KEY WORDS
Bone atrophy, Maxilla, Follow-up, All-on-four,
Full arch, Immediate loading

Cohort study

IMMEDIATE ALL-ON-FOUR FULL-ARCH REHABILITATION OF THE MAXILLA: A RETROSPECTIVE COHORT STUDY WITH A MEAN FOLLOW-UP OF 8 YEARS

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PURPOSE. To report the outcomes of all-on-four treatment of patients with completely edentulous maxilla and a mean follow-up of 8 years after loading, and to investigate risk factors associated with marginal bone loss and/or the occurrence of biological or mechanical complications.

MATERIALS AND METHODS. A total of 112 patients (64 women and 48 men; mean age at intervention 64.0 ± 9.2 years, range 44-81 years) either presenting with edentulous maxillae or who underwent tooth extractions because of severe periodontal disease and/or caries were included in the study. All participants were assessed after implant surgery and every year thereafter, with a mean follow-up period of 8.3 years (3025 days, range 2508-3650 days). Primary outcome measures were prosthesis and implant success, while secondary outcome measures were peri-implant marginal bone loss, as measured on periapical radiographs, and biological and mechanical complications.

RESULTS. Thirteen patients dropped out (11.6%). The implant survival rate at the end of the follow-up period was 95.5%. Six implants failed in three patients and the prostheses had to be replaced. Biological and mechanical complications were reported in 17 (17.1%) and 18 (18.1%) patients, respectively. The average marginal bone level at baseline was -0.02 mm. Significant marginal bone loss was observed at 10-year follow-up (2.4 mm). Multivariate logistic regression analysis showed a significant association (P <0.01) between smoking and marginal bone loss >3 mm. Finally, a significant (P = 0.01) association was observed between bruxism and mechanical complications.

CONCLUSIONS. The high implant and prosthesis survival rate, the acceptable amount of bone loss, and the moderate incidence of biological and mechanical complications indicate that the all-on-four treatment can be considered a viable option for immediate fixed prosthetic rehabilitation of the edentulous maxilla.

CONFLICT OF INTEREST STATEMENT.
Tommaso Grandi serves as consultant for J Dental Care, Modena, Italy. This study was completely self-financed, and no funding was sought or obtained, not even in the form of free material.

INTRODUCTION

The rehabilitation of masticatory function and aesthetics in completely edentulous patients has been revolutionized, going beyond the conventional option of removable dentures, thanks to the introduction of implant-supported restorations[1]. However, restoration of the edentulous maxilla with implants can be challenging for clinicians, because the poor quality and quantity of residual jawbone may be a limiting factor for placement of a sufficient number of implants, making it difficult to achieve adequate primary implant stability[2].

Indeed when teeth in the posterior maxillary region, especially molars, are lost, a process of advancing sinus pneumatization and expansion begins[3]. Hence, most patients wearing complete removable dentures complain of progressive loss of stability during speech and mastication, and request a fixed rehabilitation option[4].

Generally, the rehabilitation of a total edentulous jaw with conventional implant-supported fixed restorations in patients with severe atrophy involves bone grafting, sinus floor augmentation, and soft tissue management[5]. However, these procedures can cause increased patient morbidity, nerve damage, additional treatment time and costs, and complications such as infection or graft failure. Hence clinicians have been prompted to find alternatives for using the existing bone to place implants in areas with reduced bone volume and/or density, especially posterior regions.

To this end, the all-on-four concept was introduced in by Dr. Paulo Malò. The principle of the all-on-four concept is to insert four implants – two anterior implants in an axial position and two posterior implants with a tilt of up to 45° – in completely edentulous jaws to support a fixed immediately loaded prosthesis. Its aim was to offer a simple, low-cost procedure to patients with completely edentulous jaws, and the technique was first applied by Malo in 2003[6] in mandibles and later, in 2005, in maxillae[7]. It is based on the optimal number of four implants to support the complete arch prosthesis. Indeed, good clinical outcomes have been reported with the use of fewer than five implants to support full arch prostheses in both the maxilla and the mandible. Placing more than four implants seems not to increase success rates, but could increase bone loss and consequently the prevalence of peri-implantitis[8,9].

Furthermore, by reducing the number of implants to four, each implant can be placed without coming into conflict with adjacent implants.[7] The use of four implants, placed as "cornerstones", in the maxilla, is encouraged by the fact that it provides favourable load distribution[10].

The provisional or fixed implant-supported full-arch prosthesis can be immediately loaded[4], a predictable procedure today. Early studies show that patients treated with immediately loaded implants in edentulous jaws report a high level of satisfaction[11-14]. Indeed, immediate implant function provides psychological benefits to patients as well as a reduction in overall treatment time, increasing the appeal of implant treatment[15].

In one study, Brånemark et al. used four implants placed parallel to each other to support a full-arch prosthesis[8]. However, now posterior implants can be tilted, enabling longer implants to be placed with improved bone anchorage due to increased bone-to-implant contact[16]. This allows the final prostheses to hold as many as 12 teeth, shortening the cantilever length[5]. In recent years, several clinical studies have reported that tilting the distal implants for the immediate rehabilitation of partially and fully edentulous jaws may lead to benefits such as improved bone anchorage, the avoidance of long cantilevers, and the possibility of increasing the distance between anterior and posterior abutments to achieve a better load distribution[17]. However, to increase the probability of success, care needs to be taken to anchor the implants optimally[6].

