Preliminary Data of a Prospective Clinical Study on the Osseotite NT Implant: 18-month Follow-up

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Purpose: *This article provides preliminary clinical results on the Osseotite NT implant, which was developed to simplify surgical procedure and cover an extended range of indications. Placement characteristics of NT and standard Osseotite implants were also compared in an in vitro study.* ***Materials and Methods:*** *The in vitro placement characteristics of NT and standard Osseotite implants of 4.0 mm diameter and 8.5 to 15 mm in length were compared. In addition, a total of 182 NT implants (96 maxillary and 86 mandibular) were placed in 92 patients; of these, 87.9% were placed using a 1-stage technique. The implants were placed in healed sites (43.9%), fresh extraction sockets (37.4%), or recent extraction sites (2 months postextraction) (18.7%). Before restoration, healing times of 3 to 4 months in the mandible and 5 to 6 months in the maxilla were allowed. The entered implant length in the osteotomy site before contacting the bony walls (EILOS) was compared, as well as the number of turns and the time required to seat the implants. Cumulative survival rates (CSRs) were calculated for up to 18 months of follow-up after surgery.* ***Results:*** *The EILOS was between 47.3% and 57.6% of implant length for the NT implants; for the standard implants, it was between 12.0% and 21.2%. With the NT implants, the number of turns and the placement time were reduced by 61% to 64% and 61% to 65%, respectively. In the clinical study, 4 implants failed during the healing period; none failed after prosthesis placement. The CSR was 97.79% for implants placed into fresh or recent extraction sites; in healed sites, the CSR was 98.75%. The cumulative prosthetic success rate was 100%.* ***Discussion:*** *This new implant design is seated with special drills; the drilling sequence requires less time and less torque than that used for standard implants. The low failure rate after prosthetic loading was consistent with that observed for standard Osseotite implants.* ***Conclusion:*** *These preliminary data suggest that the NT implant can be predictable in healed sites and fresh or relatively recent extraction sockets.* INT J ORAL MAXILLOFAC IMPLANTS 2005;20:448–454

Key words: *dental implants, extraction sites, implant surfaces, titanium implants*

For the last 25 years, most cylindric endosseous titanium implants have been parallel-walled in design. Recently, conical tapered implants have been introduced to cover wider and more demanding indications.[1–7] They have been specifically designed for use in fresh extraction sites, alveolar ridges with a buccal concavity, narrow edentulous spaces limited by the converging roots of adjacent teeth,[2,3] and bone of limited quantity or poor quality. However, they can also be used in standard clinical situations.

The Osseotite natural tapered (NT) (Implant Innovations/3i, Palm Beach Gardens, FL) is a conical tapered implant with an original approach in terms of shape design and a hybrid surface specifically conceived to cover an extended range of clinical indications.[3] The purpose of this article was to identify the clinical placement characteristics of this implant and to evaluate the preliminary clinical data in an up-to-18-month follow-up.

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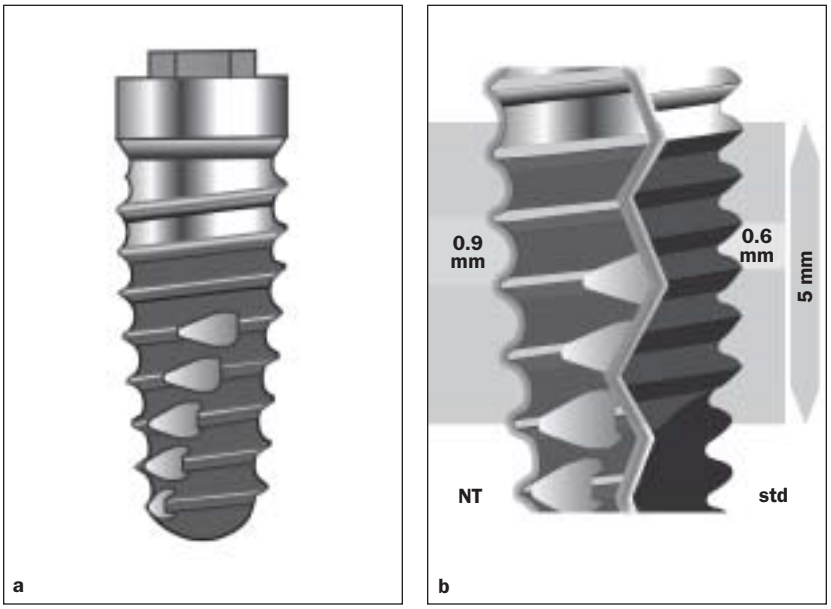

