



Scientific Evidence

*Summary Of Published Research Studies
On The OSSEOTITE® Implant System*



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Prospective, Multicenter Clinical Studies Of Long Term OSSEOTITE® Implant Performance

1. Davarpanah M, Martinez H, Celletti R, Alcoforado G, Tecucianu JF, Etienne D. **A prospective multicenter evaluation of 1583 3i Implants: 1- to 5-year data.** *Int J Oral Maxillofac Implants.* 2002;17:820-8.

In this evaluation of the performance of BIOMET 3i Threaded Implants, 1583 implants were placed between 1995 and 1999 in 528 patients at 13 European clinical centers. Of these, 545 were OSSEOTITE Implants. Clinical and radiographic evaluations were performed annually. A total of 55 study implants were failures with 47 occurring within 6 months. In this study, a cumulative survival rate of 96.5% was observed five years after implant placement, with 97.2% survival in the maxilla and 95.8% in the mandible.

2. Testori T, Del Fabbro M, Feldman S, Vincenzi G, Sullivan D, Rossi Jr. R, Anitua E, Bianchi F, Francetti L, Weinstein RL. **A multicenter prospective evaluation of 2-months loaded OSSEOTITE Implants placed in the posterior jaws: 3-year follow-up results.** *Clin Oral Impl Res.* 2002;13:154-161.

Eleven edentulous and 164 partially edentulous patients received a total of 405 OSSEOTITE Implants placed in the posterior regions with a one-stage surgery and provisional restorations with occlusal loading at 2.0 ± 0.7 months. Prior to loading, four mandibular and two maxillary implants failed. Three mandibular failures occurred after loading, yielding a post-loading implant survival rate of 98.9% for the mandible and 100% for the maxilla with up to three years of follow-up. OSSEOTITE Implants in this study were capable of maintaining function when the conventional four-to-six month healing period was reduced to two months.

3. Mayer TM, Gunsolley JC, Feldman S. **The single-tooth implant: a viable alternative for single tooth replacement.** *J Periodontol.* 2002;73:687-93.

This prospective, multicenter five-year clinical trial was designed to evaluate the performance of OSSEOTITE Implants placed under conditions of increased risk supporting single-tooth restorations. Seventy-one implants were placed in 59 patients and followed for 30.9 to 60 months (mean 45.9 months). A total of 13 implants (18.4%) were placed in soft, poor quality bone. Bone augmentation and immediate replacement of extraction sockets were also performed if indicated. One implant failed yielding a 98.6% success rate.

4. Davarpanah M, Martinez H, Celletti R, Alcoforado G, Tecucianu J-F, Etienne D. **OSSEOTITE Implant: 3-year prospective multicenter evaluation.** *Clin Impl Dent Related Res.* 2001;3:111-118.

Of the 413 OSSEOTITE Implants placed in 142 patients, 271 (65.6%) were posterior implants and 142 (74.4%) were anterior implants. The cumulative survival rate was 96% after three years. For the 187 short implants (8.5 and 10mm), the survival rate was 98.4%. Twelve of the 14 failures occurred prior to prosthetic loading. Marginal bone loss was monitored radiographically for 385 implants and at three years the bone levels were at the first thread for 91.4% of the implants. In this study, the survival rates of the OSSEOTITE Implants were consistent regardless of implant length.

5. Sullivan DY, Sherwood RL, Porter SS. **Long term performance of OSSEOTITE Implants: a six-year follow-up.** *Compend Contin Educ Dent.* 2001;4:326-334.

A preliminary, interim report in 1997 of this prospective, multicenter study reported five failures out of 147 OSSEOTITE Implants placed in 75 patients. Four of the failures occurred in one medically-compromised patient. Follow-up evaluations at second-stage surgery, at six-months and at annual intervals continued until the final recall at 74.1 months, with no reports of additional failures.

6. Khang W, Feldman S, Hawley CE, Gunsolley J. **A multicenter study comparing DAE and machined-surfaced implants in various bone qualities.** *J Periodontol.* 2001;72:1384-1390.

This randomized-controlled study compares the performance of 247 OSSEOTITE Implants and 185 machined-surfaced implants. At least one of each implant type was placed using a two-stage approach in each of 97 patients. The implants supported fixed prostheses, hybrid prostheses and overdentures. Pre-loading success was 95.0% for the OSSEOTITE Group (12 failures) and 86.7% for the machined group (24 failures) ($P < 0.01$). After 36 months post-loading, cumulative success rates in poor quality bone were 96.8% for OSSEOTITE Implants and 84.8% for machined-surfaced implants.

7. Testori T, Wiseman L, Woolfe S, Porter SS. **A prospective multicenter clinical study of the OSSEOTITE Implant: a four-year interim report.** *Int J Oral Maxillofac Implants.* 2001;16:193-200.

At four study centers, 485 OSSEOTITE Implants were placed primarily in posterior regions (N=355) of 181 patients. Restorations included 58 single-tooth, 123 short-span and 28 long-span restorations. Six implant failures occurred prior to loading and no implant failures were reported after loading with four years of follow-up evaluations. Five failures occurred in the maxilla. Of 153 short implants (10mm or less), one failure was observed. The cumulative success rates were 99.4% for the posterior mandible and 98.4% for the posterior maxillae.

Prospective, Multicenter Clinical Studies Of Long Term OSSEOTITE® Implant Performance (continued)

8. Grunder U, Gaberthuel T, Boitel N, Imoberdorf M, Meyenberg K, Andreoni C, Meier T. **Evaluating the clinical performance of the OSSEOTITE Implant in maxillary and mandibular posterior areas: defining prosthetic predictability.** *Compend Contin Educ Dent.* 1999;20:628-640.
A total of 219 OSSEOTITE Implants were placed primarily in the posterior regions of 74 patients according to a conventional two-stage surgical protocol with a mean healing time of 6.2 ± 2.0 months. At a 34.4 month interim evaluation, a total of three implants in the posterior maxilla had failed prior to loading. No implant failures occurred after prosthetic restoration. The cumulative survival rates were 99.4% for the posterior implants and 100% for all implants post-loading. Once restored at second-stage surgery, the OSSEOTITE Implants in this study maintained a stable state of integration.
9. Lazzara RJ, Porter SS, Testori T, Galante J, Zetterqvist L. **A prospective multicenter study evaluating loading of OSSEOTITE Implants two months after placement: one-year results.** *J Esthet Dent.* 1998;10:280-289.
At ten study centers, 155 patients received a total of 429 OSSEOTITE Implants according to an early loading protocol. Eighty-three single-tooth and 129 short-span provisional restorations were placed at 2.1 ± 0.7 months. Six of seven implant failures occurred prior to loading resulting in a cumulative survival rate (CSR) of 98.5% at 12.6 months and after 10.5 months post-loading, the CSR was 99.8%.
10. Sullivan DY, Sherwood RL, Mai TN. **Preliminary results of a multicenter study evaluating a chemically enhanced surface for machined commercially pure titanium implants.** *J Prosthet Dent.* 1997;78:379-386.
A total of 147 OSSEOTITE Implants was placed in 75 patients and monitored for gingival health with clinical evaluations and for crestal bone levels with radiographs. Evaluations of follow-up data for up to three years indicated five implant failures. This clinical study was the first to report on the performance of OSSEOTITE Implants and the cumulative success rate in this study was calculated to be 96.6%.

Clinical Performance Of OSSEOTITE Implants With Abbreviated Healing Times And Immediate Loading Protocols

1. Tealdo T, Bevilacqua M, Pera F, Menini M, Ravera G, Drago C, Pera P. **Immediate function with fixed implant-supported maxillary dentures: a 12-month pilot study.** *J Prosthet Dent.* 2008;99:351-60.
Twenty-one patients were enrolled in this immediate loading study for the placement of maxillary OSSEOTITE and OSSEOTITE Tapered Implants in support of fixed partial and fixed full prostheses. The objective was to compare the following variables: parallel walled and tapered implant shapes; healed bone and extraction sites; vertical and tilted implant positioning. The screw-retained prostheses were constructed from BIOMET **3i** Restorative Components and inserted the day after surgery. Bars for full-arch restorations were manufactured from palladium-alloy and the occluding surfaces were restored with acrylic resin. In this study, there were no significant differences in crestal bone loss for implant variables regarding: vertical/tilted placement, parallel-walled/tapered design, healed-bone/extraction sites. The mean follow-up time was 20 months and the cumulative survival rate for all 103 implants was 92.8%.
2. Testori T, Del Fabbro M, Capelli M, Zuffetti F, Francetti L, Weinstein RL. **Immediate Occlusal Loading and tilted implants for the rehabilitation of the atrophic edentulous maxilla: 1-year interim results of a multicenter prospective study.** *Clin Oral Implants Res.* 2008;19:227-32.
This one-year interim analysis of immediate fixed full-arch prostheses compares implant survival and marginal bone level outcomes for titled and axially oriented implants. A total of 44 patients were treated with OSSEOTITE Tapered Implants in the maxilla and followed for a mean of 22.1 months (range 3-42 months). For each case, one implant in the posterior of each side of the jaw was placed with a 30-35° tilt to the distal. Four axial (vertical) implants were placed in the anterior. A provisional screw-retained prosthesis was delivered within 48 hours. A total of five implant failures occurred. Three were axially-positioned implants declared after 2, 8 and 15 months. Two tilted implants failed after 4 and 18 months of function. At 12 months from the baseline, mean crestal bone loss measurements were 0.8 ± 0.5 mm for tilted implants and 0.9 mm \pm 0.4 mm for axial implants. No statistically significant difference was recorded.

