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Immediate flapless full-arch rehabilitation of edentulous jaws on 4 or 6 implants according to the prosthetic-driven planning and guided implant surgery: A retrospective study on clinical and radiographic outcomes up to 10 years of follow-up

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Abstract

Objectives: to retrospectively evaluate clinical and radiographic outcomes of immediate, flapless full-arch prostheses, supported by 4/6 implants according to prosthetic-driven planning and guided surgery.

Materials and Methods: The study involved 28 edentulous patients (20 female/8 males; average age 67.75 ± 8.627 years), 32 prostheses (17 all-on-4/15 all-on-6) and 164 implants. The Implants survival, prostheses success/survival, peri-implant marginal bone loss, incidence of biological and prosthetic complications were evaluated. Multiple linear regression analysis was performed to analyze the influence of implant and patient characteristics on marginal bone loss.

Results: Cumulative implant survival rate was 89.7% for all-on-four (seven failures) and 99.0% for all-on-six (one failure) after a mean follow-up of 6.46 ± 2.236 years (range 1–10 years). Cumulative prosthesis success rate was 51.5% (58.8% for all-on-four/ 43.8% for all-on-six). Prosthesis survival rate was 88.2% for all-on-four. No failure was registered in all-on-six. Mean value of marginal bone loss was 1.38 ± 0.1.28 mm at 5-year and 2.09 ± 0.56 mm at 10-year follow-up. No difference was found in the mean value of marginal bone resorption between all-on-four (1.56 ± 1.61 mm) and all-on-six (1.20 ± 0.85 mm) ($p = 0.104$) and between tilted (1.22 ± 1.29 mm) and axial implants (1.44 ± 1.27 mm) ($p = 0.385$) after 5-year follow-up. The incidence of biological complications was 1.0% in all-on-six (one mucositis) and 10.3% in all-on-four (two peri-implantitis). Prosthetic complications affected teeth of final rehabilitations with 3 detachments, 10 chippings or fractures, and 3 severe occlusal wears.

Conclusions: Based on the results and within the limitations of the present study, the implant-supported hybrid prosthesis according to prosthetic-driven planning and

guided surgery showed to be an efficient, safe, and effective approach to rehabilitate edentulous jaws.

KEYWORDS
all on four, all on six, computer-aided implant dentistry, dental implants, dental implant loading, immediate, dental prosthesis, implant-supported, flapless implant surgery, full-arch implant prosthesis, immediate loading, jaw, edentulous/rehabilitation, jaw, edentulous/surgery, surgery, computer-assisted, survival analysis, template-guided surgery, tilted implants, treatment outcome

Summary box

What is known

Long-term follow-up data on fixed full-arch implant-supported rehabilitation of edentulous jaws according to the computer-guided surgical prosthetic protocol and immediate loading are limited. In most papers on this issue, the follow-up ranged between 1 and 60 months, and only a few studies reported a more extended period.

What this study adds

The present long-term retrospective study reports cumulative implant and prosthetic survival rates, marginal bone loss, and the incidence of biological and prosthetic complications up to 10 years of follow-up. Referred data might increase information on the effectiveness of edentulous jaws rehabilitation according to digital protocol and help clinicians make decisions.

1 | INTRODUCTION

The introduction of computer-aided design/computer-assisted manufacture (CAD/CAM) technologies in conjunction with computed tomography (CT) has dramatically improved the feasibility to rehabilitate edentulous jaws with fixed full-arch implant-supported prostheses, allowing flapless surgery and immediate loading even in the presence of critical bone volume.[1]

Computed tomography (CT) or Cone Beam CT (CBCT) scans and 3-dimensional surgical planning software allow the clinician to analyze the patient's anatomic structures and prosthetic parameters and to virtually plan the optimal implant position and direction. The rapid prototyping consents to produce stereolithographic templates which, transferring virtual planning to the operative field, are especially useful in edentulous jaws lacking anatomic landmarks for surgical reference.[2] Furthermore, transferring the implant position from the presurgical plan to the dental laboratory makes it feasible to prefabricate an all-acrylic resin fixed complete prosthesis for immediate loading.

The computer-guided surgical-prosthetic protocol offers several clinical advantages, such as using all the available residual bone to avoid regenerative procedures, reducing the number of surgical procedures, decreasing the intervention duration and invasiveness, avoiding anatomic limitations, shortening the time frame between surgery and prosthesis delivery and the overall "chair time," and minimizing patient postoperative discomfort, swelling, and pain, with good predictability of functional and aesthetic results.[3,4] Furthermore, this procedure, decreasing morbidity and overall treatment times and improving quality of life, achieve greater patient acceptance and satisfaction than extended surgical protocols or removable prostheses.[5]

Flapless-guided surgery, not needing mucoperiosteal flap elevation and suture, is less time-consuming and reduces bleeding and post-surgical complications (swelling, hematoma, hemorrhage, trismus). Furthermore, a flapless approach maintains the osteogenic potential and the blood supply to the underlying bone and implants, keeping the periosteum in contact with the bone and the supraperiosteal plexus intact.[1,2,6,7]

Nowadays, several computer-aided implant placement procedures are available, which differ in software, template manufacturing, guiding device, stabilization, and fixation.[8] The NobelGuide® concept (Nobel Biocare) is a computer-guided surgical protocol that, using surgical planning software, converts data of digital imaging and communications in medicine (DICOM) files from CT or cone-beam CT (CBCT) scans into 3-dimensional computer images, to virtually perform implant surgery, to transfer the virtual planning to the operating field with a surgical template, and to manufacture prefabricated fixed acrylic prosthesis.[9–11]

The present single-center retrospective study aimed to evaluate in the mean follow-up of 6.46 ± 2.236 years (range 1–10 years) implants survival, prostheses success/survival, marginal bone loss, and the incidence of biological and prosthetic complications of immediate and flapless rehabilitation of edentulous jaws with fixed full-arch prostheses, supported by four or six implants according to NobelGuide® computer-guided surgical protocol (Nobel Biocare, Göteborg, Sweden).

The study was approved by the Institutional Board of "Sapienza" University of Rome, Italy (n.63/2021 Prot.n.000505 del 26/04/2021)

and registered in ClinicalTrials.gov (Identifier: NCT05307029). The manuscript drafting followed STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines from the EQUATOR web site.11.[12]

2 | MATERIAL AND METHODS

2.1 | Study sample

In this retrospective cohort study, participants were recruited from edentulous patients rehabilitated with fixed full-arch prosthesis on four or six implants according to the Nobelguide® protocol between Jun 2009 and December 2019 at the Oral Surgery Unit, Policlinico Umberto I, "Sapienza" University of Rome, Italy.

Inclusion criteria for the rehabilitation were: (1) mandibles or maxillae edentulous or with hopeless teeth; (2) patient's request of fixed implant restorations; (3) patients in general good health (ASA-1/ASA-2). Exclusion criteria were: (1) compromised systemic conditions; head/neck irradiation or chemotherapy within 2 years; (3) bisphosphonate therapy; (4) metabolic bone diseases; (5) insufficient bone volume; (6) mouth opening less than 50 mm inadequate to place surgical instrumentations. History of periodontitis or smoking habit were not considered exclusion criteria. No randomization was applied. The choice of four or six implants to support the prosthesis was based on the patient's clinical and radiographic features. Each patient received detailed descriptions of treatment and trial protocol, after which written informed consent was obtained. The study was conducted in accordance with the 1975 Declaration of Helsinki on medical protocols and ethics and its later amendments.

