

***A Prospective Clinical Evaluation Of The
OSSEOTITE® 2 Dental Implant System:
Effectiveness Assessment.***

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Introduction

Evolutions in dental implant design have led to improved performance outcomes despite the expanded use of implant therapy across a wider range of patients. Implant materials, surfaces, abutment connection systems, and the components used to place the implants have all contributed to maintaining good performance while more patients and complicated cases are considered for implant therapy. Historically, the pioneering implant cases were organized as multi-unit fixed prostheses where the connection across implants provided stabilization. Recognized as essential for successful osseous fixation, initial implant stability remains a primary design consideration. For contemporary implant cases, such as immediate replacement of extraction sites, immediate loading,¹ single-tooth replacements² and placement in grafted sites,³ conditions for optimal initial stability are less likely. To address increasing expectations for effectiveness, engineering enhancements on dental implants to increase initial stability are therefore essential.⁴

Threshold For The Release Of A Modified System

The external-hexed OSSEOTITE® implant was launched in 1996 and the internal-connection OSSEOTITE® Certain® implant was launched in 2003. These have seen numerous design configurations over the years. Incremental changes to these implant systems include a tapered apical portion, an expanded implant seating platform, and a medialized abutment emergence that establishes an integrated platform-switch function. These various design configurations addressed contemporaneous needs of the clinician and patient. Attention continues to be focused on making further improvements to the performance of the OSSEOTITE® implant to address evolving needs.

Over the last several years, a consistent and pointed message received from clinicians is to examine further improvements in initial implant stability. Using creative

thinking, utilizing material science, and by observing the practice habits of effective clinicians, BIOMET **3i** engineers and designers advanced several macro-geometric design proposals for improving initial osseous engagement. When used according to the recommended placement procedures, these enhancements are the foundation for a new implant: The OSSEOTITE® 2 implant.

The modifications embodied in OSSEOTITE® 2 implants (Figure 1) include a longer straight-wall section of the implant, thread design changes, and changes in the apical cutting flutes. The existing Certain® and external-hex parallel-wall implants have a degree of apical taper. The OSSEOTITE® 2 implant has a smaller tapered segment at the apex thus extending the length of the straight portion. There is also a reduction in the height of the cutting flutes that varies proportionately with increasing implant dimension. On the 5 and 6mm

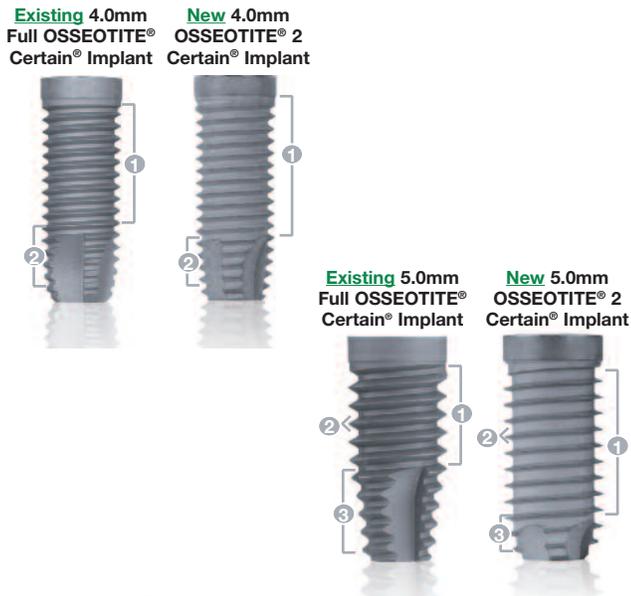


Figure 1: Representative design modifications

versions of the new implant, the apical portion has been modified to address the specific needs of the locations where these implants will be used. By having the thread form that continues to a more apical position, these wide diameter implants are designed to provide increased engagement with softer, low density bone where they are more likely to be used. This apical feature is not required of the 3.25 and 4mm diameter configurations and no change was made to those. The original Certain® internal-connection implant required the strength of titanium alloy to overcome loading forces capable of deforming or causing the implant collar to expand and affect abutment stability. Advances in materials processing however, have provided commercially-pure titanium capable of use in internal-connection implants. This material will be used in most new BIOMET **3i** implant designs. Lastly, the 5 and 6mm OSSEOTITE® 2 implant design inherits the thread design from the BIOMET **3i** Tapered Implant that has been shown to achieve high initial success rates in several projects.^{5,6}

Form Follows Function

When considered independently, these design elements would constitute an incremental enhancement to an existing implant design. When combined however, these

elements are designed to improve implant stability by increasing initial bone-to-implant contact or IBIC. As distinguished from the histological reference, IBIC is defined here as: the proportion of the subcrestal implant surface area that is placed in close approximation to osteotomy bone at implant placement. By reducing the apical taper, revising the thread design, and reducing the cutting flutes, there is more total implant surface area available for direct engagement with the osteotomy wall (Figure 1).

