Summaries of Scientific Publications

NanoTite™ and OSSEOTITE® PREVAIL® Implants

August 2009
Introduction
Primary implant stability is considered to be a prerequisite for implant success and may be especially critical for immediate loading procedures. Primary stability depends on the case, bone density, jaw region, osteotomy preparation, surgical technique and both implant design and surface treatment. Preclinical studies have shown that implants with the NanoTite Surface, created by adding calcium phosphate nano-crystals to the OSSEOTITE® Dual Acid-Etched (DAE) surface, have higher rates and extent of Bone-to-Implant Contact (BIC) in comparison to implants with the DAE surface alone. The objective of the present single-center study was to place NanoTite Implants using a strict protocol based on primary stability for the immediate loading of single, unilateral and full-arch fixed restorations.

Materials and Methods
Criteria for immediate loading included a minimum torque value of 25Ncm and an ISQ value of ≥55 measured with an Osstell Mentor Device. Of 38 patients, 35 who met the inclusion criteria had cases that satisfied the criteria for immediate loading. Study implants were NanoTite Certain® PREVAIL Implants (diameter of 4/5/4mm x lengths of either 8.5, 10, 11.5, 13 or 15mm) and were placed into undersized osteotomies with a countersinking technique to engage cortical bone with the expanded collar design. The final drill was chosen according to the predominant local bone quality. In Type I bone, the final drill diameter selected was 3.25mm; in Type II bone, 3.0mm; and in Type III and IV bone, 2.75mm. A total of 102 implants were restored: 64 implants with QuickBridge® Provisional Components for multiple-unit restorations, 14 implants with PreFormance® Posts for single-tooth restorations and 24 implants with maxillary full-arch fixed prostheses (four cases) (Fig. 1). Single-unit restorations were restored without occlusal contact. Follow-up evaluations were scheduled at 3, 6 and 12 months to assess oral hygiene, mucosal health, prosthetic function and radiographic marginal bone regression. Definitive restorations were placed at six months at which time ISQ values were measured.

Results
Of the 102 implants, one implant supporting a 3-unit fixed partial denture in the anterior maxilla failed at three months. According to Life-table analysis, the cumulative survival rate after one year was 99.2% and success criteria of Grade 1, (according to the guidelines of Albrektsson and Zarb) was determined for 93% of the study implants. One restoration, a provisional unilateral fixed partial denture, became mobile due to abutment screw loosening. Mean bone loss was 0.37mm and ISQ units scored at implant placement ranged from 55 to 87 and the mean value was 73.4 ± 8.

Discussion
A modified drilling protocol intended to achieve primary stability was accomplished by adapting the final drill to the bone density. Use of this recommendation appears to have accounted for the success of the immediately-loaded cases presented here. In addition, placing implants into undersized osteotomies with insertion torque values of at least 25Ncm and the lower limit ISQ value of 55 units is also important to achieve primary stability. By splinting multi-unit restorations and placing single-unit restorations out of occlusion, the risk of micromotion at the implant interface is reduced during the healing period when de novo bone formation takes place.

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Immediate Provisionalization of NanoTite™ Implants in Support of Single-Tooth and Unilateral Restorations: One-Year Interim Report of a Prospective, Multicenter Study

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Introduction
The original two-stage implant healing protocol allowing implants to heal submerged for four to six months was intended to address concerns of micromotion, which could potentially disturb healing and result in implant failure. Study results soon showed that submerged healing time periods could be reduced and in fact be eliminated by placing an immediate provisional restoration, which included many benefits such as restoring the patient to function without a waiting period and reducing chairtime. Due to concerns for bone loading trauma however, prostheses were primarily limited to fixed multi-unit restorations placed without occlusal contacts and in locations where lateral support or cross-arch stabilization could be provided. The objective of the present, prospective, multicenter study was to immediately load NanoTite Implants with single-tooth restorations and unilateral fixed restorations in a broad range of patients, representative of those seen in a typical dental practice.

