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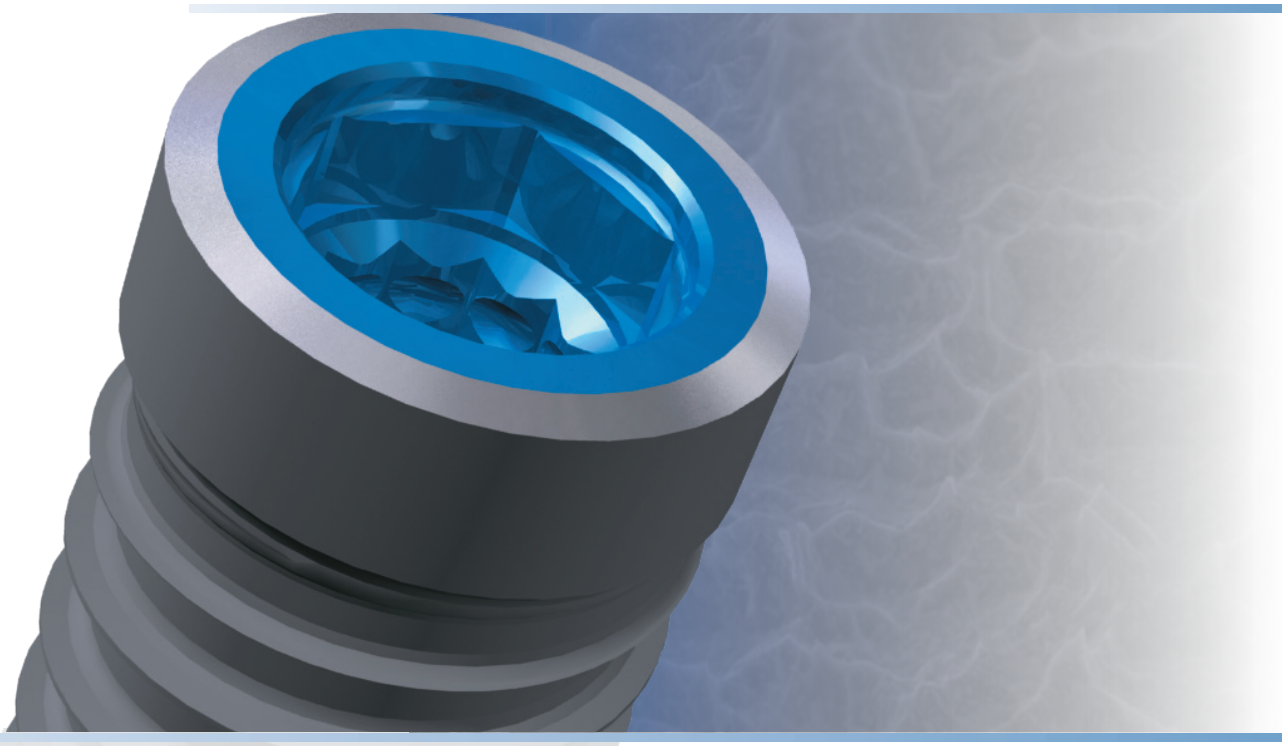

Special Supplement

Summaries of Scientific Publications

BIOMET ***3i*** NanoTite™ Implants

Official Publication of The INSTITUTE for Implant & Reconstructive Dentistry™

*The Institute for Implant and Reconstructive Dentistry is a Training and Education Facility of BIOMET **3i** LLC.*

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Immediate occlusal loading of NanoTite™ PREVAIL® Implants: A prospective 1-year clinical and radiographic study

Östman PO†, Wennerberg A, Albrektsson T.

Clin Implant Dent Relat Res. 12(1):39-47, Mar 2010.

Study Design: Prospective, Single-Center, Observational
Major Product(s): BIOMET ***3i*** NanoTite PREVAIL Implants
Clinical Scenario: Immediate Loading
Sample Size: 102 Implants
Reported Outcome(s): Clinical Survival – 1-Year Post Placement, Marginal Bone Resorption – 1 Year Post Placement

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.

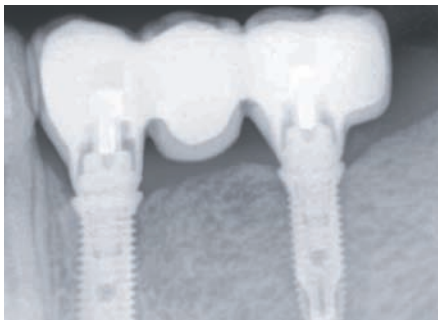
Aim

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

Investigators report 99.2% 1-year survival when immediately loading BIOMET *3i*'s NanoTite PREVAIL Implants.

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 at least 25Ncm prior to final seating and an implant stability quotient above 55. A total of 102 NanoTite PREVAIL Implants (BIOMET ***3i***, Palm Beach Gardens, FL) (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%).



