A Computed Tomographic Scan–Derived Customized Surgical Template and Fixed Prosthesis for Flapless Surgery and Immediate Loading of Implants in Fully Edentulous Maxillae: A Prospective Multicenter Study

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ABSTRACT

Background: Based on three-dimensional implant planning software for computed tomographic (CT) scan data, customized surgical templates and final dental prostheses could be designed to ensure high precision transfer of the implant treatment planning to the operative field and an immediate rigid splinting of the installed implants, respectively.

Purpose: The aim of the present study was to (1) evaluate a concept including a treatment planning procedure based on CT scan images and a prefabricated fixed prosthetic reconstruction for immediate function in upper jaws using a flapless surgical technique and (2) validate the universality of this concept in a prospective multicenter clinical study.

Materials and Methods: Twenty-seven consecutive patients with edentulous maxillae were included. Treatments were performed according to the Teeth-in-an-Hour™ concept (Nobel Biocare AB, Göteborg, Sweden), which includes a CT scan–derived customized surgical template for flapless surgery and a prefabricated prosthetic suprastructure.

Results: All patients received their final prosthetic restoration immediately after implant placement, that is, both the surgery and the prosthesis insertion were completed within approximately 1 hour. In the 24 patients followed for 1 year, all prostheses and individual implants were recorded as stable.

Conclusion: The present prospective multicenter study indicates that the prefabrication, on the basis of models derived from three-dimensional oral implant planning software, of both surgical templates for flapless surgery and dental prostheses for immediate loading is a very reliable treatment option. It is evident that the same approach could be used for staged surgery and in partial edentulism.

KEY WORDS: Brånemark System®, dental implants, drilling templates, guided surgery, prospective clinical study, TiUnite™

Although the classic osseointegration protocol,[1] which prescribed a period of unloaded healing of the endosseous implant, gives excellent long-term results when proper implant geometry and a proper surface are used,[2] there are indications for early or even immediate loading of implants. It has been proposed that the term *immediate loading* should be reserved for oral implants that are subject to a full occlusal load within a few days, whereas *early loading* means after 1 to 2 weeks.[3] All occlusal loading after more than 2 weeks, even if the implant has been protruding intraorally, should be coined *delayed loading*. These categories can be related to biomechanical and histologic differences.[4]

There are an increasing number of properly analyzed clinical reports, in addition to some anecdotal case reports, indicating that implants in edentulous patients

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that are loaded immediately can provide acceptable success rates.[5–9] These authors concluded that implants rigidly connected over the midline offer a survival rate comparable to that of implants loaded after a healing period of months.[6] The few articles often deal with the symphyseal area because the latter offers the best biomechanical properties for good primary implant stability.

Thus, immediate splinting of freshly installed implants to spread chewing forces evenly may lead to a better outcome. Splinting could be achieved by providing a final fixed prosthesis at the time of implant insertion. Based on a three-dimensional implant planning software for computed tomographic (CT) scan data,[10] customized surgical templates and final dental prostheses could be designed to ensure a high precision transfer of the treatment planning to the operative field and an immediate rigid splinting of the installed implants, respectively.[3] The first report using this concept concerned the results on eight patients only, in whom the used surgical templates were seated on the jawbone after a flap was raised. Reassured by the good results, this concept was further developed to include flapless surgery, in which the surgical template is placed on the gingiva. A preliminary report on this less invasive approach indicated excellent short-term results.[11]

The aim of the present study was to (1) evaluate a concept including a treatment planning procedure based on CT scan images and a prefabricated fixed prosthetic reconstruction for immediate function in upper jaws using a flapless surgical technique and (2) validate the universality of this concept in a prospective multicenter clinical study.

MATERIALS AND METHODS

Centers and Patients

Twenty-seven patients were included in this prospective study. The three participating clinical centers, two university based, are located in Belgium, Sweden, and Switzerland. The last two centers started with treating one patient each, who acted as a pilot case, before the inclusion of their patients in the present study. The purpose was to allow them to familiarize themselves with the concept.

The patients ranged in age from 34 to 89 years, with a mean age of 63 years. Five patients were smokers (with 3 patients smoking more than 10 cigarettes per day), and 22 patients were nonsmokers. Most of the patients had been edentulous for more than 5 years (n = 14), 5 patients for 1 to 5 years, and 7 for less than 1 year. To be included, a patient had to be in such a physical and mental condition that the 1-year follow-up could be expected to be carried out without problems. The subject had to be fully edentulous in the maxilla and have sufficient bone volume to harbor at least six implants of at least 10 mm in length. The intermaxillary relation had to be neutral. Exclusion criteria were limited but involved previous cancerous tumors, irradiation in the head and neck area, chronic bone disease, bone grafting, and extraction sockets in the area to be treated.

