

# Marginal Bone Loss with Mandibular Two-Implant Overdentures Using Different Loading Protocols and Attachment Systems: 10-Year Outcomes

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**Purpose:** The aim of this study was to evaluate long-term marginal bone levels for two unsplinted implants supporting mandibular overdentures using conventional and early loading protocols with different implant surfaces and attachment systems. **Materials and Methods:** A cohort of 106 edentulous participants (mean age: 65 years) was treated with mandibular two-implant overdentures opposing complete maxillary dentures. Participants were randomly allocated into three loading protocol groups using four implant systems; single-stage surgery was performed for all participants, followed by an unsplinted prosthesis using six different attachment systems. Standardized intraoral radiographs taken at baseline (loading) and over 10 years appraised marginal bone levels mesially and distally from reference points under magnification. Three calibrated examiners repeated measurements, diminishing intra- and interobserver variability. Progressive attrition of participants occurred as a result of deaths, dropouts, and emigration. Seventy-nine participants (74.5%, mean age: 72 years) were available at the 10-year recall. Differences in bone loss among different loading protocols, implant surfaces, and attachment systems were tested using chi-square and one-way analysis of variance tests. **Results:** Minimal, time-dependent, long-term marginal bone loss occurred with all loading protocols. Annual marginal bone loss progressed at low levels after the first year with episodes of bone loss and gain. There was stability in marginal bone levels over the long term, with the majority of remodeling occurring during the first year of function. Roughened implant surfaces may be beneficial during the early remodeling period. The amount of marginal bone loss in the first year of loading differed significantly by loading protocol and implant surface, whereas attachment system had a minor influence. Differences were not reflected in the success rates calculated using standard criteria. The remaining participants at 10 years were classified as successful related to the criterion of marginal bone loss, irrespective of the determining criteria for success. **Conclusions:** Either a 2-, 6-, or 12-week loading protocol for mandibular two-implant overdentures is possible in the long term, irrespective of the attachment system used. Minimal marginal bone loss may be attributed primarily to mandibular basal bone remaining from long-term edentulism. Revision of the current implant success criteria to offer a stricter limit is desirable. *Int J Prosthodont* 2010;23:321–332.

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Stable marginal bone levels around oral implants are the key determinant of a successful treatment outcome. All of the factors influencing marginal bone levels have not been determined; however, it has been proposed that the time of loading a prosthesis may have some influence on the amount of marginal bone loss seen.<sup>1</sup> Conventional loading of mandibular two-implant overdentures has been accepted as an established treatment protocol, supported by sound evidence of long-term recorded changes in marginal bone levels<sup>2–8</sup> and being labeled as a “model for implant success.”<sup>9</sup> Recently, both early and immediate loading protocols have been aggressively promoted commercially to supposedly take advantage of shorter

healing periods and to enable patients to benefit from improved outcomes sooner. However, without sufficient long-term data supporting these protocols, it is still premature to consider them acceptable clinically.<sup>10</sup>

The importance of marginal bone level stability has been reflected in several different success criteria,<sup>11-18</sup> with minor differences in the criterion of marginal bone loss. The evaluation of marginal bone loss has highlighted the significance of differences in bone quantity and quality of either zone I or II of residual ridges, thus expressing different implant success rates to be expected over the long term.<sup>13</sup> There is also a question of whether the different rates of residual ridge resorption occurring in edentulous ridges are related to the marginal bone loss seen around implants.<sup>19</sup> Previous reports have confirmed that the alveolar process and the basal portion behave differently.<sup>20,21</sup> This is shown by the age-related increase in cortical porosity and thinning occurring primarily in the alveolar process, whereas the basal portion remains more intact. The rapid residual ridge resorption seen immediately after the extraction,<sup>22-24</sup> as the remodeling process of the crestal bone commences, may also be similar to the marginal bone loss seen around implants placed in higher bone quantity. On the other hand, longer periods of edentulism are represented with lower bone quantity and at a more stabilized residual ridge resorption rate. This terminates at the basal bone and may indicate that implants in these circumstances would show less marginal bone loss not only during the initial healing period, but also in the long term. Therefore, the possible influence of different bone quantity must be accounted for when evaluating the changes of marginal bone levels around oral implants.

The most commonly used success criterion<sup>11</sup> allows up to 0.2 mm of annual bone loss after the first year of loading. However, it fails to account for the early period of healing or remodeling, which is when the greatest marginal bone loss occurs. This particular criterion also ignores the potential effects of other factors, such as loading protocols. This not only may affect the marginal bone levels during the initial healing phase, but also sequentially over time. Other limitations of success criteria include the ambiguity of the wording "average of 1.5 mm of bone loss in the first year of loading,"<sup>14</sup> since the word "average" could refer to per implant or per patient. On the other hand, the significance of these thresholds suggested by different success criteria is questionable. There is no evidence showing that they can actually act as true prognostic determinants of an implant or a predictor for future cumulative bone loss thereafter.<sup>25,26</sup>

Calculating marginal bone loss at the patient level<sup>27</sup> rather than at the implant level has shown to dilute the value of marginal bone loss by the number of implants

present.<sup>26</sup> This is crucial, especially where severe marginal bone loss affects a single site but is not reflected in the mean figures. Analyzing at the patient level also means that a failed implant would be removed from the calculations, thus "improving" the bone level measurements and delaying the early detection of a statistically or clinically significant amount of marginal bone loss. In addition, averaging out the measurements from the two measured sites (mesial and distal) of a given implant and presenting the mean values could also mask any severe bone loss occurring at one of those surfaces. The rationale for this method of evaluation, however, is logical, especially when it has been shown that there is an association of multiple implant failures in the same individual, known as the "clustering effect."<sup>25,26,28,29</sup> To avoid some of the shortcomings of analyzing the marginal bone loss data at the patient level, it may be useful to dichotomize the individual values and establish a threshold level for severe bone loss to identify any participant with implants affected by such severe bone loss.

