

# Direct Implant Loading in the Edentulous Maxilla Using a Bone Density–Adapted Surgical Protocol and Primary Implant Stability Criteria for Inclusion

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## ABSTRACT

*Background:* Long healing periods and submerged implant placement are commonly used in the maxilla. This extends the time of oral handicap and makes the use of immediate loading protocols an attractive option. The current clinical literature on direct loading of dental implants in the maxilla is limited.

*Purpose:* The purpose of this prospective clinical study was to evaluate the clinical outcome and stability of directly loaded Brånemark System® or Replace Select® Tapered implants (Nobel Biocare AB, Göteborg, Sweden) after using a modified surgical protocol and inclusion by primary implant stability. In addition, a reference group treated according to a two-stage protocol was used for comparison.

*Materials and Methods:* Twenty patients planned for prosthetic rehabilitation with implant-supported bridges in the edentulous maxilla participated in the study group. The final decision on immediate loading was made after implant placement using insertion torque and resonance frequency analysis (RFA) as acceptance criteria. All patients were included, and 123 oxidized implants (TiUnite™, Nobel Biocare AB) were placed using a surgical protocol for enhanced primary stability. A screw-retained temporary bridge was delivered within 12 hours and a final bridge within 3 months of implant placement. The patients were monitored through clinical and radiographic follow-up examinations from implant placement to at least 12 months. Marginal bone level was measured at bridge delivery and after 12 months of loading. Additional RFA measurements were made after 6 months of loading. A reference group comprising 20 patients with 120 implants treated according to a two-stage protocol was used for comparison.

*Results:* One (0.8%) of the 123 implants in the study group failed, and no implant was lost in the reference group. The cumulative survival rates after 12 months of loading were thus 99.2% and 100% for immediate and delayed loading protocols, respectively. The marginal bone resorption was 0.78 (SD 0.9) in the study group and 0.91 (SD 1.04) in the reference group. RFA showed a mean value of 62.9 (SD 4.9) implant stability quotient (ISQ) at placement and 64.5 (SD 4.8) ISQ after 6 months for immediately loaded implants (not significant). The corresponding figures for the reference groups were 61.3 (SD 8.8) ISQ and 62.6 (SD 7.0) ISQ (not significant). There were no statistically significant differences between the groups at any time point.

*Conclusion:* The use of six to seven implants for immediate loading of a fixed provisional bridge is a viable option for implant treatment of the edentulous maxilla, at least when good primary implant stability can be ensured.

**KEY WORDS:** dental implants, edentulous maxilla, immediate loading, insertion torque, primary stability, prospective study, resonance frequency analysis

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Current protocols for routine treatment of the edentulous maxilla using Brånemark System® (Nobel Biocare AB, Göteborg, Sweden) implants to support a fixed bridge still make use of submerged implant placement and long healing periods. For the patient seeking treatment, this means an extended period of oral hand-

icap owing to a suboptimal or absent denture. The use of immediate loading protocols is therefore an attractive option. Compared with a two-stage protocol, immediate function of dental implants not only means an instant reduction in the oral handicap, it also results in shorter treatment time and less service of the provisional constructions. Moreover, in cases of a failed bridge on tooth abutments, the use of a provisional denture is rendered unnecessary if the teeth and implants are placed in the same surgical session.

One-stage surgery and immediate/early implant loading are today regarded as a routine option for the totally edentulous mandible.<sup>1</sup> Numerous studies have reported outcomes similar to those of two-stage protocols,<sup>2–18</sup> and some risk factors for implant failure have been identified.<sup>19</sup> The good outcome may be due to the dense bone of the mandible and the ease in obtaining secure primary implant stability.<sup>20</sup> Optimal stabilization and resistance to bending forces obtained by placing implants in an arch form are other contributing factors.