Inspection of OSSEOTITE® 2 implants placed in bone blocks and analysis using computer modeling has confirmed the increase in IBIC versus the original OSSEOTITE® design. This greater extent of surface approximation is considered valuable for two reasons: the first is based on principles of contact osteogenesis where the establishment of fibrin connection to the titanium oxide allows osteogenic cells access to the implant surface. Secondly, the reduction of the gap between bone and the implant surface may serve to increase initial stability, ensuring the integrity of the fibrin connection, allowing maximal migration of osteogenic cells to the implant surface where they may generate bone matrix outwards towards the osteotomy wall. Contact osteogenesis remains the primary hypothesis to explain the improvements in implant performance with modifications to the titanium surface⁷ (Figures 2 and 3).

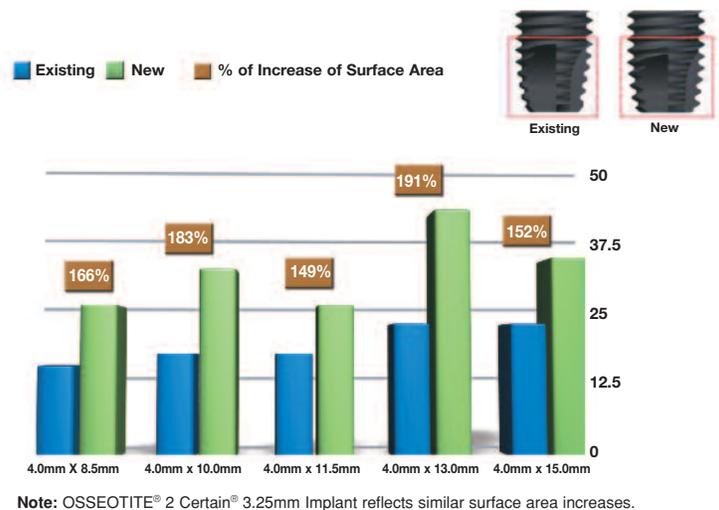
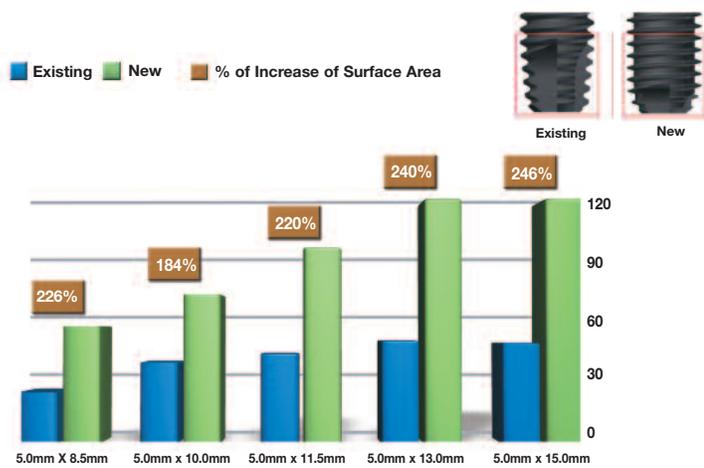


Figure 2: OSSEOTITE® 2 Certain® Implant 4.0mm Diameter Apical Surface Area



Note: OSSEOTITE® 2 Certain® 6.0mm Implant reflects similar surface area increases.

Figure 3: OSSEOTITE® 2 Certain® Implant 5.0mm Diameter Apical Surface Area

Associated with this increased proportion of bone to implant contact is the finding that placement torque force required to seat the implant is increased. The extent of insertional force that is applied to OSSEOTITE® 2 implants reflects the application of the IBIC concept in the clinical scenario. Having an implant designed specifically for increased IBIC allows for a formal evaluation of the hypothesis for improved outcomes with the increase in initial implant stability. Several prospective clinical evaluations are underway to test the outcomes of these design changes and test the hypothesis of increased IBIC on initial stability and the potential for improved outcomes. One of these clinical evaluations is described here: a prospective evaluation of the effectiveness of the OSSEOTITE® 2 system. Effectiveness relates to how well a treatment works in practice, as opposed to efficacy, which measures how well it works in clinical trials under controlled conditions. This report describes the conditions and outcomes of the OSSEOTITE® 2 clinical evaluation from evaluators using the new system for the first time.