The evaluation of radiographic bone level changes around implants is currently the only available method for distinguishing success from survival. Therefore, it is crucial that a standardized radiographic method is used and the implants are followed up sequentially to provide reliable longitudinal data. The importance of standardizing the radiographic method has been documented extensively.<sup>30-37</sup> However, there are studies<sup>5,38-40</sup> that used extraoral radiographs such as orthopantomograms for measuring changes in marginal bone levels, apparently because of difficulties in placing intraoral films in severely resorbed anterior mandibles. This inevitably leads to doubtful comparison among studies reporting marginal bone level measurements using different radiographic methods.<sup>10</sup>

The emergence of both early and immediate loading protocols is linked to the reporting of enhanced osseointegration with moderately roughened implant surfaces. These modified approaches have been promoted to preserve marginal bone levels, as well as achieve rapid osseointegration.<sup>41,42</sup> The impact of roughened implant surfaces on the stability of marginal bone levels over the long term is poorly understood. Bone loss associated with these surfaces must be distinguished from natural bone remodeling during the healing period and the time-dependent nonpathologic marginal bone loss.<sup>1</sup>

Various overdenture attachment systems have been investigated in association with the long-term stability of marginal bone levels. Theoretically, differences in the resiliencies of the attachment systems could result in different stress transfers to the implants, demonstrating this effect in marginal bone loss clinically. This effect may be more influential during the first year of

loading, when the greatest remodeling of the peri-implant bony architecture occurs. The influence of the resiliencies of overdenture attachment systems on marginal bone levels around implants supporting mandibular overdentures is complex. There are still only a limited number of *in vivo* studies<sup>43-47</sup> investigating the stress patterns around such implants. Studies have shown minor differences in marginal bone loss between the splinted and unsplinted designs.<sup>45,47-49</sup> On the other hand, whether the differences in the resiliencies of the unsplinted design would show any radiographic differences in the stability of marginal bone levels is yet to be investigated.

The aim of this research was to evaluate long-term marginal bone levels for two unsplinted implants supporting mandibular overdentures using conventional and early loading protocols with different implant surfaces and attachment systems.

## Materials and Methods

### Patients

One hundred six edentulous participants with a history of difficulties with their complete dentures and at least 8 to 15 mm of residual anterior mandibular bone were previously selected using standardized inclusion and exclusion criteria.<sup>50</sup> These edentulous participants with a conventional complete maxillary denture opposing an unsplinted mandibular two-implant overdenture are part of an ongoing randomized controlled trial in the Oral Implantology Research Group, Sir John Walsh Research Institute, School of Dentistry, University of Otago, New Zealand. The mean age of the original cohort was 65.3 years ( $\pm 7.4$  years), and patients had originally been edentulous for a mean period of 34.7 years ( $\pm 13.4$  years). Overall, 38% were men.

Participants, on commencement of the clinical trial, were allocated randomly to one of three loading protocol groups using a sealed envelope technique. The conventional loading group involved a 12-week loading protocol, whereas the early loading groups were divided into 2- and 6-week loading protocols. Twelve patients were allocated to each loading protocol, except for the 2-week Brånemark group, which had only 10 patients assigned because of funding limitations, not allowing allocation to the 6- and 12-week loading groups. Participants were further randomly allocated to one of four different implant systems.<sup>51</sup> One of these implant systems used a turned titanium implant surface (original conical Brånemark implant, Nobel Biocare). This conical Brånemark implant was originally used for maxillary bone grafting procedures but thereafter marketed for overdentures. The other three implant systems (Southern Implants; Steri-Oss, Nobel Biocare;

and Straumann) had titanium surfaces roughened to varying extents: sandblasted, acid-etched; acid-etched, machined; and sandblasted, large-grit, acid-etched (SLA) respectively. Each participant was provided with one of six different overdenture attachment systems (Fig 1). Further details regarding the participants and surgical protocols have been provided in previous reports.<sup>52,53,55-57</sup>

Prior to loading (baseline), 5 participants failed to return; the resulting 101 participants were examined. Of these, 4 participants, all of whom were in the Steri-Oss group, suffered early implant failure of one implant each, which was subsequently replaced, and 1 participant from the 2-week loading group dropped out of the clinical trial before the 1-year recall. These replacement implants, however, were not included in the marginal bone level analysis. No implants failed after loading except for one, which was removed at the 10-year recall. Progressive attrition of participants occurred with deaths, dropouts, and emigration, which meant that 79 participants (74.5%) with a mean age of 72 years were assessed at the 10-year recall.

The Steri-Oss attachment system (rubber matrix) became obsolete during the study period and required excessive prosthodontic maintenance compared to the other systems.<sup>50,58</sup> Participants still using the Steri-Oss system at the 5-year recall were offered the opportunity to have their attachment systems converted to the Locator (Innova Corporation and Zest Anchors) attachment system (Figs 1k and 1l) from the beginning of year 6 until the 10-year recall.

### Radiographic Data Collection and Marginal Bone Level Measurements

Standardized intraoral radiographs were taken at baseline (loading) and at the 1-, 2-, 3-, 5-, 8-, and 10-year recalls by one examiner. A modified radiograph technique<sup>36,53</sup> was used where the respective matrix of each implant system was included in separate Rinn holders (XCP Instrument, Dentsply Rinn), thus allowing a standardized radiograph to be taken for each implant with an extended-cone Phillips Secondent machine of 60 kV and an exposure time of 0.8 seconds. The same films were used for all intraoral radiographs (size 0, Kodak DF 54 Dental Film Ultraspeed, Eastman Kodak). These were then developed using the appropriate fresh chemical solutions in an automatic processor.

To assess marginal bone loss, mesial and distal bone levels were measured on the shielded radiographs with a Peak loupe, which had a scale in tenths of a millimeter and  $\times 7$  magnification. Specific reference points (Fig 2) were used to measure marginal bone loss by three calibrated examiners, with measurements being repeated to allow monitoring of intra- and

**Fig 1** Implant overdenture attachment systems.



**Fig 1a (left)** Brånemark 2.25-mm ball patrix (reprinted from Payne et al<sup>52</sup> with permission).

**Fig 1b (right)** Brånemark gold matrix (reprinted from Payne et al<sup>52</sup> with permission).



**Fig 1c (left)** Straumann 2.25-mm retentive anchor (reprinted from Payne et al<sup>50</sup> with permission).

**Fig 1d (right) (top)** Straumann gold clip and **(bottom)** Straumann titanium matrix with stainless steel spring (reprinted from Watson et al<sup>54</sup> with permission).



