Technique for Placement of Oxidized Titanium Implants in Compromised Maxillary Bone: Prospective Study of 290 Implants in 126 Consecutive Patients Followed for a Minimum of 3 Years After Loading

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Purpose: This prospective clinical study evaluated the performance of 290 tapered, anodic oxidized (TiUnite) titanium implants placed in compromised bone in a consecutive series of 126 patients. Materials and Methods: Inclusion criteria were: (1) a need for dental implants in either a single-tooth or partially edentulous segment, (2) sufficient medical fitness to undergo the procedure, (3) enough bone to enable placement of a 10-mm or longer implant, and (4) compromised bone, as judged by computed tomography and confirmed by clinical findings, in at least one implant site. Implants were placed and left unloaded for at least 6 months (mean 9.9 ± 3.9 months) before placement of the first provisional prosthesis and followed for at least 3 years after loading. Marginal bone was measured by an independent radiologist. Results: A second-stage uncovering was required for approximately half the implants. Failure of osseointegration was observed for only two implants; all other implants provided the intended prosthetic support during the entire observation period. The overall implant survival rate after 3 years of loading was 99.3%. The average mean changes in the marginal bone level showed stability (~2.70 mm, ~2.67 mm, and ~2.74 mm at 1, 2, and 3 years postloading, respectively). Conclusions: Using a modified surgical technique that minimized the osteotomy dimensions, tapered implants with an oxidized surface proved to be a predictable support for fixed prostheses in both grafted and ungrafted compromised bone. Marginal bone levels were stable throughout at least 3 years of follow-up. Int J Oral Maxillofac Implants 2009;24:325–334

Key words: bone grafts, bone quality, dental implants, marginal bone, titanium oxide

Both bone quality and implant surface topography influence bone response after implantation,1 and an implant’s surface properties play a significant role in its success and biocompatibility.2 Titanium dental implants have been successful in bony anchorage for single-tooth and multiple units for more than 4 decades. By 1985, researchers recognized that the titanium itself is not the biocompatible material; rather, the titanium oxide surface layer is biocompatible.3 An implant with a highly crystalline and phosphate-enriched titanium oxide layer characterized by a microstructured surface with 1- to 10-µm open pores (TiUnite, Nobel Biocare, Göteborg, Sweden) better maintains primary mechanical stability and shortens the time needed to achieve secondary biologic osseous stability than does a machined-surface implant.4–11 Titanium oxide-enriched implants thus may be more suitable for use in challenging conditions involving compromised bone.

Implant macrodesign also plays an important role in the success of implant treatment. Implants with a tapered body have better primary stability and thus a higher likelihood of integration than parallel-walled body designs11–15; this may be because tapered implants distribute forces into the surrounding bone more uniformly. Tapered implants such as the Replace Select also are associated with more uniform compaction of the surrounding bone along the periphery of the osteotomy and greater early stability, permitting successful immediate occlusal loading12–16 and higher long-term success rates.11 Wider implants are more stable initially, as judged by

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resonance frequency analysis, perhaps in part because of the greater surface area that is in contact with bone, whereas longer implants are not. Features that increase primary stability are particularly important when placing implants in regions of compromised bone (eg, type IV bone), where the likelihood of failure is higher.11,16,17

The aim of this study was to evaluate a customized osteotomy technique for placement of TiUnite Replace tapered implants in compromised bone with regard to long-term implant stability and maintenance of marginal bone.

MATERIALS AND METHODS

Criteria for Selection of Patients
Subjects requiring dental implants were recruited from the author’s private, referral-based periodontal practice and included if (1) they were medically able to withstand the procedures and (2) they either possessed sufficient residual host bone in three dimensions to allow placement of a 10-mm or longer implant or could receive reconstructive procedures to create that amount of bone. Whether residual or grafted, the bone in at least one site had to be compromised (type IVA, B, or C as described by Lekholm and Zarb18 and by Bahat19) or have no cortical bone (type V) for the patient to be included in the analysis. Computerized tomography (CT) scans were obtained on a GE Discovery 16 scanner (GE Healthcare, Chalfont St Giles, United Kingdom) with axial slices being captured at 1-mm intervals. Two-dimensional axial and panoramic views and three-dimensional bone views were then constructed. Such scans depict the type, quality, and quantity of bone accurately. In all cases, bone status was validated by intraoperative assessment with instruments.