Inclusion criteria in the study sample were: (1) patients with a minimum of 1-year functional loading; (2) adherence to every 6-month recall program, consisting of the clinical assessment, oral prophylaxis, and oral hygiene instructions; (3) availability of clinical charts, radiographs, and intraoral photographs from the start of the treatment to the end of the follow-up ≥1 year. Exclusion criteria were the inability to comply with maintenance schedules and ambiguous information. Patients were categorized into two groups according to implants number: Group 1 patients rehabilitated with four implants, two axial and two tilted, and Group 2 patients rehabilitated with six axial implants. Data collection, performed in 2021, was related to the patient (age, gender, systemic diseases, smoking habit), implants (number, location, dimensions, inclination), prostheses (multi-unit abutment [MUA] height, opposite dentition) and biological and prosthetic complications.

2.2 | Digital guide protocol

In all patients, medical and dental history was obtained and clinical examinations, photographs, and panoramic radiographs were performed. The patient's existing denture that satisfied support, stability, occlusion, and vertical dimension was used as a radiographic guide. Alternatively, a new removable prosthesis or a template was made on a new aesthetic and functional set-up. Six buccal and three oral spherical radiopaque gutta-percha markers (1,5 mm diameter and 1 mm depth) were 3-dimensionally placed on the prosthesis or radiographic template surface. A silicone interocclusal index was obtained to stabilize the prosthesis or radiographic guide during radiographic exams.[8-10] According to the double-scan technique: the first scan involved the patient wearing the denture or radiographic guide with the radiopaque markers and stabilized with the silicone interocclusal index; in the second, the prosthesis or radiographic guide alone outside the patient mouth was scanned. The data on the anatomical structures and ideal prosthetic teeth position, acquired by the two sets of scans and matched through radiopaque markers, were loaded in the Digital Imaging and Communication in Medicine (DICOM) files, transferred to Procera® NobelGuide software program (Nobel Biocare) and converted into 3-dimensional computer images. On 3-dimensional computer images, the surgeon virtually planned the number, position, length, width, and inclination of implants across the arch in the optimal surgical and prosthetic distribution. From the planning data, a surgical template with appropriate drilling sleeves to guide implant placement in the virtually planned position was manufactured using stereolithography. (Procera® Nobel Guide -Nobel Biocare).

In all patients, regardless of the jaws or planned implants number, the intervention was performed in aseptic conditions under oral sedation with diazepan 0.25 mg/kg (Valium 5 mg, Roche) and local anesthesia with 2% mepivacaine and 1:100000 adrenalin (Carbocaine, AstraZeneca, Milan, Italy). Implants were placed flapless according to the drilling NobelGuide procedure using the stereolithographic surgical template, held in the correct position by the silicone surgical index in occlusion to the opposing arch, and fixed to the bone with anchor pins.

Within 24 h, 10-unit screw-retained acrylic provisional full-arch rehabilitations with no metal wire or caste bar reinforcement and without distal extensions were delivered to patients. Habitual occlusion was adopted, and interferences in excursive dynamic movements were removed to avoid excessive implant micromotion, which may jeopardize the osseointegration process.[13] Abutments and provisional prosthesis fitting were checked clinically and with periapical radiographs using the parallel long-cone technique and a standardized film holder (Rinn Centratore XCP Evolution 2003, Dentsply, Rome, Italy). After occlusion checking, the screw access holes of the temporary cylinders were sealed with cotton pellets and composite resin.

Post-surgical management included amoxicillin 875 mg plus clavulanic acid 125 mg (Augmentin, GlaxoSmithKline S.p.A., Verona, Italy) two times daily for 7 days, and ketoprofen 200 mg of (Ibifen, Aprilia, Latina, Italy) for a maximum of three times daily according to individual analgesic needs. Oral hygiene and post-operative home-care instructions included chlorhexidine di-gluconate 0.12% (Curasept, Curaden Healthcare srl, Saronno, Varese, Italy) mouthwash twice a day for 2 weeks, a soft toothbrushing for another 2 weeks followed by normal brushing and flossing, smoking discontinuance at least for 1 week, a soft diet for 2 months.

After 4–6 months from implants placement, the acrylic provisional prosthesis was replaced with a screw-retained final prosthesis

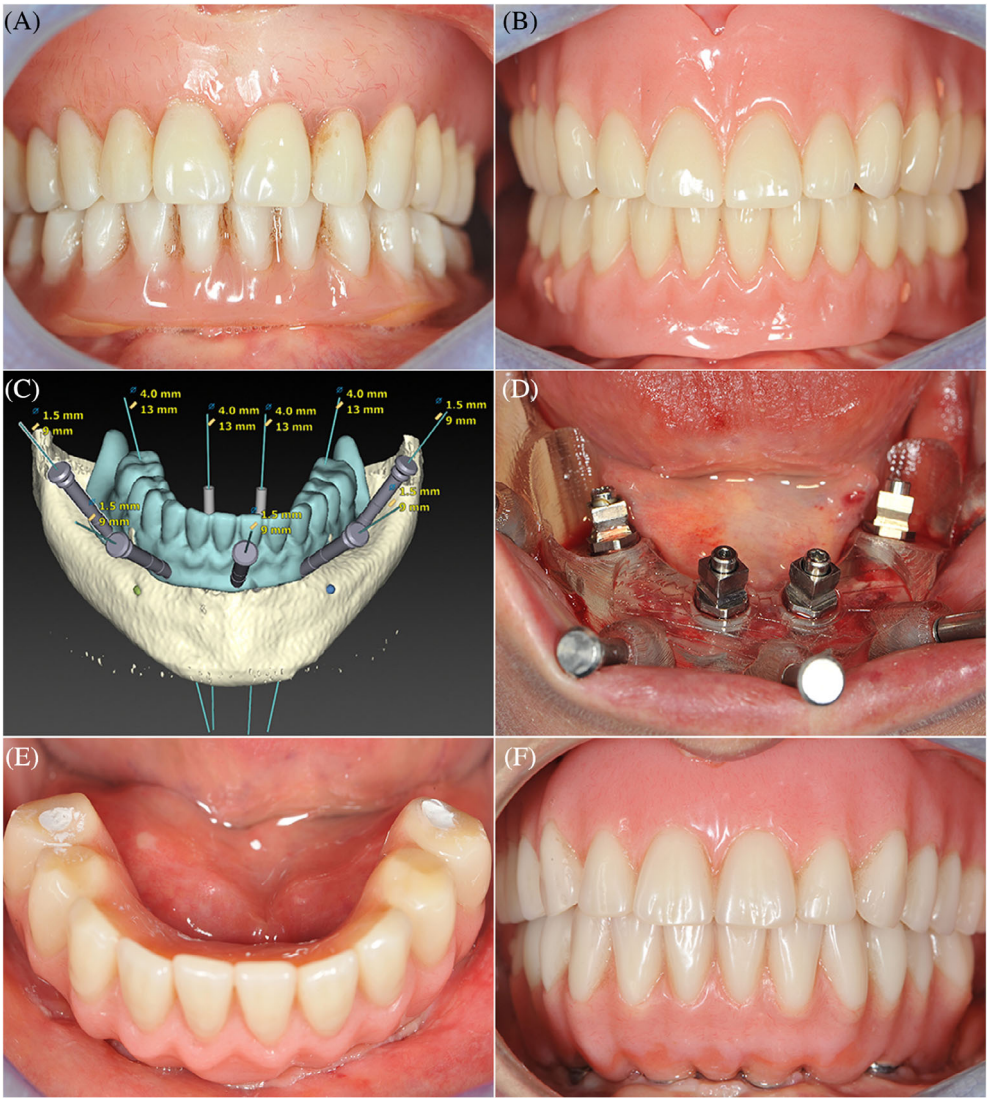

FIGURE 1 A clinical case illustrating digital guide protocol: (A) patient's existing denture; (B) new removable prosthesis with gutta-percha markers to be used as a radiographic guide; (C) 3-dimensional computer planning; (D) intraoperative view of surgical template stabilized with anchor pins and implants; (E) immediate loading with the screw-retained provisional prosthesis; (F) definitive acrylic resin fixed prosthesis.

with distal cantilevers extended to the first molars (12 elements), supported by a metal framework with acrylic resin teeth (Figure 1).

