The Influence of Early Loading on Bony Crest Height and Stability: A Pilot Study

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Purpose: The aim of this prospective pilot study was to investigate differences in changes in implant stability and crestal bone height between loaded and unloaded dental implants at 4 months after placement. ***Materials and Methods:*** In the test group, 20 implants were placed in the anterior region of the mandible in 10 patients. They were connected with a Dolder bar within 10 days and placed into function immediately. In the control group, 21 implants were placed in the anterior region of the mandible in a 2-stage procedure in 12 patients. The implants used were TiUnite, with a diameter of 3.75 mm and a minimum length of 10 mm. Resonance frequency analysis was used to measure differences in implant stability, with the implant stability quotient (ISQ) as the unit of measure. An instrument was developed to measure the bone level directly. On a customized abutment, a probe with a stopper measured the distance between the shoulder of the instrument and the bone. Measurements were made on all 4 sides of each implant. Intra- and interexaminer variability showed an agreement that was greater than 99% (kappa > 0.99) for both sets of measurements. ***Results:*** In the early loading group, the mean change in ISQ was -0.08 ± 0.77 and the mean bone loss from buccal, mesial, distal, and lingual sites was 0.69 ± 0.15 mm. In the unloaded group, the mean change in ISQ was 1.33 ± 1.65 and the mean bone loss from buccal, mesial, distal, and lingual sites was 0.53 ± 0.18 mm. There was no statistically significant difference across the 2 treatment groups. The changes in bone height at buccal and lingual sites were not statistically different from the changes at mesial and distal sites. When gender was included as a factor, the changes in stability and bone loss were statistically smaller among female patients than among male patients. ***Conclusion:*** In this preliminary study, early loading did not show an influence on bony crest height and stability in TiUnite implants placed in the anterior mandible during the first 4 months of service. *Int J Prosthodont 2005;18:506–512.*

Following placement of an endosseous implant, a number of determinants influence osseointegration, resulting in success or failure. Half of the few reported failures occur within the first year following placement[1,2] and are characterized by implant mobility and loss of crestal bone height. It has been suggested that early failures may be caused by excessive mechanical stresses and poor initial stability, in addition to short implant length and poor bone quality.[3,4] The stability of such implants is related to their biomechanical properties and the amount of bone in contact with the implant.[5,6]

Recent publications support the concept of early/immediate loading mainly for specific host bone sites. Most of these reports, however, are case series; very few are controlled trials that include a control group of unloaded implants.[7–10] It has been suggested that early implant stability has an impact on bone healing, and early failures may be caused by excessive mechanical

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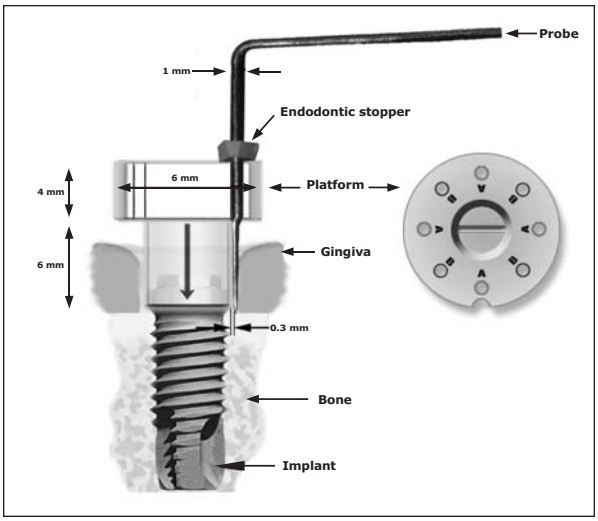

Fig 1 The BB gauge instrument.