For all subjects, a comprehensive surgical and restorative treatment plan was developed.20 This included a full dental and medical history and preoperative intraoral calibrated radiographs in addition to the CT scans. Medical consultation was obtained to ensure that all patients were acceptable candidates for elective surgery. If a subject was initially deemed unfit, the unfavorable medical or dental conditions were corrected or minimized. Subjects who were cigarette smokers were informed that smoking increases the implant failure rate21,22 and asked to comply with a smoking reduction regimen.

Description of Series
Between January 2002 and June 2003, 69 women and 57 men received a total of 290 consecutively placed implants with a TiUnite surface (Replace Tapered, Replace Select Tapered, Nobel Biocare, Yorba Linda, CA) for restoration of single-tooth and partially edentulous sites (Table 1). All implants were placed in the maxilla, with 118 (41%) in the anterior and 172 (59%) in the posterior (Table 2). Type III, IV, or V bone was present at the sites of placement of 88% of the anterior implants and 96% of the posterior implants (Table 3).

Surgical Protocol
All areas of previous infections were curetted mechanically while being irrigated with chlorhexidine gluconate 0.12% topical oral solution. Sterile 2 × 2-inch gauze sponges impregnated with hydrogen peroxide 3% in a 3:1 ratio with chlorhexidine to peroxide were packed gently into the surgical area for 3 to 4 minutes. The site was then debrided with a rotary instrument and further irrigated chemically.

A principal objective was to obtain primary implant stability. To achieve this in areas of reduced bone quality, enlargement of the osteotomy site and the number of surgical entries into each site were minimized.16,18,23 A final drill with a diameter smaller than the manufacturer’s recommendation was used.
and a stepped preparation technique was customized for each site using traditional twist drills instead of the tapered/stepped drills (Nobel Biocare, Yorba Linda, CA) that are part of the normal Replace Tapered implant drilling sequence. When using the 2-mm twist drill, the cutting resistance was monitored to determine the minimum osteotomy diameter that would seat the implant (Fig 1).

Special care was taken to avoid any deviation between intended and actual implant positions. For each patient, intraoral access was evaluated preoperatively; it was assessed relative to the length of the implant and its mount, the various drill selections and extensions, and any deflection by the lip (Figs 2 and 3). Periapical radiographs were taken intraoperatively whenever questions arose regarding implant position relative to vital anatomic structures.

Whenever insufficient bone was present initially to enable placement of a 10-mm implant, a two-dimensional onlay or three-dimensional J-graft plus sinus inlay autogenous bone graft was performed (three anterior; 67 posterior). All bony irregularities at the recipient site were removed, and the site was smoothed to create maximum surface contact with the bone block. A flap with anterior advancement was used prior to closure to gain additional tissue range and achieve primary closure of the expanded surgical site. These flaps require precise design, gentle manipulation, and repeated trial closure to prevent undue tension. The sites of all staged autogenous bone block grafts were allowed to heal for a minimum of 6 months before implants were placed. At both grafted and native sites, particulate autogenous bone was used to fill in small spaces around the implants at the time of their placement. All implants had either a cover screw or a short healing abutment placed for an unloaded two-stage or one-stage protocol.

A radiograph was obtained immediately after surgery. Antibiotics and nonsteroidal anti-inflammatory drugs were given to all subjects, who were instructed to use ice packs and consume cold drinks for 3 days. Chlorhexidine rinse was prescribed for 2 to 3 weeks, along with the use of cotton swabs soaked with chlorhexidine 3 to 4 times a day for 3 to 4 months.