The same experienced surgeon (GLM) performed all virtual planning, surgery, and prosthetic rehabilitation.

The recall visits for clinical and prosthetic re-evaluation were scheduled at 1, 3, 6, and 12 months. In addition, every 6 months, patients underwent a maintenance care program consisting of clinical and prosthetic assessment, professional oral hygiene care with supragingival debridement, dental hygiene instructions. Check periapical radiographs were performed once a year. Throughout follow-up, prostheses were not removed unless of biological or prosthetic complications.

2.3 | Clinical and radiographic endpoints measures

Clinical and radiographic endpoints measured in the study were implants survival, prostheses success/survival, implant marginal bone loss, and incidence of biological and prosthetic complications.

Implants were defined "surviving" as meeting well-established criteria during the entire observation period, such as lack of pain or discomfort; absence of clinically detectable mobility when tested with opposing instrument pressure; absence of infection or inflammation; no peri-implant radiolucency on periapical radiographs; lack of progressive or severe bone loss.[14,15] Implants were considered "failing" when they did not fulfill the success criteria and needed to be removed or replaced.

Prostheses were defined as "success" if in function, free of complications, without modifications and meeting patient comfort and aesthetics during the entire observation time; "surviving" if remained in situ with modifications; and "failing" if needed to be removed or replaced.[11,16,17]

Implant marginal bone loss (MBL) was the difference in marginal bone level from the functional loading time with the provisional prosthesis (baseline) to the end of the follow-up measured in millimeters on periapical radiographs. Periapical radiographs of each implant were taken every year using the parallel long-cone technique and a standardized film holder (Rinn Centratore XCP Evolution 2003, Dentsply,

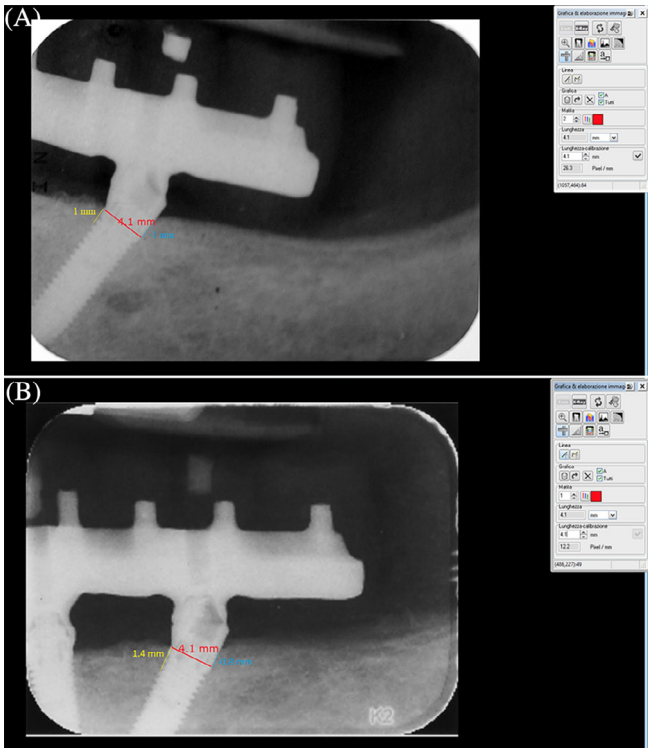

FIGURE 2 Measurement on periapical radiographs of a tilted implant: (A) baseline; (B) 5-year follow-up.

Rome, Italy). In some patients with high alveolar ridge resorption, the film holder was adjusted manually to obtain the orthogonal film position towards the implant axis. The clear visualization of the implant threads was a prerequisite to accept or reject the radiographs for evaluation.[18,19] Selected radiographs were scanned at 600 dpi and digitized (Expression 21 110 000 XL, Epson). The calibrated software (DBSWIN 5, Durr Dental, Ludwigsburg, Germany) was used to estimate marginal peri-implant bone level variations, and known implants diameter were taken as reference (Figure 2). Two calibrated investigators, not involved in the patients' treatment, measured the distance from the implant platform to the first visible bone-to-implant contact on each implant's mesial and distal aspects, and the average value was calculated. The implant platform was the horizontal or orthogonal interface between implant and abutment for axial and tilted implants.[10] Any disagreement was solved by consensus, and a third investigator was consulted when it was not initially possible to achieve complete agreement (defined as a difference between the measurements made by the two experts of >0.1 mm). Inter- and intra-operator variability in assessing MLB was evaluated on 30 randomly chosen periapical radiographs.

Biologic complications included pain, inflammation/infection under fixed prostheses, soft tissue hypertrophy/hyperplasia, soft-tissue recession/dehiscence, peri-implant mucositis, peri-implantitis.[18–20]

Prosthetic complications included detachment/incisal and occlusal wear/fracture/chipping/replacing of denture teeth, fracture of implant, prosthesis or framework, loosening/fracture of abutment or occlusal screw, loosening/fracture of the prosthetic screw.[17,21]

Periodontal indexes were not used in the data analysis due to difficulty accurately performing probing around the implants without removing full-arch prostheses.[20]

2.4 | Statistical analysis

Data were evaluated using standard statistical analysis software (version 20.0, Statistical Package for the Social Sciences, IBM Corporation, Armonk, NY, USA). A database was created using Excel (Microsoft, Redmond, WA, USA). The dependent variables included implant survival rate, prosthesis success/survival rate, marginal bone loss, and the incidence of biological and prosthetic complications during 1–10 years of follow-up. The relationship between the dependent variables and the following independent variables were explored: type of prosthesis (all-on-four/all-on-six), tilted implants (yes/no), and opposing dentition (natural teeth including removable partial denture/ removable complete denture/ implant-supported fixed hybrid prosthesis).

Descriptive statistics, including mean ± SD values and percentage, were calculated for each variable. The Shapiro–Wilk test was used to determine whether or not the data conformed to a normal distribution in the continuous variables.

Intraclass correlation coefficient (ICC) was used to evaluate the inter-(ICC = 0.892) and intra-examiner (ICC = 0.944) calibration.

One-way repeated-measures ANOVA was used to identify statistically significant differences during 1–10 years of follow-up in the mean value of marginal peri-implant bone level. Pairwise comparisons were performed with Bonferroni correction for multiple comparisons.

To identify if a statistically significant mean difference existed in the marginal peri-implant bone level between implants axial versus tilted, all-on-four versus all-on-six, and in the three different categories of opposite dentition at 5 years of follow-up, paired-samples *t*-test and One way ANOVA were used.

