A Prospective Multicenter Clinical Study of the Osseotite Implant: Four-Year Interim Report

Tiziano Testori, MD, DDS[1]/Lorne Wiseman, BSc, DDS, FACD[2]/
Spencer Woolfe, LDS, RCSI, MS[3]/Stephan S. Porter, DDS, MSD, MS[4]

This article reports the 4-year interim results of a multicenter study evaluating the clinical performance of the Osseotite dental implant. At 4 study centers, 485 Osseotite implants were consecutively placed in 181 patients (219 were placed in the mandible and 266 in the maxilla). A total of 355 implants were placed in posterior regions. Short implants (10 mm or less) represented 31.5% (n = 153) of all implants placed in this study. Patients were restored with 210 restorations, distributed as 123 short-span prostheses, 58 single-tooth replacements, 28 long-span prostheses, and 1 maxillary overdenture. At this 4-year interim evaluation, the mean time from implant placement to the most recent evaluation was 52.6 ± 3.0 months, with a mean loading time of 43.3 ± 3.8 months. Of the 485 implants placed, there have been 6 failures. All implant failures occurred prior to loading and were categorized as early implant failures. Five of the 6 failures occurred in the maxilla. Only one of the 153 short implants failed to integrate. Baseline radiographs were obtained at prosthesis connection. Radiographic analysis 1 year post-restoration showed a mean bone loss of 0.09 ± 0.7 mm. From baseline to the end of the second year of function, an overall mean bone loss of 0.13 ± 0.8 mm was recorded, indicating no additional bone was lost after the first year of implant function. At 4 years, the cumulative implant success rate for all implants placed in this study was 98.7%, with a 99.4% success rate in the posterior mandible and 98.4% success rate in the posterior maxilla. Results of this 4-year interim analysis indicate that this implant achieved a high success rate in posterior regions and that all failures with this implant in this patient population occurred prior to implant loading. When the clinical success of implants 10 mm or shorter was compared to that of implants greater than 10 mm in length, the shorter implants in this study performed similarly to longer implants. (Int J Oral Maxillofac Implants 2001;16:193–200)

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The development of biologically driven implant surface technologies offers the clinician the opportunity to improve treatment outcomes and provide more predictable implant treatment for their patients. It is well documented that the surface characteristics of implanted materials can influence the healing and growth of tissues adjacent to the implant surface. With our increasing knowledge of the interaction between specific implant surface characteristics and the resulting biologic response, future implant surface designs may have the potential to improve implant performance beyond what is being achieved today.

Historically, the 2 most common methods used to modify the surface of titanium dental implants are grit- or sandblasting[1–6] or plasma-spraying with titanium or calcium phosphate (hydroxyapatite [HA]).[1,7–10] The Osseotite implant (Fig 1) incorporates a surface texture prepared by a process of thermal dual acid-etching the titanium implant surface with hydrochloric and sulfuric acid (HCl/H_2SO_4), which results in a clean, highly detailed surface texture devoid of entrapped surface material and impurities.[11,12] In a recently published report describing the mechanisms of endosseous implant integration, Davies[13] discussed how this surface micro-texture enhances fibrin attachment to the implant surface during the clotting process and how this early healing

[1]Visiting Professor, Section of Implantology, Department of Periodontology, University of Milan, San Paolo Hospital, Italy.
[2]Diplomat Periodontics, Montreal, Quebec, Canada.
[3]Private Practice, Dublin, Ireland.
[4]Private Practice, West Palm Beach, Florida.

Reprint requests: Dr Tiziano Testori, via Maurizio Monti No. 1, 22100 Como, Italy. Fax: +39 031 301 083. E-mail: ttestor@tin.it

Fig 1 Design and micro-appearance of the Osseotite implants used in the study. The implant has a machined surface at the coronal aspect and a dual acid-etched portion from the third thread to the apex.

event influences the early development of bone-to-implant contact. In an earlier study by Klokkevold and associates,[11] a mechanical and histologic evaluation of this same implant surface seemed to support an early healing phenomenon by showing improved implant anchorage within the bone at earlier time periods in comparison to a machined implant surface. In a recently published human histologic study using a dual-surfaced implant model in the posterior maxilla, Lazzara and coworkers[14] reported twice the amount of bone-to-implant contact on this implant surface at 6 months of healing, compared to a machined implant surface. The histologic results reported in that study suggested that in the less dense, more trabecular bone typically found in the posterior maxilla, the micro-texture of the implant surface appeared to have improved the biologic response of the surrounding bone as compared to the machined implant surface. In 1997, Sullivan and colleagues[12] presented a 3-year interim analysis of this same implant and reported 96.6% implant success. A more recent study by Grunder and coworkers[15] reported 98.6% implant success at 3 years.

