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A 3-D CAD/CAM technique in full-arch implant supported rehabilitations: the Virtual Implant-Prosthetic Procedure (VIPP Technique). A prospective longitudinal study

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ABSTRACT

Aim The purpose of this study is to evaluate the success of a new three-dimensional CAD/CAM processing technique in full-arch implant supported rehabilitations of edentulous patients.
Materials and methods Healthy patients with edentulous mandible and/or maxilla arch were selected for the present study. The Full-Arch Implant Supported Virtual Protocol has been applied with immediate loading fixed rehabilitation. Effectiveness of digital and surgical planning, marginal bone loss, implant and prosthetic failure were recorded at 6-and 12 months follow up.
Results Seventy-six implants were placed in 15 patients, and 15 full arch rehabilitations were delivered. Patients found smile design previsualization very effective (93%), guided surgery very effective (94%), and immediate loading and temporization very effective (92%). No implant were lost (survival rate = 100%). At the 6-months radiographic evaluation, average perimplant crestal bone loss was 0.56 ± 0.12 mm for maxillary implants (n = 64), 0.59 ± 0.16 for mandibular implants (n = 12) and 12-months average perimplant crestal bone loss was 0.67 ± 0.11 mm for maxillary implants (n = 64) and 0.69 ± 0.16 for mandibular implants (n = 12). Two unscrewing episodes and one provisional prosthesis fracture occurred. No paresthesia and no prosthetic complications in definitive prostheses were registered in the whole sample.

Conclusions Within the limitations of the present study, the Virtual Implant-Prosthetic Procedure could be a satisfactory treatment in edentulous patients.

KEYWORDS 3-D CAD CAM technique; Full-arch rehabilitations; Implant-supported prostheses.

INTRODUCTION

Digital technologies are used in many fields of medicine and dentistry. An increasing use of digital technologies for the diagnosis was underlined in recent years and used for the Virtual Prosthetic Planning (1, 2) guided surgery and implant supported rehabilitations (3, 4).
The advent of Cone Beam Computer Tomography (CBCT), the improvement of intra-oral scanners (IOS) and lab-scans made it possible the tridimensional digital reconstruction of the patient's anatomy (5, 6, 7). Recently, thanks to the development of dental software and hardware it is possible to match the various stages of the processing, allowing the integration and the dialogue between the different technologies (8). The clinician is able to carry out the whole implant-prosthetic rehabilitation in a digital project, pre-viewing the final result. This opportunity certainly appears convenient for the diagnostic and prognostic aspect but also as a communication tool to help patients understand, showing them in advance the aesthetic and functional

final result of the proposed treatment (9, 10, 11).
The opportunity to integrate the prosthetic and the implant project helps the correct guided implant positioning (6) (optimized either for bone volumes available and to absorb the masticatory loads) and the fabrication of an adequate prosthesis, in compliance with the intermaxillary relationship, the function and the occlusal balance, the soft tissue support (12), respecting the vertical dimension.
The purpose of this article is to evaluate the success of full-arch implant-supported rehabilitations made through a fully digital approach in edentulous patients. The Strobe guidelines (Strengthening the Reporting of Observational Studies in Epidemiology) were followed (13).

MATERIALS AND METHODS

Patient selection

This prospective longitudinal study was performed at the Dentistry Department, IRCCS San Raffaele Hospital, Milan (Italy). Edentulous healthy patients were evaluated from May 2015 to March 2016.
The inclusion criteria were as follows.

- Patients over the age of 18 years of both genders and any ethnicity.
- Totally edentulous at least in one jaw.
- Adequate bone volume defined as divisions A, B, or C according to Misch classification (14).
- Appropriate bone density defined as Misch classes D1, D2, or D3 (14).
- Prior to treatment, a decision towards an immediately loaded implant supported fixed complete dental prostheses had to be made.
- Patients had to be physically and psychologically able to undergo conventional surgical and restorative procedures.

Exclusion criteria were as follows.

- Smokers.
- Immunosuppression.
- Bleeding issues without adequate treatment.
- Active treatment of malignancy.
- Drug abuse.
- Psychiatric illness.
- Intravenous bisphosphonate therapy.
- Uncontrolled systemic diseases (e.g. diabetes).
- Active infection or inflammation in the area of planned implant treatment at time of surgery.
- Previous radiation therapy in the head and neck area.
- Severe parafunctional habits such as bruxism and clenching.

All diagnoses were made clinically and radiographically. All patients gave written informed consent and the local ethical committee approved the study. All patients underwent oral hygiene procedures, panoramic radiographs and CT-scans before surgery. Moreover all patients received, after the surgical protocol, an immediate loading rehabilitation, and after 6 months the definitive prostheses were made by CAD-CAM procedures. Immediate loading procedure was performed only if each implant was inserted at least at 35 Ncm.