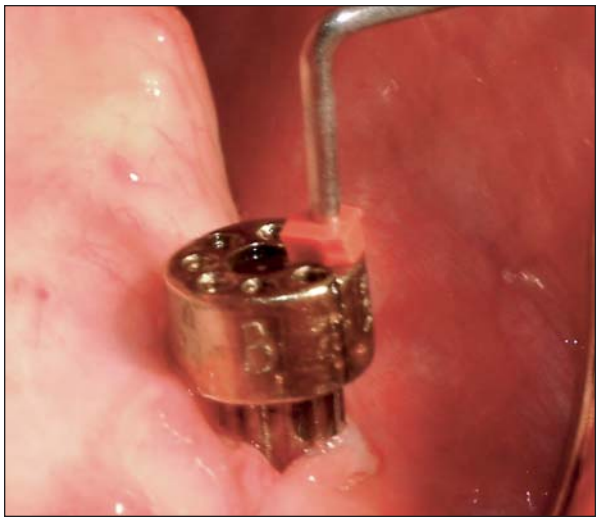

Fig 2 Measurement of bony crest height using the BB gauge instrument.

stresses and poor initial stability.[3,4] It is therefore possible that immediate implant function could influence the quality of bone healing. To evaluate this statement, the changes in bony crest height and the implant stability were monitored in this short-term study.

The aim of this prospective study was to investigate the difference in changes in implant stability and the difference in loss of bony crest between early loaded and unloaded TiUnite dental implants (Nobel Biocare) at 4 months postplacement. This time interval corresponds to the usual healing time protocol. The null hypothesis was that no differences in the peri-implant crestal bone loss and implant stability would be recorded in early loaded implants in comparison to implants placed according to the conventional (delayed) loading method after 4 months of healing.

Materials and Methods

Patients

Twenty-two patients received 1 or more dental implants (n = 41 implants). The test group (early loading group) was composed of 10 patients who had 2 TiUnite implants placed at the positions of the mandibular canines and had an overdenture (OD) connected to a Dolder bar within 10 days after the surgery. All the ODs opposed a complete denture. The control group (the unloaded group) comprised 12 patients with 21 implants placed in the anterior mandible using a traditional 2-stage protocol. There were 4 male and 6 female patients in the early loading group, and 4 male and 8 female patients in the unloaded group. All the patients were over 45 years old, and every female patient was postmenopausal.

Informed consent was obtained from all the patients, and the investigation was approved by the Human Ethics Committee at the University of Toronto.

Patients were included if they met the following criteria:

- Test group patients had to be completely edentulous patients and willing to have implants placed in the anterior region of the mandible.
- Control group patients could be completely or partially edentulous and had to be willing to have implants placed in the anterior region of the mandible. Because the implants in this group remained unloaded for the duration of the study, both edentulous and partially edentulous patients were accepted.
- All patients had to be at least 18 years of age at surgery.
- Bone morphology had to allow placement of a regular-diameter (3.75 or 4.0 mm) implant that was at least 10 mm in length.

Patients were excluded if they had any condition that might interfere with bone healing, eg, bone diseases, diagnosed osteoporosis, uncontrolled diabetes, or fibrous dysplasia.

The 3 criteria of implant success that are generally accepted in the literature are a lack of clinical signs and symptoms of disease, lack of implant mobility, and stable peri-implant bone levels.[11–18] Resonance frequency analysis (RFA) was used to measure changes in implant stability, and we developed a de novo instrument to measure changes in crestal bone height. Lack of clinical signs and symptoms is a difficult factor to calibrate; consequently, it was not included in this study.

Crestal Bone Measurements: Development of a New Instrument

A new instrument, called the "BB gauge," was developed (Figs 1 and 2).[21] The instrument is composed of a customized machined abutment with a hex attachment and an attached platform that is oriented perpendicular to the abutment (ie, at a 90-degree angle). The platform has perforations that accommodate a vertical probe to measure bone height at different positions around the implant. The attachment ensures reproducibility of the probing entry points into the gingiva. Once the probe is inserted and pressed down until it reaches the bone, the degree of penetration is marked at the top of the platform by an endodontic rubber stopper. The level of pressure applied to the probe was not calibrated, since after testing it was not found to affect the measurement. The probe is then removed and carried to a microscope, where a measurement is made from the tip of the probe to the level of the mark made on the probe, resulting in a continuous number. An electronic digital caliper with readings in hundredths of a millimeter was used.

