A retrospective study of edentulous patients rehabilitated according to the ‘all-on-four’ or the ‘all-on-six’ immediate function concept using flapless computer-guided implant surgery

Key words computerised tomographic scan, flapless surgery, full edentulism, guided surgery, immediate loading

Purpose: To report the outcome of an implant therapy protocol using 4 or 6 implants supporting immediately loaded fixed prostheses following 3D software planning and flapless guided surgery.

Materials and methods: A total of 30 patients (24 women, 6 men), mean age of 53 years (range 35–84 years) were treated with 195 immediately loaded implants (97 NobelSpeedy Groovy and 98 Brånemark MKIII Groovy) supporting 25 maxillary and 17 mandibular fixed full-arch acrylic prostheses and followed for 1 year. The Procera Software v1.6 and v2.0 was used to plan implant position and to obtain a surgical template for the guided flapless implant placement. To perform immediate loading, the implants had to be inserted with torque of at least 35 Ncm. Provisional prostheses were made before surgery using software planning and were placed in the same session as the implants. Definitive restorations were delivered 6–12 months after surgery. Outcome measures were failures of the prosthesis and of the implants, marginal bone level changes, complications, clinical time and patient satisfaction.

Results: Four patients with full edentulism and 26 with advanced periodontitis were enrolled in this study. A total of 195 implants were immediately loaded (128 implants were placed in the maxilla and 67 implants were placed in the mandible). Four implants out of 195 failed in three patients during the healing period: 2 in the maxilla (1 straight and 1 tilted), and 2 in the mandible (both of them tilted). Three of them were successfully replaced. One year after loading there were no dropouts and no failure of the definitive prosthesis occurred. In three cases, the surgical template fractured during surgery. In one patient, a new impression had to be taken to fit the provisional prosthesis onto the implants. Three patients were subjected to surgery and systemic antibiotics to treat apically infected implants.

Conclusions: The ‘all-on-four’ and ‘all-on-six’ treatment protocol combined with computer-guided flapless implant surgery could be a viable and predictable treatment. Some complications occurred that were successfully treated. However, this technique could be sensitive to the experience of the surgeon and a learning curve is required.
Introduction

For patients with severe periodontal disease or full edentulism, it would be a great clinical advantage to restore function and aesthetics in the same session with a minimally invasive flapless surgical approach, and immediate placement of a provisional prosthesis, thereby significantly reducing morbidity, treatment time and costs. Immediate loading can be a viable solution in cases of full edentulism and several studies have demonstrated that immediately loaded full arch fixed prostheses represent a valid treatment option with a high survival rate of both implants and prostheses.

Different protocols have been developed for the immediate rehabilitation of edentulous jaws. One of these is the ‘all-on-four’ concept. This concept implies the placement of four strategically positioned implants, two mesially and two distally placed and tilted. By using this procedure, bone augmentation procedures may be avoided in cases with reduced residual bone volumes. As in any other immediate function application when sufficient primary stability is achieved, the probability of a successful treatment outcome is high. In some cases, when planning a full arch ceramic rehabilitation in patients with poor bone quality (type IV), it might be advisable to move from the ‘all-on-four’ protocol to the ‘all-on-six’ protocol, thereby placing four anterior straight implants and two tilted implants distally.

Nowadays, advancements in computer science and technology allow a combination of the conventional ‘all-on-four’ treatment protocol with 3D software planning after computerised tomography (CT) examination, guided minimally invasive surgery, and immediate provisional prosthesis delivery. The purpose of the software program is to help dentists when planning the implant position. A customised surgical template allows transfer of the planned implant position, and a prefabricated acrylic resin prosthesis is made. Treatment time and post-surgical discomfort are reduced since implants can be placed without elevating a flap and a provisional prosthesis can be delivered in the same session.

The purpose of the present study was to retrospectively evaluate the clinical outcome of the ‘all-on-four’ and ‘all-on-six’ protocol in fully edentulous jaws using 3D software planning, guided flapless surgery and immediate provisional delivery.