Follow-up evaluation of the subjects was at weekly or biweekly intervals for the first 2 months. Any negative soft tissue changes or adverse reactions were addressed by immediate intervention, including removal of debris or foreign bodies and irrigation with chlorhexidine, hydrogen peroxide, or other antiseptic. Whenever these interventions did not eliminate the adverse local reaction, flaps were raised, cover screws or healing caps were retightened, or loose flaps were coapted. During the healing period, implant stability, occlusal relationships, and soft tissue health were monitored regularly.

**Restorative Protocol**

Whenever possible, fixed provisional restorations were supported by the remaining teeth, even if they carried a poor prognosis and ultimately would be extracted. As an alternative, provisional implants or additional implants beyond what would normally have been necessary were placed to support immediate provisional restorations. In all cases, every possible effort was made to reduce transmucosal loading of the implants. Whenever hopeless teeth served as abutments for the provisional restorations, these were later extracted, and implants were placed in those sites after the initial (study) implants had osseointegrated. The initial implants then supported a provisional restoration that protected the newly placed implants.
In situations where it was not possible to protect the implant from loading, the implant was submerged and uncovered later. The remaining implants were treated in a one-stage unloaded protocol. Depending on soft tissue healing and contours, some of the study implants received two separate provisional restorations. The first was delivered when the implant was uncovered or the healing abutment was removed. After the soft tissue had matured and its contours had stabilized, the first provisional prosthesis was either adjusted or replaced by a second one that reflected the contours of the stabilized tissue. Prostheses were removed routinely for assessment of soft tissue healing and implant integration. No impressions were taken until at least 6 months after implant placement.

Radiologic Analysis
All baseline radiographs were obtained using precision metal x-ray holders (Masel Orthodontics, Bristol, PA). All follow-up radiographs that were performed by the author were also done with this technique. In 28 patients, follow-up of the impression technique or abutment placement was done by other clinicians using the technique employed by the author, digital radiographs, or a Rinn Uni-Grip holder (Dentsply, Elgin, IL). Radiographs were planned for the day of implant placement, the time of impression coping placement or abutment placement and provisionalization, and at successive 6-month intervals through at least 36 months from the date of provisional restoration placement. Additional radiographs were
obtained if the patient reported pain or discomfort or if there was deterioration of the soft tissues. The images were examined for vertical bone loss and radiolucency around the implants.

Using the implant-abutment junction as a reference point, the marginal bone levels on the mesial and distal aspects of the implants were measured to the nearest 0.1 mm at 7× magnification by a single independent radiologist at Göteborg University, Göteborg, Sweden. A negative value indicated bone apical to the reference point. All bone levels that were coronal to the reference point were recorded as zero.

Once the definitive restorations were luted, the metal-ceramic restorations were not removed routinely. All subjects were questioned periodically about pain and chewing function.

Statistical Methods
Descriptive statistics and actuarial life table analysis were used to calculate cumulative survival rates. The Mann-Whitney U test was employed to compare marginal bone levels of implants placed in grafted and nongrafted sites and conducted at the 5% significance level based on the implant as a unit. Implant success was defined as suggested by Albrektsson et al.25

RESULTS
Evaluation using an electric handpiece (DEC 500; Nobel Biocare) demonstrated that all implants were fully seated and stable at the determined length to an applied minimum of 40 Ncm without further rotation.18 In the approximately 50% of treatments that required a two-stage approach, the original provisional restorations were remade 2 to 3 weeks after second-stage surgery. An acrylic resin provisional restoration was placed on all the implants for a minimum of 3 months before a metal-ceramic restoration was provided. For all implants, the first provisional restoration was placed an average of 9.9 ± 3.9 months after implant placement.