Diagnosis and prosthetic planning

Impressions of upper and lower arches were taken with alginate, stone casts and wax were traditionally made and functionalized (15,16). Occlusal and vertical dimensions were tested with the wax, to check reference occlusal planes, and to evaluate the phonetic parameters (according to Pound, 1978), and the peri-oral tissues support (17, 18). The functionalized wax was used during the CBCT exam, in the correct occlusal position, with a fiducial marker as a reference for the x-ray evaluation, applied on the wax (Scan Marker 3-Diemme, Cantù, Italy). Stone models and wax (with and without the Scan Marker) were acquired with a laboratory scanner (Top Scan, Open Technology, Rezzato, Brescia, Italy), both separately and in occlusal relationship. The dental technician had to place the model in the scanner, perform a first scan (to obtain the patient anatomy STL file), then mount the radiologic guide (wax) on the stone model and perform a second optical scan. In this way two STL files, in the same reference system, are obtained: the first representing the patient's anatomy, the second the prosthetic planning and the volumetric reference system. Photographic protocol included intra-oral and extra-oral photographs. A digital project of the aesthetic aspect of the new smile on dedicate bi-dimensional software (Digital Smile System 2D-Digital Smile System-Italy) was created (Fig. 1, 2, 3). The Smile Design project 2D (Digital Smile System, Digital Smile System, Varese, Italy), the STL files of the laboratory scanner were imported to a 3D software (Dental CAD, EGS Solution Srl, Bologna, Italy) and overlapped (Fig. 4, 5). The CAD software (Dental CAD, EGS Solution Srl, Bologna, Italy) allows the tridimensional design of the temporary prosthesis, according to volumes, occlusal planes, phonetic and aesthetic parameters established by the wax.

Implant planning

Each patient was scanned wearing the radiologic guide (functionalized wax) with a single scan protocol, taking care to include the 3D-Marker (Scan Marker 3-Diemme, Cantù, Italy) in the acquisition volume, and the results exported in standard DICOM format (Fig. 6). The DICOM dataset obtained from the CBTC exam represented the anatomy, STL files resulting from lab optical scan showed the real anatomy without distortion, both files were imported in the medical imaging software (3-Diagnosys 5.1, 3DIEMME Srl , Cantù, Italy). The data described was superimposed with a "best-fit" algorithm in a user-independent way. The result was the best possible match between the files, evaluated by the mean error value calculated by the software for every match (suggested acceptable values range between 0,05 and 0,3 mm). After importing the anatomy STL file it was possible to use

FIG. 1

FIG. 1-3 The digital project of the aesthetic aspect of the new smile on dedicate bi-dimensional software (Digital Smile System, Varese, Italy).