The encouraging early experiences of immediate loading in the mandible and the development of new implant designs and surfaces have inspired researchers to further explore applications of immediate loading. Outcomes of immediate implant loading in the edentulous maxilla have previously been reported, although the number of documented cases is low in comparison with treatments of the edentulous mandible.<sup>21–29</sup> In pioneering studies with the Brånemark technique, 8 to 11 turned implants were placed, of which 6 to 10 were immediately loaded.<sup>21,22</sup> With this protocol, Tarnow and colleagues reported no losses of 14 immediately loaded implants in two patients<sup>21</sup> and Horiuchi and colleagues lost 2 of 36 (5.6%) implants in five patients.<sup>22</sup> In a 1-year study on immediate loading using turned implants, Glauser and colleagues lost 2 of 18 (11.1%) implants in the totally edentulous maxilla.<sup>23</sup> Olsson and colleagues treated 10 consecutive edentulous patients with oxidized titanium implants connected by a provisional bridge in the maxilla.<sup>25</sup> Nine patients received six implants each and one patient received eight implants. After 1 year of loading, four implants (6.6%) were lost owing to infection in one patient. The losses were not considered to be due to the immediate loading per se, and no implants were lost in the remaining nine patients. The authors suggested that the use of a surface-modified implant may have contributed to the successful outcome. In a recent randomized comparative study using SLA implants, Fischer and

Stenberg reported no implant losses during one year, either in a test group of 16 patients subjected to early loading or in a control group comprising 8 patients treated with delayed loading.<sup>28</sup> Interestingly, the authors found significantly less marginal bone resorption around the early-loaded implants.

The purpose of the present prospective clinical study was to evaluate the clinical outcome and stability of directly loaded oxidized titanium implants after a modified surgical protocol and inclusion by primary implant stability. In addition, a reference group treated according to a two-stage protocol was used for comparison.

## MATERIALS AND METHODS

### Study Group and Preliminary Inclusion Criteria

Twenty patients (10 female and 10 male; mean age 73 years, range 58–87 years) planned for treatment with implant-supported bridges in the edentulous maxilla participated in the study group. The presurgical evaluation included clinical and radiographic examinations. The patients were preliminarily selected from consecutive referrals and considered as candidates for immediate loading owing to (1) no general contraindications for oral surgery, (2) an implant site free from infection, and (3) the presence of residual bone sufficient to house six implants at least 10 mm long.

All patients were thoroughly informed about the procedure and gave written consent to inclusion in the study. All patients were healthy. Two patients were smokers.

### Surgery and Final Inclusion Criteria

All patients were informed that the final decision on whether to load was taken during surgery according to the following criteria: (1) a minimum insertion torque of 30 Ncm before final seating of the implant as measured with an Osseocare™ drill unit (Nobel Biocare AB) and (2) an implant stability quotient (ISQ) value above 60 for the two posterior fixtures and a total sum of 200 (mean ISQ 50) for the four anterior fixtures as measured with an Osstell™ instrument (Integration Diagnostics AB, Göteborg, Sweden).

Prophylactic antibiotic and sedative cover was provided by administration of 3 g of amoxicillin (Amimox®, Tika Läkemedel AB, Lund, Sweden) and diazepam (Stesolid®, Alparma, Stockholm, Sweden) (0.3 mg/kg body weight) orally 1 hour prior to surgery. Infiltration anesthesia with lidocaine (Xylocaine®-Adrenaline, AstraZeneca, Södertälje, Sweden) was used. The edentu-

lous crest was exposed through a midcrestal incision. After reflection of the flap, the optimal implant position was decided on both aesthetic and biomechanical considerations. A small fenestration was opened into the sinus to identify the anterior border of the sinus wall (Figures 1–3). Tilting the most posterior implants distally enabled placement in the most posterior position possible, reducing the need for cantilevers (Figure 4). Bone quality and quantity were determined according to Lekholm and Zarb's criteria (Table 1).<sup>30</sup> Implants were placed in undersized sites to enhance primary stability. The final drill size was determined as follows: In bone determined as quality 2 to 3, the final drill was 2.85 mm. In type 4 bone, a final drill of 2.85 mm and a Mk IV fixture or a Replace Select® Tapered implant with reduced drilling depth of final burr (Nobel Biocare AB) were preferred. Countersinking was limited to a shallow angle to engage as much of the crestal bone as possible. Resonance frequency analysis (RFA) measurements were performed using an Osstell™ instrument (Integration Diagnostics AB). In cases with remaining teeth, extraction was undertaken after patients were included on the basis