†Author has a financial relationship with BIOMET ***3i*** LLC resulting from speaking engagements, consulting engagements and other retained services.

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 one hour and the final constructions were 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 one year was 99.2%. The average marginal bone resorption was 0.37mm (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.

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

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.

Immediate provisionalization of NanoTite™ Implants in support of single-tooth and unilateral restorations: 1-year interim report of a prospective, multicenter study

Östman PO†, Hupalo M†, del Castillo R†, Emery RW†, Cocchetto R, Vincenzi G, Wagenberg B, Vanassche B, Valentin A, Clausen G†, Hogan P, Goene R†, Evan G, Testori T†.

Clin Implant Dent Relat Res. 12 Suppl 1:e47-55, May 2010.

Study Design: Prospective, Multicenter, Observational
Major Product(s): BIOMET ***3i*** NanoTite Implants
Clinical Scenario: Immediate Loading
Sample Size: 335 Implants
Reported Outcome(s): Clinical Survival – 1-Year Post Placement

Background

Clinical studies reporting immediate loading of endosseous implants for edentulous cases and for fixed partial restorations with satisfactory survival rates have been well documented. Implants with a recently developed, nanometer scale surface topography (NanoTite, BIOMET ***3i***, Palm Beach Gardens, FL), created by discrete crystalline depositions (DCD) of calcium phosphate nano-crystals onto a dual acid-etched (DAE) surface, showed enhanced early fixation in preclinical studies when compared with DAE-surfaced implants. These outcomes suggest DCD-surfaced implants may be advantageous for immediate loading approaches.

Objectives

The aim of this prospective, multicenter, observational study is to report clinical outcomes for DCD-surfaced implants placed in immediate functional support of single- and multiple-unit restorations according to an immediate loading protocol.

Multicenter study reports 94.9% 1-year survival when immediately loading BIOMET *3i*'s NanoTite Implant.

Materials and Methods

One hundred eighty-five patients enrolled at 15 international study centers received a total of 335 implants supporting 216 immediate provisionalizations consisting of 128 single-tooth restorations and 88 fixed restorations.

†Authors have a financial relationship with BIOMET ***3i*** LLC resulting from speaking engagements, consulting engagements and other retained services.

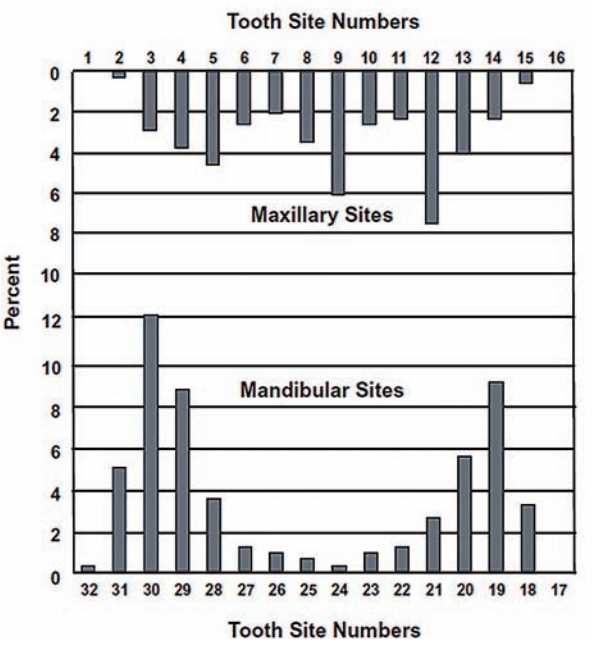
Of the 335 implants, 77% are located in posterior and 23% in anterior regions with 55.5% of the total in mandibles and 44.5% in maxillae. Patients were evaluated for implant mobility, gingival health, symptomatology and radiographic outcomes.

Results

At the time of this 1-year interim report, a total of 17 failures have been observed in 11 patients, yielding a cumulative survival rate of 94.9%.

Conclusions

Relative to other prospective, multicenter studies of immediately loaded implants with various surface enhancements, NanoTite™ Implants performed comparatively well when immediately provisionalized with single-tooth and fixed restorations.



Randomized control study of implants placed simultaneously in maxillary sinus grafts: Interim report

Luongo G, Nadjmi N, Alcoforado G, Cordiolo G, Cordaro L, Calvo-Guirado JL†, Caputi S.

Poster Presentation P306: European Academy of Osseointegration, 19th Annual Meeting: 2010 October 6-9; Glasgow, UK.

