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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

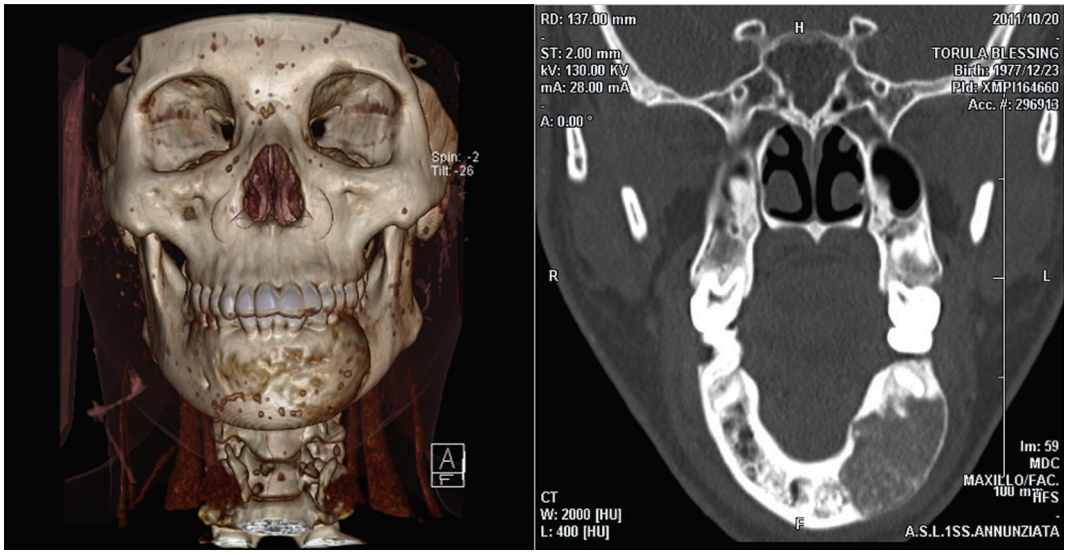

Fig. 1. Computed tomogram before tumour ablation (aggressive osteoblastoma).

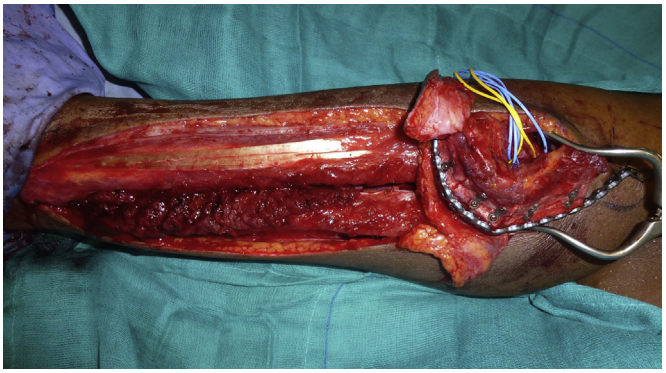

Fig. 2. Double barrel fibula free flap. Intraoperative view.

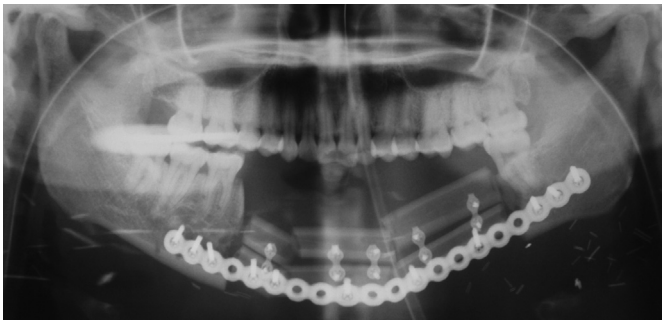

Fig. 3. Panoramic X-ray after mandible reconstruction with double barrel free flap.

300 mg clindamycin twice a day) after surgery. Prior to the start of surgery, patients rinsed with chlorhexidine 0.2% mouthwash for 1 min. Local anaesthesia was induced by using a 4% articaine solution with epinephrine 1:100.000 (Ubistein; 3M Italy SpA, Milan, Italy). All of the patients were sedated with diazepam (Valium 10 mg, Roche) preoperatively.