Materials and Methods

Study Description

This prospective, observational clinical evaluation documents the effectiveness of the OSSEOTITE® 2

system for treating partially edentulous patients. Implants, associated drills and components, and a High Torque Indicating Ratchet Wrench (H-TIRW) (Figure 4) were provided to evaluators who agreed to



Figure 4: BIOMET 3i High Torque Indicating Ratchet Wrench (H-TIRW)

document cases from their private practice clinic. The project's goal is to characterize the placement experience with the OSSEOTITE® 2 implant system and determine if the new design produces the anticipated effects. Of primary interest is the association of initial bone engagement provided by the enhanced IBIC that may relate to higher implant success outcomes.

Investigators were selected from those currently using the Certain® straight-walled implants and who expressed interest in evaluating the new implant. Information on the new system was provided along with osteotomy preparation procedures and implant placement steps. No other protocol was promoted in terms of patient selection or the type of cases to be included in the evaluation – these were to be selected by the evaluators as a part of the clinical treatment of their patients. Each evaluator was requested to document at least 10 cases using the full range of implant dimensions within six months. Details of each case were documented on standardized data forms that collected patient demographics, baseline variables, surgical techniques,

measurement of insertion torques, restorative types, and integration outcomes. Data forms were collected and processed by the BIOMET **3i** Clinical Research Department.

Results

A total of 42 evaluators from 16 countries provided case information for 216 patients and 312 implant placement procedures from February 2010 to March 2011 as illustrated in Figures 5 and 6.

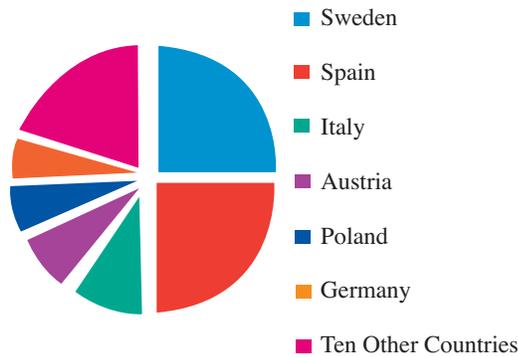


Figure 5: Source Of Cases

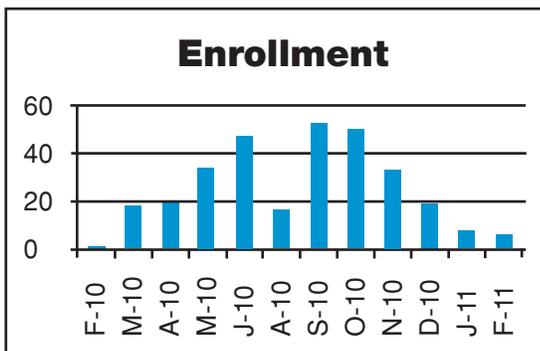


Figure 6: Enrollment By Month February 2010 - March 2011

Patients included in the evaluations had an average age of 52.3 ± 14 years and 57% are female. Implants placed in these cases are primarily in the posterior regions (73.9%) and in the maxillae (57%). Implant dimensions used in the cases are evenly divided between standard and wide-diameter implants. Implant lengths range from 8.5 to 15 mm as illustrated in Figure 7. Conditions of the implant sites were reported as having over three months of healing following tooth loss (63%) with 18% having

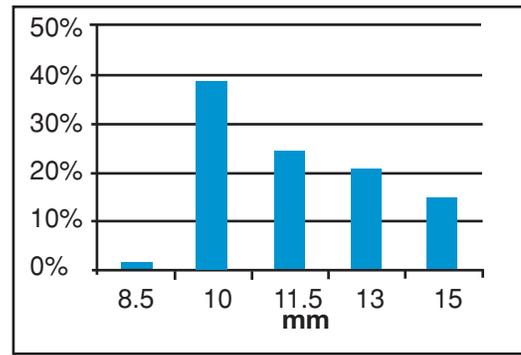


Figure 7: Implant Distribution By Length

less than three months healing, and 14% of implants were immediate replacements of an extracted site. Most sites are in native bone (88%) with the remainder having been treated with grafting material. The quality of bone as assessed during osteotomy preparation was reported as dense in 12% of cases, soft in 23%, and the rest was reported as in between these two ranks (65%). Use of a bone tap was reported for 13% of all implants. Most implants were placed in an epicrestal manner (68%) with 26% subcrestal and only 6% placed supracrestal. The initial bone-implant fit was rated by the evaluator as either “firm” or “tight” in 96% of reported cases with 4% reported as “loose”.

