

A 4-Year Prospective Clinical and Radiological Study of Maxillary Dental Implants Supporting Single-Tooth Crowns Using Early and Delayed Loading Protocols

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ABSTRACT

Background: Recent studies have showed that immediate/early loading of dental implants is a clinically feasible concept with results similar to those for standard two-stage procedures, especially in the mandible. However, there are only a few studies regarding the immediate/early loading of maxillary implants supporting single-tooth crowns.

Purpose: The aim of this study was to compare the clinical and radiological outcomes of early- and delayed-loaded dental implants supporting single-tooth crowns in the maxilla.

Materials and Methods: Twenty-nine patients were consecutively treated between 2000 and 2002 with 59 Brånemark System MK III TiUnite implants (Nobel Biocare AB, Göteborg, Sweden) in the maxilla. Two groups were formed according to the loading protocols. In the test group, definitive implant-supported single crowns were delivered to 19 patients 6 weeks after the implant placement. In the control group, definitive implant-supported single crowns were delivered to 10 patients 6 months after the implant placement. Clinical and radiographic parameters were recorded at baseline, 1 to 4 years. Implant stability measurements have only been performed at 4-year follow-up recall.

Results: Overall, three implants were lost during the study period. Two implants were lost in the test group including 36 implants, which indicated a survival rate of 94.4%. One of the lost implants was replaced and then osseointegrated successfully. One implant was lost in the control group during the healing period, which indicated a survival rate of 95.7%. The average marginal bone loss was 1.11 mm for 56 implants after 4 years. There were no significant differences in marginal bone levels, insertion torque, and resonance frequency values between the two groups.

Conclusion: The results of this study indicate that 6 weeks of early loading period for TiUnite-surface titanium implants in the maxilla is reliable and predictable for this patient population and may offer an alternative to the standard loading protocol.

KEY WORDS: dental cement, dental implants, early loading, maxilla, single implant crown

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The use of dental implants in clinical practice for the treatment of total and partial edentulism has become a well-documented surgical and prosthetic procedure in the past 30 years.¹⁻⁵ The replacement of single teeth using dental implants has been a prosthodontic approach, allowing greater preservation of adjacent teeth and solving the esthetic problems of alternative procedures, such as resin-retained fixed prostheses during the last 15 years.⁶⁻⁸

Three types of loading protocols have been stated in the consensus report⁹ as follows:

1. Immediate loading: The prosthesis is connected to the implants the same day the implants are inserted.
2. Early loading: The prosthesis is connected at a second procedure, earlier than the conventional healing period of 3 to 6 months.
3. Delayed loading: The prosthesis is connected at a second procedure after a conventional healing period of 3 to 6 months.

Most standard protocols in implant dentistry suggest a healing period of 3 months for mandible and 6 months for maxilla.^{10–12} However, the time required for treatment, the need for additional surgical procedures, and especially the need for indefinite periods of temporization are obstacles that sometimes prevent the patients from implant treatments. To remove these obstacles, it would be beneficial to load implants within few weeks after implant placement. Studies regarding different types of prostheses have shown that early loading of mandibular implants can provide treatment outcomes comparable to those achieved using standard healing periods before loading.^{13,14} The early loading of implants supporting a full arch prosthesis in the edentulous maxilla has also been studied.^{15–17} However, only a few studies regarding early loading of implant-supported single-tooth crowns in the maxilla are available in the literature.¹⁸

The purpose of this study was to evaluate both clinical performance and marginal bone conditions of TiUnite implants (Nobel Biocare AB, Göteborg, Sweden) supporting single-tooth crowns placed in the maxilla. A further aim was to make a comparison between early- and delayed-loaded maxillary dental implants supporting single-tooth crowns.

