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RESEARCH ARTICLE

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Dynamic navigation guided surgery and prosthetics for immediate loading of complete-arch restoration

Alessandro Pozzi DDS, Adjunct Associate Professor[1,2] | Lars Hansson MDT, Owner[3] | Paolo Carosi DDS, MSc, PhD Student[4] | Lorenzo Arcuri DDS, PhD, Assistant Professor[5]

[1]Goldstein Center for Esthetic and Implant Dentistry, Department of Restorative Sciences, Augusta University, Augusta, Georgia

[2]International Center Oral rehabilitation, Rome, Italy

[3]LH Dental Design Solutions, Virginia Beach, Virginia

[4]Department of Chemical Science and Technologies, Materials for Health, Environment and Energy – Dentistry, University of Rome Tor Vergata, Rome, Italy

[5]Department of Clinical Sciences and Translational Medicine, University of Rome Tor Vergata, Rome, Italy

Correspondence
Alessandro Pozzi, International Center Oral rehabilitation, Viale Liegi 44, 00198 Rome, Italy.
Email: apozzi@augusta.edu

Abstract

Objective: To assess clinical and radiological performance of novel digital workflow integrating dynamic guided surgery, to streamline execution of implant placement, soft and bone tissue sculpturing, and immediate delivery of navigation guided complete-arch prosthesis.

Materials and Methods: This proof of concept prospective single cohort study investigated 10 consecutive patients (three males, seven females; mean age 62.5 ± 8.9 years; range, 48–75) requiring at least one complete-arch fixed dental prostheses (FDP) in both jaws, treated between January and August 2019. Primary outcomes were implant and prosthetic success rates, surgical and prosthetic complications. Secondary outcomes were marginal bone loss (MBL), implant stability quotient (ISQ), periodontal parameters (plaque and bleeding indexes).

Results: Sixty implants (32 NobelParallel TiUltra and 28 NobelActive TiUltra, Nobel Biocare) were placed and 14 complete-arch FDPs immediately loaded (mean follow-up 16.2 ± 1.7 months, 14–18). One implant failed and was immediately replaced. No other surgical or biological complications occurred, accounting for a cumulative success rate of 98.3%. No prosthetic complication occurred, leading to 100% prosthetic success rate. Mean ISQ at implant placement was 71 ± 2.8 (65–78). The mean MBL was −0.53 ± 0.28 mm (−0.22 to −1.12 mm). Plaque and bleeding scores were 14.4 ± 8.18 and 7.15 ± 4.4, respectively.

Conclusion: Within the limitations of this proof-of-concept dynamic navigation was effective to deliver in the planned coordinates both implants and prosthesis and guide bone and soft tissue sculpturing. Immediate loading of digitally prefabricated esthetically driven complete-arch FDP was facilitated, resulting in high implant and prosthetic success rates.

Clinical Significance: The investigated digital workflow integrating dynamic navigation may overcome the difficulties related to immediate positioning and loading of digitally prefabricated complete-arch FDP. The navigation guided soft and bone

tissues sculpturing, associated to xenogeneic collagen matrix grafting, represented a predictable technique to achieve the digitally planned interface, reestablishing the mucosal dimension required for the protection of underlying bone while maintaining tissue health.

KEYWORDS
CAD/CAM, dynamic navigation, full-arch, guided bone reduction, guided surgery, immediate loading

1 | INTRODUCTION

The modern workflow for guided implant-supported complete arch fixed dental prostheses (FDP) relies on the following interrelated digital milestones: three-dimensional (3D) imaging and digital planning, static, or dynamic guided surgery, intraoral or extraoral optical surface scanning of the patient intraoral anatomy (IOS/EOS) and computer-aided design/computer-aided manufacturing (CAD/CAM) prosthetics.[1,2] The growing interest in minimally invasive implant placement with the option of delivering immediately a prefabricated provisional prosthesis, have led to the development of numerous guided surgery systems and technologies. The new technological advancements have significantly improved data acquisition, leading to a more realistic, and accurate 3D rendering of the implant site characteristics and neighboring anatomy, and providing more insight into surgical, prosthetic, and esthetic requirements of the treatment. The facial analysis with the smile design was highly advised to drive the complete arch treatment planning toward a successful face rejuvenation, rehabilitating the patient with the original centric relation, vertical dimension, and skeletal relationship between the jaws.[3-6] Superimposition and 3D rendering of the facial skeleton, soft tissue, and dentition by fusing different sets of 3D imaging files (digital imaging and communications in medicine [DICOM]) and stereolithography (STL) files, resulted in the creation of the virtual dental patient (VDP).[7-9] This systematic digital method enhanced a comprehensive treatment plan, based on a non-invasive simulation of the surgical and prosthetic outcomes, as well as of the critical zone of the soft tissue interface, in a more logical and interdisciplinary manner than the conventional analogic approach.[6,10]

Computer-assisted implant positioning included static and dynamic systems. Static guided surgery is synonymous with a predetermined implant position without real-time visualization of the implant site preparation as it's being achieved by means of a CAD/CAM template, with metal sleeves and a coordinated surgical instrumentation.[11] Clinicians cannot change the pathway of the drills unless the guided surgical procedure is interrupted, the template removed and the drilling and implant positioning are continued free-hand. No intraoperative position changes can be made with a fully guided static system.[12,13] Dynamic guided surgery or navigation allowed a real-time visualization of implant site preparation while the drills are on function, without any template hiding the surgical field or hampering the soft tissue handling.[14,15] Dynamically assisted full surgical guidance was possible, deviations from the predetermined plan can be assessed and the related adjustments of position made at any time during the surgery.[16,17] Currently, the original dynamic navigation concept was implemented to orchestrate the surgical and prosthetic aspects to achieve ideal site-specific results and meet patient expectations of anticipate a natural-appearing with an immediate temporary FDP.[9,18] The sophisticated algorithms of the 3D implant planning software allowed the digital design of a prefabricated biologically driven prosthesis, whose contours take into account the distance to the bone and the advised soft tissue height to maintain a healthy restorative interface and the marginal bone loss (MBL) within the criteria of implant success over time.[19-22] This previously published protocol named digitally assisted soft tissue sculpturing (DASS) can be integrated with the dynamic navigation technology to sculpture the restorative interface, in order to allocate the immediate DyNav temporary prosthesis in the 3D planned position, and act as a prosthetic scaffold to enhance soft tissue interface scalloping and maturation.[10] Today, the main challenge still remains how to precisely position the immediate temporary prosthesis the day of the implant positioning in the same coordinates as digitally planned.[9] The aim of this proof of concept prospective single cohort study was to report the 1-year clinical and radiologic outcomes of patients treated with a novel digital workflow integrating dynamic surgery, to streamline the execution of implant placement and the immediate delivery of a navigation guided prosthetics.