Clinical Performance Of OSSEOTITE® Implants With Abbreviated Healing Times And Immediate Loading Protocols (continued)

3. Galli F, Capelli M, Zuffetti F, Testori T, Esposito M. **Immediate non-occlusal versus early loading of dental implants in partially edentulous patients: a multicentre randomized clinical trial. Periimplant bone and soft-tissue levels.** *Clin Oral Implants Res.* 2008;19:546-52.

This report presents the periimplant and marginal bone level changes comparing early and immediate load healing times on the same data set as Testori et al. 2007, which reported implant and restorative success. In this randomized-controlled, prospective, multicenter study, a group of fifty-two OSSEOTITE Implants were loaded at two months (early) and a group of 52 implants were loaded within 48 hours. Periapical radiographs were taken at implant placement, 2, 8 and 14 months to determine marginal bone level changes. Soft tissue stability (height of the clinical crown) was measured on plaster casts poured from alginate impressions taken at 8 and 14 months. After 14 months, crestal bone loss for both groups averaged 1.1mm and there were no statistically significant changes in soft tissue parameters from the baseline.

4. Testori T, Galli F, Capelli M, Zuffetti F, Esposito M. **Immediate nonocclusal versus early loading of dental implants in partially edentulous patients: 1-year results from a multicenter, randomized controlled clinical trial.** *Int J Oral Maxillofac Implants.* 2007;22:815-22.

In this prospective study, 52 partially edentulous patients were enrolled at four study centers and randomized to either an immediate nonocclusal loaded group or an early loaded group. The protocol for immediate loading included: a torque of >30 Ncm for inserting single implants; >20 for splinted implants; under-preparation of the osteotomy in soft bone (shaping drill diameter 1mm less than implant diameter); provisional prostheses placed at 48 hours and left out of occlusion. Twenty-five Full OSSEOTITE Tapered Implants were placed in each group. At two months in the group, acrylic resin was added to restorations so that adjustments would place them into occlusion. In the early loaded group, provisional restorations were placed at two months in occlusal contact. All implants received screw-retained permanent prostheses eight months post implant placement surgery. One implant failed in the immediately-loaded group after two months and no prosthetic complications were reported during 14 months of follow-up.

5. Capelli M, Zuffetti F, Del Fabbro M, Testori T. **Immediate rehabilitation of the completely edentulous jaw with fixed prostheses supported by either upright or tilted implants: a multicenter clinical study.** *Int J Oral Maxillofac Implants.* 2007;22:639-44.

The restorative technique of placing tilted posterior implants (25 to 35 degrees) in edentulous jaws increases the distance between these implants and anterior implants that are placed upright. The premise allows the use of longer implants eliminating the need for bone augmentation. The provisional complete denture is loaded within 48 hours and the permanent prosthesis is delivered at three months. In this multicenter study, 65 patients enrolled at four centers, had a total of 24 mandibles treated with 96 OSSEOTITE Tapered Implants and 41 maxillae treated with 246 OSSEOTITE Tapered Implants. The permanent dentures were retained with Gold-Tite® Screws. With up to 52 months of follow-up, a total of five implant failures were recorded and all occurred in the maxilla. Of the tilted implants, one failure occurred during the first 12 months and a second during the second year of function. Crestal bone loss at 12 months showed no significant differences by jaw location or by upright versus tilted. All prostheses survived.

6. Sullivan D, Vincenzi G, Feldman S. **Early loading of OSSEOTITE Implants after placement in the maxilla and mandible: a five-year report.** *Int J Oral Maxillofac Implants.* 2005;20:905-912.

A total of 526 OSSEOTITE Implants were placed according to a single-stage surgical protocol and were allowed a nonsubmerged healing period of two months. 64.5% mandibular and 34.6% maxillary implants supported 118 single-tooth, 134 short-span and 16 long-span restorations. Annual follow-up evaluations monitored mobility, mucosal health, symptomology and radiolucency. Eleven implants failed with eight occurring prior to loading. After five years, the cumulative success rate in this study was 97.9%.

7. Schropp L, Kostopoulos L, Wenzel A, Isidor F. **Clinical and radiographic performance of delayed-immediate single-tooth implant placement associated with periimplant bone defects. A 2-year prospective, controlled, randomized follow-up report.** *J Clin Periodontol.* 2005;32:480-7.

This study compares single-tooth OSSEOTITE Implants placed according to an immediate loading protocol (10 day average post-extraction, N=13 patients) with those placed according to a delayed loading protocol (three months post-extraction, N=13 patients). Two-year survival rates were 91% for the immediate group and 96% for the delayed group. Probing pocket depths were reduced up to 1.4mm on average, from the time of implant placement to two years for both groups. The mean marginal bone loss for both groups was 0.7mm. Follow-up data also demonstrated that the periimplant bone defects present at extraction sites at the time of implant placement did not affect long-term pocket depths, marginal bone loss or restorative function.

Clinical Performance Of OSSEOTITE® Implants With Abbreviated Healing Times And Immediate Loading Protocols (continued)

8. Ibanez JC, Tahhan MJ, Zamar JA, Menendez AB, Juaneda AM, Zamar NJ, Monqaut JL. **Immediate Occlusal Loading of double acid-etched surface titanium implants in 41 consecutive full-arch cases in the mandible and maxilla: 6- to 74-month results.** *J Periodontol.* 2005;76:1972-81.

A total of 343 OSSEOTITE Implants were used to treat 23 mandibular and 25 maxillary cases. Implants were loaded with provisional full-arch restorations within 48 hours. For 12 to 74 months of clinical and radiographic follow-up observations, two implants were considered failures, although remain as surviving study implants. In this study, a success rate of 99.42% was observed.

9. Lazzara RJ, Testori T, Meltzer A, Misch C, Porter S, del Castillo R, Goene RJ. **Immediate Occlusal Loading (IOL®) of dental implants: predictable results through DIEM® Guidelines.** *Pract Proced Aesthet Dent.* 2004;16:3-15.

With a foreword by Dr. Dennis Tarnow, this article discusses the increasing interest of clinicians to provide the treatment alternative of immediately loaded dental implants. The BIOMET 3i DIEM Protocol was demonstrated with clinical cases. When the concept of Immediate Occlusal Loading of implants is supplemented with innovative implant components (eg, BIOMET 3i IOL Abutments), these factors provide dental professionals with a set of simple guidelines to increase the predictability of such treatment.

10. Drago CJ, Lazzara RJ. **Immediate provisional restoration of OSSEOTITE Implants: a clinical report of 18-month results.** *Int J Oral Maxillofac Implants.* 2004;19:534-541.

Ninety-three OSSEOTITE Implants were immediately restored with fixed single-unit provisional restorations left out of occlusion. Definitive restorations were placed at eight to 12 weeks and followed for at least 18 months (average of 20.3 months). Seventy-five of the 77 implants satisfying inclusion criteria achieved osseointegration resulting in a 97.4% cumulative survival rate. These results are comparable to results in other studies for implants placed according to one or two stage healing protocols restored after two or more months.

11. Testori T, Meltzer A, Del Fabbro M, Zuffetti F, Troiano M, Weinstein RL. **Immediate Occlusal Loading of OSSEOTITE Implants in the lower edentulous jaw. A multicenter prospective study.** *Clin Oral Impl Res.* 2004;15:278-284.

Sixty-two patients with edentulous mandibles were treated at four study centers with 325 OSSEOTITE Implants. Each case was occlusally loaded with a full-arch screw-retained prostheses with distal extensions (hybrid prostheses) four hours after surgery. Patients received final prostheses at six months. Two implants failed to integrate within two months of occlusal loading. A cumulative implant success rate of 99.4% was achieved for a period of 12 to 60 months post-placement (mean 28.6 ± 14.1 months). Crestal bone loss around the immediately loaded implants was similar to that reported for implants placed with standard loading protocols.