Materials and methods

The present study was reported according to the transparent guidelines for observational (cohort) studies (STROBE: http://www.strobe-statement.org). Thirty patients (24 women and 6 men) with advanced periodontitis (26 patients) or who were totally edentulous when enrolled in the study (4 patients), a mean age of 52.9 years (range 35 to 84 years), were consecutively treated in a private clinic. Ten patients were smokers and one patient reported a history of non-insulin-dependent diabetes. A total of 195 implants (97 Speedy Groovy implants: 74 in the maxilla and 23 in the mandible; and 98 Brånemark MKIII Groovy implants: 54 in the maxilla and 44 in the mandible; Nobel Biocare, Göteborg, Sweden) were placed between December 2006 and December 2008. In the maxilla, 128 implants were placed (14 patients received six implants and 11 patients received four implants). Sixty-seven implants were placed in the mandible (four implants in 16 patients, and one patient received three implants because he already had two implants placed in another clinic). In total, 42 fixed implant-supported cross-arch bridges were inserted (28 ‘all-on-four’ rehabilitations in maxillae and 17 mandibles, and 14 ‘all-on-six’ rehabilitations in maxillae). Main selection criteria were:

- edentulous jaws, or arches with non-retainable teeth in need of fixed implant restorations
- a residual bone volume allowing the placement of implants with a diameter of at least 3.3 mm and a length of at least 10 mm, as well as an insertion torque of at least 35 Ncm.

Patients with a mouth opening of less than 4 cm, poor oral hygiene, heavy smokers (>20 cigarettes per day) and poorly controlled systemic diseases were excluded. The implants used all had a diameter of 3.3–4.0 mm and a length of 10–18 mm.

Pre-treatment, surgical and prosthetic procedures

Prior to implant treatment, all patients with teeth with periodontitis received periodontal treatment involving scaling and root planing to reduce the
bacterial contamination before implant surgery. All periodontally involved teeth were extracted 30–78 days prior to surgery. The pre-treatment recordings consisted of anamnesis as well as clinical and radiological evaluation (with initial CT scan); an impression with alginate was made and poured in a cast to form the study model; and clinical pictures were also taken. At a second pre-treatment, a silicon impression was made in order to obtain the final cast and inter-arch relationships were recorded. For the radiographic guide a removable prosthesis as a radiographic template was made. Six buccal and three palatal holes were made at different levels of the removable prosthesis and filled with radiopaque gutta-percha. A silicone interocclusal record was made to serve as a radiographic index during the first CT scan (Dental CT scanner, Promax, Planmeca, Helsinki, Finland) of the patient with the removable prosthesis acting as radiographic guide. A second CT scan of the removable prosthesis alone with the same orientation as in the mouth was also made. Once CT scan data were transferred to a computer, the 3D software planning was performed using the Procera Nobel Guide software v1.6 and v2.0 (Figs 1 to 3) (Nobel Biocare). The planning data were then sent to a manufacturing plant (Nobel Biocare, Göteborg, Sweden), and a surgical template with metallic cylinders guiding the implants in the same position as in the virtual planning was fabricated. At the laboratory a working cast was made as derived from the surgical template, and then mounted in an articulator to create an all-acrylic resin fixed complete denture.

One hour before surgery, patients received antibiotics (amoxicillin and calvulanic acid 500/125 or 875/125 mg, or diacetylmidemycin 900 mg [Momicine, Inibsa, Barcelona, Spain] for patients allergic to penicillin), ibuprofen 600 mg (Zambon, Barcelona, Spain) and were sedated with diazepam 5–10 mg (Roche, Madrid, Spain) if needed. Mouth rinses with 0.2% chlorhexidine were performed for 1 min prior to surgery. Local anaesthesia was administered using articaine 40 mg with epinephrine 0.01 mg/ml (Scandinibsa; Inibsa Laboratorios, Barcelona, Spain). The surgical template was placed using a surgical index and stabilised with three anchor pins. The implant surgery was performed following the manufacturer’s instructions (Figs 4 to 8).
In cases of insufficient keratinised mucosa, a 2-mm drill was used to indicate preparation of the implant site, the surgical template was removed and a small flap was elevated to secure at least 1 mm of keratinised mucosa around the implant. The surgical template was then fixed again, taking care not to injure the small flaps during the drilling procedure.

