



A Prospective, Randomized-Controlled Study of BIOMET 3i Tapered Implants Placed by Students in Graduate Programs

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ABSTRACT

BACKGROUND: The success rate for implants placed by dental students early in their implant residency programs has been suggested to be lower than for experienced clinicians. The objective of this prospective study was to document the success rates of NanoTite and Osseotite-surfaced Certain Tapered implants in graduate training programs. **MATERIALS AND METHODS:** All study implants are the Certain Tapered system (BIOMET 3i, Palm Beach Gardens, FL) made from titanium alloy Ti6Al4V, having an internal connection and either the Osseotite or NanoTite surface. An Internet database is used to randomly assign implant sites to either implant surface group and also to record the placement data and restorative outcomes. The study is under way at several University Periodontal and Maxillofacial Oral Surgery graduate programs in the United States. All patients qualified to receive dental implants provided informed consent to be included in the study. The specific placement techniques are those directed by the teaching staff at the individual study centers. Restorative designs and procedures are also at the discretion of the treating clinicians. **RESULTS:** At the time of this interim report a total of 423 patients (mean age 55.5 ± 17.0 years) have been enrolled over a period of 29 months with a total of 453 Tapered implant placements documented in the database. Most students had not yet placed their first dental implant. Implant assessment data ranges up to 30 months during which time 10 implant failures were declared. Failures were not clustered being distributed in 9 patients treated by 8 students and were evenly divided between the implant surface groups. The overall cumulative survival rate for these Tapered implants is 97.8% (97.9% for NanoTite Tapered and 97.7% for Osseotite Tapered). **CONCLUSION:** Considering that most students had never placed a dental implant, the relatively high cumulative survival rates in this study suggests that contemporaneous teaching programs are effective in training new operators in dental implantology.

BACKGROUND

A prospective study of dental implants was designed to determine if a difference could be assessed between implants that have the same macro design but with different surfaces. To obtain the best power for detecting a difference various scenarios were explored specifically looking for conditions that would challenge integration success. Usually this approach looks for patient conditions associated with high risk for failures, e.g., osteoporotics, irradiated mandibles. For this project the premise was to evaluate the earliest portion of a student's implant placement learning curve where an expectation of lower implant success was anticipated. Although it is generally recognized that implant success is varied during the early phase of a clinician's training, data from the collaborative VA Study (Morris et al, The Dental Implant Clinical Research Group) supports this assertion. The authors suggest that a higher proportion of implant failures occur in cases treated by graduate students. The specific objective of this prospective study was to document the success rates of NanoTite and Osseotite-surfaced implants placed in several graduate training programs. Several graduate programs at major universities in the USA were recruited for participation and the multicenter project is referred to as "College Bowl". This is a report of the project at one of these centers.

MATERIALS AND METHODS

This is a prospective randomized comparison of Osseotite-surfaced (control) and NanoTite-surfaced (test) Tapered implants placed in patients who needed treatment for restoration of edentulism or partially edentulous cases. The admission criteria were relatively unrestrictive, allowing most patients considered likely of returning for follow-up evaluations. Data was gathered for patient demographics, baseline dental status, osteotomy preparation, implant placement outcomes, confirmation of integration at the first impression-taking visit, some restorative outcomes, and annual confirmation of integration for three years. The study protocol did not require any specific intervention so that study data represents the program's and patient's standard care plan.

The study was approved by the UAB institutional review board and all patients provided informed consent. Each patient received at least two implants allowing for the placement of at least one test and one control implant. An electronic data management system (registry) was used to register participants, collect baseline and outcome data, randomize the placement of test and control implants, and report study progress outcomes. Data was gathered on the Resident-participants ("students") in terms of their education history, and the number of implants they personally placed prior to the start of the study. All implants used in the study were titanium-alloy, tapered implants (Biomet3i, Palm Beach Gardens, FL) placed with drills and components designed for the tapered implant.