The present article reports the 4-year interim data from an ongoing prospective multicenter study designed to evaluate the clinical performance of the Osseotite implant when placed in the posterior regions of the mandible and the maxilla for the support of partial prostheses.

MATERIALS AND METHODS

Four private practice centers in Europe and North America participated in this study. Osseotite implants (3i/Implant Innovations, Palm Beach Gardens, FL), in lengths of 7, 8.5, 10, 11.5, 13, 15, and 18 mm and diameters of 3.25, 3.75, 4, 5, and 6 mm, were available for use at each participating study center. Implant lengths and diameters were selected for each patient based on individual clinical needs.

Patients enrolled in this study included males and females at least 18 years of age who were physically able to tolerate conventional implant surgical and prosthetic procedures and were willing to comply with all aspects of implant treatment and follow-up evaluations. Patients reporting a history of immune system disorders, uncontrolled diabetes mellitus, metabolic bone disease, smoking more than 10 cigarettes a day, pregnancy, therapeutic radiation to the head or neck within the past 12 months, along with individuals with evidence of severe bruxing or clenching, were excluded from this study. Local exclusion criteria included active inflammation or infection in the area(s) that were treatment-planned for implant placement or a need for bone augmentation at the time of implant placement.

Prior to the start of the study, an investigators' meeting was convened to finalize the protocol and establish standards for surgical techniques, procedures, and evaluation of clinical outcomes. Each investigator was the primary operator for each study surgery. Implants were placed using a conventional 2-stage, submerged surgical protocol, allowing 4 months of healing for implants placed in the mandible and 6 months in the maxilla prior to Stage 2 surgery. Implants were positioned with the top of the cover screw level with the crest of the alveolar ridge. Implant diameters and lengths for each surgical site were selected according to the individual clinical situation and bone dimension, so that there was a minimum of 1 mm of bone surrounding the lateral and apical aspects of each implant. The bone density (quality) at each implant site was determined based on the resistance encountered during preparation of the osteotomy and was scored as dense, normal, or soft.

Stage 2 surgery (implant uncovering) was performed no earlier than 4 months after implant placement for implants placed in the mandible and 6 months in the maxilla. After implants were uncovered, either a healing abutment or definitive abutment was attached to the implant. The stability of each implant was evaluated immediately after abutment connection by application of alternating pressure perpendicular to the abutment with 2 opposing metal instrument handles. Prosthetic procedures began as soon as 2 weeks following Stage 2 surgery, and prostheses were placed as soon as possible after laboratory fabrication. Single-tooth implants were restored with cement-retained crowns. Short-span

restorations (2 to 5 units) were either cemented or screw-retained directly to the implant or to an intermediary abutment. Cement-retained, short-span prostheses were affixed to the underlying abutment with provisional cement (Temp Bond, Kerr, Romulus, MI) to allow for removal of the prosthesis if necessary to evaluate the stability of individual implants.

Implants were evaluated at the following times: postoperative assessments after Stage 1 and Stage 2 surgery; 6 months, 12 months, 18 months, and 24 months after loading; and then annually for up to 5 years following prosthesis placement. Radiographs were taken immediately following implant placement, at the time of prosthesis placement (baseline), after 6 and 12 months of loading, and then annually for the duration of the study. Changes in crestal bone levels were measured by calibrated examiners using electronic calipers at 3× magnification. During postrestorative follow-up appointments, the mobility of single-tooth implants was evaluated as previously described. Cement-retained prostheses were not removed unless radiographic and/or soft tissue changes indicated that progressive bone loss was occurring around the implant or that the implant was failing. Screw-retained prostheses were removed annually for evaluation of implant stability.

The criteria used for determining implant success in this study included: *(1)* no clinically detectable mobility of the implant; *(2)* no radiographic evidence of peri-implant radiolucency or rapidly progressive bone loss; *(3)* no recurrent or persistent peri-implant infection; and *(4)* no patient complaint of implant-associated pain, neuropathies, or paresthesia.

