

***NanoTite™ Tapered Implants:
An Implant Designed For Performance***

Review And Clinical Results





NanoTite™ Tapered Implants: Review and Clinical Results

INTRODUCTION

For more than ten years and with documentation from numerous global multicenter clinical evaluations, the OSSEOTITE® Surface has proven to be one of the most well-researched implant surfaces.¹⁻⁸ Clinical studies on the OSSEOTITE Surface have documented the benefits of increased contact osteogenesis, especially in poor-quality bone. A study initiated in February 2006 evaluated the preparation and placement of BIOMET 3i's Tapered OSSEOTITE Implants. Twelve centers reported results on 133 patients and 208 implants (123 tapered implants, 85 non-tapered control implants) with four reported failures to date (see Table 1). This evaluation confirmed the effectiveness of the BIOMET 3i Tapered Implant Design and led to the development of the NanoTite Tapered Implant now available from BIOMET 3i.*

Table 1.
Results From Multicenter Clinical Trials On OSSEOTITE Implants

Centers	Tapered Implants	Non-Tapered Control Implants	Total	Failures	Cumulative Survival Rate (%)
12	123	85	208	4	98.1

CLINICAL DATA

Two clinical centers have reported the results of their use of the NanoTite Tapered Implant System for 471 consecutively treated implants. See Table 2 below.

Table 2.
Raw Data From The Two Clinical Centers On NanoTite Tapered Implants

Implants Placed	Maxillary	Mandibular	Totals
Center #1 (NJ)			
Anterior	82	35	117
Posterior	126	114	240
Sub Totals	208	149	357
Center #2 (CA)			
Anterior	65	14	79
Posterior	21	14	35
Sub Totals	86	28	114
Grand Totals	294	177	471

A total of 357 tapered implants were placed in Clinical Center #1 (NJ) using multiple implant loading protocols including extraction and immediate implant placement, immediate non-occlusal loading and unloaded healing. The center reported two failures: one, two months post implant placement (prior to occlusal loading) and one, three days post implant placement. The implant Cumulative Survival Rate was 99.4%

A total of 114 tapered implants were placed in Clinical Center #2 (CA). A number of these implants have been in place for less than three months. Thus far, Clinical Center #2 has reported no implant failures.

The implants noted in Table 3 from Clinical Centers #1 (NJ) and #2 (CA) were followed for up to 18 months. See Table 3 below.

Table 3.
Post Occlusal Loading Clinical Data (NJ and CA centers) On NanoTite Tapered Implants

Post Occlusal Loading (Months)	Number
0-6	310
7-12	78
13-18	1
Not yet restored	82
Total	471
Cumulative Survival Rate	99.4%

DISCUSSION

The original tapered implants were designed as threaded, tapered implants that mimicked the taper of natural tooth roots. Tapered implants were indicated for use in areas of poor or limited bone quality/quantity and were thought to be the treatment of choice in fresh extraction sites, areas with convergent roots and in areas associated with boney undercuts within an alveolus.¹¹⁻¹³

The original NT Implants were machined with a wider thread pitch (0.9mm versus 0.6mm for parallel-walled implants). The increased thread pitch meant that with each turn, these tapered implants advanced deeper into osteotomies than did implants with less thread pitch. For example, a 5mm progression in the osteotomy was obtained with an NT implant within 5.5 turns (5 turns X 0.9mm); a parallel-walled implant has to be turned 8.5 times to advance 5mm.¹¹ Therefore, operating times per NT implant were decreased

*Data on file

when compared to the operating times associated with parallel-walled implants: 61-64% less than the operating times associated with parallel-walled implants.^{11, 14} In the case of 8.5mm long NT implants, Davarpanah et al reported that the implants did not engage the walls of the osteotomies until 57.7% of the implant was in contact with the osteotomy versus 21.2% of the parallel-walled implants that were in contact with the osteotomy.¹¹

DESIGN CHARACTERISTICS OF NANOTITE™ TAPERED IMPLANTS

BIOMET **3i** introduced the current tapered implant design in August, 2006. This design is available with two different surfaces: NanoTite and OSSEOTITE®; and two configurations - Tapered and Tapered PREVAIL®. The tapered implant design closely approximates the shape of a natural tooth root and may be beneficial in various clinical situations such as:

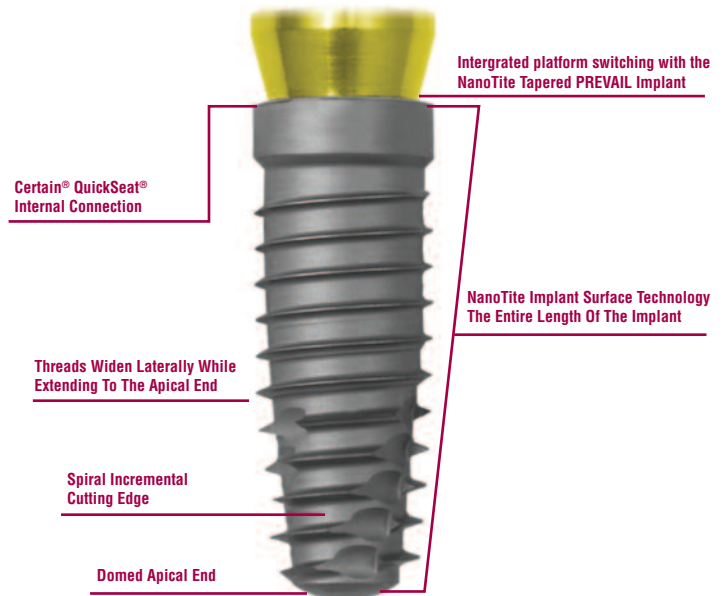
- Immediate Implant Placement In Extractions Sites
- Immediate And Accelerated Loading Protocols
- Sites With Convergent Roots Of Adjacent Teeth
- Sites With Ridge Concavities
- Simultaneous Grafted Sites And Implant Placement
- Implant Placement With Sinus Lift Procedures
- Aesthetic Areas Where Bone Preservation Is Critical
- Locations Requiring Short Or Wide Implants
- Soft Bone (Type IV)

The tapered design has an implant thread angle of 35° and a crest width of 0.004/0.002". This results in a tall, thin thread design, which may help achieve initial mechanical implant stability with threads that widen laterally and extend to the implant's apical aspect. The thread angle, depth and pitch produce an anchoring "bite-in-bone" response at the time of implant placement. The macroscopic shape of NanoTite Tapered Implants may potentially enhance the initial primary stability throughout the length of the implant. Preclinical studies have shown that the surface treatment of NanoTite Implants also increases Bone-to-Implant-Contact (BIC) versus the OSSEOTITE Implant alone.* The apical end of the implant has a domed shape in order to reduce trauma in anatomic areas where implant placement may closely approximate vital structures (inferior alveolar canal, sinus membrane).

Finally, the implant threads are self-tapping with progressive cutting edges in a helical pattern, with trailing thread relief. The implant restorative platform is color coded for easy

*Data on file

THE NANOTITE TAPERED PREVAIL IMPLANT

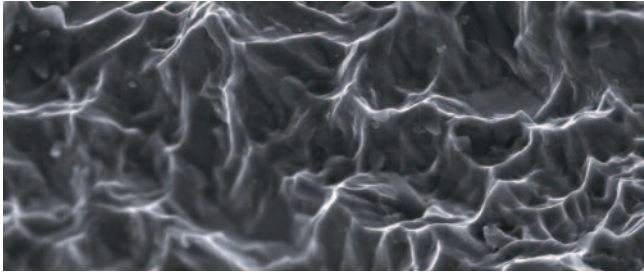


identification. The implant/abutment connection is available in Certain QuickSeat Internal Connection and External Connection configurations.

