# Digitally Planned, Immediately Loaded Dental Implants with Prefabricated Prostheses in the Reconstruction of Edentulous Maxillae: A 1-Year Prospective, Multicenter Study

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## ABSTRACT

*Background:* The introduction of digital planning programs has made it possible to place dental implants in preplanned positions and being immediately functionally loaded by using prefabricated prostheses.

*Purpose:* The aim of this multicenter study was to describe the 1-year results of digitally planned, immediately loaded edentulous maxillae.

*Materials and Methods:* A total of 312 implants (Brånemark System®, TiUnite RP, Nobel Biocare, Göteborg, Sweden) in 52 patients from eight Scandinavian clinics were digitally planned, surgically as well as prosthetically, by using the NobelGuide® (Nobel Biocare AB, Göteborg, Sweden) and received prefabricated, immediately loaded fixed prosthetic constructions in the maxillae. Individual implant stability was manually tested at 1-year follow-up.

*Results:* All patients received a Procera Implant Bridge® (Nobel Biocare AB); however, in two cases, the bridges were reconstructed due to misfit. In five patients, difficulties in getting the surgical guide completely in position, and in five patients, getting the prostheses completely seated, were noted.

All but four patients fulfilled the 1-year follow-up. Two implants were lost during the study period, resulting in a cumulative survival rate of 99.4%. The mean marginal bone resorption from implant placement to the 1-year follow-up was 1.3 mm (SD 1.28). More than 2 mm of marginal resorption was noted in 19% of the implants at this instant. The most frequently reported complications during the first year were gingival hyperplasia and prosthesis-related problems (prosthesis screw loosening, occlusal fractures, and occlusal adjustments).

*Conclusion:* The 1-year results in this multicenter are promising regarding implant and bridge stability; however, the study is planned to be running for at least 3 years.

KEY WORDS: dental implants, digital planning, edentulous maxillae, immediate loading, prefabricated bridge, surgical guide

## INTRODUCTION

Rehabilitation of totally maxillary edentulous patients following the Brånemark[1,2] concept is well accepted and documented. Brånemark and colleagues[3,4] recommended two-stage surgical techniques and healing periods of 3 to 6 months, depending on the actual implant stability due to bone quality and bone quantity.

Recent research has focused on finding simpler and faster treatment techniques while still maintaining the excellent results of previous methods. Shorter healing periods, 6 to 12 weeks, after the installation of the implants, before loading are now recommended.[5]

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**TABLE 1 Distribution of Implants in Relation to Jaw Position**

| 18 | 17 | 16 | 15 | 14 | 13 | 12 | 11 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| — | — | 2 | 46 | 6 | 50 | 6 | 47 | 46 (1) | 7 | 46 | 7 (1) | 47 | 1 | 1 | — | 312 |

Distribution of implants: 35% are placed in the posterior upper jaw; 65% are placed in the anterior upper jaw; 90% are placed in positions 15, 13, 11, 21, 23, and 25.
Number of implants with implant failures within brackets.

Several studies, although not prospective or randomized, have been published regarding immediate loading (<24 hours) in selected cases; these take special account of bone quality and quantity, and controlled occlusal loads.[6–8] The introduction of a digital, surgical planning method based on a computed tomography (CT) scan made it possible to place implants in preplanned positions.[9] The assessment of this new technique, presented as Teeth-in-an-Hour® (TiaH) (Nobel Biocare AB, Göteborg, Sweden), requires multicenter studies because it involves (1) CT scan; (2) flapless surgery; (3) the installation of implants via a template and therefore (4) a modified way of cooling during drilling; (5) a new abutment design; and (6) preformed dental constructions being immediately loaded.[6,7,9] A 1-year follow-up study on 26 patients showing good results regarding implant stability and patients' satisfaction was presented by van Steenberghe and colleagues.[10]

The purpose of this investigation was to present the 1-year results of TiaH when using the technique in a Scandinavian, prospective, multicenter study approach on totally edentulous maxillae.

A hypothesis was formulated that patients treated according to the TiaH concept should experience similar implant and prosthesis survival and marginal bone reactions after 1 year as compared with patients treated according to the original two-stage protocol with healing periods before loading of 6 months.

## MATERIALS AND METHODS

This prospective multicenter study comprised eight clinics in Scandinavia, which were either university hospital clinics, private, or local health authority clinics, all specializing in dental implant treatments. No clinic had any previous experience of the actual method; all had, however, attended a 1-day theoretical course that included training in placing implants using a three-dimensional computer program. A total of 52 patients were included between August 2004 and January 2006.

Criteria for inclusion were a history of maxillary edentulousness of at least 1 year, healthy subjects (ASA 1–2),[11] the absence of medication likely to influence bone metabolism and maxillary bone disease, a neutral horizontal jaw relation, and maxillary alveolar bone capable of harboring six implants of at least 10 mm in length.