Fig 1a The NT Osseotite implant. Note the tapered conical shape and the 3-mm machined portion at the occlusal aspect of the implant.

Fig 1b Comparison of the pitch of standard (std) and NT Osseotite implants. The pitch of the NT (0.9 mm) is wider than that of the standard implant (0.6 mm). At each turn, the NT implant advances deeper in the osteotomy than the standard implant; this reduces the time required for implant placement.

MATERIALS AND METHODS

Implant Design and Microstructure

The NT implants used in this study were tapered conical implants with an external hex. The NT implant is available in 4 diameters: 3.25 mm, 4.0 mm, 5.0 mm, and 6.0 mm. It has a rounded apex (Fig 1a), and its taper increases from the apex to the implant restorative platform. For example, the 4.0-mm-wide implant has a diameter varying from 2.5 mm at the apex to 4.1 mm at the restorative platform. The hex of the small-diameter implants (3.25 mm wide) has the same height as that of the standard cylindric Osseotite implant but is narrower (2.5 mm versus 2.7 mm). Additional changes from cylindric Osseotite implants include an increased pitch of the external threads (0.9 mm versus 0.6 mm), as shown in Fig 1b. This design change was made to facilitate implant seating in the osteotomy. The presence of multiple additional cutting flutes facilitates the bone cutting process. Threads run throughout the implant length, starting from the apex, with 3 progressive helicoidal patterns angled at 120 degrees. This self-tapping threading is similar to the incremental cutting edge (ICE) design of the cylindric Osseotite implants.

NT implants feature a hybrid surface similar to that of other Osseotite implants. The most coronal 3 mm of the implants are machined; the rest of the implant surface is thermo-etched in a hydrochloric/sulfuric acid mixture.[8] This hybrid surface provides 2 surfaces for an optimized response at the soft tissue level as well as the bone level.

In Vitro Study

The NT placement procedure differs substantially from standard implant placement; therefore, the 2 procedures were compared. The placement of NT and standard implants was computer-simulated with computer-assisted drawing (CAD) software following the drilling sequence described in the manufacturer's instructions. NT and standard implants 4 mm in diameter and 8.5 to 15 mm in length were chosen. The entered implant length in the osteotomy site before contacting the bony walls (EILOS) was compared for each implant length. In addition, the time required for implant seating was also compared at 15 and 20 rpm, as well as the number of turns required to reach final implant seating. To calculate the time, the distance advanced per turn according to insertion speed was divided by the remaining length (total implant length minus EILOS). No standard implants were used in the clinical study.

Clinical Study

Inclusion and Exclusion Criteria. Patients of either sex older than 18 years were enrolled in the study. They had to be physically able to tolerate conventional surgical and prosthetic procedures and willing to comply with all aspects of the treatment and the follow-up schedule. Patients were excluded from the study if they had immune system disorders, uncontrolled diabetes, or metabolic bone disease. Smoking more than 15 cigarettes a day was also an exclusion factor, as well as therapeutic radiation treatment to the head within the past 12 months. Active inflammation in the area intended for implant place-

Table 1 Quadrant Implant Distribution

	Anterior	Posterior	Total
Maxilla	23 (12.6%)	73 (40.1%)	96 (52.7%)
Mandible	17 (9.3%)	69 (37.9%)	86 (47.3%)
Total	40 (22.0%)	142 (78.0%)	182 (100%)