2 | MATERIALS AND METHODS

This investigation was designed as a proof of concept prospective single cohort study pilot to future randomized clinical trials. This study was written according to the strengthening the reporting of observational studies in epidemiology (STROBE) statement for improving the quality of observational studies (http://www.strobe-statement.org).[23] Patient recruitment and study outcomes were monitored by the Scientific Review Board of the University of Rome Tor Vergata, Italy. The investigation was conducted in compliance with the Declaration of Helsinki for biomedical research involving human subjects as amended in 2008 and according to the industry regulations (the International Conference for Harmonization Guideline for Good Clinical Practice and ISO14155). Any patient of both sexes, aged 18 years, requiring at least one complete-arch implant-supported FDP, of both jaws, after signature of the informed consent was enrolled. Patients were

informed of the nature of the study, benefits, risks, and possible alternative treatments and provided consent prior to inclusion in the study, as well as any follow-up evaluations required for the clinical study. All patients were treated in one specialized rehabilitation center treated between January and September 2019. All the implants were positioned by means of a dynamic navigation system (X-Guide, X-Nav Technologies, Inc, Lansdale, PA) by one expert clinician who performed all surgical and prosthetic procedures. One dental laboratory qualified in CAD/CAM technology manufactured all the temporary polymethyl methacrylate (PMMA) (Whitepeaks, Whitepeaks Dental Solutions GmbH & Co, Essen, Germany) and the definitive zirconia-based screw retained FDPs. The following inclusion criteria were used: (1) Healthy patients; (2) both full mouth bleeding on probing and a full mouth plaque index lower than or equal to 25%; (3) a residual alveolar crest sufficient to accommodate a straight regular platform implant of at least 10 mm length and 5 mm width; (4) a bone height and width of at least 5 mm distal to the first premolar, to position angulated implants; (4) resonance frequency analysis (RFA) implant stability quotient (ISQ) 64.

Exclusion criteria were general medical (American Society of Anesthesiologists, ASA, Class III or IV) and/or psychiatric contraindications; pregnancy or nursing; any interfering medication such as steroid therapy or bisphosphonate therapy; alcohol or drug abuse; heavy smoking (>10 cigarettes/day), radiation therapy to head or neck region within 5 years, untreated periodontitis; high and moderate parafunctional activity, absence of teeth/denture in the opposite jaw; unavailability to attend regular follow-up visits; poor oral hygiene, and motivation.

3 | DIGITAL WORKFLOW

All the patients received a comprehensive clinical and digital examination including cone beam computed tomography (CBCT) performed with the *smiling scan* protocol, previously published by the Authors[6] and an IOS (Trios3, 3Shape, Copenhagen, Denmark). A high speed CBCT device (Scanora 3Dx, Kavo Dental GmbH, Biberach, Germany) with an amorphous silicon detector was used to scan the patient with the following settings: field of view 140 mm height, 100 mm width, high resolution (voxel sizes 0.25 mm), kV 90, mA 10, and an effective exposure time 6 s. The patient was exposed to CBCT, displaying a broad smile for the duration of the examination. The *smiling scan* technique is an effective, easy to use, and low-cost technique to render VDP showing a broad smile under static conditions (Figures 1–3). Prior to acquisition of the CBCT scan, a prefabricated thermoplastic device with three radiopaque fiducials (X-Clip, X-Nav Technologies) was placed on the teeth of the dental arch involved in the implant surgery. The clip device was removed after the CBCT, appropriately labeled, and stored for later use during implant surgery to hold the patient tracking array. In case of terminal dentition and edentulous patients, the clip was replaced by five fiducial self-drilling titanium bone screws (4–5–6 mm in length) (TriStar Screw X-Nav Guided Surgery System Kit, Impladent LTD, New York, NY), positioned into the bone, prior the CBCT, buccally or lingually along the arch to be treated, by means of a 5 mm soft tissue full thickness incision. Thereafter the CBCT examination was performed with wax rims accommodated in the mouth or with the complete removable dental prostheses properly relined, to stabilize the jaws in the patient centric relation. Moreover, in case of complete edentulism of one or both dental arches the *smiling scan* and the integration of the planned prosthesis within the craniofacial model was achieved through the double scan technique with fiducial markers-based matching.[24] In the aforementioned scenario, a radiographic acrylic resin guide was fabricated, duplicating the patient denture properly addressing the vertical dimension, phonetics and esthetics, and trimming the buccal flange in order to better visualize into the software the interplay between the ideal prosthetic contour at the cervical level and the edentulous ridge.[6] The superimposition of the CBCT and IOS, through the matching of the resulting DICOM and STL data files, required the identification of corresponding landmarks in both scanning datasets. The proprietary algorithm software (DTX ImplantStudio, Nobel Biocare AG, Kloten, Switzerland) automatically overlays the DICOM data with the STL data. The prosthetically driven implant positioning was facilitated by the tooth-design software tool (*smart setup*) that digitally

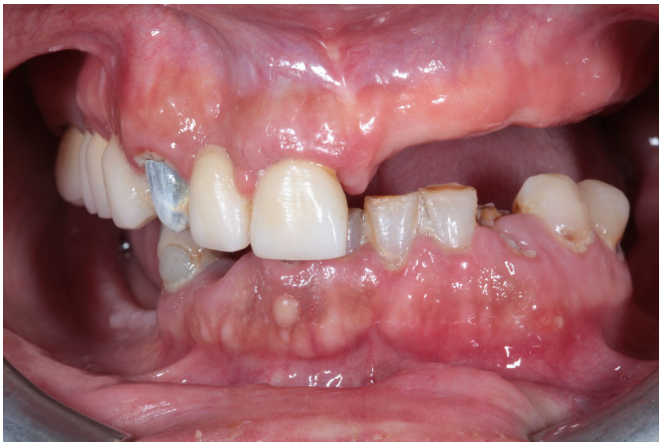

FIGURE 1 Terminal dentition patient with bone and soft tissue deformities, teeth, and bone super-eruption, collapse of the vertical dimension of occlusion and reduced inter-arch clearance

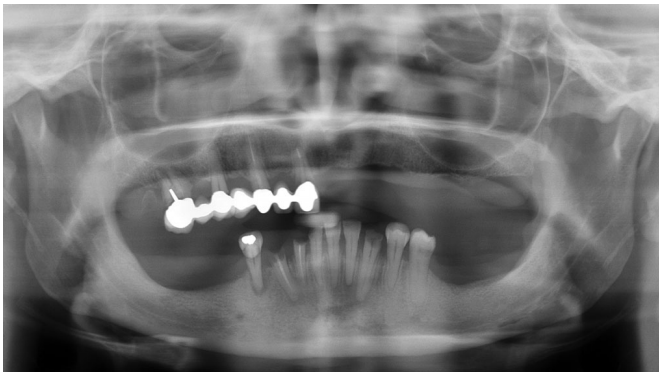

FIGURE 2 Pre-operative ortopantomograph

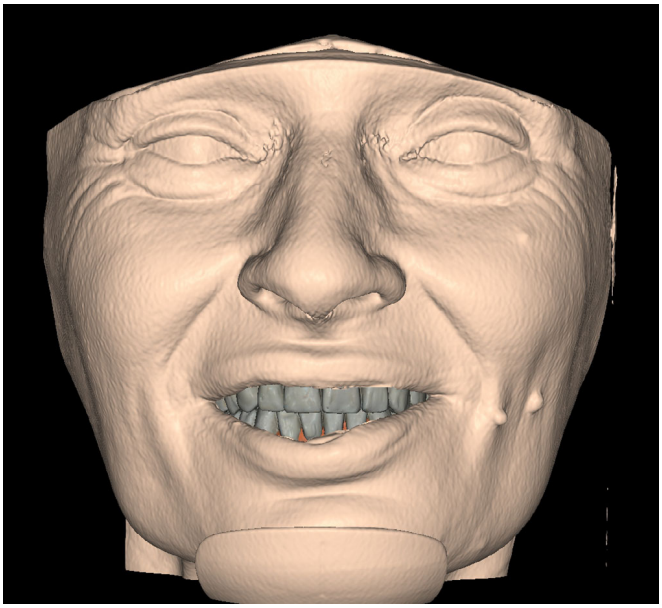

FIGURE 3 Smiling scan technique with digital wax-up. The cone beam computed tomography scan was taken with wax rims in the patient mouth to restore the centric relation and the skeletal relationship between the jaws

