

Low implant insertion torque allows minimal bone loss: A multicenter 2-year prospective study

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Abstract

Objective

The aim of this multicenter prospective study was to evaluate the survival rate of implants after insertion using low torque (< 35 N cm), by recording measurements from resonance frequency analysis (RFA), probing pocket depths and changes in interproximal crestal bone level.

Materials and methods

This multicenter prospective clinical study was performed in partially edentulous subjects. The patients treated in the study received 1–4 SPI implants (Alpha-Bio Tec, Petah Tikva, Israel), which were loaded 4 months after implantation. Measurements of torque and RFA were recorded immediately after implant insertion. New RFA measurements were taken at the time of implant exposure surgery, prior to connection of the healing abutments. Baseline measurements of bone level were taken both directly and radiographically immediately after insertion and were compared with measurements taken during the 2-year follow-up period.

Results

Of 88 treated subjects, 83 completed the 2-year follow-up. Of 137 implants, 5 were lost. The survival rate after 2 years of follow-up was 96.5% and the mean marginal bone loss was 0.531 mm. The mean measurement for RFA at the time of implantation was 74.92 and this increased to 76.26 prior to insertion of the prostheses.

Conclusion

Within the limits of the study, implants inserted with low torque (< 35 N cm), displayed high survival rates with high RFA scores and minimal bone loss at the 2-year mark after implantation.

Keywords

Implants; bone loss; RFA; resonance frequency analysis.

Introduction

Nowadays, dental implants are widely used as a treatment for fully and partially edentulous patients, and the survival rate has been reported to be high.^{1,2} However, certain risk factors may predispose to an increased risk of implant failure and a lower success rate. Risk factors for implant failure can be divided mainly into 2 groups.³ The first group of risk factors includes surgical technique, retention technique, the primary stability of the implant, and variables affecting the implant prosthesis, such as the length, diameter and location of the implant. The second group involves patient-related factors, such as smoking, diabetes, alcohol abuse, oral hygiene habits and a history of periodontitis. Controversy remains, however, concerning the linkage between certain risk factors and dental implant failure.³⁻⁶

Dental implant success may be characterized by initial and long-term stability of the implant and healthy periimplant hard and soft tissue.⁷ It is widely accepted that marginal bone loss of approximately 1.0 mm during the first year after prosthetic loading and subsequent annual bone loss not exceeding 0.2 mm are consistent with successful treatment.^{8,9}

A wide variety of techniques have been used for measuring implant stability at various clinically relevant reference points in time. The techniques currently most often used to measure stability are insertion torque, Periotest and resonance frequency analysis (RFA).¹⁰ While clinically useful, insertion torque is limited to implant insertion and thus cannot be used to determine secondary stability. Conversely, RFA is a noninvasive and widely used method to quantify implant stability at any stage during implant treatment and the follow-up period.^{11,12} The RFA technique for measuring implant stability was developed by Meredith and co-workers almost 30 years ago and is commercially available as the Osstell device.¹² A sensor (SmartPeg) is mounted on top of the implant and the sensor is then brought to vibration by gently moving it with magnetic pulses. The sensor will vibrate for a short while and then stop. If the implant stability (stiffness of the bone-implant interface) increases, then the vibration frequency of the sensor will increase. Resistance to vibration of the transducer by the surrounding bone is registered by a small computer device and measured in hertz. Hertz are converted to ISQ (Implant Stability Quotient)

values ranging from 1 to 100; the higher the ISQ, the greater the implant stability. This method is known as RFA.¹³

Dentists feel better whenever an implant is inserted using high torque (< 35 N cm). There are some publications claiming that this is an ultimate demand for immediate loading. However, using low insertion torques yields favorable survival rates with optimal marginal bone levels compared with the accepted norm.¹⁴

In 2004, the SPI implant system (Alpha-Bio Tec, Petah Tikva, Israel) was introduced to the dental market. The implant has an internal hexagon connection and is available in several lengths and diameters. The implant surface is sandblasted and acid-etched (NanoTec). Its tapered core and sharp threads result in firm bone grip, which enables stable insertion and high primary stability.