**Fig 1e (left)** Southern 3.25-mm ball patrix (reprinted from Watson et al<sup>54</sup> with permission).

**Fig 1f (right)** Southern plastic matrix (reprinted from Watson et al<sup>54</sup> with permission).



**Fig 1g (left)** Southern 2.25-mm ball patrix (reprinted from Payne et al<sup>50</sup> with permission).

**Fig 1h (right)** Southern gold/platinum matrix (reprinted from Payne et al<sup>50</sup> with permission).



**Fig 1i (left)** Steri-Oss ball patrix (reprinted from Tawse-Smith et al<sup>53</sup> with permission).

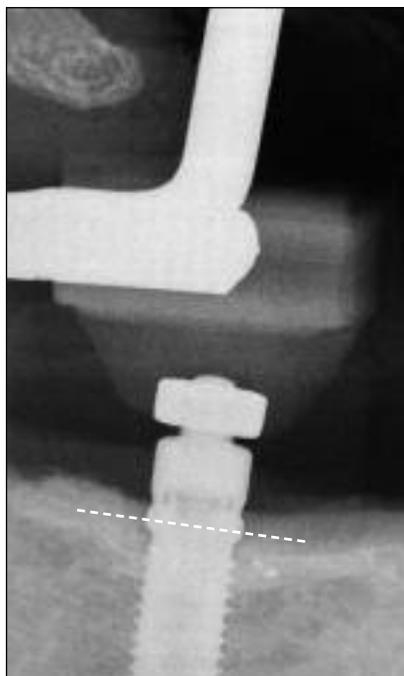
**Fig 1j (right)** Steri-Oss rubber matrix (reprinted from Watson et al<sup>54</sup> with permission).



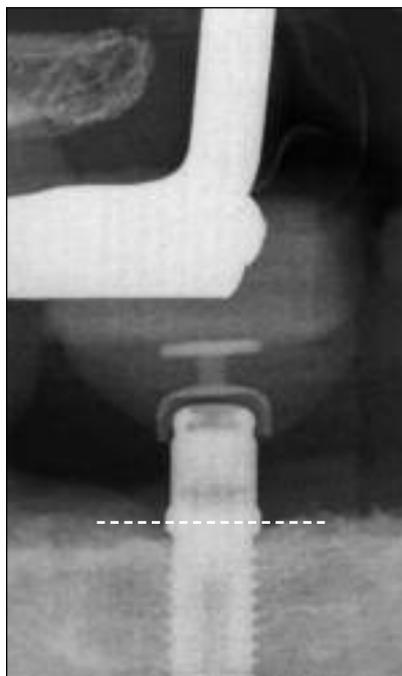
**Fig 1k (left)** Locator abutment.

**Fig 1l (right)** Locator insert.

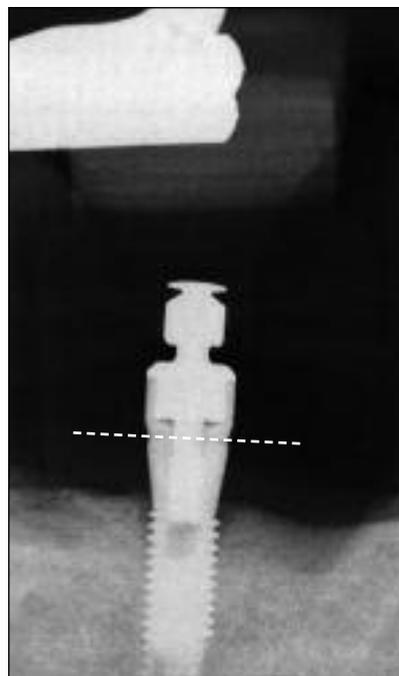
**Fig 2** Reference point for each implant system.



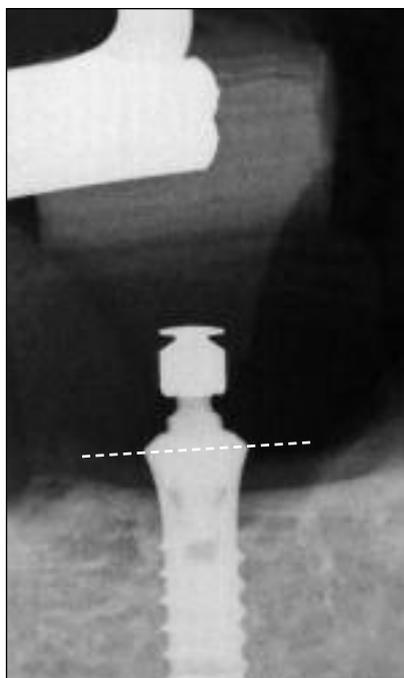
**Fig 2a** Steri-Oss implant and 2.25-mm-diameter O-ring abutment. Reference point: 1 mm below the abutment-implant junction.



**Fig 2b** Steri-Oss implant and Locator. Reference point: 1 mm below the abutment-implant junction.



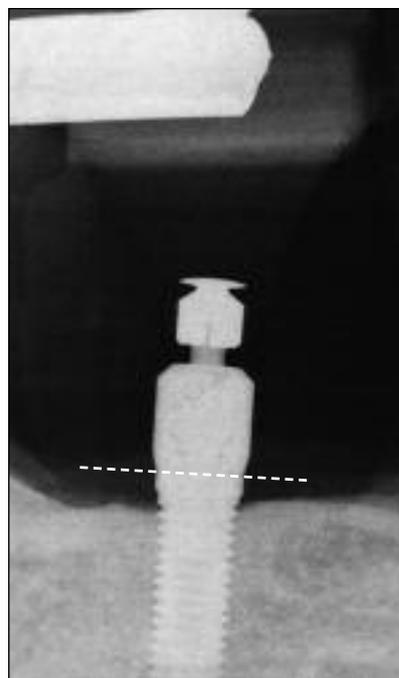
**Fig 2c** Brånemark implant and mini 2.25-mm-diameter ball abutment. Reference point: at the abutment-implant junction (3.5 mm was subtracted for comparison purposes because of the conical neck).



