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Implant treatment software planning and guided flapless surgery with immediate provisional prosthesis delivery in the fully edentulous maxilla. A retrospective analysis of 15 consecutively treated patients.

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Key words   *computed tomography-guided implant surgery, immediate loading, software planning*

Aims: To evaluate the clinical outcome of fully edentulous patients in the maxilla, who were treated with immediately loaded implant-supported cross-arch bridges using computer-aided implant surgery.

Materials and methods: The clinical outcome of 15 consecutive patients (5 males and 10 females) with a mean age of 52 years (range 40 to 70), with edentulous arches and treated with implant-supported cross-arch bridges was evaluated. Two computed tomography scans were performed, the first with the patient wearing the denture/radiographic guide and the radiographic index, and the second of the denture alone. The guided flapless surgical procedure was performed under local anaesthesia. Ninety implants were placed. The implant length ranged from 10 to 13 mm and the implant diameter was either 4.3 or 5 mm. All implants were immediately loaded with screw-retained provisional acrylic prostheses prepared in advance and delivered immediately after surgery. Clinical and radiographic follow-up visits were scheduled at 6, 12 and 18 months from surgery; implant survival rate, marginal bone levels, patient satisfaction and any complications were recorded.

Results: After the follow-up period of 18 months, two patients each lost one implant. After 18 months, patients lost, on average, 1.6 mm of peri-implant marginal bone. A patient satisfaction questionnaire at 18 months revealed a very high level of satisfaction with the treatment.

Conclusion: Although limited by the number of patients, it can be concluded that software- and computed tomography-guided surgical planning for completely edentulous arches provides reliable results with high success rates.

■ Introduction

The two-stage surgical approach for implant placement was first documented by Brånemark[1] in 1977 and today represents the most documented protocol for placing implants. Comparable results have been reported with the one-stage surgical procedure and transmucosal healing of implants[2,3]. The one-stage surgical procedure, combined with early and immediate implant function has been proven to be a valid approach with both submerged and transmucosal implants in full-arch edentulous patients, both at first and for other indications later on[4].
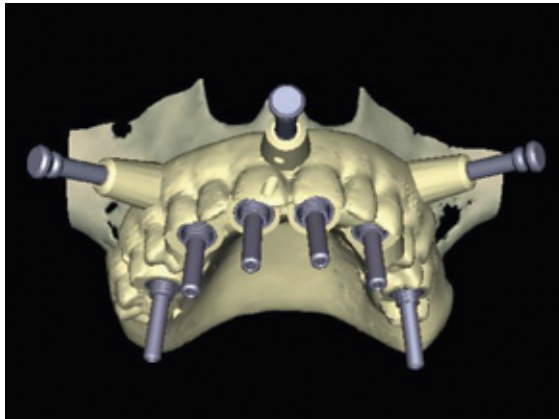
Fig 1 Three-dimensional diagnostic analysis and virtual implant planning (NobelGuide Procera Software).
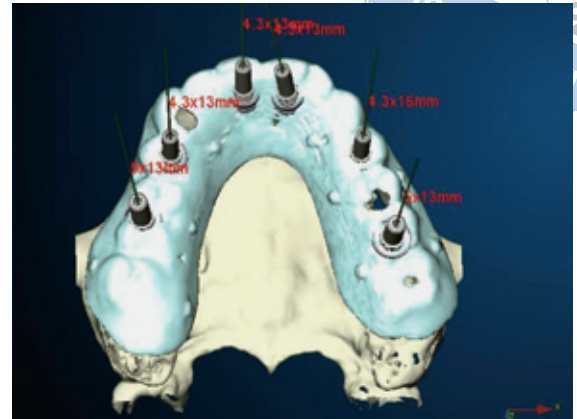

Fig 2 Three-dimensional diagnostic analysis and virtual implant planning (occlusal view).

