

PROSPECTIVE CLINICAL EVALUATION OF 835 MULTITHREADED TAPERED SCREW-VENT IMPLANTS: RESULTS AFTER TWO YEARS OF FUNCTIONAL LOADING

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Multithreaded tapered screw implants have been used for several years, but lack of clinical documentation about marginal bone stability and survival rates have raised concerns about the design among some clinicians. This study prospectively evaluated the survival rates, success rates, and marginal bone stability of multithreaded tapered screw implants. A total of 835 implants in diameters of 3.7 mm (9%), 4.7 mm (76%), and 6.0 mm (15%) were placed in 328 patients using a single-stage, delayed-loading protocol. The implants were restored with a variety of prostheses and monitored over 2 years of functional loading. Five implants failed and were removed before loading. Cumulative implant survival was 99.4% ($n = 835$); differences between mandibular (99.0%, $n = 408$) and maxillary (99.8%, $n = 427$) implants were not statistically significant ($P > .20$). Mean marginal bone resorption was 1.66 mm (± 0.13 mm). Six implants failed to meet the success criteria by sustaining mesial and distal bone loss below the first implant thread; however, they remained stable and continued functioning without pain or inflammation. Cumulative implant success was 98.6% ($n = 835$); differences between maxillary (98.6%) and mandibular (98.8%) implants were not statistically significant ($P > .20$). Success rates by implant diameter were 98.6% (3.7 mm), 98.4% (4.7 mm), and 100% (6 mm). After 2 years of functional loading, survival and success rates for multithreaded tapered implants placed in a nonsubmerged protocol equaled or surpassed those of single-thread, straight-walled implant historical controls.

Key Words: implants, multithreaded, tapered screw-vent, single-stage, prospective

INTRODUCTION

The success of cylindrical root-form dental implants over the past 30 years has hinged on the ability to achieve primary stability, which is a prerequisite for bone cell differentiation and osseointegration.¹⁻² When anatomical conditions complicate

or preclude the ability to stabilize an implant at the time of placement, the osseointegration and long-term implant survival can be compromised. Tapered dental implants more closely approximate natural tooth root morphology than cylindrical implant designs, and were initially introduced a decade ago as a treatment option for missing lateral incisors,³⁻⁵ narrow or concave ridges,^{3,6-7} interdental sites compromised by convergent roots of adjacent teeth,^{3,6-7} and immediate implantation into tooth extraction sockets.^{3,8-10} To date, the only published retrospective clinical study of tapered single thread implants placed

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in various clinical situations reported a 98.6% success rate at stage-2 exposure.⁶

More recently, the addition of multiple lead threads to tapered implant designs has been reported to increase implant stability by compressing low-density bone along the entire length of the implant during insertion.¹¹⁻¹⁴ One study¹⁵ used resonance frequency analysis (RFA) to test the primary stability of a tapered implant design with double lead threads along with 4 conventional single-thread implant types in human cadaver bone. In low-density, type IV¹⁶ bone, the tapered implant showed the highest RFA values, suggesting the greatest primary stability.¹⁵ When the RFA data from all bone qualities were pooled, the tapered design still exhibited improved stability compared to the standard straight-walled designs.¹⁵ Improved primary stability from implant geometry may have a significant effect on success rates.¹⁷

In finite element analysis (FEA) studies of tapered implant designs, however, the findings have been mixed. One FEA study¹¹ compared tapered implant geometry to a standard straight-walled design and found that the former enhanced stress and strain distribution. In contrast, other FEA research¹⁸ found that maximum stresses and strains were concentrated around the apex of a tapered implant design in low-density bone, and that increased stresses and strains could compromise implant stability. To date, limited¹⁹ prospective clinical research has been published on multithreaded tapered implants to reinforce or repudiate either of these findings.

The purpose of this clinical study was to prospectively evaluate tapered multithreaded dental implants during 2 years of functional loading in humans.

MATERIALS AND METHODS

Patient selection

Consecutive patients with partial or complete edentulism were recruited in the private practice of the first author according to strict selection criteria (Table 1). All patients were carefully evaluated for treatment suitability, and informed patient consent was obtained prior to treatment.