Life-table analysis and Kaplan–Meier survival curves were used to evaluate and compare the implant survival rate, prosthesis success and survival rate, and incidence of biological and prosthetic complications in the all-on-four versus all-on-six. The log-rank test for trend was used to detect possible differences between survival and success curves late in the period of the study, and the Breslow test and the Tarone-Ware test for trend were used to investigate early differences. Multiple linear regression (backward stepwise) analysis was performed to ascertain the effects of independent variables on the mean value of marginal peri-implant bone level at 5 years of follow-up. Multicollinearity was evaluated by inspecting correlation coefficients and Tolerance/VIF values. In each test, the cut-off for statistical significance was $p \leq 0.05$.

3 | RESULTS

3.1 | Descriptive data of study sample

The study sample included 28 patients (20 female/8 males; average age of 67.75 ± 8.627 years, ranging from 53 to 86 years) with a mean

TABLE 1 Implant and prosthetic descriptive data.

	Parameter	All-on-four	All-on-six
Jaw	Maxilla	36	60
	Mandible	34	34
Implant location	Anterior	40	34
	Posterior	30	60
Implant inclination	Axial	38	86
	Tilted	32	8
Implant length	7 mm	6	4
	8.5 mm	//	8
	10 mm	9	29
	11.5 mm	8	10
	13 mm	41	43
	15 mm	5	//
	18 mm	1	//
Implant diameter	3.3 mm	2	6
	3.75 mm	//	23
	4 mm	68	41
	5 mm	//	20
	5.5 mm	//	4
MUA height	1 mm	24	90
	2 mm	12	//
	4 mm	32	4
	5 mm	2	//
Opposing dentition (prosthesis)	Natural teeth	8	6
	Complete removable prosthesis	6	//
	Implant-supported prosthesis	2	10

follow-up of 6.46 ± 2.236 years (range 1–10 years). Only one patient was a heavy smoker (more than 20 cigarettes per day), and three subjects had systemic diseases (diabetes and or hypertension) under pharmacological control. Five subjects were treated in both arches for a total of 33 full-arch fixed rehabilitations, supported by 164 implants (NobelSpeedy Groovy®, Nobel Biocare). Out of 33 prostheses, 17 were all-on-four (eight in mandible/nine in maxilla) and 16 all-on-six (six in mandible e 10 in maxilla).

Inserted implants (40 tilted and 124 axial) had the diameter ranging from 3 to 5.5 mm (62% = 4 mm) and length ranging from 7 to 18 mm (50.9% = 13 mm). In the 69.9%, multi-unit abutment (MUA) height was 1 mm (range 1–5 mm).

All patients received definitive screw-retained prostheses, with a metal framework veneered by acrylic base and stock prosthetic teeth. The opposing dentitions were implant-supported fixed hybrid prostheses in eight patients (12 prostheses), natural teeth including removable partial dentures in 14 patients, and removable complete dentures in six patients. Implant and prosthetic descriptive data were illustrated in Table 1.

Furthermore, initial bone and soft tissue thickness were measured on 3-dimensional computer images of the virtual planning. The mean value of bone thickness was 1.48 ± 0.62 and 1.63 ± 0.59 on buccal and oral aspects, respectively. The mean value of soft tissue thickness was 1.90 ± 0.65 buccally, 2.82 ± 1.70 orally, and 3.08 ± 0.90 vertically to the crestal top.

3.2 | Implant survival

A total of eight implants, all in the maxilla, failed in three female patients (seven in the all-on-four, one in all-on-six), giving a cumulative implant survival rate of 89.7% for all-on-four and 99.0% for all-on-six up to 10 years of follow-up. (Supplementary Table 1). A log-rank test reported a statistically significant difference in the survival distribution for the two different types of prosthesis ($p = 0.007$) (Figure 3).

In a patient, all four maxillary implants failed to maintain osseointegration without inflammation or infection signs in the second year of follow-up. Implants were replaced with the 2-stage surgical protocol and left load-free and submerged for 6 months using a conventional removable complete denture as interim prosthesis. At the uncovering, all implants showed clinical mobility due to lack of osseointegration and were removed, requiring a definitive reverse back to a removable denture. Several factors might have affected the

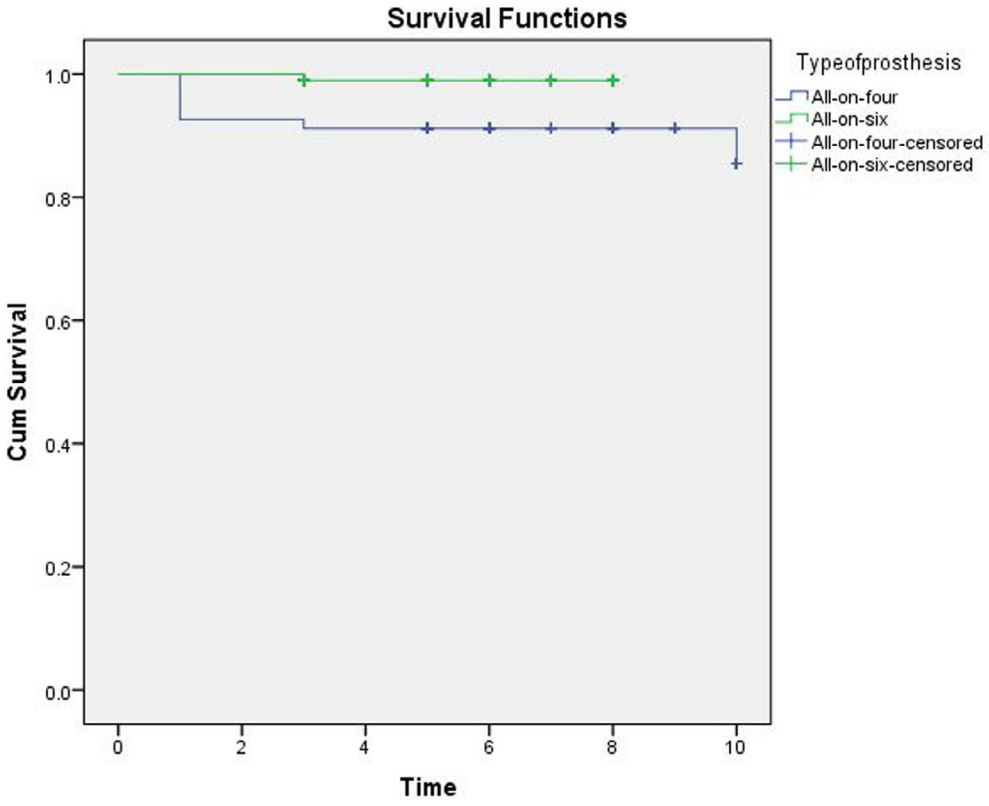

FIGURE 3 Kaplan–Meier curve for implants survival between all-on-four and all-on-six.

impaired bone healing: history of periodontitis, type IV bone (thin cortical and low trabecular density), heavy smoking status not discontinued (more than 20 cigarettes/day), and chronic alcohol consumption, which influenced bone turnover activity, and functional forces of natural teeth in the opposite arch.[22]

The other three implants in all-on-four rehabilitation failed between the first and fourth year. One tilted implant in the 2.4 site was not integrated and removed during the first 6 months of function. Two new axial implants were inserted in 2.4, and 2.5 positions, and a removable denture was delivered. At the time of taking impressions for the final rehabilitation, peri-implantitis was diagnosed around implants 1.4, 1.2, and 2.2, which was treated with resective surgery. A new prosthesis supported by five implants was delivered. After 3 years of function, implants 1.4 and 2.2 were lost, and the patient was rehabilitated with an overdenture supported by three remaining implants splinted with a bar.