RESULTS

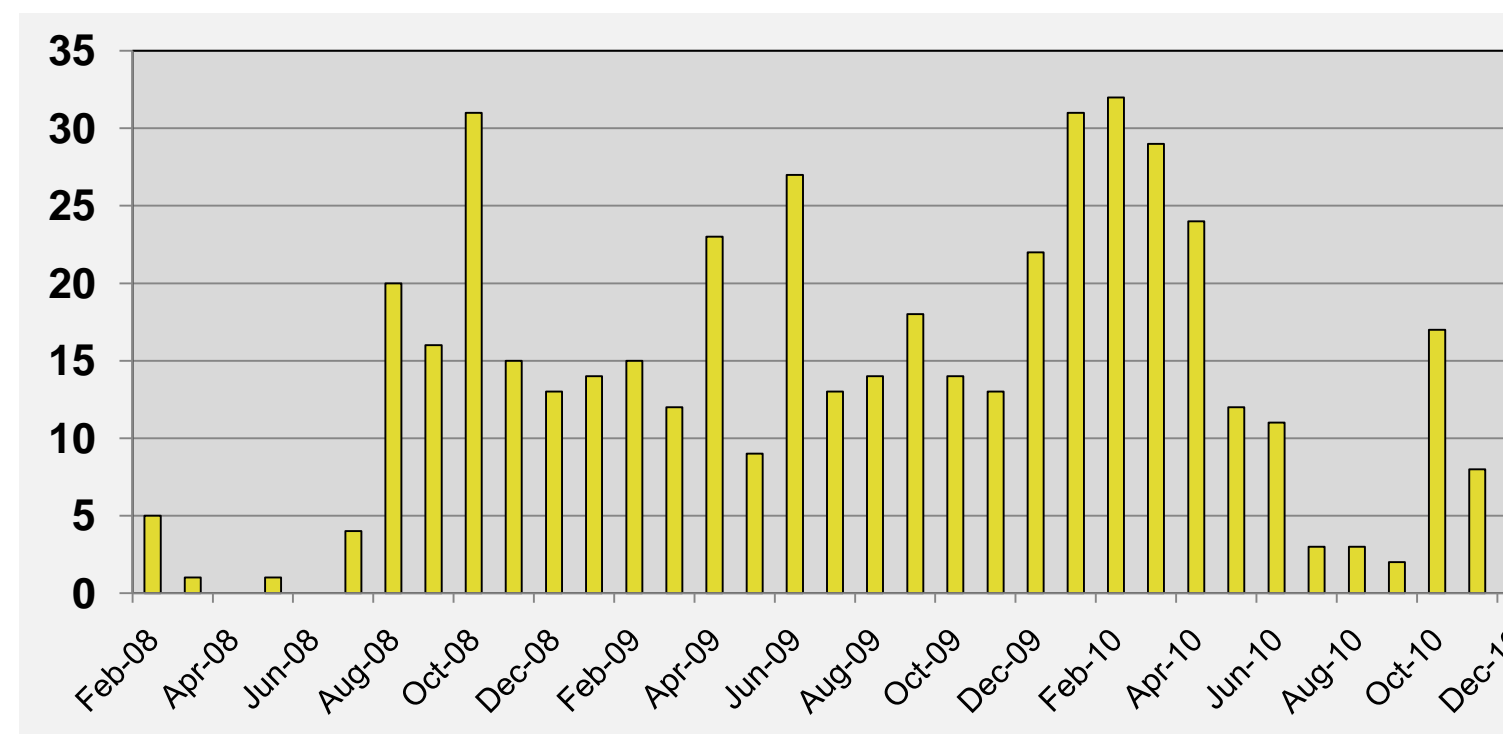


Figure 1. Distribution of patient enrollment by time

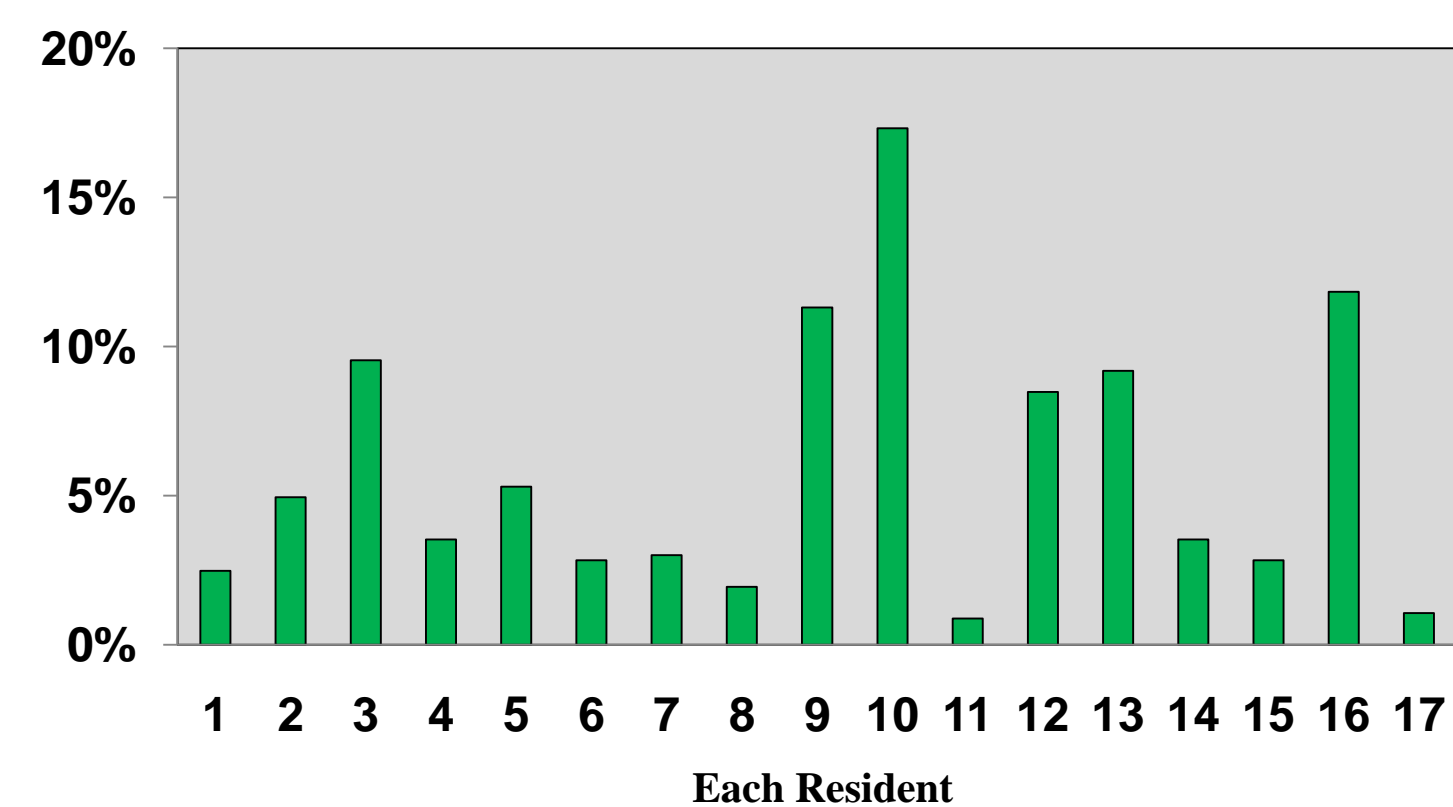


Figure 2. Distribution of implant cases by participating resident

A total of 423 patients were enrolled in the project across all university centers. At UAB three successive classes of first-year Resident students participated in the study from 2007 – 2010 with a total of 24 Residents registering for the project and 17 who actively participated. The average number of implants placed by these Residents prior to their participation in the project was 17 with a range of 0 to 62. Ten Residents reported having no direct implant experience prior to the study. All but three had no previous experience with the implant system used in this study.