Implant design

The study implant was a new, self-tapping, tapered screw design with triple lead threads (Tapered Screw-Vent, Zimmer Dental Inc., Carlsbad, Calif) that was first introduced at the commencement of the study (March 2000). Made of medical grade 23 titanium alloy (Ti-6Al-

4V ELI), the implant's surface consisted of a 1-mm machined cervical region above a microtextured (MTX) body. The multithread configuration extended from the apex to 2.5 mm below the top of the implant, and enabled placement three times faster than similar implants with a single thread pattern.^{12,20} Faster implant placement can be advantageous for patients who are unable to open their mouths for a long period of time, when saliva flow is important, or when numerous implants are placed. All three implant diameters were used in this study: 3.7, 4.7, and 6.0 mm. The implants were designed with an internal connection that created a frictional interface with the assembled abutments.²¹⁻²²

Surgical protocol

All implants were placed under local anesthesia by the same surgeon. Oral antibiotics were routinely prescribed as a prophylactic measure (amoxicillin, 2 grams per day during 6 days from the day of surgery). Patients were instructed to use chlorhexidine digluconate (0.12%) immediately prior to surgery and as a postoperative mouth rinse. To decrease the risk of implant or screw fracture, implant lengths and diameters were selected according to the largest dimensions that each clinical situation would allow. Consequently, some patients received tapered implants of different diameters and lengths, as dictated by their anatomy. At the time of placement, a cylindrical healing collar was immediately attached to each implant and the soft tissues were sutured around it for a nonsubmerged healing protocol. When implants were placed in type 3 or 4 bone, existing removable prostheses were relieved. When implants were placed in type 1 or 2 bone,¹⁶ the removable prostheses were relined with soft or hard acrylic resin. Sutures were removed after soft tissue healing approximately 5 days later.

Osseointegration recall

Following a nonsubmerged healing period of 2 to 3 months in the mandible and 3 to 5 months in the maxilla, lateral pressure, percussion, and a periapical radiograph were used to clinically assess the osseointegration of each implant.²³

Restorative treatment

Definitive restorative procedures were commenced immediately following verification of clinical osseointegration. The implants were restored with a variety of fixed or removable restorations based on the preferences of the clinicians and the clinical needs and desires of the patient.

TABLE 1
Patient selection criteria

Inclusion criteria	Exclusion criteria
Adults who had completed their final growth	General pathologies that would contraindicate implant treatment or a surgical procedure, such as high risk for subacute bacterial endocarditis, uncontrolled diabetes, and immunocompromised patients (including HIV-positive serology or currently receiving chemotherapy)
Ability to understand and sign the informed consent form prior to starting treatment	Heavy smoking (more than 20 cigarettes daily)
Ability and willingness to comply with the study requirements	Untreated periodontitis
Adequate bone volume to accommodate the planned endosseous dental implant procedure with or without previous bone grafting	Insufficient bone height, interarch space, vestibulolingual space, or mesiodistal space

Crestal bone evaluation

Standardized periapical radiographs using a parallel-ling technique (Rinn System, Dentsply Rinn, Elgin, Ill) were obtained at the time of osseointegration evaluation 2 to 5 months after implant placement, and at annual implant recalls. Sometimes this technique resulted in images that excluded the apex of the implant. This was considered acceptable if at least 5 threads in the cervical region of the implant were visible and if crestal bone resorption could be adequately assessed. Crestal bone resorption was measured both mesially and distally from the top of the implant neck to the lowest observed point of crestal bone in intimate contact with the implant (CBC). Visual analysis of the periapical radiographs was performed with the aid of a magnification system (X-Produkt, Malmö, Sweden). Implants presenting with a mesial and distal CBC above the first thread were considered normal. Even when available, panoramic radiographs were never used to assess crestal bone loss.

Criteria for implant success and data analysis

Criteria for implant success previously described by Albrektsson²⁴ were used, except for vertical bone loss. In this study, an implant was considered a failure when both mesial and distal marginal bone levels were

below the first thread. A χ^2 test was used to compare qualitative data between groups ($\alpha = 0.05$).

RESULTS

A total of 328 patients (219 females, 109 males) with a mean age of 58 years (range = 19–74 years) were enrolled in the study. The patients were treated with 837 implants placed via a nonsubmerged protocol, except for 2 implants placed in 2 patients. In the latter cases, an osseous defect was present around each implant at time of placement, leaving exposed threads. Bone chips were harvested and placed in the defect and flaps were sutured over the surgical site. These 2 implants became osseointegrated and were successfully loaded. Because the surgical protocol was different for those 2 implants, however, it was decided to withdraw them from the study.

