AICRG, PART II: CRESTAL BONE LOSS ASSOCIATED WITH THE ANKYLOS IMPLANT: LOADING TO 36 MONTHS

Cherng-Tzeh Chou, DDS
Harold F. Morris, DDS, MS
Shigeru Ochi, PhD
Lori Walker, DDS
Deborah DesRosiers, DDS, MS

Problem: The Ankylos endosseous dental implant is a new implant design that will be available in the United States in early 2004. It features an internal tapered abutment connection, a smooth polished collar without threads at the coronal part of the implant body, and a roughened surface with variable threads on the body of the implant fixture. A precise, tapered, conical abutment connection eliminates the microgap often found in 2-stage implant systems. This microgap may allow the accumulation of food debris and bacteria, as well as micromovement between the parts during clinical function, both of which can lead to a localized inflammation and crestal bone loss. Purpose: The purpose of this section of the study was to assess any crestal bone loss associated with this new implant. Method: The clinical performance of this new implant design was studied under well-controlled clinical conditions. Over 1500 implants were placed and restored. The vertical crestal bone loss was measured "directly" between the time of implant placement and uncovering, using a periodontal probe. Serial dental radiographs were taken between loading, and the 12-, 24-, and 36-month follow-up visits to determine "indirect" crestal bone loss within a specific period. Results: Bone loss varied among the participating centers from less than 0.5 mm to 2.0 mm. The largest amount of bone loss occurred between the time of implant placement and uncovering, using a periodontal probe. Serial dental radiographs were taken between loading, and the 12-, 24-, and 36-month follow-up visits to determine "indirect" crestal bone loss within a specific period. Results: Bone loss varied among the participating centers from less than 0.5 mm to 2.0 mm. The largest amount of bone loss occurred between the time of implant placement and uncovering, following loading, the mean bone loss for all implants for a period of 3 years was about 0.2 mm/y. Conclusions: The extent of the crestal bone loss after loading was minimal for patients regardless of age, gender, prosthetic applications, bone density, and remote or crestal incisions, as well as for smokers or nonsmokers. Bone loss per year is well within the guidelines of 0.2 mm/y proposed by others.
BACKGROUND

The United States National Institutes of Health (NIH)/National Institute of Dental Research Consensus Conference Development Statement in 1988 stressed the need for long-term clinical studies to compare the clinical performance of different types of implants under conditions similar to those encountered in the dental office. Stable bone levels are believed to be critical to the long-term success of an implant because excessive bone loss can lead to peri-implantitis and the eventual loss of the implant. In view of the lack of extensive and creditable crestal bone loss data during the 1988 NIH Consensus Conference, it was suggested that future studies include longitudinal evaluation of radiographic changes in the supporting bone. Dentistry has long been concerned about crestal bone loss, and the potential influence of implant design certainly warrants additional research. Dentistry is without an acceptable worldwide consensus as to how to accurately measure any changes in the crestal bone and what, if any, loss represents acceptable limits.

Many clinical studies fail to measure crestal bone loss between placement and abutment connection (ie, uncovering/abutment connection). Most information in the literature includes data only for the period from loading of the prosthesis to a specific follow-up period after loading. Bone loss has been reported to range from 0.5 mm to as high as 2 mm within the first year of implant placement. More recently, in 2002 Warren et al reported that crestal bone loss of between 1.0 and 1.5 mm may occur almost immediately after second-stage surgery and implant loading. In view of the limited data from scientific clinical studies, additional data are needed. The range of bone loss, from implant placement to 36 months following restoration, can vary widely from 0.0 to 2.1 mm. Initial breakdown of the implant-tissue interface generally starts at the crestal region of successfully integrated implants for both 1-stage and 2-stage implants with about 0.2 mm of loss after the first year of clinical function. The loss of crestal bone has also been reported to be influenced by the location of the implant/transmucosal abutment interface (ITAI) relative to its relationship to the crestal bone. Scanning electron microscopic evaluation of failed implants has demonstrated significant amounts of plaque accumulation at the ITAI, which may produce localized inflammation and subsequent crestal bone loss. Cochran et al suggest that the crestal bone loss around implants may be attributed to the biological width that is physiologically formed at the abutment-implant connection.

In 1997, Herman et al studied the crestal bone loss in relation to the location of the microgap that exists between the implant fixture and the abutment in 2-stage im-
plants. He reported that the bone density adjacent to the microgap appeared less dense than other areas of bone and that the bone level was consistently found to be located below this gap. Bone remodeling for 2-stage implants generally occurs after abutment connection. It has been suggested that this change may be a response to the presence of the microgap. More recent studies suggest that the influence of the microgap is dependent less on its size than on the fact that movement occurs at the interface between the implant fixture and the abutments of 2-stage implants. This movement may influence the amount of crestal bone loss.

