwerk GmbH, Bürmoos, Austria). After seating of the implant, RFA was analysed with an Osstell ISQ (Integration Diagnostics AB, Göteborg, Sweden).

TABLE 1 Bone Quality and Quantity

Bone Quantity	Bone Quality 1	2	3	4	No. of Implants
A	3	2	9 (1)	0	14
B	0	19	26	13	58
C	0	19	22	5	46
D		6	1	14	21
Total	3	46	58	32	139

Failure within bracket. Bone quality and quantity were assessed according to Lekholm and Zarb's[15] criteria.

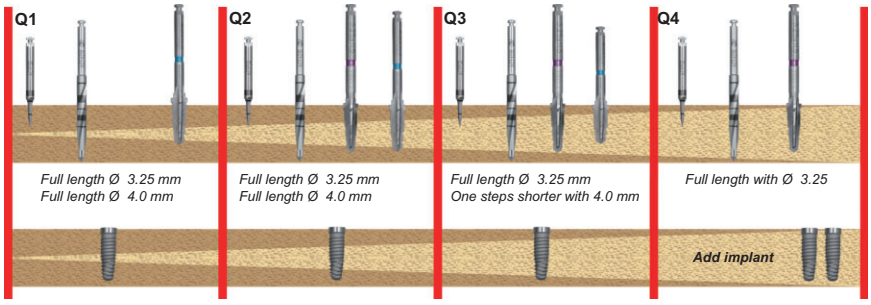

Figure 3 Drilling protocol used in the study for a 4.1 mm implant. Implants were placed according to a diagnostic drill protocol, meaning that selection of the final Quad Shaping Drill size was based on bone quality to increase initial stability.[4] In Type 1 and 2 bone, the final drill size was 4.0 mm; in Type 3 and 4 bone, the final diameter of the osteotomy was reduced.

TABLE 2 Number of Prosthetic Construction and Number of Implants

Site	No. of Prosthetic Construction	No. of Implants
Total maxilla	7	45
Partial maxilla	21 (1)	51 (1)
Partial mandible	9	23
Single maxilla	16	16
Single mandible	4	4
Total	57	139

Failure within bracket.

At this stage the decision was made whether to proceed and immediately load the implant or to cancel the study protocol and use a two-stage or one-stage healing approach, thereby dropping the patient from the study. The decision was based on the following final inclusion criteria: a minimum insertion torque of 30 Ncm before the final seating of the implant and an ISQ above 55 measured with the Osstell ISQ instrument. Forty-two patients had been invited to participate in the study. All met the inclusion criteria. A total of 139 implants supporting 57 fixed prostheses were included (Tables 2 and 3). For the first 10 days after implant installation, the patients were prescribed Fenoximetylpenicillin, 3 grams/day (Kåvepenin antibiotic), mouth rinsing with chlorhexidine (0.1% twice per day), and a diet consisting of soft food.

Prosthetic Procedures

Before adaptation and suturing of the mucosal flaps, PreFormance® Posts (BIOMET 3i) or conical abutments with QuickBridge® components (BIOMET 3i) were placed to be used for support of the provisional restorations. Cantilevers were allowed in the study but were restricted from exceeding 5 mm.

Twenty single-tooth implants were placed, and for these, the PreFormance Post was ground to fit into occlusion. All temporary constructions were made chair-side. A prefabricated translucent strip crown (Frasaco, 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 (Provicol QM®, Voco, Cuxhaven, Germany) with the rubber dam in place. In Figure 4 a typical single-unit treatment is illustrated.

Thirty partially edentulous (74 implants) and seven fully edentulous maxillae cases (45 implants) were included in the study (see Table 2). All these cases were temporarily rehabilitated with the QuickBridge[16] method. All temporary constructions were placed in light centric occlusion contact. In Figure 5 a typical multi-unit treatment is illustrated.

Three to four 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. This was done either by conventional open tray impression (37 prostheses) or by the Encode® (Biomet 3i) impression system (20 prostheses). The Encode impression system is a digital impression system where impression is taken on the healing abutment. On the model a CAD–CAM individual abutment is fabricated.