All patients completed an informed consent form, and the study had the approval of the local ethics committee at each of the participating centers.

Treatment Concept Procedure

Treatments were performed according to the Teeth-in-an-Hour™ concept (Nobel Biocare AB, Göteborg, Sweden), which includes a CT scan–derived customized surgical template for flapless surgery and a prefabricated customized prosthetic suprastructure. The procedures are described in detail below.

Image Acquisition. After a thorough clinical examination has been performed, including a medical and dental history, the subject is prepared for a high-resolution spiral CT. For this scan, an occlusal index is first produced (Figure 1). The patient gently bites on this index during the CT scan to ensure proper positioning of the denture. The patient's existing denture has to be well aligned to the mucosa and must correspond to the planned fixed prosthesis. If not, a specially created prosthesis replica with teeth is prepared.

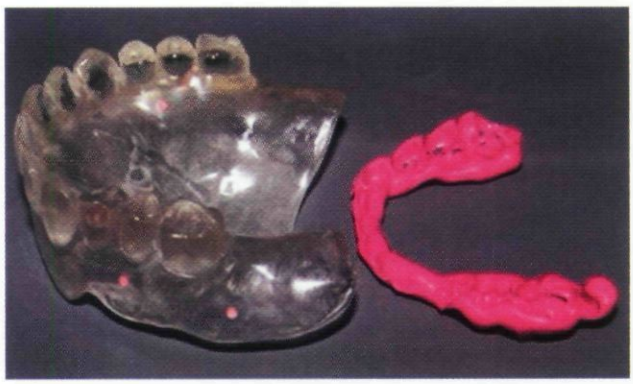

Figure 1 Before the computed tomographic (CT) scan, an occlusion index is prepared and the patient's denture or a prosthesis replica is equipped with spherical radiopaque gutta-percha markers (1 mm diameter). The index ensures proper positioning of the prosthesis replica during the CT scan.

Also, the denture or the prosthesis replica is prepared before the scanning. At least five small (Ø 1 mm) gutta-percha balls are inserted in the prosthesis surface, acting as radiopaque markers, randomly spread over the prosthesis (see Figure 1).

The CT protocol consists of two scans. First, the patient, wearing the index and the prosthesis, is scanned with the occlusal plane parallel to the axial slices. Immediately after the scanning, a second CT scan of the prosthesis itself is performed using the same CT scanner settings. The two resulting sets of axial CT slices are fused on the basis of the radiopaque gutta-percha markers. This double-scan procedure allows very accurate imaging of the prosthesis and easy fusing of the prosthesis CT scan to the patient CT scan.

Surface representations of the bone and the prosthesis are computed from these CT data sets and loaded into the three-dimensional image-based treatment planning software using state-of-the-art fast rendering techniques (Oralim®, Medicim, Sint-Niklaas, Belgium).

Three-Dimensional Image-Based Treatment Planning. The treatment planning can now be performed by the clinician. The virtual scene with the patient's CT data is inspected with a three-dimensional viewer (Figure 2, left larger window), presenting a general overview of the scene. To visualize the cross-sectional reslices (see Figure 2, right window), the clinician interactively manipulates a curve in the three-dimensional viewer that guides these reslices along the maxillary crest (see Figure 2, left window). With the zoom, rotate, and translate tools, every detail can be inspected (Figure 3). The virtual three-dimensional scene of the planning environment is interactively composed. By a simple click of the mouse, the prosthesis can thus be introduced or removed from the image (Figure 4). The software is fully three-dimensional, allowing the clinician to visualize concomitantly three planar views of the object (the jaw bone and/or prosthesis) in one image (Figure 5).

Placing an implant is done intuitively by indicating a point on top of the jawbone crest and another more apically, mimicking the use of a drill. When the implant is thus apparent, the clinician can change the length, width, inclination, position, etc. Every change concomitantly appears in both viewers because they are fully related views of the same object. The program indicates the minimal distances between implants and a security zone of 1.5 mm around the implants. The clinician also plans three horizontal stabilizing pins for the surgical template between the implant sites (Figure 6).

Once the treatment planning has been approved by the surgeon and the restorative dentist, it is digitally sent to the Procera workstation (Nobel Biocare AB) for further manufacturing of a stereolithographic model.