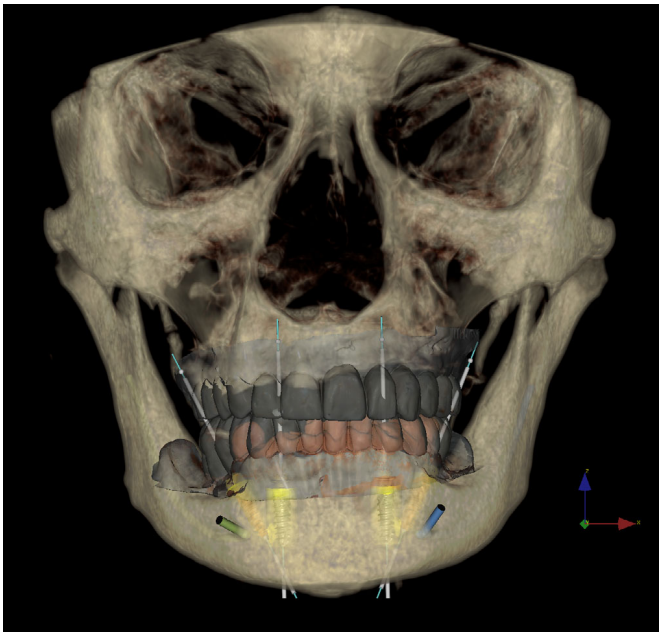

FIGURE 5 Prosthetically and soft tissue driven implant positioning in the mandible. The bone and dental super-eruption was compensated by the navigation guided osteotomy

designed the complete-arch wax-up (Figures 4 and 5). In case of the double scan protocol the implant planning was driven by the 3D rendering of the clinically validated radiographic guide.

The DyNav protocol relied on 3–4 guiding pins, digitally designed at the perio-restorative interface of the immediate temporary restoration, in order to facilitate the delivery of the prefabricated complete-arch prosthesis in the digitally planned coordinates and the immediate loading. Such guiding pins were digitally designed as attachments of the prefabricated prosthesis in order to be aligned and fit 3–4 corresponding bone recipient sites (5 mm in length and 4 mm in width) strategically planned as "mini-implants" in-between the supporting implants.

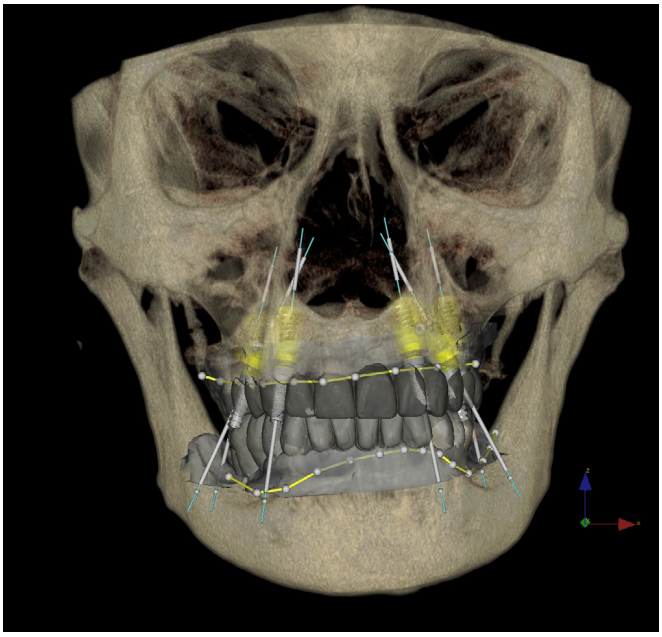

FIGURE 4 Prosthetically and soft tissue driven implant positioning in the maxilla. The segmented yellow lines highlighted the upper and lower bone crest deformities and vertical super-eruption and atrophy

The approved 3D planning file, including the all the implants coordinates and the digital wax-up was exported and uploaded into the dynamic navigation system (X-Guide, X-Nav Technologies). The proprietary algorithm of the navigation software allowed to integrate and transform the DICOM file in segmented interrelated STL file embedding the face, the skull, the intraoral surface anatomy (dental and soft tissue), the digital wax-up, and the implant coordinates. The segmented multiple interrelated STL files were then exported to the prosthetic software (DTX StudioLab, Nobel Biocare AG) to design the DyNav immediate complete arch temporary FDP and plan the dynamic navigation assisted bone reduction in case it's needed (Figures 6 and 7). The soft-bone tissue interface could be digitally designed in order to simulate the ideal ridge form to house the overall prosthetic framework, considering at the same time the minimum soft tissue thickness required to protect the underlining bone.[20-22,25-27] A well-fitting perio-restorative interface was designed, adapting the prosthetic contour of the temporary FDP to the digitally designed soft and bone tissue architecture regardless the type of restorative interface (FDP-1, –2, and –3).[28] The prosthetic software allowed a clear visualization of the relationship between the soft and bone tissues and the prosthetic contour at the cervical area, facilitating the digitally assisted soft-bone tissue sculpturing (DASS) technique.[10] The DASS

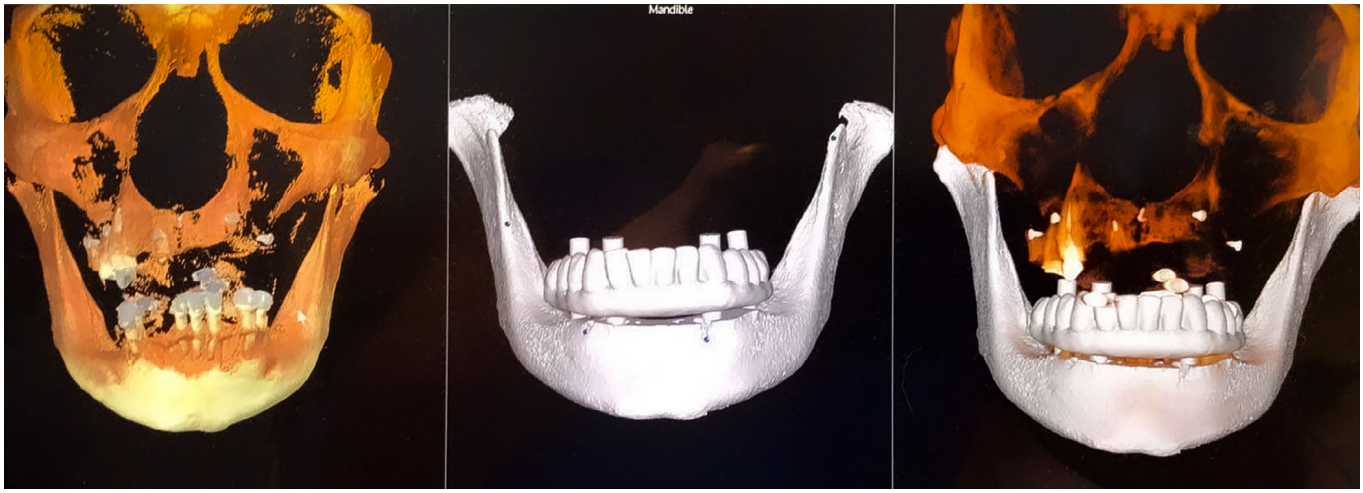

FIGURE 6 the multiple segmented interrelated stereolithography files, connecting the DyNAv prosthesis design to the mandible to transfer into the navigation system the coordinates for the prosthetically driven guided bone reduction