The female to male ratio was 2 : 3, and the mean age was 72 years (range 37–85). Forty-five of the patients (87%) reported themselves to be nonsmokers at the start of the treatment, and 48 patients (92%) were classified as nonbruxists.

The patients were informed of the study protocol and written consent was obtained in all cases. Clinical evaluation occurred after 2 weeks, 1 month, 3 months, 6 months, and 1 year and will be performed after 2 and 3 years of function. At these instances, the following was registered: the habit of bruxism, affected marginal soft tissue, local pain, the patients' subjective and objective opinions of the treatment, and the willingness of the patients to recommend the treatment to others.

Altogether, 312 implants were placed. The positions are shown in Table 1. Alveolar bone quality and quantity, as defined by Lekholm and Zarb,[12] are detailed in Table 2. The specific types of implants, length, and diameter of implants and length of abutments are shown in Table 3. The surgical and prosthetic

**TABLE 2 Distribution of Patients with Regard to Bone Quality and Bone Quantity according to Lekholm and Zarb,[12] at Implant Placement**

| | 1 | 2 | 3 | 4 | 5 | Total |
|---|---|---|---|---|---|---|
| A | 12 | 4 | 81 (1) | 29 | — | 126 (1) |
| B | — | 42 (1) | 65 | 27 | — | 134 (1) |
| C | — | 2 | 12 | 33 | 2 | 49 |
| D | — | 1 | — | 1 | 1 | 3 |
| Total | 12 | 49 (1) | 158 (1) | 90 | 3 | 312 (2) |

Number of implants with implant failures within brackets.

**TABLE 3 Number of Placed Implants and Abutments**

| | | Maxilla |
|---|---|---|
| MkIII TiUnite 3.75 | 10 mm | 7 |
| | 11.5 mm | 8 |
| | 13 mm | 57 (1) |
| | 15 mm | 147 (1) |
| MkIII TiUnite 4.0 | 10 mm | 3 |
| | 11.5 mm | 2 |
| | 13 mm | 13 |
| | 15 mm | 75 |
| Total | | 312 |
| Abutment, 3.7-mm long | | 234 (2) |
| Abutment, 5.0-mm long | | 78 |
| Total | | 312 |

Number of implants with implant failures within brackets.

procedures have previously been described by van Steenberghe and colleagues[9] in 2005. In short, the maxilla and an optimized maxillary denture were scanned by CT, the two scans were digitally combined within the planning program (NobelGuide®, Nobel Biocare AB); implants were digitally placed; and a surgical template was fabricated. A fixed construction in titanium/acrylic (Procera Implant Bridge®, Nobel Biocare AB) was made prior to surgery. At surgery, the implants were placed using the template for guidance in the exact preplanned positions, making it possible for the prosthodontist to attach the construction immediately. It was connected to the implants via newly designed expandable abutments. The patients were instructed to eat only soft foods for 2 to 3 weeks after surgery and were routinely monitored as stated previously. Phenoxymethyl penicillin was prescribed perioperatively and continued for 10 days postoperatively. Analgesics containing paracetamol or nonsteroid anti-inflammatory drugs were prescribed for the immediate postoperative period.

Radiologic evaluation, using a parallel intraoral technique, was performed immediately after bridge installation, after 1 year, and will be performed at 3-year follow-up. The marginal bone level, calculated as the mean of measurements mesial and distal to each implant, was evaluated by an independent radiologist.[13] The reference point chosen for the reading was the implant/abutment junction, and this was recorded as 0. Two hundred thirty-seven implants were radiologically evaluated at 1-year follow-up. Seventy-five implants were by the radiologist regarded as technically inadequate or did not show the exact threads of the actual implant mesially and distally and were therefore regarded as not readable and excluded.

Individual implant stability was manually tested after the removal of the supra-constructions at 1-year follow-up and will also be performed after 3 years. The methods of evaluation in this study will fulfill the standards stated by Albrektsson and Zarb.[14]

## RESULTS

Forty-eight patients have passed the 1-year checkup. One patient failed to fulfill the follow-up for medical reasons, and one patient was withdrawn due to disappointment of the aesthetic outcome of the prosthesis. Two patients were excluded during the first year because the treating clinic decided not to participate in the study. Two implants have been found unstable and have subsequently been removed, thus making 99.4% of the installed implants stable after the first year. The present status of the follow-up is shown in Table 4.