Nowadays, a growing need exists for patients to be rehabilitated with a fixed implant-supported prosthesis delivered just after surgery and to minimise patient discomfort. This means that patients' function and aesthetics are restored, and therefore that patients can be back to work and their social life within a short period of time. A substantial number of patients present edentulous areas with insufficient bone volume. In these cases, bone augmentation techniques are used, which are associated with substantial post-operative morbidity. Thus, it would be of great clinical advantage for patients to have dental implants placed flapless and immediately loaded with a prosthesis, delivered just after surgery. Post-operative morbidity and treatment times could be reduced significantly[5,6]. Furthermore, the use of three-dimensional (3D) planning software as a diagnostic tool, allowing a precise assessment of available bone could minimise the need for bone augmentation procedures.

Based upon these assumptions, the present study aims to retrospectively evaluate the clinical and a radiographic outcome of fully edentulous patients treated with 3D software planning, guided flapless surgery and immediate delivery of provisional prostheses.

■ Materials and methods

Fifteen consecutive patients (5 males and 10 females) with a mean age of 52 years (range 40 to 70) with edentulous maxillas were treated. Ten patients were non-smokers, three patients smoked up to 10 cigarettes a day, and two patients smoked more than 10 cigarettes per day. Seven patients were completely edentulous. The remaining eight patients with hopeless teeth were rendered edentulous 2 to 3 months before implant placement. The patients were enrolled after preliminarily providing their written informed consent and provided that they met the following inclusion criteria: fully edentulous maxilla; age 18 years or older; at least 10 mm of bone height and 4.5 mm of bone width as determined via a computed tomography (CT) scan and for at least six implants to be inserted in an arch conformation. Patients were excluded if they presented with general contraindications for implant surgery; irradiation of the head and neck area in the last 12 months; poor oral hygiene and motivation; active periodontal disease, uncontrolled diabetes; pregnant or lactating women; substance abuse; psychiatric problems; severe bruxism, clenching habits or inability to open the mouth sufficiently to accommodate surgical tooling.

All potentially eligible patients passed through the following clinical phases. First, the patients were subjected to a clinical evaluation and a medical history was taken. Preliminary screening, including intraoral and panoramic radiographs, was performed to evaluate potential patient eligibility. In the second phase, eligible patients received oral hygiene instructions, impressions and baseline photographs, measurements with a facial bow for aesthetic/functional evaluation, and informed consent was collected. In the laboratory, study models were mounted in a mean value articulator. If needed, diagnostic wax setup and modification or remaking of the denture were
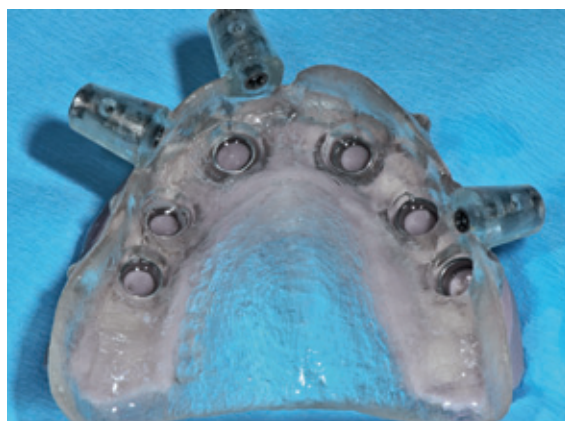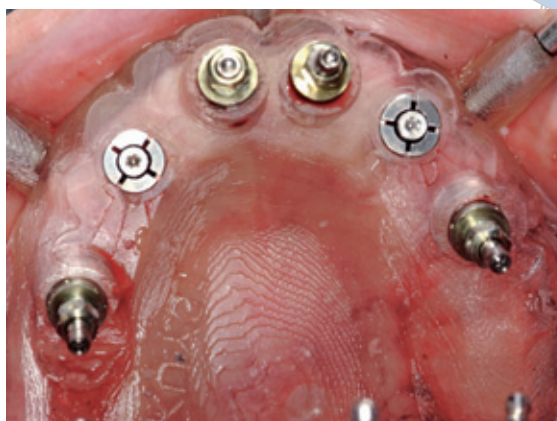
Fig 3   Surgical template.