Hardware. The surgical template is produced on the basis of a stereolithographic model of the prosthesis. The template is made of medically approved acrylic and contains metallic sleeves in which removable stainless steel

Figure 2 The left (larger) viewer, the three-dimensional viewer, presents a general overview of the maxilla with the planned implants. In this viewer, a green curve following the jawbone crest is clearly visible. This curve guides the cross-sectional reslices seen in the right reslice viewer. The clinician interactively manipulates this curve to adjust the position of the cross-sectional reslices. The reslice viewer gives easy access to the image data for initial positioning of the implant.

Figure 3 With the zoom, rotate, and translate functions of the three-dimensional viewer, any detail can be inspected meticulously.

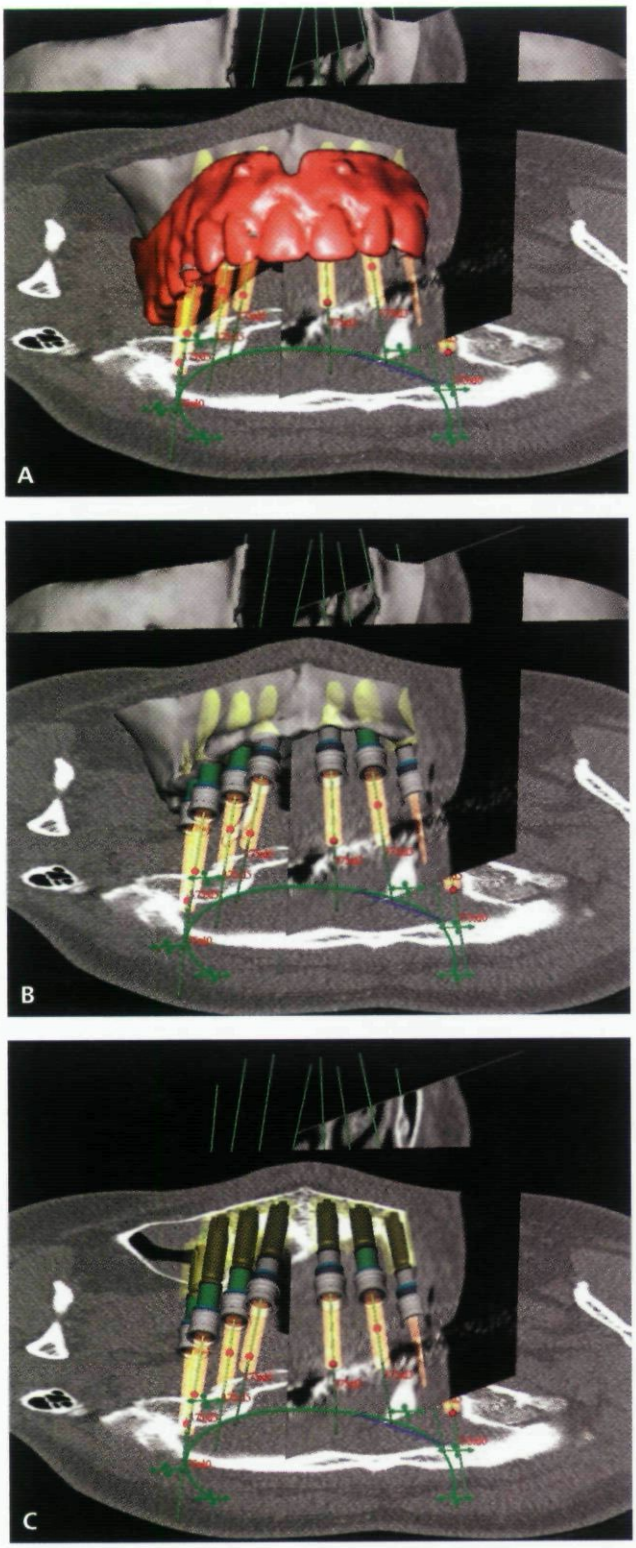

Figure 4 The virtual scene is filled with the objects that are important for performing implant treatment planning. At all times, the visibility of the objects, such as the computed tomographic slices, cross-sectional reslices, bone surface, or prosthesis surface, can be switched on and off. In (*A*), all objects are visualized. Depending on the details that are inspected, the prosthesis can be temporarily hidden (*B*), as well as the maxilla (*C*). Also, the axial slice or reslices can be displayed or hidden. In this way, only the data needed during the planning step are visualized.