TABLE 3 Implant Length of Included Implants

Implant Length	Diameter 4.1	Diameter 5.0	Total No.
15 mm	77 (1)	3	80 (1)
13 mm	28	7	35
11.5 mm	2	0	2
10 mm	17	2	19
8.5 mm	2	1	3
Total	126	13	139

Failure within bracket.

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 and thereafter yearly. Patients' oral hygiene was treated and maintained on an individual basis.

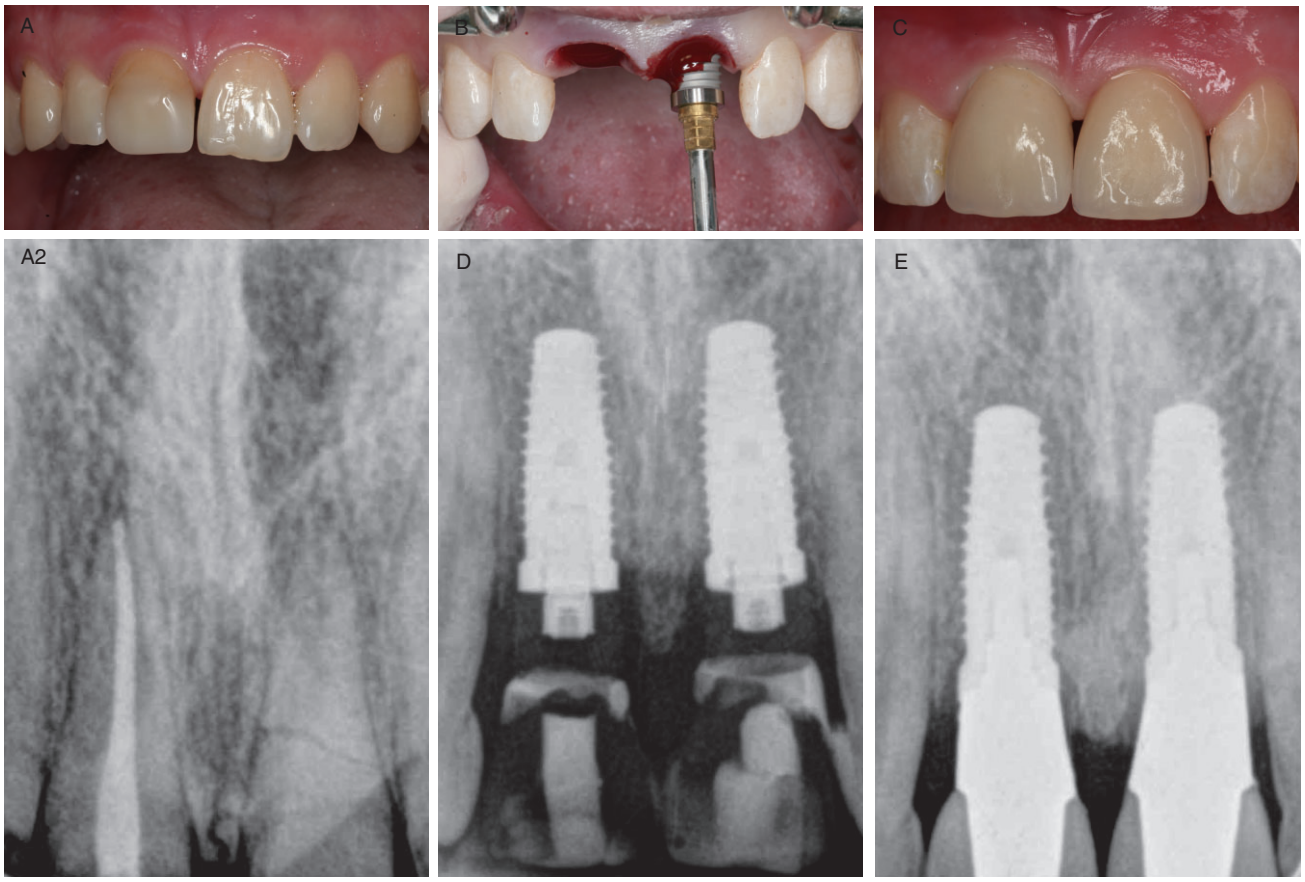

Figure 4 A typical single-unit treatment is illustrated. (A) Preoperative clinical photograph. Note the root fracture and internal root resorption on x-ray. (B) NanoTite Tapered Implants, 5mm (D) × 13mm (L) were placed. Final torque was 70 Ncm. (C) For the definitive restorations two all-porcelain crowns were cemented onto the patient specific Zirconia Abutments. (D) Baseline radiograph. (E) Postoperative 1-year follow-up.

Marginal Bone Resorption

The marginal bone levels were evaluated from digital radiographs by a radiologist (AE). Intraoral periapical radiographs were exposed after implant surgery to establish baseline and subsequently at 1 year of function. All radiographs were displayed in software (Illustrator® CS, Adobe Systems Inc., San Jose, CA, USA) on a 24-inch LCD screen (iMac Apple Inc, Cupertino, CA, USA). The screen resolution was 1,920 × 1,200 pixels. The measuring tool of the software was used to make the measurement, taking the magnification into account. The brightness, contrast, and zoom of the images were adjusted to achieve optimal measuring conditions. Crestal bone loss was determined by measuring the distance from the implant-abutment junction 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. The error of the radiographic measurements was assessed by double recordings of one randomly selected implant per patient. The mean difference between recordings was at baseline 0.05 mm (SD 0.86) and at 1 year 0.07 mm (SD 0.76).

RESULTS

Implant Survival

One of the 139 implants showed rotational mobility after 4 months at the visit scheduled for impressioning for a 3-unit permanent bridge. The failed implant showed radiographic signs of loss of integration. The implant was located in the posterior maxilla, in quality 3 bone. The overall cumulative survival rate (CSR) for implants in the study is 99.4% after 1 year (Table 4).

Resonance Frequency Analysis

RFA were performed for all 139 study implants, and the ISQ units were scored at implant placement. Units