**Fig 2d** Straumann implant and 2.25-mm-diameter retentive anchor. Reference point: at the implant shoulder.



**Fig 2e** Southern implant and 3.25-mm-diameter abutment. Reference point: at the abutment-implant junction.



**Fig 2f** Southern implant and mini 2.25-mm-diameter ball abutment. Reference point: at the abutment-implant junction.

**Table 1** Mean Marginal Bone Levels by Loading Protocol and Implant System

| Loading protocol/<br>implant system | Baseline                 |                         | 1 y                      |                         | 3 y                     |                         | 5 y                     |                         | 10 y                    |                         |
|-------------------------------------|--------------------------|-------------------------|--------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
|                                     | Mean (SD)                | Combined                | Mean (SD)                | Combined                | Mean (SD)               | Combined                | Mean (SD)               | Combined                | Mean (SD)               | Combined                |
| 2 wk (n = 34)                       |                          |                         |                          |                         |                         |                         |                         |                         |                         |                         |
| Brånemark*<br>(n = 10)              | 3.28 (0.86)              | 2.55 (1.16)<br>(n = 34) | 3.70 (0.86)<br>(n = 10)  | 2.87 (1.22)<br>(n = 33) | 3.72 (0.98)<br>(n = 10) | 2.86 (1.29)<br>(n = 31) | 3.71 (0.99)<br>(n = 10) | 2.98 (1.35)<br>(n = 30) | 3.95 (1.00)<br>(n = 10) | 3.05 (1.31)<br>(n = 28) |
| Straumann<br>(n = 12)               | 3.22 (0.69)              |                         | 3.56 (0.79)<br>(n = 11)  |                         | 3.53 (0.85)<br>(n = 10) |                         | 3.74 (0.98)<br>(n = 10) |                         | 3.51 (0.67)<br>(n = 9)  |                         |
| Southern<br>(n = 12)                | 1.26 (0.39)              |                         | 1.54 (0.40)<br>(n = 12)  |                         | 1.48 (0.40)<br>(n = 11) |                         | 1.51 (0.50)<br>(n = 10) |                         | 1.58 (0.70)<br>(n = 9)  |                         |
| 6 wk (n = 36)                       |                          |                         |                          |                         |                         |                         |                         |                         |                         |                         |
| Straumann<br>(n = 12)               | 2.90 (0.68)              | 1.62 (1.12)<br>(n = 34) | 3.16 (0.71)<br>(n = 12)  | 1.79 (1.19)<br>(n = 34) | 3.12 (0.62)<br>(n = 12) | 1.73 (1.18)<br>(n = 34) | 3.18 (0.59)<br>(n = 11) | 1.73 (1.21)<br>(n = 33) | 3.06 (0.60)<br>(n = 8)  | 1.74 (1.18)<br>(n = 25) |
| Southern<br>(n = 12)                | 0.89 (0.56)              |                         | 1.00 (0.59)<br>(n = 12)  |                         | 1.01 (0.58)<br>(n = 12) |                         | 1.06 (0.73)<br>(n = 12) |                         | 1.36 (1.01)<br>(n = 7)  |                         |
| Steri-Oss<br>(n = 12)               | 0.96 (0.45)              |                         | 1.09 (0.54)<br>(n = 10)  |                         | 0.92 (0.51)<br>(n = 10) |                         | 0.96 (0.58)<br>(n = 10) |                         | 0.95 (0.62)<br>(n = 10) |                         |
| 12 wk (n = 36) <sup>†</sup>         |                          |                         |                          |                         |                         |                         |                         |                         |                         |                         |
| Straumann<br>(n = 12)               | 2.40 (0.83)              | 1.40 (0.94)<br>(n = 33) | 2.76 (0.95)<br>(n = 10)  | 1.56 (1.07)<br>(n = 33) | 2.73 (1.25)<br>(n = 9)  | 1.54 (1.16)<br>(n = 31) | 2.77 (1.21)<br>(n = 10) | 1.62 (1.16)<br>(n = 32) | 2.33 (1.28)<br>(n = 6)  | 1.45 (1.00)<br>(n = 26) |
| Southern<br>(n = 12)                | 1.15 (0.51)              |                         | 1.25 (0.45)<br>(n = 12)  |                         | 1.27 (0.66)<br>(n = 12) |                         | 1.39 (0.62)<br>(n = 11) |                         | 1.56 (0.57)<br>(n = 11) |                         |
| Steri-Oss<br>(n = 12)               | 0.78 (0.63)              |                         | 0.80 (0.66)<br>(n = 11)  |                         | 0.78 (0.64)<br>(n = 10) |                         | 0.82 (0.62)<br>(n = 11) |                         | 0.73 (0.73)<br>(n = 9)  |                         |
| Overall mean (SD)                   | 1.86 (1.18)<br>(n = 101) |                         | 2.07 (1.29)<br>(n = 100) |                         | 2.03 (1.33)<br>(n = 96) |                         | 2.09 (1.37)<br>(n = 95) |                         | 2.11 (1.36)<br>(n = 79) |                         |

SD = standard deviation.

\*For comparative purposes, a value of 3.5 mm was subtracted because of the conical neck of the Brånemark implant.

<sup>†</sup>One patient in the 12-week loading protocol was not available for the 3-year recall but returned for the 5-year recall.

interobserver variability. The calibrated examiners in the current study agreed that three implant systems (Brånemark, Straumann, and Steri-Oss) had clearer demarcation of the implant-abutment junction than the fourth (Southern Implants).

