Immediately Loaded Titanium Implants with a Porous Anodized Surface with at Least 36 Months of Follow-Up

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ABSTRACT

Background: Results from some studies clearly suggest that immediate loading can achieve equal success rates as those found in delayed or unloaded implants. There is still a lack of knowledge about the role of surface oxide properties during the peri-implant bone healing processes.

Purpose: The aim of this study was a clinical follow-up study of immediately loaded implants with a porous anodized surface.

Materials and Methods: A total of 142 TiUniteTM (Nobel Biocare, Göteborg, Sweden) implants were inserted from January to September 2001. All implants have been used in fixed restorations. Fifty implants were inserted in completely edentulous mandibles, and 69 implants were inserted in completely edentulous maxillae. All 119 implants were subjected to immediate functional loading (IFL) (immediate restoration with full occlusal contact). The other 23 implants, inserted in 12 patients, underwent immediate nonfunctional loading (INFL) (immediate restoration without occlusal contact) in different anatomical configurations (single tooth, small bridges in the anterior mandible, anterior maxilla, and posterior maxilla). All 142 implants have been followed for at least 3 years.

Results: All implants appeared to be osseointegrated from a clinical and radiographic point of view. No failures were observed in the IFL and INFL groups. The implant success was 100%. The mean marginal bone loss was 0.8 and 1.0 mm at 12 and 36 months, respectively.

Conclusion: Implants with a porous anodized surface appear to work well under an immediate loading state in the long term.

KEY WORDS: immediate loading, implant surfaces, porous anodized surface

Adecrease in the healing period before implant loading is welcomed by both patients and clinicians.^{1,2} Immediate loading has been described in combination with mandibular bar-retained overdentures, complete arch-supported prostheses, and partial edentulism.³⁻⁷ Immediate loading has aesthetic, physiological, and functional advantages.³ Most of the studies in

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immediate loading have been carried out in patients with an edentulous mandible.4 Results from some studies clearly suggest that immediate loading can achieve equal success rates as those found in delayed or unloaded implants.⁵ Immediate loading reduces the number of surgical interventions and shortens the time between surgery and prosthetic delivery.⁶ Terminology describing immediate loading of implants in the current literature can be misleading and has been used with a degree of ambiguity.7 Immediate loading has been used to describe loading implants on the same day of the surgery as well as loading a number of days following the surgery.⁷ Primary stability and absence of micromovements are considered fundamental prerequisites for osseointegration.^{8,9} Rigid splinting and minimal lateral force application are critical factors for success.10

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Sufficient implant length, insertion torque, and bone quality as well as bicortical anchorage are factors considered to influence primary implant stability.¹¹ It has been suggested that it is not the absence of loading per se that is critical for osseointegration, but rather the absence of excessive micromotion at the interface. Micromotion consists of relative movement between the implant surface and surrounding bone during functional loading and above a certain threshold excessive interfacial micromotion early after the implantation interferes with local bone healing, predisposes to a fibrous tissue interface, and may prevent the fibrin clot from adhering to the implant surface during healing.¹¹

Even if the immediate loading concept can be a realistic treatment alternative in various jawbone regions,¹¹ nevertheless, it is acknowledged that further investigation of the mechanical properties and biologic activities of bone around early and immediately loaded implants is necessary before further acceptance of the procedure can be expected. Even if immediate loading seems to be predictable, it is technique sensitive and should be used very carefully.6 The immediate loading of Brånemark® implants (Nobel Biocare AB, Göteborg, Sweden) has already been successfully reported in the literature. Surface chemical composition is of great importance for bone response.¹² There is still a lack of knowledge about the role of surface oxide properties during the periimplant bone healing processes.¹³ It has been reported that the mean values of the removal torque values increased with an increase of the oxide thickness.13 Surface oxide properties are regarded to be of great importance in establishing a successful osseointegration.¹⁴ Oxidized implants showed higher mean peak values of removal torque,¹⁵ and a 95% increase in surface area compared to conventional turned implants.¹⁶ Zechner and colleagues¹⁷ reported that anodically roughened implants may provide a similar bone-implant contact percentage as hydroxyapatite-coated implants.

The TiUnite[™] (Nobel Biocare AB) surface is created through anodic oxidation resulting in an increased TiO₂ layer, surface roughness, and an enlarged surface area.¹⁸ In a histological study in monkeys using TiUnite implants, it was found that a thin layer of bone covered most of the implant threads and that the overall low bone density did not inhibit the strong osteoconductive potential of this surface.¹⁶ In a human-retrieved immediately loaded TiUnite implant, we found a very high bone-implant contact percentage (60%), even if the implant had been inserted in the posterior maxilla.¹⁹ Sul found that the bone in contact with the TiUnite surface was more homogenous and more densely mineralized.¹⁵ Moreover, the anodized surface was reported to enhance cellular adhesion.²⁰

The aim of this study was a clinical follow-up study of immediately loaded implants with a porous anodized surface.

PATIENTS AND METHODS

Patients

A total of 29 patients (13 males, 16 females), mean age of 52 years (range from 23 to 65 years) participated in this study. The protocol was approved by the ethics committee of our university and the patients gave their written informed consent. All patients were consecutively included.

