original research article

UPPER JAW IMPLANT RESTORATION ON SIX IM-PLANTS WITH FLAPLESS GUIDED TEMPLATE SURGERY AND IMMEDIATE LOADINGS: 5 YEARS RESULTS OF PROSPECTIVE CASE SERIES

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SUMMARY

Background. To evaluate the clinical and radiographic outcomes of upper jaws fixed cross-arches prosthesis on 6 implants installed with 3D software planning, flapless guided surgery, and immediate loading.

Methods. Healthy patients aged 18 years or older at the time of implant placement, in need to be re-stored with an immediately loaded implant-supported screw-retained cross-arch fixed dental prosthesis in the maxilla were included in the present study and treated using computer-assisted template-guided surgery. In order to be immediately loaded implant sites were prepared and an insertion torque ranging between 35-45 Ncm was applied. A prefabricated screw-retained temporary prosthesis was delivered the day of the surgery. The evaluated outcomes were: implant cumulative survival rate (CSR), prosthe-sis survival, any technical and biologic complications, and peri-implant marginal bone level changes, probing pocket depth (PPD), and bleeding on probing (BOP).

Results. Twenty-two patients (16 females and 6 males) with a mean age of 63.4 years received 132 im-plants to support 22 cross-arch screw-retained fixed dental prostheses. At the end of the study, no pa-tients dropped out. Three implants failed in 3 patients resulting in a CSR of 97.77%. No final prosthe-sis failed resulting in a CSR of 100%. No major biological or prosthesis complications were recorded. After an initial mean marginal bone loss of 1.10 ± 0.38 mm, (95% CI 0.95 to 1.25 mm), at 12 months follow-up, slightly marginal bone loss was reported with time, resulting in a mean marginal bone loss of 1.58 ± 0.41 mm, (95% CI 1.41 to 1.75 mm), at the 5-year follow-up. At 60 months follow-up mean PPD value was 2.44\pm0.49 mm, (95% CI 2.24 to 2.64 mm), mean BOP value was 1.34 ± 0.87 , (95% CI 0.98 to 1.70 mm).

Conclusion. Within the limitations of this study it can be concluded that computer guided surgery and immediate loading on 6 implants seem to represent a viable option for the immediate fix rehabilitations of completely edentulous upper jaws.

Key words: computer guided surgery, immediate loading, template based surgery.

Introduction

The standard surgical protocol for guided implant placement comprises a diagnostic step (clinical and radiographic examination), a planning step, and a surgical step, where the surgeon implements what was planned (1). In the last decade, treatment planning involving implant placement has changed from a surgical approach, focused on bone availability, to prosthetically driven planning using a computerguided, template-assisted approach (1, 2). The growing interest in minimally invasive surgery, together with the possibility of fitting prostheses with immediate function, have led to the devel-



opment of software and digital workflows allowing for the planning and manufacturing of a surgical guide and provisional prosthesis that can be inserted immediately after the implant surgery step (2-5). Therefore, implant position can be optimized according to the esthetic and functional needs, and an interim prosthesis can be manufactured prior to the surgical procedure, allowing immediate function (5-12). The typical dental implant surgical approach, that was introduced in the early 1980s requires two steps (13), and the use of a removable bridge or denture during the healing period. In the 1990s (14) it was first shown that implants could be placed and restored in a single visit: this procedure, known as immediate loading, needed a full day of coordinated surgical, restorative, and dental laboratory interaction. Advancements in computerized tomography (CT) scans (15), coupled with computer-assisted treatment planning (16), and a double CT scan approach (10), allowed for the virtual planning of placement of implants in 3-dimensional (3D) orientation relative to the bone. soft tissue, and final planned prosthesis. In 2002, the concept of software planning and surgically guided techniques combined with immediate loading was clinically introduced in Leuven, Belgium (17). These early treatments were limited to the edentulous maxilla and required a full-thickness mucoperiosteal flap. Later, the procedure was refined to include flapless implant placement through virtual planning by producing a stereolithographic surgical template incorporating precision titanium drilling sleeves (4). The limited scientific evidence available reveals that regarding implant survival rates, guided surgery has not obvious differences compared with the conventional protocols (18). However, biologic and technical complications as well as specific procedurerelated adverse events during guided implant placement have been reported (5). According to D'haese et al. (19) most frequently, surgical and mechanical complications are recognized to be specifically associated with computer-guided,