drill guides with varying inner diameters can be fitted. The template sleeves correspond to the location and the inclination of the planned implants. Furthermore, the inner diameters of the drill guides correspond precisely to the diameters of the drills and implants (Figure 7). The surgical template also contains three lateral metallic sleeves with a narrow diameter. These are used for drilling in the axial plane through the soft tissue and into

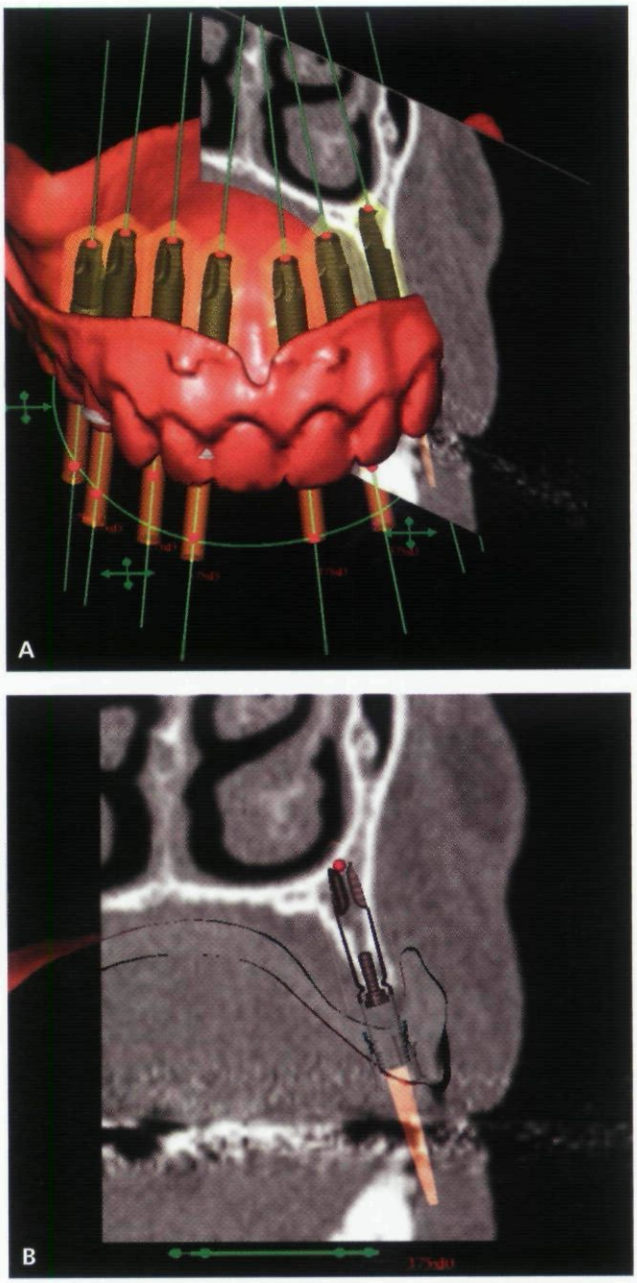

Figure 5 Together with the three-dimensional scene (*A*), a dedicated cross-sectional reslice viewer (*B*) is included on which the position of the implant with respect to a reslice is visualized. Changes in the position of an implant in the reslice viewer (*B*) are simultaneously visualized in the three-dimensional viewer (*A*) because all viewers are looking at the same virtual scene but with a different virtual camera.

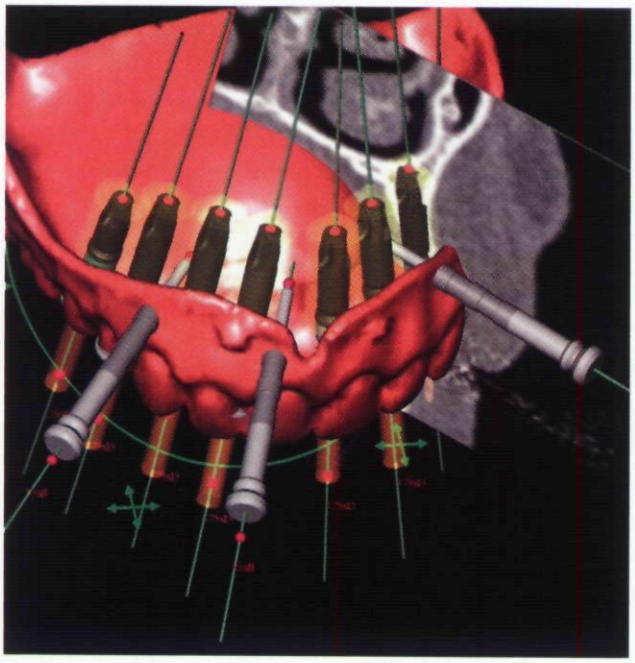

Figure 6 The surgical template stabilizing pins are also planned.

the jawbone and for insertion of provisional stabilizing pins throughout the surgical procedure.