The surgical template was positioned using a surgical index fitted to the opposing arch and fixed with three to five anchor pins. NobelReplace Tapered Groovy implants (Nobel Biocare) were placed in the planned anatomic sites according to one-stage surgical procedure using a flapless approach. The drill sequence was chosen according to the manufacturer's instructions in relation to the bone quality. However, in the presence of poor-quality bone, the implant sites were under-prepared. The implant insertion torque values were measured and recorded during surgery using a surgical unit (OsseoCare Pro Drill Motor Set, Nobel Biocare) (Figs. 4 and 5). Before or immediately after implant installation, patients underwent soft tissue management to augment the attached gingiva around implants and to improve function (Fig. 6).

Implants were immediately loaded with a screw-retained prefabricated prosthesis if the insertion torque was ≥35 Ncm (Figs. 7 and 8). Viceversa, a two-stage protocol was used and the implants were loaded 4 months after implant placement, according to a conventional loading protocol. Anti-inflammatory (ketoprofen 80 mg twice daily) therapy was prescribed for 4 days postoperatively as an analgesic. Omeprazole 20 mg was given on the day of operation and then daily for 6 days. Chlorhexidine gluconate mouthwash 0.2% was prescribed for 1 min twice daily for 4 weeks.

All patients were enrolled in an implant maintenance program. The patients received oral hygiene instructions, and clinical examinations were performed weekly for 3 months, and then monthly. Clinical follow-up was scheduled at 3, 6, and 12 months after surgery, and the annually up to 4 years.

2.2. Outcome measures

The primary outcome measures are described below.

2.2.1. Success and survival criteria

The success and survival criteria used in this study were modifications of the success criteria suggested by Van Steenberghe (Van Steenberghe, 1997), who state that a “successful implant” is achieved when the following criteria are fully fulfilled: does not cause allergic, toxic, or gross infectious reactions either locally or systematically; offers anchorage to a functional prosthesis; does not show any signs of fracture or bending; does not show any mobility, when individually tested by tapping or rocking with a hand instrument; and does not show any signs of radiolucency on an intraoral radiograph using a paralleling technique strictly perpendicular to the implant–bone interface.

2.2.2. Implant failure

Implants had to be removed at implant insertion due to lack of stability, implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, or any technical complications (e.g., implant fracture) rendering the implants unusable. The stability of individual implants was assessed at delivery of definitive prostheses by tightening the abutment screw with a torque of 20 Ncm, and at 12 months applying at implant level an unscrewing torque of 20 Ncm and at 24 and 48 months by the percussion test.

Complications comprised any biologic (pain, swelling, suppuration, etc.) and/or technical complication (fracture of the framework and/or the veneering material, screw loosening, etc.).

The secondary outcome measures are discussed below.

2.2.3. CBCT peri-implant marginal bone level changes

In both groups, CBCT scans were performed at baseline 12, 24, and 48 months. The DICOM data were exported and opened using OnDemand3D software version 1.0.9.3223 (Cybermed Inc., Irvine, CA, USA) to perform all measurements. A superimposition of the pre- and postoperative DICOM data was performed based on unchanged anatomical areas (e.g., the cranial base) and manually checked for a complete match by using the Fusion adjunctive module (Cybermed Inc.). Marginal bone level was defined as the distance between the top of the implant head shoulder and the most coronal level of direct bone-to-implant contact. Mesial and distal values, recorded both palatal/lingual or vestibular, were averaged for each implant. Marginal bone remodelling was calculated as the difference between the reading at the examination and the baseline value. An independent radiologist performed the bone-height measurements.

2.2.4. Peri-implant mucosal response

Probing pocket depth (PPD) and bleeding-on-probing (BOP) were measured by a blinded operator with a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing, Chicago, IL, USA) at 6 and 12 months, 24, 48 months. Three vestibular and three lingual values were collected for each implant and averaged at patient level. An independent hygienist performed all of the periodontal measurements.

Each patient was asked whether he/she experienced any functional improvements with the fixed prostheses; he/she was satisfied overall; and he/she would undergo the same procedures again. The questionnaires were collected and analysed by an independent, blinded outcome assessor at 1-, 2- and 4-year follow-ups.

