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

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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)

Key words: clinical trial, dental acid etching, dental implants, multicenter study, titanium

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 sandblasting1–6 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/H2SO4), 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, Davies13 discussed how this surface micro-texture enhances fibrin attachment to the implant surface during the clotting process and how this early healing

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event influences the early development of bone-to-implant contact. In an earlier study by Klokkevold and associates, 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 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 presented a 3-year interim analysis of this same implant and reported 96.6% implant success. A more recent study by Grunder and coworkers 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 inter-
mediary 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 nec-
essary 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 place-
ment, 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. Dur-
ing 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 fail-
ure 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 pos-
terior 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).

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 dehis-
cences, 4 lingual plate perforations, 2 perforations
of the inferior border of the mandible, and 1 alveo-
lar canal violation.

The distribution of implants by length and diam-
er is shown in Table 3. The distribution of pros-
theses by type (Fig 3) included 58 single-tooth
restorations, 123 short-span (2 to 5 units) fixed par-
tial prostheses (281 implants), 28 long-span (6 to 14
units) restorations (144 implants), and 1 maxillary
 overdenture (2 implants). Of the 211 implant-supp-
ported restorations, 55% were located in the max-
illa 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 1 Patient Demographics

<table>
<thead>
<tr>
<th>Patients</th>
<th>n</th>
<th>Mean age (y ± SD)</th>
<th>Smokers (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>76 (42%)</td>
<td>56.1 ± 15.9</td>
<td>14 (18%)</td>
</tr>
<tr>
<td>Female</td>
<td>105 (58%)</td>
<td>54.9 ± 14.9</td>
<td>23 (22%)</td>
</tr>
<tr>
<td>Total</td>
<td>181</td>
<td>55.4 ± 15.3</td>
<td>37 (20%)</td>
</tr>
</tbody>
</table>

*Average cigarette consumption per day: 12.5 for men, 12.1 for
women, and 12.2 overall.
Table 2  Distribution of Implants by Length and Location

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

Table 3  Distribution of Implants by Length and Diameter

<table>
<thead>
<tr>
<th>Implant Length</th>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3.25 mm</td>
</tr>
<tr>
<td>7 mm</td>
<td>0</td>
</tr>
<tr>
<td>8.5 mm</td>
<td>4</td>
</tr>
<tr>
<td>10 mm</td>
<td>2</td>
</tr>
<tr>
<td>11.5 mm</td>
<td>0</td>
</tr>
<tr>
<td>13 mm</td>
<td>11</td>
</tr>
<tr>
<td>15 mm</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>18 (3.7%)</td>
</tr>
</tbody>
</table>

Fig 2  Distribution of study implants according to tooth position.
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

<table>
<thead>
<tr>
<th>Location</th>
<th>Type 1 (dense)</th>
<th>Type 2 (normal)</th>
<th>Type 3 (soft)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All locations</td>
<td>9.9</td>
<td>75.2</td>
<td>14.9</td>
</tr>
<tr>
<td>Maxilla</td>
<td>0.9</td>
<td>41.6</td>
<td>12.1</td>
</tr>
<tr>
<td>Anterior</td>
<td>—</td>
<td>14.3</td>
<td>1.6</td>
</tr>
<tr>
<td>Posterior</td>
<td>0.9</td>
<td>27.3</td>
<td>10.5</td>
</tr>
<tr>
<td>Mandible</td>
<td>9.0</td>
<td>33.6</td>
<td>2.8</td>
</tr>
<tr>
<td>Anterior</td>
<td>2.5</td>
<td>6.7</td>
<td>1.6</td>
</tr>
<tr>
<td>Posterior</td>
<td>6.5</td>
<td>26.9</td>
<td>1.2</td>
</tr>
<tr>
<td>Total anterior</td>
<td>2.5</td>
<td>21.0</td>
<td>3.2</td>
</tr>
<tr>
<td>Total posterior</td>
<td>7.5</td>
<td>54.2</td>
<td>11.7</td>
</tr>
</tbody>
</table>

Table 5 Implant Failure Analysis

<table>
<thead>
<tr>
<th>Center</th>
<th>Sex</th>
<th>Age at stage 1 surgery (y)</th>
<th>Implant diameter (mm)</th>
<th>Implant length (mm)</th>
<th>Location</th>
<th>Bone quality</th>
<th>Time since placement (mo)</th>
<th>Time of failure (mo)</th>
<th>Reason for failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>F</td>
<td>48</td>
<td>3.75</td>
<td>13</td>
<td>Posterior maxilla</td>
<td>2</td>
<td>13.3</td>
<td>Pre-loading</td>
<td>Pain</td>
</tr>
<tr>
<td>B</td>
<td>F</td>
<td>53</td>
<td>3.75</td>
<td>15</td>
<td>Anterior maxilla</td>
<td>2</td>
<td>6.2</td>
<td>Pre-loading</td>
<td>Mobility</td>
</tr>
<tr>
<td>B</td>
<td>F</td>
<td>49</td>
<td>3.75</td>
<td>15</td>
<td>Posterior maxilla</td>
<td>2</td>
<td>8.5</td>
<td>Pre-loading</td>
<td>Mobility</td>
</tr>
<tr>
<td>B</td>
<td>F</td>
<td>18</td>
<td>3.75</td>
<td>13</td>
<td>Posterior mandible</td>
<td>2</td>
<td>3.3</td>
<td>Pre-loading</td>
<td>Mobility</td>
</tr>
<tr>
<td>M</td>
<td>F</td>
<td>34</td>
<td>3.25</td>
<td>13</td>
<td>Anterior maxilla</td>
<td>2</td>
<td>3.9</td>
<td>Pre-loading</td>
<td>Mobility</td>
</tr>
<tr>
<td>C</td>
<td>F</td>
<td>54</td>
<td>5</td>
<td>7</td>
<td>Posterior maxilla</td>
<td>3</td>
<td>11.2</td>
<td>Pre-loading</td>
<td>Mobility</td>
</tr>
</tbody>
</table>
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 animal11,16–18 and
human histologic studies. 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 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. 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 of the Brånemark System failures. When Lazzara and colleagues studied implants under an early loading protocol, 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. 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.

**REFERENCES**