Surgical and Prosthetic Procedure

One hundred eighty-four Brånemark System Mk III fixtures with a TiUnite™ surface (Nobel Biocare AB) were placed, ranging from six to eight implants per patient. The implants were inserted through the surgical template sleeves with the template placed on the maxillary soft tissues, that is, through a flapless surgical procedure (Figures 8 and 9). The surgical template had been rendered aseptic by keeping it in a concentrated alcohol-chlorhexidine solution. After the template had been rigidly anchored to the jawbone by the

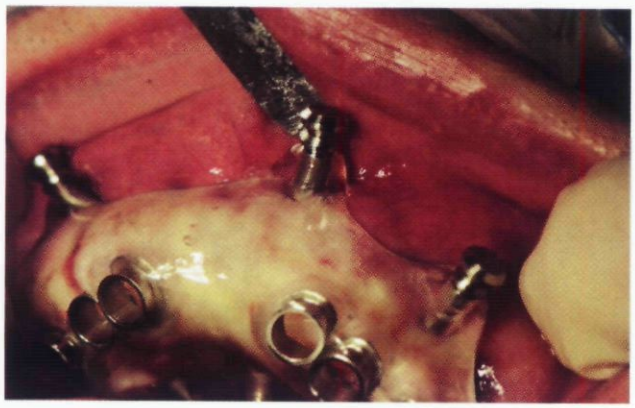

Figure 7 The surgical template with the stabilizing pins placed on the maxillary soft tissues for flapless surgery. One can see the intact gingiva through one of the template sleeves.

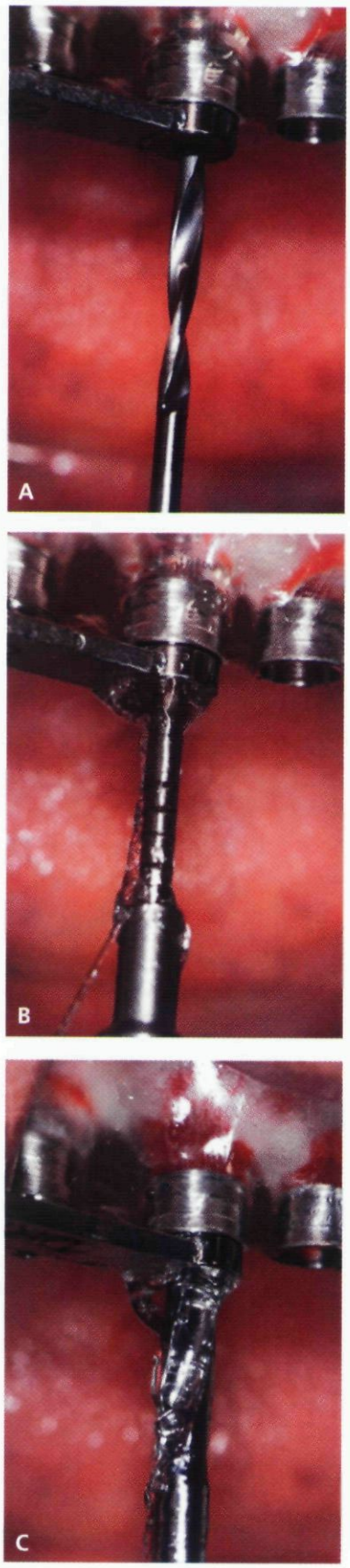

Figure 8 *A–C,* Close-ups of the drill guides with three different diameters, matching the series of drills used. The drill guides, which can be inserted in the metal template sleeves, ensure perfect guidance to the drills.