The anatomy, physiology, histology, and embryology of bone in the oral cavity have been discussed extensively. The relationship of the biological properties to crestal bone response, as related to dental implants, has been reported. Chiarelli discussed the differences in the histology and bone response at the bone-implant interface, depending on the type of bone present at the implant site. Albrektsson et al. were among the first to propose criteria for the evaluation of dental implant success, which included the criterion of vertical bone loss. Their criterion suggested the loss should be less than 0.2 mm annually after the first year of the loading of the dental prosthesis. Similar criteria were later proposed by Smith et al. Excessive crestal bone loss can be problematic for some implant systems. One study evaluated 2 implant systems for success using the crestal bone loss at less than 1.5 mm after 3 years of function as the criterion for determining success and found that only 76% to 86% of the implants could be rated as being “successful.” By changing the critical level of bone loss to less than 3.5 mm, success of the implants increased to between 93% and 100%.

Other methods for assessing crestal bone responses have been utilized throughout the evolution of the endosseous implant. Schnitman and Shulman suggested criteria for implant success be less than one third of the height of the implant. Malmqvist and Sennerby reported that vertical crestal bone loss may be as high as 2 mm and that some implants have losses greater than one third of the implant length. Different amounts of bone loss have been reported for various implant designs and surface characteristics. In spite of the lack of consensus, the values generally accepted as a reasonable guideline for bone loss is less than 1.5 mm for the first year post-loading of the prosthesis and less than 0.2 mm of additional loss for each following year.

Direct measurements of bone loss between the time of implant placement and abutment connection provides a means of determining the amount of crestal bone loss during this critical period. Although most likely the result of surgical trauma, few clinical studies attempt to determine and report this information. This was, however, a critical focus in the comprehensive, independent evaluation of this new implant. During the follow-up period, the most common method of assessing crestal bone loss involves the use of serial radiographs. The X-ray tube repositioned within 20° for all subsequent radiographs is believed to provide diagnostic radiographs. With natural teeth, the cemento-enamel junction (CEJ) is readily visible and the crestal bone height is about 1 to 1.5 mm below the CEJ. In the case of dental implants, the CEJ is not present. Indices were developed for use in large clinical studies to speed up the measurement process for crestal bone responses and to address the problems of nonstandardized radiographs. In most studies, the indices have been abandoned in favor of other methods such as subtraction radiography and simple proportional measurements of serial radiographs.

The use of radiographs to determine crestal bone loss between implant placement and uncovering using serial radiographs has not been widely used because of concerns that the radiation might damage the “new maturing bone” during the healing process. Stenstrom et al. calculated the volume of tissue...
exposed to secondary radiation originating from the 2 metal interfaces of the threads and assessed the risk for the tissue cells during a radiograph. Bone immediately in contact with the metal implants was estimated to be exposed to secondary electrons. This exposure could easily double with an implant with threads, as the 2 surfaces of the threads would contribute to the amount of exposure.

**SPECIFIC AIM**

The specific aim of this paper is to (1) determine the crestal bone loss associated with the Ankylos implant design (Friadent GmbH, Mannheim, Germany) between the time of implant placement and uncovering using direct measurements; (2) calculate the bone loss between uncovering and loading, loading of the prosthesis and 12 months, loading and 24 months, and loading and 36 months using serial radiographs; and (3) to assess the possible influence of other variables such as jaw region, age of patient, the patient’s health status, smokers vs nonsmokers, bone quality, placement incision type, and uncovering incision type.

**METHODS**

The patients for this comprehensive clinical evaluation of the Ankylos implant were recruited from 30 VA medical centers, 2 dental schools, and 2 foreign dental clinics. The study protocol was reviewed and approved by the research committees and institutional review boards at all centers before the study was activated. Both the protocol and consent forms included all information recommended in the US Food and Drug Administration (FDA) Guidelines for clinical trials. Sample size was calculated for the study to enable meaningful statistical analyses. A comprehensive operations manual, which contained detailed information about all procedures to be followed during the course of the study, was developed and provided to all participating centers. All clinical investigators were provided training and standardization at a 2-day meeting prior to the start of the study. Training included patient screening (inclusion and exclusion criteria), surgical procedures to be followed for placing the Ankylos implant, restorative procedures, and completion of study forms. The procedures to be followed in the event of failure of an implant, a complication, or serious adverse event were also clearly defined. Over 1500 implants were placed to support dental prostheses. The implant prostheses designs included maxillary (anterior) completely edentulous cases, maxillary posterior partially edentulous cases, mandibular (anterior) completely edentulous cases, and mandibular posterior partially edentulous cases. Single-tooth restorations were placed in appropriate locations depending on the clinical needs of the patient.