template-assisted surgery, including but not limited to misfit of the surgical guide, fractures of the complete acrylic denture, and misfit of the suprastructure (19). However, excellent clinical results were also reported by using this technique (5-8). When restoring edentolous jaws most used approaches are the all on four or all on six approaches (8). Tallarico et al. didn't find any differences in a RCT where comparing these two approaches (8). Anyway, only few studies have analyzed the clinical and radiological outcome of upper jaw cross-cross-arches on 6 implants installed with guided templates and immediate loaded (2). The aim of this prospective case series study is to evaluate the clinical and radiographic outcomes of upper jaws fixed cross-arches prosthesis on 6 implants installed with 3D software planning, flapless guided surgery, and immediate loading. This study followed the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines (20).

Materials and methods

This study was designed as a prospective case series study in which clinical and radiological data analysis was carried out on consecutively treated private patients to be prosthetically restored with fixed full arches upper jaw prosthesis. The investigation was conducted according to the principles embodied in the Helsinki Declaration of 2008. At the preliminary visit all patients were duly informed on the nature of the study and an informed consent was signed by every patient.

Patients of any race and gender, edentulous in the upper jaw or with hopeless teeth in need to be restored with full arches prosthesis, sufficient bone volume to insert 6 implants, and sufficient keratinized tissue of at least 5 mm around the planned implant position, were included in the study if they were at least 18 years old and in good gen-

Sweden), two CT scans were performed: one

with the patient wearing the radiographic guide

eral health, physically and psychologically able to undergo conventional implant surgery and restorative procedures (ASA-1, ASA-2). Exclusion criteria were: presence of systemic diseases (i.e. hematological disease, uncontrolled diabetes, serious coagulopathies and diseases of the immune system); irradiation to the head or neck region within 12 months before surgery; severe bruxism or clenching habits; pregnancy; poor oral hygiene; poor motivation to return for scheduled follow-up visits. The included patients were treated in the same dental office, by surgeons and prosthodontists with considerable clinical expertise in immediate loading procedures. According to the above criteria patients were consecutively enrolled and treated with six implants and an immediately loaded implant supported fixed full prosthesis, following the 3D software treatment planning, according to a guided implant protocol (Nobel Guide/Clinician Nobel Biocare AB, Goteborg, Sweden).

For all cases, the following surgical and prosthetic protocol was followed. The patients were subjected to a clinical evaluation, and a medical history was taken. Informed consent was collected. Preliminary radiographic screening was performed using panoramic orthopantomograph. A careful clinical examination of the patients was performed assessing jaw sizes and relationships, bone volume and occlusal relationships. Eligible patients received oral hygiene instructions, and impressions and baseline photographs of their dentition were taken. Registrations with a facial bow were also taken for aesthetic/functional evaluation. After the diagnostic phase, for each patient, the teeth to be removed and the implants to be inserted was determined. From each impression, a removable prosthesis, (used as radiographic guide) was customized according to the aesthetic and functional evaluations. Guided flapless implant insertion was planned 3-4 months after teeth removal. In accordance with the NobelGuide/Nobel Clinician. TM data acquisition protocol (Nobel Biocare, Gothenburg,

