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Guided implant surgery after free-flap reconstruction: Four-year results from a prospective clinical trial

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ABSTRACT

Aim: The aim of this prospective clinical study is to assess the 4-year outcomes of implant-supported restorations performed using a computer-guided template-assisted flapless implant surgery approach in patients reconstructed with fibula or iliac crest free flaps.

Materials and methods: Twelve jaws in 10 patients were reconstructed with osteomyocutaneous free flap after tumour resection or gunshot wound, after complete healing computer-assisted template-based flapless implant placement, based on prosthetic and aesthetic analysis, was performed using a customized protocol. Treatment success was evaluated using the following parameters: survival of implants/prostheses, prosthetic and biologic complications, marginal bone remodelling, soft tissue parameters and patient satisfaction.

Results: A total of 56 implants were placed; the implants ranged between 8 and 16 mm in length and were either 3.5, 4.3 or 5 mm wide. All the patients have reached the 4-year follow-up. Three implants were lost accounting for an overall implant survival rate of 94.6%. No prosthesis were lost. Some complications were recorded. Four years after loading the mean marginal bone loss was 1.43 ± 0.49 mm at the palatal/lingual site and 1.48 ± 0.46 mm at the vestibular site. All the patients showed healthy soft tissues with stable probing depth (4 .93 ± 0.75%) and successful bleeding on probing values (12 ± 5.8%); 90% of patients were satisfied of the treatment at the 4-year follow-up.

Conclusions: Computer-guided template-assisted flapless implant surgery seems to be a viable option for patients undergoing reconstruction with free flaps after tumour resection or gunshot trauma, although many challenges remain. A high degree of patient satisfactorily was reported.

1. Introduction

Bone continuity defects following tumour ablation, osteoradionecrosis, or other causes may lead to facial contour disfigurement, large oronasal and oro-antral communications, impaired speech, chewing, swallowing, saliva retention, and other problems. Fibular and iliac-crest free flaps are highly reliable in the reconstruction of mandibular and maxillary large bone defects (Hidalgo, 1989) and are used as both osseomuscular and osteomyocutaneous flaps. Moreover, they allow the simultaneous restoration of bone continuity and both mucosal (cheek, palate, floor of the mouth, etc.) and cutaneous (chin, cheek, etc.) soft tissue deficiencies (Hidalgo, 1989; Riaz and Warraich, 2010).

Patients with defects of the oral cavity often present with both complete or partial edentulism and defects of the alveolar ridge, which can lead to significant impairment of masticatory function. With the use of free flaps as a microvascular reconstructive option, dental prosthetic rehabilitation is possible even if the accurate placement of a prosthetic or an aesthetic implant poses challenges (Hayter and Cawood, 1996; Chiapasco et al., 2006). Examples of these challenges include insufficient bone height, altered soft

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tissue, and xerostomia that reduces the vacuum effect between dentures and underlying immobile soft tissue (Meloni et al., 2012). Additionally, an irradiated mucosa is frequently unable to tolerate the friction created by an acrylic base (Meloni et al., 2012). Although the use of fixed/removable prostheses retained by a system attached to the implant is an option, the reconstructed mandible cannot confer adequate mechanical retention for the prosthesis during mastication (Chiapasco et al., 2006). Therefore, an implant-supported fixed dental prosthesis may offer the best solution for dental rehabilitation with free flaps.

Implant-based dental restorations in patients in whom reconstruction was performed with a fibular flap have several demonstrated benefits (Jaquiéry et al., 2004; Carbiner et al., 2012), such as sufficient stabilisation of the prosthesis, even in patients with marked irregularities of the hard- and soft tissue anatomy. Furthermore, this approach compensates for small local soft tissue deficiencies and thus, by supporting the lip profile, contributes to an improved aesthetic result. Compared with conventional dentures, implant-based dental restorations improve functional aspects such as chewing, swallowing, and speaking, in addition to reducing the load on the soft tissues and the risk of mechanical irritation, with consequent ulceration and discomfort (Chiapasco et al., 2000; Meloni et al., 2012).

However, complications, such as imprecise implant installation and compromised aesthetics and function, may arise with implant-based rehabilitation in patients with free fibular flap reconstructions (De Riu et al., 2012). These complications can be avoided or reduced by using computer-assisted template-based flapless implant surgery. This procedure allows for accurate flapless implant placement using an acrylic surgical guide generated from a preoperative computed tomography scan (Meloni et al., 2010; Pozzi et al., 2014). The implant position is planned preoperatively on a virtual model of the reconstructed mandible with reference to the planned prosthesis. The virtual planning of the implant position and the actual placement using a computer-generated surgical guide can be carried out with a high degree of precision, even through a very thick layer of soft tissues, while avoiding obstacles in the reconstructed bone, such as screws or osteotomy sites (Meloni et al., 2012).