Study Design: Prospective, Multicenter, Randomized Control
Major Product(s): BIOMET ***3i*** NanoTite™ Certain® PREVAIL® Implants
Clinical Scenario: Simultaneous Placement in Sinus Grafts
Sample Size: 311 Implants
Reported Outcome(s): Clinical Survival – 1-Year

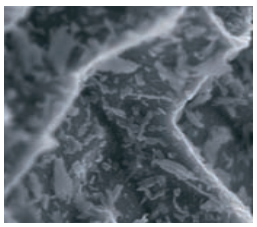
Background

Augmentation of the maxillary sinus with a lateral approach and several months of healing before implant placement has proven to be an effective technique for restoration of sites in significantly resorbed maxillae. Simultaneous implant placement with sinus grafting surgery offers benefits to both the clinician and the patient by eliminating a surgical intervention leading to more timely prosthetic function. The approach, however, is challenging and few contemporaneous randomized-controlled studies are available with a wide range of success rates having been reported. It is plausible that the procedure is technique-sensitive and baseline variables may impact outcomes.

Aim

This prospective, multicenter, randomized-controlled study was designed to determine if implants placed simultaneously with maxillary graft augmentation have equivalent outcomes as compared with implants placed after 4 months of graft healing.

Methods



Seven European centers have been involved in this study. Patients requiring either uni- or bilateral-sinus grafts with ≤ 5mm of residual vertical bone height qualified for inclusion. Cases were randomly assigned to: simultaneous (test) cases in which implants were placed during sinus augmentation or delayed (control) cases in which grafts were allowed to heal for 4 months before implant placement surgery. All implants are the NanoTite Certain PREVAIL System and placed in a two-stage procedure with 4 months of submerged healing. Implant performance is assessed annually for 3 years.

†Author has a financial relationship with BIOMET ***3i*** LLC resulting from speaking engagements, consulting engagements and other retained services.

Results

Ninety-six patients were enrolled. One hundred and forty-four cases were treated with a total of 311 study implants under evaluation of which 170 are test and 141 are control implants. Following 12 months of observation, 23 implants were declared failures (92.6% survival) with a 94.3% survival rate in the control group and 91.2% survival rate in the test group.

IMPLANT DIMENSIONS				BONE ASSESSMENTS		
	CONTROL (%)	TEST (%)			CONTROL (%)	TEST (%)
DIAMETER				***QUALITY***		
4 mm	75.9	72.1		DENSE	10.1	18.4
5 mm	24.1	27.9		MEDIUM	41.8	34.8
LENGTH				SOFT	48.1	46.8
8.5 mm	0.6	0		***FIT***		
10 mm L	18.4	18.6		TIGHT	42.1	52.5
11.5 mm L	38.6	29.3		FIRM	57.2	43.3
13 mm L	32.9	36.4		LOOSE	0.7	4.3
15 mm L	9.5	15.7				

Comparison of baseline variables between treatment groups.

Conclusions and Clinical Implications

This European multicenter study reports 91.2% and 94.3% survival in simultaneous and 4 month delayed sinus grafting procedures utilizing BIOMET *3i*'s NanoTite™ Implant.

Being that this is a randomized-controlled study, at the time of this interim report, the difference in success rates might reflect inherent technical challenges and clinical experience associated with the simultaneous approach, although the benefits are yet to be demonstrated pending a longer follow-up period. Furthermore, analysis of baseline variables, including initial and post-augmentation maxillary ridge dimensions, implant dimensions and implant positions in the grafts may provide insight as to the conditions associated with treatment success.

Immediately provisionalized postextractive implants in a population with risk factors

Briccoli L, Menini I, Barone R, Clauser C.

Poster Presentation P112: European Academy of Osseointegration, 19th Annual Meeting: 2010 October 6-9; Glasgow, UK.

Study Design: Prospective, Multicenter, Observational
Major Product(s): BIOMET ***3i*** NanoTite™ Tapered Implants
Clinical Scenario: Immediate Provisionalized Post Extractive Implants
Sample Size: 240 Implants
Reported Outcome(s): Clinical Survival – 4 to 27 Months Post Definitive Restoration

Background

Few studies reporting on the effect of systemic conditions on post extraction implant survival have been published. Therefore, evidence for systematic factors as risk for implant survival is still lacking. The aim of this multicenter prospective study is to assess the survival rate and the role of risk factors after immediate restoration of single post-extractive implants.

Materials and Methods

Entry criteria included the extraction of a single tooth excluding molar teeth and untreated periodontitis. Cases with putative risk factors were not excluded.