MATERIALS AND METHODS

Twenty-nine patients (mean age 40 ± 11 ; 16 male, 13 female) treated in three clinics (one university clinic, two private clinics) were included in this study according to the following criteria: age between 20 and 60 years, systemic disease contradicting oral surgery, adequate bone volume to receive an implant $>3.75 \times 10$ mm, natural teeth present both mesial and distal to the missing tooth, and willingness to give informed consent. Patients were excluded if any of the following were evident: previous bone grafting in the area of the missing tooth, untreated caries, uncontrolled periodontal disease, condition, or medication that might com-

TABLE 1 Distribution of Single-Tooth Edentulous Sites Treated with Implants

Location	Number of implants	
	Group T	Group C
Maxillary central region	8	4
Maxillary lateral region	6	4
Maxillary canine region	1	1
Maxillary premolar region	12	9
Maxillary molar region	9	5

promise healing or osseointegration, unrealistic expectations for the treatment.

Test Group

The informed consent was signed by each patient before implant surgery. Antibiotic prophylaxis was administered orally 1 hour before each surgery. Thirty-six Brånemark System MK III TiUnite implants (Nobel Biocare AB, Göteborg, Sweden) with regular platform (RP) were inserted using one-stage surgical technique in 19 patients. The insertion torque values of the implants were recorded at implant surgery using an OsseoCare system (Nobel Biocare AB). The surgeries were carefully performed with the guidance of a template to decrease the risk of damage to the adjacent teeth. The edentulous site treated with implants and the length and diameter of the implants used are shown in Tables 1 and 2. Previously constructed removable acrylic (Meliodent, Heraeus Kulzer, Ltd., Berkshire, Germany) partial prostheses replacing missing tooth/teeth were temporarily relined and delivered to the patients after the implant surgery.

All patients were called for impression procedures 1 month after implant placement. Preliminary

TABLE 2 Dimensions of Implants

Dimensions (diameter and length, mm)	Number of implants	
	Group T	Group C
3.75×15.0	12	6
3.75×13.0	5	3
3.75×11.5	6	2
4.00×13.0	3	1
4.00×11.5	5	5
4.00×10.0	5	6

impressions were taken with a stock tray using alginate (CA37, Cavex, Haarlem, the Netherlands). The impression copings were secured to each implant before the final impression procedure. The final impressions were taken with a custom-made resin tray (Heraeus Kulzer, Werheim, Germany), which had window/windows to allow access for impression coping screws/screws, using Impregum polyether impression material (ESPE Dental-Medizin, Seefeld, Germany). A part of Impregum polyether impression material (ESPE Dental-Medizin) was carefully syringed around the impression coping to ensure complete coverage of the coping itself. After setting of the impression material, the coping screws were unscrewed and the impressions removed from the patients' mouth. An implant replica (Nobel Biocare AB) was screwed on the top of the impression coping, and the impression was poured following the manufacturer's instructions.

Because two implants failed before abutment connection, 34 CeraOne abutments (Nobel Biocare AB) were screwed on top of the implant replicas and then wax copings (Nobel Biocare AB) were placed for all abutments. Wax was added directly to the wax coping using the same waxing procedures for each abutment. Regular porcelain-fused-to-metal definitive crowns with porcelain occlusal surfaces were fabricated. A high gold containing alloy (Degudent® U, Degussa Dental, Hanau-Wolfgang, Germany) was used for metal copings, and porcelain (Ceramco, Degussa Dental) was applied to them. CeraOne abutments (Nobel Biocare AB) were screwed to the implants. All definitive restorations in contact with antagonist teeth were cemented with temporary cement (Temp Bond NE, Kerr, Salerno, Italy) 6 weeks after implant placement.

Control Group

Twenty-three Brånemark System MK III TiUnite implants (Nobel Biocare AB) with RP were inserted using two-stage surgical technique in 10 patients. The insertion torque values of the implants were recorded at implant surgery using an OsseoCare system (Nobel Biocare AB). Five months after implant placement, second-stage surgeries were performed, and healing abutments were screwed to the implants. The definitive implant-supported single crowns were fabricated according to the same steps described earlier and were delivered to the patients 6 months after implant placement.

