A Bone Quality-Based Implant System: First Year of Prosthetic Loading

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KEY WORDS
Crestal bone loss
Radiographic changes
Success rates
Prospective study
Implant success rate
BioHorizon implants
Bone quality
Implant design

INTRODUCTION

Implant dentistry is often the treatment of choice to replace missing teeth in both partially and completely edentulous patients. In the past, the clinician would evaluate the intra-arch sites of available bone greater than 7 mm in height and 5 mm or greater in width. Implants would then be inserted into those sites to support a prosthesis. An implant of identical design and diameter was selected for each. The only variable from one patient to another was the number and length of the implants. As the bone volume decreased, the implant number and length would decrease. Today, a number of reports have emphasized the importance of the quantity and quality of bone for both the surgical and pros-
thetic survival of dental implants. The volume and density of the recipient bone have also been shown to be determining criteria to establish proper treatment plans with adequate number of implants and sufficient surface area.\(^2,3\) Inappropriate implant number or design in poor quality bone have resulted in higher failure rates.\(^4,6\) Early loading failure has been a frequently reported complication, especially in soft bone.\(^7-11\) Methods reported to decrease failures include the use of larger surface area implants, surface coatings, and progressive bone loading.\(^12\)

A patented process to design an implant to optimize the amount of strain to the recipient bone at the cellular level within ideal physiologic limits was begun in February 1994.\(^13\) The mechanical properties of different bone densities were identified and correlated to Misch’s four bone densities classification.\(^2,3,14\) A finite element analysis resulted in the development of four different implant designs, one for each type of bone quality observed in the jaws\(^15,16\) (Fig 1). In an animal study conducted in 1996, 16 Maestro dental implants were inserted in eight dogs. Histological analysis was performed on half of the implants after stage II uncovering at 3 months and the other half 6 months after the prosthetics were loaded. The results confirmed the presence and maintenance of a lamellar bone-implant interface (Fig 2).\(^17\) A histological report with double tetracycline bone labeling of an implant retrieved from a patient after 12 months in function also confirmed the presence of lamellar bone at the implant-bone interface. The bone turnover rate was 1 to 3 \(\mu\)m per day and similar to the surrounding bone turnover,\(^18\) which is less than 50% per year (Fig 3). This turnover rate is greatly improved compared with the greater than 500% rates adjacent to other implants reported in the literature.\(^19\)

The BioHorizons system philosophy is based upon the tenet that to minimize strain at the implant-bone interface, the surface area needs to be optimized where the mechanical stresses are greatest and the bone quality (that is, strength) is poorest. As a result of patented optimization techniques, as much as a 450% increase in functional surface area is obtained when compared with other implant designs currently available (Table 1).\(^20\) Functional surface area is defined as that portion of a root-form dental implant that is able to dissipate compressive and tensile loads to the bone.\(^20\) In this system, implants are identified by their diameter and coded D1, D2, D3, and D4 to reflect the bone density for which they are indicated (ie, a D4 implant is designed for D4 bone). Their design specifically addresses the quality of bone and modifies the surface area in relation to the changes in strength and modulus of elasticity.\(^15,16\) As a result, the surface area is greater in softer bone, which generally occurs more often in the posterior regions, where the stresses are also highest. The bone quality can be assessed before surgery by computerized tomography scan Hounsfield values, by estimation by arch location or during surgery by the tactile sense of the surgeon, or by the torque indicator in the handpiece.\(^21,22\) One implant length, based upon the bone density and implant diameter, is also predesigned. For example, the 5-mm-diameter implant for the densest bone (D1 bone) is 9 mm long, whereas the D4 implant is 12 mm long. The 4-mm-diameter implants are 1 mm longer than their 5-mm-diameter counterparts. Although the implants are provided in only one length for each width and bone density, their overall functional surface area is greater than for traditional implants 5 mm longer.

A preliminary report demonstrating 98.9% surgical success of 364 implants was previously published.\(^23\) The primary purpose of this article is to update the previous report. The results of the prostheses inserted in the first 103 patients 12 to 26 months after the prosthetic was loaded are presented. In addition, data relevant to the surgical survival and crestal bone loss during the stage I surgery to stage II uncover, stage II to prosthesis delivery, and prosthesis delivery to 1 year of loading are reported.