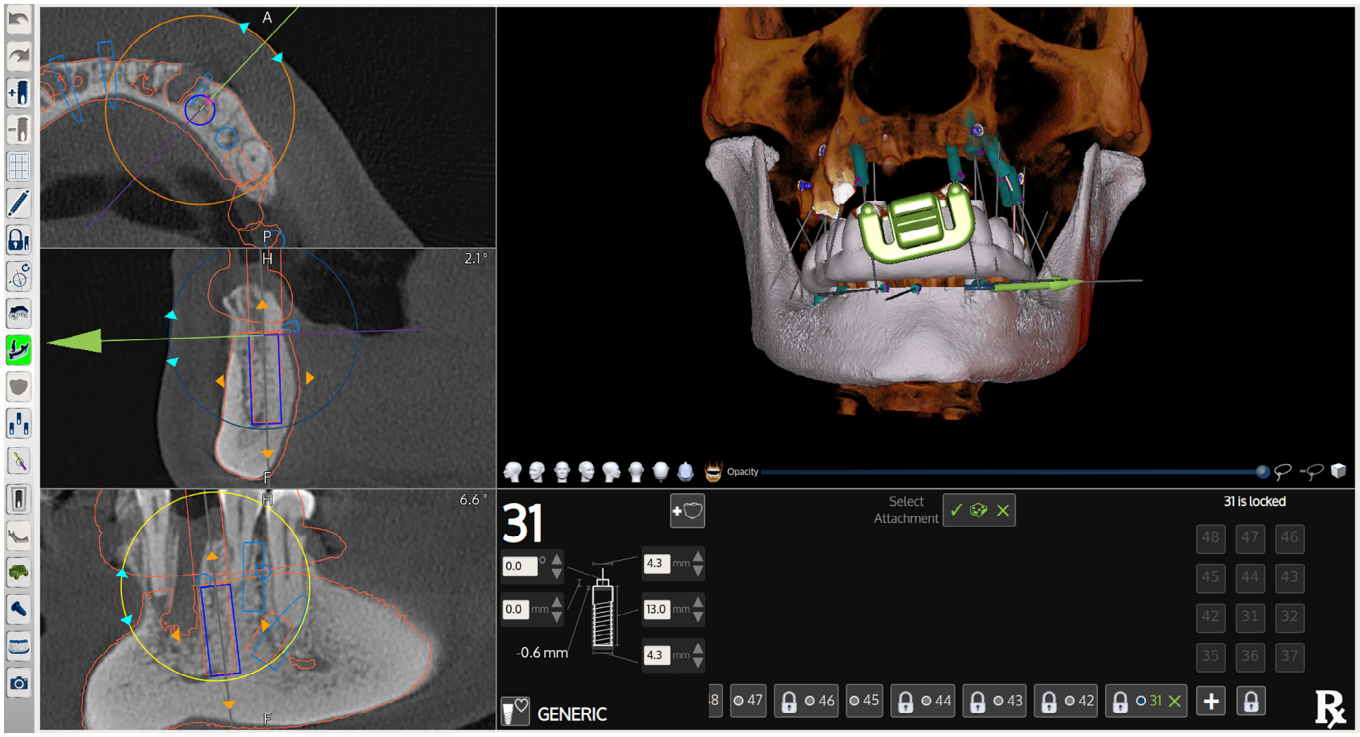

FIGURE 7 the superimposition of the DyNAv prosthesis and the mandibular bone osteotomy stereolithography files onto the patient anatomy allowed to clearly visualize in the screen of the navigation system the bone reduction interface

technique aims to achieve a consistent 3 mm distance from the prosthetic contour and the bone interface by means of a digitally planned soft-bone tissue sculpturing and the proper design of the restorative interface regardless if it's scalloped or flat. In case of FD-1 and 2, the digital design of the prosthetic contour at the pontic sites followed the concepts of the biological pontic design previously published by the authors with a tight but non-compressive contact with the soft tissue to allow easy hygienic access to the supporting implants to improve oral hygiene maintenance and reduce the risk of biological complications.[20]

In case of FDP-3 prosthetic design, virtual bone reduction was planned, and a temporary FDP with a pink-resin interface designed accordingly (Figures 8 and 9). In addition, the implant abutment files were used to create access holes for the titanium temporary cylinders to be attached at the end of the surgery. A fully adjustable virtual articulator set up was used to dynamically verify the occlusion according to the real patient values recorded with an electronic face-bow (Arcus Digma, KavoDental GmbH). The overall DyNav digital workflow was summarized in the diagram presented in Figure 10.

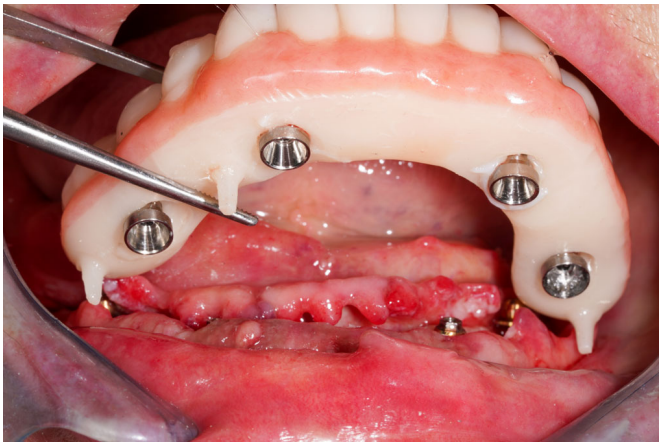

FIGURE 8 the intaglio surface of the pink assisted DyNav lower prosthesis with the prosthetic guided pins and the connected temporary cylinders

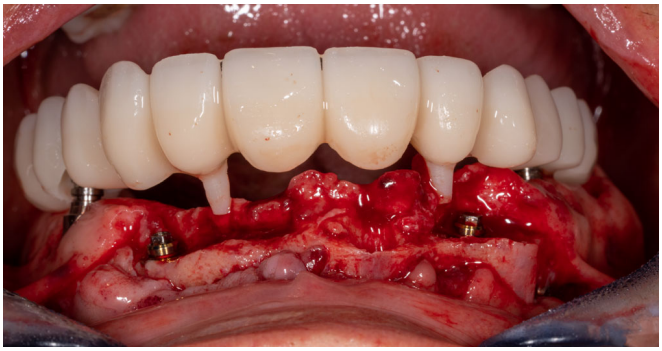

FIGURE 9 The pink-free DyNAv upper prostheses with the guide pins to be inserted in the related bone recipient sites to drive the positioning in the digitally planned coordinates

4 | CALIBRATION

Calibration of the surgical handpiece and the patient tracking array was performed prior to surgery. The handpiece calibration determined the relationship between the geometry of the handpiece tracking array and the axis of the drill. The navigation algorithm automatically related the patient tracking array geometry to the CBCT images of the fiducials, represented by the three radiopaque landmarks of the prefabricated thermoplastic device or by the heads of five fiducial self-drilling titanium bone screws (4–5–6 mm in length) in case of edentate or edentulous patients respectively. In case of the fiducial bone screws workflow, a dedicated calibration probe was used to touch the screw-head in order to couple with their CBCT images. The surgical handpiece and patient tracking arrays must be within the line of sight of the overhead stereo cameras to be accurately tracked on the monitor. Hence, a link between the preoperative planning coordinate system and the tracking coordinate system is automatically generated. This stereo tracking algorithm triangulated the two arrays continuously, to determine their precise position and orientation in a common coordinate frame during the surgery. The dynamic connection of the drill body and tip with the patient's CBCT anatomy and the implant coordinates pre-planned into the software is visualized with high magnification on a dedicated screen to guarantee an accurate navigation through a real-time coordination of the surgeon's hands and eyes.[18]