Fig 4   Guided insertion of six implants.

performed. If required, extractions were performed at least 6 to 8 weeks before a CT scan and 3 months before implant placement. Finally, the patients passed through a functional, aesthetic, and phonetic evaluation. If positive, references points, filled with a radiopaque marker (e.g. gutta-percha), were inserted in the denture/radiographic guide. A silicone interocclusal record was also made as a radiographic index, and the denture was then duplicated.

In accordance with the NobelGuide™ data acquisition protocol (Nobel Biocare, Zurich, Switzerland), two CT scans were performed. The first of the patient wearing the denture/radiographic guide as well as the radiographic index, and the second of the denture alone. CT scan data were then transferred to the NobelGuide Procera® software program (Nobel Biocare) for 3D diagnostic analysis and virtual implant planning. Anatomical conditions had to allow the placement of at least six implants in the ideal position for prosthetic rehabilitation (Figs 1 and 2). The software planning data were sent to the manufacturer (Nobel Biocare), where a surgical template with hollow metallic sleeves was produced to guide implants in the same position as had previously been virtually planned. Based upon the surgical guide and the model obtained with the planned position of the implants, full acrylic resin provisional prostheses were prefabricated.

The surgical procedure was performed under local anaesthesia with articaine chlorhydrate plus 1:100,000 adrenaline. All patients were given diazepam (Valium, 10 mg, Roche) as a sedative agent before surgery. Antibiotics (amoxicillin 875 mg and clavulanic acid 125 mg) were given 1 hour

Fig 5   Six implants were placed flapless.

before surgery and b.i.d. for 6 days thereafter. An anti-inflammatory drug (ketoprofen 80 mg) was administered b.i.d. for 4 days postoperatively (twice daily). An antacid agent (omeprazole 20 mg) was given on the day of surgery and once daily for 6 days postoperatively. Each patient rinsed with chlorhexidine gluconate (0.2%) for 1 minute before the intervention. Surgical templates were placed intraorally in the right position also in relation to the opposing arch and then fixed with three anchor pins. After correct placement and stabilisation of the surgical template (Fig 3), flapless implant surgery was performed in accordance with the drilling protocol for the type of implant used (NobelReplace Tapered Groovy, Nobel Biocare) (Figs 4 and 5). Implants were inserted with a preset insertion torque of 35 to 45 Ncm. In total, 90 implants (NobelReplace Tapered Groovy) were placed. The implant length ranged from 10 to 13 mm and the implant diameter was 4.3 or 5 mm.

Fig 6 Prefabricated provisional prosthesis.

Fig 7 Prefabricated provisional prosthesis after immediate loading.

Fig 8 Procera titanium implant bridge.

Fig 9 Definitive bridge (Procera titanium framework and resin teeth) in position.

All implants were immediately loaded with the prefabricated provisional prosthesis (Figs 6 and 7). When needed, minor adjustments to correct occlusion were made. Ice packs were provided, and a soft diet was recommended for 1 month. All patients were included in an implant maintenance program. Smokers were asked to refrain from smoking for at least 48 hours postoperatively. Chlorhexidine gluconate mouthwash (0.2%) was prescribed for 1 minute b.i.d. for 2 weeks. The patients were instructed regarding oral hygiene and recalled every 3 months for an appointment for maintenance. In order to be deemed successful, implants were required to meet all of the following criteria: clinical stability, patient-reported function without any discomfort and the absence of infection.

After 6 months, the prostheses were removed and the implants were individually tested for stability. The definitive prosthetic restorations, either Procera Implant bridge Titanium (Fig 8) as the framework and composite resin as aesthetic material (Fig 9) or Procera Implant Bridge Zirconia (Nobel Biocare) and ceramic (Fig 10), were then used.