For the purpose of describing the timing of implant failure reported in this study, implant failure that occurred after implant placement but prior to prosthesis attachment was considered early implant failure. Implant failure occurring after implant restoration and loading was considered late, even if failure occurred within 6 months of loading.

RESULTS

In total, 485 implants were consecutively placed in 181 patients (76 males and 105 females) (Table 1). At the time of implant placement, patient ages ranged from 18 to 86 years, with a mean age of 55.4 years. Age distribution was similar for both male (56.1 years) and female (54.9 years) populations.

Implant distribution by dental arch was 219 in the mandible and 266 in the maxilla (Table 2). A total of 356 implants (73.4%) were placed in locations posterior to the maxillary and mandibular canines. Mandibular implants were located most frequently in molar areas (Fig 2), whereas in the maxilla, implants were placed most often in premolar areas. Short implants, defined for this report as 10 mm or shorter, represented 31.5% (153) of the implants placed in this investigation (Tables 2 and 3).

Table 1 Patient Demographics

Patients	n	Mean age (y ± SD)	Smokers (%)*
Male	76 (42%)	56.1 ± 15.9	14 (18%)
Female	105 (58%)	54.9 ± 14.9	23 (22%)
Total	181	55.4 ± 15.3	37 (20%)

*Average cigarette consumption per day: 12.5 for men, 12.1 for women, and 12.2 overall.

Bone density values recorded by each surgeon during implant site preparation are illustrated in Table 4 and were scored as dense in 9.9% of sites, normal in 75.2% of sites, and soft in 14.9% of sites. In total, 10.5% of all posterior maxillary sites were classified as soft bone by surgeons, whereas only 1.2% of posterior mandibular sites were classified as soft bone.

While not specified as an exclusion criterion in the protocol, it may be important to note that 42 implants were placed as immediate replacements for extracted teeth. Surgical complications included 2 maxillary sinus perforations, 12 buccal plate dehiscences, 4 lingual plate perforations, 2 perforations of the inferior border of the mandible, and 1 alveolar canal violation.

The distribution of implants by length and diameter is shown in Table 3. The distribution of prostheses by type (Fig 3) included 58 single-tooth restorations, 123 short-span (2 to 5 units) fixed partial prostheses (281 implants), 28 long-span (6 to 14 units) restorations (144 implants), and 1 maxillary overdenture (2 implants). Of the 211 implant-supported restorations, 55% were located in the maxilla and 45% were located in the mandible.

The mean healing time from implant placement to second-stage surgery was 5.1 ± 2.6 months and 6.7 ± 2.7 months for implants placed in the mandible and maxilla, respectively. The mean time interval between implant placement and restoration and loading was 9.3 ± 4.1 months. The mean time interval between implant loading and the most recent follow-up evaluation was 43.3 ± 3.8 months. The total mean implantation time was 52.5 ± 3.0 months for all implants evaluated in this study.

At this 4-year interim evaluation, 16 patients (8.8%) representing 39 implants (7.4%) were lost to follow-up. Reasons for patient dropout included

Table 2 Distribution of Implants by Length and Location

Implant length	Mandible		Maxilla		Total
	Anterior	Posterior	Anterior	Posterior	
Short implants					
7 mm	0	4	0	3	7
8.5 mm	0	14	2	8	24
10 mm	6	78	13	25	122
Total	6 (1.2%)	96 (19.7%)	15 (3.1%)	36 (7.4%)	153 (31.5%)
Long implants					
11.5 mm	1	8	4	13	26
13 mm	11	54	39	95	199
15 mm	30	13	24	40	107
Total	42 (8.6%)	75 (15.4%)	67 (13.8%)	148 (30.8%)	332 (68.5%)