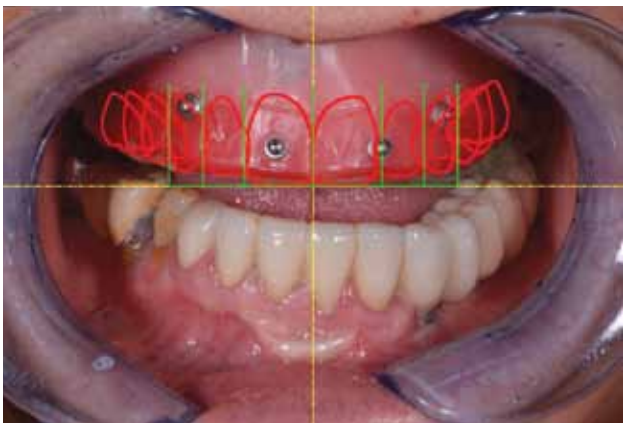

FIG. 2

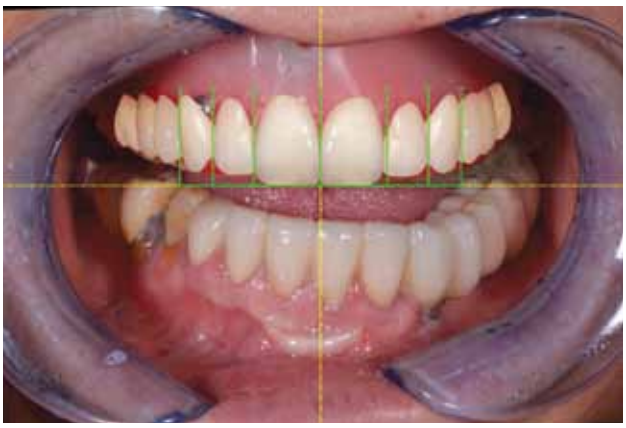

FIG. 3

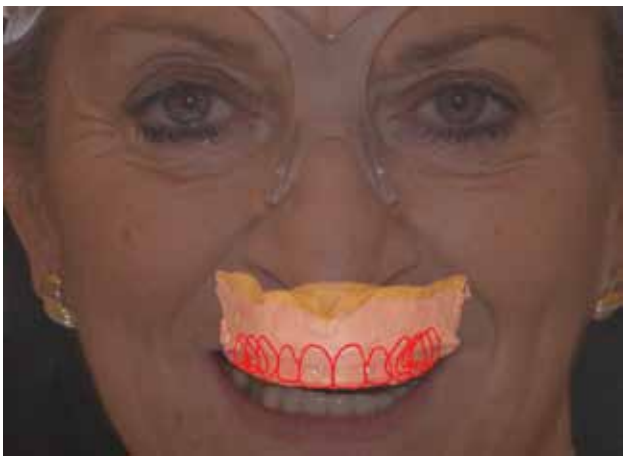

FIG. 4

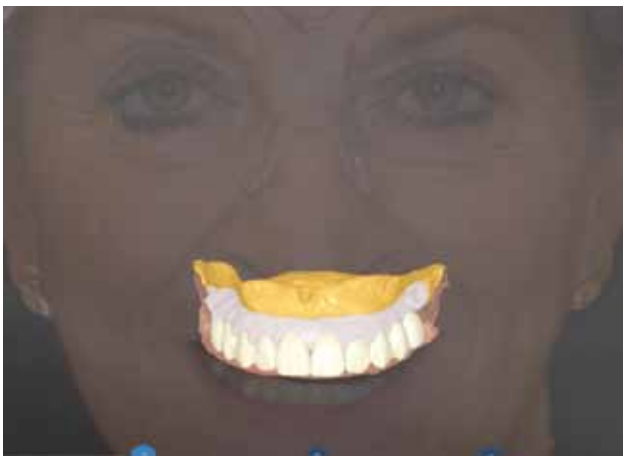

FIG. 5

FIG. 4-5 The overlapping of the Smile Design project 2D (Digital Smile System, Varese) and the STL files of the laboratory scanner, into the 3D software (Dental CAD, EGS Solution Srl, Bologna, Italy).

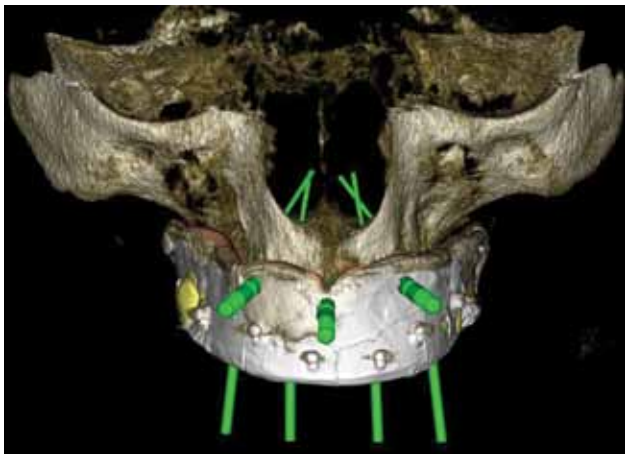

FIG. 6 The Patient scanning ,with the 3D-Marker (Scan Marker 3-Diemme, Cantù, Italy).

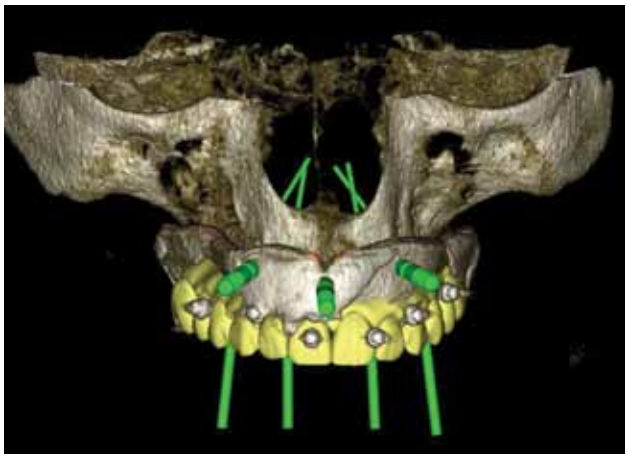

FIG. 7 The positioning of the implants using both the bone guide and the CAD design.