The ‘all-on-four’ protocol was used in both jaws except when ceramic rehabilitations were planned in maxillae with medium or poor bone quality (type III and IV). In these cases, two additional implants were placed. Two tilted implants were placed distally with prosthetic emergence at the second premolar or first molar for minimum distal extension. The other
four implants were placed in the anterior part of the jaw. The implant necks were positioned at the bone level crest.

After implant placement, to facilitate abutment seating, excess soft tissues were removed (Fig 9) with a punch (guided soft tissue punch 32Z2007.00, MDL, Delebio, Italy) or a round blade scalpel for microsurgery (mini scalpel blade 69 ref MB 69 Hu Friedy microblades, Hu-Friedy, Leimen, Germany). When a small flap was raised, it was repositioned with a polyglycolide resorbable suture (Perma Sharp™ Hu-Friedy Fast Absorbable Synthetic Sutures, suture C-3, 5-0, Hu-Friedy). The anterior straight abutments were then placed first (Multi-Unit; Nobel Biocare) followed by the posterior 30-degree angulated abutments, using a repositioning jig (Fig 10). Abutments were placed after the application of a chlorexidine 0.2% spray.

The prefabricated prosthesis was inserted immediately after surgery (Figs 11 to 13). In the case of the ‘all-on-four’, a posterior cylinder was not placed, to allow for adjustments to be made and a primary fitting to be obtained. For the ‘all-on-six’, when more than two cylinders were placed and stability could be observed, adjustments were performed in mouth. In case of lack of stability, an impression with multi-unit abutments with a duplicate of the transparent resin radiological template and copings for indirect impression were taken (impression coping bar closed tray multi-unit 29093, Nobel Biocare), using Impregum Soft (3M ESPE, Seefeld, Germany). The laboratory performed the required adjustments in the same session. In some cases, an anterior cylinder was released to change a straight multi-unit abutment to a 17-degree angulated abutment to obtain a better prosthetic emergence (this cannot be done by the virtual design of the software), followed by the adjustments of the pre-fabricated prosthesis.

For anterior implants, angulated and straight multi-unit abutments were set at 17 degrees and those for posterior implants at 30 degrees, and tightened to 10 Ncm. These abutment angulations were chosen to avoid vestibular emergence of the prosthetic screw access holes. Periapical radiographs were taken to check the correct seating of the abutments. The emergence positions of the screw access holes for posterior implants were normally at the level of the second premolar. Provisional prostheses were designed to hold a minimum of 10 teeth. In every case, soft splints were fabricated to avoid overloading. Occlusion was checked. Patients were recommended a soft diet regimen, and given oral hygiene instructions.

Post-surgery antibiotics (amoxicillin and clavulanic acid 500/125 or 875/125 mg, augmentin [GlaxoSmithKline, Madrid, Spain] or diacetylmidecamycin 900 mg [Inibsa], for patients allergic to penicillin) and analgesics (ibuprofen 600 mg once every 12 h and paracetamol 650 mg, [Gelocatil, Gelos, Barcelona, Spain] or metamizole 650 mg [Nolotil, Boehringer Ingelheim, Barcelona, Spain] once every 8 h) were prescribed for 1 week.

Follow-up visits were scheduled each week for the first month after surgery, and once a month thereafter up to the sixth month. Final prostheses were delivered between 6 and 12 months after surgery. Most final prosthesis frameworks were made in milled titanium prosthetic frameworks (Procera Implant Bridge, Nobel Biocare) and included 12 teeth, with a maximum of a one-unit cantilever.
A hard splint was delivered 2 weeks after the definitive prosthesis placement.

A strict maintenance protocol was adopted. The first follow-up visit was 1 week after the insertion of the final prosthesis and then after 1, 3 and 6 months: oral hygiene, occlusion, and soft tissues were checked and the hard splints were reviewed.