Table 2 Distribution of the Implants in Regard to Length and Diameter

	Diameter				
Length	3.5 mm	4 mm	5 mm	6 mm	Total
10 mm	0	17	4	0	21 (11.5%)
11.5 mm	0	25	24	9	58 (31.9%)
13 mm	7	44	14	9	74 (40.7%)
15 mm	4	23	2	0	29 (15.9%)
Total	11 (6.0%)	109 (59.9%)	44 (24.2%)	18 (9.9%)	182 (100%)

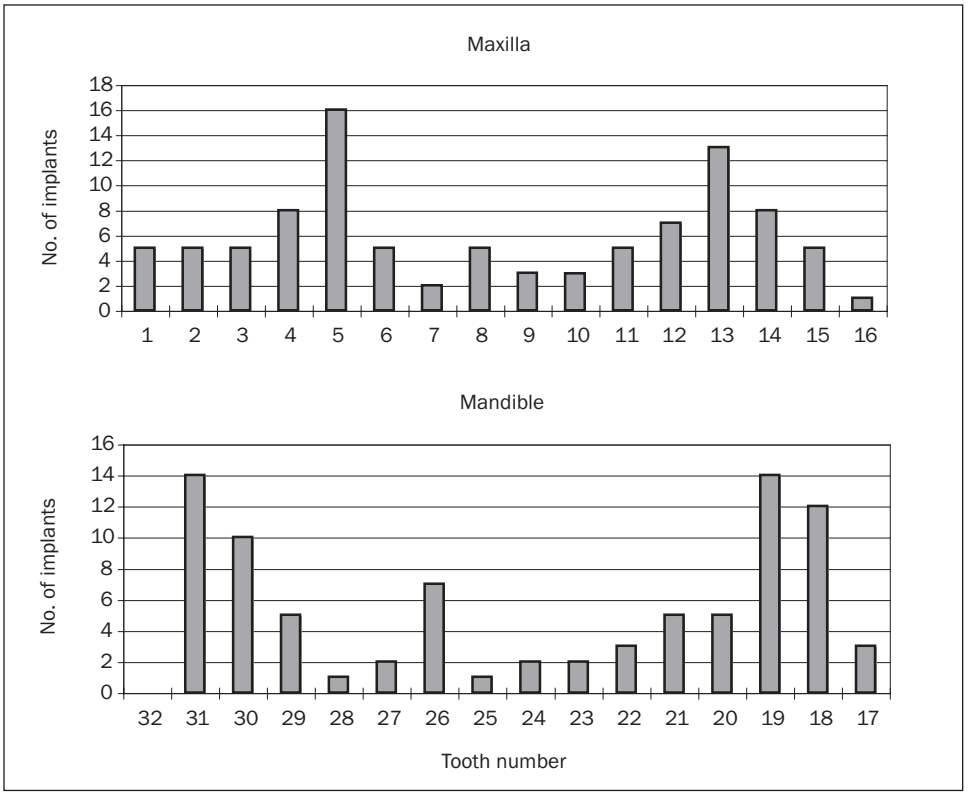

Fig 2 Implant distribution according to implant site. Universal tooth numbers are shown.

ment and need for allogenic bone grafting at the implant site were local contraindications. At least 1 mm of bone had to be available at the buccal and lingual aspects of the implant and 1 to 2 mm beyond the apices. Patients with evidence of severe bruxing or clenching were also excluded.