Materials and Methods
In a six-month period, 15 international study centers sought to enroll 15 patients each. A total of 335 NanoTite Certain® PREVAIL® Implants were placed in 185 patients (56% female and 44% male) with a mean age of 51.5 years. Investigators had their choice of restorative procedures, BIOMET 3i Prosthetic Components and whether to place restorations in contact with opposing dentition or out of occlusion. Within 48 hours of implant placement, 216 provisional prostheses were delivered: 128 single-tooth restorations and 88 unilateral restorations (Fig. 1). Most of the investigators selected PreFormance® Posts and the majority of all abutment preparations were performed chairside, with 80% of all cases having cement retention. Definitive restorations were delivered at six months post-implant placement and provisionalization. Annual follow-up visits were scheduled for five years at which time implant and prosthesis function were to be assessed.

Results
After one year of follow-up, 17 implants in 11 patients have failed and the one-year cumulative survival rate for 335 implants is 94.9%. Of the failed implants, 15 were associated with signs and/or symptoms of infection or persistent paresthesia or radiolucencies. Eighty-two percent of all implant failures were declared within the first three months after implant placement prior to definitive restorative procedures.

Discussion
The design of this prospective, multicenter study intentionally included unrestricted admission criteria and the single-tooth and short-span fixed restorations were allowed to be in direct occlusal contact. Because such a large number of clinical centers participated in the study, details were provided on the restorative approaches and components that the investigators selected. These may prove to have had an impact on the performance of the NanoTite Implants that contain a complex nanotopography with higher rates of Bone-to-Implant Contact (BIC) when compared to the untreated dual acid-etched OSSEOTITE® Surface. A large proportion (60%) of single-tooth restorations were placed in this study and based on a Medline Database search (380 citations) that resulted in twelve qualified peer-reviewed publications, this study has the largest number of immediately-loaded single-tooth restorations (128) to date with a comparable Cumulative Survival Rate (CSR) of 94.9%.

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Introduction

Observations have shown that the distance between two adjacent implants can affect lateral bone loss and interproximal bone peak resorption that occurs after implants are exposed to the oral environment. A distance of more than 3.0mm between two adjacent implants appears to preserve the interproximal bone peak and results in only 0.45mm of resorption on average. An interimplant distance of 3.0mm or less, however, increases bone-peak resorption to 1.04mm, compromising support of interimplant papillae. Studies have shown that the platform switching technique results in almost 70% less vertical bone resorption in comparison to conventional matching implant-abutment-systems. The effects of platform switching on horizontal bone loss have not been previously explored. This study was designed to examine the effects of platform switching on both vertical and horizontal bone loss when implants are placed less than 3.0mm apart.

Materials and Methods

Eighty-two adjacent OSSEOTITE® PREVAIL® Implants were placed in 37 patients (20 women and 17 men), with 27 pairs placed in the maxilla and 14 in the mandible. At six and 24 months after the implants were definitively restored, periapical radiographs were taken, employing a mouthpiece to ensure a parallel technique and reproducibility. The distances between the two implants were measured at the shoulder in horizontal and vertical directions to compare levels to preoperative radiographs. If the bone peak extended coronally beyond an imaginary line connecting the two implant-abutment interfaces, it was expressed as a positive number in millimeters. If the bone peak did not reach the imaginary line, it was expressed as a negative number.

Results

The mean distance between implants was 2.23mm and no pair of implants was placed more than 3.0mm apart. Mean vertical bone resorption was 0.62mm and the mean horizontal component was 0.60mm. The peri-implant crestal bone peak was preserved in 26 of the 41 cases and the mean bone height preservation above an imaginary line connecting the two implant-abutment interfaces was 0.24mm. In seven cases, the implants were placed less than 2.0mm apart and yet the distance from the crestal bone peak to the imaginary line connecting the two implant-abutment interfaces was still positive.

Discussion

Because the design of this study required at least four abutment disconnections for the purposes of collecting radiographic data, it was reasonable to predict that these procedures may have had an impact on bone resorption. The results showed, however, that the mean vertical bone loss was 69% less (0.62mm), as compared to standard bone loss reported in the literature for non-platform switched implants (2.0mm) (Fig. 1). Regarding horizontal bone loss, there was also an improvement in preservation of bone - 57% (0.60mm) in comparison to previously published data for non-platform switched implants (1.4mm) (Fig. 1).

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Introduction
Early attempts at immediate loading of implants into extraction sites failed, in part, due to a lack of understanding of the biological and mechanical principles. In order to achieve predictable implant and aesthetic outcomes for immediate loading, the patient’s periodontal biotype and bone density, the inter-implant distance, the design of the abutment-implant connection and restoration, as well as formation of the biologic width, must all be considered. The concept of platform switching addresses the marginal bone resorption that occurs as the biologic width is re-established. Primary stability is critical to implant survival and it can be measured by insertion torque and determined by Resonance Frequency Analysis (RFA) expressed as Implant Stability Quotients (ISQ). The objective of this study was to report outcomes for implants immediately restored with the BIOMET 3i DIEM System for edentulous mandibles and maxillae.