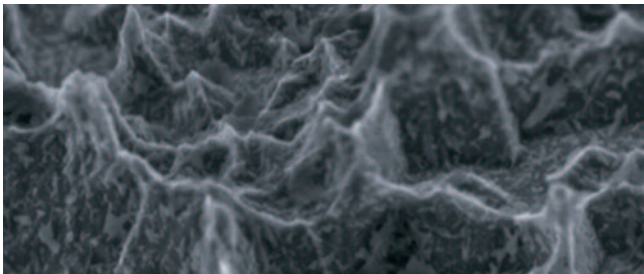
The Tapered NanoTite Implant is a modified hybrid implant where coverage of both the OSSEOTITE Surface and the nanoscale crystals extend to the base of the collar versus the OSSEOTITE Surface.⁹ Preclinical studies have demonstrated a substantial improvement on the rate and extent of osseointegration on the NanoTite Surface. This enhanced osseointegration is occurring at early time points.¹⁶

OSSEOTITE SURFACE / NANOTITE SURFACE

The NanoTite Implant builds on the success of the OSSEOTITE Surface by creating a more complex surface topography and maximizing the potential biological benefits of Calcium Phosphate (CaP). Through a solution-based process of particle self-assembly called Discrete Crystalline Deposition (DCD™), individual crystals of CaP are deposited onto the implant surface and occupy approximately 50% of the OSSEOTITE Substrate Surface.⁹ In so doing, the DCD Process also increases the micro-surface area by 200%¹⁰, providing greater micro-complexity for new bone attachment and formation.



OSSEOTITE® Surface at 20,000x



NanoTite™ Surface at 20,000x

The complex architecture at the nano-scale renders the NanoTite Implant a Bone Bonding® Surface by the interlocking of the newly formed cement line matrix of bone with the implant surface.

SITE PREPARATION AND DRILLING PROTOCOL

Each element of the NanoTite Tapered Implant System: Surgical Tray, Quad-Shaping Drills (QSDs), Depth/Direction Indicators (NTDIs), Bone Taps and Implants—has been color-coded for easy identification. In addition, the packaging has been designed to facilitate optimal delivery efficiency.



Quad Shaping Drill (QSD)

Depth/Direction Indicator (NTDI)

Precision QSD Shaping Drills and Depth/Direction Indicators have been designed to match each implant's diameter and length for proper preparation, confirmation and implant placement. The stepped drill

design allows for better visibility of crestal and subcrestal reference points. The four cutting flute design facilitates cutting stability and decreases friction between the drills and the osteotomy walls. Drill pointed end tips allow for vertical downward cutting during osteotomy preparation and corresponding NTDIs ensure appropriate depths and angles during osteotomy preparation.

The specifications of the NanoTite Tapered Implant System and the corresponding QSDs and NTDIs are held to rigorous tolerances to provide a closely integrated implant-to-osteotomy fit. Consequently, the NanoTite Tapered Implant may require reasonably high levels of insertion torque to seat completely within the osteotomy.

The recommended drill speed for all QSD drills in the Tapered Implant System is 1200-1500rpm. The QSDs should not be pumped during preparation of the osteotomy. Prior to implant placement to help fully seat the implant into the osteotomy, irrigation and suction of the osteotomy is recommended in order to remove residual bone debris. The recommended implant placement speed is 15-20rpm. In some instances, the implant placement torque may exceed 50Ncm; therefore, use of a ratchet wrench may be necessary.



Bone Taps For Tapered Implants

When placing a NanoTite Tapered Implant, the need to tap the osteotomy may occur, especially in dense bone (Type 1). To facilitate placement, BIOMET 3i developed a Bone Tap Kit with length specific taps that match each tapered implant for optimal site preparation. While tapping in dense bone (Type I) is recommended prior to implant placement, undersizing the osteotomy by at least one shaping drill diameter is recommended for implant placement in softer bone (Type IV).*

*Refer to the BIOMET 3i Surgical Manual (CATSM) for detailed surgical protocols.

CONCLUSIONS

Based on the results of the data reported in this paper, the BIOMET **3i** Tapered Implant shows promise in answering clinical challenges related to poor quality and quantity of bone that have been the purview of tapered implants. One hundred forty seven of the 471 implants reported in this multicenter clinical trial were placed into areas of known poor quality bone (posterior maxillae). This tapered design was used successfully in implant sites such as immediate post extraction with implant placement and in areas associated with natural anatomic challenges such as in areas of converging roots and alveolar undercuts.

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