Patient Study. Between April 2002 and January 2003, 92 patients were treated with 182 NT implants placed under sterile conditions in an operating room. The patient population consisted of 56 women (60.9%) and 36 men (39.1%); the mean age at implant placement was 59.8 ± 14.6 years. A majority of the implants (52.7%) were placed in the maxilla; 37.9% were placed in the posterior mandible and 40.1% in the posterior maxilla. Quadrant distribution is given in Table 1. Implant site distribution is shown in Fig 2. Implant lengths varied as follows: 10 mm (11.5%), 11.5 mm (31.9%), 13 mm (40.7%), and 15 mm (15.9%), as shown in Table 2. The majority of the implants (59.9%) were 4.0-mm-wide implants (Table 2). During surgery, implant sites were categorized as dense bone (5.5%), normal bone (65.5%), or soft bone (29.0%), according to the classification of Trisi and Rao.[9] Submerged implants were allowed to heal for 3 to 4 months in the mandible and 5 to 6 months in the maxilla. They were then restored following traditional prosthetic procedures.

The NT implants were placed in healed and postextraction sites. Eighty implants (43.9%) were placed in healed sites, 68 implants (37.4%) were placed in fresh extraction sockets, and 34 implants (18.7%) were placed according to a delayed immediate protocol. Delayed implants were placed 2 months after tooth extraction (Table 3); this delay was prescribed in cases of traumatic extraction involving loss of cortical bone, suppurative infection, or extraction sockets too large to accommodate a large-diameter implant with sufficient primary stability. Of the 182 implants, 136 (74.7%) supported fixed partial dentures (FPDs) and 46 (25.3%) supported 46 single crowns (SCs).

Surgical Procedures. Most implants (n = 160, 87.9%) were placed in a supracrestal position following a 1-stage procedure. The submerged technique was used for 22 implants (12.1%) in cases where firm primary stability could not be achieved, bone grafting had been done at the site, or the patient had to wear a transitional removable prosthesis. The specific morphology of the conical implant required the use of special drills with a distinct geometry. Drilling was first performed as for standard implants with a round bur and a 2-mm twist drill. The final drilling length was determined by the 2-mm twist drill. To place a 3.25-mm-diameter implant, the corresponding 3.25-mm shaping drill was used. For the larger implants, all the shaping drills of the previous diameters were used. For example, to place a 6.0-mm-wide implant, the shaping drills of the 3.25-, 4.0-, 5.0- and 6.0-mm-wide implants were used. The shaping drill followed the conical implant shape and corresponded to each implant diameter; therefore, the osteotomy site closely matched the implant geometry. Because of the efficient cutting design of the drills, drilling was performed at 300 rpm, as recommended by the manufacturer. This lower speed provided better control and allowed precise drilling of the osteotomy.

When thick cortical crestal bone was encountered, the flared pilot drill (from 2 mm to 3 mm) was used after the 2-mm twist drill. Tapping was rarely performed. When soft bone was encountered, the site was underdrilled to increase primary stability of the implants, and the shaping drill of the corresponding implant diameter was omitted in the drilling sequence; only the previous ones were used. The bone collected by the conical drills was used to fill the bone defects in postextraction sites and to better shape the bone contour in the case of implants placed in a reduced alveolar ridge.

Prosthetic Procedures. The prosthetic procedures with NT implants were identical to those used to restore traditional external-hex implants, because prosthetic components (impression copings, abutments, and screws) are related to the size of the implant restorative platforms. The implant restorative platforms of Osseotite and Osseotite NT implants are the same. All restorations were cement-retained.

Table 3 Implant Placement Procedure Used Following Tooth Extraction

	Placement			
	In healed sites	Immediate	Delayed	Total
Maxilla	34	40	22	96
Mandible	46	28	12	86
Total	80 (43.9%)	68 (37.4%)	34 (18.7%)	182

Survival Criteria. The survival criteria included *(1)* absence of detectable clinical implant mobility, *(2)* absence of pain, *(3)* absence of peri-implant infection, and *(4)* absence of radiolucency around the implants. Patients who did not attend the last recall were to be considered dropouts.

Statistical Analysis. Life table analyses with cumulative implant survival rates (CSRs) and survival rate at 9 months were calculated, as well as cumulative prosthesis success rates.