**Materials and Methods**

A 5-year, prospective clinical study was initiated in 1996 to evaluate the clinical performance of a bone density-based dental implant system, the BioHorizons Maestro System. Specifically, the study was designed to evaluate the effect of variables such as implant design and bone density (that is, bone quality) on dental implant quality of health and overall implant survival. Disqualifying systemic factors for po-

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**Figures 1–6**

**Figure 1.** The Maestro Dental Implant System manufactured by BioHorizons Implant Systems is designed for each of the four bone densities found in the mouth. **Figure 2.** A Normanski and polarized light photomicrograph shows a Maestro dental implant loaded for 6 months with substantial concentric lamella of the formed osteons as well as interstricood lamellae indicating the presence of mature formed osteons between the threads. (Courtesy of D. E. Stefflik, Medical College of Georgia, Augusta, Ga.) **Figure 3.** Photomicrograph of a patient with double tetracycline bone labels, separated by two 1-month intervals prior to removal of a 12-month loaded Maestro dental implant in the maxillary first premolar region. This demonstrates bone remodeling of 1 to 3 \(\mu\)m per day. (Courtesy of M. Sharawy, PhD, Medical College of Georgia, Augusta, Ga.) **Figure 4.** This mandibular first molar has bone above the Maestro D2 implant body platform after 1 year of loading. The total bone loss is recorded as 0 mm, rather than a positive number, which would decrease the mean vertical bone loss data. (Courtesy of F. Dietsch-Misch.) **Figure 5.** Two maxillary centrals are splinted together, supported by Maestro D2 and D3 implants. The 1-year total bone loss is 0.4 mm on the D2 implant (left) and 0.5 mm on the D3 implant. This corresponds to the 0.5 mm smooth collar below the implant platform. (Courtesy of C. M. Misch.) **Figure 6.** A photograph taken 1 year after loading of an implant-supported fixed prosthesis in the maxilla and mandible.
tential study participants included (but were not limited to) severe hypertension, uncontrolled diabetes, symptomatic thyroid disorder, pregnancy, and any other debilitating disease or unwillingness or inability to comply with the study requirements. Implant site disqualifying criteria included the presence of an allograft or autograft with inadequate healing, fibrous dysplasia, osteitis deformans, residual roots, history of head or neck radiation therapy, untreated periodontitis, and inadequate oral hygiene.

There were 104 patients; 79 women and 25 men. At the time of the implant insertion, the patients ranged in age from 21 to 68 years. Forty-two patients had implants inserted in the maxillary arch, and 62 patients had implants placed in the mandible. There were eight completely edentulous maxillae and 22 completely edentulous mandibles. All regions of the mouth received implant treatment (ie, anterior, posterior, maxilla, and mandible).

Radiographic evaluation consisted of panoramic radiographs supplemented with lateral cephalograms, periapical radiographs, and computerized tomograms when indicated. The standardized surgical protocol for the bone quality–based implant system has been previously published. The first 94 implants in this study were inserted with the platform 0.5 mm above the crest of the bone, which placed the external hex 1.5 mm above the bone and the first-stage cover screw 1.7 mm above the crest of the ridge. This protocol was then modified to insert the platform of the implant level with the height of the facial contour of bone for D1, D2, and D3 implants, and to countersink the platform of D4 implants 0.5 to 1 mm below the crest. The implants were allowed to heal from 3 to 8 months, depending on the bone density (longer for less dense bone) and the patients’ appointment schedule.

The clinical surgical failure of the implant was assessed by the clinician on the basis of any one of the following: lack of rigid fixation; presence of persistent and irreversible pain or infection; peri-implant radiolucency; loss of bone support over more than half the length of the implant; uncontrolled exudate; improper placement angulation; and implants unable to be used in the final restoration (which we termed “sleepers”).

Any adverse event was reported on a separate form. The clinician also noted whether the cover screw perforated the soft tissue during the healing phase. The patient’s medical status and oral hygiene were noted at each appointment. Implants were restored following the progressive bone loading protocol. During the prosthetic restoration phase, implant health was assessed using the following criteria: presence or absence of pain; mobility; probing depths; presence or absence of gingival inflammation; exudate; radiolucency; level of gingiva; and width of keratinized tissue. Follow-up evaluation after final prosthesis delivery of each implant included the same criteria. Examinations were scheduled at 3 and 6 months, 1 year, 18 months, and 2, 3, 4, and 5 years. Radiographs of the prostheses and implants were scheduled at the time of prosthesis delivery, at 6 months, and at 1, 2, 3, 4, and 5 years. The prostheses were also evaluated for adverse events such as porcelain fracture, abutment screw loosening, and un cemented prostheses. Implant health was evaluated using Misch’s Implant Quality Scale, where categories I and II correspond to optimum to satisfactory implant health, category III to compromised health, and categories IV and V to implant failure. All sleepers would be counted as failures; however, there were none present in this study (Table 2).