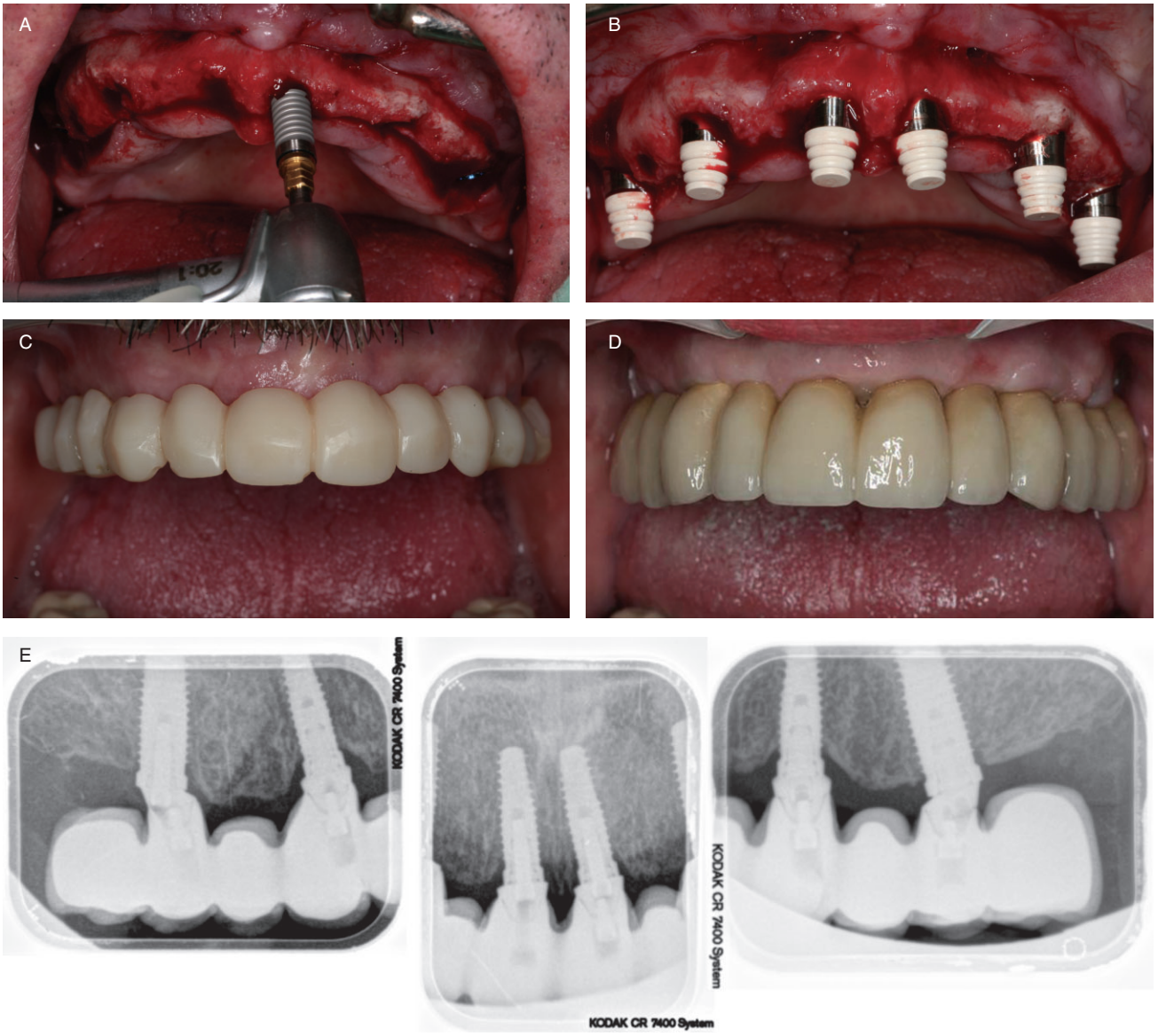

Figure 5 A typical multi-unit treatment is illustrated. (A) Six NanoTite Tapered Implants were placed for a totally edentulous maxilla. (B) After implant placement Low profile abutments and QuickBridge components were mounted in order to fabricate a temporary construction. (C) Three months following soft tissue maturation, the patient was seen for fabrication of the definitive restoration. (D) For final prosthesis a CAM StructSURE Copy Milled prosthesis was placed. (E) One-year radiographic follow-up.

ranged from 56 to 84 and the mean value was 73.1 (SD 6.3).

Final Seating Torque

Final seating torque ranged from 30 to 70 with a mean value of 53.1 (SD) Ncm.

Implant Surface Topography

The surface on the NanoTite Tapered Certain implants used in the present study had an average height

TABLE 4 Life Table of NanoTite Tapered Certain Implants

Interval	Implants in Interval	Failures	CSR
0 >> 6 months	139	1	99.4%
6 >> 12 months	138	0	99.4%
12 >> 18 months	138	0	99.4%
18 >> 24 months	138	0	99.4%
24>>	138	–	–

CSR, cumulative survival rate.

TABLE 5 Surface Topography of NanoTite Certain Tapered Implants

	Sa µm (SD)	Sds 1/mm2 (SD)	Sdr % (SD)
Neck, turned surface	0.21 (0.06)	136,006 (12,578)	5.64 (1.42)
Etched surface	0.32 (0.07)	183,380 (17,028)	15.35 (2.78)

deviation of 0.2 µM for the turned neck part and 0.32 µM for the etched part of the implant (Table 5).

Marginal Bone Resorption

The average bone loss for 111 readable implants was calculated to be 1.01 mm (SD 0.85) after 1 year of follow-up (Table 6, Figure 6). Fifty-three implants (48%) showed more than 1.1 mm of bone loss, and 9 of these 53 implants (8%) showed more than 2 mm of bone loss after 1 year.