The aim of this multicenter prospective study was to evaluate the survival rate of implants after insertion using low torque, by means of recording measurements from RFA, probing pocket depths and monitoring changes in the interproximal crestal bone level.

Materials and methods

Study design

This prospective study was designed as a controlled multicenter clinical trial, and it involved the participation of the following 4 medical centers in China: West China Hospital of Stomatology, Chengdu; Stomatology Hospital of Shandong University, Jinan; Yantai Stomatological Hospital, Yantai; and Affiliated Stomatology Hospital of Tongji University, Shanghai.

The study was conducted in accordance with the 1964 Declaration of Helsinki (and all subsequent amendments) and Good Clinical Practice (ISO 14155:2003). It was approved by the ethics committee of Sichuan University and was submitted to the other centers for approval prior to commencement of the study. The study was registered at www.clinicaltrials.gov (registration No. NCT02367261).

Subjects and implants

Subjects were selected according to the following predetermined inclusion and exclusion criteria:

Inclusion criteria

1. Men and women over the age of 18 years who were in need of 1–4 implants.
2. Patients able to understand the requirements of the study and willing and able to comply with its instructions and schedules.
3. Patients who provided written informed consent to participate in the study prior to any study procedure.
4. Patients in good general health in the opinion of the principal investigator, as determined by the medical history and oral examination.

Exclusion criteria

1. Immediately loaded implants.
2. Patients requiring bone augmentation.
3. Patients receiving treatment with bisphosphonates.
4. Patients receiving treatment with anticonvulsant drugs or anticoagulant drugs (international normalized ratio under 1.8).
5. Patients with untreated periodontal disease and poor oral hygiene.
6. Patients with a history of alcohol, narcotic or other drug abuse.
7. Patients undergoing steroid therapy.
8. Patients receiving radiotherapy, chemotherapy or any other immunosuppressive treatment, or who had received radiotherapy in the last 5 years—patients who had received radiotherapy to the head and neck region at any time in the past.
9. Patients with metabolic bone disorders.
10. Patients with uncontrolled bleeding disorders, such as hemophilia, thrombocytopenia and granulocytopenia.
11. Patients with degenerative diseases.
12. Patients with osteoradionecrosis.
13. Patients with renal failure.
14. Organ transplant recipients.
15. HIV-positive patients.
16. Patients with malignant diseases.
17. Patients with diseases that compromise the immune system.
18. Patients with uncontrolled diabetes mellitus (hemoglobin A_{1c} level above 6.5%).
19. Patients with psychotic diseases.
20. Patients with hypersensitivity to any of the components of the implant in general or to titanium in particular.
21. Pregnant or lactating women.
22. Lack of patient cooperation.
23. Patients with uncontrolled endocrine diseases.

24. Patients with any systemic condition that precluded surgical procedures.
25. Patients with parafunctional habits, such as bruxism.
26. Patients with temporomandibular joint disease.
27. Patients with various pathologies of the oral mucosa, such as benign mucous membrane pemphigoid, desquamative gingivitis, erosive lichen planus, oral malignancy and bullous erosive diseases of the oral mucosa.
28. Patients who required flapless procedures.
29. Patients who smoke over 10 cigarettes a day.

The most important inclusion criteria were subjects over 18 years old who had good general and dental health. The most important exclusion criteria were as follows: immediate implantation, smokers of over 10 cigarettes a day, alcohol abuse, various medical conditions as specified by the clinician, and pregnant or lactating women.

Surgical protocol

All subjects received 1–4 SPI implants. Using a delayed implant approach, all implants were inserted 4 months after tooth extraction. The implants were 3.3–5.0 mm in diameter and 8.0–13.0 mm in length. Implant surgeries were performed under local anesthesia and followed standard surgical techniques. After flap elevation, the implant bed was prepared using medical-grade stainless-steel drills (Alpha-Bio Tec) with progressively increasing diameter, in accordance with the drilling protocol (**Table 1**). The implant insertion torque was measured with a physiodispenser machine (NSK, Stevenage, U.K.; Nouvag, Goldach, Switzerland), which was placed at the level of the crestal bone. RFA was measured immediately after implant placement using an Osstell device (Osstell, Gothenburg, Sweden). A periapical radiograph was taken as a baseline, using a paralleling technique.