### Crestal Bone Loss

Intraoral radiographs (vertical bite wings and periapical) were taken at the time of presurgical assessment, at first- and second-stage surgery, after prosthesis insertion, at 6 months and 1 year after prosthesis insertion, and yearly thereafter. Crestal bone remodeling was evaluated by scanning each radiograph at a minimum resolution of 600 dpi into a computer system designed to measure bone gain or loss within 0.1 mm by means of a magnified image. The known thread pitch of each implant design was used to calibrate the measurements for each implant, thereby adjusting for the effect of any misalignment of the film plane relative to the implant axis on the apparent crestal bone position. Six measurements were made for each implant (three on the mesial aspect and three on the distal aspect) and then aver-

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**Table 1**

<table>
<thead>
<tr>
<th>Thread surface area for different types of thread form implants†</th>
<th>Manufacturer‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter (mm)</td>
<td>Surface area (mm²)</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------</td>
</tr>
<tr>
<td>4.0</td>
<td>1.59</td>
</tr>
<tr>
<td>3.75</td>
<td>1.27</td>
</tr>
<tr>
<td>3.8</td>
<td>1.11</td>
</tr>
</tbody>
</table>

† Each surface area is calculated for a 10-mm length without the crest module and without coatings or surface condition.
‡ BioHorizons Implant Systems Inc, Birmingham, Ala; Nobel Biocare, Gothenburg, Sweden; Steri-Oss, Yorba Linda, Calif.
§ D1 indicates the most dense bone; D4, the least dense bone.

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* Courtesy of T. Strong, Birmingham, Ala.
† Each surface area is calculated for a 10-mm length without the crest module and without coatings or surface condition.
‡ BioHorizons Implant Systems Inc, Birmingham, Ala; Nobel Biocare, Gothenburg, Sweden; Steri-Oss, Yorba Linda, Calif.
§ D1 indicates the most dense bone; D4, the least dense bone.
**TABLE 2**

Misch Implant Quality Scale

<table>
<thead>
<tr>
<th>Group</th>
<th>Clinical Conditions</th>
</tr>
</thead>
</table>
| I (optimum health)  | No pain or tenderness on palpation, percussion, or function. Rigid fixation; no horizontal or vertical mobility under a 500-g load (IM 0).  
<1.5 mm crestal bone loss from stage II.  
<1.0 mm bone loss in preceding 3 years.  
After first year, stable probing (sulcus) depth <4 mm.  
No exudate history.  
No radiolucency.  
0 to 1 bleeding index. |
| II (satisfactory health) | No pain or tenderness on palpation, percussion, or function. Rigid fixation; no horizontal or vertical mobility under a 500-g load (IM 0).  
1.5 to 3 mm crestal bone loss.  
<1.0 mm bone loss in preceding 3 year periods.  
May be >4 mm probing depth from the original tissue thickness or 1st year bone loss, but stable in last 3-year periods.  
Past transient exudate history (+) or (−)  
No radiolucency.  
0 to 1 bleeding index (may have a transient BOP 2 condition). |
| III (compromised health) | No pain on palpation, percussion, or function.  
With or without slight tenderness.  
Initial rigid fixation; to 0- to 0.5-mm horizontal (IM 0 to 2) mobility after prosthesis delivery; no vertical mobility.  
>3 mm bone loss the first year.  
>1 mm crestal bone loss in preceding 3 years, but less than half total bone loss (implantitis).  
>5 mm probing depth and increasing in preceding 3 years.  
With or without history of exudate 1 to 2 weeks in last 3 years.  
With or without slight radiolucency around crestal portion of implant.  
1 to 3 bleeding index. |
| IV (clinical failure—any of the following conditions) | Pain on palpation, percussion, or function.  
>0.5 mm mobility horizontally; any vertical mobility (IM 3 to 4).  
Uncontrolled progressive bone loss.  
More than half loss of bone supporting the implant.  
Uncontrolled exudate  
Generalized radiolucency. |
| V (absolute failure) | Implants unable to be used in the final restoration.  
Implants surgically removed.  
Implants exfoliated. |

The platform of the implant crest module was used as a reference point for measuring crestal bone changes.

The differences between mean bone level measurements at stage I and stage II surgeries, stage II to prosthesis delivery, and prosthesis delivery to the first year of loading were calculated and analyzed statistically. In the present study, any bone levels above the reference point were recorded as 0 bone loss, rather than a positive number, which would decrease the overall bone loss data. For testing the differences among the four density groups (D1, D2, D3, and D4), Kruskal-Wallis one-way analysis of variance was used. The Mann-Whitney U-test was used to test between the implant bodies that were countersunk and those that were not countersunk.