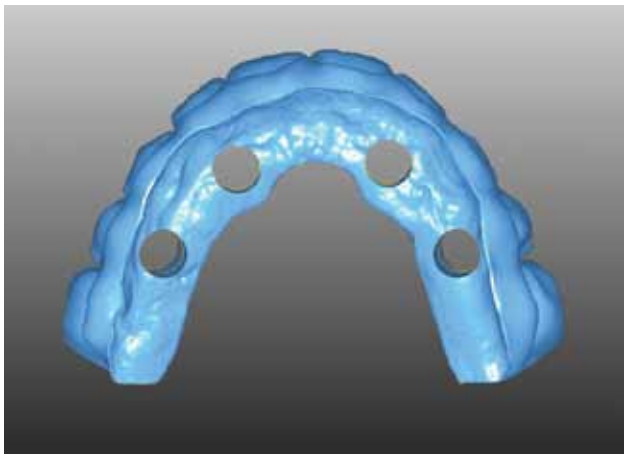

FIG. 8-9 The passage of the abutments in the prosthetic structure.

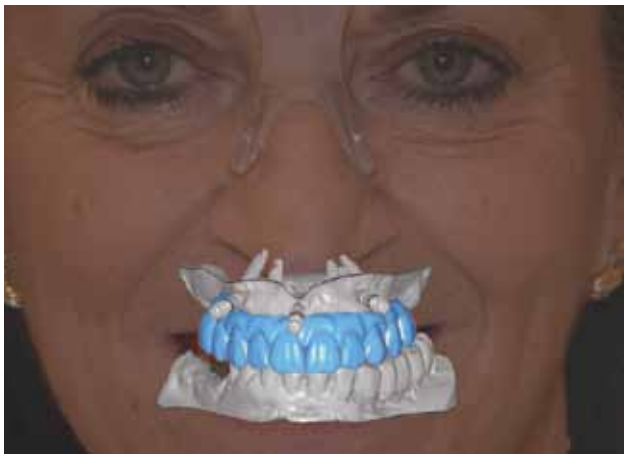

FIG. 9 The passage of the abutments in the prosthetic structure.

the same mathematical transformation to put into the software all the connected files, such as the virtual wax-up, the antagonist arch scan, both exported from the dental technician software. When the "virtual patient" was finally set up it was possible to add the implants from the library for a "prosthetic-driven" surgery.
The approved 3-D prosthetic project has been imported into the medical imaging software (3-Diagnosis 5.1, 3DIEMME Srl, Cantù, Italy). The correct placement of the prosthesis was obtained by the automatic merge procedure of the reference observed in CBCT data and by the 3-D prosthetic project. The positioning of the implants has been improved using both the bone guide and the CAD design (Fig. 7). Moreover, it gave a choice of prosthetic connections, shaping the passage of the abutments in the prosthetic structure (Fig. 8, 9).

Surgical guide modelling

The final project was exported and automatically converted into a set of tools, that indicated the exact position of the drill sleeves. These project files were imported in a "free-form" modelling software (Plasty-CAD 1.2, 3-DIEMME, Cantù, Italy) that enabled the technician to select the surgical guide contact surface on the patient anatomy and automatically generated the guide file, taking into account the sleeves positions exported from the clinician's plan. A working model with the implant replica holes corresponding to the implants was obtained as well and mounted in the real laboratory articulator, replacing the original stone models (Fig. 10). All the objects modeled in the previous steps are manufactured with the same rapid prototyping stereolithography apparatus.

Prosthetic CAD-CAM modelling

The implants and abutments virtual files were exported from the planning software into the laboratory prosthesis modelling software (Dental CAD, EGS Solution Srl, Bologna, Italy), in order to convert the virtual wax-up into a provisional prosthesis file to manufacture the

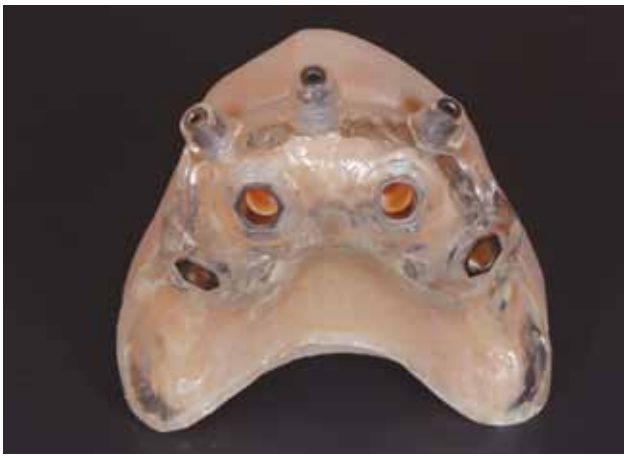

FIG. 10 The working model with the surgical guide positioned.