5 | SURGICAL AND PROSTHETIC PROTOCOL

Depending on the recipient site characteristics, conventional (with flap) or flapless surgical procedure was performed. The dynamic navigation system did not require a dedicated drill kit. Any type of drill can be used to prepare the implant site after calibrating the drill length. The drills were used in their normal sequence to prepare the implant site. The 360° dynamic navigation control of the implant site preparation allowed the operator to perform a low speed drilling ranging from 250 rotations per minute (RPM) and 500 RPM according with the bone density. Despite of the low speed drilling, copious irrigation was used to avoid overheating. A 4 mm twist drill was used to prepare into the bone the DyNav guiding pin recipient sites according to digitally planned trajectory and with the guidance of the dynamic navigation. A five-axis milling machine (DWX-51D, Roland DG, Shizuoka-ken, Japan) fabricated the complete arch FDP from a multilayered PMMA (Whitepeaks, Whitepeaks Dental Solutions GmbH & Co) to confer a natural esthetic appearance. The soft tissue reduction was performed with a mucotome connected to the contra-angle and guided by the navigation system, in order to carve selectively the soft tissue at the implant and pontic sites. The navigation guided bone reduction was performed marking the osteotomy line first with a round surgical drill and cutting the bone with carbide fissure drill connected to a contra-angle or straight handpiece dynamically controlled by the navigation tracking system. Thereafter, the DyNav temporary prosthesis was used as a prosthetic scaffold to guide the final detailing of the soft and bone tissues surgical sculpturing by means of a microblade (CK-2 Small Full Radius Scalpel, KavoKerr, Orange, CA) and the piezotome insert OT4 under copious irrigation (Piezosurgery touch, Mectron spa, Carasco, Italy).

The fresh alveolar sockets were filled with 0.25–1 mm granules of slowly resorbing bone substitute material (Bio-Oss or Bio-Oss Collagen, Geistlich Pharma, Wolhusen, Switzerland), which was hydrated using the patient's blood mixed with antibiotic solution (Rifocin 250 mg/10 ml, Sanofi-aventis, Milan, Italy). A porcine, porous, resorbable, and volume-stable collagen matrix (Fibrogide, Geistlich Pharma AG) was positioned between the soft and bone tissue interface and the prosthetic contour in order to enhance the soft tissue regeneration, avoiding bone exposure[10,29-31] (Figures 11–13).

The PMMA FDP was positioned in the mouth by means of the guidance of the prosthetic pins, inserted into the respective bone recipients' sites. The esthetic and functional pin-guided positioning was verified inviting the patient to close the mouth up to find the digitally planned occlusion. Thereafter, nonengaging titanium temporary cylinders were screwed onto the implants and the FDP relined with an auto-polymerizing polyurethane resin (Structur 3, Voco Dental,

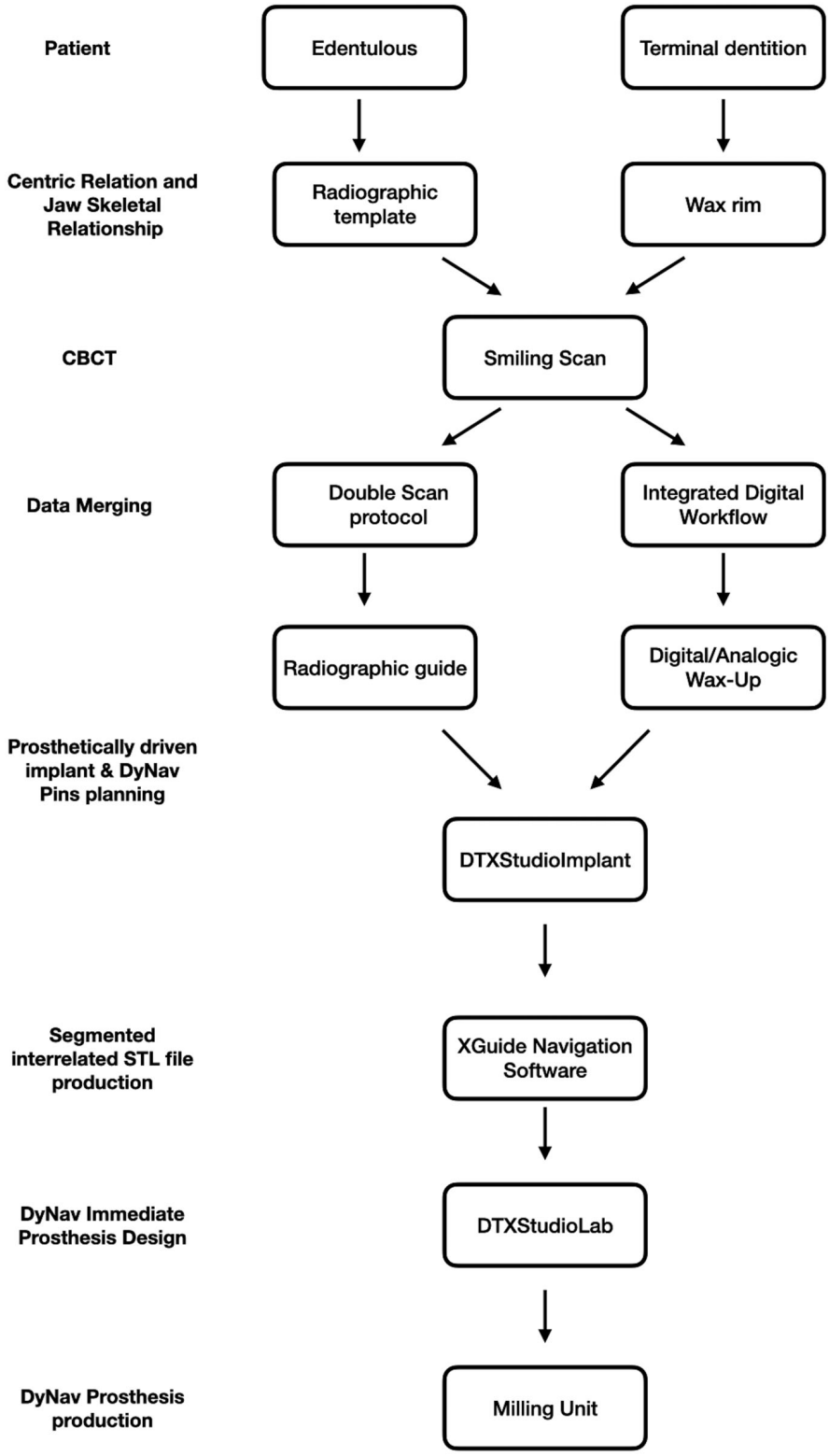

FIGURE 10 DyNAv radiological, digital and clinical workflow

Cuxhaven, Germany). Minor functional and esthetic adjustments were performed in case it's needed. After an uneventful healing period of 3 and 4 months in the mandible and the maxilla respectively, a definitive impression were made with a conventional open tray technique, according to a previously published protocol.[32] The definitive zirconia-based implant-supported screw-retained (ZrPIB) FDP was designed with the prosthetic software (DTX Studio Lab, Nobel Biocare AG) and subsequently milled at a centralized industrial production facility according to Authors previously published protocols[1,33] (Figures 14–19).