DISCUSSION

The present clinical investigation has demonstrated a CSR of more than 99% at 1 year for 139 NanoTite Tapered implants that were loaded immediately despite many of these being placed in the posterior or soft bone sites. This successful outcome could be attributed to the results showing an insertion torque of more than 30 Ncm for all study implants. Firm primary stability is an important factor when an immediate loading protocol is used. The relatively high mean final torque (53 Ncm) supports earlier studies that slightly tapered and tapered implant design shows a higher primary stability compared with a straight-walled implant configuration, especially in types 3 and 4 bone quality.[8,17] Friberg et al.[18] showed that the slightly tapered implant more frequently required a higher insertion torque and showed a significantly higher primary stability compared with straight, parallel-walled implant. This difference in stability leveled out over time, and these two different implants exhibited similar secondary stability at abutment operation and at the 1-year visit. Our results from a previous study[4] showed a high survival rate (99.2%) for 165 immediately loaded implants in edentulous maxillae when using adapted surgical protocols in combination with slightly tapered (38%) or tapered implants (27%) where the bone was judged to be qualities 3 or 4 (46% and 15%, respectively).

The RFA measurements obtained at implant placement also indicate a good primary stability with a mean

TABLE 6 Marginal Bone Resorption at 1-Year Follow-Up

	NanoTite Tapered Implants	
	(m + d)/2	
Number	111	
Mean value (SD)	1.01 (0.85)	Percent (%)
<0	6	5
0	2	2
0.1–1.0	50	45
1.1–2.0	44	40
2.1–3.0	8	7
>3.0	1	1
Total	111	

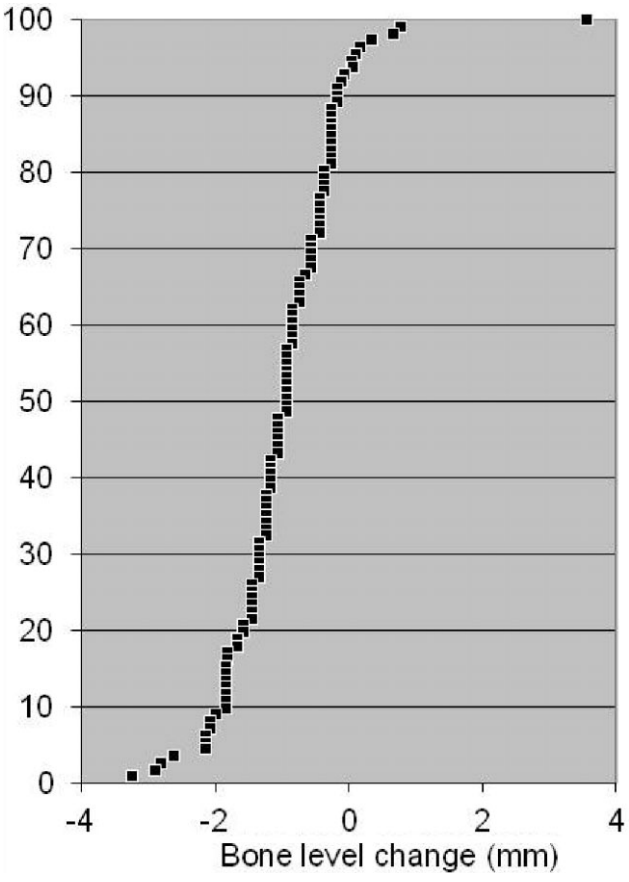

Figure 6 Analyses of bone resorption according to Wennström et al.[27] displaying bone loss for each evaluated implant.

ISQ of 73.1. Earlier findings from the group[8] showed a mean ISQ of 67 when analyzing 905 parallel-walled and slightly tapered implants after an adaptive drill protocol aiming for high primary stability. It is notable that all measurements in this study were made with the latest Osstell ISQ (Osstell AB, Gothenburg) and could not be compared 100% with the data collected in the previous study measured with the older devises from the Osstell Company.