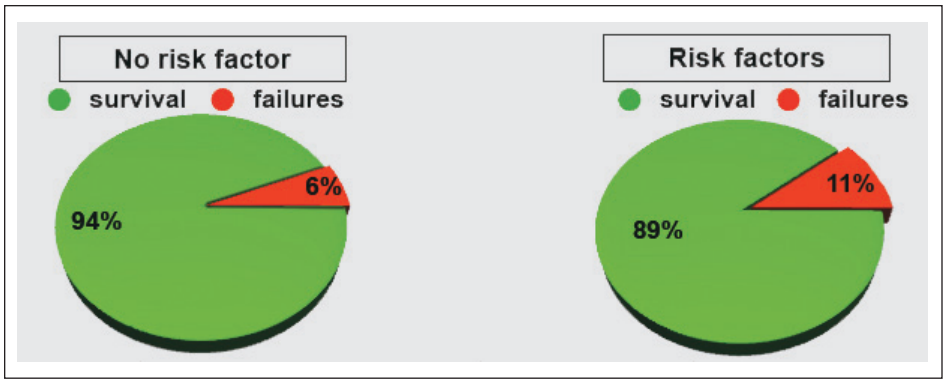
Putative risk factors included the following:
Smoking habit, bruxism and other parafunctions, diabetes, suppuration, treated periodontitis, u-shaped bone dehiscences, anticoagulants, calcium antagonists, previous assumption of bisphosphonates, antibiotics and/or steroids in the preoperative week and an inability to assume preoperative amoxicillin.

This multicenter study demonstrates BIOMET *3i*'s NanoTite Tapered Implant System is successful 9 out of 10 times despite significant patient risk factors and a challenging immediate clinical scenario.

The implants were inserted immediately after tooth extraction without elevation of surgical flaps. Cone-shaped implants with nanocrystals of hydroxylapatite (NanoTite Certain® Tapered Implants, BIOMET ***3i***, Palm Beach FL) were selected to increase primary stability and wound healing speed. Provisionalization was carried out within 48 hours after surgery. The definitive restoration was scheduled in three months after implant placement.

Results

Data on 240 implants in 240 patients (aged 17 to 84) was gathered at 16 centers by February 2010. Risk factors were identified in 178 cases (74.17%).



Early minor complications were recorded in 24 cases in the first postoperative week. Implants were lost before the definitive prosthesis was placed in 24 of the 240 cases (failure rate 10%). The failure rate in the group without risk factors was 6.5%.

The definitive prosthesis was delivered to 171 patients: the remaining surviving implants still support a provisional crown. Late minor complications were recorded in 18 cases. Neither recession nor failures were observed after the definitive prosthesis (follow-up 4 to 27 months). Patients' satisfaction for the definitive restoration rated 9.5 on the average (range 7 to 10). On a scale of 0 to 10 (0 being lowest, 10 highest) most cases rated a 10. Failures and complications appeared to be associated mostly with thin periodontium and lack of antibiotic prophylaxis.

Conclusions

Immediate provisionalization with non-functional loading is a relatively safe option for postextractive implants in the short run, even in cases with risk factors.

Vertical augmentation with interpositional blocks of anorganic bovine bone vs. 7mm-long implants in posterior mandibles: 1-year results of a randomized clinical trial

Felice P, Pellegrino G, Checchi L, Pistilli R, Esposito M.

Clin Oral Implants Research 21(12):1394-403. Dec 2010.

Study Design: Prospective, Single-Center, Randomized Control
Major Product(s): BIOMET ***3i*** NanoTite™ Implants
Clinical Scenario: Mandibular Augmentation Versus 7mm Implants
Sample Size: 59 Implants
Reported Outcome(s): Clinical Survival – 1-Year Post Loading, Marginal Bone Resorption – 1-Year Post Loading

Objectives

To evaluate whether 7mm implants could be an alternative to longer implants placed in vertically augmented posterior mandibles.

Materials and Methods

Sixty patients with posterior mandibular edentulism with 7-8mm bone height above the mandibular canal were randomized to either vertical augmentation with anorganic bovine bone blocks and delayed 5-month placement of ≥10mm implants or received 7mm-long implants. Four months after implant placement, provisional prostheses were delivered, and were replaced after 4 months with definitive prostheses. The outcome measures were prosthesis and implant failures, any complications and peri-implant marginal bone levels. All patients were followed one year after loading.

Investigators publish 96.6% 1-year survival results utilizing short (7mm) BIOMET *3i* NanoTite Implants.

Results

One patient dropped out from the short implant group. In two augmented mandibles, there was insufficient bone to place 10mm-long implants possibly because the blocks had broken apart during insertion. One prosthesis could not be placed when planned in the 7mm group vs. three prostheses in the augmented group, because of early failure of one implant in each patient. Four complications (wound dehiscence) occurred during graft healing in the augmented group vs. none in the 7mm group. No complications occurred after implant placement. These differences were not statistically significant. One year after loading, patients of both groups lost an average of 1mm of periimplant bone. There were no statistically significant differences in bone loss between groups.

Mean radiographic periimplant marginal bone levels between groups and time periods:

	Implant placement *N* Mean (SD) 95% CI	Loading* *N* Mean (SD) 95% CI	1 year after loading* *N* Mean (SD) 95% CI
Short implants	30 0.79 (0.41) 0.63, 0.95	29 1.37 (0.53) 1.17, 1.57	29 1.79 (0.54) 1.59, 1.99
Long implants	30 0.65 (0.28) 0.55, 0.76	30 1.21 (0.42) 1.06, 1.37	30 1.65 (0.42) 1.49, 1.81

*All changes from baseline statistcally different (P<0.001).