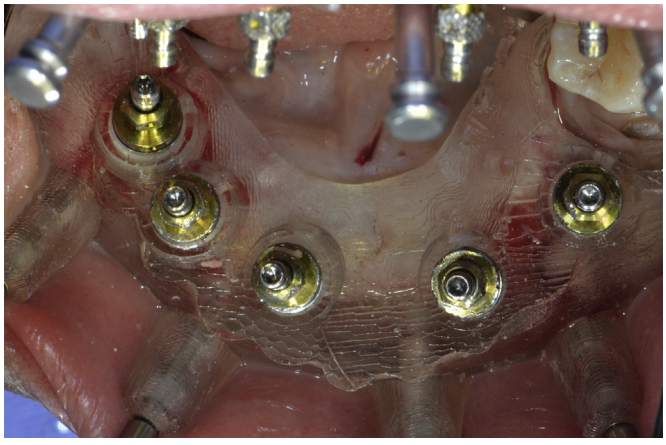

Fig. 4. Guided implants installations. Occlusal view.

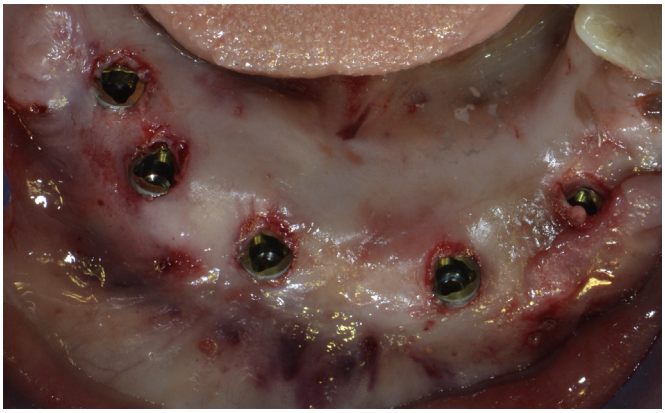

Fig. 5. Implants after flapless installation. Occlusal view.

2.3. Statistical analysis

The statistical analysis was performed for numeric parameters such as marginal bone level and soft tissue parameters using SPSS for Mac OS X version 22.0 (SPSS, Chicago, IL, USA). A descriptive analysis was performed using mean and standard deviation (SD). The patient was used as the statistical unit of the analysis.

3. Results

Fifteen patients were considered eligible, but five patients refused to adhere to the strict clinical and radiological follow-up and were not enrolled. Thus, 10 patients (6 male, 4 female), mean age 52.3 years with 12 reconstructed ridges were considered eligible and treated (Table 1). Four patients underwent irradiation and implants were installed 2 years after the end of the radiotherapy. Eleven reconstructions were performed with fibula free flaps and one with iliac crest free flaps. Five reconstructions were mandibular arches, 1 was a maxillary arch, 4 were partial mandible arches, and 2 were partial maxillary arches. A total of 56 implants (NobelReplace Tapered Groovy; Nobel Biocare), ranged between 8 and 16 mm length, and 3.5–5 mm in wide, were installed: 51 were installed in the reconstructed ridge and 5 in native bone; all implants installed in the reconstructed ridge emerged from microvascular soft tissue (skin and muscle). All implants were inserted according to the pre-planned template position; no changes of the implant position were needed. All implants were in the right vertical position after removal of the guide. In any case, implant threads were exposed in the oral cavity after implant installation. All implants were inserted according to a computer-guided flapless approach and in no case was it necessary to raise a flap. All patients reached at least 4 years of follow-up. No drop-outs occurred during the entire follow-up. Three implants placed in three different patients were lost before delivery of the final prosthesis. The overall implant survival rate was 94.6% (Table 2). All of the failed implants were removed. These implants were not replaced, and all of the patients were rehabilitated with the remaining implants. No prosthesis failed at the 4-year follow-up, yielding in a prostheses survival rate of 100%.

Postoperative recovery after implant placement surgery was uneventful for all patients, but a transient discomfort was reported by one patient during the first week that resolved spontaneously within 10 days.