After that period, follow-up visits were made every 6 months. Panoramic and periapical radiographs were taken at provisional delivery the same day as the surgery, when inserting the final prosthesis, and at a minimum of 1 year of function of the final prosthesis (Fig 14).

The following outcome measures were assessed.

- Success of the prosthesis: the prosthetic reconstructions are stable and in good function and without complication in fabrication or removal.
- Implant success measured as individual implant stability in absence of pain, infection and radiolucency. A lack of mobility was recorded clinically when the straight and angulated multi-unit abutments were inserted with a torque of 35 Ncm and 15 Ncm, respectively, to make the final prosthesis.
- Any complications that occurred during the entire follow-up period (1 year after implant placement): mechanical complications (fracture or loosening of mechanical and prosthetic components), biological factors (such as pain or infection) and bone resorption, were assessed through both periapical and panoramic radiographs. Absence of functional (phonetics and chewing ability) and aesthetic complication factors.
- Radiographic evaluation, based on periapical radiographs obtained using the parallel technique with a film holder (Planmeca Oy, Helsinki, Finland) after abutment placement during surgery, and panoramic radiographs after the provisional prosthesis placement. The same procedure was carried out at the time of final prosthesis placement, and 1 year after loading. The reference point for reading the radiographs was the implant platform (the horizontal interface between the implant and the abutment). Marginal bone remodelling was defined as the difference in marginal bone level observed at delivery of the definitive prosthesis relative to the bone level at the time of surgery.
Clinical time to place implants and provisional prostheses were assessed.

Patient satisfaction with the treatment, and whether the new technique was considered worthwhile.

Results

All 30 patients were followed up to 1 year after loading. Regarding immediate loading, a total of 195 implants were placed in 30 patients. In total, four out of 195 immediately loaded implants (two Speedy Groovy in the maxilla and two MK III Groovy in the mandible) failed in three patients before placement of the final prosthesis. Out of three patients, only one patient was a smoker (although she reduced consumption 20 days prior to the surgery); the patient lost a tilted implant in the maxilla (position 25) after 4 months and it was replaced in position 26 after 4 days with an implant of the same length and width. The second patient lost a tilted implant in the mandible (position 45) after 4 months, and a replacement implant was placed in position 46 after 8 days. In the same patient, another implant failed in the maxilla (position 23) after 12 months, before placing the final prosthesis. This was an ‘all-on-six’ case, and at the patient’s request the implant was not replaced. The third patient lost a tilted implant in position 45 after 5 months. A new implant of the same length and a larger diameter was placed, and left unloaded. The replaced implants were left unloaded until the definitive prostheses were placed. The cumulative implant survival rate was 98% (98.5% in the maxilla and 97% in the mandible).

All implants were inserted with a torque of 35 Ncm. The majority of implants were engaged bicortically. Four small flaps had to be elevated in four patients because of insufficient keratinised mucosa width. In three patients, the surgical template fractured during surgery due to an implant that was inserted with a torque > 50 Ncm, or because there was insufficient acrylic around the metallic cylinders. This might explain the poor fit between the prosthesis and the implants when they were inserted, requiring some adjustment by releasing some cylinders when the provisional prosthesis did not fit onto the implants.

A total of 195 implants were loaded immediately, supporting 42 fixed provisional prostheses. In some cases, more cylinders than those recommended by the manufacturer were released to obtain an insertion and a passive adjustment without changing the maxillo-mandibular relationship. One cylinder was released because of fracture of the surgical template, and the others by changing from straight to 17-degree angulated abutments either for aesthetics or because abutments were too short. The cylinders were splinted in the mouth and the work was completed in the laboratory. In only one patient was an impression made because the prosthesis was unstable in the mouth after releasing three cylinders, and the prosthesis was adjusted in the laboratory.

The average surgical time ranged from 15 to 45 min. Adjustment time to insert these prostheses ranged from 60 to 150 min. The prostheses were placed a maximum of 3 h after surgery.