The remaining 835 implants placed nonsubmerged ranged in diameter from 3.7 mm ($n = 77$; 9%) to 4.7 mm ($n = 634$; 76%) and 6.0 mm ($n = 124$; 15%). Implant distribution according to location is shown in Table 2a. Wider implants were mostly placed in the posterior region, with the widest-diameter (6.0 mm) implants placed mainly in the molar region (89%). Implant distribution according to length is presented in Table 2b. The more frequently used implants were 10 and 13 mm. Mean length tended to decrease as implant diameter increased. Forty of the 328 patients under-

TABLE 2A
Distribution of implants by diameter and tooth location

Implant diameter	Jaw location		Total implants, n (%)	Incisors, n (%)	Canines, n (%)	Bicuspid, n (%)	Molars, n (%)
	Mandible	Maxilla					
3.7 mm	43	34	77 (9%)	22 (29%)	8 (10%)	41 (53%)	6 (8%)
4.7 mm	317	317	634 (76%)	71 (11%)	68 (10%)	244 (39%)	251 (40%)
6.0 mm	47	77	124 (15%)	1 (1%)	2 (2%)	10 (8%)	111 (89%)
Total	408 (49%)	427 (51%)	835 (100%)	94 (41%)	78 (22%)	295 (35%)	368

TABLE 2B
Distribution of implants by diameter and length

Implant diameter	Implant length (%)				Mean length
	8 mm	10 mm	13 mm	16 mm	
3.7 mm	6.5%	44.1%	40.3%	9.1%	11.6 mm
4.7 mm	13.1%	42.6%	31.3%	13%	11.4 mm
6.0 mm	18%	49.6%	31.6%	0.8%	10.6 mm

went a bone grafting procedure a few months before implant placement. Sometimes, a localized graft was performed at time of implant placement. Except for the two implants withdrawn from the study, the graft did not affect the most cervical region of the implant site and the nonsubmerged protocol was applied. No patient was lost to osseointegration recall.

The implants were restored with 379 fixed prostheses and 10 removable prostheses. Table 3 shows distribution of prosthetic treatment by patient.

Survival rates

Five implants (4 in the mandible, 1 in the maxilla) were lost during the 2- to 5-month healing period. The 830 remaining tapered implants were all restored with a definitive prosthesis. During the first year of loading, 28 patients (51 implants) were lost to follow-up. During the second year, 13 patients (51 implants) were lost to follow-up. Survival rate was 99.8% in the maxilla and 99.0% in the mandible; there was no statistically significant difference ($P > .20$) between these two groups. The 5 implants removed were 4.7-mm-wide implants. Survival rate was 100% for 3.7-mm implants, 98.7% for 4.7-mm implants, and 100% for 6.0-mm implants; there was no statistically significant difference between these three groups ($P > .50$). The global cumulative survival rate at 2 years for multithreaded tapered implant was 99.4% (Table 4).

Implant failure analysis

Twenty days after placement, acute bone infection with associated pain and suppuration was observed around one 8-mm mandibular implant, which was

removed. A 10-mm mandibular implant was removed after 24 days because of pain under axial percussion and slight mobility. Three other implants were removed at the time of osseointegration evaluation. One was an 8-mm mandibular implant demonstrating pain under axial percussion and bone loss beyond the second thread. The second was a 16-mm maxillary implant with bone loss beyond the third thread, and the third was an 8-mm mandibular implant with slight pain when unscrewing the healing abutment. None of the failed implants had been placed in a grafted site and none of the patients in whom they occurred were smokers. Four failed implants were replaced by implants placed in the same sites after 3 to 6 months. The implant associated with acute infection was replaced by another implant placed in a more mesial site. These replacement implants were all placed after June 2001 and successfully restored, but excluded from the present study.

Marginal bone levels

After a 2-year loading period, mean marginal bone resorption was 1.66 mm (± 0.13 mm). When bone level was below the first thread (2.5 mm below the top of the neck) both mesially and distally, the implant was not considered a success. This was observed for 6 implants (4 patients): 5 in the maxilla and one in the mandible. Those implants were not removed, however, because they were stable, painless, and exhibited no sign of inflammation.

Success rates

Implant success rates were 98.6% in the maxilla and 98.8% in the mandible; there was no statistically significant difference ($P > .20$) between these two groups. By implant diameter, success rates were 98.6% for 3.7-mm implants, 98.4% for 4.7-mm implants, and 100% for 6.0-mm implants; there was no statistically significant difference between these three groups ($P > .50$). The global cumulative success rate at 2 years for the multithreaded tapered implants was 98.6% (Table 4).