12. Testori T, Del Fabbro M, Galli F, Francetti L, Taschieri S, Weinstein R. **Immediate Occlusal Loading the same day or the day after implant placement: comparison of 2 different time frames in total edentulous lower jaws.** *J Oral Implantol.* 2004;30:307-13.

This prospective study evaluates the Immediate Occlusal Loading of a total of 116 OSSEOTITE Implants in edentulous mandibles supporting full-arch restorations placed on either the day of implant surgery (eleven patients) or the day after surgery (8 patients). For each case, five to six implants supported hybrid, metal-reinforced acrylic resin provisional prosthesis with distal extensions. Of the total, 84.5% were placed in the interforaminal region. Definitive prostheses were delivered three months after surgical procedures. This interim analysis reported a mean follow-up of 37.8 ± 16.5 months during which time two failures were declared in the same-day loaded group (CSR = 96.9%) and one failure in the day-after group (CSR = 98.1%). All failures occurred during the first two months post-operative. No statistical significance in implant survival rates could be determined between groups due to the small number of implant failures.

13. Testori T, Bianchi F, Del Fabbro M, Smuckler-Moncler S, Francetti L, Weinstein RL. **Immediate non-occlusal loading vs. early loading in partially edentulous patients.** *Pract Proced Aesthet Dent.* 2003;15:787-794.

This study followed two treatment groups: immediately loaded (IL=14 patients) and early 2-month loaded (EL=18 patients) for up to two years of observation. In the IL group, 35 OSSEOTITE Implants and 17 OSSEOTITE Tapered Implants were placed and restored with 17 fixed partial dentures. Primary stability at implant placement was scored according to insertion torque and Resonance Frequency Analysis. In the EL group, 30 OSSEOTITE Implants and 19 OSSEOTITE Tapered Implants were placed supporting 21 FPD's. Both groups were balanced for baseline variables including patient demographics, implant dimensions, location and bone density. Success criteria at recall appointments consisted of testing for mobility, signs and symptoms of infection, and radiological evidence of marginal bone loss and periimplant radiolucencies. With up to 24 months of observation, the cumulative survival rate for IL implants was 96.15% and for EL implants was 97.96%.

Clinical Performance Of OSSEOTITE® Implants With Abbreviated Healing Times And Immediate Loading Protocols (continued)

14. Testori T, Del Fabbro M, Szmukler-Moncler S, Francetti L, Weinstein RL. **Immediate Occlusal Loading of OSSEOTITE Implants in the completely edentulous mandible.** *Int J Oral Maxillofac Implants.* 2003;18:544-551.
Fifteen patients with edentulous mandibles received 103 OSSEOTITE Implants and titanium hybrid prostheses with acrylic resin teeth according to two immediate loading protocols. Nine cases were loaded with temporary prostheses at four hours, which remained in function for six months and six cases were restored with the definitive final prostheses at 36 hours. The four-year cumulative survival rate was 98.9% for implants and 100% for the prostheses.
15. Cocchetto R, Vincenzi G. **Delayed and immediate loading of implants in the aesthetic zone: a review of treatment options.** *Pract Proced Aesthet Dent.* 2003;15:691-8; quiz 700.
Contemporary practitioners are able to restore function and aesthetics using materials that are compatible with patient's biological requisites. This article reviews loading protocols. BIOMET 3i's Externally Hexed and OSSEOTITE XP® (Expanded Platform) Implants can be used for immediate implant placement, immediate loading and flapless surgeries. A case was presented for immediate crown connection in the anterior zone and included primary stability, splinting multiple units and the use of non-functional loading.
16. Ibanez JC, Jalbout ZN. **Immediate loading of OSSEOTITE Implants: two-year results.** *Implant Dent.* 2002;11:128-36.
Eighty-seven OSSEOTITE Implants were immediately loaded to restore 11 edentulous cases. Two mandibular and two maxillary cases received screw-retained provisional prostheses the day of surgery. Three mandibular and four maxillary cases were loaded 48 hours after surgery with final screw-retained, porcelain-fused-to-metal prostheses. Up to three years of follow-up data included clinical and radiographic data with no reports of implant failure.
17. Testori T, Del Fabbro M, Feldman S, Vincenzi G, Sullivan D, Rossi Jr. R, Anitua E, Bianchi F, Francetti L, Weinstein RL. **A multicenter prospective evaluation of 2-months loaded OSSEOTITE Implants placed in the posterior jaws: 3-year follow-up results.** *Clin Oral Impl Res.* 2002;13:154-161.
Eleven edentulous and 164 partially edentulous patients received a total of 405 OSSEOTITE Implants placed in the posterior regions with one-stage surgery and provisional restorations at 2.0 ± 0.7 months. Prior to loading, four mandibular and two maxillary implants failed. Three mandibular failures occurred after loading yielding a post-loading implant survival rate of 98.9% for the mandible and 100% for the maxilla with up to three years of follow-up. OSSEOTITE Implants in this study were capable of maintaining function with the noted survival rates when the conventional 4 to 6 month healing period was reduced to two months.
18. Testori T, Szmukler-Moncler S, Francetti L, Del Fabbro M, Trisi P, Weinstein RL. **Healing of OSSEOTITE Implants under submerged and immediate loading conditions in a single patient: a case report and interface analysis after 2 months.** *Int J Periodontics Restorative Dent.* 2002;22:345-53.
Three of 11 OSSEOTITE Implants placed in Type IV soft bone in the mandible were retrieved after two months of healing. The histologic section for the implants that had been left submerged and unloaded showed 38.9% Bone-To-Implant Contact. The other two implants had been immediately loaded in support of a splinted provisional denture retained on six implants; Bone-To-Implant Contact was 64.2%. Marrow spaces showed thin, neofomed bone trabeculae on the implant surfaces. In this case study, clinical observations of osseointegration were documented for OSSEOTITE Implants left either submerged for healing or immediately loaded.

Studies Evaluating OSSEOTITE® Implants With Enhanced Design Features

The Internal Hex Connection: OSSEOTITE Certain® Implant And QuickSeat® Connection

1. Drago CJ, O'Connor CG. **A clinical report on the 18-month cumulative survival rates of implants and implant prostheses with an internal connection implant system.** *Compend Contin Educ Dent.* 2006;27:266-71.
In forty-five patients, a total of 83 OSSEOTITE Certain Implants were placed in support of single crowns. Forty-seven implants were placed according to a single-stage surgical approach and 36 implants were placed in two-stages with a healing time of two months. Abutments were retained with Gold-Tite® Screws torqued to 20Ncm. Survival criteria for implants included the following: absence of mobility, infections and periapical radiolucencies. Success criteria for restorations included marginal integrity, presence of interproximal and occlusal contacts. One implant was lost due to blunt trauma and one implant presented with an implant/abutment interface that was mobile. According to the survival criteria, the CSR for implants was 98.8% at 18 months and the prostheses were rated as 100% successful.
2. Gross M, Kenealy J, Stach RM. **OSSEOTITE Certain attachment mechanism predictive for adequacy of implant-abutment interface.** 35th Annual Meeting & Exhibition of the AADR March 8-11, 2006 (Orlando, Florida) Poster presentation.
This analysis determines the extent to which the audible/tactile feedback of the OSSEOTITE Certain Implant's abutment connection correlates with radiological validation of abutment seating. Six hundred and nine assessments were obtained from prospective clinical trials when investigators attached impression copings or abutments and reported feedback from the mechanism. 93.8% assessments detected signals that were associated with adequate seating on radiographs. There were no cases of a click feedback falsely reporting good seating of components. The results showed an association between the click feedback and radiographic outcomes of the implant-abutment interface and suggested that the click mechanism was predictive and that obtaining confirmatory radiographs may not be essential.
3. Suttin Z, Gubbi P, Berckmans B. **Efficacy of internal connection vs. external hex dental implant assemblies subjected to bending moments.** Academy of Osseointegration Annual Meeting 2005 (Orlando, Florida) Poster presentation.
In response to bending moments, an external hex implant assembly is primarily reliant on the bending strength of the screw whereas an internal connection assembly is reliant on the screw, abutment and to some extent, the implant. This study used Finite Element Analysis to assess resistance to bending moments and compared the difference between an external hex and the OSSEOTITE Certain QuickSeat (internal hex) Connection assembly. 3-D computer-aided-design models were used to analyze the effects of bending moments, screw preloads and screw diameters on tensile stress found in the abutment-interface region. The results showed that the external hex assembly was more reliant on the screw and more sensitive to pre-load than the OSSEOTITE Certain QuickSeat Connection.
4. Castellon P, Block MS, Smith M, Finger IM. **Immediate implant placement and provisionalization using implants with an internal connection.** *Pract Proced Aesthet Dent.* 2004;16:35-43.
Restorative techniques for single missing teeth have evolved to include implant placement and provisionalization protocols immediately following extraction. Use of the BIOMET 3i OSSEOTITE Certain Implant System was presented in this article with clinical cases demonstrating the clinical and biological parameters necessary for immediate implant provisionalization. The use of a clinically versatile implant system with a reliable internal connection verification system may result in predictable restorative success.
5. Finger IM, Castellon P, Block M, Elian N. **The evolution of external and internal implant/abutment connections.** *Pract Proced Aesthet Dent.* 2003;15:625-32.
The success of implant dentistry has increased in its popularity as a restorative option for the treatment of edentulous patients. This article introduced key new developments in implant treatment and highlighted the various design characteristics of OSSEOTITE Certain (internally interfaced) Implants. It demonstrated the implants' clinical application with a step-by-step, clinical case presentation.