The inclusion criteria were controlled oral hygiene, the absence of any lesions in the oral cavity, sufficient residual bone volume to receive implants of at least 3.3 mm in diameter and 10 mm in length, resonance frequency analysis (RFA) values >60 implant stability quotient (ISQ), and implant insertion torque (IIT) >25 Ncm; in addition, the patients had to agree to participate in a postoperative control program.

The exclusion criteria were insufficient bone volume, bone quality type D4, a high degree of bruxism, smoking more than 20 cigarettes per day and excessive consumption of alcohol, localized radiation therapy of the oral cavity, antitumor chemotherapy, liver diseases, blood diseases, kidney diseases, immunosupressed patients, patients taking corticosteroids, pregnant women, inflammatory and autoimmune diseases of the oral cavity, poor oral hygiene, RFA <60, and IIT <25 Ncm.

Data Collection

Before surgery, radiographic examinations were done with the use of periapical radiography, orthopantomograph, and computerized axial tomography scan. In the follow-up period, periapical radiographs were used.

In each patient, peri-implant crestal bone levels were evaluated by calibrated examination of periapical x-rays. Measures were recorded after surgery and at each year follow up. The measurements were carried out mesially and distally to each implant, calculating the distance between the fixture/abutment joint and the most coronal point of contact between the bone and the



Figure 1 Crestal bone level (CBL) and fixture/abutment joint (FAJ) (case 1).

implant (Figure 1). The bone level recorded just after the surgical insertion of the implant was the reference point for the following measurements. The measurement was rounded off to the nearest 0.1 mm. A Peak Scale Loupe® (Peak Optics, GWJ Co., Hacienda Heights, CA) with a magnifying factor of 7× and a scale graduated in 0.1 mm was used. All the measurements were made by the same examiner (M.D.).

Peri-implant probing was not performed because a controversy still exists regarding the correlation between probing depth and implant success rates.

Implant success was evaluated according to the following criteria: (1) absence of persisting pain or dysesthesia; (2) absence of peri-implant infection with suppuration; (3) absence of mobility; and (4) absence of persisting peri-implant bone resorption greater than 1.5 mm during the first year of loading and 0.2 mm/year during the following years.

Implants

A total of 142 TiUnite implants were inserted from January to September 2001. Of these, 127 were Mk III and 15 were Mk IV. Fifty implants were inserted in com-



Figure 2 Preoperative periapical x-ray (case 1).

pletely edentulous mandibles, and 69 implants were inserted in completely edentulous maxillae. All 119 implants were subjected to immediate functional loading (IFL) (immediate restoration with full occlusal contact) (Table 1). The other 23 implants, inserted in 12 patients, underwent immediate nonfunctional loading (INFL) (immediate restoration without occlusal contact) in different anatomical considerations, single tooth (Figures 2 and 3), small bridges in the anterior mandible (Figure 4), anterior maxilla, and posterior maxilla (Table 2). All 142 implants have been followed for at least 3 years (Table 3).

Surgical and Prosthetic Technique

All patients underwent the same surgical protocol. Antimicrobial prophylaxis was obtained with

TABLE 1 Immediately Functionally Loaded Implants							
	Number of Cases	Number of Implants	Number of Implant Failures	Implant Survival (%)	Number of Prosthetic Failures	Prosthetic Success (%)	
Edentulous mandible	9	50	0	100	0	100	
Edentulous maxilla	8	69	0	100	0	100	
Total	17	119	0	100	0	100	



Figure 3 A mobile deciduous tooth (case 1).



Figure 4 Preoperative periapical x-ray (case 2).



Figure 6 Postoperative periapical x-ray (case 1).



Figure 5 Implant inserted in the extraction site and temporary abutment (case 1).



Figure 7 Implants into extraction sites (case 2).

TABLE 2 Immediately Nonfunctionally Loaded Implants								
	Number of Cases	Number of Implants	Number of Implant Failures	Implant Survival (%)	Number of Prosthetic Failures	Prosthetic Success (%)		
Single	6	6	0	100	0	100		
Anterior mandible	3	10	0	100	0	100		
Anterior maxilla	1	3	0	100	0	100		
Posterior maxilla	2	4	0	100	0	100		
Total	12	23	0	100	0	100		

TABLE 3 Life Table Analysis								
		Months Loaded						
	0–6	7–12	13–18	19–24	25–30	31–36	37–42	43–48
IFL	119	119	119	119	119	119	119	100
INFL	23	23	23	23	23	23	23	17
IFL + INFL	142	142	142	142	142	142	142	117
Failures	0	0	0	0	0	0	0	0

IFL = immediate functional loading; INFL = immediate nonfunctional loading.



Figure 8 Postoperative periapical x-ray (case 2).



Figure 9 Immediate temporary restoration (case 1).



Figure 10 Temporary abutments (case 2).



Figure 11 Immediate temporary restoration (case 2).



Figure 12 Immediate temporary restoration (case 2).