Materials and Methods
One-hundred and five (1OS) 4.0mm and 5.0mm diameter Certain® PREVAIL® Implants (14 maxillary and 91 mandibular) were placed in 18 edentulous patients (15 female and three male) with a mean age of 55.97 years. An ISQ reading of 60 or above was a criterion for inclusion. Full-arch prostheses were screw-retained on IOL® Abutments (BIOMET 3i) using the DIEM Protocol. Definitive impressions were taken and sent to a BIOMET 3i PSR facility. CAD/CAM CAM StructSURE® Bars were custom fabricated within six days for each case and evaluated for a passive fit. RFA was performed on the day of implant placement and at 3, 12 and 16 months. To measure mesial and distal crestal bone levels, digital radiographs were taken on the day of surgery and at 3, 12 and 16 months.

Results
One maxillary implant failed in the maxilla of a 45-year-old female smoker and was discovered at three months, the time of definitive prosthesis placement. Implants were immediately loaded in 68 patients for which the Cumulative Survival Rate (CSR) is 98.6%. Mean marginal bone loss was calculated as a change from the baseline to 16 months at 0.6mm (minimum -2.6mm and maximum 0.8mm). Mean ISQ values for the maxilla and mandible were recorded at implant placement, 3, 12 and 16 months, and are presented in Fig. 1. Data were analyzed by ANOVA according to implant diameter and width, intra-patient, location in either maxillae or mandibles, and by follow-up time period; only time was determined to be a statistically significant factor after 16 months of follow-up. There was also a difference between mandible and maxilla ISQs (Fig. 1).

Discussion
The high implant survival rate and minimal marginal bone loss reported for implants placed with the immediate loading procedure in this study may be partly attributable to the platform switching technique. It is suggested that the following factors may also have an impact on success and preservation of bone levels: primary implant stability, implant design, bone quality, occlusion, subcrestal placement of the implant to establish sufficient soft-tissue depth, a flapless surgical technique, and rigid splinting of implants at placement. Long term, prospective studies are needed to evaluate platform switching and its application to immediate loading protocols.

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Introduction
Crestal bone loss is invariably noticed following connection of the abutment on two-piece implants and is attributed to an inflammatory response to micro-organisms colonizing the microgap of the Implant-Abutment Junction (IAJ). Ericsson, et al (1992) was the first to describe a zone of Inflammatory Connective Tissue (ICT) infiltrate in the junctional epithelium of the peri-implant mucosa and suggested that this zone is a result of the immune system response. The platform switching design of the PREVAIL® Implant medializes the IAJ, which moves the ICT inward and this is associated with lower rates of crestal bone loss. To date, there have been no human histological descriptions of the tissue around healed platform switched implants. For this report, the opportunity arose to study a human specimen when an integrated PREVAIL Implant had to be retrieved due to a prosthetic complication.

Materials and Methods
A 65-year-old female received three implants, which were placed in a single-stage surgical procedure for fabrication of an implant-supported removable overdenture. All three implants were PREVAIL Implants, which were 10.0mm in length with a 4.0mm diameter body, a 4.8mm diameter extended platform and a 4.1mm diameter seating surface. Clinical and radiological examinations showed all three implants to be osseointegrated. The implant placed at the center of the mandibular symphysis however, was positioned too far lingually and would have interfered with the lingual border of the prosthetic base. The implant was removed with a 6.0mm trephine under copious saline irrigation and was immediately fixed so that it could be sectioned and processed for histologic and histomorphometric analysis.

Results
The histology shows trabecular bone in contact with the implant surface, which measures approximately 65% Bone-to-Implant Contact (BIC). Under 100x magnification, the trabeculae appeared to be surrounded by osteoblasts secreting an osteoid matrix. Figures 1, 2 and 3 are the histologic section at three magnifications showing the IAJ where adjacent collagen fibers, plasma cells and lymphocytes can be seen. A zone of ICT infiltrate is clearly distinguishable at the IAJ extending vertically 0.35mm coronal to the IAJ along the healing abutment. The infiltrate however, was not detected apical to the implant platform. In the horizontal direction, the ICT infiltrate did not extend beyond the implant platform. Upon examination, it measured 0.35mm in the same dimension as if it had extended in the apical direction on a non-platform switched implant.