In six patients, the dental implants met the required insertion torque of at least 35 Ncm for immediate function, and the prefabricated prostheses were placed immediately, although minor

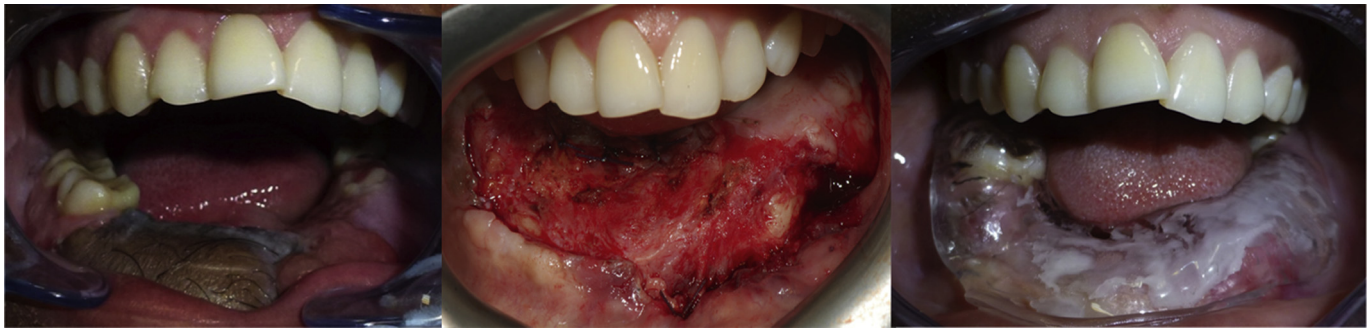

Fig. 6. Soft tissue management with customized acrylic template.

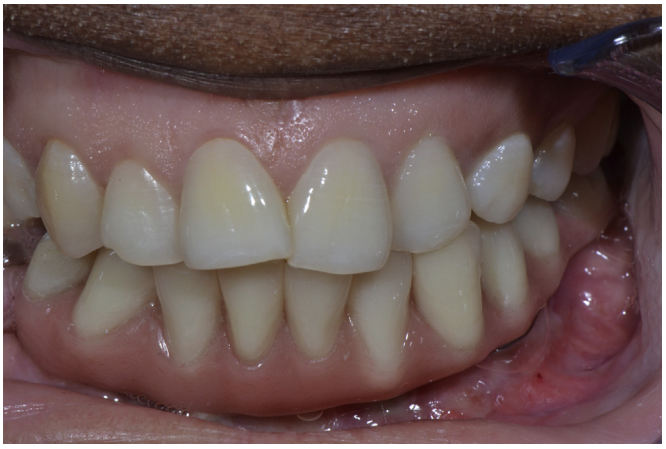

Fig. 7. Immediate loading with screw retained metal resin bridge. Frontal view.

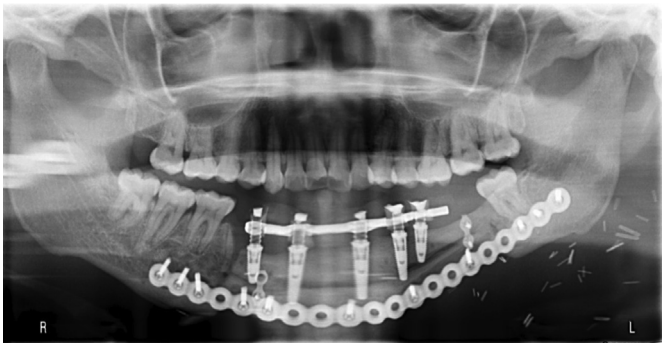

Fig. 8. Panoramic X-ray after immediate loading.

adjustments of occlusion were needed. Four patients underwent delayed loading 3 months after implant placement. In three of them, an implant level impression was taken, and a metal and acrylic resin prosthesis was delivered 4 weeks later. In one patient, who had sustained a gunshot trauma with wide maxillary and mandibular defects reconstructed with iliac crest and fibula free flaps, the anatomy of the oral cavity did not enable clinicians to make an implant-level impression. A customized acrylic resin provisional prosthesis was fitted to the implant to record the implant position and the maxillary/mandibular relationship. Afterwards, a master model was poured, and a new metal and acrylic resin prosthesis was delivered.