as well as the radiographic index, the other with the radiological template alone. CT scan data were transferred to the software program 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. The software planning data were sent to the manufacturer, (Nobel Biocare, Gothenburg Sweden), where a surgical template with hollow metallic sleeves was produced to guide the implants according to the virtually planned position. Based on the surgical guide and the cast model obtained, metal-acrylic resin screw-retained provisional prostheses were prefabricated. The surgical procedure was performed under local anesthesia with articaine chlorhydrate plus 1:100,000 adrenaline (Pierrel S.p.A., Milan, Italy). All patients were given diazepam (Valium, 10 mg, Roche US) as a sedative agent before surgery. Antibiotics (amoxicillin 875 mg and clavulanic acid 125 mg (GlaxoSmithKline S.p.A., Verona, Italy) were given 1 h before surgery and twice a day for 6 days thereafter. An anti-inflammatory drug, (ketoprofen 80 mg Dompe' S.p.A., Milan, Italy), was administered twice a day for 4 days postoperatively. An antacid agent (omneprazole 20 mg, Pensa Pharma S.p.A., Milan, Italy) was administered on the day of surgery and once daily for 6 days postoperatively. Each patient rinsed with chlorhexidine gluconate (0.2%) for 1 min before the intervention (Curasept, Curaden healthcare srl, Saronno, Varese, Italy). Surgical templates were then placed intra-orally in the correct position and in relation to the opposing arch (a silicone occlusal index was used), and then fixed with three or more anchor pins. Considerable care was taken when placing the surgical template. After correct placement and stabilization of the surgical template, flapless implant surgery was performed in accordance with the drilling protocol for the type of implant used, (NobelRe-



place Tapered Groovy, Nobel Biocare, Gothenburg. Sweden) implants were placed with a preset insertion torque of 35 to 45 Ncm. The implant length ranged from 8 to 13 mm and the implant diameter was 3.5 and 4.3. A total of 128 out of 132 implants were immediately loaded with the prefabricated screw-retained provisional prosthesis while three remaining implants placed with an insertion torque lesser than 35 Ncm were delayed loaded. When needed, minor adjustments of provisional restorations were made to correct occlusion. 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 h postoperatively. Chlorhexidine gluconate mouthwash (0.2%) was prescribed for 1 min twice a day for 2 weeks post-surgery. The patients were instructed on oral hygiene, and they returned every 3 months for a maintenance appointment. After 6 months, the prostheses were removed and the implants were individually tested for stability. The definitive prosthetic restorations, either metal as the framework and resin as aesthetic material (17 ridges) or Implant Bridge Zirconia ceramic (5 ridges), were then inserted. After final prosthesis delivery patients were checked every six months up to 5 years.

Primary outcome measures were:

Implant/prosthesis failure. Removal of implants dictated by implant mobility, progressive marginal bone loss, infection, or implant fracture. The stability of individual implants was measured by the prosthodontist at the time of temporary and definitive prosthesis delivery (6 and 12 months after implant placement, respectively) by applying 35 Ncm of removal torque. 60 months after implant placement, im-

plant stability was tested manually by the same prosthodontist with two dental mirror handles.

• Prosthetic complications, such as fractures or chipping of the provisional or definitive ceramic crown, abutment mobility and biological complications, such as wound or implant infection, mucositis, abscesses, or peri-implantitis, were recorded.

Secondary outcome measures

- Peri-implant marginal bone loss: the distance from the most coronal margin of the implant collar and the most coronal point of bone-toimplant contact, evaluated on intraoral digital radiographs taken with the paralleling technique using a film-holder (Rinn XCP, Dentsply, Elgin, IL, USA) at implant placement, initial loading, definitive restoration delivery (12 months after), and at 60 months. The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads. All readable radiographs were displayed in an image analysis program (DFW2.8 for windows, Soredex) on a 24inch LCD screen (iMac, Apple, Cupertino, CA, USA). The software was calibrated for every single image using the known distance of two adjacent threads. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.01 mm and averaged at patient level.
- Soft Tissue Parameters: probing pocket depth (PPD) and bleeding on probing (BOP) were measured by a blinded operator not previously involved in the present study (AD), using a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing, Chicago, IL, USA) at definitive restoration delivery and at 60 months. Three vestibular and three lingual measurements were collected for each implant, and averaged at patient level.

Statistical analysis

A priori sample size was not calculated. Data were collected in sheets, (Excel, Microsoft, Redmond, WA, USA), at baseline, and 12, 60 months after implant loading. Data analysis was carried out according to a pre-established analysis plan. A clinician (MT) with expertise in dentistry analyzed the data using SPSS for Windows release 18.0 (SPSS, Chicago, IL, USA). Descriptive analysis was performed for numeric parameters using means \pm standard deviations (95% confidence interval, CI). The patient was the statistical unit of the analyses.