**RESULTS**

*Surgical results*

From July 1996 to March 1997, 364 implants were placed in 104 patients. The bone densities of the patients were as follows: 41 patients had D1 bone, 183 had D2 bone, 104 had D3 bone, and 36 had D4 bone (Table 3). All implants were 4 mm in diameter. A total of four implants were lost from stage I implant placement surgery to stage II uncoverty and permucosal abutment connection (three with D2 bone and one with D3 bone) in two patients; all D2 failures occurred in the same patient and in the same posterior mandibular quadrant. This patient unthreaded the implants because they were bothering his tongue. The other implant failure also occurred in the posterior mandible. The overall surgical implant success was 98.9%, with 100% for D1 and D4 implant designs and 98.3% and 99% for D2 and D3 implants, respectively. Additional data from stage I implant insertion surgery to stage II uncoverty for these 364 implants was presented in a previous report. Additional implants were placed, and as of May 1999, the total number of consecutive implants placed in the study was 975 (55 in D1 bone, 449 in D2, 275 in D3, and 196 in D4) (Table 4). The total implant failure up to stage...
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Crestal bone remodeling

Crestal bone remodeling from stage I surgery to stage II uncovery has been measured for all surviving implants at stage II uncovery (360 from the development group and 609 additional implants). The mean vertical bone loss was 0.21 mm (SD = 0.90 mm) for implants that remained submerged during the osseous healing phase (Table 5). A higher crestal bone level than the platform of the implant was observed in 156 implants (most often in D4 surgical protocol). However, rather than report positive bone growth, the same reference point was used, and the bone loss was recorded at 0 mm. The mean vertical bone loss for implants that became exposed through the soft tissue during osseous healing was 0.20 mm. When the implant became exposed through the soft tissue during the bone-healing period, the stage I to stage II osseous remodeling increased, but the stage II to prosthesis delivery radiographic vertical bone loss was reduced to 0.12 mm (Table 5).

Stage II to prosthesis delivery bone loss

The amount of bone loss from stage II uncovery to prosthesis delivery was evaluated on the first 360 implants with periapical radiographs using a long cone technique with the central ray directed parallel the abutment to implant connection. The mean vertical bone loss when the implant was covered by soft tissue during osseous healing was 0.20 mm. When the implant became exposed through the soft tissue during the bone-healing period, the stage I to stage II osseous remodeling increased, but the stage II to prosthesis delivery radiographic vertical bone loss was reduced to 0.12 mm (Table 5).

Prosthesis results

The prosthesis report included a total of 103 patients (79 women and 24 men). Forty-two patients received a restoration in the maxilla (139 implants) and 61 received a restoration in the mandible (221 implants; Table 6). Prostheses have been in function for at least 12 months and as long as 26 months. At each recall appointment, a clinician performed an examination, recorded potential adverse events, and graded the implant quality of health. All 360 implants were quality I or II in the Misch Implant Quality Scale. The eight completely edentulous maxillae were restored with four full-arch fixed restorations (8 to 10 implants each), and four maxillary implants supported overdentures (six to eight implants each). The 22 completely edentulous mandibles were restored with seven full-arch fixed restorations (5 to 10 implants each), eight implant supported overdentures (five to seven implants

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**TABLE 3**

Implant success between July 1996 and March 1997

<table>
<thead>
<tr>
<th>Bone Density*</th>
<th>No. Inserted</th>
<th>Phase I to Phase II Lost</th>
<th>Implant Surgical Success (%)</th>
<th>Early Implant Loading Failure At 1 Year</th>
<th>Misch Quality Scale At 1 Year After Prosthetic Loading</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td>41</td>
<td>0</td>
<td>100</td>
<td>0</td>
<td>I and II = 41</td>
</tr>
<tr>
<td>D2</td>
<td>183</td>
<td>3</td>
<td>98.3</td>
<td>0</td>
<td>I and II = 180</td>
</tr>
<tr>
<td>D3</td>
<td>104</td>
<td>1</td>
<td>99.0</td>
<td>0</td>
<td>I and II = 103</td>
</tr>
<tr>
<td>D4</td>
<td>36</td>
<td>0</td>
<td>100</td>
<td>0</td>
<td>I and II = 36</td>
</tr>
<tr>
<td>Total</td>
<td>364</td>
<td>4</td>
<td>98.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* D1 indicates the most dense bone; D4, the least dense bone.

**TABLE 4**

Implant success between July 1996 and May 1999

<table>
<thead>
<tr>
<th>Bone Density*</th>
<th>No. Inserted</th>
<th>Phase I to Phase II Lost</th>
<th>Implant Surgical Success (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td>55</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>D2</td>
<td>449</td>
<td>4</td>
<td>99.1</td>
</tr>
<tr>
<td>D3</td>
<td>275</td>
<td>2</td>
<td>99.3</td>
</tr>
<tr>
<td>D4</td>
<td>196</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>975</td>
<td>6</td>
<td>99.4</td>
</tr>
</tbody>
</table>

* D1 indicates the most dense bone; D4, the least dense bone.