Remodelling of the vestibular fornix was needed before implant surgery in five patients, and a concomitant palate fibromucosal graft procedure in 3 patients, and in 2 other patients a customized acrylic template was used to remodel soft tissues (Fig. 6). The gunshot facial trauma patient was treated with skin grafts on the neo-mandibular ridge and fibromucosal grafts on the upper jaw at the time of implant placement. Postoperatively, one patient received a localised hard palate mucosal graft around a single implant at 1 month after insertion, and two patients underwent palate fibromucosa grafting 4 months after loading. The prosthesis was used to shape the thick reconstructed soft tissues in 6 patients.

One year after loading, in three patients, the metal and acrylic resin implant bridge was replaced with a screw-retained zirconia ceramic implant bridge for aesthetic reasons (Figs. 9 and 10).

Fifteen days after implant loading, one patient rehabilitated with 5 implants experienced pain and swelling of the left mandibular area. Panoramic radiographic examination showed a spontaneous mandibular fracture in the area of the left distal implant, probably due to a lack of support of the reconstructed mandible. The mandibular fracture was reduced and rigidly fixed under local anaesthesia. During surgery to repair the fracture, the left distal implant was removed.

This implant was considered a failure and included in among the three failed implants.

Four months after prosthesis delivery, 2 patients experienced pain, bleeding during tooth brushing, and aesthetic problems caused by an overgrowth of granulomatous soft tissue around the implant abutments. In these cases, the granulomatous tissue was surgically removed and substituted with palatal mucosa grafts. One patient who underwent floor of the mouth, vestibular fornix, and full-arch mandibular reconstruction presented with masticatory dysfunction related to reduced mobility of the tongue and inferior lip after prosthetic restoration. Fornix remodelling and soft tissue plastic procedures were performed, to improve masticatory function. One patient experienced fracture of the marginal prosthesis, which was repaired in the clinician office. After 14 months, 2 patients experienced tissue overgrowth around the implants and were treated with tissue excision and corticosteroid local application.

Radiologic CBCT examination showed mean marginal bone loss of 1.43 ± 0.49 mm at the palatal/lingual site and 1.48 ± 0.46 mm at the vestibular site after 4 years of function (Table 3).

All patients presented with healthy soft tissues, stable PPD, and good BOP values after 4 years. The mean PPD value per patient after 48 months was 4.93 ± 0.75 mm, and there was good bleeding on probing BOP values (12% ± 5.8%) (Table 4).

In terms of patient satisfaction with facial appearance, aesthetics, and function of the prosthetic restoration, good scores were reported in the majority of cases. All of the patients experienced functional improvements with the fixed prostheses. The results of the questionnaire are reported in Table 5.

Table 1
Patients and treatment.

Case no.	Age (y)/sex	Diagnosis	Site of defect	No. of implants	Prosthesis	Loading
1	65/M	Oral cancer	Mandible arch	5	Screw retained metal-acrylic resin	Immediate
2	70/M	Gunshot wound	Left mandible	5	Screw retained metal-acrylic resin	Delayed
3	36/F	Osteoblastoma	Right mandible	3	Screw-retained zirconia-ceramic	Immediate
4	45/F	ORN	Mandibular arch	6	Screw retained metal-acrylic resin	Delayed
5	44/F	Severe atrophy	Maxillary arch	6	Screw-retained zirconia-ceramic	Immediate
6	37/M	Gunshot wound	Left maxilla/mandibular arch	8	Screw retained metal-acrylic resin	Delayed
7	38/M	Gunshot wound	Anterior maxilla/mandibular arch	10	Screw retained metal-acrylic resin	Delayed
8	65/M	Oral cancer	Left mandible	5	Screw retained metal-acrylic resin	Immediate
9	70/F	Oral cancer	Mandibular arch	5	Screw retained metal-acrylic resin	Immediate
10	53/M	Osteoblastoma	Mandibular arch	5	Screw-retained zirconia-ceramic	Immediate

Table 2
Implants life table analysis.

Months	Patients	No. of implants	Implant failed	CSR[a]
0–12	10	56	3	94.60%
12–24	10	53	0	94.60%
24–48	10	53	0	94.60%

[a] Cumulative survival rate.

4. Discussion

This prospective observational study was designed to evaluate the 4-year clinical and radiographic outcomes of computer-guided, template-assisted, flapless implant surgery in patients who had previously undergone a reconstruction using a free flap.