Studies Evaluating OSSEOTITE® Implants With Enhanced Design Features (continued)

The Medialized Seating Surface For Platform Switching: The Certain® PREVAIL® Implant

1. Calvo Guirado JL, Saez Yuguero MR, Pardo Zamora G, Muñoz Barrio E. **Immediate provisionalization on a new implant design for esthetic restoration and preserving crestal bone.** *Compend Contin Educ Dent.* 2006;27:266-71.

Due to the impact crestal bone height has on preventing gingival recession and maintaining papilla in the aesthetic zone, the objective of this study was to determine if Platform Switching maintained crestal bone loss to a minimum, defined as <1.0mm on both the mesial and distal surfaces. Ten Certain PREVAIL Implants were used in ten maxillary cases for the immediate replacement of teeth in fresh extraction sockets. Three implants were placed at lateral incisor sites and seven at central incisor sites. The dimensions for all the lateral incisors were 4/5/4mm diameters and 13mm lengths. For central incisor sites, all diameters were 5/6/5, for five implants the lengths were 13mm and two implant lengths were 15mm. Provisional crowns were inserted at 24 hours on GingiHue® Posts. The mean distance between implant collar and alveolar crest was measured from radiographs taken at day 0, 15, 30, 60, 90 and 6-months. After six months, the resulting bone loss for implants at both maxillary incisor sites was less than 1.0mm: central/mesial = 0.05mm; central/distal = 0.07mm; lateral/mesial = 0.07mm and lateral/distal = 0.06mm.

2. Vela-Nebot X, Rodríguez-Ciurana X, Rodado-Alonso C, Segalà-Torres M. **The benefits of an implant platform-modification technique for reducing crestal bone resorption.** *Implant Dent* 2006;15:313-320.

In this study, test abutments of a lesser diameter (4.1mm) than the implant's platform (5.0mm) were inserted to create a platform modification. The implants for the test group (30 cases) and the control group (30 cases that received standard sized abutments) were placed level with the alveolar crest. After abutment attachment, the implants were followed for four to six months to assess bone loss radiographically. The mean value for bone reabsorption for the mesial measurement in the control group was 2.56mm and for the study group it was 0.79mm. Mean bone reabsorption for the distal in the control group was 2.60mm and 0.84mm for the test group.

3. Lazzara RJ, Porter S. **Platform Switching: a new concept in implant dentistry for controlling post-restorative crestal bone levels.** *Int J Periodontics Restorative Dent.* 2006;26:9-17.

At second-stage surgery, when an implant is uncovered and exposed to the oral environment, a vertical repositioning of crestal bone occurs. When Implant Innovations Inc. (BIOMET 3i) introduced wide-diameter implants in 1991, matching-diameter prosthetic components were not available. Many of these early 5.0 and 6.0mm wide implants received "standard" diameter (4.1mm) healing abutments and prosthetic components. Long-term radiographic follow-up of these "platform-switched" implants demonstrated a smaller than expected vertical loss of crestal bone height than was typically observed.

4. Baumgarten H, Cocchetto R, Testori T, Meltzer A, Porter SS. **A new implant design for crestal bone preservation: initial observations and case report.** *Pract Proced Aesthet Dent.* 2005;17:735-40.

This article introduced a new implant design: the BIOMET 3i OSSEOTITE Certain PREVAIL Implant, which incorporated the concepts of Platform Switching. A detailed clinical case was presented in which maxillary central incisors in a 28-year old male were extracted and replaced with Certain PREVAIL Implants according to an immediate non-occlusal loading procedure. Aesthetic results of midfacial and interdental soft tissue were observed.

5. Grunder U, Gracis S, Capelli M. **Influence of the 3-D bone-to-implant relationship on esthetics.** *Int J Periodontics Restorative Dent.* 2005;25:113-9.

The 3-D bone-to-implant relationship influences soft tissue aesthetics around implants. A certain amount of bone resorption occurs around implants upon uncovering and contact with the oral environment. Not only is bone volume on the buccal side of the implant and in the papillary area important, but also the distance between the implant and the adjacent tooth or implant. Missing bone can be a limiting factor for aesthetics in some cases; in other cases, it is possible to regenerate new bone. Clinicians are recommended to focus on the 3-D bone-to-implant relationship to establish ideal soft tissue aesthetics that are stable throughout time.

Studies Evaluating OSSEOTITE® Implants With Enhanced Design Features (continued)

6. Gardner DM. **Platform Switching as a means to achieving implant esthetics.** *NY State Dent J.* 2005;71:34-7.

In the case study presented in this article, the technique of Platform Switching was employed to limit both osseous and soft tissue changes with the result of creating a predictable, aesthetic result. By altering the horizontal position of the microgap, the horizontal component of bone loss after abutment connection can be reduced and the osseous dimensions maintained. As demonstrated radiographically, the height of bone was maintained after abutment connection and one year after restoration. Preservation of osseous dimensions led to maintenance of gingival architecture and pleasing aesthetic results.

7. Chiche F. Espace biologique implantaire et esthétique. **Le concept de Platform Switching.** Hors-Série Esthétique 2005;May (France).

The observation that resorption around the implant collar begins when the implant is exposed to the oral environment is a phenomenon considered to be normal. Platform Switching refers to using prosthetic components that are undersized in relation to the diameter of the implant platform. The prosthetic connection is displaced towards the center of the implant and this increases the distance separating the peripheral bone from the base of the abutment. The concept is that the area of inflammatory connective tissue is medialized and occupies a portion of the implant platform, thereby limiting direct contact with the crestal bone. The Certain® Line is an implant system to which Platform Switching can be applied.

Titanium Alloy OSSEOTITE Implants

1. Gubbi P, Berckmans B. **Characterization of OSSEOTITE Surfaces on Cp Titanium and Titanium Alloy Dental Implants.** Microscopy and Microanalysis Annual Meeting, July 30 – August 3, 2006 (Chicago, IL) Poster presentation.

The objective of this study was to characterize the OSSEOTITE Surface on commercially pure titanium (CpTi) and on Ti-6Al-4V-ELI (Ti-alloy) with qualitative and quantitative microscopy. Scanning electron microscopy (SEM) and surface mapping microscopy (SMM) were used to generate images and surface microscopy data (Sa, Sq and PV values). For both CpTi and Ti-alloy, three sample regions on 13 implants, each from a different manufacturing lot, were analyzed. Representative SEM images for CpTi and Ti-alloy were visually similar although slight differences were observed due to the inherent etching characteristics of the materials. The SMM data show no statistically significant differences ($P > 0.05$).

2. Mendes VC, Goodman R, Berckmans B, Davies JE. **Osteoconduction on acid etched cp titanium and titanium alloy surfaces.** *International Congress "World Celebration 40 years of Osseointegration"* September 2005 (Sao Paulo, Brazil) Poster presentation.

For this preclinical study on osteoconduction, custom-made bone-ingrowth chambers, "Tplants", were manufactured from either CpTi or Ti-alloy featuring an etched surface (OSSEOTITE) produced by either a dual-acid (DAE)(H₂SO₄/HCl) or citric-acid (CA) based process. One hundred Tplants were inserted in the distal femur of 50 adult male rats and retrieved for examination by scanning electron microscopy (SEM) after nine days. Both qualitative and quantitative analyses of bone ingrowth along the walls of the Tplants were measured either as a function of implant metal or the etching method. Topographically, the CpTi surfaces had larger-scale features than the Ti-alloy, which exhibited a more complex (sub-micron) microtopography. The influence of independent variables was taken into account. Results showed that the DAE CpTi surface exhibited significantly less osteoconduction than the other three groups, and that implant chambers made of Ti alloy were statistically significantly more osteoconductive than those of CpTi implants.