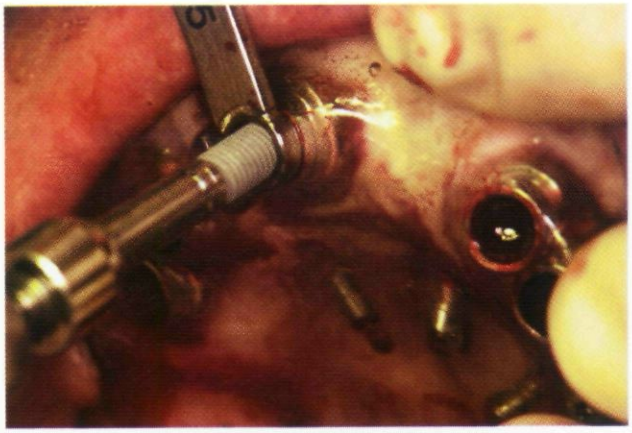

Figure 9 An implant being inserted through the surgical template with a drill guide of appropriate diameter in place. On the palatal side, one can see the stabilizing pins through the transparent surgical template.

three horizontal stabilizing pins, a first drill was used to remove the gingiva through the template sleeves. Then drilling was pursued in the usual manner using 2 mm drills, pilot drills, and 3 or 3.3 mm drills, depending on the implant diameter to be inserted (see Figure 8). Once all of the implants had been installed and the surgical template was removed, a prefabricated customized fiber-reinforced acrylic bridge was fixed by means of expanding abutments on top of the installed implants and was screw-retained (Figure 10). These expanding abutments were seated on the shoulder of the installed implants and squeezed in the metallic cylinders within the bridge, thus providing rigid fixation. The specific size of the implants used in the study can be found in Table 1. The bone quality and quantity were estimated according to the Lekholm and Zarb index (Table 2).[12]

Assessing Treatment Outcome

The enrolled patients were examined at 1 to 2 weeks and 1, 3, 6, and 12 months after surgery. This implied the assessment of prosthesis stability, periimplant soft tissue conditions, eventual bruxism or other adverse events, and individual implant stability with the prosthesis removed at the 1-year follow-up. At 3 months, the patients' opinions regarding speech, oral function, esthetics, and tactile sensation were investigated by means of a questionnaire with a visual analogue scale (VAS) from 0 to 10, where 0 meant poor and 10 excellent. The clinician's opinion on both function and esthetics was also evaluated and graded as excellent, good, acceptable, or unacceptable. Intraoral radiographs using a parallel technique were taken just after prosthesis installation or in connection with the first visit after 1 to 2 weeks and at the 1-year follow-up. The level of the marginal bone, mesial and distal to the implant, was marked in the digital intraoral images or in the scanned analogue radiographs by an independent radiologist. The implant-abutment interface was used as a reference level in the evaluation of marginal bone resorption.

RESULTS

All patients received their final prosthetic restoration immediately after implant placement, that is, both the surgery and prosthesis insertion were performed within approximately 1 hour (Figures 11 and 12).

Twenty-four of the 27 patients, including 164 implants, have passed the 1-year control visit. None of the implants failed, and all fixed prostheses were stable and functional. An additional patient preferred a removable denture after 9 months, and the fixed prosthesis was

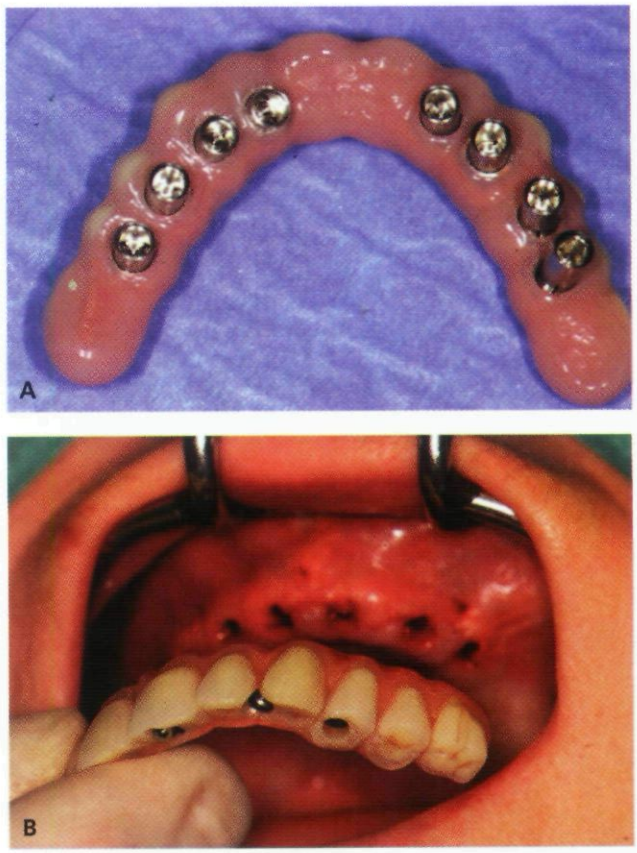

Figure 10 *A*, The maxilla with all implants inserted on which the prosthesis will be fixed. *B*, The prosthesis with the expanding abutments before placement on the implants. When this type of abutment is seated onto the implant, the screw is further tightened, which expands the abutment diameter, and thereby adjusts to the prosthesis cylinder.