Implants were exposed 4 months after implantation, and RFA measurements were taken immediately prior to connection of the healing abutments. The final prostheses were fabricated 6 months post-implantation. The occlusion of the restorations was adjusted, and oral hygiene was reinforced with the patients. Patients were recalled at intervals of 12 and 24 months after implant insertion surgery in order to evaluate the periimplant bone level and the status of the prosthetic work.

Table 1

Implant Ø (mm)	Soft bone (type IV; mm)	Medium bone (types II & III; mm)	Hard bone (type I; mm)
3.30	2.00	2.00	2.00
		2.80	2.80
			3.20 cortical
3.75	2.00	2.00	2.00
	2.80	2.80	2.80
		3.20	3.20
			3.65 cortical
4.20	2.00	2.00	2.00
	2.80	2.80	2.80
	3.20	3.20	3.20
		3.65	3.65
5.00	2.00	2.00	2.00
	2.80	2.80	2.80
	3.20	3.20	3.20
	3.65	3.65	3.65
6.00	2.00	2.00	2.00
	2.80	2.80	2.80
	3.20	3.20	3.20
	3.65	3.65	3.65
	4.10	4.10	4.10
	4.80	4.80	4.80
		5.20	5.20
			5.80 cortical

Cortical = Drill through cortical plate

Implant survival

Survival of implants was defined as those implants that were still in place 24 months after placement and that met the criteria set by Buser et al.: the absence of persistent subjective complaints (e.g., pain, foreign-body sensation and dysesthesia), the absence of periimplant infection with suppuration, the absence of mobility, the absence of a persistent periimplant radiolucency, and the possibility of restoration.¹⁵

Bone level changes

Periapical radiographs with standardized settings were taken as a baseline at the time of implant surgery and were retaken at the time of abutment connection and at 12 and 24 months postsurgery (Figs. 1–3). Digital images were

analyzed using ImageJ open software (Version 1.33, National Institutes of Health, Bethesda, Md, U.S.) by an independent reader who was blind to the study material. The implant length was used as a reference measurement, and bone level was therefore defined as the distance from the reference point to the first radiographic bone-to-implant contact; changes in mesial and distal bone levels in this region were considered to be remodeling. Mesial and distal measurements were recorded and the mean of these 2 values was used.

Statistical analysis

Bone level was calculated as the average of the mesial and distal levels at 3 time intervals (baseline and 12 and 24 months later). Repeated measures general linear models with Bonferroni

Table 1

The drilling protocol used in the study.



Variable	N (missing)	Mean ± SD (N cm)	Min, Max
Insertion torque	137 (0)	33.250 ± 9.913	5, 50

Table 2

Fig. 1
SPI implant immediately after implantation surgery.

Fig. 2
SPI implant 1 year after implantation surgery.

Fig. 3
SPI implant 2 years after implantation surgery.

Table 2
Insertion Torque During the Implantation Surgery.

adjustment for multiple comparisons were used to assess the differences between the 3 time intervals. A similar analysis was performed for pocket depths in 4 locations (buccal, lingual, distal and mesial) at 3 time intervals (6, 12 and 24 months). $P < 0.05$ was considered statistically significant. All analyses were performed with SPSS (Version 24, IBM Corp, Armonk, N.Y., U.S.). The analysis set was as complete as possible and was as close as possible to the intention-to-treat ideal of including all subjects who had received the therapy at least once.

Results

Eighty-eight patients out of 90 were included in the study. Of the 88 treated subjects, 83 participated up to the 24-month follow-up mark (2 patients had dropped out and 3 had implant failure diagnosed). The study group consisted of 47.73% men and 52.27% women and the mean age of the participants was 47.45 ± 11.15 years. The majority did not smoke at all, and 22% of the subjects smoked less than 10 cigarettes a day.