The radiographic mean bone loss was calculated to be 1.01 mm. Forty-four (40%) of the 111 readable implants showed 1 to 2 mm of bone loss and nine (8%) implants showed more than 2 mm of bone loss. Compared with a previous study[19] reported by the same group using an implant with the same surface but with a straight-walled body and platform-switched design, the implants shown more than 1 mm bone loss was only 6% in the previous study. This finding could be explained by the implant having no platform shift function in the current study. Another reason for the slightly higher bone loss could be explained by the 1.25 mm polished neck of the implant. On the other hand Heinemann et al.[20] concluded in a study that highly polished- or roughened-neck implants that are inserted into a fresh extraction socket do not differ significantly in the clinical and radiographic outcomes after various postoperative periods. Since the implants in our clinical investigation were placed under the challenging conditions of immediate loading and partly placed in soft bone, this may explain why some of the implants showed more than 1 mm bone loss.

Seemingly, our topographical evaluation of the NanoTite surface is different from what we have reported previously.[21] However, the NanoTite values quoted in the referred paper are when the implant is made from commercially pure titanium; when NanoTite of titanium alloy is used, the harder material results in smoother surface topography as evident from this analysis. In fact, we have never seen clinical implants being as smooth as those of the present study; they are about one third of the roughness of old turned Branemark implants. Having said this, NanoTite has been demonstrated with a clear nano-pattern that differs it from the Osseotite surface.[21] One cannot exclude that an unsuitably smooth microroughness may be at least partly compensated by an appropriate nano-pattern. To date, however, no one has been able to describe what would be the ideal nano-pattern of a surface. NanoTite has a documented Sa of 23 at the nanometer level.[21] The used technique did not permit evaluation of the Sdr% at the nanometer level, but it is noteworthy that scanning electron microscope (SEM) of NanoTite demonstrates a much denser nanosurface than seen on Osseotite implants.[21] Interpretations are difficult not the least because nanoindentations on NanoTite may depend on nano-compunds of HA, that may have a positive chemical effect. In the case of the actual implant surface investigated in this paper,[10] and Mendes et al.[22] presented evidence of stronger bone responses to NanoTite compared with Osseotite surfaces, despite the latter having a more optimal Sa value (admittedly, the Sdr% may have been more optimal with NanoTite). Whether studying a chemical effect or a nano-roughness effect, results may be very difficult to interpret. Anyhow, if an ideal implant exists it ought to combine optimal micro-roughness with optimal chemistry, physics, and nano-roughness.[23]

Nevertheless, the Sa of NanoTite Tapered implants was only 0.3 micrometers and the Sdr% was 15, very far away indeed from the suggested topographical optimum of Sa 1.5 micrometers and Sdr 50%.[24] However, this recommendation of ideal roughness is based on animal studies of the demonstrated strongest bone response which is not directly applicable to the clinical situation. Indeed when clinical comparisons are based on implants placed in ordinary bone sites, surface topography whether minimally rough such as old Brånemark implants or moderately rough such as most modern implant types seem to perform equally well as exemplified by a recent 5-year clinical study of a large body of implants.[25] Thus, the Balshe et al. results[26] confirm many other studies of a smaller number of implants finding no differences between turned, "machined," and moderately rough implant.[25,27] Under challenging conditions, however, such as immediate loading, implants placed in soft bone, or implants placed in irradiated bone, clinical results indeed have pointed to a preference of moderately rough surfaces[28,29] in comparison with smoother or rougher versions. Even the Balshe et al. study[26] reported that clinical results of short implants were poorer for the "machined" versions, but not so for the modern "roughened" versions of implants that had no poorer results for short implants with a due minimal area available for bone attachment. Having said this, we must stress that the number of failed implants was only one and the CSR remains 99.4% at a completed 1 year of follow-up.

CONCLUSION

Although limited to the short follow-up, immediate loading of NanoTite Tapered implants seems to be a viable option in implant rehabilitation, when insertion torque of at least 30 Ncm is achieved. Further studies are needed to authenticate the finding of this study.

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