Conclusions

When residual bone height over the mandibular canal is between 7 and 8mm, 7mm short implants may be a preferable choice than vertical augmentation, reducing the chairtime, expenses and morbidity. These one year preliminary results need to be confirmed by follow-up of at least five years.

Immediate occlusal loading of NanoTite™ Tapered Implants: A prospective 2-year clinical and 1-year radiographic study

Östman PO†, Wennerberg A, Ekestubbe A, Albrektsson T.

Clinical Implant Dentistry and Related Research 17 Jan 2012 [Epub ahead of print]

Study Design: Prospective, Single-Center, Observational
Major Product(s): BIOMET ***3i*** NanoTite Tapered Implants
Clinical Scenario: Implant Placement and Immediate Occlusal Loading of Fixed Prostheses
Sample Size: 139 Implants
Reported Outcome(s): Clinical Survival – 2-Year Post Placement, Marginal Bone Resorption – 1-Year Post Placement

Background

During the last decade, high success rates have been reported for implants placed in immediate loading procedures, when bone quality and quantity provided good implant stability. In many of these studies, straight walled implants with moderately rough surfaces were employed. Generally, tapered implant designs are becoming more popular due to standardized drill protocols and the perceived ability to gain good initial primary stability.

Aim

The purpose of the present, prospective clinical study is to evaluate clinical and radiographic outcomes for NanoTite Tapered (BIOMET ***3i***) Implants placed for the immediate loading of fixed prostheses when good primary stability is achieved.

In this study, investigators report 99.4% 2-year survival when immediately loading BIOMET *3i*'s NanoTite Tapered implants.

Materials and Methods

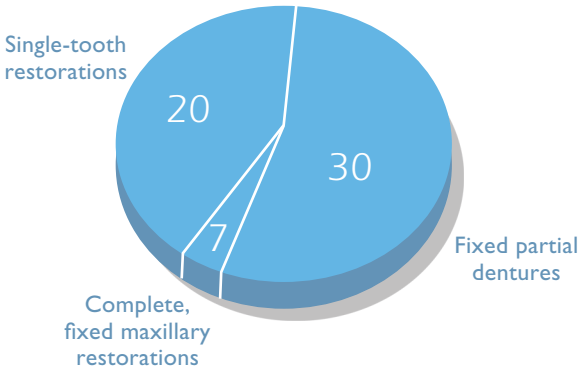
Forty-seven patients who needed implant treatment and met inclusion criteria agreed to participate in the study and were consecutively enrolled. Surgical implant placement requirements consisted of a final torque of a least 30Ncm prior to final seating and an ISQ above 55. A total of 139 NanoTite Tapered Impants (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%).

†Author has a financial relationship with BIOMET ***3i*** LLC resulting from speaking engagements, consulting engagements and other retained services.

A total of 57 prosthetic restorations 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 and 24 months of follow-up but have been fully evaluated only at the one year control in this study.

Results

Of the 139 study implants, one implant failed. The simple CSR value at two years was 99.4%. The average marginal bone resorption was 1.01mm (SD 0.85) during the first year in function.



Conclusion

Based on CSR values of our completed 2-year follow up, immediate loading of NanoTite™ Tapered implants in this study when good primary stability was achieved resulted in a CSR of 99.4%.

Placement of implants into fresh molar sites

Block MS†.

Journal of Oral and Maxifacial Surgery 69:170-174. Jan 2011.

Study Design: Case Series, Single-Center
Major Product(s): BIOMET ***3i*** NanoTite™ Tapered Implants
Clinical Scenario: Immediate Implant Placement in Extraction Sockets; 4 Month Healing
Sample Size: 35 Implants
Reported Outcome(s): Clinical Survival – Mean 17 Months Post Placement

Purpose

The purpose of this case series is to illustrate a technique for immediate placement of implants into molar extraction sites. The technique is a modification of the Walker's method.

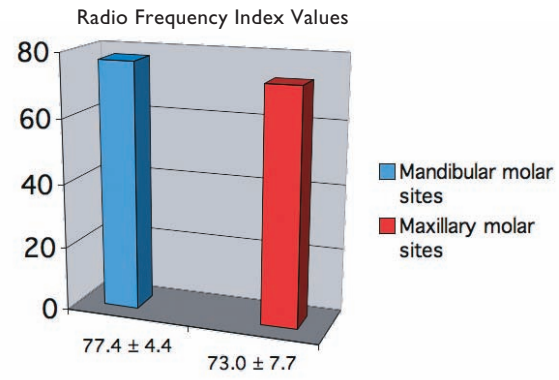
Materials and Methods

Thirty-five consecutive mandibular or maxillary molar sites were followed through restoration. Insertion radio frequency index values were recorded at immediate implant placement and after 4 months of integration.