The average measurement for insertion torque was 33.250 ± 9.913 N cm (Table 2). Of 137 implants, 132 survived. The calculated survival rate of the implants after 2 years was 96.5%. Five implants were lost during the first year of the study, while no implant was lost during the second year.

RFA measurements were taken after implant placement and retaken immediately prior to connection of the prostheses (Fig. 4). The mean immediate measurement for RFA was 74.92 ± 8.93 , while analysis at the time of implant exposure 4 months later yielded a 76.26 ± 7.42 mean score.

Changes in bone level and soft tissue

The mean change in marginal bone level at the 1-year follow-up was 0.44 ± 0.52 mm and the mean change at the 2-year follow-up was 0.54 ± 0.50 mm (Fig. 5). The average bone loss between the 1- and 2-year follow-up marks was calculated and found to be 0.105 mm.

Soft-tissue changes were monitored by probing pocket depths at 4 locations: mesial, distal, buccal and lingual (Fig. 6). The probing depths before connection of the final restoration averaged 1.04 ± 1.08 mm mesially, 0.91 ± 0.93 mm buccally, 1.04 ± 1.42 mm distally and 0.86 ± 0.88 mm lingually. At 12 months postsurgery, the average probing depths were 2.40 ± 0.80 mm, 2.08 ± 0.82 mm, 2.30 ± 0.85 mm and 2.10 ± 0.80 mm, respectively. At 24 months postsurgery, the average probing depths were 2.60 ± 1.05 mm, 2.10 ± 0.98 mm, 2.55 ± 1.11 mm and 2.33 ± 1.20 mm, respectively.

Discussion

This was a controlled multicenter prospective study that evaluated performance of the SPI implant system with 24 months of follow-up. The study demonstrated a stable survival rate of 96.5% after 1 and 2 years of follow-up. This finding correlates with previously performed studies by Artzi et al.¹⁶ and Ormianer et al.¹⁷ that showed similar implant survival rates of 96.95% and 96.6%, respectively, over longer follow-up periods.

According to Chrcanovic et al., failures of dental implants can be subdivided into early and

Fig. 4

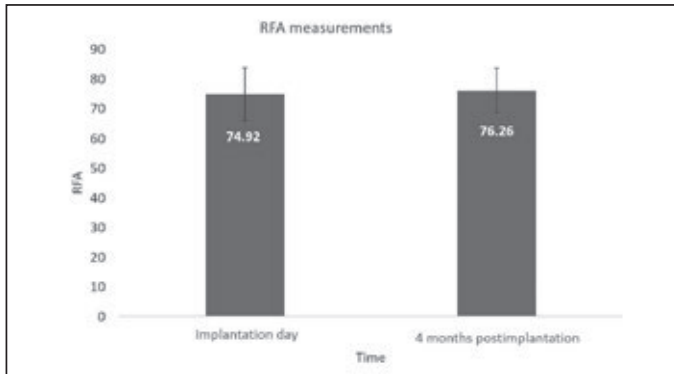


Fig. 5

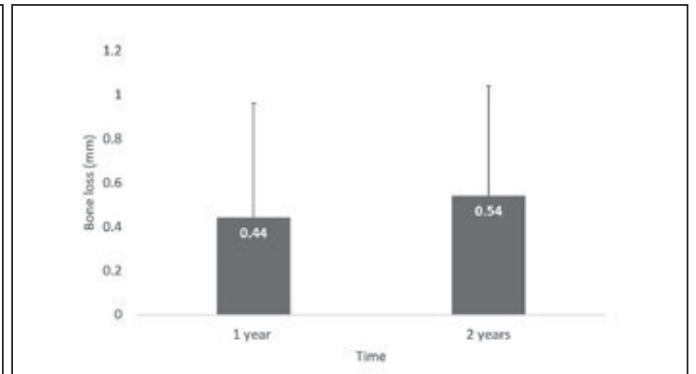
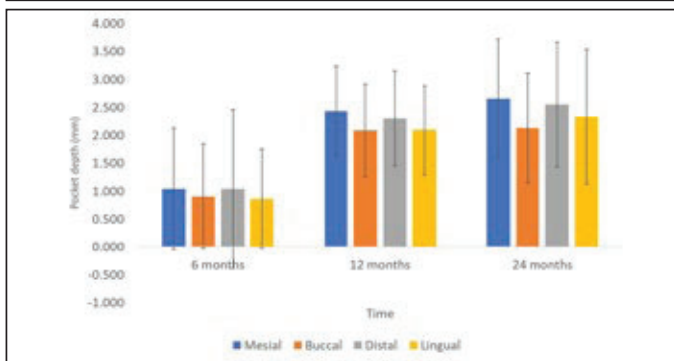