FOSS (Full OSSEOTITE Surface) Implants

1. Zetterqvist L, Feldman S, Vincenzi G, Wennström JL, Chierico A, Stach RM, Kenealy JN. **A prospective, randomized-controlled study of hybrid and non-hybrid DAE implants for the incidence of periimplantitis: A three-year interim evaluation.** Academy of Osseointegration Annual Meeting March 16-18, 2006 (Seattle, WA) Poster presentation.

The OSSEOTITE Implant introduced in 1995 featured a hybrid design with a machined surface at the collar. This design was thought to reduce risks of periimplantitis and severe complications reported for implants with rough surfaces, such as hydroxyapatite coatings, at the mucosal region. This randomized-controlled clinical trial assessed the risks of a full OSSEOTITE Surface test implant. One hundred and nine patients were restored with at least one test implant and one control hybrid implant in a multi-unit restoration and were followed for a minimum of three years. No clinical signs or symptoms or radiographic evidence of periimplantitis were reported for either implant group.

Long Term Performance Of OSSEOTITE® Implants Under Conditions Of High Risk Variables

1. Bugea C, Luongo R, Di Iorio D, Cocchetto R, Celletti R. **Bone contact around osseointegrated implants: histologic analysis of a dual-acid-etched surface implant in a diabetic patient.** *Int J Periodontics Restorative Dent.* 2008;28:145-51.

This case report presents histological observations and histomorphometric data for an integrated OSSEOTITE PREVAIL® Implant retrieved from a patient with Type 2 diabetes. This patient had the implant located in the anterior mandible adjacent to two other PREVAIL Implants, all with dimensions 4mm diameter x 10mm length, supporting an overdenture. Although no mobility or pathology was observed after two months of function, the implant was trephined (6mm diameter) due to interference with the base of the denture at the lingual border. The implant was processed, ground, sliced into three sections, and stained with von Kossa and basic fuchsin. Light microscopy (x20) revealed bone adaptation to the OSSEOTITE Surface and absence of both connective tissue and inflammatory infiltrate. Osteoblasts were identified depositing osteoid matrix (x45). The measured Bone-To-Implant Contact was 80%.

2. Goené R, Bianchesi C, Huerzeler M, Del Lupo R, Testori T, Davarpanah M, Jalbout Z. **Performance of short implants in partial restorations: three years follow-up of 7mm and 8.5mm OSSEOTITE Implants.** *Implant Dent.* 2005;14:274-280.

For this retrospective, multicenter study, a total of 188 patients received 311 short OSSEOTITE Implants placed primarily in soft bone. Of 216 partially edentulous cases, 95.2% were short-span fixed dentures placed in the posterior sextants. During three years of follow-up, 13 implants failed, yielding a cumulative success rate of 95.8%. In nine cases, implant failure occurred prior to prosthesis insertion and occlusal loading.

3. Feldman S, Boitel N, Weng D, Kohles SS, Stach RM. **Five-year survival distributions of short-length (10mm or less) machined-surfaced and OSSEOTITE Implants.** *Clin Implant Dent Relat Res.* 2004;6:16-23.

Because there is a perceived risk that short-length implants will be unable to tolerate occlusal loads, this analysis evaluates the risk for failure of short implants for machined-surfaced and OSSEOTITE Implants. The distributions of 2597 machined-surfaced and 2294 OSSEOTITE Implants between short and standard-length data sets were similar for baseline variables including width, location and restorative type. The five year cumulative success rate for the machined-surfaced standard-length implants was 2.2% greater than the machined-surfaced short-length implants: a difference which was statistically significant. The difference for OSSEOTITE Implants was 0.7% greater for standard than short-length OSSEOTITE Implants: a difference which was not statistically significant.

4. Stach RM, Kohles SS. **A meta-analysis examining the clinical survivability of machined-surfaced and OSSEOTITE Implants in poor quality bone.** *Implant Dent.* 2003;12:87-96.

Implant data for machine-surfaced implants (N = 2,614) and OSSEOTITE Implants (N = 2,288) were derived from eight prospective studies. Protocols followed a two-stage surgical approach with submerged healing for four to six months. Bone quality was assessed by operator perception of resistance during drilling as dense, normal or soft (poor). The four year cumulative survival rates were as follows: machined-surfaced group in good (dense or normal) bone = 93.6% and in poor bone = 88.2%; OSSEOTITE Group in good bone = 98.4% and in poor bone = 98.1%. In this analysis, bone quality had a definitive impact on the performance of machined-surfaced implants. In this study, OSSEOTITE Implants performed comparably in both good and poor bone.

5. Bain CA, Weng D, Meltzer A, Kohles SS, Stach RM. **A meta-analysis evaluating the risk for implant failure in patients who smoke.** *Compend Contin Educ Dent.* 2002;23:695-9,702,704.

Implant data for machine-surfaced implants (N = 2,614) were pooled from three prospective studies. Data for OSSEOTITE Implants (N = 2,274) were derived from six prospective studies and data sets were qualified for comparison. Implant protocols followed a two-stage surgical approach with an unloaded healing period of four to six months. The three-year cumulative survival rates were as follows: nonsmoking, machined-surfaced group = 92.8%; smoking machined-surfaced group = 93.5%; nonsmoking OSSEOTITE Group = 98.4%; smoking OSSEOTITE Group = 98.7%. In this study, no difference was observed between the smoking and nonsmoking groups in these patient populations, although there was a clinically relevant difference between machined and OSSEOTITE Implants.

6. Khang W, Feldman S, Hawley CE, Gunsolley J. **A multicenter study comparing DAE and machined-surfaced implants in various bone qualities.** *J Periodontol.* 2001;72:1384-1390.

This randomized-controlled study compares the performance of 247 OSSEOTITE Implants and 185 machined-surfaced implants. At least one of each implant type was placed using a two-stage approach in each of the 97 patients. Implant supported fixed prostheses, hybrid prostheses and overdentures were used and 40% were placed in poor quality bone. Pre-loading success was 95.0% for the OSSEOTITE Group (12 failures) and 86.7% for the machined group (24 failures) (P<0.01). After 36 months, there was a higher cumulative survival rate for OSSEOTITE Implants (95.0%) as compared to machined-surfaced implants (86.7%).

Studies Evaluating The Effects Of The OSSEOTITE® Surface

1. Veis AA, Papadimitriou S, Trisi P, Tsirlis AT, Parissis NA, Kenealy JN. **Osseointegration of OSSEOTITE and machined-surfaced titanium implants in membrane-covered critical-sized defects: a histologic and histometric study in dogs.** *Clin Oral Implants Res.* 2007;18:153-60.

Custom-manufactured implants (2mm x 10mm) with split surfaces, machined and OSSEOTITE, were placed into the iliac wings of three mongrel dogs (ten per animal). Bone defects were created with a trephine, 6mm in diameter, to a depth of 5mm and osteotomies were prepared in central locations of the defect with a 1.3mm drill. A 2mm peripheral gap was left surrounding the coronal aspect of the implants. Although sites were not grafted, an e-PTFE membrane was placed. After 2, 3 and 5-months of healing, implants and surrounding bone were retrieved for histological processing and analysis. Observations under polarized light microscopy compared the split implant sides showing the gradual formation of new cortical layers of bone, bone remodeling, osteoblasts and osteoclasts. Compared to the machined-surface, significantly higher BIC values were found for the OSSEOTITE Surface at two months in basal bone (27.06 ± 9.4 vs. $14.71 \pm 7.43\%$); at three months in both basal (34.42 ± 10.61 vs. $10.97 \pm 7.15\%$) and in regenerated bone (11.46 ± 7.94 vs. $5.49 \pm 4.89\%$); and at five months in basal bone (32.58 ± 11.48 vs. $23.03 \pm 14.18\%$).

2. Qahash M, Hardwick WR, Rohrer MD, Wozney JM, Wikesjö UM. **Surface-etching enhances titanium implant osseointegration in newly formed (rhBMP-2-induced) and native bone.** *Int J Oral Maxillofac Implants.* 2007;22:472-7.

The objective of this preclinical study was to compare histological outcomes (bone density and BIC) for a machined surface and the OSSEOTITE Surface in newly formed bone and in native bone. In the mandibular premolar regions of each of eight Labrador mongrel dogs, 5mm supra-alveolar periimplant defects were surgically created and one custom OSSEOTITE and two machined implants were placed. In one defect per animal a collagen sponge loaded with rhBMP-2 (0.4mg) and an e-PTFE space-providing structure were placed to induce new bone formation. After eight weeks of healing, implants were removed en bloc and processed for histological analysis. Although there were no significant differences in bone density, there were statistically significant differences in BIC for OSSEOTITE Implants compared to machine-surfaced implants and for OSSEOTITE Implants in native bone.