Results

Twenty-two patients were enrolled and treated from April 2010 to December 2013 (6 males and 16 females), with a mean age of 64.4 (range, 38-71) and 22 jaws were restored. No patient dropped out of the study and the follow-up was at least 60 months after implant insertion for all cases. No deviations from the protocol occurred. A total of 132 implants were placed, (NobelReplace Tapered Groovy, Nobel Biocare, Gothenburg, Sweden), 128 of them with an insertion torque between 35-45 Ncm, and were immediately loaded while four fixtures were delayed loaded. Three out of 132 implants were lost in 3 patients, 6 months after implant insertion. No other implants failed in the remaining part of the study accounting for a CSR of 97.77% Lost implants were not replaced. No Prosthesis failures were recorded: all final prosthetic reconstructions were stable and in good function after 60 months.

No major biological complications were recorded. Two patients had peri-implant mucosal inflammation with BOP after 6 months. Improved oral hygiene reduced the peri-implant inflammation. No major mechanical complications occurred. Five provisional acrylic bridges fractured 2-4 months after immediate loading and were repaired. Two zirconia-ceramic implant bridges had ceramic chipping at 10 and 11 months after loading, which were easily repaired. Five resin titanium bridges experienced fracture of the acrylic resin after 12, 24, 36, 45, 47 months and were repaired by the dental technician.

The average marginal bone remodeling from baseline to 12 months follow up was 1.10 ± 0.38 mm ,(95% CI 0.95 to 1.25 mm) at 60 months follow-up was 1.58 ± 0.41 mm, (95% CI 1.41 to 1.75 mm) (Table 1).

After 12 months mean PPD value was $2.63\pm0,59$ mm, (95% CI 2.39 to 2.87 mm), at 60 months, mean PPD value was 2.44 ± 0.49 mm, (95% CI 2.24 to 2.64 mm) (Table 2). After 12 months mean BOP value was 1.55 ± 0.76 , (95% CI 1.24 to 1.86 mm) at 60 months mean BOP value was 1.34 ± 0.87 , (95% CI 0.98 to 1.70 mm) (Table 3).

Discussion

The present prospective case series study was designed to evaluate the 5-year clinical and radiographic outcomes of 6 implants installed on upper jaws with flapless computer-guided template-assisted implant placement and immediate loading of screw- retained implant bridges. Because it was designed as a single cohort prospective case series study, its primary limitation was the lack of a control group. The second limitation is the relative low number of patients due to the fact that a priori sample size calculation was not performed.

The results of the present study are in agreement with previously published works on immediate loading of edentulous maxilla and mandible with fixed complete denture prostheses (8). Correct diagnosis and accurate implant planning are key factors for success in implant rehabilitation, specially for better plan the ideal implant position (7). The use of advanced 3D software planning,

Table 1 - Peri-implant mean marginal bone remodel.				
Marginal bone remodeling				
	Mean±SD	95% CI		
12 months	1.10 ± 0.38	0.95 - 1.25		
60 months	1.58 ± 0.41	1.41-1.75		
*Values represent mean ± SD (patients n = 22).				

Table 2 - Mean PPD values in mm.				
Pocket Probing Depth (PPD)				
	Mean±SD	95% CI		
12 months	2.63 ± 0.59	2.39 - 2.87		
60 months	2.44 ± 0.49	2.24 -1.2.64		
*Values represent mean ± SD (patients n = 22).				

Table 3 - Mean BoP values.			
Bleeding on Probing (BOP)			
	Mean±SD	95% CI	
12 months	1.55 ± 0.76	1.24 - 1.86	
60 months	1.34 ± 0.87	0.98 -1.70	
*Values represent mean \pm SD (patients n = 22).			