### Data Analysis

Data were analyzed using SPSS statistical software (SPSS). The bone loss for each site was computed by subtracting the follow-up bone level from the previous level recorded. Mean marginal bone loss was calculated at a patient level, and bone loss relative to multiple independent variables was tested for statistical significance using the chi-square test and one-way analysis of variance. The level of significance was set at  $P < .05$ .

## Results

### Marginal Bone Levels

Marginal bone levels at the mesial and distal sites of each implant did not show any statistically significant differences. Therefore, the values from each site were combined to result in one value of marginal bone level per participant to calculate the marginal bone loss between successive examination time points (Table 1).

### Marginal Bone Loss

The mean marginal bone loss for the cohort during the first year of loading was  $0.21 \pm 0.25$  mm, with a minor increase to  $0.29 \pm 0.53$  mm at year 10 (Table 2). During the first year of loading, there was higher marginal bone loss with the 2-week loading protocol, which was statistically significant compared to the 6- or 12-week loading protocols. The 2-week loading group ( $0.48 \pm 0.62$  mm) continued to show the highest marginal bone loss throughout the study, and the difference in the measurement was statistically significant compared to the 6-week loading protocol group ( $0.15 \pm 0.42$  mm) at year 10.

Different implant surfaces were associated with the amount of mean marginal bone loss seen (Table 3). Conical Brånemark implants with a turned surface had significantly higher marginal bone loss during the first year of loading than Steri-Oss implants (acid-etched, machined) and Southern Implants (sandblasted, acid-etched) (Table 3). The Steri-Oss implants showed bone gain of  $0.02 \pm 0.28$  mm at year 3; however, this observation could be considered less than significant considering the wide range of individual measurements. The roughened surface appears to have some influence on marginal bone levels since Brånemark implants showed the highest marginal bone loss at year 10, which was significantly higher than that of the Steri-Oss

**Table 2** Cumulative Mean Marginal Bone Loss by Loading Protocol and Implant System

| Loading protocol/<br>implant system | 1 y                      |                          | 3 y                     |                          | 5 y                     |                          | 10 y                    |                          |
|-------------------------------------|--------------------------|--------------------------|-------------------------|--------------------------|-------------------------|--------------------------|-------------------------|--------------------------|
|                                     | Mean<br>(SD)             | Combined                 | Mean<br>(SD)            | Combined                 | Mean<br>(SD)            | Combined                 | Mean<br>(SD)            | Combined                 |
| 2 wk (n = 34)                       |                          |                          |                         |                          |                         |                          |                         |                          |
| Brånemark<br>(n = 10)               | 0.42 (0.22)              | 0.31 (0.21)*<br>(n = 33) | 0.44 (0.32)             | 0.31 (0.28)*<br>(n = 31) | 0.43 (0.34)             | 0.40 (0.38)*<br>(n = 30) | 0.67 (0.71)             | 0.48 (0.62)*<br>(n = 28) |
| Straumann<br>(n = 12)               | 0.26 (0.23)              |                          | 0.26 (0.31)             |                          | 0.47 (0.46)             |                          | 0.33 (0.55)             |                          |
| Southern<br>(n = 12)                | 0.28 (0.15)              |                          | 0.24 (0.18)             |                          | 0.30 (0.36)             |                          | 0.41 (0.58)             |                          |
| 6 wk (n = 36)                       |                          |                          |                         |                          |                         |                          |                         |                          |
| Straumann<br>(n = 12)               | 0.26 (0.20)              | 0.17 (0.25)<br>(n = 34)  | 0.22 (0.28)             | 0.11 (0.33)<br>(n = 34)  | 0.20 (0.34)             | 0.13 (0.37)<br>(n = 33)  | 0.13 (0.39)             | 0.15 (0.42)<br>(n = 25)  |
| Southern<br>(n = 12)                | 0.10 (0.24)              |                          | 0.11 (0.38)             |                          | 0.16 (0.42)             |                          | 0.38 (0.46)             |                          |
| Steri-Oss<br>(n = 12)               | 0.13 (0.29)              |                          | 0.04 (0.28)             |                          | 0.00 (0.33)             |                          | 0.01 (0.37)             |                          |
| 12 wk (n = 36) <sup>†</sup>         |                          |                          |                         |                          |                         |                          |                         |                          |
| Straumann<br>(n = 12)               | 0.36 (0.24)              | 0.15 (0.27)<br>(n = 33)  | 0.31 (0.47)             | 0.14 (0.42)<br>(n = 31)  | 0.37 (0.55)             | 0.21 (0.47)<br>(n = 32)  | 0.28 (0.62)             | 0.23 (0.50)<br>(n = 26)  |
| Southern<br>(n = 12)                | 0.10 (0.19)              |                          | 0.12 (0.45)             |                          | 0.24 (0.53)             |                          | 0.42 (0.49)             |                          |
| Steri-Oss<br>(n = 12)               | 0.02 (0.26)              |                          | 0.00 (0.30)             |                          | 0.04 (0.29)             |                          | 0.02 (0.34)             |                          |
| Overall mean (SD)                   | 0.21 (0.25)<br>(n = 100) |                          | 0.18 (0.35)<br>(n = 96) |                          | 0.24 (0.42)<br>(n = 95) |                          | 0.29 (0.53)<br>(n = 79) |                          |

SD = standard deviation.

\*Statistically significant differences ( $P < .05$ ) between 2-week and 12-week loading protocols.<sup>†</sup>One patient in the 12-week loading protocol was not available for the 3-year recall but returned for the 5-year recall.**Table 3** Cumulative Mean Marginal Bone Loss\* by Implant Surface

| Implant surface                                 | 1 y                                  | 3 y                                  | 5 y                                  | 10 y                                 |
|---|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| Brånemark (turned)<br>(n = 10)                  | 0.42 (0.22) <sup>†</sup><br>(n = 10) | 0.44 (0.32) <sup>†</sup><br>(n = 10) | 0.43 (0.34) <sup>†</sup><br>(n = 10) | 0.67 (0.71) <sup>†</sup><br>(n = 10) |
| Straumann (SLA)<br>(n = 36)                     | 0.29 (0.22)<br>(n = 33)              | 0.26 (0.34)<br>(n = 31)              | 0.34 (0.45)<br>(n = 31)              | 0.25 (0.50)<br>(n = 23)              |
| Southern (sandblasted, acid-etched)<br>(n = 36) | 0.16 (0.21)<br>(n = 36)              | 0.16 (0.35)<br>(n = 35)              | 0.23 (0.43)<br>(n = 33)              | 0.41 (0.50)<br>(n = 27)              |
| Steri-Oss (acid-etched, machined)<br>(n = 24)   | 0.07 (0.27)<br>(n = 21)              | -0.02 (0.28)<br>(n = 20)             | 0.02 (0.30)<br>(n = 21)              | -0.01 (0.34)<br>(n = 19)             |

SLA = sandblasted, large-grit, acid-etched.