RESULTS

Calculated Implant Placement Characteristics (In Vitro Study)

The placement characteristics between the NT and the standard implants were different because of the shape of the drills used to place the NT implants. For the NT implant, the conical drill shape permitted the implants to penetrate deeper into the osteotomy site without contacting the bony walls. Fewer turns were necessary to seat the implants in their end position; thus, the placement procedure took less time.

Table 4 compares the EILOS for NT and standard implants. The percentage of the entered implant length is also shown for each implant length (Table 4). The EILOS for the NT ranged from 42.5% to 57.6% of the implant length, depending on the latter; for standard implants, EILOS was 12.0% to 21.2% of implant length, depending on the latter. The number of turns required to achieve final stability was 4.0 to 8.7 turns for NT implants and 11.2 to 22.1 turns for standard implants (Table 4), ie, a 61% to 64% reduction for the NT implants. The time required for placement of the NT implants was reduced by 61% to 65% (Table 4).

Survival Rates

No patient dropped out from the study. Four failures in 4 patients were recorded, 1 in the mandible and 3 in the maxilla (Table 5). Three of them were placed in

Table 4 In Vitro Comparison of Implant Placement Characteristics Between NT and Standard Implants

	EILOS (mm)	% of entered length in implant bed	Remains to enter (mm)	No. of turns until final seating	Reduction (%)	Seating time at 15 rpm (s)	Reduction (%)	Seating time at 20 rpm (s)	Reduction (%)
8.5 mm									
Standard	1.8	21.2	6.7	11.2		45		34	
NT	4.9	57.6	3.6	4.0	64	16	64	12	65
10 mm									
Standard	1.8	18.0	8.2	13.7		55		41	
NT	5.4	54.0	4.6	5.1	63	20	64	15	63
11.5 mm									
Standard	1.8	15.7	9.7	16.2		65		49	
NT	5.9	51.3	5.6	6.2	62	25	62	18	63
13 mm									
Standard	1.8	13.8	11.2	18.7		75		56	
NT	6.4	49.2	6.6	7.3	61	29	61	21	62
15 mm									
Standard	1.8	12.0	13.2	22.1		88		66	
NT	7.1	47.3	7.9	8.7	63	38	57	26	61

Table 5 Failed Implants

Patient	Sex	Age (y)	Medical condition	Procedure	Site*	Implantation site	Bone type	Implant diameter (mm)	Implant length (mm)	Reason for failure	Implant status
1	F	73	Lichen planus	1-stage	5 (14)	Extraction socket	Soft	4	11.5	Apical infection	Early failure
2	M	65	Bruxer	1-stage	2 (17)	Healed	Normal	4	11.5	Unknown	Early failure
3	M	33	–	1-stage	29 (45)	Extraction socket	Normal	4	13	Low primary stability	Early failure
4	M	69	–	1-stage	5 (14)	Extraction socket	Normal	5	13	Too close to adjacent teeth	Early failure

*Universal (FDI) tooth numbering system used.

Table 6 Life Table Analysis

Time interval	Implants at risk	Drop-outs	Failures	Survival rate on interval	Cumulative survival rate
0–6 mo	182	0	4	97.79%	97.79%
6–9 mo	178	0	0	100%	97.79%
9–12 mo	130	0	0	100%	97.79%
12–15 mo	24	0	0	100%	97.79%
15–18 mo	11	0	0	100%	97.79%

fresh extraction sockets and 1 was placed in a healed site. One implant did not achieve firm primary stability; another suffered from an apical peri-implant infection. One implant was placed in the extraction site of a large molar root and was too close to the adjacent tooth. The last implant was lost for unknown reasons. All failures occurred during the healing phase. The survival rate by the end of the healing period was 97.79%; it was 98.75% (79/80) for implants placed in healed sites, 95.59% (65/68) for implants placed in immediate extraction sites, and 100% (34/34) for delayed-placement implants. At 9 months, the implant survival rate, including the immediately placed implants, was 96.95% for 130 implants. No implant was lost after loading. The overall implant CSR was 97.79%, as shown in the life table analysis (Table 6). The prosthetic cumulative success rate was 100%.