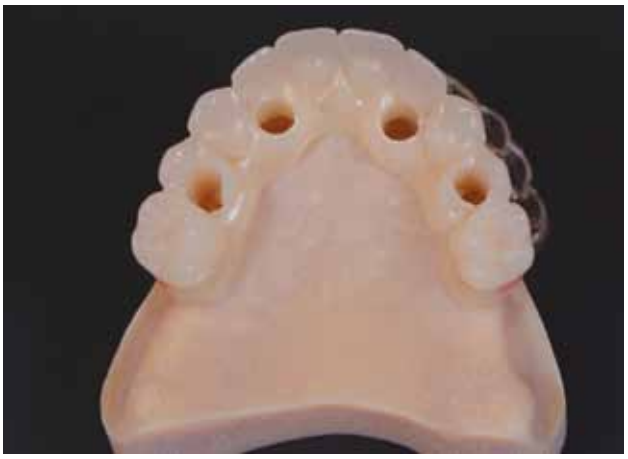

FIG. 11 The working model with the provisional prosthesis (milled in PMMA).

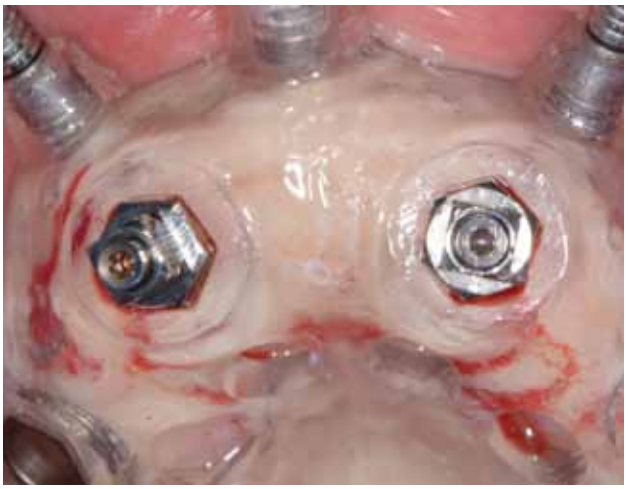

FIG. 12 The guide fixing in the patient's mouth, in flapless technique.

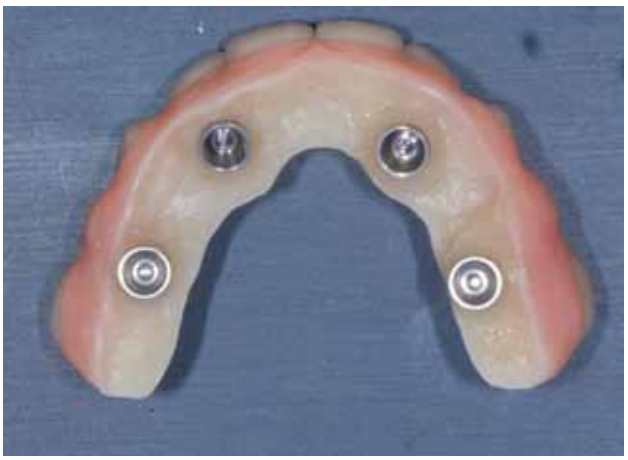

FIG. 13 The provisional CAD-CAM prosthesisdirectly realigned in the patient's mouth for the implants immediate loading.

immediate loading temporary prosthesis. The provisional prosthesis was milled in PMMA (Temp Premium, Zirkonzahn, Gais, Italy) in a single color. After the finishing procedure, the teeth were manually painted by the dental technician to fit the patient's color (Fig. 11).

Surgical procedure

One hour before surgery patients were administered 2 g amoxicillin + clavulanic acid (Augmentin, GlaxoSmithKline, Belgium), which they continued to take (1 g twice a day) for 1 week after surgery. Implant surgery was performed under local anaesthesia (Optocaine 20 mg/ml with adrenaline 1:80000, Molteni Dental, Firenze, Italy). The surgical procedure started with the guide placed in the patient's mouth (Fig. 12), followed by implant site preparation with calibrated drills and implant insertion through the guide using a dedicated implant mount, by means of a flapless technique. The diameter of the final drill was chosen in relation to the bone quality in order to optimize implant stability. The insertion of the implants followed the manufacturer's protocols (TTx system, Winsix, Biosafin, Ancona, Italy - CSR-System, Sweden & Martina, Padova, Italy), under-preparation was used to achieve an insertion torque of at least 35 Nm before final insertion of the implant and under-preparation was performed in soft bone to obtain high primary stability. The implant neck was aimed to be positioned at bone level and bi-cortical anchorage was established whenever possible as planned into the surgical virtual plan-ning. After surgery non-steroidal anti-inflammatory drugs (Brufen 600 mg, Abbott Laboratories, Chicago, IL, USA), and chlorhexidine digluconate 0.2% mouthwash were prescribed during the first 2 weeks. All patients were instructed to avoid brushing and any trauma to the surgical site and were recommended to follow a soft diet (avoiding bread and meat) for 2 months.