The third subject with all-on-six rehabilitation refused to replace a middle axial implant failed for loss of osseointegration after 3 years of function. Prosthesis remained in function supported by five implants until the end of the follow-up.

All failed implants and relative prostheses were included in the implant and prosthesis survival analysis but excluded from marginal bone loss evaluation.

3.3 | Prosthesis success/survival

Prostheses in function without modifications and meeting patients' comfort and aesthetics through the entire observation time were 10 all-on-four and seven all-on-six, with a cumulative prosthesis success rate of 51.5% (58.8% for the all-on-4 and 43.8% for the all-on-six). No difference was found in cumulative success curves between all-on-four and all-on-six ($p = 0.358$). The cumulative prosthesis survival rate of 88.2% was affected by seven failed implants related to two all-on-four prostheses. (Supplementary Table 2). No failures were registered in all-on-six rehabilitations. No difference was found in the cumulative survival curve between all-on-four and all-on-six ($p = 0.231$) (Figure 4).

3.4 | Marginal bone loss

Marginal bone loss was evaluated on 149 implants. Out of 15 excluded implants, eight failed due to lack of osseointegration, and seven had peri-implantitis. In these latter implants, MBL was associated with bleeding and/or suppuration on gentle probing and increased probing depth compared to previous examinations.

The mean value of marginal bone loss was 1.38 ± 0.1.28 mm at 5 years and 2.09 ± 0.56 mm at 10 years of follow-up (Figure 5). Post hoc analysis with Bonferroni adjustment revealed that the marginal peri-implant bone level had gradually decreased between baseline to 10 years but became statistically significant only in the last 2 years of follow-up (Supplementary Table 3). No difference was found in the mean value of marginal bone resorption between all-on-4 (1.56 ± 1.61 mm) and all-on-6 (1.20 ± 0.85 mm) ($p = 0.104$) and between tilted implants (1.22 ± 1.29 mm) and axial implants (1.44 ± 1.27 mm) ($p = 0.385$) after 5 years of follow-up.

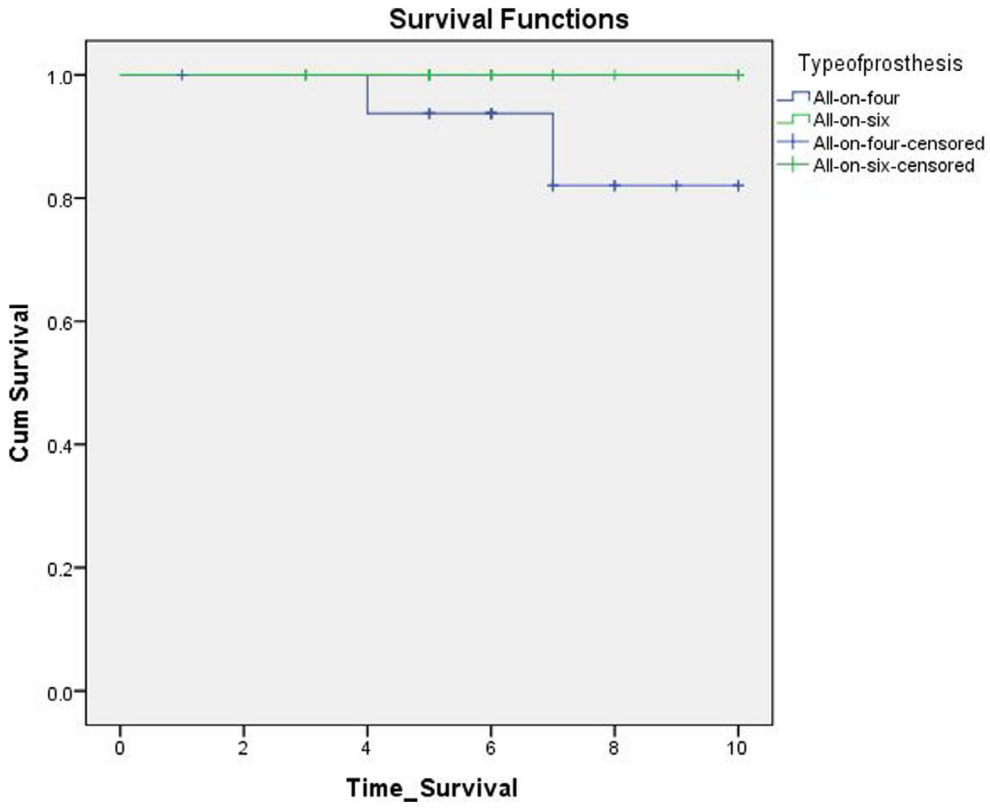

FIGURE 4 Kaplan–Meier curve for prosthesis survival between all-on-four and all-on-six.

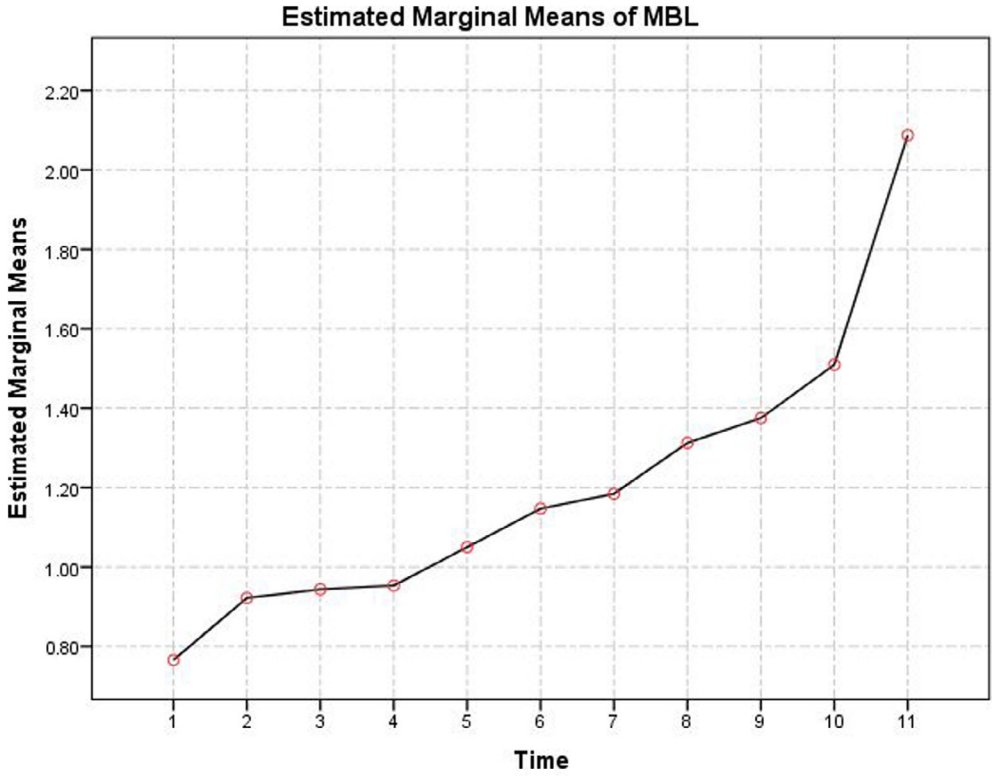

FIGURE 5 Marginal bone loss up to 10 years of follow-up.