Overall, the results at 4 years confirm the preliminary 1-year data (Meloni et al., 2012). Three implants were lost before prosthesis delivery, but no implants or prostheses failed during the entire follow-up period, resulting in overall implant and prosthetic survival rates of 94.6% and 100%, respectively. Marginal bone changes, analysed based on cone-beam computed tomography imaging of the palatal/lingual and vestibular aspects, as well as bleeding on probing and probing pocket depth values, were stable after 4 years, confirming the predictability of this approach. After a mean marginal bone loss of 1.06 mm at the palatal/lingual site and 1.10 ± 0.46 mm at the vestibular site (Meloni et al., 2012), all of the implants caused physiological bone resorption during their function. At the 4-year follow-up, 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. Although two patients were not fully satisfied with their prostheses, at the 4-year follow-up, nine of 10 patients stated that they would undergo the same therapy again. However, patient satisfaction differed between the 4-year and the 1-year measurements. This was especially the case in oral cancer patients, who expressed less acceptance of the implant due to deglutition difficulties related to limited tongue mobility. Conversely, patients with aggressive tumours experienced functional improvement, as did patients who had sustained gunshot trauma. In the latter, the amount of scarring was worse than in oral cancer patients; however, gunshot patients were more compliant and expressed greater satisfaction with the implants, both of which could be related to a renewed appreciation of life after the trauma. The further treatment of these patients must include a detailed soft tissue analysis.

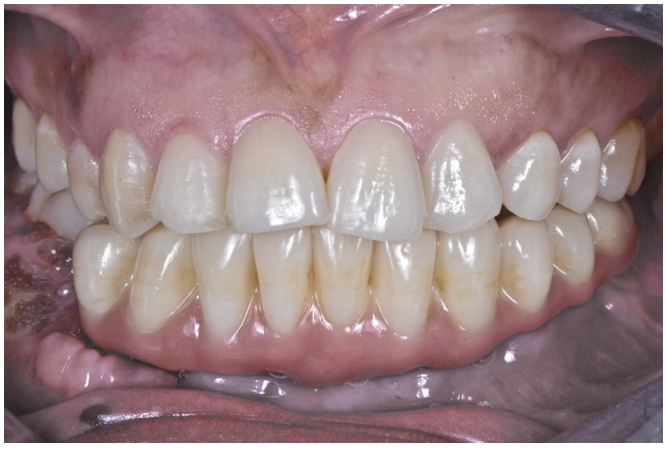

Fig. 9. Zirconia ceramic screw retained bridge after delivering. Frontal view.

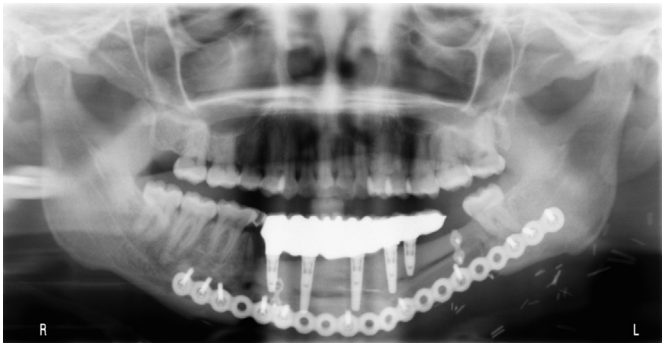

Fig. 10. Panoramic X-ray after zirconia ceramic prosthesis delivery.

The flapless approach has several advantages when used to insert implants in free flaps. First, it avoids raising a flap from the peripheral vascularisation supplying undamaged soft tissue. Second, a flapless approach is indicated in patients who have been treated with irradiation, because of the quality of the irradiated soft tissue. Third, a flapless approach is less invasive and less traumatic than a classical open flap approach. Nonetheless, the disadvantages of the flapless approach are that it is more complex, requires very precise 3D planning of the implant insertion, and involves the frequent need to thin the soft tissues before surgery, as was the case for the patient described in this report. An additional consideration regarding transplanted soft tissue is that soft tissues reconstructed with skin and muscles differ from the normally attached gingiva and alveolar mucosa. Furthermore, a frequent complication arising from the reconstruction of intraoral soft tissues with skin is the

Table 3
Peri-implant marginal bone levels changes (mean ± standard deviation).