of insertion torque and RFA measurements of implants placed in healed sites (Figure 5). Abutments (MUA, Nobel Biocare AB) and sterile impression copings were connected to the implants. Both straight and angulated abutments were used depending on implant angulation's (Figure 6). The wound was closed with resorbable sutures prior to impression.

All 20 patients met the final inclusion criteria. One hundred twenty-three oxidized titanium implants (TiUnite™, Nobel Biocare AB) of various designs (Mk III, Mk IV, Select Tapered) were implanted (Table 2).

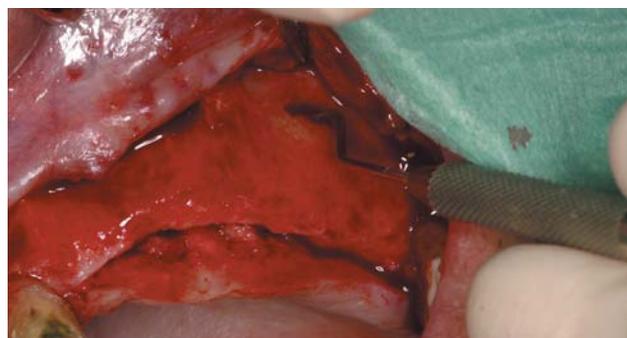
### Prosthetic Procedures

Immediately following the surgical session, a quick-setting, high-viscosity polyvinylsiloxane (Dimension™ Penta™ H Quick, 3M ESPE, St. Paul, MN, USA) impression was taken of the upper jaw using an open tray. Bite registration was performed (Figure 7), and an impression of the opposing jaw was taken. Healing caps were placed on the abutments.

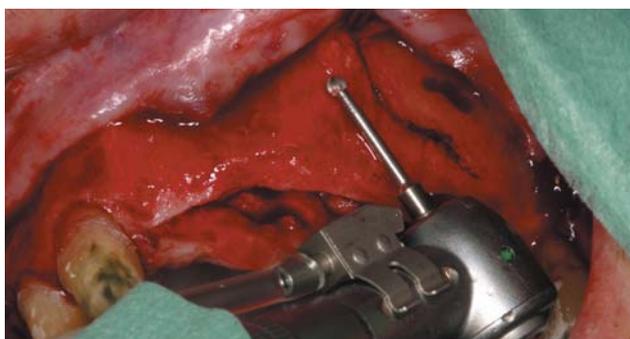
Provisional bridges with no cantilevers exceeding 5 mm were fabricated at a dental laboratory. The bridges



**Figure 1** Clinical view prior to surgical treatment. This patient had undergone extractions 6 months earlier. Three teeth were saved and used as abutments for a provisional bridge.



**Figure 2** A fenestration is made into the sinus to identify the position of the anterior sinus wall.



**Figure 3** The posterior fixture is tilted to maximize interimplant distance and reduce cantilever length.



**Figure 4** Inclination and position of the sites are carefully checked with direction indicators before final preparation and placement of fixtures.

**TABLE 1 Bone Quality and Quantity in the Test and Reference Groups**

	Direct: Test Group					Two Stage: Control Group				
	1	2	3	4	Total	1	2	3	4	Total
A	0	0	0	0	0	0	0	0	0	0
B	0	0	36 (1)*	12	48	0	6	30	36	72
C	0	6	26	24	56	0	0	27	0	27
D	0	13	0	6	19	0	12	9	0	21
Total	0	19	62	42	123	0	18	66	36	120

\*Number within parentheses indicates failure.

were delivered within 12 hours and placed in light occlusion (Figure 8). Careful adjustment of occlusion and articulation were performed to minimize lateral forces.