Figure 3 shows the radiographs of a typical patient treated with 4 NT implants placed in extraction sockets in the posterior mandible to support an FPD.

DISCUSSION

The Osseotite NT implant has been developed to simplify the surgical procedure and technique and to cover an extended range of indications, including extraction sockets, poor bone quality, and limited space between converging adjacent roots.[3] Simplification has been achieved by having the NT implants

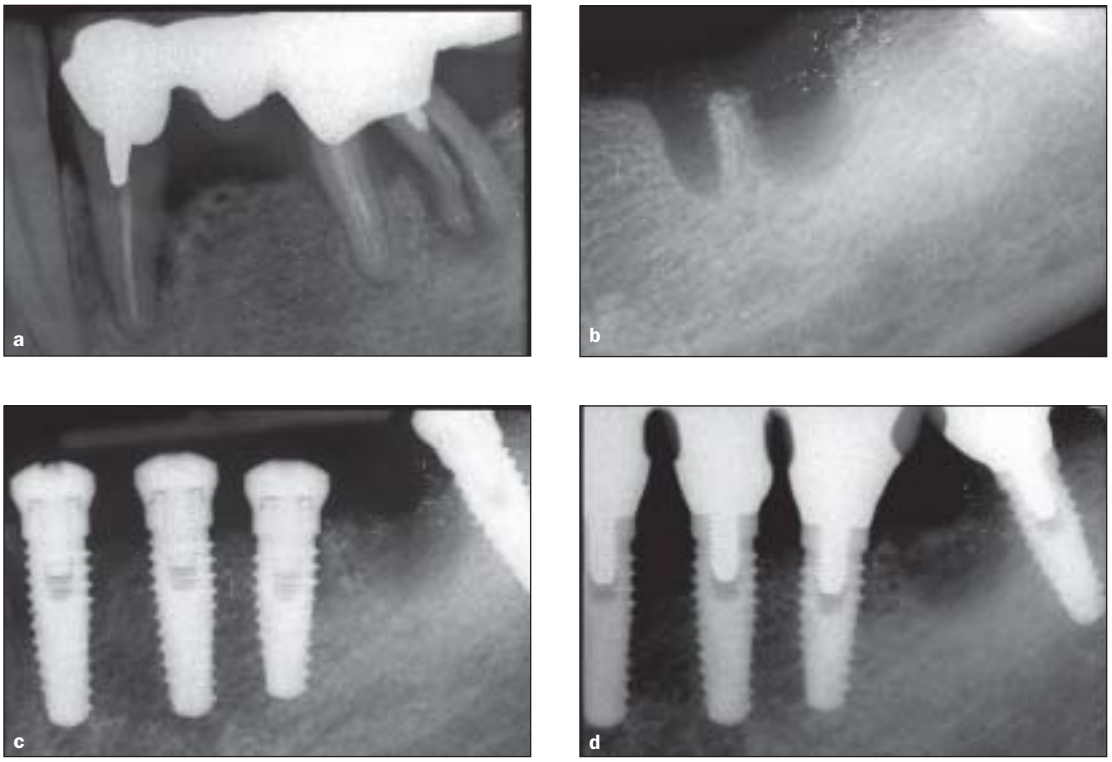

Fig 3 Radiographs of a patient treated with 4 NT implants placed in the posterior mandible in fresh extraction sockets. *(a)* An FPD supported by teeth with a hopeless prognosis. *(b)* After extraction. *(c)* Four 4 × 13 mm NT implants placed immediately after tooth extraction. *(d)* Implants restored with the definitive prosthesis; radiograph taken 6 months after loading.

engage the osteotomy sites deeper than cylindric implants. Fewer turns were required to obtain final implant seating, and the time required for implant placement was reduced by 61% to 64% in an in vitro investigation. The time reduction can become substantial when an edentulous jaw is rehabilitated with 7 to 12 implants. Another possible advantage may be alleviation of the sepsis risk associated with implant surgery.