Prosthetic protocol and immediate loading

After the guide removal, if an insertion torque of at least 35 Ncm was obtained for each implant, the provisional

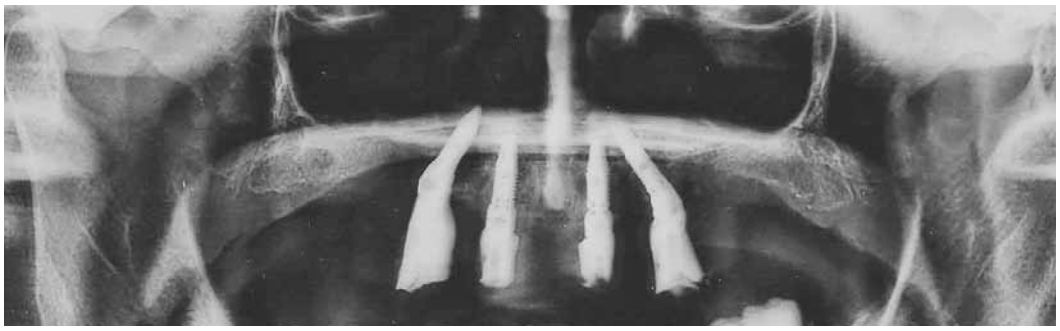

FIG. 14 Radiographic evaluation after provisional steps.

prosthesis CAD-CAM was fixed, directly realigned in the patient's mouth for immediate loading and finished in the lab (Fig. 13). The material used for the direct realignment of the temporary prosthesis was a light curing composite cement (Real Guide Dual Cem, 3-DIEMME srl, Cantù, Italy), and subsequently a resin material (Unifast Self-Curing Trad Resin, GC, Hongo, Bunkyo-ku, Japan) (Fig. 14). Articulating paper (Bausch Articulating Paper, Nashua, NH, USA) was used to check the occlusion and adjust it, if necessary. Static occlusion consisted of central contacts established on all masticatory units. Dynamic occlusion included canine/premolar guidance during lateral movements, regardless of the opposite arch settings. Screw access holes were covered with provisional resin (Fermit, Ivoclar Vivadent, Naturno, Bolzano, Italy). Final prostheses were made with monolithic Zirconia obtained by CAD-CAM procedures (Zirconia Prettau, Zirkonzahn srl, Gais, Italy) and delivered 6 months after surgery (Fig. 15).

FIG. 15 Final aesthetic result.

Follow-up

Follow-up visits were performed at 6 and 12 months after implant insertion with radiographic assessments to evaluate the marginal bone loss and the overall bone level. They were made perpendicular to the long axis of the implant with long cone parallel technique, using an occlusal custom template to measure the marginal bone level. A dedicated dentist, blind to the aims of the study, measured the changes in crestal bone height over time. The difference in bone level was measured radiographically through a specific software (DIGORA 2.5, Soredex, Tuusula, Finland). The software was calibrated for every single image using the known implant diameter at the most coronal portion of the implant neck. The linear distance between the most coronal point of bone-to-implant contact and the coronal margin of the implant neck was measured to the nearest 0.01 mm, at both mesial and distal sides, and averaged. Bone level changes at single implant were averaged at patients level and then at group level. Moreover at 6 months from implant placement, a dental hygienist performed oral hygiene procedures and measured clinical parameters (19).

Outcome measures

The outcomes considered at 6 and 12-month follow up were as follows: effectiveness of the digital prosthetic and surgical planning (using VAS Scale), implant failure, prosthesis failure, which led to implant removal (due to mobility, progressive marginal bone loss due to peri-implantitis, any mechanical complication causing implant failure), biological and prosthetic complications (number and type were recorded as single episodes for each implant), peri-implant marginal bone level changes (MBLCs). To compare MBLCs at different time points (6 and 12 months-follow up) a T-test was used. A value of $P<0.05$ was considered significant.

RESULTS

from May 2015 to March 2016, 34 edentulous patients in at least one jaw were screened at the Department of Dentistry, IRCCS San Raffaele Hospital, Milan.
Of these 34 patients, 19 were excluded for the following reasons.