**Bone loss data collection**

The surgical instructions for the Ankylos implant recommend that a tissue punch be used for removing the soft tissue covering the implant to allow for the connection of the tapered abutment. For this study, this step was modified to allow “direct bone loss” measurements between the time of implant placement and abutment connection. Although a conservative tissue flap was used to obtain these measurements, it is possible that the tissue flap procedure may have in-

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**FIGURE 2. Clinical case photographs (courtesy of Dr Cherng-Tzeh Chou, Taiwan, China). (A) Abutment connection; (B) clinical case, 4 years postloading (note health of soft tissue surrounding the implant restoration). (C) Radiograph of postloading to 24 months (no apparent clinically significant crestal bone loss). (D) Radiograph of postloading to 48 months (no apparent clinically significant crestal bone loss).**
creased the crestal bone loss reported in this section of the study. The direct measurements were made in millimeters (mm) from the top of the implant to the top of the crestal bone (Figure 1A) using periodontal probes with 1-mm divisions. All measurements were made at the time of implant placement and repeated at the time of uncovering. All measurements were rounded off to the nearest 0.5 mm. The differences in these 2 measurements determined the amount of crestal bone loss that occurred during this stage. Serial radiographs were taken at uncovering and loading, and at 12, 24, and 36 months following implant placement. The radiographs were sent to the data management center in Ann Arbor, Mich, where they were labeled with the patient’s study code and the evaluation visit that they represented. They were then catalogued for future reference.

Although the direct measurements were rounded to the nearest 0.5 mm, the radiographs were then placed on a view box and measurements were made to the nearest 0.1 mm using vernier calipers. Radiographs provide distorted images, and corrections must be made to more accurately determine the correct measurement. The actual bone loss was calculated using the equation for proportions shown in Figure 1A, and the change was entered into the computer database. All data entries were double-checked and verified to ensure that entry errors were kept to a minimum.

**RESULTS AND DISCUSSION**

Many clinical studies of crestal bone loss around endosseous dental implants do not measure the amount of crestal bone lost both for the healing period (placement to uncovering) as well as for the period from uncovering to the loading of the prosthesis. Any loss during this period is most likely associated with the surgical trauma during the preparation of the implant site. Because this loss is not caused by a characteristic of a specific implant design, it is important data that needs to be determined and separated from any bone loss that may be related to the implant. Although the tissue punch for abutment connection is recommended for this implant, to facilitate bone loss measurements tissue flaps were carefully established to minimize trauma at the time of implant placement and uncovering. Direct measurements from the top of the implant body to the top of the crestal bone were made to determine crestal bone loss during this period. It is again important to note that as a result of this deviation from the procedures recommended for abutment connection by the manufacturer, the real bone loss may actually be less than that reported in this study.

From the time of implant placement to abutment connection (uncovering), the mean crestal bone loss was 0.70 mm (the Table, Figure 1B). The 0.70 mm of bone loss is the result of the surgical trauma that occurs at
the time of implant placement and not the implant design. The slightly higher loss in Bone Quality-1 (BQ-1) is also most likely caused by frictional heat during the preparation of the implant site in dense bone in some less experienced clinical research centers. Between the time of abutment connection and loading of the prosthesis, there was an additional increase of 0.11 mm (total 0.81 mm) of bone loss, which can also be attributed to the original surgical trauma at the time of placement.

The mean crestal bone loss for all study implants from the time of loading of the prosthesis to 12, 24, and 36 months of clinical loading is shown in the Table and Figure 1B. The amount of crestal bone loss during the period from loading to 12 months was 0.15 mm (SE = 0.04), which is well within the guidelines of 0.2 mm/y following loading. For the period of 24 months following loading, the mean loss was 0.48 mm (SE = 0.09), which represented an annual increase in the loss of bone of slightly more than 0.2 mm. For the period from loading up to 36 months, the crestal bone loss increased to 0.65 mm (SE = 0.03), an additional increase of 0.16 mm. These small increases averaged around 0.2 mm over the 36 months postloading period, and although any crestal bone loss is of clinical interest, the losses recorded would not be large enough to be clinically significant. The total overall mean loss from the time of implant placement to 36 months was only 0.60 mm, which is less than that reported for other implants. From the time of loading, the mean crestal bone loss each year fell within the range (0.2 mm/y) recommended as a guideline for clinical success of endosseous dental implants (the Table, Figure 1A and B).