3. Lucente J, Trisi P, Galante J, Kenealy JN. **Reintegration success of OSSEOTITE Implants after intentional counter-torque liberation: a prospective study in the edentulous human mandible.** *Implant Dent.* 2006;15:178-185.

An implant that rotates during abutment screw tightening may not necessarily constitute implant failure. Therefore, in this study, custom implants were placed at the symphysis of the anterior mandible in 11 patients and intentionally counter-torqued at second stage surgery (T1). The implants were returned to original positions, allowed to heal for a period and counter-torqued again (T2). The results show that the peak values for T2 were greater than T1 values for most of the test implants. Histology staining showed distinction between old and new bone, which formed during the remodeling process.

4. Ramaglia L, Di Spigna G, Saviano R, Postiglione L, Capece G, Rossi G. **Proliferation and differentiation of human fibroblast cells on titanium implant surfaces.** Europerio June 29-30-July 1, 2006 (Madrid, Spain) Accepted for Poster presentation.

In order to evaluate whether surface roughness affects periimplant healing, human gingival fibroblast cells were cultured *in vitro* on CpTi disks featuring either a machined or OSSEOTITE Surface. A 3H-thymidine incorporation assay was used to measure DNA synthesis. The production of extracellular matrix (ECM) proteins was assayed by immunoassay and by immunoblotting with specific antibodies. The results show no significant difference in adhesion of fibroblasts and cell proliferation after three hours and up to 14 days between the two surface topographies. The OSSEOTITE Surface showed a favorable interaction with human gingival fibroblasts and may not modify the biological behavior of human gingival fibroblasts *in vivo*.

5. Romanos G, Testori T, Degidi M, Piatelli A. **Histologic and Histomorphometric findings from retrieved, immediately occlusally loaded implants in humans.** *J Periodontol.* 2005;76:1823-1832.

This study includes two edentulous mandibular cases in which additional OSSEOTITE Implants were placed and immediately loaded for retrieval after two and four months. Bone-To-Implant Contact (BIC) for the two implants in the two month healing case were 38.9% and 64.2%. For the four month biopsies, histology revealed bone contacting the entire implant surface and the presence of old bone and new bone formation. BIC was 80% and 81.5% for the two samples. Independent of location or implant design, all of the immediately loaded implants in this series of cases showed formation of new bone at the implant interface.

Studies Evaluating The Effects Of The OSSEOTITE® Surface (continued)

6. Veis AA, Trisi P, Tsirlis AT, Parissis NA, Desiris AK, Lazarra RJ. **Osseointegration of OSSEOTITE and machined titanium implants in autogenous bone graft. A histologic and histomorphometric study in dogs.** *Clin Oral Impl Res.* 2004;15:54-61.
Twenty-two 10mm custom split-surfaced (OSSEOTITE and machined) implants were placed between the cranial and caudal dorsal iliac spine at the iliac wing of two adult mongrel dogs. A 2mm artificial bone defect was created around the coronal 5mm of each implant, filled with particulate autogenous bone graft and covered by a membrane. The apical 5mm of the implants were stabilized in basal bone. After five months of healing, the resulting Bone-To-Implant Contact (BIC) at the OSSEOTITE Surface (46.4%) was significantly higher than at the machined side (28.5%) in regenerated bone. The OSSEOTITE BIC (32.3%) was also significantly higher than the machined surface (17.2%) in basal bone areas.
7. Weng D, Hoffmeyer M, Hürzeler MB, Richter EJ. **OSSEOTITE vs. machined surface in poor bone quality. A study in dogs.** *Clin Oral Impl Res.* 2003;14:703-708.
Following extraction of premolars in five fox hounds and eight months healing, two machined and two OSSEOTITE Implants were inserted into the mandible with the apex located in the "hollow" part of the mandible, where bone quality is poor. After four months of healing, density measurements revealed similar bone contents in the apical areas for both implant groups. The OSSEOTITE Implant surface however, had a significantly higher mean Bone-To-Implant Contact (62.9%) compared to the machined (39.5%) surface.
8. Ogawa T, Nishimura I. **Different bone integration profiles of turned and acid-etched implants associated with modulated expression of extracellular matrix genes.** *Int J Oral Maxillofac Implants.* 2003;18:200-210.
T-shaped hollow implants with machined and OSSEOTITE Surfaces were placed into rat femurs. At two weeks, the Bone-To-Implant Contact (BIC) rate for OSSEOTITE was six times higher than the BIC rate for the machined surface, and 2.5 times higher at four weeks. Using reverse transcriptase-polymerase chain reactions, the mRNA expression of selected extracellular matrix genes was accelerated and up-regulated at the OSSEOTITE Surface in comparison to the machined surface at initial healing stages. This data provided evidence that the gene regulation of bone healing was occurring at the local level of the OSSEOTITE Surface *in vivo*.
9. Trisi P, Lazzara R, Rebaudi A, Rao W, Testori T, Porter SS. **Bone-implant contact on machined and OSSEOTITE Surfaces after 2 months of healing in the human maxilla.** *J Periodontol.* 2003;74:945-56.
Using a split-surfaced custom implant, this study evaluated Bone-To-Implant Contact (BIC) after two months of submerged healing in the posterior maxilla of 11 patients. 47.8% mean BIC on the OSSEOTITE side was statistically higher than 19.0% mean BIC on the machined side. In areas of low-density bone, the difference was even greater. Compared to an estimation based on the surrounding bone volume, which represented the expected BIC, the actual BIC observed for OSSEOTITE was 39% greater. For the machined surfaces, the actual BIC decreased 44%. The results demonstrated that sufficient bone for functional loading existed on the OSSEOTITE Surface after two months of healing.
10. Trisi P, Lazzara R, Rao W, and Rebaudi A. **Bone-implant contact and bone quality: evaluation of expected and actual bone contact on machined and OSSEOTITE Implant surfaces.** *Int J Periodontics Restorative Dent.* 2002;22:535-545.
A new technique uses histomorphometrics to estimate the percentage of Bone-To-Implant Contact (BIC) that may be expected on an implant surface in relation to the quality of the surrounding bone. Measurements and estimates were for a custom split-surfaced (OSSEOTITE and machined) implant that was placed in the posterior maxilla of 11 patients and allowed to heal for six months. The actual mean BIC for the OSSEOTITE Surface was greater than the expected mean BIC calculated with this technique. For the machined surface, the actual BIC was mostly lower than expected. The OSSEOTITE Surface appeared to exert a positive, conductive effect on the bone approaching the implant surface.
11. Ozawa S, Ogawa T, Iida K, Sokotjo C, Hasegawa H, Nishimura R, Nishimura I. **Ovariectomy hinders the early stage of bone-implant integration: histomorphometric, biomechanical and molecular analyses.** *Bone.* 2002;30:200-210.
OSSEOTITE Implants were placed in the femurs of ovariectomized (ovx) and sham-operated control rats to study whether female gonadal hormone deficiency interfered with osseointegration. T-cell implants had hollow chambers for bone ingrowth and unthreaded implants were used for push-in tests. The ovx group had approximately half the push-in value as compared to the control group, although differences diminished after week 4. Total RNA samples were examined and significant upregulation of genes was observed in the sham-implant group. The results suggested a biphasic effect of female gonadal hormone deficiency that may temporarily interfere with the early implant-tissue integration process and which may be associated with failure to upregulate a selected set of bone extracellular matrix genes. Once established, however, functional bone-implant integration could be achieved, even in ovariectomized rats.

Studies Evaluating The Effects Of The OSSEOTITE® Surface (continued)

12. Vernino AR, Kohles SS, Holt Jr. RA, Lee HM, Caudill RF, Kenealy JN. **Dual-etched implants loaded after 1- and 2-month healing periods: a histologic comparison in baboons.** *Int J Periodontics Restorative Dent.* 2002;22:399-407.

A total of 80 OSSEOTITE Implants was functionally loaded with single crowns after either one or two months and biopsied following three months of function. Bone-tissue contact along a standardized region of each implant was calculated. Implants loaded after one month of healing had a mean of 76.6% + 14.4%, and implants loaded after two months of healing had a mean of 77.2% +/- 12.2% bone contact (P = .81). Reducing the surgical healing time from two months to one month did not statistically affect the amount of bone observed at the tissue-implant interface.