A statistically significant increase of marginal bone resorption was reported when natural teeth (1.70 ± 1.73 mm) were compared with implant-supported prostheses (1.01 ± 0.62 mm) ($p = 0.017$) as opposite dentition. No difference was found in the mean of marginal bone resorption between natural teeth and removal of complete denture (1.29 ± 0.65 mm) in the opposite dentition ($p = 0.447$).

The multiple linear regression analysis showed a statistical association between the mean value of marginal bone loss after 5 years of

TABLE 2 Multiple backward stepwise linear regression models (with $p = 0.05$ to enter and $p = 0.10$ to leave) of marginal bone loss at 5 years of follow-up.

	β Coefficient	95.0% CI	*p* value
Implant length	−0.200	−0.328 to −0.072	0.002
Opposite natural teeth	0.980	0.518 to 1.442	<0.001
Buccal bone thickness	−0.383	−0.797 to 0.032	0.070
Crestal soft tissue thickness	0.351	0.061 to 0.642	0.018

Note: The following variables were used in the multiple backward stepwise linear regression model: buccal and oral bone thickness; buccal, oral, and crestal soft tissue thickness; implants diameter; implants length; Opposite natural teeth (yes/no). Models included adjustment for age, gender, jaw, implant location, angulation, and MUA-height. Results of reduced model that best explains the data were reported. Test to see if data met the assumption of collinearity indicated that multicollinearity was not a concern.

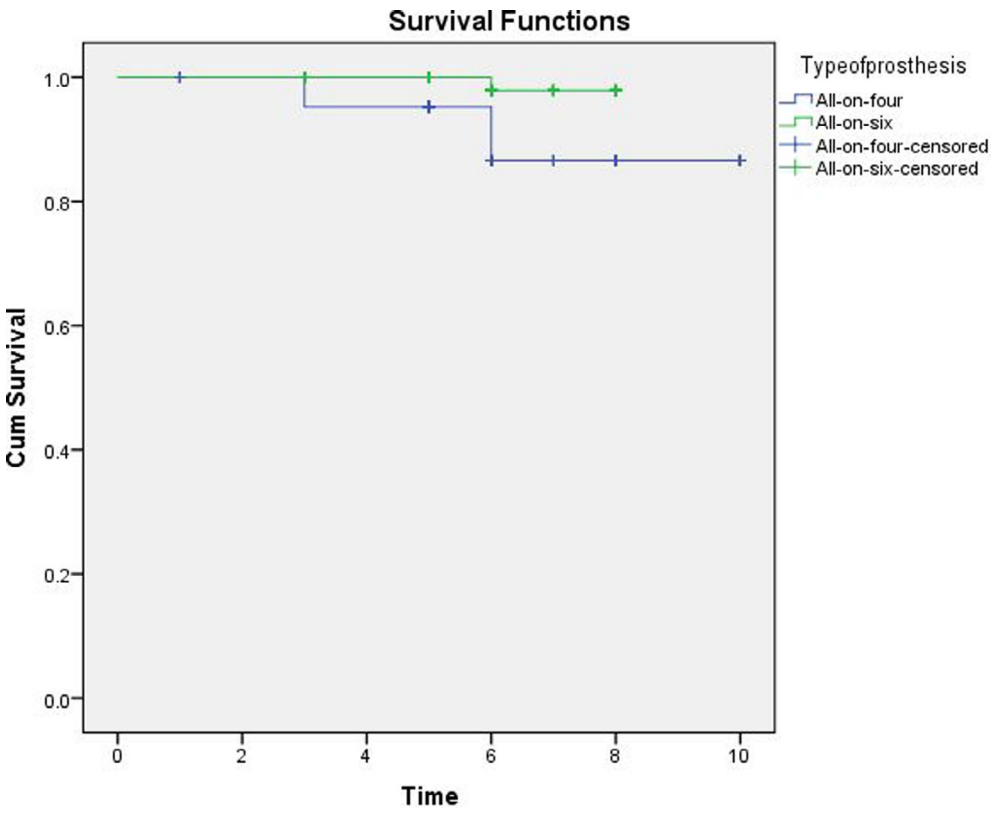

FIGURE 6 Kaplan–Meier curve for biological complications between all-on-four and all-on-six.

loading and the following variables: implant length, natural teeth in the opposite dentition, initial buccal bone, and crestal soft tissue thickness (Table 2). According to the regression coefficient, marginal bone loss was lower when associated with the increase of implant length and initial buccal bone thickness and greater in association with crestal soft tissue increasing and natural teeth in the opposite dentition.

3.5 | Biological complications

The incidence of biological complications in 10-year follow-up was 1.0% for all-on-six (one implant with mucositis in one subject) and 10.3% for all-on-four (seven implants with peri-implantitis in two subjects) (Supplementary Table 4), with a statistically significant difference between the two groups ($p = 0.014$) (Figure 6). Peri-implant mucositis of the right distal implant arising at 6-year post-loading in patient rehabilitated with maxillary all- on-six, was resolved with nonsurgical treatment, including mechanical debridement, local application of chlorhexidine gel, and increased optimal self-performed biofilm control. Peri-implantitis was treated with resective surgery at 3-year follow-up in the female patient already mentioned for implants failure, with only one implant surviving at 6 years. Reconstructive therapy was successfully adopted in the second female subject, with all four maxillary implants showing peri-implant lesions during the sixth year of function.

No further biological complications occurred.

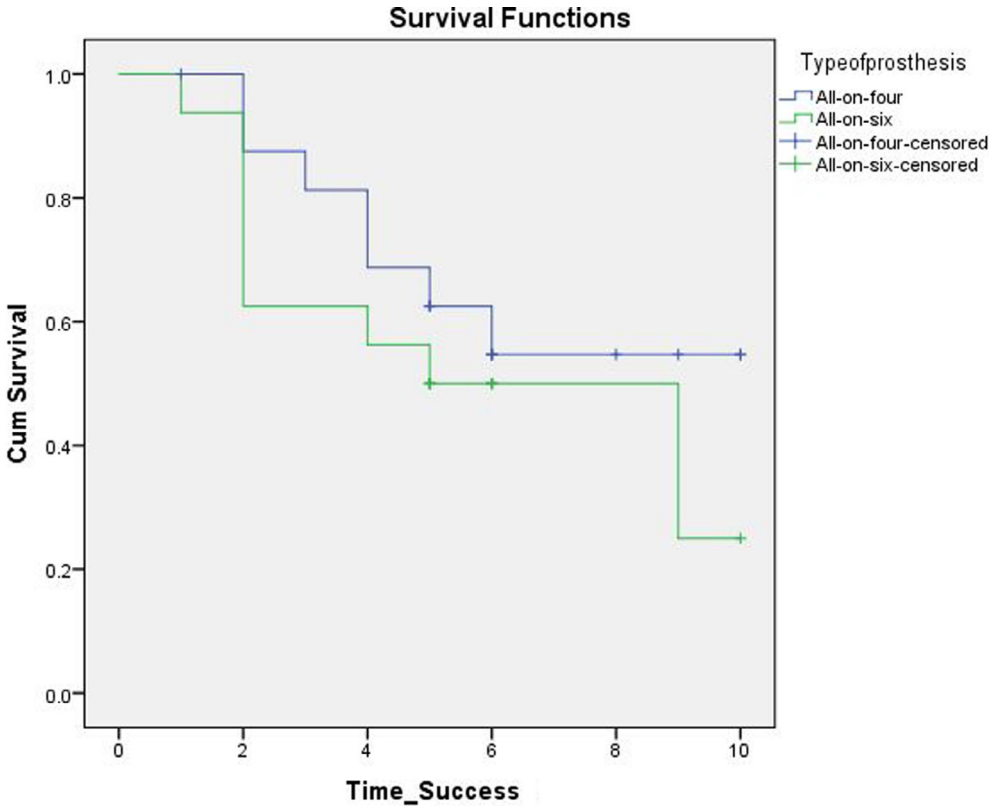

FIGURE 7 Kaplan–Meier curve for prosthetic complications between all-on-four and all-on-six.