In this study, clinicians documented a 97.1% survival rate when immediately placing BIOMET *3i*'s NanoTite Tapered Implant in extraction sites.

Results

One implant failed in this series. Average insertion radio frequency index values were 77.4±4.4 for 30 mandibular molar sites and 73.0±7.7 for maxillary molar sites.



Conclusions

Immediate placement of implants into selected sites was highly successful and has excellent potential.

†Author has a financial relationship with BIOMET ***3i*** LLC resulting from speaking engagements, consulting engagements and other retained services.

A prospective, randomized-controlled study of NanoTite™ and OSSEOTITE® PREVAIL® Implants for the immediate loading of fixed maxillary dentures

Östman PO†, Hernandez-Alfaro F, Calderon MG.

Poster Presentation P80: Academy of Osseointegration, 26th Annual Meeting: 2011 March 3-5; Washington DC

Study Design: Prospective, Multicenter, Randomized Control
Major Product(s): BIOMET ***3i*** NanoTite and OSSEOTITE PREVAIL Implants
Clinical Scenario: Immediate Loading in the Maxilla
Sample Size: 116 Implants
Reported Outcomes(s): Clinical Survival – 3 Years Post Placement

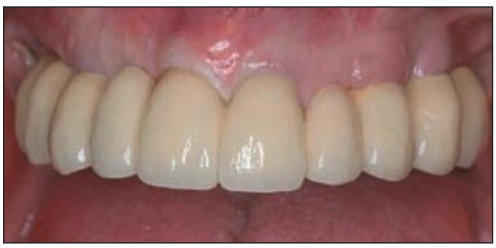
Objective

This randomized-controlled study evaluates the treatment of maxillary edentulism with fixed prostheses supported by immediately loaded implants with either NanoTite or OSSEOTITE surfaces (BIOMET ***3i***, Palm Beach Gardens, FL). The study specifically assesses the integration success and duration of failure-free function of implants and prostheses to determine if the addition of a surface nanotopography feature can improve performance for this treatment modality.

In this study, investigators report 100% 3-year survival when immediately loading BIOMET *3i*'s NanoTite PREVAIL Implants.

Materials and Methods

Patients were randomly assigned to receive either test (NanoTite) or control (OSSEOTITE) implants. All implants are made from Ti-alloy having an internal Certain® connection, a 4mm diameter straight-wall threaded body and having an expanded collar providing an integrated platform-switch function (PREVAIL). The immediate loading approach required installation of full-arch provisional prostheses supported by 4 to 8 implants within 48 hours of implant placement.



†Author has a financial relationship with BIOMET ***3i*** LLC resulting from speaking engagements, consulting engagements and other retained services.

The definitive prostheses were inserted at 6 months and follow-up clinical and radiological evaluations continue annually for up to 5 years.

Results

A total of 18 cases were treated separately by 3 clinicians. Eight cases were supported by 51 test implants and 10 cases were supported by 65 control implants. 72.7% of test implants were placed in bone assessed as soft, 27.3% in normal bone and no test implants were placed in dense bone. Of the control implants, 75.4% are in soft bone, 15.4% in normal and 9.2% in dense bone. According to location, 43.1% of test implants and 53.8% of control implants are in posterior sites while 56.9% of test implants and 46.2% of control implants are in anterior sites. Similarity in baseline variables allows a comparison of performance and success rates between groups. All NanoTite™-surfaced implants integrated successfully and maintained function yielding a 3-year cumulative survival rate of 100% and there were no reports of prosthetic failures. For control implants, 3 were declared failures for a CSR of 95.3%.

	Total Implants	%Anterior	%Posterior
All	117	51.3	48.7
Control	66	46.2	53.8
Test	51	56.9	43.1

Distribution (%) of implants in anterior and posterior of maxilla.

Lengths (mm)	8.5	10.0	11.5	13.0	15.0
% Control	0	20.0	20.0	44.6	15.4
Test	2.0	5.9	7.8	51.0	33.3

Distribution (%) of implants in both treatment groups by length.

Conclusions

In this study, NanoTite-surfaced implants performed better than OSSEOTITE®-surfaced implants suggesting that the surface nanotopography may play a role in outcomes for cases of immediate loading in edentulous maxillae.

Outcomes from a retrospective study of 626 sequential cases of BIOMET ***3i*** Tapered Implants

Stach R, Kenealy J.

Poster Presentation P89: Academy of Osseointegration, 26th Annual Meeting: 2011 March 3-5; Washington DC.