- Disorders that contraindicated surgical procedures (n=11), among which decompensated diabetes (n = 1), previous radiation therapy in the head and neck area (n = 3), severe malocclusion (n = 1), severe parafunctions (bruxism) (n = 4), inadequate bone volume (division D of Misch) (n = 2).
- Inadequate bone density (density D4 Misch) (n = 1).
- Patients refusing to collaborate (n = 1).
- Lack of oral hygiene (n = 6).

A total of 76 implants were placed in 15 patients. They received a full arch rehabilitation of one jaw, 12 patients

		length 11 mm	length 13 mm	lenght 15 mm
MAXILLA n=64	diameter 3.3 mm	2	20	18
	diameter 3.8 mm	2	12	10
MANDIBLE n=12	diameter 3.3 mm	2	3	3
	diameter 3.8 mm	2	1	1

TABLE 1 Implants dimensions and position.

6 moths follow up	Number	Rate
Implant failure	0	0
Prosthetic un-screwing	2	2.63%
Fixture fracture	0	0
Perimplantitis	0	0
Provisional prosthesis fracture	1	1.31%
Episode of Pus	0	0
Pain	0	0
Paresthesia	0	0

TABLE 2 Implant failure, prosthetic failure, biological and mechanical complications.

received a maxillary rehabilitation and 3 received a mandibular rehabilitation. All prostheses were supported by 4 or 6 implants. In total, 15 rehabilitations were made (Table 1).

Implant failure

No Implant failure was registered (Table 2). The survival rate was 100% at 6 and 12-months follow up. No fixture fracture occurred.

Biological and prosthetic complications

Biological and prosthetic complications are reported in table 2. One provisional prosthesis fracture was found. Two unscrewing episodes of provisional prosthesis were detected in two patients. In definitive prostheses, an absence of fractures was found. No paresthesia and no prosthetic complications in definitive prostheses were registered in the whole sample. Patients found their smile design previsualization very effective (93%), the guided surgery very effective (94%), and the immediate loading and temporization very effective (92%) (Table 3).

Peri-implant MBLC

Marginal Bone Level (MBL) was recorded at 6 and 12 month follow-ups (Table 4). Radiographic evaluation at 6-months showed that average peri-implant crestal bone loss was 0.56 ± 0.12 mm for maxillary implants (n = 64 implants), 0.59 ± 0.16 for mandibular implants (n = 12 implants) and at 12-months average perimplant crestal bone loss was 0.67 ± 0.11 mm for maxillary implants (n = 64 implants) and 0.69 ± 0.16 for mandibular implants (n = 12 implants) . No statistically significant difference in marginal bone loss were found at 6 and 12-month follow-up evaluations (P>0.05).

	Very effective	Effective
Smile design previsualization	93%	7%
Guided surgery	94%	6%
Immediate loading and temporarization	92%	8%

TABLE 3 Effectiveness of digital previewing , guided surgery and immediate loading.

	Implant Position	
Bone Loss	maxilla n=64	mandible n=12
6 months (mm)	0.56 ± 0.12	0.59 ± 0.16
12 months (mm)	0.67 ± 0.11	0.69 ± 0.16

TABLE 4 Marginal bone loss at 6, 12 months from implant placement.

DISCUSSION

The aim of this study was to investigate the survival rate of implants in healthy edentulous patients, treated with a fully digital approach, both prosthetic and surgical, also in order to understand the importance of the digital approach in the prosthetic phase of the treatment and subsequently in surgical steps. The recent raging of the digital technologies as Coachman et al. described in 2017, has changed not only the diagnostic prosthetic phase, with the use of photography, software 2-D or 3-D, intra oral scanner, but also the surgical one, with the improvement of specific softwares for surgical planning (9). The esthetic planning, as Rufenacht reported in 1990, is the first step of the prosthetic treatment, both with the traditional and the digital approach, as the same parameters have in fact to be evaluated (20). Casaglia et al. in 2016 defined photography as one of the most important tools as initial steps of the esthetic planning and diagnosis , useful for examination, diagnosis and treatment planning, legal and