Periapical radiographs were taken upon implant insertion, and at 6, 12 and 18 months using a long cone parallel technique. The reference points for radiographic evaluation were the implant platform (the horizontal interface between the implant and abutment) and the first bone-to-implant contact. The marginal bone remodelling was calculated as the difference between the reading at the examination and the baseline value. Mesial and distal bone height measurements were averaged for each implant. The radiographs were repeated when quality was poor. An independent radiologist made the bone height measurements. Implant survival rate, bone levels at baseline and 6, 12 and 18 months were analysed with descriptive statistics.

■ Results

The follow-up period was 18 months, and was uneventful in all but two patients (who underwent a second surgical treatment to replace failed implants). All other patients felt comfortable and none withdrew from the study. The two lost implants failed after 6 months at the time of provisional prosthesis removal. All of the remaining implants were successful, resulting in a cumulative survival rate at 18 months of 97.8% (Table 1).

Three days after surgery, 10 patients had no postoperative pain and 5 had mild pain; 7 patients reported no swelling and 8 reported mild swelling. Two provisional prostheses did not fit and just
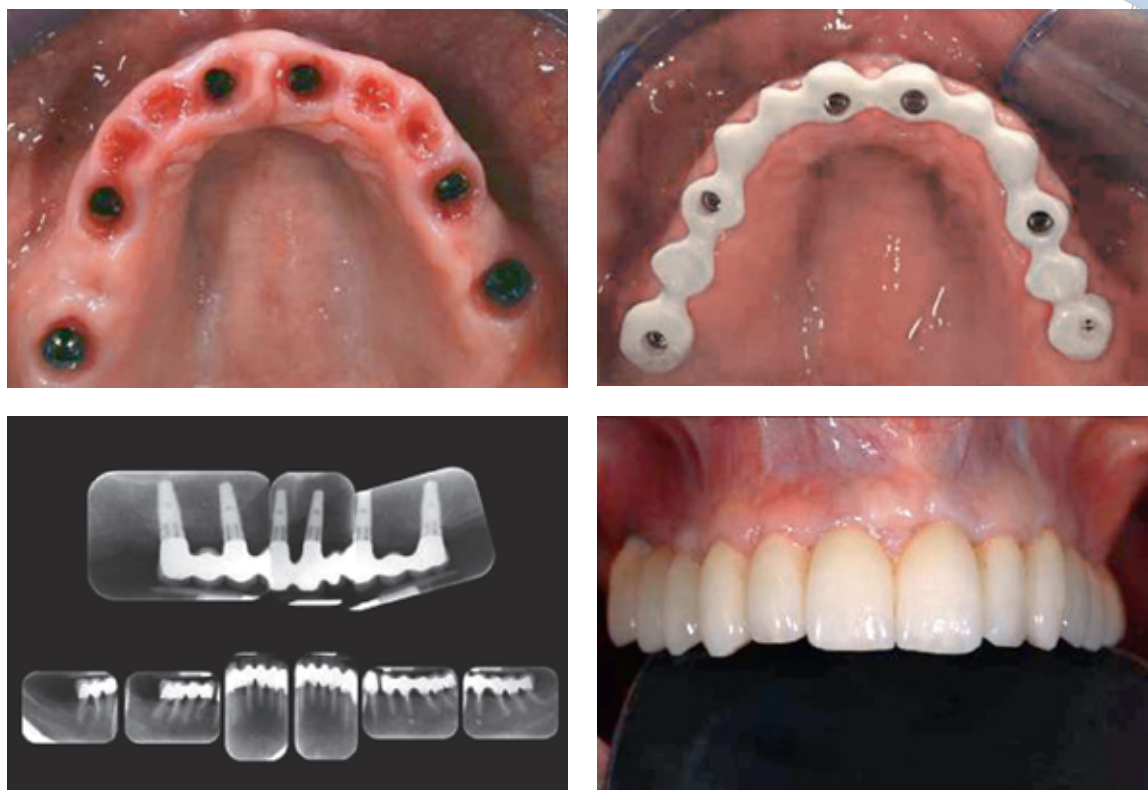
Fig 10 Definitive bridge (Procera zirconia framework and ceramic teeth) in position.