TABLE 1 Distribution of Implants According to Length and Diameter

	Implant Length, mm	
	3.75	4.0
7–8.5*	4	1
10–11.5	27	12
13–15	82	61
Total	110	74

*These patients also had at least six implants of at least 10 mm length inserted according to the inclusion criteria.

therefore removed. The patient was thereafter classified as withdrawn. However, the 1-year follow-up was done and showed stable implants. The last two patients have been observed at least 6 months. Because the immobility of the individual implants was checked with the prostheses removed at the 1-year visit, they could all be considered successful. The incidence of bruxism was recorded in six patients during follow-up. At the 1-year follow-up, four patients showed signs of an inflamed gingiva or alveolar mucosa. This corresponds to the hyperplasia, which was reported in these patients during follow-up. Other complications reported were moderate postoperative pain for a few days up to 1 month (four patients; the others had no pain whatsoever), marginal fistula (one patient, who healed after 3 weeks), occlusal material fracture (two patients), and loose retaining screw (one patient). A slight discrepancy in the abutment-implant interface was seen in one case and a midline deviation in another case. The functional and esthetic outcome is reported from both the clinician's and the patient's viewpoint in Table 3 and Figure 13.

The marginal bone resorption after 1 year of follow-up was 1.2 mm (SD 1.1) mesially and 1.1 mm (SD 1.0) distally of the implant ($n = 125$ implants).

TABLE 2 Number of Implants in Relation to Bone Quality and Quantity

Bone Quantity	Bone Quality					Total
	1	2	3	4	5	
A	0	13	8	0	0	21
B	1	40	28	3	0	72
C	1	24	50	11	1	80
D	0	0	4	0	0	4
Total	2	77	83	14	1	184

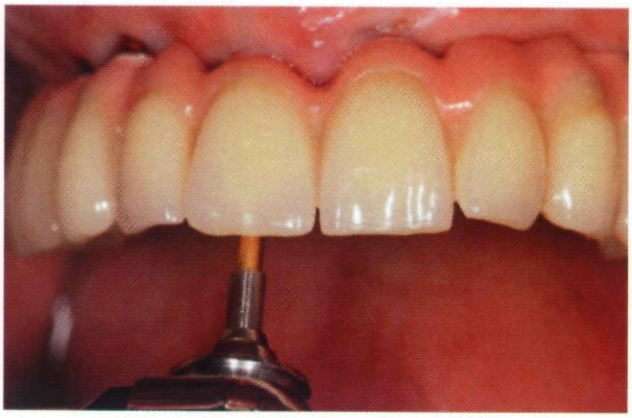

Figure 11 The final prosthesis in place within approximately half an hour after the completion of the surgery. The esthetic outlook depends on the craftsmanship of the dental technical laboratory.

DISCUSSION

It appears from the data collected on 27 consecutive patients in 3 centers that this treatment concept can easily be applied. Indeed, the experience of clinicians at two of the three centers was limited to one pilot patient at the start of the prospective study, although they are very experienced clinicians.

Even though a number of studies have been presented on immediate loading,[5–9] there are fewer publications on implants in the maxilla.[13–17] Moreover, the few studies available on immediate maxillary full-arch rehabilitation clearly lack comprehensive protocols, whereas the current concept presents a meticulous, step-by-step treatment procedure. The short-term implant success rate of 100% seen in the present study is reassuring for immediate loading in edentulous maxillae and for the flapless surgical approach. Postoperative pain was limited and was reported by only four patients. This blind surgical technique has previously been described as a successful alternative for implant insertion.[15] The

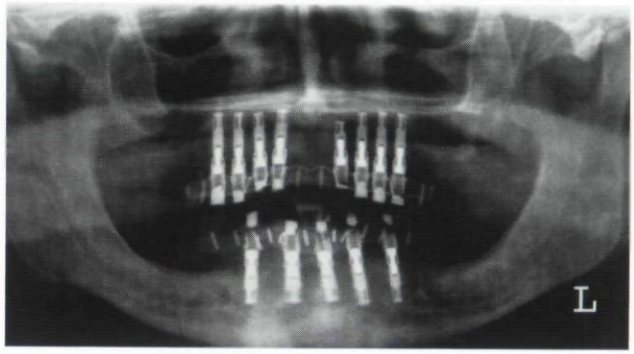

Figure 12 The radiologic control of a patient who has undergone the same procedure in the opposing jaw.