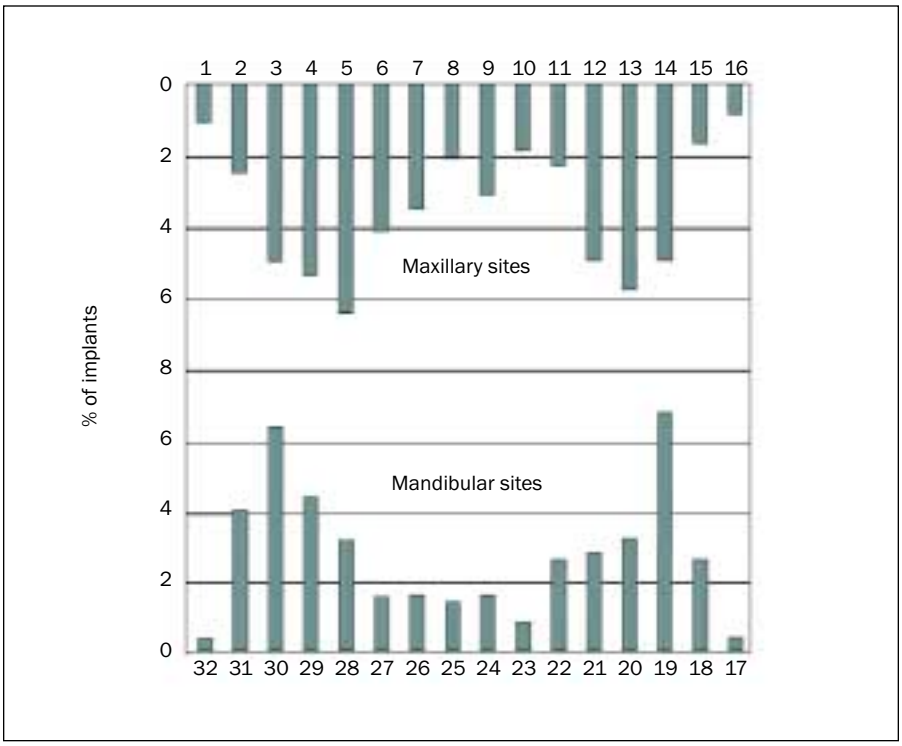

Fig 2 Distribution of study implants according to tooth position.

Table 3 Distribution of Implants by Length and Diameter

Implant length	Diameter					Total
	3.25 mm	3.75 mm	4 mm	5 mm	6 mm	
7 mm	0	0	0	6	1	7 (1.4%)
8.5 mm	4	15	0	3	2	24 (4.9%)
10 mm	2	92	6	19	3	122 (25.2%)
11.5 mm	0	16	3	6	1	26 (5.4%)
13 mm	11	163	8	12	5	199 (41.0%)
15 mm	1	103	1	1	1	107 (22.1%)
Total	18 (3.7%)	389 (80.2%)	18 (3.7%)	47 (9.7%)	13 (2.7%)	485

geographic relocation and economic limitations for continuing restorative procedures and follow-up evaluations. Prior to withdrawal from the study, no implant failures or implant-related complications were observed in these patients.

The mean bone level change during the first year of implant function, calculated as a comparison between radiographs obtained at the time of prosthesis insertion (baseline) and those obtained at the end of 12 months of loading, was 0.09 ± 0.7 mm. Mean bone loss, as measured from baseline levels to the end of the second year of function, was 0.13 ± 0.8 mm.

The implant failure analysis for patients is illustrated in Table 5. Six implants failed to integrate in 6 patients. Four of the 6 implant failures occurred in a single study center. Four of the 6 implant failures occurred in posterior sites, and 5 of the 6 implant failures occurred in the maxilla. All implant failures occurred prior to loading, were identified at or before Stage 2 surgery, and were classified as early implant failures. Five of the 6 failed implants exhibited mobility during manual examination or during abutment connection, and 1 implant was removed because of complaints of implant-related pain. Of the 153 short implants, only 1 (7 mm long) failed to integrate.

Table 4 Analysis of Bone Quality

Location	Bone quality (% of sites)		
	Type 1 (dense)	Type 2 (normal)	Type 3 (soft)
All locations	9.9	75.2	14.9
Maxilla	0.9	41.6	12.1
Anterior	—	14.3	1.6
Posterior	0.9	27.3	10.5
Mandible	9.0	33.6	2.8
Anterior	2.5	6.7	1.6
Posterior	6.5	26.9	1.2
Total anterior	2.5	21.0	3.2
Total posterior	7.5	54.2	11.7