Clinically, treatment time was saved for several reasons. First, the NT implants were introduced deeper into the osteotomy sites before contacting the walls. When the implants contacted the osteotomies, a mean of 57.6% of an 8.5-mm-long NT implant had entered the osteotomy site versus only 21.2% of a standard implant of the same length. Second, the thread pitch of an NT implant is wider than that of a standard implant, 0.9 mm versus 0.6 mm, so at each turn the NT implants advance deeper into the osteotomies. For example, a 5-mm progression in the osteotomy is obtained with an NT implant within 5.5 turns, whereas for a standard implant, this is achieved after 8.5 turns (Fig 1b). The number of turns necessary for final implant stabilization is therefore reduced.

The altered surgical technique and the presence of additional cutting flutes allowed implant placement with application of a lower torque. All NT implants were fully seated with the drill unit at 45 Ncm. If a torque greater than 45 Ncm is necessary to achieve implant seating, this indicates that the osteotomy site is not prepared deep enough. The implant should be removed, and the osteotomy should be prepared deeper.

Some authors have suggested that implant placement with a higher torque correlates with higher primary stability.[10] Nevertheless, the lower torque used to place the NT implants led to primary stability in bone types 1 and 2 similar to the primary stability achieved for standard implants, as measured by resonance frequency analysis.[11] Furthermore, in bone types 3 and 4, the primary stability of the NT implant was increased by 20% when compared to a standard implant.[7] This was probably the result of the tight adaptation between the implant and the walls of the osteotomy. Osseotite NT implants may also benefit from the osteophilic properties of the Osseotite surface.[11–17]

Four implants failed. The overall CSR was 97.79%; in healed sites, the CSR was 98.75%. All implant failures occurred during the healing period. No implant failed after prosthesis placement, resulting in 100% prosthetic success. For standard Osseotite implants, Grunder and coworkers[15] reported a high prosthetic predictability because all failures were recorded before loading. This chronologic failure pattern was further confirmed by Testori and associates[16] in a 4-

year report on 485 Osseotite implants placed in 181 patients, where all failures (n = 6) occurred before loading. Davarpanah and colleagues[17] evaluated 413 Osseotite implants after 3 years; 12 of the 14 failures could be categorized as early and the other 2 as late. This failure chronology has been maintained as well for Osseotite implants placed within early loading protocols. Lazzara and coworkers[12] published a 1-year report on 429 early loaded Osseotite implants; in that study, 6 of the 7 failures occurred during the healing period. In a 3-year report on implants loaded after 8 weeks, Testori and associates[14] confirmed this pattern; 6 of the 9 failures in their study occurred during the 8-week healing period.

In a review article, Esposito and associates[18] noted that for machined-surface implants, late failures during the first year of loading account for approximately half of failures. Subsequently, these authors stated that failure to establish osseointegration because of host-related factors, ie, bone quality and quantity, might be revealed within 1 year of loading. If implants fail after at least 1 year of loading, implant failure may be attributed to overloading or periimplantitis. This observation might be valid for machine-surfaced implants; however, for Osseotite implants, several studies[12,14–17] have documented a drastic decrease in the failures after loading. This pattern has been attributed to the acid-etched Osseotite surface[13] and has been documented in report of other rough-surfaced implants.

Although preliminary, these results are promising. For the standard Osseotite implant, evaluation after 3 or 4 years did not lead to substantial modifications in implant prognosis when compared to evaluation immediately after loading.[14,16,17] In the present study, clinically stable implants have been considered to be successful implants, but crestal bone levels have not been analyzed.

In this study, early loading of the NT implants was not addressed because most (56.1%) implants were placed in postextraction sockets, either immediately or after 2 months. The standard healing periods of 3 to 4 months in the mandible and 5 to 6 months in the maxilla were followed to obtain osseointegration. However, it would be relevant to evaluate NT implants placed in extraction sockets and loaded after 8 weeks of healing.