Examinations

After prosthetic treatment, a standard follow-up program including implant survival, marginal bone changes, and technical complications was designed for all patients. The patients were checked every 3 months in the first year, and every 6 months in the subsequent years. All the patients regularly returned to the clinic for recalls.

Implant Survival Examination. The implant survival was judged on the following criteria, which were described by Albrektsson and colleagues:¹⁹ absence of mobility, absence of painful symptoms, absence of peri-implant radiolucency during radiographic evaluation, and absence of progressive marginal bone loss.

Radiographic Examination. Standardized intraoral radiographic examinations were performed for all patients using the paralleling technique and a plastic film holder.²⁰ The radiographs were taken on the day of the implant placement and in the subsequent years. The radiographs were scanned to digital files, and marginal bone changes were measured on a computer using an image analysis software (Adobe Photoshop, Adobe Systems, Inc., San Jose, CA, USA) by one examiner using the implant/abutment junction as a reference. The average of mesial and distal marginal bone changes were recorded for each implant. The distance between two threads of the implant was used for calibration of measurements.

Prosthodontic Examination. The prosthodontic results were recorded as successful at the final evaluation if the implant-supported single crown remained in place and if there had been no technical complications such as loosening of abutment screw, decementation of definitive crown, or prosthesis (porcelain) fracture.

Resonance Frequency Analysis (RFA). Osstell machine was used for RFA (Integration Diagnostics AB, Göteborg, Sweden). RFA was performed at the 4-year follow-up visit only. At these recalls, both crowns and abutments were removed from the patient, and RFA measurements were taken on implant level using an L-shaped transducer (Integration Diagnostics AB). The measurements were given in implant stability quotient (ISQ) units (Integration Diagnostics AB).

TABLE 3 Mean Marginal Bone Levels (mm SD), from Implant/Abutment Junction during 4 Years

	Surgery	1 year	2 years	3 years	4 years
Group T	0.35 ± 0.09	1.05 ± 0.15	1.2 ± 0.14	1.32 ± 0.14	1.41 ± 0.15
Group C	0.3 ± 0.05	1.1 ± 0.1	1.24 ± 0.09	1.38 ± 0.1	1.46 ± 0.1

Statistical Analysis

Descriptive analysis of the raw data was performed with commercial statistical software (SPSS 11.0, SPSS, Inc., Chicago, IL, USA). The Mann–Whitney test was used to compare the marginal bone level and implant stability measurements between the two groups since the criteria for using parametric tests were not fulfilled. Spearman's test was used to detect any correlations between insertion torque and ISQ values. In connection with statistical evaluations, a *p* value of 0.05 was considered statistically relevant.

RESULTS

Of the 59 dental implants included in the present study, three were lost during the follow-up period. In the test group, one of two failed implants that was placed in central position was lost 1 month after the implant placement, while the other one placed in the first molar position was lost 3 months after the implant placement. In the control group, one implant placed in the second premolar position was lost during the healing period. The failed implant placed in the central position was replaced after 2 months of healing period and was osseointegrated uneventfully. The survival rates of the implants were 94.4 and 95.7% for the test and control groups, respectively.

Radiographic measurements and evaluation of marginal bone changes were performed for each implant at baseline and after 1 to 4 years. The detailed average marginal bone levels during 4 years are presented in Table 3. No significant differences in marginal bone resorption were observed between the two groups during the study period (*p* > 0.05). It was found that the mean marginal bone resorption was 1.11 mm for 56 implants at 4-year evaluation.

Both mean insertion torque and resonance frequency values are presented in Table 4. No significant differences in insertion torque and resonance frequency values were observed between the two groups (*p* > 0.05).

Strong correlation was found between insertion torque and ISQ values for 56 implants (*r* = 0.638, *p* < 0.001).