Fig. 6



late failures, depending on whether they occur either before/at abutment connection surgery (early) or after occlusal loading of a prosthetic restoration (late).¹⁸ Failures in each of these 2 distinct periods may be associated with different factors. Early failure of an implant results from an inability to establish intimate bone-to-implant contact. Based on our data, the excellent stability and integration of SPI implants was evident within 4 months after implantation (before connection surgery), even though the average insertion torque did not exceed 35 N cm.

The average insertion torque used in this multicenter study yielded quite a low degree of bone loss 2 years after implant insertion surgery. The drilling protocol used in the study resulted in a low insertion torque, accompanied by quite a high RFA reading. The torque in this study is much lower than the values reported in the literature.^{19, 20} Lower insertion torques yield favorable survival rates with optimal marginal bone levels compared with the accepted norm.^{14, 21} In contrast, studies in which high insertion torque was implemented demonstrated significant bone loss compared with low insertion torque.^{19, 20}

In order to identify the risk factors associated with implant failure, a multivariate Cox model was formulated, and a rigorous model was selected that was constructed with statistically

significant variables ($P < 0.05$) identified by bivariate Cox regression analysis. As a result, 2 variables were statistically associated with implant failure: tobacco use ($P = 0.021$) and alcohol use ($P = 0.047$). In the multivariate model, however, only tobacco use remained statistically associated with implant failure. These results are in accordance with those of several previous studies.^{18, 22, 23}

The mean amount of bone loss detected in the study was 0.426 mm at 1 year postimplantation and 0.531 mm at the 2-year mark. These results are in agreement with those of Artzi et al.¹⁶ and Ormianer et al.¹⁷, which reported bone loss of 0.78 mm at the 3-year follow-up and 2.00 mm at the 9-year follow-up.

In addition, this minimal rate of bone loss was accompanied by improved RFA measurements, which may be associated with increased implant stability. The results suggest that the SPI implants allowed progressive biological integration with their bony housing.

Probing depths before connection of the final restoration connection were 1.04 ± 1.08 mm mesially, 0.91 ± 0.93 mm buccally, 1.04 ± 1.42 mm distally and 0.86 ± 0.88 mm lingually. At 1 year postimplantation, the probing depth measurements had increased to 2.40 ± 0.80 mm, 2.08 ± 0.82 mm, 2.30 ± 0.85 mm and 2.10 ± 0.80 mm, respectively, and at 2 years

Fig. 4

RFA measurements immediately after implantation and during reopening surgery.

Fig. 5

Changes in bone loss over time.

Fig. 6

Changes in pocket depth at 4 locations over time.

postimplantation, they had increased to 2.60 ± 1.05 mm, 2.10 ± 0.98 mm, 2.55 ± 1.11 mm and 2.33 ± 1.20 mm, respectively.

The analysis thus revealed that probing depths increased moderately compared with the baseline over the period of the study, and one may conclude that a more fastidious oral hygiene regimen was required by all subjects, especially with regard to the implant sites, even though bone loss measurements were not found to be higher at these sites. None of the implants were diagnosed with periimplant mucositis or periimplantitis, according to the diagnostic criteria,²⁴ such as bleeding on probing.

Conclusion

Within the limits of the study, implants inserted with low torque displayed high RFA scores, minimal bone loss and a high survival rate at 24 months after implantation.

Competing interests

The authors declare that there are no competing interests. Prof. Ofer Moses serves as an external medical adviser for Alpha-Bio Tec. The study was funded by Alpha-Bio Tec.

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