CONCLUSION

This study showed that the surgical protocol of NT implants was somewhat simplified and shortened when compared to that used for standard implants. This implant was used advantageously in healed and postextraction sites. Although preliminary, the clinical data from this limited patient population showed that the NT implant was predictable, with survival rates at least comparable to those documented for standard Osseotite implants.

REFERENCES

1. Callan DP, Hahn J, Hebel K, et al. Retrospective multicenter study of an anodized, tapered, diminishing thread implant: Success rate at exposure. Implant Dent 2000;9:329–336.
2. Shapoff CA. Clinical advantages of tapered root form dental implants. Compend Contin Educ Dent 2002;23:42–48.
3. Rosenlicht JL. SwissPlus Implant System, Part 1: Surgical aspects and intersystem comparisons. Implant Dent 2002; 11:144–153.
4. Sahiwal IG, Woody RD, Benson BW, Guillen GE. Macro design morphology of endosseous dental implants. J Prosthet Dent 2002;87:543–551.
5. Schiroli G. Immediate tooth extraction, placement of a Tapered Screw-Vent implant, and provisionalization in the esthetic zone: A case report. Implant Dent 2003;12:123–131.
6. Fugazzotto PA. Guided bone regeneration at immediate implant insertion and loading: A case report. Implant Dent 2004;13:223–227.
7. Davarpanah M, Martinez H. Morphologie implantaire conique. Alternatives 2003;17:19–25.
8. Testori T, Szmukler-Moncler S, Francetti L, et al. Immediate loading of Osseotite implants. A case report and histologic analysis after 4 months of occlusal loading. Int J Periodontics Restorative Dent 2001;21:451–459.
9. Trisi P, Rao W. Bone classification: Clinical-histomorphometric comparison. Clin Oral Implants Res 1999;10:1–7.
10. Friberg B, Sennerby L, Meredith N, Lekholm U. A comparison between cutting torque and resonance frequency measurements of maxillary implants. A 20-month clinical study. J Oral Maxillofac Surg 1999;28:297–303.
11. Testori T, Bianchi F, Del Fabbro M, Szmukler-Moncler S, Francetti L, Weinstein RL. Immediate non-occlusal loading vs early loading in partially edentulous patients. Pract Proced Aesthet Dent 2003;15:787–794.
12. Lazzara RJ, Porter SS, Testori T, Galante J, Zetterqvist LA. A prospective multicenter study evaluating loading of Osseotite implants two months after placement: One-year results. J Esthet Dent 1998;10:280–289.
13. Lazzara RJ, Testori T, Trisi P, Porter SS, Weinstein RL. A human histologic ananlysis of Osseotite and machined surfaces using implants with 2 opposing surfaces. Int J Periodontics Restorative Dent 1999;19:117–129.
14. Testori T, Del Fabbro M, Feldman S, et al. A multicenter prospective evaluation of 2-months loaded Osseotite implants in the posterior jaws: 3-year follow-up results. Clin Oral Implants Res 2002;13:154–161.
15. Grunder U, Gaberthuel T, Boitel N, et al. Evaluating the clinical performance of the Osseotite implant: Defining prosthetic predictability. Compend Contin Educ Dent 1999;20:628–633.
16. Testori T, Wiseman L, Woolfe S, Porter SS. A prospective multicenter clinical study of the Osseotite implant: Four-year interim report. Int J Oral Maxillofac Implants 2001;16:193–200.
17. Davarpanah M, Martinez H, Celletti R, Alcoforado G, Tecucianu JF, Etienne D. Osseotite implant: 3-year prospective multicenter evaluation. Clin Implant Dent Relat Res 2001;3:111–118.
18. Esposito M, Hirsch JM, Lekholm U, Thomsen P. Biological factors contributing to failures of osseointegrated oral implants. (I). Success criteria and epidemiology. Eur J Oral Sci 1998;106: 527–551.