II uncovery is six implants. No implants in D1 or D4 bone failed; four in D2 bone failed; and two in D3 bone failed. Therefore, as of May 1999, overall surgical implant success was over 99.4%, with 100% success for D1 and D4 implants and 99.1% and 99.3% success for D2 and D3, respectively. Implants in this surgical report consist of 4- and 5-mm-diameter designs and are inserted in all bone densities and regions of the mouth. Implant success in this report is not related to bone density, location, or size of implant.
TABLE 6
Prosthesis results

<table>
<thead>
<tr>
<th>No.</th>
<th>Patients</th>
<th>Prostheses</th>
<th>No. of Implants per Prosthesis</th>
<th>No. of Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxilla</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Totally edentulous</td>
<td>8</td>
<td>Fixed Overdenture RP-4</td>
<td>8 to 10</td>
<td>37</td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
<td></td>
<td></td>
<td>65</td>
</tr>
<tr>
<td>Partially edentulous</td>
<td>18</td>
<td>19</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>34</td>
<td>35</td>
<td>74</td>
<td></td>
</tr>
<tr>
<td>Mandible</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Totally edentulous</td>
<td>22</td>
<td>Fixed Overdenture RP-4</td>
<td>5 to 10</td>
<td>43</td>
</tr>
<tr>
<td>Overdenture RP-5</td>
<td>8</td>
<td>5 to 7</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>22</td>
<td>112</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partially edentulous</td>
<td>11</td>
<td>12</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>3</td>
<td>19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>4</td>
<td>36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>5</td>
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<tr>
<td>1</td>
<td>6</td>
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<td></td>
</tr>
<tr>
<td>Total</td>
<td>39</td>
<td>40</td>
<td>109</td>
<td></td>
</tr>
<tr>
<td>Totals</td>
<td>103</td>
<td>105</td>
<td>360</td>
<td></td>
</tr>
</tbody>
</table>

Each maxillary overdenture was supported by three to seven implants, and seven soft tissue and implant supported overdentures (three to four implants each). The partially edentulous patients were restored with 31 single-tooth replacements (29 patients), and 152 implants supported two- to six-unit fixed restorations in 44 patients. All fixed prostheses were fabricated with porcelain fused to noble metal or all noble metal and were cement retained. All implant overdentures used a screw-retained bar and O-rings for retention of the prosthesis. The denture teeth were acrylic or composite. All cemented prostheses were fabricated following the progressive bone loading protocol described by Misch.3 Of the 104 original patients, one patient (who lost three D2 implants) needed an additional stage I implant surgery and was removed from the restoration study. This patient was accounted for in the surgical failure reports. This patient had three additional implants inserted and successfully uncovered at stage II. Therefore, there are 105 prostheses in function for 103 patients, with 360 implants in the first-year prosthetic loading report.

Adverse prosthetic events

All 360 implants and prostheses remained in function during the length of the study. There were no early implant loading failures and very few adverse prosthetic events during the first 12 to 26 months. There were no fractures of porcelain, resin, or metal structures of the prostheses. No incidence of implant component fracture occurred. No final prosthesis became uncemented (most were retained with a zinc oxide and EBA cement). One implant-supported overdenture patient had aesthetic complaints with her opposing partial denture and was removed from the restoration study. This patient was accounted for in the surgical failure reports. This patient had three additional implants inserted and successfully uncovered at stage II. Therefore, there are 105 prostheses in function for 103 patients, with 360 implants in the first-year prosthetic loading report.

Early loading bone loss

From prosthesis delivery to loading at 12 months, the mean early loading bone loss for the 105 restorations was 0.29 mm (SD = 0.99 mm), with a range from 0.22 mm (SD = 0.31 mm) to 3.1 mm (SD = 0.99 mm). The mean vertical bone loss average represents a crestal bone level above the first thread of the implant body. All thread patterns of the four implant designs were represented in these 103 patients. All four different areas of the mouth (anterior and posterior maxilla, and mandible) were treated with implants during the study. The mean average early loading bone loss was not found to be statistically different for the different bone densities or arch locations.

Discussion

Surgical survival

Lekholm and Zarb26 listed four bone qualities found in the anterior regions of the jawbone. Regardless of the different bone qualities, all bone was treated with the same implant design and standard surgical and prosthetic protocols. Following these protocols, Schnitman et al27 reported results with a 10% difference in implant survival between quality II and quality III, and as much as 22% implant failure in soft bone for the posterior maxilla. Engquist et al28 reported the loss of 38 of 191 implants in the maxilla in type IV bone (20% loss) and 8 out of 148 mandibular implants (5% loss) before stage II surgery with the Nobel Biocare implant. Jaffin and Berman3 reported an overall 8.3% surgical and initial healing loss in 444 maxillary implants with softer bone with Nobel Biocare implants. Friberg et al3 reported...
ed a 4.8% Nobel BioCare implant failure at stage II uncovering for 732 maxillary posterior implants. Quirynen et al.\(^{29}\) reported a 4.1% Nobel BioCare implant loss at stage II uncovering of 269 implants in the maxilla. Fugazzotto et al.\(^{30}\) reported 22 failures out of 34 IMZ cylinder implants placed in quality IV bone, a 65% failure rate. Sullivan and Sherwood\(^{31}\) indicated a 6.4% stage II failure rate in the maxilla (12 of 188) and a 3.2% failure in the mandible (7 of 216). A report from the Dental Implant Clinical Research Group\(^{30}\) (DICRG) studying Paragon implants concluded that quality I bone had the highest surgical failure rate (4.3%), followed by quality IV (3.9%), quality II (2.9%), and quality III, which had the fewest failures, at 2.6%. The overall implant surgical failure was 3%; the maxilla had better survival at stage II surgery (98.1%) than the mandible (96.4%). It must be emphasized that these reports only present implant failures up to stage II uncovering. Hence, the literature contains many reports that indicate an implant surgical failure ranging from 3.2% to 5% in good-quality bone (D2 and D3) and 1.9% to 20% in the maxilla, with most reports indicating greater failure rates (up to 65%) in maxillary implants and soft bone.