13. Abrahamsson I, Zitzmann NU, Berglundh T, Linder E, Wennerberg A, Lindhe J. **The mucosal attachment to titanium implants with different surface characteristics: an experimental study in dogs.** *J Clin Periodontol.* 2002;29:448-55.

After implants had healed for three months, abutments with OSSEOTITE or machined surfaces were connected to study the composition of the soft tissue barrier. After six months during which plaque control had been maintained, biopsies including the implant and surrounding soft and hard tissues were obtained. Profilometry showed the attachment between the periimplant mucosa and abutments was similar from both a quantitative and a qualitative aspect and was comprised of a barrier epithelium and a zone of connective tissue. The "inner" zone of the connective tissue was composed of about 30-33% fibroblasts and 63-66% collagen. The soft tissue attachment that formed was not influenced by the roughness of the titanium surface.

14. London RM, Roberts FA, Baker DA, Rohrer MD, O'Neal RB. **A histologic comparison of a thermal dual-etched implant surface to machined, TPS and HA surfaces: bone contact in vivo in rabbits.** *Int J Oral Maxillofac Implants.* 2002;17:369-76.

Implants with DAE, Machined, TPS and HA surfaces were placed in rabbit tibia and assessed histomorphometrically after one to eight weeks. The OSSEOTITE Surface achieved higher levels of bone contact percentage than the other surfaces. There was no correlation between degree of roughness and bone contact percentage. The specific texture of the OSSEOTITE Surface yielded more contact, possibly as the result of better fibrin clot retention and growth factor enhancement, particularly in early healing.

15. Park JY, Gemmell CH, Davies JE. **Platelet interactions with titanium: modulation of platelet activity by surface topography.** *Biomaterials.* 2001;22:2671-82.

CpTi disks with four different surfaces were evaluated for platelet activities, measured by quantifying platelet adherence, platelet-derived microparticle (MP) formation and P-selectin expression. Platelet adhesion was increased on OSSEOTITE and grit-abraded surfaces compared to machined and polished surfaces. Platelet-derived microparticle formation and P-selectin expression also showed increased activation of platelets on OSSEOTITE and grit-abraded surfaces. Because increased activation of platelets may lead to up-regulation of osteogenic responses during bone healing, these results may explain the enhanced osteoconductivity known to occur with OSSEOTITE Surfaces in comparison to machined surfaces.

16. Testori T, Szmukler-Moncler S, Francetti L, Del Fabbro M, Scarano A, Piattelli A, Weinstein RL. **Immediate loading of OSSEOTITE Implants: a case report and histologic analysis after 4 months of occlusal loading.** *Int J Periodontics Restorative Dent* 2001;21:451-9.

A histologic evaluation was performed on two immediately loaded mandibular OSSEOTITE Implants, which were retrieved after four months of function from one patient. The protocol involved bilateral splinting of six implants, of which six were immediately loaded and six were left to heal in a submerged manner. Histomorphometric evaluation revealed high levels of Bone-To-Implant Contact ranging from 78% to 85%.

17. Abrahamsson I, Zitzmann NU, Berglundh T, Wennerberg A, Lindhe J. **Bone and soft tissue integration to titanium implants with different surface topography: an experimental study in the dog.** *Int J Oral Maxillofac Implants.* 2001;16:323-332.

In 5 beagle dogs, 4 machined implants and 4 hybrid OSSEOTITE Implants were placed and abutments were connected after three months. After six months, biopsies were obtained and processed. In ground sections, Bone-To-Implant Contact (BIC) and bone density assessments were made in 2 different zones: Zone I represented the marginal level of BIC to a position 4mm above the apex and Zone II represented the apical 4mm of the implant. For machined implants, the BIC was 56.1% in Zone II and 58.1% in Zones I & II. The corresponding BICs for OSSEOTITE Implants were significantly larger: 76.7% and 72.0%.

Studies Evaluating The Effects Of The OSSEOTITE® Surface (continued)

18. Klokkevold PR, Johnson P, Dadgostari S, Caputo A, Davies JE, Nishimura RD. **Early endosseous integration enhanced by dual acid etching of titanium: a torque removal study in the rabbit.** *Clin Oral Impl Res.* 2001;12:350-57.

Because torque removal forces have been used as a biomechanical measure of endosseous integration, this study compared OSSEOTITE, TPS and machined surfaces. Groups of six rabbits with OSSEOTITE, TPS and machined implants placed in femurs were sacrificed after one, two and three months of healing. Implants were removed by reverse torque rotation with a digital torque-measuring device. At one month, the stability of the OSSEOTITE Implant was comparable to that of TPS. The results demonstrated that OSSEOTITE Implants developed enhanced bony anchorage compared to machined implants to a level which was comparable to that achieved by the topographically more complex TPS surface.

19. Park JY, Davies JE. **Red blood cell and platelet interactions with titanium implant surfaces.** *Clin Oral Impl Res.* 2000;11:530-539.

This study investigated initial blood cell-implant interactions on implant surfaces by observing the blood components that remained at the surface following freeze-fracture of clotted and fixed human blood. At the interface, immunolabeling identified predominantly fibrin and red blood cells. The OSSEOTITE Surface showed, qualitatively, more platelets than machined surfaces. These early blood cell-implant interactions may play a key role in the osteoconduction stage of periimplant bone healing responses to micro-roughened implants.

20. Ogawa T, Ozawa S, Shih J, Ryu K, Sukotjo C, Yang J-M, Nishimura I. **Biomechanical evaluation of osseous implants having different surface topographies in rats.** *J Dent Res.* 2000;79:1857-1863.

The objective of this study was to validate an established rat push-in test model to assess the degree of osseointegration by the breakpoint load at the implant-tissue interface and to compare the effects of different implant surface topographies. Miniature titanium implants were placed at the distal edge of adult rat femurs and push-in test values were obtained at four post-implantation healing points (weeks 0, 2, 4 and 8). Values significantly increased in a time-dependent manner. Values for the OSSEOTITE Surface showed significantly greater push-in test values than did machined implants throughout the experimental period ($p < 0.0001$).

21. Cordioli G, Majzoub Z, Piatelli A, Scarano A. **Removal torque and histomorphometric investigation of 4 different titanium surfaces: an experimental study in the rabbit tibia.** *Int J Maxillofac Implants.* 2000;15:668-674.

This study obtained removal torque values and Bone-To-Implant Contact for the OSSEOTITE Surface and compared the data to values for machined, grit-blasted and plasma-sprayed surfaces. Using the rabbit tibia model with a five week healing period, histomorphometric and removal torque data revealed a significantly higher percentage of Bone-To-Implant Contact and removal torque for OSSEOTITE Implants compared to machined, blasted and plasma-sprayed implants. Throughout a short healing time of five weeks, the OSSEOTITE Surface in this study, achieved 33% greater Bone-To-Implant Contact and provided enhanced mechanical interlocking.

22. Lazzara RJ, Testori T, Trisi P, Porter SS, Weinstein RL. **A human histologic analysis of OSSEOTITE and machined surfaces using implants with two opposing surfaces.** *Int J Periodontics Rest Dent.* 1999;19:117-129.

Implants were threaded, titanium and 2mm x 5mm in dimension. One side received the OSSEOTITE Surface and the opposite side had a machined surface. Eleven patients received a test implant placed in the posterior maxilla (Types III and IV bone), which was allowed to heal submerged for six months. Samples were removed with surrounding hard tissue and the mean Bone-To-Implant Contact (BIC) was calculated for each surface. The mean BIC for OSSEOTITE ($72.96\% \pm 25.13\%$) was statistically significantly higher ($P < 0.05$) than the mean BIC for machined surfaces ($33.98\% \pm 31.04\%$). In the poorer quality bone typically found in the posterior maxilla, a statistically significantly higher percentage of bone contacted the OSSEOTITE Surface when compared to the machined surface.

23. Baker D, London RM, O'Neal R. **Rate of pull-out strength gain of dual-etched titanium implants: a comparative study in rabbits.** *Int J Oral Maxillofac Implants.* 1999;14:722-728.

A rabbit tibia model was used to measure an Instron peak pull-out force for OSSEOTITE Implants in comparison to machined-surfaced implants. The failure shear loading tests were carried out in five rabbits at weeks 1, 2, 3, 4, 5 and 8. Beginning at week three, there was a statistically significant difference ($P < .01$) in strength between OSSEOTITE and machined implants and a significant increase in strength between weeks 5 and 8 (a 3.2-fold greater increase). OSSEOTITE Implants demonstrated a more rapid rate of pull-out strength gain and remained significantly stronger throughout the study.