All the definitive ZrPIBs were inserted 4–6 months after implant placement (Figures 14–16). Patients were recalled after 15 days for a

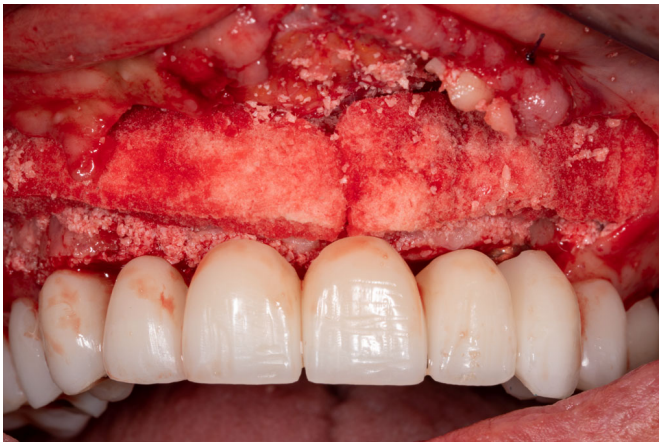

FIGURE 11 the digitally assisted soft tissue sculpturing technique is completed with the bone and soft tissue xenogeneic grafting to configurate the perio-restorative scalloped interface

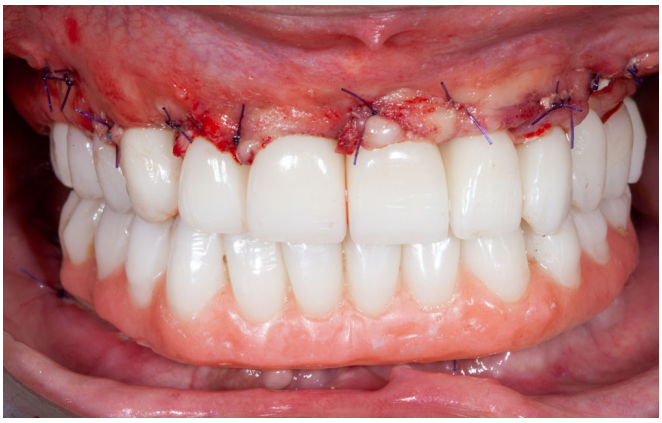

FIGURE 12 the upper and lower DyNav prostheses immediately delivered and loaded the day of the surgery

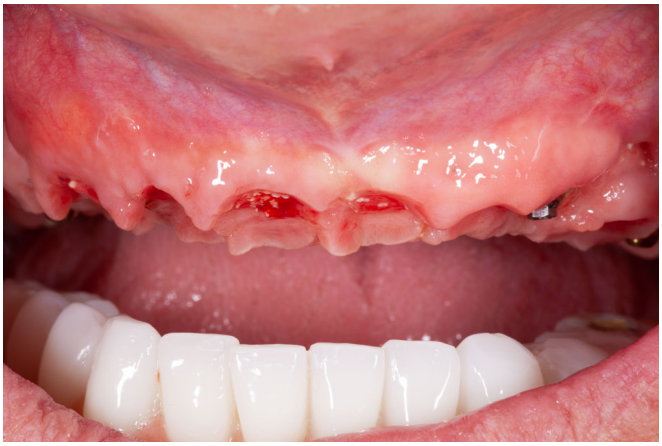

FIGURE 13 the soft tissue enhancement and maturation determined by the scaffold effect of the DyNav prosthesis and the xenogeneic soft tissue matrix grafting

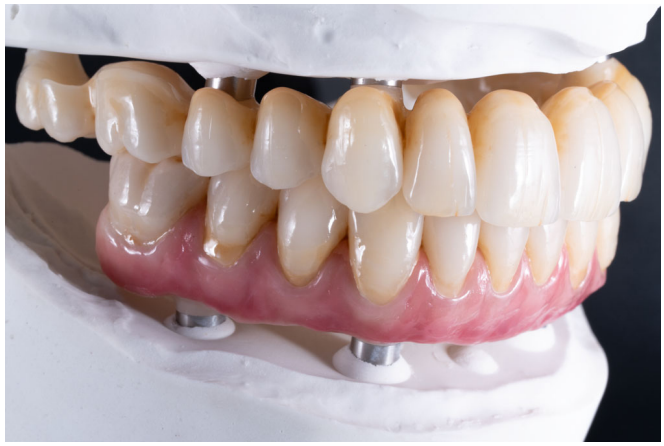

FIGURE 14 The definitive zirconia based screw retained fixed dental prostheses. The upper prosthesis was designed to match the scalloped restorative interface while the lower one was pink assisted to compensate for the massive bone and soft tissue atrophy

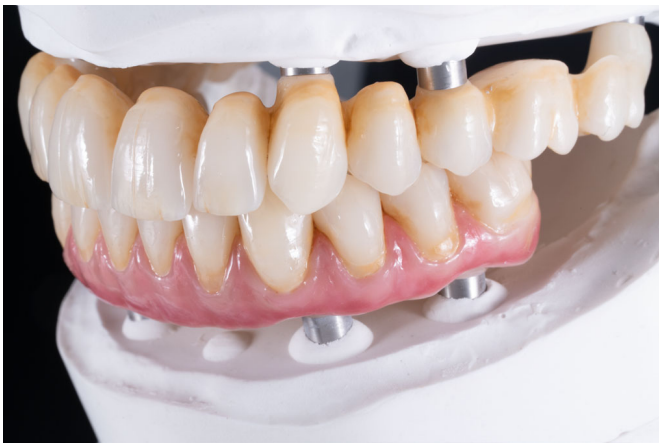

FIGURE 15 The posterior teeth were designed as monolithic and just stained on the surface while the anteriors to address the esthetic demands of the patient and better design and control the occlusion as lithium dislicate crowns

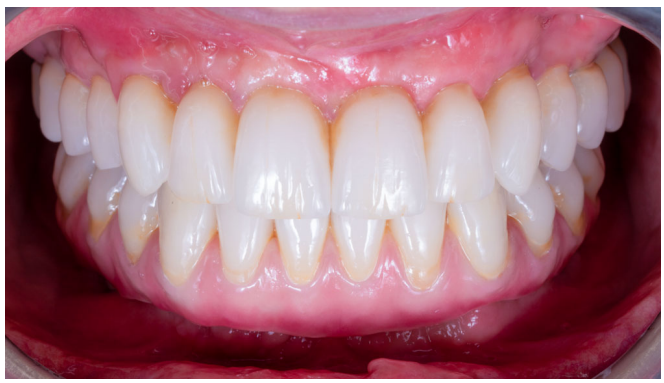

FIGURE 16 the upper and lower definitive fixed dental prostheses integrated in the patient mouth

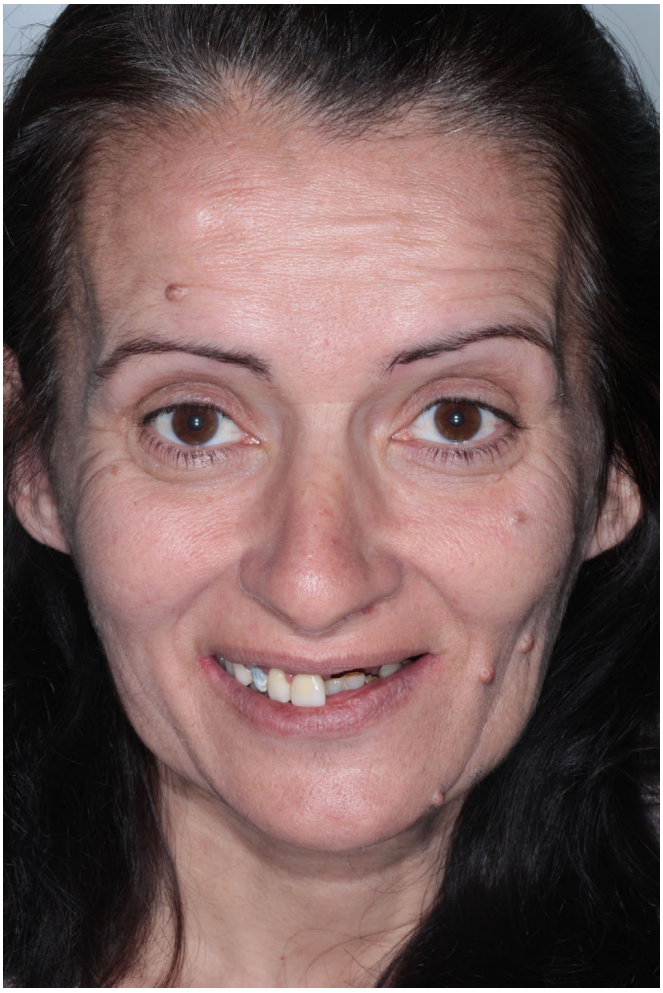

FIGURE 17 Patient face pre-op view with all the typical characteristics of the terminal dentition