Study Design: Retrospective, Multicenter, Observational
Major Product(s): BIOMET ***3i*** NanoTite™ and OSSEOTITE® Tapered Implants
Clinical Scenario: Implant Placement (various scenarios) by 25 Representative Clinicians
Sample Size: 836 Implants
Reported Outcome(s): Clinical Survival – Mean 28.3 Months Post Placement

Background

The placement of tapered–apex dental implants requires specific osteotomy preparation instrumentation. Drills for tapered implants establish a finite osteotomy depth for which care is needed to ensure the proper implant descent and seating. Implant design and the instruments provided for osteotomy preparation contribute to the elements needed for successful use of tapered implants. The aim of this evaluation was to document the success of a new tapered implant in a large population.

Materials and Methods

A protocol for conducting a retrospective study was submitted to high-volume users of the BIOMET ***3i*** Certain® Tapered Implant System to solicit participation and contribution of data. Participants gathered information from their first 20 patients receiving Tapered Implants between June 2008 and December 2009. No exclusion criteria were applied. Data collection was done on standardized forms and processed in one database management system. Baseline variables included: demographics (gender, age at implant placement), diabetes, smoking behavior, implant site assessment (bone density), placement approach (2-stage, single stage, immediate provisionalization), and restorative type (single-unit, fixed multiple-unit, overdenture). Outcome variables included the implant's functional status and survival on the date of the patient's last evaluation.

In this study, twenty five centers document a 98.4% mean survival rate when utilizing BIOMET *3i*'s NanoTite Tapered Implant.

Results

A total of 46 clinicians were approached for participation in the study with 25 providing completed data records (54% compliance). The total number of patients represented in the dataset is 473 having 626 prosthetic cases supported by 836 BIOMET ***3i*** Certain® Tapered Implants. Implant diameters ranged from 3.25 to 6mm and lengths from 8.5 to 13mm. Implant locations were 63% posterior, 37% anterior, with 56% in maxillae and 44% in mandibles. A total of 13 implant failures were reported for a cumulative survival rate of 98.4%. Of the failures, 12 were in the maxillae and one in the mandible and evenly divided across implant dimensions.

Performance Variables		Implants	Failures	Survival Rate
Location	Maxilla	469	13	97.2
	Mandible	357	1	99.7
	Anterior	207	5	97.6
	Posterior	619	9	98.5
Bone Quality	Soft	151	4	97.4
	Normal	424	9	97.9
	Dense	251	1	99.6

Conclusion

Tapered implants in this retrospective analysis, placed in a variety of cases and locations, were found to have clinically acceptable success rates.

A prospective, randomized-controlled study of BIOMET *3i* Tapered Implants placed by students in graduate programs

Reddy M.

Poster Presentation P78: Academy of Osseointegration, 26th Annual Meeting: 2011 March 3-5; Washington DC.

Study Design: Prospective, Single-Center, Randomized Control
Major Product(s): BIOMET *3i* NanoTite™ and OSSEOTITE® Tapered Implants
Clinical Scenario: Implant Placement (various scenarios) by Dental Students
Sample Size: 453 Implants
Reported Outcome(s): Clinical Survival – Up to 30 Months Post Placement

Background

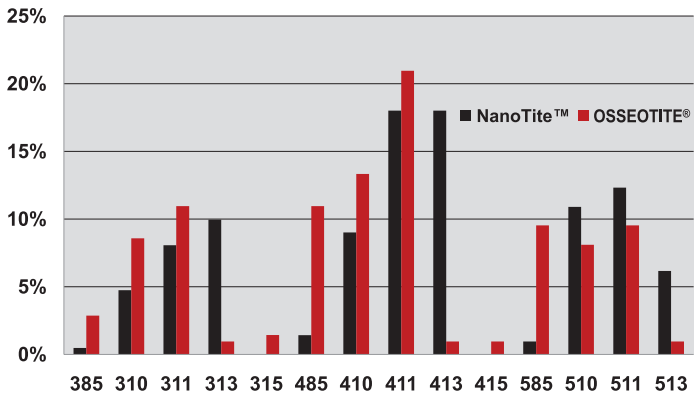
The success rate for implants placed by dental students early in their implant residency programs has been suggested to be lower than for experienced clinicians. The objective of this prospective study was to document the success rates of NanoTite and OSSEOTITE-surfaced Certain® Tapered Implants in graduate training programs.

In this study, dental students with limited implant experience achieved 97.9% survival with the BIOMET *3i* NanoTite Tapered Implant.

Materials and Methods

All study implants were the Certain Tapered Implants System (BIOMET *3i*, Palm Beach Gardens, FL) made from titanium alloy Ti6A14V, having an internal connection and either the OSSEOTITE or NanoTite Surface. An internet database was used to randomly assign implant sites to either implant surface group and also to record the placement data and restorative outcomes. The study is underway at several university periodontal and maxillofacial oral surgery graduate programs in the United States. All patients qualified to receive dental implants provided informed consent to be included in the study. The specific placement techniques are those directed by the teaching staff at the individual study centers. Restorative designs and procedures are also at the discretion of the treating clinicians.