\*Negative values indicate bone gain.

<sup>†</sup>Statistically significant differences ( $P < .05$ ) between Brånemark turned surface and the remaining implant surfaces.

implants and Straumann implants. However, it was difficult to determine the significance of the influence of the roughened surfaces due to other confounding variables, such as implant design.

Data on the marginal bone loss seen with the different overdenture attachment systems are presented in Table 4. The Steri-Oss implants with the rubber O-ring matrix showed the lowest amount of marginal bone loss after the first year of loading. This marginal bone loss was lower than that with all other attachment systems except for the Southern plastic caps. There was no statistically significant difference among the different overdenture attachment systems at year 5. Because

the Steri-Oss rubber O-rings were discontinued after year 5, the annual marginal bone loss seen with Steri-Oss rubber O-rings (years 1 to 5) was compared to that of Locators (years 6 to 10). There was no statistically significant difference between the two time points with the different attachment systems, and hence, data related to the Steri-Oss and Locator groups were combined for analysis as a single group for the study period. After 10 years of service, the Steri-Oss rubber O-ring/Locator showed the least amount of bone loss, which was comparable to the low amount of marginal bone loss seen with Straumann gold and titanium attachment systems.

**Table 4** Cumulative Mean Marginal Bone Loss\* by Attachment System

| Attachment system  | 1 y         | 3 y          | 5 y         | 10 y         |
|--|-------------|--------------|-------------|--------------|
| Brånemark (n = 10)   | 0.42 (0.22) | 0.44 (0.32)  | 0.43 (0.34) | 0.67 (0.71)  |
| 2.25-mm ball patrix and gold matrix                                      | (n = 10)    | (n = 10)     | (n = 10)    | (n = 10)     |
| Straumann (n = 24)   | 0.24 (0.24) | 0.21 (0.33)  | 0.34 (0.53) | 0.17 (0.57)  |
| 2.25-mm retentive anchor and gold clip                                   | (n = 21)    | (n = 19)     | (n = 19)    | (n = 14)     |
| Straumann (n = 12)   | 0.39 (0.16) | 0.34 (0.35)  | 0.34 (0.32) | 0.36 (0.38)  |
| 2.25-mm retentive anchor and titanium matrix with stainless steel spring | (n = 12)    | (n = 12)     | (n = 12)    | (n = 9)      |
| Southern (n = 12)  | 0.28 (0.15) | 0.24 (0.18)  | 0.30 (0.36) | 0.41 (0.58)  |
| 2.25-mm ball patrix and gold/platinum matrix                             | (n = 12)    | (n = 11)     | (n = 10)    | (n = 9)      |
| Southern (n = 24)  | 0.10 (0.21) | 0.12 (0.40)  | 0.20 (0.47) | 0.40 (0.47)  |
| 3.25-mm ball patrix and plastic matrix                                   | (n = 24)    | (n = 24)     | (n = 23)    | (n = 18)     |
| Steri-Oss (n = 24)   | 0.07 (0.27) | -0.02 (0.28) | 0.02 (0.30) | -0.01 (0.34) |
| 2.25-mm ball patrix <sup>†</sup> with Locator abutment <sup>‡</sup> ;    | (n = 21)    | (n = 20)     | (n = 21)    | (n = 19)     |
| Rubber matrix <sup>‡</sup> with Locator insert <sup>‡</sup>              |             |              |             |              |

\*Negative values indicate bone gain.

<sup>†</sup>Baseline to year 5.<sup>‡</sup>Year 6 to year 10.**Table 5** Four-Field Table at Patient Level

| Year | No. of participants (%) |                      |                       |                       |                 |          |
|------|-------------------------|----------------------|-----------------------|-----------------------|-----------------|----------|
|      | Success*                | Success <sup>†</sup> | Survival <sup>‡</sup> | Survival <sup>§</sup> | Unaccounted for | Failure  |
| 1    | 91 (85.8%)              | 100 (94.3%)          | 9 (8.5%)              | 0 (0.0%)              | 6 (5.7%)        | 0 (0.0%) |
| 3    | 86 (77.4%)              | 94 (88.7%)           | 10 (9.4%)             | 2 (1.9%)              | 10 (9.4%)       | 0 (0.0%) |
| 5    | 85 (76.4%)              | 91 (85.9%)           | 10 (9.4%)             | 4 (4.4%)              | 11 (10.4%)      | 0 (0.0%) |
| 10   | 79 (74.5%)              | 79 (74.5%)           | 0 (0.0%)              | 0 (0.0%)              | 27 (25.5%)      | 0 (0.0%) |