Discussion
Although the etiology of marginal bone remodeling is unknown, the most likely explanation is that it is a local inflammatory response to bacteria in the microgap of the IAJ. The inflammatory cell infiltrate that typically is observed adjacent to implants after exposure to the oral environment extends coronal to the IAJ (0.5 to 0.75mm) and apical to the IAJ (0.5 to 0.75mm). The ICT infiltrate is separated from the alveolar bone by a 1.0mm wide layer of healthy connective tissue and this seal serves to function as a barrier against bacterial invasion. When abutments of smaller diameter are placed, the distance from the microgap at the IAJ to the crest of the alveolar bone is greater such that the ICT is shifted inward and its impact on bone loss is reduced. In fact, the present study shows that by medializing the IAJ, the dimensions of the ICT are less in both coronal and apical directions.
Evaluation of Peri-Implant Bone Loss Around Platform-Switched Implants

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Introduction

Numerous studies in the literature on the physiology of marginal bone loss around endosseous implants attribute bone regression to the 1.5 to 2.0µm microgap between the abutment and seating platform of two-piece implants. This microgap has been associated with an Inflammatory Connective Tissue (ICT) infiltrate. The “biologic width”, a physiologic dimensional constant consisting of 1.0mm of connective tissue, 1.0mm of epithelium and 1.0mm of sulcus that exists adjacent to natural teeth has also been observed adjacent to implants. Inflammatory cells in the ICT may break the seal of the biologic width and affect osseous mechanisms. The platform switching concept of placing an abutment with a diameter smaller than the seating surface of the implant was first reported by Lazzara and Porter (2006), who observed preservation of marginal bone resorption on wide diameter BIOMET 3i Implants (5.0mm and 6.0mm) on to which they had placed abutments of smaller diameters. Platform switching restricts the ICT above the seating platform and has been observed to reduce crestal bone loss. This prospective clinical and radiographic study was designed to assess marginal bone levels around PREVAIL® Implants, which have an integrated platform switching feature, in comparison to non-platform switched implants.

Materials and Methods

Study implants were OSSEOTITE® Certain® (control) and OSSEOTITE Certain PREVAIL Implants (test). Both implant types have an internal connection and are fully dual acid-etched. A total of 45 patients were enrolled; 13 single-tooth implants (56 control and 75 test) were placed with a one-stage, flapless, subcrestal surgical technique. These were allowed to heal for eight weeks at which time provisionalization took place. After eight weeks in provisional restorations, the patients returned for placement of the definitive prostheses (porcelain fused-to-metal crowns). The patients were followed for at least 12 months. Standardized periapical radiographs were taken at implant placement, at the time of provisionalization, at definitive prostheses delivery and after 12 months of loading. Marginal bone was analyzed at each interval, which was calculated with computer-aided software.

Results

One patient who had received one test and one control implant dropped out of the study. One test implant in another patient did not achieve primary fixation, thus 73 test and 55 control implants remained. These were followed for up to one year post-loading. The cumulative survival rates were 98.3% for the test group and 100% for the control group. Mean crestal bone loss after one year of function was 0.95 ± 0.32mm for the platform switched implant group and 1.67 ± 0.37mm for the control group (P= .001) (Table 1).

Discussion

The peri-implant bone resorption that occurs after the uncovering of implants at second-stage surgery is a widely acknowledged physiologic bone response. Articles on platform switching have included histometric bone level outcomes and histological observations in animals and clinical studies. In the present study, the average 0.95mm of marginal bone loss for the PREVAIL® Implants after one year of function was statistically significant in comparison to the 1.6mm bone loss for the control group. This was less in comparison to bone loss reported in other studies. Minimizing marginal bone loss may help ensure implant stability, preserve soft tissue and maintain aesthetic gingival contours.

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Table 1

<table>
<thead>
<tr>
<th></th>
<th>No. Placed</th>
<th>Implant Platform (mm)</th>
<th>No. Lost</th>
<th>No. Failed</th>
<th>Success Rate (%)</th>
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<td>1</td>
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<tr>
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<td>0</td>
<td>100</td>
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