No post-surgery complications such as pain, inflammation or haematoma occurred. There were no phonetic, aesthetic or chewing ability problems.

Eight patients experienced fractures in their fixed provisional acrylic prostheses during the healing period, which were repaired in the clinic; these patients disregarded instructions to stay on a soft diet during the first months. The prostheses were repaired and instructions were given to the patients to minimise the overloading of their prostheses, insisting on the use of the soft splint. No other mechanical complications occurred.

Three patients had to be surgically debrided for peri-implant apical infection and received both topical (Perio Film®, Italmed, Florence, Italy) and systemic antibiotics (amoxicillin and calvulanic acid 500/125 or 875/125 mg, or augmentin or diacetylmidecamycin 900 mg for patients allergic to penicillin) and bone substitute (Bone bank, Transplant Services Foundation, Mejia Lequerica, Barcelona, Spain). The problems were successfully solved and it was observed radiographically that the periapical radiolucency at the apex of the implant disappeared. At 1 year, radiographic examination showed stable bone levels for all implants except for two implants that had bone loss up to the second thread. In some cases, the base of the tilted multi-unit abutment was left infrabony, and remodelled bone was observed up to the shoulder of the implant.
All prostheses were successful 1 year after loading. The new protocol described involved additional costs compared to conventional placement (such as new provisional prosthesis and double scanning). All patients were very satisfied with this technique, and said that it was worthwhile and they would undergo the same treatment again.

**Discussion**

No prosthesis failed. A 98% success rate for the implants is comparable to results of other studies for immediate loading protocols with computer-guided flapless surgery, which reported survival rates of 95%23 and 97.8%24. In a previous study, the ‘all-on-four’ and ‘all-on-six’ protocol with conventional flap surgery was performed: the survival rate was 96.7%13. Four loaded implants were lost in three patients, possibly for overloading because they did not follow the soft diet recommendations and were not careful with the use of the prosthesis. All patients were treated with a similar protocol despite the different degrees of bone resorption and bone quality. It is possible that implants were inserted with an apparent torque of 35 Ncm but that owing to friction between the components (Guided Implant Mount Bmk SystRP with Guided Sleeve of the surgical template) the actual torque at the implant was lower. All prostheses survived on the remaining three implants until the replacement implants were loaded.

The present computer-guided treatment protocol allowed the implant rehabilitation procedures to be simplified and shortened for both the patient and the clinical team. Immediate loading of flapless placed implants delivers benefits to the patients, especially when it comes to their social life and professional activities. The post-surgical period is more comfortable since patients have their fixed provisional acrylic prostheses during the healing period. In some cases, the maxillo-mandibular space was limited and the prostheses needed to be reinforced. Several patients also experienced fractures of their fixed provisional acrylic prostheses during the healing period. In one case, the procedure time was approximately 3 h because a new impression had to be taken to fit the provisional prosthesis onto the implants.

Clinical data about the application of the software planning program are limited14,16. One study14 reported that both surgery and prosthetic placement were performed within approximately 1 h; however, in the present study the average time to complete the procedure (adding surgery and placement of the provisional prosthesis time) was between 75 and 195 min, which is similar to that reported elsewhere16. In one case, the procedure time was approximately 3 h because a new impression had to be taken to fit the provisional prosthesis onto the implants.

The limitations of the present study include its retrospective design, the short follow-up period, the lack of an independent assessment, and the radiographic evaluation of marginal bone loss, which was very approximate. Prospective studies are needed to further evaluate the immediate function concept using flapless computer-guided implant surgery.

This protocol involves additional costs compared with conventional placement (such as a new provisional prosthesis and double scan). However, all patients said that the treatment had been worthwhile and that they would undergo the same treatment again.
Conclusions

The ‘all on four’ and ‘all on six’ protocols for rehabilitation of completely edentulous jaws with placement of immediate fixed prostheses through computer-guided flapless surgery could be an effective and predictable treatment, with the potential for great acceptance among patients, the clinical team and the laboratory. However, this technique could be sensitive to the experience of the surgeon and a learning curve is required.

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