\*Success rate based on criteria of Roos et al.<sup>15</sup><sup>†</sup>Success rate based on criteria of Albrektsson and Isidor.<sup>14</sup><sup>‡</sup>Survival rate based on criteria of Roos et al.<sup>15</sup><sup>§</sup>Survival rate based on criteria of Albrektsson and Isidor.<sup>14</sup>**Table 6** Cumulative Success Rate (%) by Loading Protocol

| Loading protocol        | 1 y       |                       | 3 y       |                       |           |                       | 5 y       |                       |           |                       | 10 y  |      |       |       |
|-------------------------|-----------|-----------------------|-----------|-----------------------|-----------|-----------------------|-----------|-----------------------|-----------|-----------------------|-------|------|-------|-------|
|                         | ≤ 1.0 mm* | ≤ 1.5 mm <sup>†</sup> | ≤ 1.4 mm* | ≤ 1.9 mm <sup>†</sup> | ≤ 1.8 mm* | ≤ 2.3 mm <sup>†</sup> | ≤ 1.8 mm* | ≤ 2.3 mm <sup>†</sup> | ≤ 2.8 mm* | ≤ 3.3 mm <sup>†</sup> |       |      |       |       |
| 2 wk                    |           |                       |           |                       |           |                       |           |                       |           |                       |       |      |       |       |
| Brånemark               | 80.0      | 84.8                  | 100.0     | 100.0                 | 70.0      | 83.9                  | 90.0      | 96.8                  | 80.0      | 83.3                  | 100.0 | 93.3 | 100.0 | 100.0 |
| Straumann               | 81.8      |                       | 100.0     |                       | 80.0      |                       | 100.0     |                       | 80.0      |                       | 80.0  |      |       |       |
| Southern                | 91.7      |                       | 100.0     |                       | 100.0     |                       | 100.0     |                       | 90.0      |                       | 100.0 |      |       |       |
| 6 wk                    |           |                       |           |                       |           |                       |           |                       |           |                       |       |      |       |       |
| Straumann               | 83.3      | 90.6                  | 100.0     | 100.0                 | 75.0      | 90.3                  | 91.7      | 96.8                  | 81.8      | 93.3                  | 90.9  | 96.7 | 100.0 | 100.0 |
| Southern                | 100.0     |                       | 100.0     |                       | 100.0     |                       | 100.0     |                       | 100.0     |                       | 100.0 |      |       |       |
| Steri-Oss               | 87.5      |                       | 100.0     |                       | 100.0     |                       | 100.0     |                       | 100.0     |                       | 100.0 |      |       |       |
| 12 wk                   |           |                       |           |                       |           |                       |           |                       |           |                       |       |      |       |       |
| Straumann               | 80.0      | 93.8                  | 100.0     | 100.0                 | 88.9      | 93.3                  | 100.0     | 100.0                 | 90.0      | 90.3                  | 90.0  | 96.8 | 100.0 | 100.0 |
| Southern                | 100.0     |                       | 100.0     |                       | 91.7      |                       | 100.0     |                       | 81.8      |                       | 100.0 |      |       |       |
| Steri-Oss               | 100.0     |                       | 100.0     |                       | 100.0     |                       | 100.0     |                       | 100.0     |                       | 100.0 |      |       |       |
| Cumulative success rate | 89.7      |                       | 100.0     |                       | 89.1      |                       | 97.8      |                       | 89.0      |                       | 95.6  |      | 100.0 | 100.0 |

\*Success rate based on Roos et al.<sup>15</sup>: First year limit of 1.0 mm with an annual loss of 0.2 mm thereafter.<sup>†</sup>Success rate based on Albrektsson and Isidor<sup>14</sup>: First year limit of 1.5 mm with an annual loss of 0.2 mm thereafter.

### Implant Success Rates

The implant success rates at the patient level were calculated using two different success criteria of acceptable annual marginal bone loss.<sup>14,15</sup> These success rates are presented in Table 5.<sup>13</sup> None of the participants were categorized as failures at the patient level in terms of excessive marginal bone loss.

Cumulative success rates were calculated and presented by loading protocol (Table 6). With the more generous limit of 1.5 mm in the first year of loading,<sup>14</sup> all participants met the criterion and were consequently classified as successful, whereas 89.7% of participants qualified as successful according to the other criterion.<sup>15</sup> This difference in the first year success rates was statistically significant, as well as at years 3 and 5. The

conical Brånemark group with the turned surface using the 2-week loading protocol showed the lowest success rates up to the 5-year recall. At year 10, all remaining implants had marginal bone loss of less than 2.8 mm, consequently resulting in a 100% success rate regardless of which success criterion was used.

## Discussion

The purpose of this longitudinal research was to scrutinize the changes in the marginal bone levels around two implants supporting mandibular overdentures using different loading protocols, implant surfaces, and attachment systems. The 10-year marginal bone level data showed a minimal overall mean marginal bone loss of 0.3 mm, which was in agreement with two other long-term studies.<sup>7,59</sup> This outcome, however, was lower than those reported in other long-term studies<sup>3,4</sup> showing up to 1.66 mm over 12 years. The reason for such low long-term marginal bone loss in the current randomized trial may be associated with the low bone quantity of participants, which were class C or D<sup>60</sup> due to long-term edentulism (mean:  $34.7 \pm 13.4$  years), leaving only basal bone, which has been shown to resorb at a slower rate.<sup>61,62</sup> Comparison with other studies should be taken with caution since it is difficult to make a valid assessment when there are differences in the methodology of each study. The conventional loading protocol group in this randomized trial showed 0.23 mm of marginal bone loss after 10 years, which was lower than that reported in other long-term studies.<sup>3,7,8</sup> van Steenberghe and colleagues<sup>3</sup> also showed that there was significantly higher marginal bone loss from 4 to 8 years, but that phenomenon was not observed in the present study.

In the first year of function, 0.21 mm of marginal bone loss occurred—well below the recommended limits.<sup>14,15</sup> This low measurement was comparable to another study<sup>63</sup> that reported 0.32 mm with a similar patient group. The statistically higher marginal bone loss seen with the 2-week loading protocol indicates that loading implants prematurely causes more marginal bone loss, especially during the early remodeling period. However, whether these statistical differences are also clinically significant is doubtful, considering all remaining 2-week loading protocol group implants had survived at the 10-year recall and the overall marginal bone loss was well below the recommended limits. The marginal bone levels appeared to plateau after the first year of loading, which is in agreement with other studies.<sup>2,4,7,63,64</sup> Regardless of the amount of marginal bone loss reported, the general pattern of marginal bone loss occurring in the first year of loading and slow minor bone level changes thereafter was uniform among long-term studies.