Radiographic analysis of 128, 167, and 80 implants was possible at the 1-, 2-, and 3-year postloading follow-up appointments, respectively. Seventeen patients (19 implants) were dropped from the study because of poor compliance. In addition, one patient died and could not be followed after the time of loading. Two implants failed, both anterior and both in the same subject, within 1 year after loading. After 3 years of postloading follow-up, life table analysis revealed an overall cumulative survival rate of 99.3% (95% confidence interval, 98.0% to 100%) for the entire series, 98% for anterior implants, and 100% for posterior implants (Table 4).

The greatest change in marginal bone levels occurred between the time of implant insertion and loading. The mean marginal bone level at implant insertion was –0.53 ± 0.93 mm (n = 263), while at the time of loading it was –2.08 ± 1.07 mm (n = 232). Thirty-two percent of the implants showed a bone loss exceeding 2 mm between the time of implant insertion and loading. Bone loss before loading is more likely in areas of poor-quality or reconstructed bone, and healing can take considerably longer than 6 months, again calling attention to the importance of customizing treatment to each patient’s individual situation. As indicated in Table 5, stabilization of marginal bone levels occurred after 1 year of follow-up. At the 3-year postloading follow-up, the mean marginal bone level was –2.74 ± 1.06 mm (n = 80). From the time of loading to the 3-year follow-up, the mean marginal bone loss was 0.67 ± 1.06 mm (n = 64). No individual implant showed more than 4.75 mm of bone remodeling during the 3-year follow-up period.

Seventy sites (24%) were subjected to bone grafting. The mean marginal bone levels were similar for implants placed in grafted and nongrafted sites: –0.62 ± 0.99 mm (n = 59) and –0.51 mm ± 0.92 mm (n = 204), respectively. However, a significantly higher mean marginal bone level was found at the time of loading in grafted sites: –1.83 ± 0.94 mm (n = 58) versus –2.16 ± 1.11 mm (n = 174) for ungrafted sites (P = .035). Twenty-one percent of the implants placed in
grafted sites and 35% of the implants placed in native bone showed bone loss exceeding 2 mm between the time of implant insertion and loading (Table 5). No clinically significant differences were found between implants placed in grafted sites and those placed in nongrafted sites when comparing bone levels at any other follow-up examination. As indicated in Table 5, bone remodeling after loading was minor for implants placed in both grafted and nongrafted sites. At 3 years after loading, the mean marginal bone level for grafted sites was \(-2.53 \pm 1.05\) mm \((n = 26)\) and for nongrafted sites it was \(-2.83 \pm 1.06\) mm \((n = 54)\). This amounts to a loss of \(0.43 \pm 1.07\) mm at grafted sites and \(0.79 \pm 1.04\) mm at nongrafted sites from the time of loading to the 3-year postloading follow-up examination (Figs 4 to 6).

### DISCUSSION

Implant survival in grafted or compromised maxillary bone has undergone steady improvement over the past 25 years. In 1991, Jaffin and Berman reported a 65% 5-year survival rate among implants placed in type IV bone.\(^{26}\) In 1999, Lekholm et al reported a 77% overall 3-year survival rate for implants placed in sites augmented with various autogenous grafting methods.\(^{27}\) In 2005, Wiltfang et al showed an overall 5-year success rate of 93.1% for implants placed in sinus inlay and autogenous onlay graft sites in the severely resorbed maxilla.\(^{28}\) That study also demonstrated early bone loss, associated with grafts, that stabilized after 12 months. The current finding of an

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### Table 5  Marginal Bone Loss (mm) Between Implant Insertion and Loading and Between Loading and 3-Year Follow-up