In the present report, the overall surgical survival of the 975 BioHorizons Maestro dental implants from stage I to stage II in all bone densities is 99.4%. The combined survival rate from stage I implant insertion surgery to stage II uncovering for D3 and D4 implants in soft bone is 99.6%. Therefore, the specific implant designs of one length and optimized thread design for each bone density have resulted in improved surgical survival.

**Surgical crestal bone remodeling: stage I to stage II bone levels**

Crestal bone remodeling in the interval between implant placement and uncovering is not routinely reported. Reports in the literature relative to crestal bone loss often use the conditions at the prosthetic attachment or at second-stage surgery as the baseline from which future bone loss is measured.\(^{31,32}\) Other reports routinely use the location of the first thread as the baseline measurement.\(^{33,34}\) Bone loss measurements are difficult to compare if the reader is not provided with the reference point for the measurement. A survey of the literature reveals that each study (sometimes reporting on the same implant design) defines the reference point in different terms.

A unique technique of measurement by Moberg et al.\(^{35}\) for the ITI implant used a periapical radiograph of the entire implant body. The original crestal bone level was measured from the apex of the implant. Future bone loss measurements was also computed in this manner. Bone resorption values during the first year after installation were 0.32 mm (SD = 0.68) and 0.19 mm (SD = 0.63) mesially and distally, respectively, for single-tooth implants. However, the need to obtain a full-length image of the implant on a periapical radiograph using a parallel technique that does not distort the crestal bone, especially in the anterior regions, makes this technique difficult to reproduce. With this same implant system, Pham et al.\(^{36}\) found maxillary implants underwent greater initial bone loss than implants in the mandible, and the longer the healing time, the greater the bone loss observed. The reference points to measure bone loss were the apical border of the implant, the location of the implant shoulder or crown margin, and the first crestal bone-implant contact. The position of the alveolar bone was measured as a percentage of the total implant length by a computer. The report provides rates of bone change rather than absolute values. The average bone loss was 0.48 mm to 0.96 mm for the unloaded healing periods of 3 to 6 months.

The DICRG\(^{37}\) reported on crestal bone loss with radiographs taken at implant placement, at implant uncovering, and at the first 6 months of loading. For the period between implant placement and second-stage uncovering, using the top of the implant as a baseline, an overall average of 0.94 mm of bone loss was observed by use of the Spectra system (Paragon Implant Corporation). The bone density was not related to surgical crestal bone remodeling.

In the present study, the stage I to stage II mean vertical bone loss was 0.21 mm (SD = 0.90 mm). The decrease in surgical bone remodeling in this report compared with others may be related to a decrease in heat generation (and related bone necrosis), with the use of a sequenced drill diameter increase of 0.5 mm compared with the 0.7- to 1-mm increments of other drilling systems.\(^{38}\) The difference in bone loss relative to the initial position with the crest of the ridge was not found to be statistically significant (Mann-Whitney, U-test; U = 0.781, p = 0.54). It is hypothesized that as more implants are added to the data, these numbers will prove to be more relevant. The higher the profile of the implant during healing, the greater at risk of early loading, which may contribute to crestal bone loss.\(^{39}\) In addition, the higher profile more often causes implant exposure through the soft tissue into the oral cavity during initial healing, which often causes bone loss from bacterial invasion of the healing screw to implant connection area or the establishment of a connective tissue zone above the bone. In the present study, when the implant became exposed through the soft tissue, the crestal bone loss increased to 0.36 mm. This observation concurs with the results of Toljanic et al.\(^{40}\) who found that the incidence of bone loss increased 3.9 times when the implant was exposed during the osseous healing phase.

**Stage II to prosthesis delivery bone loss:**

**the transition period**

The amount of bone loss that occurs from the stage II uncovering to the delivery of the prosthesis has not been previously reported in the literature. The
mean vertical bone loss in this interim report of 360 implants was 0.20 mm when the implants require surgical uncover- covery of the soft tissue over the im- plants, and 0.12 mm when the im- plants were already exposed during osseous healing and did not require a surgical soft tissue uncover.