Months	No. of implants	Vestibular site	Palatal/lingual site
12	53	1.10 ± 0.49 mm	1.06 ± 0.50 mm
24	53	1.20 ± 0.45 mm	1.12 ± 0.50 mm
48	53	1.48 ± 0.46 mm	1.43 ± 0.49 mm

Table 4
Soft tissue parameters PPD and BOP values (mean ± standard deviation).

Months	No. of implants	PPD	BOP
12	53	4.70 ± 0.80 mm	16 ± 5.0%
24	53	4.85 ± 0.82 mm	13 ± 5.2%
48	53	4.93 ± 0.75 mm	12 ± 5.8%

Table 5
Satisfaction questionnaire.

Satisfaction questionnaire	No	Not sure	Yes	Follow-up (mo)
Has the fixed prothesis improved the quality of life?	1	1	8	12
Was it worth the cost?	1	0	9	12
Would you undergo the same therapy again?	1	0	9	12
Has the fixed prothesis improved the quality of life?	1	1	8	24
Was it worth the cost?	1	0	9	24
Would you undergo the same therapy again?	1	0	9	24
Has the fixed prothesis improved the quality of life?	2	0	8	48
Was it worth the cost?	1	0	9	48
Would you undergo the same therapy again?	1	0	9	48

hyperplastic/inflammatory response of the skin and subcutaneous tissues around implant abutments. Formation of the granulomatous tissue may cause pain and bleeding during tooth brushing. This phenomenon was previously described by other authors (Jaquiéry et al., 2004) and was reported in all patients who underwent delayed prosthetic loading during the implant healing period. However, in some cases, the problem resolved spontaneously 1–2 months after loading. Thus, although no specific data are available for confirmation, reconstructed skin is probably not a suitable tissue for use around implants and may react negatively in the oral environment.

A satisfactory solution to this unique problem is lacking and may require an individualised approach. For example, in some cases, the palatal mucosa was harvested from the hard palate and grafted around the implants after skin removal to obtain an adequate zone of firmly attached mucosa around the implants. In other cases, only the soft tissue remodelling initiated by the prosthesis was sufficient to change the soft tissue thickness, resulting in attached peri-implant tissue. In one patient, skin or mucosal grafts were associated with fornix remodelling and deepening before implant surgery. In another patient, the need for a larger extension of the soft tissue graft was recognised only during implant placement.

The long transmucosal path creates a clinical challenge for prosthetic treatment and oral hygiene procedures. Using the 3D software, clinicians can analyse the soft tissue path and plan longer implants rather than simply longer abutment shoulders. This allows the micro-gap between the implant platform and the abutment to be placed just under the soft tissue margin (Bashutski et al., 2013; Buser et al., 2013; Mandelaris and Vlk, 2014). Although this strategy is unreasonable for normal healthy patients, it represents the only solution for those with large reconstructions of the jaw and a very thick muscle layer. Moving the micro-gap between the abutment and the implant platform so that it is located 2 mm under the soft tissue simplifies the prosthetic procedure. Ideally, implants with a long machined neck should be used in these cases, but this kind of implant is not available for computer-guided installation.

The results of this study support our hypothesis that the surgical template obtained by virtual implant planning offers a prosthetic advantage and may be the only way to obtain a fixed implant-supported prosthesis in complex cases. However, this approach requires adaptation of a technique (CT-guided flapless surgery) developed to treat healthy patients with wide mouth openings but an otherwise normal anatomy. By contrast, patients undergoing large facial reconstructions typically have small mouth openings; flat reconstructed ridges; reduced tongue and lip mobility; a thickened, retracted mucosa; and skin scars. Additionally, the surgical and prosthetic hardware may be problematic because of the drill length, surgical template dimension, and difficultly in achieving a correct tridimensional template setting on the flat reconstructed ridges. These peri-operative challenges may be a serious pitfall of the procedure, and suggest the need for specific surgical training and knowledge regarding the selection of the best solution for individual patients. Moreover, problems with the prosthesis may arise at the time of loading, especially in patients with gunshot trauma. These problems stem from difficulties performing an accurate prosthetic and aesthetic analysis before implant placement in patients with thick ridges and few anatomic reference points. Consequently, the prosthesis should be modified immediately at the moment of prosthetic loading or after a few months to improve occlusion contacts and further prosthetic plans and aesthetics.