In this study, measurements of the bony crest height were obtained at the buccal, lingual, mesial, and distal sides of the implant. These measurements were done for both treatment groups at the time of implant placement, before the surgical flap was closed. Then, after 4 months, the measurements were repeated. The gingiva was locally anesthetized for the patients in the test group when needed, and the probe was slid through or beside the soft tissues to the bone. The measurements for the patients in the unloaded group were done after the flap was raised during stage 2 surgery.

Implant Stability Measurements

The instrument used to measure implant stability is a resonance frequency analyzer (RFA) (Osstell, Integration Diagnostics). The resonance frequency (RF), with results given as an implant stability quotient (ISQ), is determined by the stiffness of the implant-bone system. Since the stiffnesses of the implant components and transducer are constant, differences in RF are mainly a reflection of differences of the interfacial bone stiffness and changes in bone height.[19]

This was a novel study, and averages and variations in RF were not available for sample size calculations. Therefore, a sample size of 10 patients in each group was chosen arbitrarily.

Two measurements of the RF for each implant were done at the implant level. The transducer was placed perpendicular to the ridge and screwed on at 10 Ncm with a manual torque controller (RFA measurements are unaffected by screw tightness over 10 Ncm[20]). The transducer was removed between each measurement, and a third measurement was taken if the first 2 were not identical. The mean value was used for analysis.

In both groups, measurements of the RF and the exposed implant height above the bone crest were made at the time of placement of the implants. The measurements were repeated 4 months after placement (± 7 days) in both groups, since 4 months is the usual healing time protocol used at the University of Toronto between stage 1 and 2 surgeries. These results were then analyzed to determine whether implants subjected to early loading are associated with greater instability and/or bone loss in comparison to implants allowed to heal undisturbed for 4 months (Fig 3).

Statistical Analysis

To account for clustering of the data points (ie, observations taken from the same subject are likely to be related to each other, even if they are taken from different implants), a repeated-measures approach was implemented in all subsequent analysis. This method allowed us to incorporate the covariance between observations into the statistical models and significance testing.

The Chi-square test was used to compare both groups with respect to gender (Fig 4). To compare initial implant stability, repeated-measures analysis of variance (ANOVA) was used.

A series of repeated-measures ANOVAs was performed to find differences between the 2 groups in terms of implant stability, bone height changes, and gender. Analysis of covariance was used to include implant length as a factor. A nonparametric test (the Wilcoxon rank-sum test) was also utilized to evaluate the changes in ISQ. When this test was done, only 1 implant per patient was chosen randomly by the statistical software (Stata 7, StataCorp) to take into account the clustering of data.

To determine whether bone changes were different at mesial and distal sites versus buccal and lingual, Pearson's correlation test was used.

For all those tests, statistical significance was declared when $P < .05$. Data were presented as means ± standard errors (SE).

Results

Baseline Differences

As an initial step, the 2 groups were compared with respect to their gender distribution and ISQs at baseline to ensure that gender-related differences unrelated to treatment were not present from the onset of the study. These values were tested using a series of repeated-

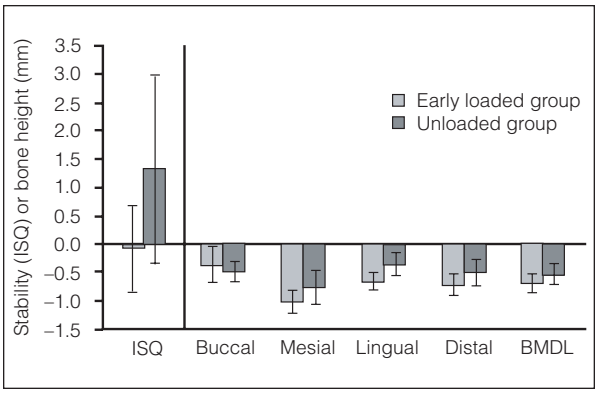

Fig 3 Comparison of changes in stability and bone height by type of treatment (early versus delayed loading). Bars represent mean changes, while error bars represent 1 standard error.