TABLE 3 Esthetic and Functional Evaluation by Clinicians at 1-Year Follow-Up Visit

	Esthetics (n = 24)	Function (n = 24)
Rating	n	n
Excellent	18	16
Good	3	8
Acceptable	2	0
Nonacceptable	1*	0

*Midline deviation: the bridge will be remade.

benefits are evident. Nevertheless, aseptic surgical conditions are mandatory and were strictly controlled for in this prospective study. It is known that microbial contamination during foreign-body insertion may be detrimental for the outcome.[18]

The surgery time was short, sometimes less than half an hour. The prosthetic time was even shorter, even if sometimes minor occlusal adjustments were needed.

The present multicenter study indicates that, using the protocol described above to ensure proper surgical template positioning, a high precision of transfer of the planning to the operative field can be achieved that is similar to when the template is seated on the bone.[3] This observation contradicts unsubstantiated doubts recently raised.[19] Indeed, all prostheses could be fixed immediately on the inserted implants because the axes of the latter coincided with the metal sleeves of the former (see Figure 10). There were some slight deviations of the used versus the planned implant lengths and diameters. There were three different reasons for this, according to the clinicians. One reason was that, at implant installation, the surgeon thought that a longer implant might improve implant stability. In another case, the surgeon had a feeling that he would penetrate the nasal or sinusal cavity and chose a shorter implant. The third reason was due to the suggestion of the dental technical laboratory, which on the jaw model sometimes removed more of the soft tissues to allow deeper seating of the implants. This would guarantee full masking of the abutment by the prosthesis. It has been demonstrated that even without using this transfer system, a better match between the planned and used implant characteristics is achieved, although at a less impressive level, when planning is done in a three-dimensional mode instead of a two-dimensional mode.[20]

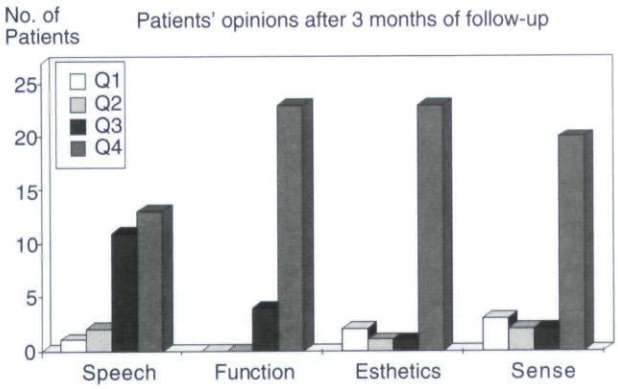

Figure 13 The diagram represents the percentages of all marks in each quartile of the visual analogue scale, where Q4 is the quartile with the highest scores.

Less satisfaction with speech was reported by half of the patients at 3 months. This is a well-known side effect of implant-supported prostheses, both fixed and removable. Jacobs and colleagues reported that this was especially true soon after the installation of a fixed prosthesis on implants but unrelated to the presence of interdental spaces.[21] Many of the patients in the control group of this cross-sectional study also had speech problems.

Bruxism was also regularly observed. This is known to be a risk factor when present at immediate loading of implants.[22] In the present study, bruxism was recorded only from the 1-month control onward, and the incidence remained stable over the 1-year observation period. Thus, it is difficult to hypothesize that it is due to the treatment as such. Indeed, bruxism was not an exclusion criterion in this study. Subjectively, patients considered both jaw function and tactile sensitivity as good to excellent, even though five patients scored less than 5 on the VAS with 10 as the maximum. The role and initiation of bruxism should be further investigated.

Inflammation of the soft tissues, both the gingiva and alveolar mucosa, was clearly related to plaque accumulation. Indeed, several patients had difficulty maintaining a proper oral hygiene regimen. This was probably due to the fact that they had been edentulous in the upper jaw for a while. In some, the morphology of the dental prosthesis rendered plaque control difficult.

The change in marginal bone level was similar to that which was observed in the study by Glauser and colleagues on immediate loading.[9] It could be hypothesized that a flapless surgical technique would show less marginal resorption compared with surgery with an open flap. However, future studies will provide more knowledge on marginal bone level changes after flapless surgery.

CONCLUSIONS

The present prospective multicenter study indicates that prefabrication, on the basis of models derived from three-dimensional oral implant planning software, of both surgical templates for flapless surgery and dental prostheses for immediate loading is a very reliable treatment option. It is evident that the same approach could be used for staged surgery and partial edentulism.

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