Outcomes From A Retrospective Study of 626 Sequential Cases of BIOMET 3i Tapered Implants

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ABSTRACT

BACKGROUND: The placement of tapered–apex dental implants requires specific osteotomy preparation instrumentation. Drills for tapered implants establish a finite osteotomy depth for which care is needed to ensure the proper implant descent and seating. Implant design and the instruments provided for osteotomy preparation contribute to the elements needed for successful use of tapered implants. The aim of this evaluation was to document the success of a new tapered implant in a large population. **METHODS:** A protocol for conducting a retrospective study was submitted to high-volume users of the Biomet 3i Tapered Certain implant system to solicit participation and contribution of data. Participants gathered information from their first 20 patients receiving Tapered implants between June 2008 and December 2009. No exclusion criteria were applied. Data collection was done on standardized forms and processed in one database management system. Baseline variables included: demographics (gender, age at implant placement), diabetes, smoking behavior, implant site assessment (bone density), placement approach (2-stage, single-stage, immediate provisionalization), and restorative type (single unit, fixed multiple unit, overdenture). Outcome variables included the implant's functional status and survival on the date of the patient's last evaluation. **RESULTS:** A total of 46 clinicians were approached for participation in the study with 25 providing completed data records (54% compliance). The total number of patients represented in the dataset is 473 altogether having 626 prosthetic cases supported by 836 Biomet Tapered Certain implants. Implant diameters ranged from 3.25 to 6 mm and lengths from 8.5 to 13 mm. Implant locations were 63% posterior, 37% anterior, with 56% in maxillae and 44% in mandibles. A total of 13 implant failures were reported for a cumulative survival rate of 98.4%. Of the failures, 12 were in the maxillae and one in the mandible and evenly divided across implant dimensions.

CONCLUSION: Tapered implants in this retrospective analysis, placed in a variety of cases and locations, were found to have clinically acceptable success rates.

BACKGROUND

Prospective clinical trials are uniquely qualified for determining the efficacy of treatments or interventions. Prospective studies are characterized by having admission criteria that specifically promote a more homogenous study population to reduce biological noise and improve statistical power. When medical products are commercialized and used in a heterogeneous population the performance of the product may not be the same. Gathering usage data from a large group of practitioners allows for an analysis of product *effectiveness.*

This retrospective multicenter study is designed to evaluate the performance of Biomet 3i Tapered implants placed within a specific time period and followed for at least one year to determine the effectiveness of these implants.

MATERIALS & METHODS

Centers in North America known to be users of the Biomet 3i Tapered implant system were contacted for their interest in participating in a retrospective analysis. A protocol describing the selection of patients to be included in the study and the data items to be collected were sent for their review and consideration. The protocol specified that all patients who received Tapered implants between June 2008 and December 2009 were to be documented and no patients excluded for any reason.

Study implants are of the Natural Tapered System (Biomet 3i, Palm Beach Gardens, FL) (Figure 1). Requests for participation were sent to 52 centers in North America along with standardized data forms and instructions for their completion.

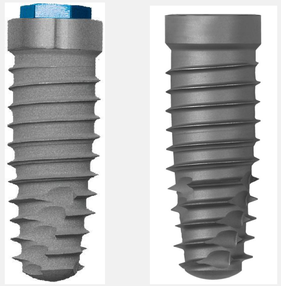

Figure 1. Biomet 3i Tapered Implants: external and internal connection system variants.

Follow-up correspondence was made with each investigational center to ensure comprehensive understanding of the study design and data gathering procedures. Data were recorded on the basis of 1) patient, 2) case, and 3) implant as one patient may have several cases (independent prostheses) each supported by numerous implants. Data were gathered on implant placement date, implant catalog number, placement site, bone density at implant site, placement approach (1 or 2-stage), healing duration, loading date, and date of last in-office examination. Implant outcomes included any signs or symptoms of implant mobility, infection and intervention.

RESULTS

Data were provided by 25 of 52 centers (49% collaboration). A total of 494 patients (48% men and 52% women) with a mean age of 56.2 (SD 15) years were reported. Patient prostheses were supported by a total of 831 Tapered implants. Implant dimension distribution has over 77% of 4 and 5 mm diameter and 73% among the 10 to 13 mm lengths. Patient baseline health variables included 14% smokers and a 7% rate of diabetes.

Implants were placed generally in the posterior regions (63%) and in the maxilla (57%) as recorded in Table 1. Of the implants 66% were NanoTite surfaced Tapered implants and 33% Osseotite Tapered implants. The fully-etched version of the Tapered implant was used in 43% of all cases. Use of single-stage placement approach was recorded in 49% of all cases with 4% of those cases being associated with an immediate loading prosthesis.

The duration of observation of these implants – the time from implant placement to the last recorded clinic examination visit - was a mean of 28.3 5.4 months. During this time a total of 14 implant failures were recorded distributed across 12 centers, for a total implant survival rate of 98.3%. The failures were proportionately divided between implant surfaces: 98.4% survival for NanoTite-surfaced Tapered implants and 98.2% for the Osseotite-surfaced implants. A slightly higher survival rate was observed for mandibular implants (99.7%) than for maxillary implants (97.2%). Additional implant outcomes data and their relationship to baseline variables of location and bone density are illustrated in Table 2.

	Anterior	Posterior	TOTAL
Maxilla	25.7	31.0	56.7
Mandible	11.6	31.7	43.3
TOTAL	37.3	62.7	100

Table 1. Percentages of implants by locations.

Performance Variables		Implants	Failures	Survival Rate
Location	Maxilla	469	13	97.2
	Mandible	357	1	99.7
	Anterior	207	5	97.6
	Posterior	619	9	98.5
Bone Quality	Soft	151	4	97.4
	Normal	424	9	97.9
	Dense	251	1	99.6

Table 2. Implant outcomes as survival rates (%) according to baseline variables of location and bone quality.

CONCLUSIONS

This retrospective study reports usage of Tapered implants across 25 centers where survival rates above 97% are observed in various conditions such as when placed according to a single-stage and delayed healing approach. Successful utilization of the Tapered Implant was observed across all centers with an average of two year's of clinical observation.

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