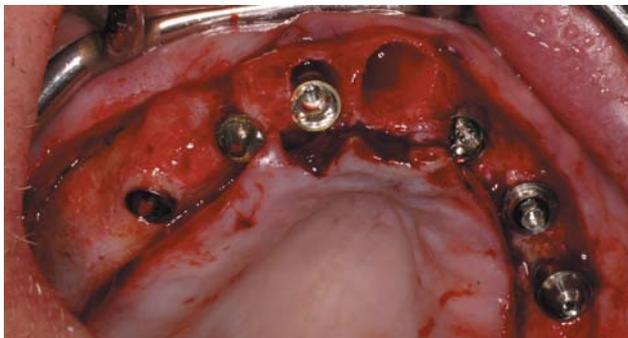
Three months after fixture installation, a new impression was taken for the manufacture of a permanent bridge (Figure 9). All but one were Procera® Implant Bridges with acrylic or porcelain teeth (Nobel Biocare AB) (Table 3 and Figure 10). Distal cantilevers were allowed. The occlusion was adjusted to minimize loading of the distal cantilevers. For surgical and prosthetic treatment, see Figures 1–10.

### Postoperative Measures

For 10 days after implant installation, the patients received 3 g of penicillin V (Kåvepenin, AstraZeneca), mouth rinsing with chlorhexidine 0.1% twice a day, and the recommendation to eat soft food.

### Follow-Up

All patients were enrolled in a strict and individually designed program focusing on maintaining oral hygiene and soft tissue health. The patients were



**Figure 5** An implant in the socket after extraction of the right lateral incisor. In this cases, measurements (cutting resistance and ISQ) are made on placed implants before extraction of the remaining teeth. If the inclusion criteria are not met, a two-stage procedure will be carried out and the teeth will be used for the provisional bridge during implant healing.

instructed and evaluated by a dental hygienist until the oral hygiene was sufficient. In addition, the stability of the provisional/permanent bridge was checked on these occasions. Measures were immediately taken if a bridge was found to be mobile, that is, tightening of gold screws and replacement in case of fractures.

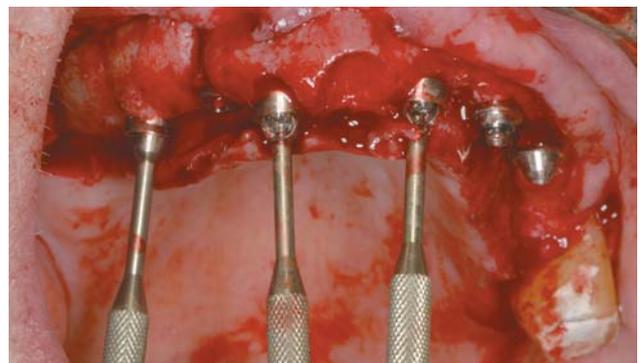
Clinical and radiographic follow-ups were performed by the treating dentist's team 3, 6, and 12 months after delivery of the provisional bridge and annually thereafter. Additional implant stability measurements were performed at the 6-month appointment.

### Marginal Bone Resorption

The marginal bone level around each implant was evaluated on periapical radiographs taken at delivery of the provisional bridge (baseline) and after 1 year in function. The distance from the implant/abutment junction to the marginal bone level was measured at the mesial and distal aspects of each implant by an independent radiologist.

### Survival Criteria and Withdrawn Patients

An implant was regarded as failed if it was removed for any reason. All stable implants without symptoms of pain or infection were regarded as survivors. No patients