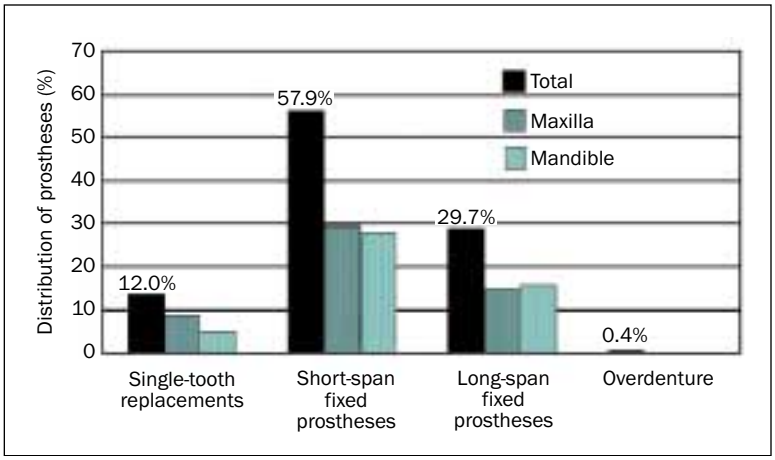

Fig 3 Distribution of prosthetic treatment, shown as a percentage of overall restorations and their distribution between maxillary and mandibular sites.

Table 5 Implant Failure Analysis

Center	Sex	Age at stage 1 surgery (y)	Implant diameter (mm)	Implant length (mm)	Location	Bone quality	Time since placement (mo)	Time of failure	Reason for failure
A	F	48	3.75	13	Posterior maxilla	2	13.3	Pre-loading	Pain
B	F	53	3.75	15	Anterior maxilla	2	6.2	Pre-loading	Mobility
B	F	49	3.75	15	Posterior maxilla	2	8.5	Pre-loading	Mobility
B	F	18	3.75	13	Posterior mandible	2	3.3	Pre-loading	Mobility
B	M	34	3.25	13	Anterior maxilla	2	3.9	Pre-loading	Mobility
C	F	54	5	7	Posterior maxilla	3	11.2	Pre-loading	Mobility

Table 6 Life Table Analysis

Interval (mo)	No. of implants at risk	No. of failures	Duration	Lost to follow-up	Interval survival rate	Cumulative survival rate
0 to 3	485			1	100.0%	100.0%
3 to 6	484	2		3	99.4%	100.0%
6 to 9	479	2		2	99.6%	99.6%
9 to 12	475			10	99.8%	99.2%
12 to 15	465	2		10	100.0%	99.2%
15 to 18	453			8	100.0%	98.7%
18 to 21	445			7	100.0%	98.7%
21 to 24	438			3	100.0%	98.7%
24 to 27	435			3	100.0%	98.7%
27 to 30	432			2	100.0%	98.7%
30 to 33	430			1	100.0%	98.7%
33 to 36	429				100.0%	98.7%
36 to 39	429				100.0%	98.7%
39 to 42	429				100.0%	98.7%
42 to 45	429			3	100.0%	98.7%
45 to 48	426		36	1	100.0%	98.7%
48 to 51	389		104	2	100.0%	98.7%
51 to 54	283		128		100.0%	98.7%
54 to 57	155		135		100.0%	98.7%
57 to 60	20		20		100.0%	98.7%

Duration = time from implant surgery to the date of last documented determination of success.

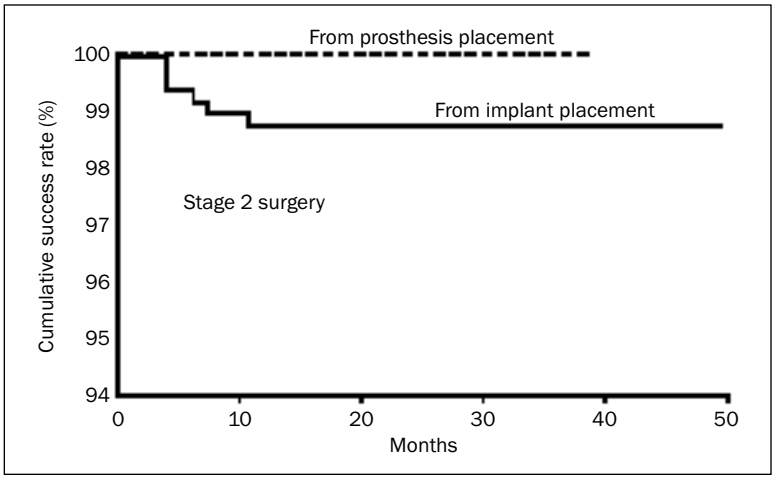

Fig 4 Life table analysis showing the cumulative success rate of study implants. Curves are included for implants from the time of placement (solid line) and from the time of prosthetic loading (dotted line).