Fifty patients received the preformed, fixed dental construction immediately after the placement of the implants. In two cases, however, it was not possible to get

**TABLE 4 Life Table Showing the Cumulative Survival Rate for Implants and Prostheses**

| Time Period | Implants | Failed | WD | Missing | CSR % | Prostheses | Failed | WD | Missing | CSR % |
|---|---|---|---|---|---|---|---|---|---|---|
| Loading to 2 weeks | 312 | — | — | — | 100.0 | 52 | 2 | — | — | 96.2 |
| 2 weeks to 1 month | 312 | — | — | — | 100.0 | 52 | — | — | — | 96.2 |
| 1–3 months | 312 | 1 | — | — | 99.7 | 52 | — | 3 | — | 96.2 |
| 3–6 months | 311 | — | — | — | 99.7 | 52 | — | — | — | 96.2 |
| 6 months to 1 year | 311 | 1 | 6 | 18 | 99.4 | 51 | — | — | 1 | 96.2 |

Two prosthetic constructions, initially in place, were for technical reasons later remade.
CSR = cumulative survival rate; WD = withdrawn.

**TABLE 5 Unexpected Events/Complications**

| | At Implant Insertion | At Prosthesis Connection |
|---|---|---|
| Occlusal index | 3 | — |
| Surgical guide | 2 | — |
| Surgically related | 4 | 6 |
| Abutment connection | — | 7 |
| Bridge connection | — | 5 |
| Open bite/occlusal adjustments | — | 3 |

The registrations were made on patient level, registered on 18 patients of a total of 52 patients.

the constructions completely in place due to misfit, and one construction was therefore remade, and in one case, the construction was temporarily seated on four implants and later sectioned and laser welded to achieve a proper fit to all the implants.

Surgical problems were mainly related to misfit of the surgical silicone index in three patients or the surgical guide in two patients. Difficulties in the proper placement of the implants were also noted. Problems while installing the implants were found in four patients. The newly designed abutments were also, in some cases, difficult to be in exact positions. At the prosthesis connection, problems in 10 patients were related to getting the construction in the exact position, and in three patients, major occlusal corrections were necessary (Table 5). Because of the difficulties in maintaining adequate oral hygiene, one prosthesis was remade using standard abutments to achieve better hygienic conditions.

Absence of postoperative pain was recorded in more than 90% of the patients during the 2-week postoperative interval, and in general, only minor surgical-related problems, that is, swelling and minimal bleeding, were recorded.

Marginal alveolar bone resorption after 1 year was seen with a mean of 1.3 mm (SD 1.28). More than 2 mm of resorption was noted in 19% of the implants (Table 6). A plot diagram shows more clearly the distribution of the measurements (Figure 1).

Inflamed mucosa was noted at 66 sites (23%), and local pain was noted at 10 sites (3%) at the 1-year checkup.

**TABLE 6 Mean Marginal Bone Loss in Relation to Implant/Abutment Junction from Implant Insertion to 1-Year Follow-Up; Values Are Calculated as Mean of Mesial/Distal Values**

| | Mesial | Distal | All |
|---|---|---|---|
| Number* | 235 | 237 | 237 |
| Mean value (mm) | −1.28 | −1.33 | −1.30 |
| SD | 1.36 | 1.35 | 1.28 |
| | *n* | *n* | *n* | % |
| 2.1–3.0 (mm) | 1 | — | — | — |
| 1.1–2.0 (mm) | 1 | 2 | 1 | <1 |
| 0.1–1.0 (mm) | 8 | 6 | 8 | 3 |
| 0 (mm) | 53 | 48 | 37 | 16 |
| −1.0–0.1 (mm) | 33 | 47 | 60 | 25 |
| −2.0–1.1 (mm) | 99 | 83 | 85 | 36 |
| −3.0–2.1 (mm) | 21 | 32 | 28 | 12 |
| −4.0–3.1 (mm) | 11 | 7 | 10 | 4 |
| <−4.0 (mm) | 8 | 9 | 8 | 3 |

*Including X-rays taken at the 1-month visit of three patients (18 implants).

## DISCUSSION

The treatment of edentulous maxillae with fixed implant-supported constructions is predictable and well documented with good long-term results using healing periods of 6 months before loading, with either one-stage or two-stage procedures.[2,15] The clinical trend of today is toward simpler and faster treatments; however, the documentation before the implementation of new methods is often scarce and inadequate. The present technique seems promising: digital planning; implant

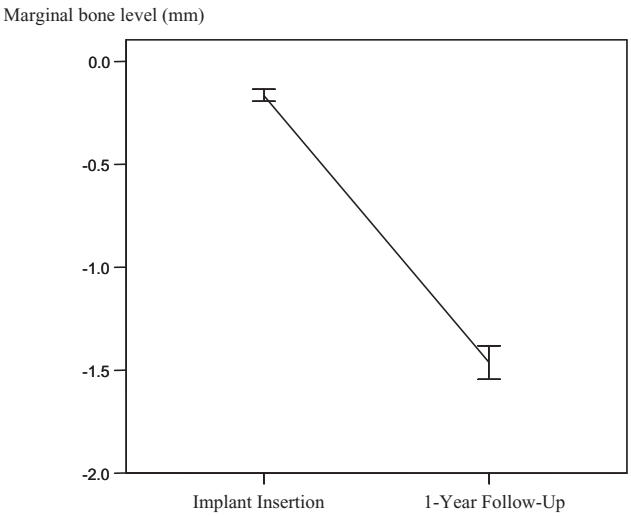


**Figure 1** All implants with registered visits at both implant insertion and 1-year follow-up ($n = 237$) are included. Marginal bone level presented as mean of distal and mesial values ± SEM.