**Figure 6** Angulated abutments mounted and directed for optimal angulation before flap closure.

**TABLE 2** Type and Length of Implants in the Test Group

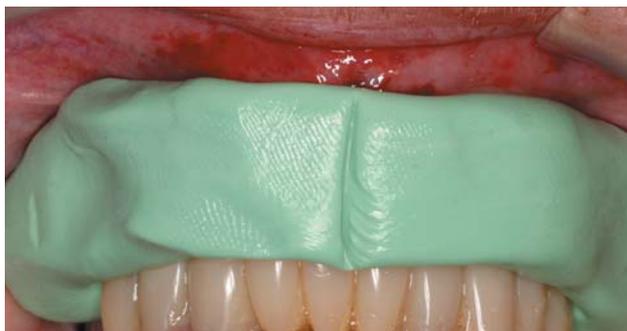
Fixture Type	Length, mm	Placed	Failed
Brånemark Mk IV	13	1	0
TiUnite	15	25	0
	18	22	0
Brånemark Mk III TiUnite	10	2	0
	11.5	3	0
	13	4	0
	15	21	0
	18	12	0
Replace Select Tapered	13	6	0
	16	27	1
Total		123	1

dropped out during the study; all attended the scheduled follow-up examinations.

**Reference Group**

A group of 20 patients (8 female and 12 male; mean age 64 years, range 50–80 years) previously treated with implant-supported bridges in the maxilla by the same team following a two-stage protocol were used as the reference group. The subjects represented consecutive treatments immediately prior to the treatment of the test group.

One hundred twenty implants (Nobel Biocare AB), 11 Mk IV implants with turned surfaces and 109 Mk III with oxidized surfaces (TiUnite), had been placed in the reference group (Table 4). A healing period of 6 months had been used between implant placement and abutment connection. All patients received a fixed bridge (Table 5) within 4 to 6 weeks after abutment connection surgery.



**Figure 7** Bite registration with a putty index.



**Figure 8** A temporary bridge is delivered 6 to 12 hours after surgery. No cantilevers exceeding 5 mm are accepted. Occlusion and articulation are carefully checked to minimize lateral forces and overload.

**Statistics**

The Mann-Whitney *U* test was used to verify possible differences between the groups. A difference was considered if *p* < .05.

**RESULTS**

**Clinical Observations**

Few complications were observed during the follow-up. Two patients in the direct loading group experienced fracture of the provisional bridge, one owing to bruxism and one owing to trauma. The bridges were repaired and could be used until replacement with a permanent bridge. A third patient in the test group showed extensive gingivitis and candidiasis, which was treated with antimycotics and oral hygiene measures.

**Implant Survival**

One (0.8%) of the 123 implants placed did not integrate and was subsequently removed. In the control group, no implants were lost. The overall cumulative survival rates after 1 year were 99.2% for the study group and 100% for the reference group. No further



**Figure 9** Situation after 3 months of loading. The soft tissue is mature, and an impression for the final bridge is taken.

**TABLE 3 Bridge Types Used as Final Construction in the Test Group**

Construction Type	<i>n</i>
Carbon fiber/acrylic	1
Procera Implant Bridge/acrylic	8
Procera Implant Bridge/porcelain	11
Total	20

implant failures were experienced beyond the first annual examination (Table 6).

### Marginal Bone Resorption

For immediately loaded implants, the marginal bone level was situated 0.54 mm (SD 0.85 mm) below the reference point at baseline and 1.30 mm (SD 1.06 mm) after 1 year of loading. The corresponding figures for the reference group implants were 0.59 mm (SD 0.82 mm) and 1.46 mm (SD 1.07 mm) at baseline and after 1 year, respectively. The mean change of marginal bone level was 0.78 mm (SD 0.90 mm) for immediately loaded implants and 0.91 mm (SD 1.04 mm) for reference group implants (Table 7). The differences were not statistically significantly different.

### Resonance Frequency Analysis

RFA showed a mean value of 62.9 ISQ (SD 4.9) at placement. Measurements at the 6-month follow-up showed a mean value of 64.5 ISQ (SD 4.8). For the control group, the mean values were 61.3 (SD 8.8) at placement and 62.6 (SD 7.0) at the 6-month follow up (Table 8). There were no statistically significant differences between time points or groups.