by using converted CT scans, reduces the risk of damaging nearby vital structures and allows for more precise planning than conventional CT scans (21). According to these concepts, computer-guided minimally invasive implant treatment protocols, have changed the way of approaching edentulous patients (2, 3, 22). In fact, the use of guided surgery could reduce the risk of damaging anatomical structures while exploiting the residual bone volume, also allows a sensible reduction of surgery time, while delivering immediate implant supported temporary bridges (3, 5, 23). In this article all cases used a full arch immediate loading technique with temporary bridge, avoiding a direct definitive bridge

delivery. In fact, deviation of the virtual plan of few degrees can prevent a perfect passive fit of the bridge (19). To overcome this problem for immediate loading, we always use a screw-retained metal-acrylic temporary bridge and a presumed passive fit it is obtained directly in the oral cavity using resin to connect the temporary cylinder to the metal framework avoiding the of multi-unit abutment. The final use CAD/CAM customized implant bridge is directly connected to the implant neck and the passive fit of the framework (titanium or zirconia bridge) is clinically evaluated before final prosthesis delivery (7). If a sufficient amount of keratinized gingiva is present, flapless implant placement delivers several advantages to the patient: minimal swelling, pain and discomfort, elimination of a second surgical procedure, maintaining the soft tissue architecture, and leaving the periosteum intact on buccal and lingual aspect of the ridge which, maintains a better blood supply and thus could reduce the bone resorption (2, 9, 24). On the other hand, flapless guided surgery presents increased risks compared to open surgical approaches due to the inability of the surgeon to verify the accuracy of the guide intra-operatively and to compare the clinical implant position with the virtual planned position (2). For this reason, guided flapless surgery requires greater surgical experience in implant placement and, in particular in guided surgery (2, 7), but after a correct learning curve, this kind of procedures are extremely precise with several advantages such as less morbidity with a traditional approach (22). In the present study the overall 5-year mean MBL was 1.58±0.41 mm, demonstrates well maintained marginal bone level in the medium-term perspective. Nevertheless, the relative low number of implants could not give a really strong evidence, moreover these results could be generalized only to upper jaw restorations. Little evidence from RCT or systematic reviews is present on the preferred or best number of implants to be

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used for the support of a fixed complete dental prosthesis in the edentulous maxilla or mandible, and not consensus has been reached (25-29-32). Recently Tallarico et al. didn't find any differences when comparing upper jaw cross arches prosthesis supported by 4 or 6 implants (22), while Meloni et al., found high survival rate and stable marginal bone remodeling in a retrospective study of upper jaw cross-crossarches prosthesis supported by 6 implants installed with computer-guided template-assisted surgery (2). This study seem to better support the all on six concept when restoring edentulous upper jaws.

Conclusion

Within the limitations of this case series study, mainly the relatively low number of patients treated it can be, computer guided surgery and immediate loading of 6 implants inserted in edentulous maxillas seem to represent a viable option.

Acknowledgements

We would like to acknowledge Andrea Cialente for his technical support.

Conflicts of interest

All the Authors declare that they have no competing interests.

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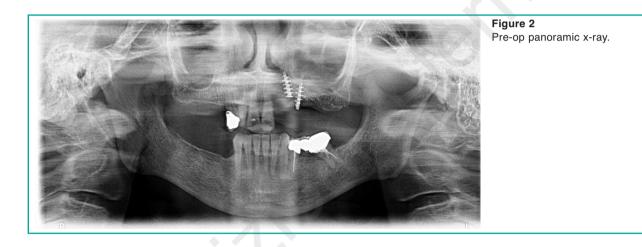
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Figure 1 Pre-op pictures frontal view.



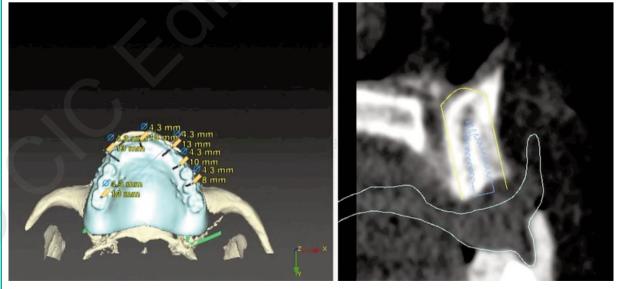


Figure 3 3D virtual planning.





Figure 4 Flapless computer guided implant installation.



Figure 6 Final prosthesis delivery frontal view.



Figure 5 Immediate loading with screw retained metal-resin implant bridge.