Final implant seating was accomplished with the drill unit and handpiece (DU/H) in 50% of all cases and the High Torque Indicating Ratchet Wrench (H-TIRW) in the remaining cases. This split was due to the evaluator’s preferred technique. For the implants placed with the H-TIRW, the mean peak insertion torque value is 52.3 ± 16 Ncm and for implants placed with the DU/H the mean value is 40.4 ± 10.3 Ncm. The distribution of peak insertion torque forces is illustrated in Figure 8. For the cases where the bone tap was used, the mean peak torque values for the ratchet wrench and DU/H are 54.5 and 41.6Ncm, respectively. For cases associated with insertion torques above 80Ncm, there were five reports of a “sensation” of the driver stripping although there were no instances of the internal hex or the driver stripping.

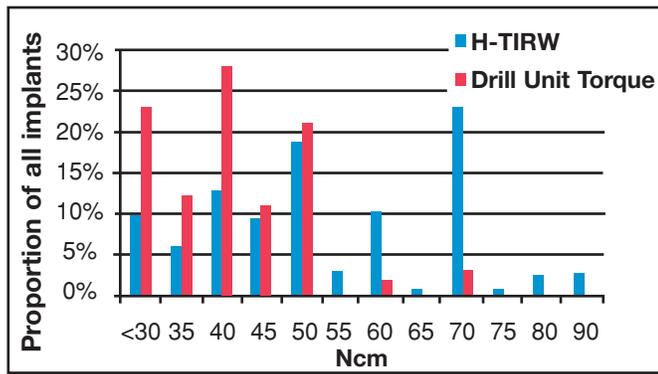


Figure 8: Peak Insertion Torques

Of the 32 implants in this series that were immediate replacements of an extraction site, all but two were placed without a tap. These immediate replacement cases had a greater proportion of wide-diameter (18 wide; 14 standard) implants and had a mean peak insertion force of 59.6 ± 18 Ncm. All but one were placed in native bone and 80% of these sites were scored as having dense or normal bone density. Most of these implants were considered as having tight or firm initial placement with only one scored as loose. Regarding the use of healing abutments, conventions used by the evaluators in this project found 63% of all implants placed in a single stage approach with 61% of all cases designed around single tooth restorations.

Implant integration was assessed at the installation of the temporary and permanent prosthesis. Immediate loading cases constituted 58% of all implants with another 22% loaded before three months healing and 20% after four months (Figure 9). In this evaluation, a total of six implants in five patients at five centers have been reported as failing to integrate for a six month survival rate of 98%. Of these, two implants were associated with post operative infection. Otherwise, no other associations can be made of the failures. The implant dimensions are evenly divided between standard and wide diameter configurations, the bone quality was scored as normal or dense at these sites, the initial bone fit was either tight or firm for all, and the lowest peak insertion force across the failures was

40Ncm. These implants were also evenly distributed between DU/H and the H-TIRW placement.

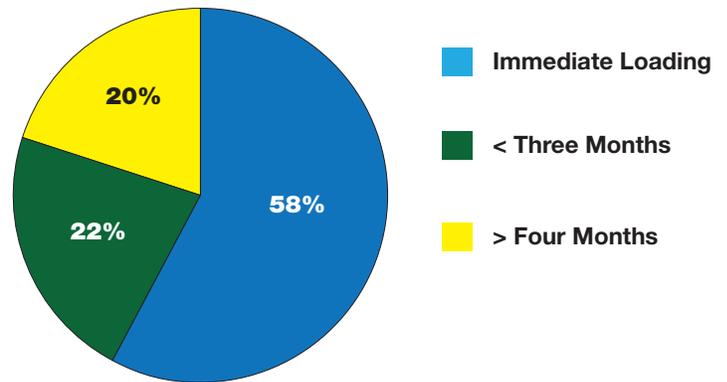


Figure 9: Time To Implant Loading

Discussion

This evaluation of the OSSEOTITE® 2 implant system benefits from the availability of the H-TIRW for documenting the insertion torque for this new implant design. This baseline variable is relatively new for implant studies. Due to evaluator preference, the implants reported in this project are evenly divided between those driven by the DU/H and an H-TIRW. An analysis of the cases performed using the DU/H and the H-TIRW found similarities in these cases in terms of patient demographics, implant dimension usage, and distribution of bone quality at the sites. Assuming that the two groups are otherwise matched, it would suggest that the actual torque forces are the same for the two groups.