A life table analysis of all study implants (Table 6, Fig 4) shows a cumulative success rate (CSR) of 98.7% 1 year after implant placement. With no implant failures occurring after loading, the 2, 3, and 4-year follow-up CSRs remained at 98.7% (Table 6). The 4-year implant success rates for the anterior and posterior mandible were 100% and 99.4% (1 implant failure), respectively, while the implant success rates in the anterior and the posterior maxilla were 97.6% and 98.4%, respectively. Of the 181 study patients, 37 (118 implants) reported smoking an average of 12.2 cigarettes/day. Two implants in this group failed, yielding a CSR of 98.3%.

DISCUSSION

The biologic response to the dual acid-etched Osseotite implant surface has been investigated in several preclinical mechanical and animal[11,16–18] and

human histologic studies.[14] These indicate a positive influence of this textured implant surface on the biologic response of bone in terms of early bone apposition, a higher percentage of direct bone-to-implant contact, and strong implant anchorage. The present prospective multicenter study was intended to evaluate the effect of this micro-textured implant surface as it relates to the long-term clinical success of the implant.

Recently, Davies[13] described several processes involved in the early development of the bone-to-implant interface. During the initial healing period, Davies proposed, it is the osseoconductive characteristics of the roughened implant surface and its interaction with the surrounding blood clot that result in a more rapid and extensive development of the bone-to-implant interface. This theory may explain in part the human histologic results reported by Lazzara et al[14] for the Osseotite implant surface. The authors used small dual-surfaced implants placed in the posterior maxilla and reported a mean bone-to-implant contact value of 72.9% on the surface and a 33.9% bone-to-implant contact on the opposing machined-surface portion of the same implant after 6 months of unloaded healing. The potential effect of developing more apposing bone along the implant surface may be the influencing factor in the results observed in the present clinical study.

With nearly 4 years of post-loading data, a cumulative success rate (CSR) of 98.7% and a post-loading CSR of 100% suggest that this surface can significantly reduce the incidence of post-loading implant failures. From a historical perspective, Esposito and colleagues' review[19] of the Brånemark System machined-surface implant shows that late failures accounted for approximately half of all reported implant failures. A similar occurrence of early and late post-restorative implant failures is reported in 2 articles evaluating the 3i machined-surface threaded implant.[20,21] In these 2 articles, late failure of the machined-surface 3i implant also accounted for nearly half of all reported implant failures.

Grunder and colleagues[15] reported their 2-year post-loading interim evaluation of 219 Osseotite implants supporting fixed prostheses. Most of the implants were located in posterior areas, which are normally associated with higher failure rates related to poor-quality bone and higher occlusal load. The authors found a similar implant failure pattern as in the present clinical study—only early implant failures—with the observation of 3 failures discovered prior to second-stage surgery and no post-loading failures. When Lazzara and colleagues[22] studied these implants under an early loading protocol (prosthetic loading after 2 months of healing), a similar pattern of early implant failures was seen. Whether the micro-texture surface is responsible for the decrease in late failures needs to be confirmed elsewhere; however, the benefit of this clinical performance can be appreciated by the clinician and the patient.

There is a tendency for shorter-length (≤ 10 mm) machined-surface implants to fail more often than longer implants.[20,21,23–27] This tendency was not observed for the shorter implants placed in this study. Of the 153 short implants placed (31.5% of the total study implants), only one 7-mm implant, which was placed in the posterior maxilla in a site recorded as soft bone, failed to osseointegrate (Table 4). It is possible that the difference in biologic response between the machined implant surface and the micro-textured surface is responsible for the difference in the survival rates for short implants. If surface characteristics are shown to promote short implant performance, this could lead to an increased use of shorter-length implants in areas previously not considered suitable for implant restorations because of insufficient vertical bone height.

CONCLUSION

After 4 years of post-loading follow-up, a cumulative implant success rate of 98.7% was observed for all the implants placed in this study. All implant failures in this study occurred prior to restorative loading and may be classified as early implant failures.

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