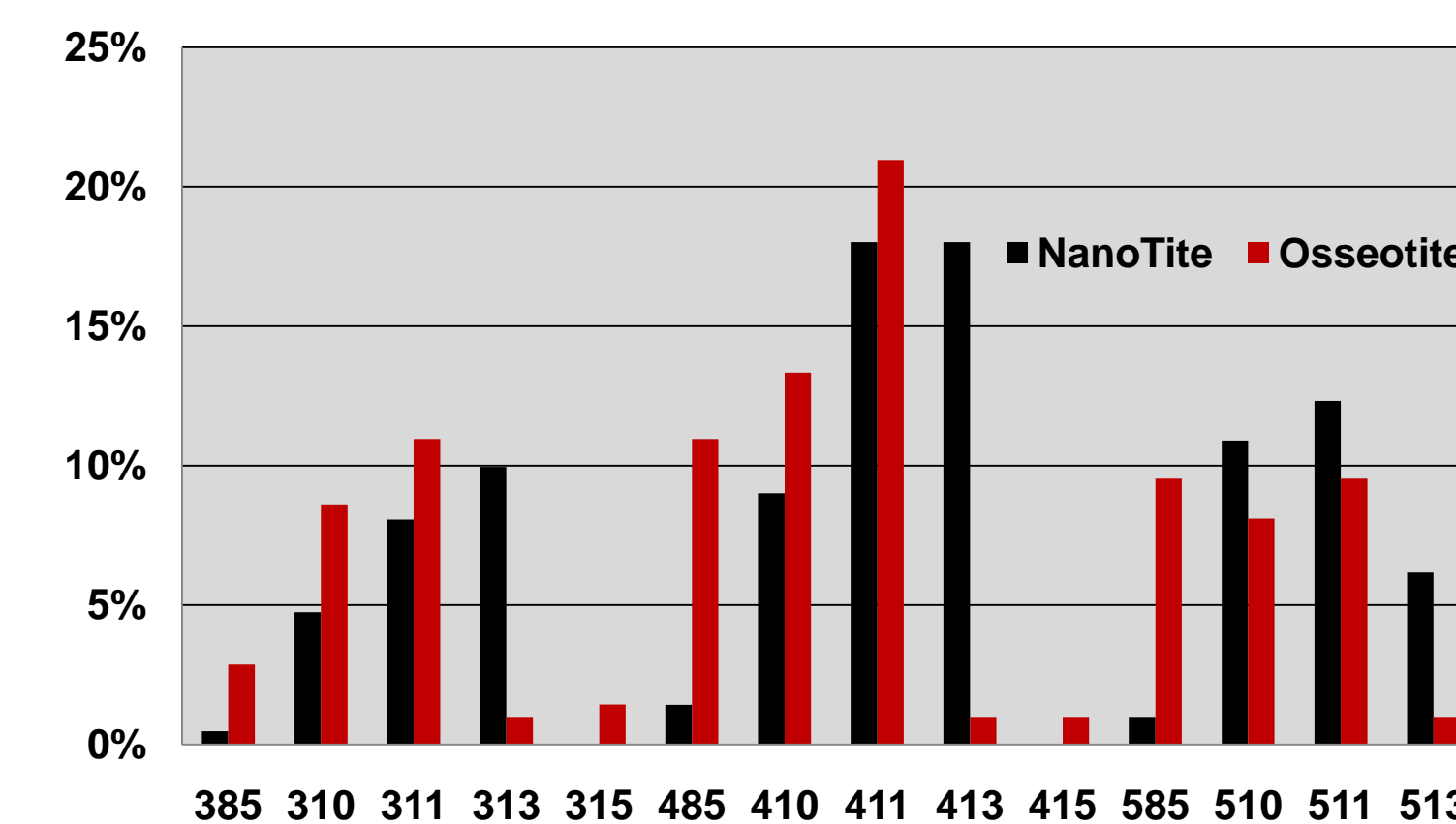


Figure 3. Distribution of Implants by surface type and dimension.

Over three successive years a total of 268 patients were enrolled by first year Residents; the distribution of patient enrollment by time is illustrated in Figure 1. The study patients were treated with 365 cases (prostheses) which were supported by a total of 459 implants. Patient demographics included an average age of 58 ± 15 years, ranging from 19 to 87 years and evenly divided by gender.

The number of implants placed by each participant over the course of the project ranged from 96 to a low of 5 implants and the distribution across all 17 participants is represented in Figure 2. The average number of implants placed by each Resident was 30 ± 26 ; the large standard deviation value representing this difference in implant placement rates.

Implants were distributed evenly between maxillae and mandibles but most placed in posterior locations (85%) and this distribution of placement sites is illustrated in Figure 3. Implant dimension distribution (Figure 3) shows that about half are 4 mm diameter and most lengths between 11.5-13 mm.

Restorative cases included single tooth restorations, and short- and long-span fixed prosthesis cases. The duration of implant healing time ranged from immediate to delayed loading and about 5% of all implant placement cases were immediate replacements of extracted sites. A total of 7 implant failures were recorded for a one-year CSR of 98.5%. The failures include four Osseotite-surfaced and 3 NanoTite-surfaced implants and were distributed across 5 patients and 5 Residents.

DISCUSSION

Wound healing and animal studies have provided compelling evidence that a nano crystalline calcium phosphate surface may improve early wound healing over an acid-etched surface.

The premise of the study was to use the incidence of implant failures occurring in the early part of a student's learning curve to allow differences in implant surface types to be observed.

The results of the study show a very high implant success rate and this reduces the power to determine implant surface contributions to integration success.

CONCLUSIONS

- The results of the study demonstrate that high clinical implant success may be obtained from students early in their implant learning program.
- The relatively high cumulative survival rates in this study suggests that contemporaneous teaching programs are effective in training new operators in dental implantology.

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