During the prosthesis fabrication, there are increased loads applied to the implants compared with the osseous healing period. The torqueing of abut- ments with a 30-Ncm force applies shear forces to bone, especially at the crest. The transitional prostheses are higher profile and more likely to receive forces from mastication or from the tongue during swallowing. The ini- tial transitional prosthesis is out of occlu- slus contact for 2 to 4 weeks with the progressive loading protocol. The tem- porary is then placed in function 2 to 4 weeks (or longer and dependent upon bone density) before the delivery of the final restoration. The overall treatment time of prosthesis fabrication from stage II is usually 2 to 3 months. Since the crest module of this implant has a 0.5-mm smooth, polished collar below the platform, the bone in this re- gion is more at risk of stress-related bone loss, since shear rather than ten- sion or compression is transferred to the bone.21 As a result, increased loads to the crestal bone region may be responsible for this transitional bone loss period. It is likely that the transitional period bone loss is multifactorial with bacterial contamination and stress-re- lated bone loss the likely etiology.29

Another theory to explain this transi- tional bone loss is the “biologic length” concept of James41, which ex- plains the bone loss as a result of the need for connective tissue to separate the oral epithelium from the underly- ing bone. This theory can also explain the additional bone loss seen for exposed implants during the osseous healing period.

**Early loading failure**

Early loading implant failure has been repeatedly reported in the literature, and may range from 2% to 5.6% in good-quality bone and 22% to 50% failure in the poorest quality bone.10,42-45

Hutton et al identified poor bone quantity as the highest risk of implant failure in a study of 510 implants with an overall failure rate in the maxilla nine times greater than in the mandible.

Friedberg et al, Jaffin et al, and Jemt et al reported early implant failures as great as 35%, especially implants im- bedded in bone of poor quality, after surgical survival of implants. Zarb and Schmitt reported early loading failures in approximately 3.5% of completely edentulous mandibular patients. Naert and Quirynen observed 2.5% early loading failure rate in partially eden- tulous patients. The use of reverse torque testing during stage II uncover- y has not eliminated the complication. Late failures were reported in 7% of the maxillae and 1.4% of mandibles by Sullivan and Sherwood after reverse torque testing had already identified surgical failures. A 5.6% early loading failure may affect up to 15% of the restorations restored, since three or more implants may be used in each prosthesis.9 As a consequence, early loading failure is a major concern for the implant team. The loss of an implant within 6 months of uncover is a con- cern to the restoring dentist, since the patient may feel the failed implant is a consequence of the restorative procedure.

To date, out of 360 implants restored in this study, there was no early load- ing failure, even in the less dense bone types. This may suggest that implants of optimized surface area such as those used in this study are able to minimize stresses to the interface, which is weak- est during the first year when the bone is remodeling from surgery. In addi- tion, progressive bone loading is a ben- efit to decrease the risk of early load- ing failures and was used in the study for all fixed restorations.

**Adverse events of prosthetics**

Screw loosening is a prosthetic comp- lication frequently reported in the liter- ature. Haas et al found 12 incidences of screw loosening out of 76 implants (22.8%), especially in the mandibular molar region. Jemt et al reported on 106 single-tooth replacements and ob- served 34 screw loosening events, ranging in time after implantation from 1 week (17), 1 month (7), 6 months (5), and 1 year (5). Becker and Becker also reported on screw loosening in their study of 21 single-tooth implants and found that three screws loosened once in 2 weeks, two loos- ened twice in 6 months, and three loos- ened three times during 1 year. All three of these authors used the Nobel BioCare implant. Behr et al evaluated the ITI and IMZ implants for screw loosening. In a range of removable and fixed prostheses, 138 ITI implants had six abutment screws loosen at least once within the first year. The 50 IMZ implants restored with similar resto- rations sustained nine abutment screw loosening at least once a year. No data were reported if a screw become loose more than once.

There was only one report of screw loosening in the present study; this oc- curred in the maxillary canine single- tooth replacement. The design of the abutment fixation screw used in the present study is the same design as used by NASA and in orthopaedic joint replacements. This unique design increases the preload on the screw and decreases the risk of loosening. In addi- tion, the external hex is 1 mm in height and the platform of the 4-mm diameter implant is 4.2 mm, rather than the standard 0.7 mm external hex design and 4.1 mm prosthetic platform diameter used in other implant de- signs. Both of these factors directly de- crease the stress on the fixation screw.51 In addition, the machine tolerances of the abutment to implant hex compo- nents fit are within 3 μm, which de- crease rotation and forces on the abut- ment screw. Lastly, it is believed that
the greater number of threads on the abutment screws compared with those of many other systems, contribute to the decreased number of abutment screw loosening.