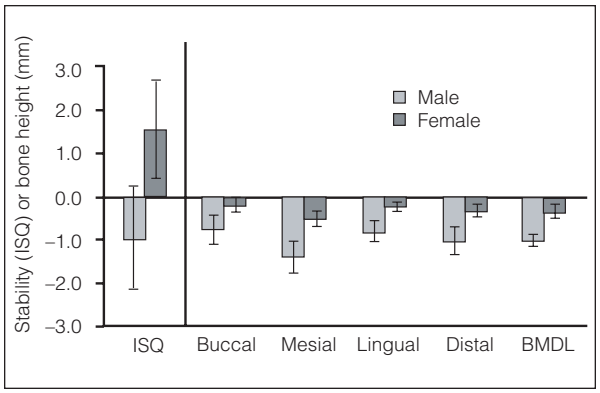

Fig 4 Comparison of changes in stability and bone height by gender. Bars represent mean changes, while error bars represent 1 standard error.

measures ANOVAs for initial implant stability and the Chi-square test for gender. No significant differences were found.

Changes in Bone Level

To assess whether the magnitude of bone loss differed across the 2 treatment groups, and to take into account the clustering of data, a series of repeated-measures ANOVAs was performed (Table 1). There was no significant difference in bone loss across the 2 treatment groups. All of the bone loss measurements (with the exception of buccal in the test group) were significantly different from zero, which implies that there was a significant change in bone height in both groups between the measurements taken at baseline and those taken at 4 months.

In addition, the interaction between sex and treatment group was tested for each of the above outcome measures. Gender was included as a factor in these models to determine whether the magnitude of change observed was related to the sex of the patient. A series of repeated-measures ANOVAs was performed. The changes in bone loss at the mesial and the distal were consistently smaller among female patients than among male patients (Table 2).

Among male patients, all 4 of the bone loss measurements were significantly different from zero, implying that there was a significant degree of bone loss during the first 4 months following the procedure. Among female patients, only bone loss measurements taken at the buccal side of the implant were found to experience no significant change in bone height during the first 4 months. All other changes were significantly different from zero.

Table 1 Comparison by Group of Changes in Stability (ISQ) and Bone Height (mm)

Measurement	Early loading	Unloaded
Change in stability (ISQ)	-0.08 ± 0.77	1.33 ± 1.65
Change in bone height (mm)		
Buccal	-0.36 ± 0.31	-0.48 ± 0.17
Mesial	-1.01 ± 0.21	-0.76 ± 0.29
Lingual	-0.66 ± 0.15	-0.35 ± 0.20
Distal	-0.72 ± 0.19	-0.51 ± 0.23
BMDL	-0.69 ± 0.15	-0.53 ± 0.18

BMDL = the average of all sites.
No significant differences ($P < .05$) were found between the 2 groups.

Table 2 Comparison by Gender of Changes in Stability (ISQ) and Bone Height (mm)

Measurement	Men	Women
Change in stability (ISQ)	-0.96 ± 1.56	1.56 ± 1.14
Change in bone height (mm)		
Buccal	-0.76 ± 0.32	-0.20 ± 0.17
Mesial	-1.40 ± 0.34	-0.51 ± 0.17
Lingual	-0.81 ± 0.25	-0.24 ± 0.11
Distal	-1.01 ± 0.30	-0.33 ± 0.13
BMDL	-1.01 ± 0.14	-0.36 ± 0.18

BMDL = the average of all sites.
Significant differences ($P < .05$) were found between men and women.

There was no evidence of a difference across the 4 measurements (ie, the 4 implant sides), but the changes experienced by women were significantly smaller than those experienced by men ($P < .0001$).