FIGURE 18 Patient post-op view with the pleasant esthetic outcome and face rejuvenation determined by the recovery of the centric relation, vertical dimension, and skeletal relationship between the jaws

further occlusion adjustment and every 4–6 months for professional hygiene and occlusion assessment. A rigid, acrylic night-guard was delivered to protect the veneering porcelain from occasional parafunctional habits. The patient was informed to consult the clinic immediately if complications occurred.

6 | OUTCOME MEASURES

An independent blinded assessor recorded all of the measurements and gathered the related data. Primary outcomes were implant and prosthetic success rates, surgical, and prosthetic complications. Secondary outcomes were MBL, ISQ, and periodontal parameters (plaque and bleeding indexes at implant level). The implant success and survival criteria used in this study were modifications of criteria suggested by Van Steenberghe.[19] A "successful implant" is an implant that: (1) does not cause allergies, toxicity, or gross infectious reactions either locally or systemically; (2) offers anchorage to a functional prosthesis; (3) does not show any signs of fracture or bending; and (4) does not show any signs of radiolucency on an intraoral radiograph using a paralleling technique strictly perpendicular to the implant bone interface. A "surviving implant" was defined as an implant remaining in the jaw and stable. Even if all success criteria were not fulfilled. On the other hand, a failed implant was an implant that had been removed.[18] Prosthetic success was evaluated using modified criteria suggested by the California Dental Association.[34] A "surviving prosthesis" is a prosthetic reconstruction that is stable and in good function. Complications were defined as any biological (pain, swelling, suppuration, etc.) and/or mechanical complications (fracture of the abutment and/or the veneering material, screw loosening or fracture, etc.). Marginal bone levels were assessed using intraoral digital periapical radiographs at implant placement (base-line) and after 1-year from the definitive prosthesis delivery. Intraoral radiographs were taken with the parallel technique by means of a periapical radiograph with a dedicated holder. Periapical X-rays were collected and forwarded to one independent radiologist not informed on the aims of the study. The

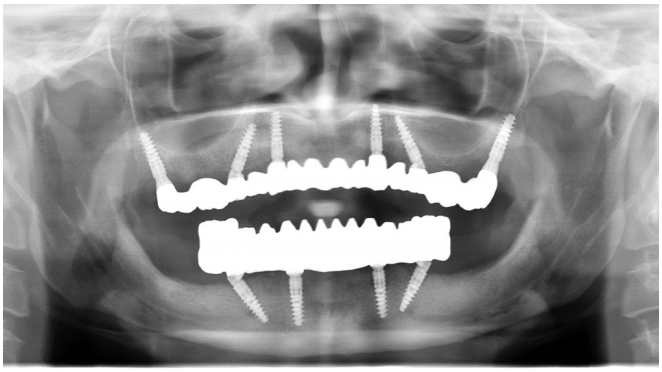

FIGURE 19 Final ortopantomograph with the zirconia based definitive fixed dental prostheses directly seated and screw retained at the multi-unit abutment level

periapical X-rays were loaded onto Osirix MD 7.5 image diagnosis and analysis software package (Pixmeo SARL, Geneva, CH) on a Mac Pro Workstation (iOS 10.13.6) adjusting the density and contrast for optimal visibility of the crestal bone. For measurements, the images were magnified 15–20 x and all distances taken in pixels. The mesio-distal width of the implant was measured by drawing a reference line from edge to edge along the implant–abutment junction. The distance between the outer edge of the implant platform and the first bone-to-implant contact point was measured on both mesial and distal surfaces of the implant. Either positive or negative measurement depending on whether the bone level was above/coronal or below/apical to the reference line, respectively. Using the correlation between the known (in mm) and measured (in pixels) width of the implant as a calibration reference, all pixel measurements were converted to mm. MBL was subsequently calculated for paired radiographs from baseline (the day of implant placement) to last follow up by an independent and blinded radiologist.

The ISQ was recorded using a patented technology (Osstell, W&H, Göteborg, Sweden) respectively. Plaque and bleeding indexes were recorded at implant level.[35] Each implant was examined on four aspects (mesial, distal, vestibular, palatal). The percentage of sites in which plaque could be find, regardless its amount, was recorded. Briefly, any site in which plaque could be detected by naked eye or with a probe. The same was made for bleeding index, considering positive any site that showed bleeding on probing. Descriptive analysis was performed using mean ± standard deviation.

7 | RESULTS

A total of 10 patients were treated. All patients (three males and seven females; mean age 62.5 ± 8.9 years; range, 48–75 years) were consecutively enrolled in this study and the data collected analyzed. One patient was smoker with an average daily consumption of 8.2 cigarettes (range, 5–10 cigarettes). No dropout occurred during the entire follow-up, and all data collected were evaluated in the statistical analysis. All patients were treated according to the allocated interventions with no deviation from the original protocol. A total of 60 implants (32 NobelParallel TiUltra and 28 NobelActive TiUltra, Nobel Biocare AB) were placed. Twenty-four axial implants and 36 angulated implants were placed, and all of them had a 4.3 mm platform. Six patients presented as opposite dentition ceramic implant-supported FDPs, four patients natural teeth, and two patients natural teeth and ceramic implant-supported FDPs. All patients were followed for at least 1 year in function (mean 16.2 ± 1.7 months range, 14–18 months). One implants out of 60 failed before the definitive prosthesis delivery. The failed implant (4.3 × 13 mm in the pterygoid region) was immediately replaced by 4.3 × 15 mm implant, after having modified the navigation planned implant insertion trajectory. Therefore, the analysis was undertaken on 61 implants while the success rate was calculated on 60 implants, leading to a 98.3% implant success rate. No prosthetic complication occurred resulting in a prosthetic survival and success rate of 100%. The mean MBL between implant placement and the last follow-up was −0.53 ± 0.28 mm (−0.22 to −1.12 mm). Implants were placed with a mean ISQ of 71 ± 2.8 (65–78). Plaque and bleeding scores were 14.5% ± 8.18% and 7.15% ± 4.4%, respectively.

8 | DISCUSSION

The present prospective observational study was designed to evaluate clinical and radiographic outcomes of a novel digital workflow integrating dynamic surgery, to streamline the execution of implant placement and the immediate delivery of a navigation guided complete-arch prosthetics. Because it was designed as a single cohort study, the primary limitation of the current investigation was the lack of a control group. However, the authors identified no published reports on complete-arch minimally invasive guided treatment, integrating dynamic navigation technology to drive into the digitally planned coordinates both implants and prosthesis. Moreover, this investigation was a proof-of-concept study and a pilot for future multicenter randomized clinical trials with sample size calculation. Nevertheless, 12 *DyNav* immediate temporary complete-arch implant-supported FDPs supported by 60 implants were performed on 10 patients, who were observed for at least 1 year (mean 16.2 ± 1.7 months range, 14–18 months), allowing some preliminary and generalizable conclusions to be drawn, even if a prospective power analysis with sample size calculations was not performed.