The availability of a reliable and affordable torque-indicating instrument for use in implant placement procedures, such as the High Torque Indication Ratchet Wrench (H-TIRW), allows for an accurate assessment of insertional torque. The device is supplied with instructions for use in forward and reverse-torque directions and reports force from 50 to 90Ncm. There are only two moving parts and the wrench is designed for autoclave sterilization. Calibration is accomplished by assuring the force indicating arrow is positioned at the first or zero-scale mark. Care must be

taken to avoid applying force on the mid-portion of the force indicator arm as this may bend it and set the wrench out of calibration. Evaluators report becoming proficient with the use of the wrench after a few uses. A separate wrench for low torque applications (L-TIRW) including restorative component installation is also available and these are useful for counter-torque testing of implants for confirmation of integration success.

For most studies, resonance frequency assessment (RFA) is used as the primary determinant of implant stability.^{8,9} ISQ values for the implants in the current study were not collected. In a recent study of 4,135 implants, the role of initial stability was the focus of a project where implant placement force and RFA values were used to assess initial stability.⁹ The authors conclude that peak insertion torque is more influenced by bone density and RFA correlates more closely with implant length. In that project, the mean peak torque value was 34.8 ± 19.4 as measured by DU/H. Of the implants placed as immediate extraction replacements, those also had slightly higher insertion force values as compared to the values obtained from healed sites. Considering the uneven nature of osteotomies prepared in extraction sites, these findings are counterintuitive.

The mean peak insertion force values from OSSEOTITE® 2 implants (Figure 10) reported in this project are different than values reported for three other studies where the insertion force for Branemark Mark III implants were measured.^{10,11,12} Peak insertion force values

in these studies range from 39.4 to 41.5 Ncm as measured by the DU/H. If these force values are accurate, the differences in these mean peak insertion force values compared to those for the OSSEOTITE® 2 reported here may reflect the design differences between the two implants.

In this evaluation, the high proportion of implants with a tight or firm fit suggests that the design of the implant and the components used for osteotomy preparation increase the initial stability of the implant. Data from a prospective observational study supports the correlation of initial stability and implant success.¹³ The authors note the value of real-time feedback from the implant placement tools that aid the surgeon and help determine the amount of unloaded healing time required for each case.

The combination of increased surface area, an increase in IBIC, the addition of tactile feedback via the H-TIRW, and confirmed placement force as documented by this calibrated instrument, may be a significant contribution to the incremental improvements that are required of implant systems. These design features suggest that the OSSEOTITE® 2 implant system is capable of achieving higher primary stability. Along with the tactile feedback afforded by the H-TIRW, these offer a reliable means of determining if accelerated loading procedures may be employed.

Reports of clinical effectiveness are associated with heterogeneous datasets as the lack of specific admission criteria allows for a wide range of patient cases. In this evaluation, the OSSEOTITE® 2 implant, which is designed to achieve higher initial stability, achieved a 98% integration success rate.



Figure10: OSSEOTITE® 2 Implants

Author and Affiliations

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James N. Kenealy, Pharm.D. has degrees in pharmacology from the University of California, Santa Barbara and clinical pharmacy from the University of California, San Francisco. His pharmaceutical career includes a residency at UC San Francisco's Drug Study Unit and Clinical Research responsibilities at Key Pharmaceuticals; Nova Pharmaceuticals, Baltimore MD, Corvita Corporation, Miami FL and Cordis Corp, Miami Gardens, FL. Clinical Research experiences include developing drug and medical devices in pulmonary, cardiovascular, neurosurgical, oncology, vascular surgery and dental orthopedics. Dr. Kenealy has been a member of the BIOMET **3i** Clinical Research Department since 1995 and is the author of peer-reviewed journal articles and symposia posters.

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*While these surgeon experiences are true, the results are not necessarily typical, indicative or representative of all procedures in which the BIOMET **3i** Implant and related components are used. The BIOMET **3i** components have been used successfully in patients. However as with any implant device, there are surgical and post-operative factors, which ultimately may result in unpredictable variable outcomes. These factors include, but are not limited to, the patient's pre and post-operative health conditions, bone quality, number of surgical procedures and adherence to instructions regarding the procedural guidelines. Due to these variables, it is not possible to predict or warrant specific results, patient or clinician satisfaction.

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