The magnitude of the change in bone height was not significantly different across the 2 groups (Table 1). When gender was compared, bone loss measurements obtained at the mesial and distal sides of the implant showed significant gender differences in both groups.

Changes in Stability

A series of repeated-measures ANOVAs was performed to assess changes in stability across the 2 groups. No significant differences were found.

A nonparametric test (the Wilcoxon rank-sum test) was used to determine whether the difference in changes in ISQ between the 2 groups was statistically significant. To take into account the clustering of data, only one implant per patient was chosen randomly. The results showed that the difference was not significant between the test and control groups. When the interaction between sex and treatment groups was tested using ANOVA, the changes in stability were consistently smaller among female patients than among male patients (Table 2). The magnitude of the change in stability was not significantly different across the 2 groups.

Length of implant (10, 11.5, 13, or 15 mm) was not found to be significant in determining changes in ISQ and bone height. Group and gender were included in this series of repeated-measures analysis of covariance.

Discussion

Changes in Bone Level

Tests of the reliability and validity of the new bone-height measuring device have been done on a pig mandible and on human tissues.[21] The results showed excellent reliability, with an interobserver correlation coefficient of 0.99, as well as good evidence for validity, with a standard deviation of 0.04 mm and a measurement error of 0.02 mm. A comparison of measurements taken with and without surgical flap reflection showed no statistical difference.

Traditionally, radiographs are used to measure crestal bone levels around implants, but no data on buccal and lingual bone loss could be found. The reaction of bending and the general direction of fatigue crack growth propagation affect the buccolingual dimension,[22] and it has also been suspected that early bone loss often occurs on the buccal of the implant.[15] Our new measurement device permitted measurement at all 4 sides of each implant.

Statistical significance was not shown between the 2 groups in changes in bony crest height. This may indicate that immediate loading did not adversely affect the rate of bone healing around the implants.

To date, 2 controlled studies have compared the amount of early bone loss under ODs supporting immediately loaded and conventionally loaded implants. Randow et al[9] studied 88 MK II Brånemark implants (Nobel Biocare) that were immediately loaded in 16 patients and 30 implants that were loaded after 4 months in 11 patients. Eighteen months after abutment connection, bone height changes were compared. There was no statistically significant difference between the groups. The mean bone resorption for the immediate group was 0.4 ± 0.6 mm, compared to 0.8 ± 0.3 mm for the delayed loading group. The difference in means was explained by the different methods used to measure bone level.[9] The second study, by Lorenzoni et al,[23] used 14 immediately loaded Frialit-2 implants (Friadent) compared with 28 unloaded controls in an in-patient study on 7 people. As in the present study, the implants in the mandibular canine positions were immediately loaded with a Dolder bar-retained OD, and 4 other implants were used as controls and followed for 6 months. After 6 months, the mean bone level changes were 0.9 ± 0.4 mm loss for the loaded implants and 0.33 ± 0.34 mm for the unloaded group. The difference was significant ($P < .001$). However, they used a 1-mm-gauge periodontal probe and estimated only to the nearest 0.5 mm, which is not precise enough to detect small differences. In the present study, there was no significant difference between the 2 groups. However, there was a trend similar to the study of Lorenzoni et al.[23]

The available histologic reports reveal that in normal situations with favorable primary stability, early or immediate loading does not impede osseointegration, and the percentage of bone-implant contact is similar, if not higher, in immediately loaded implants than in conventionally delayed loading situations.[24–28] Romanos et al[24,27] observed more bone formation in areas with increased compression (according to the angulation of the implant and the vertical orientation of the loading forces).