**Early loading crestal bone loss**

Early loading crestal bone loss has often been reported to be greater than the initial bone remodeling after surgery. The Branemark clinic’s protocol to measure bone loss was outlined in 1981 by Adell et al. The authors measured “marginal” bone loss, starting from a reference point located at the edge between the vertical and conical parts of the implant head. This reference point is located 0.8 mm apically from the platform of the implant. In addition, the surgical protocol for the standard 3.75-mm-diameter fixture results in the implant being countersunk 1.0 mm below the crest of the ridge. Using this protocol, Adell reported a 1.2 mm marginal bone loss. However, the marginal bone loss resulted in a crestal bone loss of 3 mm (1 mm + 0.8 mm + 1.2 mm) from the initial crestal bone level. Other research in the literature that used Nobel BioCare implants reported bone loss of different values, but with different reference points as well. Ivanoff et al. and Aparicio et al. reported on 5-mm-diameter Nobel BioCare fixtures and found bone loss greater than for the standard fixture. However, these reports selected the top of the fixture as the reference point for the larger diameter (0.8 mm higher than the standard fixture) and reported the avoidance of countersinking, compared with the countersink and lower reference point used in the standard 3.75-mm fixture in the same report. Bone loss was reported to be as high as 1.12 mm, or an average of 0.71 mm (SD = 0.71 mm), after the first year of function, and at the fourth year was as high as 1.46 mm, with an average of 0.97 mm (SD = 0.90 mm).

Interestingly, although reports take highly variable reference points on the implant in regard to where the bone loss is measured, many authors compare their results to the 1986 Criteria of Success of Albrektsson et al., which specified that implant success required marginal bone loss of less than 1.5 mm during the first year and less than 0.2 mm annually thereafter. A subtle selection of the words to define the reference point by the author may escape the reader. In addition, the reference point is seldom defined in the abstract.

The DICRG study of the Paragon implant reported an average of 1.15 mm of crestal bone loss from stage II uncovering to the first 6 months of loadings in addition to the average 0.94 mm lost during the osseous healing phase. The bone loss was directly related to the density of the bone (0.68 mm for D1 bone, 1.1 mm for D2 bone, 1.26 mm for D3 bone, and 1.44 mm for D4 bone). These results concur with other reports. De Bruyn et al. in a prospective study of the Paragon implant, also found an additional 1.47 ± 1.2 mm (range, −1 to 4 mm) bone loss after the first year of loading. Malmqvist and Sennerby also reported a high proportion of Paragon implants with vertical bone loss of more than 2 mm, and many with bone loss greater than one-third of the length of the implant.

In the present study, the early loading bone loss with a bone quality-based implant system implants after the first 12 months in function averaged a mean value of 0.29 mm (SD = 0.99 mm) using the top of the platform as the reference point. There was no statistical difference between the implants exposed during osseous loading or those that remained covered. Hence, the cumulative bone loss from stage I surgery to 12 months after loading averages 0.70 mm from the crest of the bone for implants that had soft tissue over the implant during stage I to II, and 0.77 mm for implants that became exposed through the tissue during osseous healing. These measurements are above the first thread of the implant body (Figs 4–9). The implant has a 0.5-mm smooth, polished portion below the platform of the implant crest module. The polished metal was not designed to transfer compressive or tensile loads to the bone. On the contrary, it loads bone in shear, and bone is 65% weaker to shear loads than compressive loads. As a result, polished, smooth collars at the crestal region of the implant increase the risk of crestal bone loss. The 0.5-mm region of the bone quality-based implant crest module was designed to accommodate the expected bone loss from stage I surgery to prosthesis delivery.

**Conclusion**

An interim report of a prospective study using a bone quality–based implant system was presented. To date, 975 implants have been uncovered, with 360 implants supporting 105
implants that have been in use for 12 or more months. Implant prosthetic survival is 100%, with no early loading failures after stage II uncoverage. Past clinical reports have indicated the majority of failures or crestal bone loss occurs by the first year after loading. The average bone loss is well within clinical guidelines of soft tissue health and compare very favorably to the results of other implant designs. Unlike other reports, the results of this interim report suggest that early crestal bone loss does not depend upon the bone density or arch location (mandible, maxilla, anterior, posterior). The modified geometry of each implant type is specifically designed to address anatomic weaknesses such as poor bone density, volume, unfavorable biomechanics, and location. This interim report suggests the bone quality shortfalls can be compensated by optimized implant designs specific for each bone quality.

ACKNOWLEDGMENTS

The authors recognize the financial assistance of BioHorizons Implant Systems Inc in providing support and supplies for this study. Special thanks to Denise Zuzow for processing the implant survival and related data. Thanks also to Jill Bertelson for typing and coordinating this manuscript.

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