Results



At the time of this interim report a total of 423 patients (mean age 55.5±17.0 years) have been enrolled over a period of 29 months with a total of 453 Tapered Implant placements documented in the database. Most students had not yet placed their first dental implant. Implant assessment data ranges up to 30 months during which time 10 implant failures were declared. Failures were not clustered, being evenly distributed in 9 patients treated by 8 students and were evenly divided between the implant surface groups. The overall cumulative survival rate for these Tapered Implants is 97.8% (97.9% for NanoTite Tapered and 97.7% for OSSEOTITE Tapered).

Conclusion

Considering that most students had never placed a dental implant, the relatively high cumulative survival rates in this study suggests that contemporaneous teaching programs are effective in training new operators in dental implantology.

Immediate implant placement and immediate restoration in infected sites

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Study Design: Retrospective, Single-Center, Observational
Major Product(s): BIOMET ***3i*** NanoTite™ Tapered Implants
Clinical Scenario: Implant Placement and Restoration in Infected Extraction Sites
Sample Size: 77 Implants
Reported Outcome(s): Clinical Survival – Up to 24 Months Post Placement

Background

The assumption that active infection is a contraindication for immediate implant placement has recently been challenged. Excellent implant survival rates have been reported even when implants were placed immediately in infected extraction sockets and provisionalized within 36 hours.

Objective

To further evaluate the impact of non-occlusal loading on implants placed in cleaned periodontically or endontically infected extraction sites, the present retrospective study examined the results of 77 implants placed in 63 patients and was followed for between 3 and 24 months.

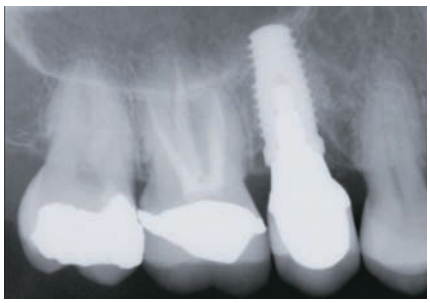
In this study, the clinician documented a 98.7% survival rate when immediately placing and provisionally restoring BIOMET *3i*'s NanoTite Tapered Implants in infected extraction sites.

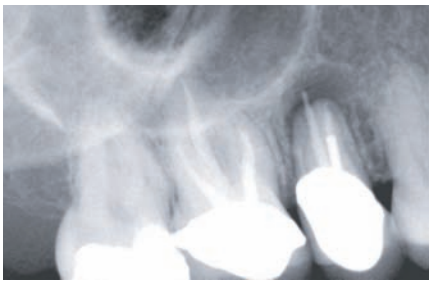
Materials and Methods

This study includes patients who presented with active periodontal or endodontic lesions. Hopeless teeth were extracted, followed by placement and immediate temporization of one or two implants. All patients were treated with the same protocol. All surgeries were conducted with lidocaine (1:100,000) using either a flapless technique or a mini-flap. The teeth were extracted, and each site was meticulously curetted with hand instruments and flushed with 3cc of .12% chlorhexadine gluconate, followed by saline. Preparation of the osteotomy(ies) was performed following the manufacturer's protocol for NanoTite Tapered PREVAIL® Implants (BIOMET ***3i***, Palm Beach Gardens, FL). Residual periimplant gaps were filled with mineralized xenograft. A cement- or screw-retained provisional restoration was immediately attached to the implant(s) and adjusted to eliminate any occlusal loading.

†Author has a financial relationship with BIOMET ***3i*** LLC resulting from speaking engagements, consulting engagements and other retained services.

Initial post-operative follow-up occurred at 7 to 14 days. Patients then returned every 2 weeks, on average, for the first 8 weeks. Post-operative, implant maintenance was performed between 3 and 4 months.





Results

A total of 77 implants were placed in 63 patients, 24 male and 39 female. Forty-nine patients received one implant and 14 patients received two implants. All of the 2-implant placements were splinted. The mean implant stability quotient (ISQ) at the time of placement was 80.71 (range 72-85). Final insertion torque readings ranged from 90 to 110; the mean was 98.71. At the time of the maintenance appointment, the reverse torque testing showed 76 of the 77 implants to be osseointegrated (98.7%). After follow-up ranging from 3 to 24 months, all 76 of the osseointegrated implants had survived.

Conclusion

The results of this retrospective study confirm that excellent primary stability and subsequent osseointegration can be achieved when implants are placed immediately into periodontally or endodontically infected extraction sites that have been disinfected and thoroughly debrided, in conjunction with an oral antibiotic regimen and then non-occlusally loaded. After up to two years of follow-up, the overall implant survival rate was 98.7%.