<table>
<thead>
<tr>
<th>Time/mean loss (mm)</th>
<th>All sites (%)</th>
<th>Grafted sites (%)</th>
<th>Nongrafted sites (%)</th>
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<tr>
<td>Insertion–loading</td>
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<td></td>
</tr>
<tr>
<td>&lt; 0</td>
<td>9(^*) (4)</td>
<td>2 (4)</td>
<td>7 (4)</td>
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<td>0</td>
<td>19 (9)</td>
<td>4 (8)</td>
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<td>10 (19)</td>
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<td>&gt; 4.0</td>
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<tr>
<td>Mean</td>
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<tr>
<td>SD</td>
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<td>1.01</td>
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<td>No. of implants surveyed</td>
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<td>53</td>
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<td>4 (18)</td>
<td>11 (26)</td>
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<td>4 (6)</td>
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<td>1 (2)</td>
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<tr>
<td>3.1–4.0</td>
<td>1 (2)</td>
<td>0 (0)</td>
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<tr>
<td>Mean</td>
<td>0.67</td>
<td>0.43</td>
<td>0.79</td>
</tr>
<tr>
<td>SD</td>
<td>1.06</td>
<td>1.07</td>
<td>1.04</td>
</tr>
<tr>
<td>No. of implants surveyed</td>
<td>64</td>
<td>22</td>
<td>42</td>
</tr>
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</table>

\(^*\)Mean of mesial and distal values.

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![Fig 4](image-url)  
**Fig 4**  Box plot of all available values on marginal bone level at the different follow-up visits. Boxes show medians, quartiles, and extreme values. Circles show outliers (cases with values between 1.5 and 3 box lengths from the upper or lower edge of the box). Asterisks show extreme cases (cases with values more than 3 box lengths from the upper or lower edge of the box). The box length is the interquartile range.
**Fig 5** Example of outcome. (a) Preoperative view of a severely periodontally involved right quadrant. (b) Time of discharge to restorative clinician after healing abutment placement. (c and d) Radiographic follow-up at 26 months.

**Fig 6** Another example of outcome.

**Fig 6a** Preoperative radiograph shows significant deficiency of residual alveolar bone.

**Figs 6b to 6e** Intraoperative photographs show three-dimensional reconstruction. Sinus inlay grafting is most apparent radiographically; horizontal and vertical cranial cortical grafts were used to reconstruct the arch profiles. Strategic temporary use of hopeless teeth helps prevent early transmucosal loading of graft.

**Figs 6f and 6g** Radiographs at (f) 8 months after grafting and (g) nearly 2 years later.

**Fig 6h to 6j** (h) Implants at start of restorative process. (i) One-year follow-up radiograph. Note that the right second molar was removed after its use for support of the provisional restoration. (j) Two-year follow-up results. Early bone loss has not worsened.
overall 99.3% 3-year postloading survival rate for implants placed in compromised and grafted sites is a gratifying extension of that overall trend of improvement.

Increasing knowledge regarding the proper handling of dental implants and a deeper understanding of implant surface–bone interactions have contributed to the improved survival rates. The results of the present study as well as others indicate that modifications to the implant placement surgical technique, the implant surface,15,29–31 and the implant macro design22,33 are particularly important to the survival of implants.

Studies have shown a more robust early bone response to the TiUnite surface than to machined surfaces.5–10 When Glauser et al compared machined and TiUnite surface Brånemark System implants in immediate loading applications, they found that the TiUnite surface implants exhibited significantly better survival rates.15,30 Results similar to those of the current study also have been reported when TiUnite surface implants were placed in patients subjected to reconstructive jaw surgery or in soft bone.12,34,35

In addition to the oxidized surface, implants in the current study had a tapered body. Previous results have indicated that implants with this design distribute forces into the surrounding bone in a more uniform way than parallel-walled self-tapping implants, and they are associated with more uniform compaction of the surrounding bone.12–15 The primary stability of tapered implants has been superior to that of implants with straight-body designs.10 Cumulative survival rates between 98.6% and 100% have been reported when placing such implants.36,37 This is well in line with the current study results.

The finding in the present study that the use of a wide implant in a socket with undermined or thinned cortical bony housing and thin periodontium stood a greater likelihood of recession (3 of 53 cases) suggests that extra care should be taken when planning to place wide-diameter implants in esthetically critical compromised sites.