In this research, a four-field table<sup>13</sup> was used to present the outcomes of implants at the patient level<sup>27</sup> based on aforementioned success criteria. Originally, four-field table<sup>13</sup> analysis was used at the implant level; however, with the emerging emphasis on assessing implant success at the patient level,<sup>27</sup> the authors felt that the success rates of this study should also conform to the recommendation. This meant that participants with one surviving implant who were still included in the study could theoretically be classified as successful as long as they met the marginal bone loss criteria.<sup>14,15</sup> Labeling these patients as “successful” in the recall must be questioned since the success of the remaining single implant may depend on replacement of the failed implant. This raises another question of whether analyzing the implant success rates at a patient level, especially when there are only two implants per participant, is valid.

Since the mean marginal bone loss in this study was calculated at the patient level, the success rates did not coincide with previous papers<sup>52,53,55–57</sup> that calculated marginal bone loss at the implant level. The early success rates of this study were comparable to those from recently published studies.<sup>65–68</sup> However, there are some limitations in comparing the current data to other studies due to the different time points for radiographic examinations to measure the changes in the marginal bone levels. Studies evaluating marginal bone loss around implants have used different success criteria, and there is no uniformity in baseline and annual recall time points. In the current study, baseline radiographs were taken at the time of loading, with sequential measurements done annually from the time of implant placement. The rationale for measuring the changes in the marginal bone levels from the time of loading was to examine the changes when the implants were in function, which is in agreement with a recent study.<sup>26</sup> Inevitably, this ignores the changes in the marginal bone levels during the initial healing period since there was no radiograph taken at the time of implant placement. However, with the stability of marginal bone levels observed in the current study and no significant association between the marginal bone loss during the first year of loading and the consequential marginal bone loss, it is questionable whether the observation of marginal bone levels immediately after implant placement is crucial in determining implant prognosis.

The calibrated examiners agreed that to measure the changes in the marginal bone levels to within tenths of a millimeter required intensive training. Previous studies<sup>69–71</sup> have challenged the sensitivity and reliability of radiographs in measuring true bone loss, with the latest consensus criticizing the clinical observation of marginal bone levels at 0.1-mm intervals and therefore recommending 1.0-mm increments instead.<sup>72</sup> It has

been argued that achieving valid bone loss measurements of less than 0.2 mm is difficult and that bone loss or gain that has been reported may be due to measurement errors, especially when minor differences in bone levels are reported.<sup>70,71,73</sup> This raises the question of whether the original recommendation for acceptable annual marginal bone loss is based on accurate data or measurement error. However, the better visibility of the reference points, as well as repeated measurements, must have a positive influence on the reliability and validity of marginal bone level measurements.

The current study used three different roughened surface implants with different loading protocols, which were then compared to the turned surface of the original conical Brånemark implants used for maxillary bone grafting and thereafter, overdenture applications. During the first year of loading, the mean marginal bone loss around turned surfaces was significantly higher than around the other implant surfaces, indicating that implants loaded as early as 2 weeks may benefit from roughened surfaces in maintaining initial marginal bone levels. However, due to the small number of conical Brånemark implants used, the findings must be interpreted with caution and the fact that the value was still within the acceptable limit according to the standard success criteria considered.<sup>14,15</sup> The lower success rate seen with the conical Brånemark implant group did not persist throughout the 10-year observation period since the mean marginal bone loss seen at the 10-year recall was well below the recommended thresholds.<sup>14,15</sup> This finding shows that the marginal bone loss seen in the first year of function does not necessarily predict poor prognosis of implants.<sup>25,26</sup>

The six different attachment systems used in this randomized trial, with various resiliencies, did not show any statistically significant differences in marginal bone levels, including Steri-Oss rubber O-rings compared to Locator systems. Prior to the study, there was some speculation that the rigid plastic caps used with Southern implants may cause more stress around the implants, thus resulting in significantly higher marginal bone loss over 10 years. In contrast to this hypothesis, the implants showed very low marginal bone loss during the first year of loading ( $0.10 \pm 0.21$  mm), with 100% of participants classified as successful.<sup>74</sup> The success rate decreased over the 5-year period to 91.3%; however, with the 10-year limit being up to 2.8 mm, 100% of participants were again categorized as successful. In this randomized trial, the Southern plastic cap and Straumann attachment systems (gold matrices and titanium matrices) demonstrated lower marginal bone levels than the other overdenture attachment systems after 10 years. However, whether this statistically significant difference is of any clinical significance is most doubtful since all attachment systems were

still classified as successful according to the marginal bone level measurements.

The calculated success rates based on two different success criteria showed statistically significant differences at years 1, 3, and 5. A higher number of participants were classified as successful by the criterion that had the additional 0.5-mm leeway in the first year of loading.<sup>14</sup> However, with the remaining participants showing a minimal decrease in marginal bone levels over 10 years, there was a 100% cumulative success rate at the 10-year recall regardless of which success criterion was used. In view of the minimal change in the marginal bone levels seen in the current study, allowing the limit of annual marginal bone loss at 0.2 mm appears to be too liberal, especially over the long term. It may be advisable to suggest a stricter annual bone loss limit, considering that the marginal bone levels around implants appear to stabilize after the first year of loading.

## Conclusions

In this randomized clinical trial of participants with mandibular overdentures supported by two unsplinted implants, minimal and time-dependent marginal bone loss occurred over 10 years. Either a 2-, 6-, or 12-week loading protocol for mandibular two-implant overdentures is possible in the long-term, irrespective of the attachment system used. Loading can occur as early as 2 weeks for periods of up to 10 years; however, roughened implant surfaces may be of benefit during the early remodeling period and the majority of remodeling occurred in the first year of function. Marginal bone loss seen with a 2-week loading protocol and a conical Brånemark turned implant surface was higher during the first year of function. The presence of mainly basal bone following long-term edentulism may contribute to the minimal marginal bone loss. However, the long-term success rates based on the standard criteria for success showed no difference after 10 years of observation. In light of the minimal amount of marginal bone loss seen over the long term, revision of the current implant success criteria is needed to offer a stricter limit.

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