The Clinical and radiologic performance of this novel digital workflow integrating dynamic navigation was encouraging within the short-term follow-up. High primary stability and bone-to-implant contact were achieved for all the implants {mean ISQ of 71 ± 2.8 (65–78)}. All the digitally designed *DyNav* prefabricated immediate prostheses were delivered and relined onto the temporary cylinders in the digitally planned position, and immediately loaded with minor adjustments of the occlusion. One implants out of 60 failed before the definitive prosthesis delivery, and was immediately replaced using the same navigation plan, after having slightly changed the original insertion trajectory and the implant

length in order to find the primary stability to be connected immediately to the temporary prosthesis.

The dynamically guided soft and bone tissue sculpturing, and reduction did not produce any clinically relevant complication. The link between the preoperative planning coordinate system, the surgical handpiece and patient tracking arrays was accurately tracked continuously by the overhead stereo cameras and the stereo tracking algorithm, determining a dynamic connection of the drill with the patient's CBCT and IOS anatomy and the interface sculpturing coordinates pre-planned into the software. The dynamically guided soft tissue carving and bone reduction was facilitated by the 3D rendering on a dedicated screen to guarantee an accurate navigation through a real-time coordination of the surgeon's hands and eyes.

Bone reduction for a complete-arch implant-supported FDP is often utilized to gain restorative space, conceal the prosthesis-tissue junction underneath the transition zone of the lip, improve the implant recipient site, and create a more cleansable surface at the tissue interface.[36,37] Inadequate reduction can lead to prosthetic failure due to material fracture, poor esthetics, or inability to perform oral hygiene procedures due to unfavorable prosthetic contours.[38] Moreover, bone reduction was quite often performed in an empiric way without any biologic and prosthetic rationale. Clinicians often removed large quantities of bone and tissue, essentially modifying the patient's anatomy to create restorative space and fit the prefabricated prosthesis, and in case of FDP-3 to address the interface between the pink restorative material and the edentulous ridge. The Authors reported in a previously published manuscript about the use of CAD/CAM technology to print-out a *scalloped guide* to recontour the bone anatomy in order to streamline the execution of a pink-free implant supported FDP.[39] Subsequently, a smooth, customized bony architecture and soft tissue interface is developed for terminal dentition and completely edentulous patients with minimum bone resorption (Cawood and Howell Class I, II, and III).[40] A system of three CAD/CAM stackable surgical guides allowed to accurately obtain the desired bone reduction, place prosthetically guided implants, and load a PMMA temporary FDP that replicates ideal tissue contours.

However, the major limitation of the stackable guide system is intrinsic in its multiple templates secured through the same anchor pin recipient sites and the related sum of deviations that may occur during their positioning. More recently, Beretta et al.[41] published a technical report on the application of CAD/CAM technology to print out a mucosa supported template used to drill the anchor-pin recipient sites, a bone-supported template, secured through the previously prepared anchor-pin recipient sites to perform the bone reduction and a template secured onto the previous one to guide the implant positioning. The major limitation of this method is related to the different anatomic supports used for the templates. Static guided surgery accuracy was related to type of support, with tooth-supported template more accurate than mucosa-supported. Bone-supported template represented the worst scenario in terms of accuracy and surgical invasiveness because of the need to raise a large full thickness flap to seat on the bone surface and moreover the digital design onto the DICOM file is not as accurate as on the IOS file.[42]

de Moura Costa et al.[43] reported on a fully digital workflow in which superimposition of facial, intraoral and CBCT scans was used to design two surgical templates (i.e., one for alveolar bone reduction and the other for implant placement) magnetically connected to ensure stability and easy positioning of the multiple guides in sequence. The temporary PMMA FDP was magnetically connected to the alveolar bone reduction template to capture the screw retained temporary cylinders. As properly disclosed by the authors the major limitation of the stackable guided surgery system was represented by the positioning in the 3D planned coordinates of the multiple templates and prefabricated-temporary FDP. Moreover, the clinical applicability of this protocol could be advised only in the FDP-3 scenario where enough clearance is available to allocate the multiple stackable templates.

To the best of our knowledge DyNav technique represented the first observational prospective study reporting on an integrated digital workflow that simplifies the immediate delivery and loading of complete-arch FDP without any template limiting the access and view of the surgical field or hampering the handling of the soft tissue. The dynamic navigation was effective to guide in the software planned coordinates both implants and prosthesis and sculpture bone and soft tissue interface accordingly. Hartman recently published a dental technique relying on accurate execution of dynamic navigation implant surgery in order to design and fabricate a single interim implant supported crown to be delivered at the time of surgery with minimal adjustments.[44] However, in case of complete-arch FDP, the prefabricated interim prostheses positioning represented a critical step in the immediate loading workflow due to the difficulties to execute its relinement onto the temporary cylinders in the same coordinates as digitally planned. The DyNav prosthetic pins were effective to drive the complete-arch FDP in the software planned position, according to the functional and esthetic requirements of the patient.

The conversion of a denture into an implant-supported screw-retained temporary FDP has become the standard method for immediate restoration in patients with complete edentulism. The most critical steps of the denture conversion process were the creation of appropriate access holes to prevent displacement of the denture by the temporary cylinders and removal of the denture flanges to facilitate both good esthetics and accessibility for oral hygiene. Oh et al.[45] reported on a digital technique for designing and fabricating a temporary FDP featured with cylinder access holes and denture flange parts easy to be cut off, to be used to reposition in the mouth the prosthesis in the digitally planned position. However, the main limitation of this technique was related to the bearing area of the denture flange that can only drive the temporary FDP in position when a flapless surgical procedure is performed.

The ability of sophisticated 3D CAD software to superimpose precisely several scans provides the dental team with the visualization tools they need to work through complex, full mouth cases levels of control to reconstructive dentistry not previously attainable.[46]

This DyNav digital workflow increased the communication among the clinician and the dental technician, providing a comprehensive

insight into the surgical, prosthetic and biologic needs that have to be accomplished by the digitally designed immediate temporary prosthesis. The mean MBL was within the criteria of implant success {−0.53 ± 0.28 mm (−0.22 to −1.12 mm)} and plaque and bleeding scores were 14.5% ± 8.18% and 7.15% ± 4.4%, respectively.

The DyNav technique and the navigation guided soft and bone tissues sculpturing represented a predictable integrated digital workflow to achieve the preplanned restorative interface (scalloped or flat). The soft tissue healing enhancement determined by the prosthetic scaffold effect of the DyNAv temporary prosthesis and xenogeneic collagen matrix grafting allowed to reestablish the mucosal dimension required for the protection of underlying tissues while maintaining tissue health.

9 | CONCLUSION

Within the limitations of study, this clinical research provides proof-of-principle evidence that *DyNav* digital workflow in combination with dynamic navigation guided surgery can facilitate the immediate delivery and loading of a facially and esthetically driven complete-arch FDP. Navigation guided soft and bone tissue sculpturing associated to xenogeneic collagen matrix grafting, resulted in high implant and prosthetic success rates while maintaining tissue health.

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DISCLOSURE

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ORCID

Alessandro Pozzi https://orcid.org/0000-0002-3052-8186

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