Albrektsson et al suggested that six variables determine lifelong dental implant integration38: (1) biocompatibility of the material, (2) implant macrostructure (shape), (3) implant microstructure (surface), (4) status of the implant bed, (5) surgical technique, and (6) prosthetic loading conditions. The current study focused on three of these variables. Two of these variables are controlled by the manufacturer: the implant macrostructure (tapered shape) and its microstructure (larger oxidized surface area achieved via greater porosity). The third variable is surgical technique. For this study, the dedicated tapered drills provided by the manufacturer were replaced by straight twist drills that provided a customized stepped preparation.

In the author’s opinion, surgical technique is of utmost importance when working in soft and reconstructed bone. Two aspects warrant special emphasis: ensuring that the desired three-dimensional orientation is achieved and undersizing of the site preparation. Maintenance of the intended three-dimensional orientation is important for optimal structural support of the restoration. Furthermore, misangulation can compromise the blood supply to fragile soft tissue and supporting bone, which in turn can lead to late soft tissue loss, with negative esthetic consequences. Preservation of the intended orientation in areas of soft and reconstructed bone when access is limited by adjacent teeth and opposing dentition requires a thorough three-dimensional evaluation of the site anatomy as well as selection of the optimal armamentarium for execution.

Deviations of drill direction in soft bone constitute an inherent risk and should be avoided. Any unplanned deviations should be counted as implant failures, as should any positioning that jeopardizes esthetics or phonetics. Causes of drill directional deviation include use of self-tapping implants and inadvertent nonaxial orientation, along with pressure of the drill or implant mounts during drilling.

Although self-tapping implants have certain insertion advantages for seating implants in dense bone, these implants present disadvantages when soft, compromised bone is encountered. First, the sharp threads of self-tapping implants cut through soft bone. In contrast, the threads of the tapered implant used in the present study push and compress the bone. Second, in soft bone, any deviation of the implant mount orientation during insertion can cause the self-tapping implant to cut in the direction of the nonvertical pressure, because the host bone does not provide sufficient resistance to maintain the orientation. Such an inadvertent deflection from the intended direction may occur because of nonaxial pressure by the operator or limitations imposed by neighboring and/or opposing teeth and the commissure of the lip. Deflection caused by the commissure can be avoided by proper preoperative evaluation of intraoral access and the selection of appropriate drills and implant mounts. When access is limited, a drill extender can provide the minimal overall length needed to avoid any unintended deflection.

It has been well established that surviving machined implants enter into a steady state with stable bone levels and an absence of soft tissue inflammation in similar applications with 5- to 10-year follow up.18,39,40 Long-term studies specifically
addressing soft tissue stability and the influence on long-term esthetic outcomes will be required to determine whether the oxidized (TiUnite) surface has a similar impact on hard tissue stability and soft tissue health.

In the present study, the implant-abutment junction was used as a reference point from which the distance to the marginal bone level was measured. At the 3-year postloading follow-up examination, the mean marginal bone loss on radiographs of 64 implants was 0.67 ± 0.66 mm from the time of abutment connection. In an earlier study by Glauser et al evaluating the effectiveness of the TiUnite surface over a 4-year period in soft bone that used a different implant macrostructure and an external hexagonal restorative platform, the mean marginal bone loss was 1.30 ± 0.90 mm. However, in the present study the greatest amount of bone loss, 1.54 ± 1.22 mm, occurred between implant insertion and loading, and a significantly higher mean marginal bone level was found at the time of loading in grafted sites than in nongrafted sites. Direct comparison by time period with the results of Glauser et al is not possible, because Glauser et al used an immediate occlusal loading protocol.

CONCLUSION

During the observation period, tapered implants with an oxidized surface (TiUnite) proved to be a predictable foundation for supporting fixed prostheses in compromised residual host bone or autogenous grafted bone. From 1 year through 3 years after loading, marginal bone levels were stable. A modified surgical technique customized to the patient that minimizes site diameter improves the likelihood of success.

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