In the present study, the mean bone loss found after 4 months was 0.71 ± 0.15 mm in the early loading group and 0.53 ± 0.18 mm in the unloaded group. After 4 months, this is slightly lower than other studies. Bryant[29] found an average of 1.4 mm of loss at loading, Adell et al[30] found 1.2 mm of loss, and Manz[31] found an average of 0.94 mm of loss with hydroxyapatite-coated implants and 1.14 mm loss with uncoated implants after 6 months. The surface of the TiUnite implants used in this study is different from the machined surface used in those studies, which may be a reason for the differences between the studies. Another prob-

lem with most of the studies is the reference point to determine bone loss. When the measurement is made from a radiograph at the time of abutment connection or during stage 2 surgery, the distance between the bone level and the reference point at the time of implant placement is unknown. It may vary from 1 implant to another, depending on whether the implant was more or less submerged at placement. Another reason could be the method of measurement. This methodologic problem can be found in several studies. There is substantial variation in the precision and accuracy of the methods used to measure and report bone loss; studies using panoramic views and nonstandardized radiographs have to be interpreted with caution.

A distinctive feature of the method of measurement used in this study was the capability of recording the buccal and lingual bony crest height. A statistical difference was not found between buccal and lingual sites compared to mesial and distal sites. If, in future studies using a larger number of implants and a wider range of patients, the results show that the buccal and lingual crests follow the mesial and distal, as seen in this study, it would validate that recording of only the mesial and distal sites is sufficient.

When gender was included as a factor in the statistics, a statistically significant difference in both stability and amount of bone loss between male and female patients was found. The changes in stability and bone height were consistently smaller among female patients than among male patients. Bryant[29] found similar results with gender when he measured the crestal bone level at the time of loading of 506 implants. Using independent associations, he found a mean bone loss of 1.50 mm in men and 1.24 mm in women ($P = .006$). After 10 years, the relationship was still significant (with a mean bone loss of 2.11 mm in male patients and 1.71 mm in female patients[29]). During the first 6 months after abutment connection, Naert et al found no effect of gender on bone level change in 1,655 implants.[32] Van Steenberghe et al[33] found that gender had no significant effect on marginal bone loss around 158 implants after 4, 8, and 12 years. All women in this study were postmenopausal. Of 13 women, 2 were undergoing hormone replacement therapy. Gender may have an influence during the early healing phase; further studies should be done on this topic.

Changes in Resonance Frequency

No differences in implant stability (ISQ) were found between the 2 treatment groups or over the 4-month period within either group. This is inconsistent with Friberg et al,[34] who found a slight decrease in stability for the majority of 75 machined Brånemark implants placed in anterior mandibles of high bone density. Sennerby et al,[35] using 20 patients and 127 implants, showed that when the primary stability is high at placement, the ISQ is more likely to be stable over time. These differences may be a result of the different types and designs of implants used, or may simply reflect the small sample size that was used in each study.

There are no published normative values or baseline data for ISQ, making comparisons difficult. However, it is useful to compare changes in bone-implant interface stiffness over time. The reading provided by the instrument is determined by the stiffness of the bone-implant interface and by the distance from the transducer to the first bone-implant contact (reflecting any change in bone level). Consequently, to know whether a change of ISQ over time is the result of bone loss, a change in the bone-implant interface, or a mixture of both, the change in bone height needs to be known. However, since there is no published standard or ratio between bone loss versus ISQ, it is not possible to know if the changes in ISQ are the result of bony crest changes or of a change in the interfacial stiffness. In the context of this study, the evidence does not permit the categorization of the use of the RFA device as a prognostic device to predict osseointegration in such a complex environment. The only conclusion that can be drawn is that, within the limits of this study, early loading does not adversely affect the stability of implants placed in dense bone.

Conclusion

This is a pilot study with clear limitations. However, in our patient sample, early loading with an OD did not significantly affect clinical stability and bone loss of implants placed in the anterior mandibles of patients over 45 years old. Before this protocol is applied to sites with lower bone density, it will be important to have a longer follow-up with a higher number of patients to explore the reliability of the trends observed in this study.

Female patients experienced a statistically smaller degree of bone loss during the first 4 months following treatment. However, those changes were within a clinically acceptable range when compared to other studies, and were not different between the 2 treatment groups. Consequently, within the limits of this study, bone changes are statistically but not clinically different in men and women, with male patients having more bony crest loss.

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