DISCUSSION

The relatively recent introduction of an immediate/early loading protocol of dental implants has eliminated many handicaps, since the typical delay to placement of an implant-supported restoration is effectively removed, only one surgical procedure is needed, and the patient benefits from not having to wear a removable provisional restoration for a long period. The number of previous studies on immediate/early loading was based upon restoration of the edentulous mandible, where bone density is known to be favorable, and cross-arch splinting is possible to minimize micromovement, which can be a principal cause of early implant failure.^{21,22}

The desire to overcome these handicaps has led to further studies investigating the outcome for immediately loaded implants in the maxilla for both splinted and unsplinted implants.²³ Other studies have also reported specifically on the survival of dental implants supporting single-tooth crowns.²⁴

In the present study, TiUnite-surface Branemark implants were used. Human²⁵ and animal²⁶ studies demonstrated that rough-surfaced implants can become osseointegrated faster than conventional machined-surfaced titanium implants. Ivanoff and colleagues,²⁵ who made one of the human studies regarding bone

TABLE 4 Mean Implant Stability Quotient (ISQ) and Insertion Torque Values, by Group

	Insertion torque	ISQ
Group T	40.5 ± 6	68.5 ± 3
Group C	39.7 ± 7	68.1 ± 2

response to TiUnite and turned Brånemark System titanium microimplants in human jawbone reported that bone-implant contact was 29% for TiUnite surface, 11% for turned surface in the maxilla, which indicated statistical difference.

The 3-year data of the test group have already been reported, and the present study confirms the previous results.²⁷ The present 4-year analysis including both test and control groups provided the results from 59 dental implants used for single-tooth crowns retained with cement. The survival rate of the early loaded implants used in the test group is consistent with previous studies.^{28,29} Norton²⁸ reported a 96.4% survival rate for immediately loaded Astra Tech implants 20.3 months (range 13–30 months) after implant placement, while Cooper and colleagues²⁹ reported a 96.2% survival rate for single-tooth implants restored 3 weeks after the first surgery.

In the present study, the average marginal bone resorptions for the test and control groups were 0.7 and 0.81 mm at 1-year recall, and 1.06 and 1.16 mm at 4-year recall, respectively, which were similar to the previous reports.^{30,31} Vigolo and colleagues³⁰ reported 0.8-mm marginal bone loss for implant-supported single crowns 4 years after implant placement. Glauser and colleagues³¹ reported 1.2-mm marginal bone loss from 99 TiUnite-surfaced Brånemark MK IV implants (Nobel Biocare AB, Göteborg, Sweden). In that study, a total of 102 implants (38 maxillary and 64 mandibular) were placed (three implants failed). The 1-year marginal bone loss in the present study is lower than that in the study by Glauser and colleagues,³¹ which may result from the distribution of the implant sites as they placed the majority of implants in posterior regions (88%) where bone quality is relatively poor.

Overall, three technical complications regarding porcelain fracture were observed during 4 years. It was considered that the porcelain fractures might have resulted from local premature contacts and relatively higher chewing forces in the males. No abutment screw loosening/fracture was found. The number of the technical complications encountered in the present study was lower than those in previous reports.²⁹ These differences may result from the patient-related factors (ie, different chewing forces) and different types of abutments/abutment screws, porcelains, and metals used.

The insertion torque values were recorded at implant placement, while ISQ values were recorded at

the 4-year follow-up visit. Both values were higher than those in previous reports.³² A correlation between insertion torque and ISQ values has also been observed. This finding is partially in agreement with the study by Da Cunha and colleagues,³² although a direct comparison with that study was not possible as they also used different type of implants, loading protocols, or different recipient sites. Significant linear correlations were found between the placement torques for apical, middle, and crestal third for TiUnite implants. The linear correlations between the placement torques for the same variables were not significant for the standard implants. The average insertion torque and ISQ values were 37.1 and 67.9, respectively. They reported no overall correlation between insertion torque and ISQ values.

CONCLUSION

Under the guidelines of the present study, TiUnite-surface titanium implants are reliable and predictable for early loading (6 weeks after the implant placement) in the maxilla.

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