Months	No. of patients	No. of implants	Failure	Cumulative survival rate
0–6	15	90	0	100%
6–12	15	88	2	97.8%
12–18	15	88	0	97.8%

Table 1 Life table analysis for implant success.

	Implant insertion	6 months	12 months	18 months
Mean	0.24	1.46	1.66	1.81
SD	0.18	0.23	0.20	0.18
Number	15	15	15	15

Table 2 Peri-implant marginal bone levels.

after surgery impressions had to be remade to allow the prostheses to fit onto the implants. A possible explanation for one of these poor fits was the fracture of the surgical template during surgery. In one patient, the provisional full acrylic resin complete denture fractured. The prosthesis was repaired and the patient was given further instructions regarding overloading of the prosthesis. Additional minor prosthetic complications included the fracture of a provisional prosthesis 4 months after loading, which was repaired chairside.

Peri-implant marginal bone levels are shown in Table 2. At 18 months, the mean marginal bone levels were 1.8 mm +/- 0.2, therefore patients lost 1.6 mm of bone from implant placement.

No patients experienced any phonetic problems during the provisional phase. Patient satisfaction is summarised in Table 3. All patients but two reported that their quality of life and lifestyle improved with the implant-supported maxillary prosthesis; all patients answered that they would undergo the same therapy again and that the treatment was worthwhile.

Table 3 Patient satisfaction 18 months after surgery.

	No	Not sure	Yes
Has the fixed maxillary prosthesis improved your quality of life?	0	2	13
Was it worth the cost?	0	0	15
Would you undergo the same therapy again?	0	0	15

■ Discussion

A large number of clinical reports indicate that early or even immediate loading of oral implants leads to acceptable to excellent results[5]. Some clinical studies[7,8] reported high survival rates in both the maxilla (between 93 and 99.2% with 15 years of follow-up) and mandible (between 93.2 and 100% with 15 years of follow-up). The results of the present study confirm that immediate loading is a reasonable alternative to the classic, two-stage procedure (which is thoroughly documented, also in resorbed fully edentulous maxillae) and involves flapless surgery and minor postoperative discomfort. Nevertheless, some complications did occur in the present study, the most common of which was difficulty when fitting the provisional prosthesis on the implant, possibly because of a deviated implant position. A possible explanation for at least one of these poor fits was the fracture of a surgical template during implant placement; the fracture of the template may have caused imprecise implant placement. To minimise the risk of imprecise implant placement, the procedure was modified slightly. First, the majority of the local anaesthesia, particularly on the palatal side, was administered after fixing the template to minimize the soft tissue deformation induced by the local anaesthetic. In addition, more than three transalveolar pins were used to improve the stabilisation of the surgical stents.

Guided implant placement is more expensive than conventional placement, due to the software, duplication of the denture, CT scan of the patient denture, surgical template, laboratory and planning time. However, the entire procedure from the surgery to the final prosthetic restoration is less invasive than the standard protocol with reduced time and minimal patient discomfort, and for this reason all patients stated that intervention was worth the cost and that they would undergo the same procedure again. A mean peri-implant marginal bone loss of 1.6 mm was similar to that observed in other studies on flapless guided surgery[9-11], but slightly higher than what is reported for conventional implant placement and what is generally expected according to some internationally accepted radiographic success criteria[12]. The main limitations of the present study are the small sample size and its retrospective design.

■ Conclusions

Although limited by the number of patients, it can be concluded that software- and CT-guided surgical planning for completely edentulous maxillae provided predictable results and a high success rate.

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