Figure 13 Contacts in protrusion are avoided (case 2).

amoxycillin 500 mg twice daily for 5 days starting 1 hour before surgery. Local anesthesia was induced by infiltration with articaine/epinephrine, and postsurgical analgesic treatment was performed with Nimesulid[™] (Merck, Cinisello Balsamo, Milano, Italy) 100 mg twice daily for 3 days. Patients had a soft diet for 4 weeks and oral hygiene instructions were provided.

After a crestal incision, a mucoperiosteal flap was elevated and implants were inserted according to the procedures recommended by the manufacturer. The implant platform was positioned slightly above the alveolar crest (Figures 5-8). The temporary abutments were placed and the provisional restoration was relined with acrylic, trimmed, polished, and cemented or screw retained 1-2 hours later (Figures 9-12). The provisional bridges were always prefabricated and adapted to the abutments; the same procedure was used for both edentulous jaws and single-tooth replacement. In partially edentulous patients, occlusal contact was avoided in centric and lateral excursions (Figure 13). After provisional crown placement, a periapical radiograph was impressed by means of a customized Rinn® holder (Rinn, Elgin, IL, USA) device (see Figures 6 and 8). This device was necessary to maintain the x-ray cone as much perpendicular as possible to a film placed parallel to the long axis of the implant. Sutures were removed 14 days after surgery. After 18 weeks from implant insertion, the provisional crown was removed and a final impression of the abutment was recorded by using a polyvinylsiloxane impression material. The final restoration was always cemented and was delivered approximately 28 weeks after implant insertion (Figures 14-17). All patients were included in a strict hygiene recall.

RESULTS

All implants appeared to be osseointegrated from a clinical and radiographic point of view. No failures were observed in the IFL and INFL groups. The implant success was 100%.

The bone level measured from the reference point was 0.8 mm at 12 months (Figures 18 and 19) and 1.0 mm at 36 months (Figures 20 and 21).

DISCUSSION

The preliminary results of this study provide evidence of clinical success after 3 years of loading. All patients resumed function quickly.



Figure 14 Final abutment (case 1).

So far, no implants have failed and no complications have been reported or recorded. The clinical evaluation of the peri-implant soft tissues of the patients disclosed excellent conditions and healthy peri-implant mucosal conditions were maintained throughout the observation period.

The 1-year results of accumulated mean bone resorption in this study also compare favorably with other data reported in the literature on standard Brånemark fixtures and self-tapping Mk II fixtures over the same period of loading,^{21,22} although these two studies refer to implant healed in a traditional two-stage mode. Using TiUnite implants, Vanden Bogaerde and colleagues²³ reported a bone resorption of 0.8 mm at 18 months, Glauser and colleagues¹¹ reported a mean bone loss of 1.2 mm at 1 year, and Calandriello and colleagues²⁴ reported a bone loss of 1.0 mm at 6 months and 1.3 mm at 1 year. A tendency for more bone formation has been found around implants with thicker oxides.²⁵

The TiUnite surface was significantly superior to the machined surface in terms of removal torque values.²⁶



Figure 15 Final restoration (case 1).



Figure 16 Final abutments (case 2).

The reasons for the stronger bone reaction to oxidized implants compared to turned controls may be the thicker oxide as such, including concomitant increase in surface roughness and surface area enlargement.¹⁸ Sul and colleagues,13 comparing implants with an oxide thickness of 600-1000nm, found that test implants demonstrated a greater bone response than control implants, and the osteoconductivity was more pronounced around the test implants. The mean values of the removal torque increased with an increase of the oxide thickness. Our findings may relate to the microporous structure, roughness at the nanometer level, and/or the surface quality features of the implants. In fact, one may speculate that there was bone ingrowth into the porous structures of the implants since the pores have a diameter of $\leq 8 \text{ mm.}^{13}$ Alterations in the surface oxide of titanium implants greatly influence the bone tissue response.¹³

Very high cumulative success rates have been reported when using implants with this surface. Vanden Bogaerde and colleagues²³ reported a success rate of 99.1% at 18 months, Glauser and colleagues¹¹ reported



Figure 17 Final restoration (case 2).



Figure 18 Periapical x-ray 1 year after loading (case 1).

a success rate of 97.1% at 1 year, Calandriello and colleagues²⁴ reported a success rate of 100% at 6 months, and Rocci and colleagues²⁷ reported a success rate of 95.5% at 1 year. These same others observed, on the other hand, a success rate of machined implants at 1 year



Figure 19 Periapical x-ray 1 year after loading (case 2).

of 85.5%.²⁷ Also, Jungner and colleagues²⁸ observed a 100% success rate in TiUnite and a 96.4% success rate in turned implants.

To our knowledge, this is the first report of a longer follow up (3 years) of implants with a porous anodized surface.

Our 100% success rate can be, probably, explained by the use of a very strict protocol and by the fact that only implants with favorable conditions were included in the study (RFA >60 ISQ, IIT >25 Ncm).

In conclusion, our results point out that it is possible to obtain longer-term very good results with the use of an implant with a porous anodized surface^{29–35} also under immediate loading conditions.

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Figure 20 Periapical x-ray 3 years after loading (case 1).



Figure 21 Periapical x-ray 3 years after loading (case 2).

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