TABLE 3
Distribution of restorations by type and patient count*

	Single tooth restoration	Partial edentulism	Complete edentulism
Fixed prosthesis, n	104	253	22
Removable prosthesis, n	0	3	7
Total patients, n	96	211	29

*2 or more adjacent missing teeth

TABLE 4

Life table analysis for implant survival and success

Interval (y)	Implants at start of interval n	Withdrawn implants n	Removed implants n	Loaded implants remaining n	Cumulative survival rate (%)	Failed implants n	Non-failed implants remaining n	Cumulative success rate (%)
Placement to loading	835	0	5	830	0.9940	5	830	0.9940
0 to 1 year of loading	830	51	0	779	0.9940	0	779	0.9940
1 to 2 years	779	51	0	728	0.9940	6	722	0.9864

DISCUSSION

The results of this prospective clinical study were comparable to previously published reports,^{25–28} on single-thread, straight-walled Screw-Vent implants, which lacked microtextured surfaces but achieved osseointegration rates of 94.2% to 97.5%. With a 98.6% success rate after 2 years of loading, the new Tapered Screw-Vent implant design and surface topography seem to have had a positive influence on clinical results, and other research¹⁹ has found that these results do not diminish after 5 years of loading. The present report stands in contrast to the results of De Bruyn et al,²⁹ who described an 11.3% failure rate in the maxilla after 6 months with Screw-Vent implants.

A multicenter study⁶ published on 1100 tapered single threaded implants reported a 98.6% success rate at exposure (second-stage surgery). The present study, with a multithreaded implant design and a nonsubmerged protocol, showed similar results after 2 years of loading.

The results of this study were also comparable to reports of good clinical results with nonsubmerged implants.^{30–41} Two-stage implants allow more prosthetic versatility and may therefore provide a better aesthetic outcome. In this study, healing abutments were placed at time of implant insertion and two-stage Tapered Screw-Vent implants were successfully used as one-stage implants. An animal study demonstrated that two-stage implants used with a submerged and nonsubmerged protocol obtained similar crestal bone levels and soft tissue adaptation.⁴² Other clinical studies have also reported high success rates with two-stage implants used with a nonsubmerged protocol.^{27,37,43–44}

In the present study, wide-diameter implants (4.7 and 6.0 mm) represented 91% of the 835 placed implants. Because they reduced the risk of implant fracture,⁴⁵ they were used whenever a mechanical risk was present. The most frequently used implant was the 4.7-mm implant (76%), which was mainly used in the posterior region (78%) and to replace canines (11%). While several authors^{46–50} have shown less

favorable results with wide-diameter implants, the results of this study were comparable to other studies reporting high success rates (94% to 98%) with wide-diameter implants.^{27,51–54}

Tapered implants have distinct advantages in soft bone. O'Sullivan et al⁵⁵ showed that a 1-degree tapered design enhances primary stability of the implant. As the tapered implant was placed into a cylindrical, undersized socket, the bone was compressed and primary stability of the implant increased.⁵⁵ These authors stated that compression may disturb the local microcirculation and lead to necrosis and bone resorption, thus they indicated the tapered implant design specifically for use in poor quality bone (types 3 and 4). In this study, however, the tapered implants were used in all qualities of bone. Insertion of the implant was always done using a special hand driver or a manual ratchet. In denser bone, high torque levels were sometimes required for final placement of the self-tapping implant. The strong internal hex connection allowed torques up to approximately 125 Ncm without fixture-mount fracture. The resultant high-insertion torques did not appear to result in greater bone resorption or lack of osseointegration.

Several studies have shown a statistical difference between maxillary and mandibular implant survival and success rates, with poorer results in the maxilla.^{21,28,41,56–57} In this study, no statistical difference was observed between maxillary and mandibular implant survival and success rates after 2 years of loading. In the maxilla, the success rate was 98.6%, which was excellent. The top of the implant was placed at the bone crest level. After 2 years of loading, the mean marginal bone resorption was 1.66 mm (± 0.13 mm). Considering that the first implant thread is located 2.5 mm below the top of the neck, it is obvious that bone remodeling did not always reach the first thread. De Bruyn et al³⁷ showed similar data after one year. While other studies have shown less marginal bone resorption, the data were not based on bone resorption during the first year of loading.^{53,57}

The rate of patients lost to follow-up was high

(12%). Reasons for missing the 2-year recall included patients living abroad or far from the dental office (38), patients moving without leaving new contact information (9), patient death (3), and patient injury in a car accident (1).

CONCLUSIONS

Excellent survival and success rates were obtained with tapered multithreaded implants using a non-submerged protocol after 2 years of loading. Five of the 835 implants were removed. The overall survival rate was 99.4%. At 2 years, 6 implants did not reach the success criteria because of mesial and distal bone loss below the first thread. They were not removed because they were stable, painless, and without signs of inflammation. The overall success rate after 2 years was 98.6%. No statistical difference in success rate was observed between maxillary and mandibular implants. The mean marginal bone resorption was 1.66 mm (± 0.13 mm) after 2 years of loading.

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