## DISCUSSION

This prospective study of 20 patients treated with immediate loading in the totally edentulous maxilla



**Figure 10** The final Procera Implant Bridge with porcelain veneering.

**TABLE 4 Type and Length of Implants in the Reference Group**

Fixture Type	Length, mm	Placed	Failed
Brånemark Mk IV turned	13	1	0
	15	7	0
	18	3	0
Brånemark Mk III TiUnite	10	2	0
	11.5	2	0
	13	13	0
	15	62	0
	18	30	0
Total		120	0

was successful because only 1 of 123 implants was lost after 1 year of loading. As a result, all patients received and maintained a fixed permanent bridge throughout the study period. Similar results were observed in the reference group treated by a two-stage procedure, although no implants were lost. Measurements of marginal bone levels showed no statistically significant differences between the groups.

From a strict scientific point of view, a randomized study design would have been preferred with patients allotted for immediate loading or a two-stage protocol.<sup>31</sup> The reason for not using randomization was our good experience with immediate implant loading in other regions<sup>32</sup> and with pilot cases in the maxilla. Moreover, the literature on immediate loading mostly indicated similar prosthesis survival rates, although more implants may be lost in some situations.<sup>19,33</sup> From the patient's perspective, it was therefore considered wrong to extend the treatment period unnecessarily. As a compromise, a historical reference group treated by the same team using a two-stage protocol was used for comparison, especially with regard to marginal bone resorption and implant stability. Only a few randomized studies on immediate/early implant loading can be found in the lit-

**TABLE 5 Type of Prosthetic Construction in the Reference Group**

Type of Construction	<i>n</i>
Carbon fiber /acrylic	0
Procera Implant Bridge/acrylic	4
Procera Implant Bridge/porcelain	16
Total	20

**TABLE 6 Life Table for Survival Rates of Directly Loaded and Two-Stage Implants**

Time Period	Direct Loading			Two Stage		
	Implants	Failed	CSR, %	Implants	Failed	CSR, %
Placement >> 1 yr	123	1	99.6	120	0	100
1 yr >> 2 yr	198	0	99.6	114	0	100
2 >> 3 yr	83	0	99.6	72	0	100
> 3 yr	36	0	—	36	—	—

CSR = cumulative survival rate.

**TABLE 7 Results from Measurements of Marginal Bone Levels at Directly Loaded and Two-Stage Implants**

	Direct Loading			Two Stage		
	Mesial	Distal	(m + d) <sup>2</sup>	Mesial	Distal	(m + d) <sup>2</sup>
Number	114	115	115	108	111	111
Mean value, mm	0.73	0.84	0.78	0.95	0.86	0.91
SD	1.01	1.01	0.90	1.14	1.21	1.04

**TABLE 8 Results from Resonance Frequency Analysis Measurements at Placement and after 6 Months of Loading for Directly Loaded and Two-Stage Implants**

Time Period	Direct Loading		Two Stage	
	Fixture Insertion	Follow-Up 6 mo	Fixture Insertion	Follow-Up 6 mo
Average	62.9 (SD 4.9)	64.5 (SD 4.8)	61.3 (SD 8.8)	62.6 (SD 7.0)
Range	51–77	54–76	37–98	46–79

erature,<sup>34</sup> and, to our knowledge, only one such study in the maxilla has been published.<sup>28</sup> In that study, no implant losses were experienced during 1 year in the test group of 16 patients or in the control group of 8 patients.

One factor contributing to the good results is probably the effort given to achieving high primary implant stability by using thinner drills and/or tapered implant designs. This surgical protocol was previously evaluated in a study in which the primary stability of 905 Brånemark implants was measured with RFA.<sup>20</sup> The influence on the primary stability of factors related to the patient, implant, and surgical technique was statistically analyzed. It was concluded that good primary stability could be achieved in all jaw regions, and if a lower ISQ limit of 60 was used for immediate loading, 85% of the implants could have been considered for immediate loading. In the present study, an ISQ of 60 was required for the distal implants and a sum of ISQ 200 was required for the four anterior implants. The rationale

was an assumption that distal implants will be subjected to higher loads owing to increased posterior bite forces, the effect of distal cantilevers, and improved load sharing between anterior implants.