3.6 | Prosthetic complications

Prosthetic complications only affected teeth of final rehabilitations with 3 detachments, 10 chippings or fractures, and 3 severe occlusal wears ([Figure 7], Supplementary Table 5). No fracture of implant, prosthesis, or framework, loosening/fracture of abutment or occlusal screw, loosening/fracture of the prosthetic screw were reported. Loss of screw access filling, mild tooth abrasion, and acrylic discolorations were not considered complications but functional wear, easily and quickly manageable chairside.

4 | DISCUSSION

The objective of the present single-center retrospective study was to report, after a mean follow-up of 6.46 ± 2.236 years (range 1–10 years), clinical and radiographic outcomes of edentulous patients rehabilitated with immediate fixed full-arch prostheses supported by four or six implants according to computer-guided and flapless surgery (NobelGuide®, Nobel Biocare).

To the best authors' knowledge, long-term follow-up data on fixed full-arch implant-supported rehabilitation of edentulous jaws according to the computer-guided surgical prosthetic protocol and immediate loading are limited. In most papers on this issue, the follow-up ranged between 1 and 60 months, and only a few studies reported a more extended period.

Referring to the all-on-four group, the cumulative survival rate of 89.9% for implants and of 88.2% for prostheses found up to 10 years of follow-up for in the present study was lower respectively than 94.5% and 97.8% reported by Lopes and colleagues at 7-years for edentulous jaws rehabilitated through the all-on-four concept and Nobelguide® protocol.[11] This difference could be due to implant failures' relatively more significant weight (7 vs 28) respecting the size of the two samples (implants 68 vs 532 and prostheses 17 vs 133). It's worthen to note that when the sample size was similar (29 patients and 176 implants), the cumulative survival rate of 89% on implant level and 83.9% on prosthesis level were found for edentulous jaws rehabilitated following computer-assisted virtual treatment planning, flapless surgery, and immediate loading during the follow-up period of up to 44 months.[23] The cumulative implant survival rate of 97% was found out of 2081 implants (380 patients, 482 jaws) in a retrospective 7-years clinical trial investigating immediate fixed full-arch dentures supported by 4–6 axial and tilted implants.[24] A 10-year cumulative implant survival rate (93.9% with 13 failures) was also reported by Kaneda and colleagues in fully edentulous mandibles treated with 220 immediate loading implants in 52 Japanese patients.[25] Furthermore, our data (7/68 in all-on-4, 1/96 in all-on-six) on implant failures contrasted with those (1/80 in all-on-4 and 6/120 in all-on-6) reported at the 5-year follow-up in a randomized controlled trial comparing edentulous maxillary jaws rehabilitated with the Nobelguide® protocol.[26]

Regarding all-on-six rehabilitations, the high cumulative survival rates (99.0%) for implants and (100%) prostheses of the present patients' cohort were in accordance with data reported in the literature on conventional implant-supported fixed complete prostheses. A systematic review and meta-analysis showed an implant survival rate

from 90.43% to 100% in the maxilla (4–12 implants per patient) and from 90%-to 100% in the mandible (2–10 implants per patient), and a prosthesis survival rate from 90% to 100% in the maxilla and from 93.75% to 100% in the mandible with follow-up from 12 to 120 months.[27] In another systematic review, cumulative implant survival rates ranged from 98.42% (95% confidence interval [CI]: 97.98–98.86) (5 years) to 96.86% (95% CI: 96.00–97.73) (10 years) and prosthodontic survival rates ranged from 98.61% (95% CI: 97.80–99.43) (5 years) to 97.25% (95% CI: 95.66–98.86) (10 years) in edentulous mandible.[28] More recently, in a retrospective study with up to 12-year follow-up, a cumulative survival rate of 98.7% for implants and 91.6% for prostheses was found after a mean observation period of 5.2 years after insertion of conventional definitive fixed complete prostheses supported by 457 implants in 71 edentulous jaws (52 patients).[17,20] The cumulative rate for prostheses free of technical complications of 58.28% (95% CI: 45.3%–69.2%) and 8.2% (95% CI: 2.8%–17.4%), at 5- and 10-years respectively was also comparable with the cumulative prosthesis success rate of 51.5% registered in the present study.[17] However, a systematic review and meta-analysis demonstrated that the use of four or six implants to support a fixed prosthesis of the completely edentulous maxilla or mandible presented similar survival rates, with no statistically significant difference at a $p < 0.05$ and a confidence interval of 95%, reporting an overall mean implant survival rate of 96%, and restoration survival rate of 99%, for a follow- up ranged from 1 to 15 years, with the median follow-up of 8 years.[29]

The mean value of the marginal bone loss at 5 years (1.38 ± 0.1.28 mm) and 10 years (2.09 ± 0.56 mm) of follow-up of the present study with no statistically significant difference between all-on-four and all-on-six was consistent with results shown in other studies. In evaluating full-arch fixed prosthetic rehabilitations supported by implants in immediate function with the All-on-four treatment concept using NobelGuide protocol, Lopes and colleagues reported the average (standard deviation) marginal bone loss of 1.30 mm (1.06 mm) overall at 5 years.[11] In a retrospective longitudinal case series of edentulous mandible rehabilitated with the all-on-four concept, the average marginal bone loss was 1.7 mm (95% CI: 1.6, 1.9; range: 0.7–4.4) measured on 281 patients, and. 2.3 mm (95% CI: 2.0, 2.7; range: 1.1–6.0) measured on 21 patients at 10 and 15 years of follow-up, respectively.[18] Likewise, the average marginal bone loss around maxillary implants supported all-on-four prostheses was 1.18 mm (95% CI: 1.16, 1.21) related to 758 patients at 5 years and 1.67 mm (95% CI: 1.58, 1.77) related to 129 patients at 10 years.[19] In addition, comparing the mean values of marginal bone resorption between all-on-four versus all-on-six, the outcomes of the present study matched to the no statistically significant difference (0.20 ± 0.06 mm; 95% CI 0.08–0.18; $p = 0.117$) reported by Tallarico and coll. For the two groups.[26]