Figure 2 represents a typical clinical case and the crestal bone response for most implants in this study. It documents the clinically favorable soft tissue response and the radiographic documentation of minimal crestal bone loss associated with this new implant system. The radiographs at 36 and 48 months postloading do not demonstrate any clinically significant amount of crestal bone loss. Because loading of the final dental prosthesis can have an effect on the amount and type of stresses the crestal bone is subjected to during clinical function, these data were recorded.

The bone loss associated with different prosthetic applications for the period from loading to 36 months is shown in Figure 3A. The largest amount of bone loss (0.8 mm) was found for the maxillary anterior completely edentulous cases, followed by the mandibular anterior completely edentulous cases (0.7 mm). The maxillary anterior jaw region is an area well known for having poor bone density, so the larger bone loss is not surprising. The maxillary posterior partially edentulous cases and the mandibular posterior partially edentulous cases both had 0.6 mm of loss in this same period. These differences among the various prosthetic applications were not statistically significant. When patients were grouped into those 60 years or younger and 60 years or
older, the amounts of crestal bone loss was strikingly similar for the period from loading to 36 months (Figure 3B).

The health of the patient is often a concern when evaluating for implant therapy. Patients being entered into the study were classified using the American Society of Anesthesiology classification.32,33 Healthy patients (ASA-1) lost 0.61 mm (about 0.2 mm/y) of crestal bone height following loading to 36 months (Figure 4A), and patients with mild systemic disease lost about the same amount of bone (0.56 mm). The largest bone loss (0.83 mm—slightly greater than 0.2 mm/y) was found for those patients with a severe systemic disease classification (ASA-3), but this was not statistically significant from that recorded for the other health groups.

The influence of smoking on endosseous dental implant health reported in the dental literature suggests that smoking may have both an adverse local and systemic affect on bone response.34-39 When grouped into smokers and nonsmokers, the loss of the height of the crestal bone around the implant was not found to be significantly different (Figure 4B). Bone density is of primary importance to implant survival. It is interesting to note that BQ-1 exhibited slightly more bone loss than the other bone densities (Figure 5A); however, the differences were not clinically significant. The slightly larger loss associated with BQ-1 is most likely related to the greater density of the bone and the surgical experience of the dentist. The type of incision (remote vs crestal) used for implant placement did not result in a significant difference in bone loss (Figure 5B) nor did the type of incision used for abutment connection (Figure 5C).

**CLINICAL RELEVANCE**

Crestal bone response is believed to be critical to the long-term clinical success of an endosseous dental implant. The Ankylos implant represents a new implant design that departs from the idea of engaging cortical bone to provide primary and long-term stability of endosseous implants. Instead, it attempts to engage trabecular bone for primary and long-term stability by directing the stress during clinical function away from the cortical bone and onto the trabecular bone. This approach is highly unusual and has considerable theoretical merit, because trabecular bone is more resilient, and when damaged by repetitive microstrains, it repairs more rapidly than the crestal bone. Aside from the bone loss that is the result of the surgical trauma, the crestal bone loss following loading was minimal from the bone loss. This suggests that the theory behind the implant design has been well thought out, and that the implant works well in a wide variety of clinical situations.

**SUMMARY AND CONCLUSIONS**

Within the conditions established in the clinical protocol for the assessment of crestal bone response, this implant design is well suited for use in the rehabilitation
of fully edentulous and partially edentulous patients of all races, ages, health status, bone density, and tobacco use. Crestal bone loss was less than the suggested limits for clinical success: less than 1.5 mm for the first year and 0.2 mm each year thereafter following loading of the prosthesis. More specifically, the data suggest the following conclusions:

- Direct measurement of the crestal bone loss caused by surgical trauma was found to be around 0.7 mm between implant placement and abutment connection. This is well within what is considered acceptable limits.
- After abutment connection, there was an additional loss of crestal bone of about 0.11 mm, which is most likely the result of a carryover effect from the surgical trauma during implant placement.
- The total overall mean crestal bone loss from implant loading to 36 months postloading was 0.6 or 0.2 mm per year, which included the loss that can be attributed to surgical trauma. This is an excellent overall response.
- The final prosthesis design, the patient’s age, the patient’s health status, the use of tobacco, the bone density, the incision type used for implant placement, and abutment connection did not produce significant differences in the amount of crestal bone loss.

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NOTE
This is government-supported research and there are no restrictions on its use. The results and opinions presented are those of the authors and do not necessarily reflect the opinions of the Department of Veterans Affairs Medical Research, the Office of Dentistry, or the American Academy of Implant Dentistry. This manuscript does not represent an endorsement of the evaluated implant by the Department of Veterans Affairs or the American Academy of Implant Dentistry.