An interim 1-year report from the study conducted by Meloni et al. (2012) showed that the computer-guided template-assisted flapless surgery approach may be a reliable treatment option for patients with fibular free-flap reconstructions. Here, we present the 4-year outcome of a prospective clinical study. This report was written in accordance with the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guidelines.

2. Material and methods

This research was designed as a prospective clinical study and was conducted at the Maxillofacial Surgery Unit of the University Hospital of Sassari between January 2009 and February 2014. Any patients who had undergone reconstruction with fibula or iliac crest free flaps (Figs. 1–3), who required dental implants supported a prosthetic restoration, who were aged 18 years or older, and who were able to sign an informed consent form were enrolled and treated consecutively. This was provided that they fulfilled the inclusion criteria and gave their written consent to take part in this study. All procedures were conducted in accordance with the principles embodied in the Declaration of Helsinki of 1975 for biomedical research involving human subjects, as revised in 2000, and with Department Research Board approval. One clinician (S.M.M.), who had considerable clinical expertise in immediate loading procedures, performed all of the surgical and prosthetic procedures, and one dental laboratory manufactured all of the restorations. Patients were not admitted in the study if any of the following exclusion criteria were present: general contraindications to implant surgery; irradiation in the head and neck area less than 1 year before implantation; untreated periodontitis; signs or symptoms of cancer recurrence; poor oral hygiene and motivation; uncontrolled diabetes; alcohol abuse; psychiatric problems or unrealistic expectations; active infection or severe inflammation in the area intended for implant placement; and inability to adhere to the strict follow-up.

Patients were informed about the clinical procedures, materials to be used, benefits, potential risks and complications, as well as any follow-up evaluations required for the clinical study. The medical history of the enrolled patients was collected and study models were made. Once informed consent was obtained, initial photographs and preoperative radiographs (panoramic X-rays, cone beam computed tomography (CBCT)), were obtained for initial screening and evaluation.

2.1. Clinical procedures

Patients were evaluated clinically but no data were recorded for statistical analysis. Study models were mounted in a fully adjustable articulator (KaVo Protar evo 7, KaVo Dental, Biberach, Germany) using a face bow, and a diagnostic wax modelled according to functional and aesthetic parameters was made. Finally, a radiological template was made. Before implant placement, all patients underwent a CBCT scan according to a double-scan protocol. Six to eight radiopaque markers (Hygenic Temporary Dental Stopping; Coltène/Whaledent, Cuyahoga Falls, OH, USA), measuring 1.5 mm in diameter, were placed in the lingual and palatal flanges of the radiological template. A centric occlusion rigid vinyl polysiloxane index (Exa-bite II NDS, GC America, Alsip, IL, USA) was made to stabilise the radiological template against the opposing dentition during the CBCT scan. An interocclusal record was made as a radiographic index with a rigid vinyl polysiloxane index (Access Blue; Centrix, Shelton, CT, USA) at the patient's centric relation and occlusal vertical dimension. Two separate scans were made: one of the patient wearing the radiographic guide and the silicon index, and the other for the radiographic guide alone. The Digital Imaging and Communication in Medicine (DICOM) data of the two sets of scans were transferred to a three-dimensional software planning program (NobelGuide, Nobel Biocare) and matched to each other. The calibration of the software was performed every 6 months according to the guidelines of the manufacturer. The software was used to place the virtual implants with positions and angulations allowing an optimal prosthetic emergence profile.

Final positions of the implants were planned into the ideal functional and aesthetic position according to the diagnostic wax, avoiding screws and the plate in the fibular flap. After careful inspection and final verification, the virtual plan was approved. Planning data for the patients who had to undergo operation using template-assisted surgery were sent to a milling centre located in Sweden (NobelProcera, Nobel Biocare), where stereolithographic surgical templates with hollow metallic cylinders to guide implant placement in the virtually planned position were fabricated. Then, based on the surgical guide and the model obtained with the planned positions of the implants, a metal and acrylic resin provisional prosthesis was manufactured. Patients received professional oral hygiene before the surgery and were instructed to rinse with a chlorhexidine mouthwash 0.2% for 1 min, twice a day, starting 2 days before the intervention and thereafter for 2 weeks. On the day of surgery, a single dose of antibiotic (2 g of amoxicillin and clavulanic acid or clindamycin 600 mg if the patient was allergic to penicillin) was administered prophylactically 1 h prior to surgery and continued for 6 days (1 g amoxicillin and clavulanic acid or