Furthermore, no significant difference ($p = 0.385$) was found between axial (1.44 ± 1.27 mm) and tilted implants (1.22 ± 1.29 mm) in the mean value of marginal bone resorption was also in accordance with the literature, suggesting that vertical implant angulation does not affect peri-implant bone level changes in immediate fixed full-arch rehabilitation of edentulous jaws. In a review with meta-analysis including a total of 5029 tilted implants and 5732 axial implants, Chrcanov and coll. Found that the different implant angles did not influence marginal bone loss (MD 0.03, 95% CI–0.03 to 0.08; $p = 0.32$). In the authors' assessment, this finding might be due to the splinting effect since fixed full-arch prosthesis with splinted implants were the most common rehabilitation observed.[30] The same conclusion was reported by Lin & Eckert in their systematic revision of scientific literature aimed to determine the clinical performance of intentionally inclined implants with respect to positioned systems following the long axis of the residual alveolar crest.[31] No difference in peri-implant marginal bone loss between tilted and straight implants (5293 implants; MD = 0.03 mm; 95% CI = −0.03 to 0.10 mm; $p = 0.32$) was also seen by Apaza Alccayhuaman and coll. in a systematic review and meta-analysis evaluating restorations supported by tilted and straight implants after at least 3 years in function.[32] Nevertheless, great variability was revealed in the mean value ranging between 0.4 and 2.0 mm for tilted and 0.5 and 1.9 mm for straight implants. Conversely, Lopes and colleagues registered a significant difference ($p < 0.001$) in the average marginal bone loss at 5 years between 1.27 mm (1.02 mm) for tilted implants and 1.33 mm (1.10 mm) for axial implants, even if the 0.07 difference was considered clinically negligible.[11]

In addition, the multiple linear regression analysis performed in the present study showed a significant correlation at 5 years of follow-up between marginal bone loss and initial buccal bone and crestal soft tissue thickness, implant length, and natural teeth in the opposite dentition.

The lower loss of marginal bone and the increase of initial buccal bone thickness was consistent with the findings of a recent systematic review evaluating the influence of facial bone thickness after implant placement into the healed ridges on the remodeled facial bone.[33] The authors reported the correlation between increasing vertical bone resorption and decreasing thickness of facial bone and mucosa, and in their opinion, the influence of facial bone thickness on future resorption might be due to blood perfusion and surgical trauma of implant placement.

Instead, the positive effect on marginal bone loss of the increase in implant length was not reflected in the literature that reports contrasting results on this issue. However, when the implant length increased, better stress distribution was observed.[34]

Conversely, the detrimental effect on marginal bone resorption of increased crestal soft tissue thickness and natural teeth in the opposite dentition differed from outcomes reported by other authors.

In a retrospective cohort study on the influence of opposing dentition on the treatment outcome of immediate implant-supported fixed prostheses for rehabilitation of completely edentulous jaws, no significant differences in marginal bone level at 5 years were found between patients with opposite implant-supported fixed prosthesis and patients with single full-arch occluding with removable prostheses or natural teeth.[35] Disagreement with our data might be due to the differences in the statistical unit (patients vs implants), type of prosthesis (titanium framework with metal-ceramic, all-ceramic crowns, metal-acrylic resin, or acrylic resin prosthetic teeth), and occlusal

concept of the different subgroups chosen according to the specific conditions and treatment plan performed and not according to specific inclusion criteria.

Unexpected was the negative effect on marginal bone loss of crestal soft tissue thickness, which disagreed with findings of the most previous papers.[36] Only a recent prospective cohort study about the influence of vertical soft tissue thickness on peri-implantitis occurrence in patients with periodontitis reported different conclusions. The results demonstrated that the peri-implant parameters, including peri-implant probing depth and marginal bone loss, increased significantly with the increase of vertical soft tissue thickness.[37]

The involvement in biological complications of only three patients for a total of eight implants (one with mucositis and seven with peri-implantitis) compared favorably with results published by other studies.[18–20] A possible explanation for these results might be adopting a strict maintenance care program. Patients were recalled every 6 months for clinical and prosthetic assessment, professional oral hygiene care with supragingival debridement, dental hygiene instructions, and yearly radiological control to evaluate marginal bone level. According to the conclusions of a systematic review about the impact of maintenance therapy on preventing peri-implant diseases, implant treatment should be integrated with peri-implant supportive therapy with a suggested minimum recall interval of 5–6 months to avoid potential biologic complications.[38] The value of implementing an oral self-care and professional oral care regimen was underscored by Bidra and coll. in a systematic review of recall and maintenance (professional and homecare) regimens of patients with implant-borne restorations.[39]

The prosthetic complications found in the present patients' cohort were lower than those reported in the literature and limited to denture teeth and definitive rehabilitations.[40] However, these results might have been affected by the limited number of implants and prostheses evaluated, absence of bruxer among patients, correct surgical and prosthetic implant planning, reduction of post-surgical loading during the first 2 months, and patients' adherence to recall programs. Indeed, recent studies have suggested that bruxism plays a role in dental implant failure and represents a contributing factor in the occurrence of biological and prosthetic complications of implant-supported restorations.[41,42] Furthermore, the type of complications limited to prosthetic teeth is reflected in the data obtained by other authors.[11,17–19,43,44]

In the literature, detachments, chippings or fractures, and occlusal wear of prosthetic teeth were related to material (accumulated fatigue or plastic deformation), prosthetic design, technicians' errors, or patients' parafunctional habits.[45] However, these complications required only easy repairs in the presence of retrievable screw-retained prostheses.

The present study's clinical and radiographic outcomes contributed to proving that edentulous jaws rehabilitated according to Nobelguide protocol has longitudinal effectiveness after 10 years with limited mean bone loss and a low rate of biological and prosthetic complications when a strict maintenance care program is observed. Nevertheless, these results should be interpreted with caution. Major inherent weaknesses were the small sample size and retrospective design. The retrospective design inherently depends on acquired data from files and records. Thus, the accuracy of the original examination and documentation may be affected by the lack of some parameters' recording. Failure to evaluate peri-implant phenotype conditions, remaining peri-implant bone after surgery, and the patient's previous periodontal disease might have directly influenced implant survival, prosthesis success/survival, marginal bone loss, and the incidence of biological and prosthetic complications.

Strengths were represented by the patients' adherence to every 6-month recall program, extended follow-up up to 10 years, and multiple linear regression analysis assessing the influence of implant and patient characteristics on marginal bone loss. Furthermore, virtual planning, surgical procedure, and prosthetic rehabilitation by the same experienced surgeon should have avoided bias due to the operator's influence. Computer-guided flapless implant surgery and immediate function in rehabilitating edentulous jaws is a sensitive technique whose outcomes also depend on the surgeon's experience. Statistically significant differences were observed between clinicians experienced, inexperienced, or with an intermediate level of expertise.[7,46] Furthermore, careful patient selection, accurate implant planning, strict adherence to computer-guided surgical-prosthetic protocol, and clinicians experienced not only in the surgical procedures but also in restorative are necessary to achieve successful treatment outcomes.

5 | CONCLUSIONS

Based on the results and within the study limitations, the rehabilitation of edentulous jaws by an immediate loaded implant-supported hybrid prosthesis according to the Nobelguide® protocol has shown to be a long-term efficient, safe, and effective approach to rehabilitate edentulous jaws. However, marginal bone loss seems to be associated with the implant length, initial buccal bone thickness, crestal soft tissue thickness, and the presence of natural teeth in the opposite dentition.

AUTHOR CONTRIBUTIONS

Gerardo La Monacacontributed to data curation, formal analysis, and interpretation, and drafted and critically revised the manuscript Susanna Annibali contributed to the conception and design of the study, and critically revised the manuscript; Stefano Di Carlo and Giorgio Pompa contributed to data analysis and interpretation, and critical revision of the manuscript; Maria Paola Cristalli contributed to data acquisition, analysis, and interpretation, and drafted the manuscript; Nicola Pranno contributed to statistics, data analysis and interpretation, and drafted the manuscript; All authors gave final approval and agree to be accountable for all aspects of the work.

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CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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