Another factor contributing to the good results may be the immediate splinting (in 90% of the cases within 6 hours) with the temporary bridge. By splinting, the implants work as a group rather than as single units, thereby compensating for lateral forces and eliminating the risk that the patient grinds only on the most superior implant.

Cases not meeting the primary implant stability inclusion criteria of the present study can also be treated with immediately loaded provisional bridges.<sup>35–37</sup> This research group has recently published a study on the use of provisional implants (PIs) as an alternative to immediate loading of permanent implants.<sup>37</sup> With this technique, small and as many 2.7 mm-wide implants as possible are placed between the permanent implants.

After closure of the flap, a provisional bridge is cemented to the PIs. That study reported that 7 of 192 PIs were removed and that 44 of 45 provisional bridges could be maintained from implant placement to abutment connection surgery. The results agree with the experiences of other researchers<sup>35,36</sup> and show that the use of PIs is a viable option for immediate loading.

A submerged healing period of 3 to 6 months was originally considered a prerequisite for achieving osseointegration of titanium implants.<sup>38</sup> Experimental studies and histology of clinically retrieved implants have shown a similar and sometimes better bone-implant contact for immediately loaded implants.<sup>39–44</sup> In the present study, a tendency toward a steeper increase and higher secondary stability were seen for the immediately loaded implants in comparison with the two-stage procedure 6 months after implant placement. The results indicate favorable remodeling under the influence of loading. Moreover, the statistically verified difference in marginal bone resorption observed by Fischer and Stenberg<sup>28</sup> and the tendency in the present study further support the idea of a stimulatory effect of loading. It is well known from orthopedic surgery that physiologic loading is a precondition for sufficient healing of fractures and maintenance of the biomechanical properties of bone. Frost postulated that both too modest and excessive loading could result in negative tissue reactions.<sup>45</sup> Thus, it seems that six implants in the maxilla with controlled loading of a provisional bridge result in stresses within physiologic limits.

All of the implants used for immediate loading had a modified surface. The anodic oxidation process used results in growth of the native oxide layer and a porous structure.<sup>46</sup> Animal experiments and histology of clinically retrieved implants have demonstrated rapid establishment of a firm direct bone-implant contact.<sup>44,47,48</sup> It seems that bone integration can occur through so-called contact osteogenesis, implying bone formation directly on the implant surface. Stability measurements have demonstrated higher resistance to torque forces than with turned titanium implants.<sup>49</sup> Moreover, RFA measurements of immediately loaded implants in the posterior maxilla have shown higher stability during functional loading for oxidized implants than for those with a turned surface.<sup>50</sup> It is therefore possible that the surface properties played a role in the clinical outcome of the present study. According to a literature review by Esposito and colleagues, a failure rate of about 7.7%

may be expected on all indications over a 5-year period, excluding grafting cases, when using turned titanium implants and two-stage protocols.<sup>51</sup> For treatment of the edentulous maxilla with fixed bridges, recent studies have presented 1-year failure rates of 5 to 6%.<sup>52,53</sup> The overall failure rate in the 20 patients of the present study was only 0.4% after 1 year, which may indicate better performance of the surface-modified implants. However, randomized clinical studies comparing turned implants with TiO<sub>2</sub>-blasted and titanium plasma-sprayed surfaces revealed no statistically significant differences with regard to survival rate when used in two-stage protocols.<sup>54,55</sup> Other factors, such as learning curve, the use of new implant geometries, and clinical techniques, may be equally important.

From the author's point of view, when changing protocol from a 2-stage to immediate-function procedure, the surgery methods can no longer be standardized. By consequently measuring insertion torque and RFA, the surgeon will, from increased experience, choose a combination of final drill and implant depending on bone quality, leading to a better primary stability and ISQ value.

It is concluded that six to seven implants can be used for immediate loading of a fixed provisional bridge in the edentulous maxilla, at least when good primary implant stability can be ensured.

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