Osteomyocutaneous free flaps are very reliable not only in the reconstruction of large composite facial defects following the resection of tumours but also in patients with osteoradionecrosis or gunshot trauma (Chiapasco et al., 2000; Meloni et al., 2012; Nocini et al., 2012; Mertens et al., 2014). Implant-supported prosthetic rehabilitation is feasible with this microvascular reconstructive option because of the sufficient volume and good bone quality.

Among the benefits of implant-based dental restoration with fibular flap reconstructions are sufficient stabilisation of the prosthesis, even in patients with marked irregularities of the hard and soft tissue anatomy, the possibility of compensating for smaller local soft tissue deficiencies, and the improved aesthetic result. Implants also support functional aspects, such as chewing, swallowing, and speech, in addition to reducing the load on the soft tissues and the risk of mechanical irritation with consequent ulceration and discomfort.

Nevertheless, prosthetic-based implant insertion still represents a major challenge in these difficult cases. The surgical procedure for implant placement can be particularly difficult because of the limited opening of the scar-contracted oral cavity or the presence of large volumes of soft tissue but little information on the profile of the underlying bone, which is necessary as a valid surgical guide. Other potential problems are related to the need to limit the exposure of frequently irradiated bone or scarred fields, which reduces surgical precision. Moreover, scars and thickened soft tissues can interfere with the prosthetic procedures, such as in obtaining fixture impressions, and may lead to imprecise results.

The classic implant approach in patients with osseous free flaps is based on radiological assessment and surgical guides made from casts to allow for adequate insertion of the implants from the ideal prosthetic perspective. In the classic approach, a full-thickness flap is raised and implants are then inserted free-hand in accordance with the surgical guide. This approach would seem to be both accurate and highly precise, because the bone can be easily visualised and the implant inserted after the full-thickness flap is raised. However, the use of this type of surgical template does not permit accurate, prosthetically driven positioning of the implant because of the difficulty in precisely defining the ideal implant position. This is because fixing the template to the bone once the thick musculomucosal flap is raised is nearly impossible.

In a previous article, our group presented a newly developed, modified, computer-assisted, guided surgical protocol for the

rehabilitation of the jaw reconstructed with a free flap (De Riu et al., 2012). With this technique, implants can be positioned to exactly match their virtual positions. Precise prosthetic guidance of the implant's position is achieved with minimal error when the computer-generated template is seated correctly and the anchor pins (five or more when possible instead of the normal three) are correctly positioned and fixed in the jaw. Moreover, implants can be inserted in minimal bone volumes, thereby avoiding the need for the removal of the screws and plate. Another advantage of this technique is the option of placing a provisional prosthetic restoration, either computer-generated or developed from the template, at the end of the operation (Malo et al., 2008; Meloni et al., 2013). The prosthesis can be loaded immediately if there is adequate primary stability, thereby reducing discomfort to the patient, shortening the treatment time, and initiating the remodelling of soft tissue overgrowth.

The advantages of a protocol consisting of prosthetic-guided implant insertion, a non-invasive surgical approach, and immediate loading are the outstanding surgical and prosthetic outcomes. Surgical templates obtained from virtual implant planning allow clinicians to insert implants in reduced, non-anatomical bone volumes using a fixed prosthetic guide.

5. Conclusion

The benefits of implant-based dental restorations in patients with maxillary or mandibular reconstructions with free flaps have been demonstrated. The anatomical and prosthetic challenges in the planning and placement of an implant-based prosthesis in these patients can be reduced by adopting a computer-assisted, guided implant surgical protocol. Our results confirm the feasibility of a good prosthetic restoration in these complex reconstructions. Within the limitations noted in this report, the combination of computer-assisted implant treatment planning and guided surgery provides a valuable tool to minimise the challenges posed by patients with maxillary or mandibular reconstructions with free flaps and to maximize their satisfaction.

Conflict of interest

This study was not supported by any company and there are no conflict of interest.

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