efficacy

forensic documentation, publishing, education, marketing and communication with patients (21, 32). Photography is also the initial phase of the digital design of the teeth, according to the plane of the face, in fact medical and dental histories, clinical examination, study models, and photographs provide the data for a proper diagnosis and treatment plan for esthetic dentistry (22, 32).
Ward in 2015 (23) described also how proportional smile design is a useful tool for evaluating and designing smiles in harmony with the face, and that the width/length ratio of the central incisor is a key determinant in providing a pleasing smile to dentists (22, 32). These findings have been supported by Coachman et al. in 2017: they described how the use of the smile design allows esthetic rehabilitative planning from a facial perspective, improves communication with the patient, integration between specialists, and predictable quality of treatment (22, 32). Today it is possible to use specific software to obtain the design of the new smile, working in a two-dimensional environment and subsequently in a CAD one, becoming 3D (9, 11). The appreciation by the patients of the aesthetic planning was also described by Cattoni et al. in 2016 (11), using a VAS scale to evaluate the data, subsequently the mock up concept to prepare teeth in a minimally invasive way, keeping the preparations on the enamel surface, and obtaining a correct survival rate of prosthetic results.
In 2014 Kapos et al. (24) reported that the survival rates of CAD/CAM fabricated crowns, abutments, and frameworks were similar to those of conventionally fabricated prostheses. Harder in 2009 (25) compared in a systematic review the published survival and complication rates of implant-supported computer-aided designing (CAD) and computer-aided manufacturing (CAM)-fabricated restorations with those of conventionally fabricated implant-supported restorations, obtaining an indefinite result, because only a small number of clinical studies reporting on implant-supported CAD-CAM fabricated restorations could be used for scientifically valid comparisons. Meloni et al. in 2010 in a retrospective analysis, described the possibility to plan the implant treatment also with a specific software, in a guided and flapless way, with an immediate loading procedure. Within the limitations of their study, it could be concluded that software and computed tomography-guided surgical planning for completely edentulous arches provided reliable results with high success rates (26).
It has been confirmed by other authors, among which Komiyama in 2012 (27)and Malò in 2007, that, within the limitations of this preliminary study, this treatment modality for completely edentulous jaws was predictable with a high survival rate (28). The effectiveness and the accuracy of computer-guided implant surgery was described by Schneider et al. in 2009, showing the validity of this surgical technique (29) As Hultin M. described in 2012, the advantages of the guided implant surgery technique are especially likely to decrease pain and discomfort in the immediate postoperative period (30).
Another advantage is the immediate function obtained with the immediate loading and realigning of the provisional prosthesis. Hultin M. described moreover that in 15 of the 28 studies an immediate function to improve the final result and the efficacy of the treatment had been achieved (30). Nowadays, a greater use of digital technologies in these project areas and digital workflow have gained more and more importance in contemporary dentistry (31). Bone levels have been assessed and the results obtained were similar to those reported by other authors who used the guided-surgery protocol (32). New technologies such as intraoral scanners, CAD-CAM methods and materials for prosthetic production, enable immediate load of prosthesis. In association to the digitally produced surgical guides and hardware for guided surgery, it permitted rehabilitative therapies to be performed with greater safety and predictability (33-38). The use of photographs and videos combined with scanned casts or intraoral scans and CBCT improves diagnosis and allows the visualization of patient outcomes. It allows the surgical position of implants to be guided by the design of the future prosthesis (39). The overlapping of photographs, casts, photographs, CBCT, intraoral scanning, extraoral scanning, have been determined to be reliable procedures (39, 40).
The purpose of this study is to demonstrate the advantages of guided implant placement and the application of fixed, implant-supported prosthetic restorations carried out with fully digital workflow. The peculiarity of the present study is the simplification of the matching of the dental design carried out on the photographs, according to the facial planes, with intraoral scans, taking advantage of the integrated three-dimensional dental libraries that allow the automatic alignment, differently to other authors, as Cattoni et al. described about esthetic dental treatments in 2016 (11). The automatic alignment is a fundamental and innovative part of the project which allows a fully digital protocol as well as an accurate respect of the design obtained in the photographic phase (11). According to the mentioned literature and the results obtained in the present study, successful implant survival rates in healthy edentulous patients seem to be related to the correct execution of the digital protocol, that helps to eliminate many analog passages as well as many manual errors. This method, therefore, allows the preview of the implant position in maxillary bone and the prosthesis placed on the abutment with all the correlation with the maxillary bone and the soft tissues, giving an interesting new method to evaluate the rehabilitation characteristics and represents an high-level device to show to the patient the esthetic result.

CONCLUSIONS

To our knowledge, the present study describes one of the only fully digital minimally invasive work-flows, offering

the clinician the possibility to use a software able to communicate and design the guided surgical implant placement (with flapless approach) as well as esthetics and function of the immediate load prosthesis, merging these two aspects in only one virtual project. Within its limitations, it shows that this protocol can be a suitable treatment option in edentulous patients. However in the literature there is a lack of further long-term data and additional studies are needed.

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