Studies Evaluating The Effects Of The OSSEOTITE® Surface (continued)

24. Davies JE. **Mechanisms of endosseous integration.** *Int J Prosthodont.* 1998;11:391-401.

Bone growth on an implant surface, termed contact osteogenesis, is a biologic response that can be subdivided into three distinct integration mechanisms. The first, osteoconduction, relies on the migration of differentiating osteogenic cells to the implant surface through a temporary connective tissue scaffold. Anchorage of this scaffold to the implant surface is dependent on implant surface topography. The second, de novo bone formation, results in a mineralized interfacial matrix laid down on the implant surface. Surface topography determines if the interfacial bone bonds to the implant. The third, bone remodeling, creates a bone-implant interface at discrete sites, comprising de novo bone formation. The author recognizes that future treatment outcomes in dental implantology will be critically dependent on implant surface designs and roughened topographies, such as the OSSEOTITE Surface.

25. Klokkevold PR, Nishimura RD, Adashi M, Caputo AM. **Osseointegration enhanced by chemical etching of the titanium surface. A torque removal study in the rabbit.** *Clin Oral Impl Res.* 1997;8:442-447.

One OSSEOTITE and one machined-surfaced implant were placed in femurs of 10 rabbits and allowed to heal for two months. The implants were removed under reverse torque rotation and the peak force was documented with a digital torque measuring device. This force value was used as a biomechanical measure of osseointegration. All but two machined-surfaced implants were observed anchored to bone. For the OSSEOTITE Implant group, the mean torque value was four times greater ($20.50 \pm 6.59\text{Ncm}$) than the mean for the machined implants ($4.95 \pm 1.61\text{Ncm}$).

Clinical Evaluations Of Prosthetic Restorations On OSSEOTITE Implants

1. Östman PO, Hellman M, Sennerby L, Wennerberg A. **Temporary implant-supported prosthesis for immediate loading according to a chairside concept: technical note and results from 37 consecutive cases.** *Clin Implant Dent Relat Res.* 2008;10:71-7.

This prospective study evaluates the QuickBridge® Chairside Technique for immediately restoring partial and edentulous cases. QuickBridge Components consist of titanium alloy cones, which attach to the implant with a screw torqued to 20Ncm and a PEEK cap, which is snap-fit to an abutment. Thirty-seven patients were treated with a total of 132 implants. The cases consisted of 10 partial mandibular, 12 partial maxillary, 7 full mandibular and 8 full maxillary immediately-loaded fixed restorations. The implants that were placed consisted of: 7 OSSEOTITE, 22 OSSEOTITE Tapered, 32 OSSEOTITE Certain® PREVAIL® and 71 NanoTite™ Certain PREVAIL Implants. During six months of follow-up no implant failures occurred. One provisional prosthesis fractured after 10 days. No adverse soft tissue reactions were observed.

2. Karamanis S, Angelopoulos C, Tsoukalas D, Parissis N. **Immediate flapless implant placement and provisionalization: challenge for optimum esthetics and function: a case report.** *J Oral Implantol.* 2008;34:52-8.

In this case study, the flapless surgical technique for the immediate replacement of an extraction socket is demonstrated. A 23 year-old woman presented with a fractured root of the maxillary right central incisor and was treated with an atraumatic extraction, and an OSSEOTITE Tapered Implant, 5mm diameter and 15mm length, placed 5mm beyond the apex of the socket. Following impressioning, a healing abutment was placed while a provisional acrylic resin crown was fabricated; six hours later the crown was connected onto a BIOMET 3i UCLA Abutment and adjusted out of occlusion. At the five month evaluation, the crown was removed and adjusted into centric occlusion and working excursions. After seven months of function, the following observations were made: the depth of the periimplant sulcus remained unchanged (1.5mm); slight interproximal bone resorption was visible radiographically (~0.3mm); no clinical signs or symptoms of implant failure were recorded; and the integrity of the soft tissue produced favorable aesthetics.

Clinical Evaluations Of Prosthetic Restorations On OSSEOTITE® Implants (continued)

3. Ramsey CD. **Single-tooth replacement of a maxillary central incisor via immediate implant placement.** *Pract Proced Aesthet Dent.* 2007;19:355-7.

When a patient presents for replacement of a maxillary central incisor, the primary concerns are matching the aesthetics of the adjacent incisors and maintaining proper phonetics. Recently, it has been proposed that the technique that best satisfies these concerns is immediate implant replacement of teeth and provisionalization. This procedure frees the patient from the discomfort of having to wear a transitional removable prosthetic, and can offer clinical benefits such as support of interproximal gingival tissues and papilla height. This case report detailed treatment of a maxillary central incisor in a 63-year-old female. Following atraumatic, flapless extraction, an OSSEOTITE Certain® Implant was placed and positioned such that it did not contact the buccal plate. The abutment was torqued to 35Ncm and after chairside preparation in the mouth, the acrylic resin provisional crown was seated. Following a four-month healing period, the definitive all-ceramic crown was delivered. Photographs of the case detailed the technique step-by-step and demonstrated how the aesthetic outcome was achieved, matching the contour, shade and texture of the adjacent incisor.

4. Schropp L, Kostopoulos L, Wenzel A, Isidor F. **Clinical and radiographic performance of delayed-immediate single-tooth implant placement associated with periimplant bone defects. A 2-year prospective, controlled, randomized follow-up report.** *J Clin Periodontol.* 2005;32:480-7.

This study compares single-tooth OSSEOTITE Implants placed according to an immediate loading protocol (10 day average post-extraction) with those placed according to a delayed loading protocol (three months post-extraction). Two-year survival rates were 91% for the immediate group and 96% for the delayed group. Probing pocket depths were reduced up to 1.4mm on average (no significant difference between groups). Follow-up data also demonstrated that the periimplant bone defects present at extraction sites at the time of implant placement did not affect long-term pocket depths, marginal bone loss or restorative function.

5. Goené R, Bianchesi C, Huerzeler M, Del Lupo R, Testori T, Davarpanah M, Jalbout Z. **Performance of short implants in partial restorations: three years follow-up of 7-mm and 8.5-mm OSSEOTITE Implants.** *Implant Dent.* 2005;14:274-80.

For this retrospective multicenter study, a total of 188 patients received 311 short OSSEOTITE Implants placed primarily in soft bone. Of 216 partially edentulous cases, 95.2% were short-span fixed dentures placed in the posterior sextants. During three years of follow-up, 13 implants failed, yielding a cumulative success rate of 95.8%. In nine cases, implant failure occurred prior to prosthesis insertion and occlusal loading. In comparison to success rates of implants in general, the short-length OSSEOTITE Implants in this study performed favorably.

6. Mayer TM, Gunsolley JC, Feldman S. **The single-tooth implant: a viable alternative for single tooth replacement.** *J Periodontol.* 2002;73:687-93.

This prospective, multicenter five-year clinical trial was designed to evaluate the performance of OSSEOTITE Implants placed under conditions of increased risk as single-tooth restorative cases. Seventy-one implants were placed in 59 patients and followed for 30.9 to 60 months (mean 45.9 months). A total of 13 implants (18.4%) were placed in soft, poor quality bone. Bone augmentation and immediate replacement of extraction sockets were also performed if indicated. One implant failed yielding a 98.6% survival rate.

7. Gaucher H, Bentley K, Roy S, Head T, Blomfield J, Blondeau F, Nicholson L, Chehade A, Tardif N, Emery R. **A multi-centre study of OSSEOTITE Implants supporting mandibular restorations: a three-year report.** *J Can Dent Assoc* 2001;67:528-33.

A total of 688 OSSEOTITE Implants was placed in 172 patients; 43.5% were placed in the anterior mandible and 66.5% in the posterior mandible. Fifteen percent of the implants were placed in soft bone, 56.9% in normal bone and 28.1% in dense bone. After 36 months, five implants had failed for a cumulative survival rate of 99.3%.

8. Grunder U, Gaberthuel T, Boitel N, Imoberdorf M, Meyenberg K, Andreoni C, Meier T. **Evaluating the clinical performance of the OSSEOTITE Implant in maxillary and mandibular posterior areas: defining prosthetic predictability.** *Compend Contin Educ Dent.* 1999;20:628-640.

A total of 219 OSSEOTITE Implants was placed primarily in the posterior regions of 74 patients according to a conventional two-stage surgical protocol with a mean healing time of 6.2 ± 2.0 months. At a 34.4 month interim evaluation, a total of three implants in the posterior maxilla had failed prior to loading. No implant failures occurred after prosthetic restoration. The cumulative survival rates were 98.4% for the posterior implants and 100% for all implants post-loading. Once restored at second-stage surgery, the OSSEOTITE Implants in this study maintained a stable state of integration.





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