installation guided by an optimized denture; and simpler surgery resulting in less postoperative morbidity, giving the possibility for immediate loading and function. Experimentally, it has been shown that digitally navigated drilling guide is a precise and predictable procedure.[16] Some reports regarding the actual method have been published; however, these have not given adequate information.[6,8,10]

The present multicenter study design was prospective, however, not controlled, randomized, or blinded and did, therefore, not gain the level of gold standard.[17] This study followed a standardized protocol, surgically as well as prosthetically, in the effort to register local as well as general factors that might influence the results.

The study included three countries, private as well as hospital clinics, and has a limited number of dropouts. As the 1-year results are presented, it is evident that at least 3 years of study period will be necessary. So far, only one other study has been published regarding early loaded maxillary fully edentulous patients.[18] The use of CT-derived planning is indeed an improvement as an optimized denture is used during planning, making it possible for prosthetically ideal positions. From both an aesthetic as well as loading point of view, implants were installed in the optimal jaw positions 1,3,5 in 90% of the total installations (see Table 1).

Flapless surgery reduces postoperative sequelae (ie, pain, swelling); however, the risk of soft tissue contamination due to punch surgery and the risk of overheating the alveolar bone due to reduced cooling while drilling must be noted. The influence on the marginal bone by the newly designed, expandable snap-on abutments is also to be evaluated.

The 1-year results demonstrated somewhat higher marginal resorption when compared with other authors who used the earlier standard and well-documented flap surgery.[17,19,20] In a recent study, direct loading has been compared with the two-stage surgery, using standard flap surgery without finding any significant differences regarding implant stability, mean marginal bone levels, or implant stability.[7] The frequency of measurements of more than 2 mm of marginal resorption is higher in this material, 19% compared with the above mentioned papers, where not more than 5% was shown after 1 year of function in a material of grafted and nongrafted edentulous maxillae.[19,20] Using this actual technique, Malo and colleagues[21] reported 1.9-mm mean marginal bone loss after 1 year, but more than 27% of observations showed more than 2 mm of bone loss. Their material is, however, limited in size and does not clearly separate the observations in the maxilla from the mandible. It must, however, be noted that the dropout of radiologically measured implants in this study is high; 75 implants of a total of 312 were not regarded as readable. It seems, therefore, that the flapless, template-derived technique is a new treatment that needs to be further focused on regarding marginal bone reactions. Implant stability was noted in all but two implants reported, giving a survival rate of more than 99%.

All but two patients received a fixed bridge, still in function after 1 year; the success rate in this aspect was 96%. Implant stability in the present study is in accordance with other reports[6,8,10,21] irrespective of the methods used.

Being new and yet not a fully evaluated treatment, the specific clinical procedures of "TiaH" are comment worthy. Unexpected events during the placement of implants were either related to instability of the surgical guide (two cases) or difficulties in positioning the silicone bite index (three cases). There might be several explanations to these technical problems: the fabrication and storage of the surgical guide, difference in the compression and the thickness of the mucosa, variation of the applied forces to the radiologic and surgical guide, and the application of the anesthetic solutions.

The prosthetic unexpected events were mainly oriented to problems at the level of implant/abutment connection. This was reported in 12 cases, most often when the mucosa was thick. Excessive occlusal adjustments were needed in three cases, probably because of the above-stated clinical and laboratory problems, of which some have not previously been reported.

## CONCLUSIONS

TiaH is a new and challenging technique that involves several new treatment procedures, each to be fully evaluated. This study involved 52 patients treated in eight clinics, all of whom received a stable, full-arch prosthetic bridge based on preoperative CT scan. In two cases, the bridges could not be immediately connected to the implants in an acceptable way and had to be reconstructed.

At 1-year follow-up, bridge stability was verified, but a high frequency of marginal bone resorption over 2 mm was noted. The initially formulated hypothesis

cannot, however, be fully accepted yet; implant and bridge stability showed similarly good results compared with more traditionally treated patients, but further studies regarding the marginal bone reactions are needed. All patients will be followed with the present study design for at least 3 years.

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## ETHICAL APPROVAL

This study is approved by the Regionala Etikprövningsnämnden in Stockholm, Sweden (Registration number 2005/373-31). No binding economic liaisons exist between the authors and the company, Nobel Biocare, Göteborg, Sweden.

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