The quality, quantity and density of the bone in the maxilla are lower, and the high masticatory forces in the posterior maxilla mean that immediate loading and therefore the implementation of the all-on-four concept in this region is considered more challenging than in the

mandible. Nonetheless, in several studies comparable cumulative survival rates for maxillary and mandibular all-on-four rehabilitations were found[11,18,19]. In fact, this method has become very commonly used for edentulous, often atrophic, upper or lower jaws, due to the possibility of maximising the use of available bone. This obviates the need for bone augmentation procedures, as well as the risks of complications arising from them[20,21]. Nevertheless, there are anatomical and treatment planning limitations for the rehabilitation with the all-on-four concept, such as: insufficient bone volume, the presence of remaining teeth that interfere with the implant placement planning, insufficient mouth opening to accommodate surgical instrumentation (at least 50 mm of mouth opening is required), or bone reduction needed due to a high smile line in the maxilla, irregular bone crest, or thin bone crest[22].

To date, many studies on the placement of dental implants with the all-on-four technique in the maxilla[5,7,12,20,21,23,24] have been published, but there is a lack of sufficient long-term data with follow-ups of more than 5 years. In fact, only one study exclusively concerning all-on-four insertion in the maxillary arch is available[25]. In that 5-13-year retrospective cohort study, Malò et al.[25] evaluated the outcomes of 4288 dental implants placed in the maxillae of 1072 patients rehabilitated via the all-on-four technique. Primary outcomes considered were cumulative prosthesis success rate and implant survival and success rates, and the values found were 99.2%, 94.7% and 93.9% respectively. Secondary outcomes measures were marginal bone loss (MBL) at 5 and 10 years, as well as biological and mechanical complications. The average MBL at 5 and 10 years was 1.18 and 1.67 mm. Biological complications occurred at 7.8% of implants, while mechanical complications occurred in 58.8% of provisional prostheses and 7.3% of definitive prostheses. Age and smoking were identified as variables significantly associated with the incidence of biological complications.

The aims of the present study were to provide further long-term data on all-on-four rehabilitation of the maxilla, and to investigate risk factors associated with marginal bone loss, and any biological or mechanical complications.

MATERIALS AND METHODS

In this retrospective study, patients with edentulous maxillae or those who needed tooth extractions due to severe periodontal disease and/or caries were enrolled. A total of 112 patients were included in the study, with a mean follow-up period after intervention of 8.3 years (3025 days). All participants were recruited and treated from January 2011 to December 2014 in a private practice (Tommaso Grandi Dental Clinic, Modena, Italy). Surgical and prosthetic procedures were performed by the same dental surgeon (TG).

The inclusion criteria were edentulous maxillae, or maxillae with non-viable teeth, in need of prosthetic full-arch maxillary rehabilitation supported by immediately loaded implants.

Patients were not accepted in the study if they met any of the following criteria:

- any uncontrolled systemic disease that could represent a general contraindication to implant surgery;
- ongoing treatment with intravenous bisphosphonates;
- emotional instability;
- substance abuse;
- ongoing maxillary radiation therapy;
- active chemotherapy;
- bone grafting procedures at planned implant sites;
- heavy smokers (more than 20 cigarettes a day);
- patients with enough bone height/width in the posterior maxillary region to allow the insertion of axially placed implants.

At their first appointment, all patients were informed about possible treatment alternatives. Written informed consent was obtained for each patient. This paper is drafted in conformity to STROBE guidelines for observational studies: epidemiology (http://www.strobe-statement.org/).

Surgical protocol

Medical history and clinical data were collected for all participants, and a cone-beam computed tomography (CBCT) scan and panoramic radiograph were taken of each in order to assess bone height and volume, as well as anatomical structures. Before implant surgery, antimicrobial prophylaxis with 1 g of amoxicillin plus clavulanic acid (or 500 mg clarithromycin if allergic to penicillin) was given twice a day, starting the night before the surgery and continued for 7 days after surgery.

On the day of surgery, patients were treated under local anaesthesia with articaine plus adrenaline 1:100,000 (Septanest Septodont articaine 4%, Septodont Corp, Saint-Maur-des-Fossés, France). Tooth extractions, when needed, were performed as atraumatically as possible, attempting to preserve the buccal alveolar bone. Extraction sockets were carefully cleaned of any granulation tissue. A mucoperiosteal flap was raised along the top of the ridge with relieving incisions on the buccal side.

All patients enrolled in present investigation were fitted with 4 tapered implants (JDEvolution, JDentalCare, Modena, Italy) with internal connection and sandblasted and acid-etched (SLA) surface. As regards the distal implants, two tilted implants were placed with the aid of a surgical guide. The surgeon planned and used the most appropriate implant lengths (10 to 15 mm) and diameters (3.2 to 4.3 mm) (**TABLE 1**), based on the patient's anatomical features, and according to clinical indications.

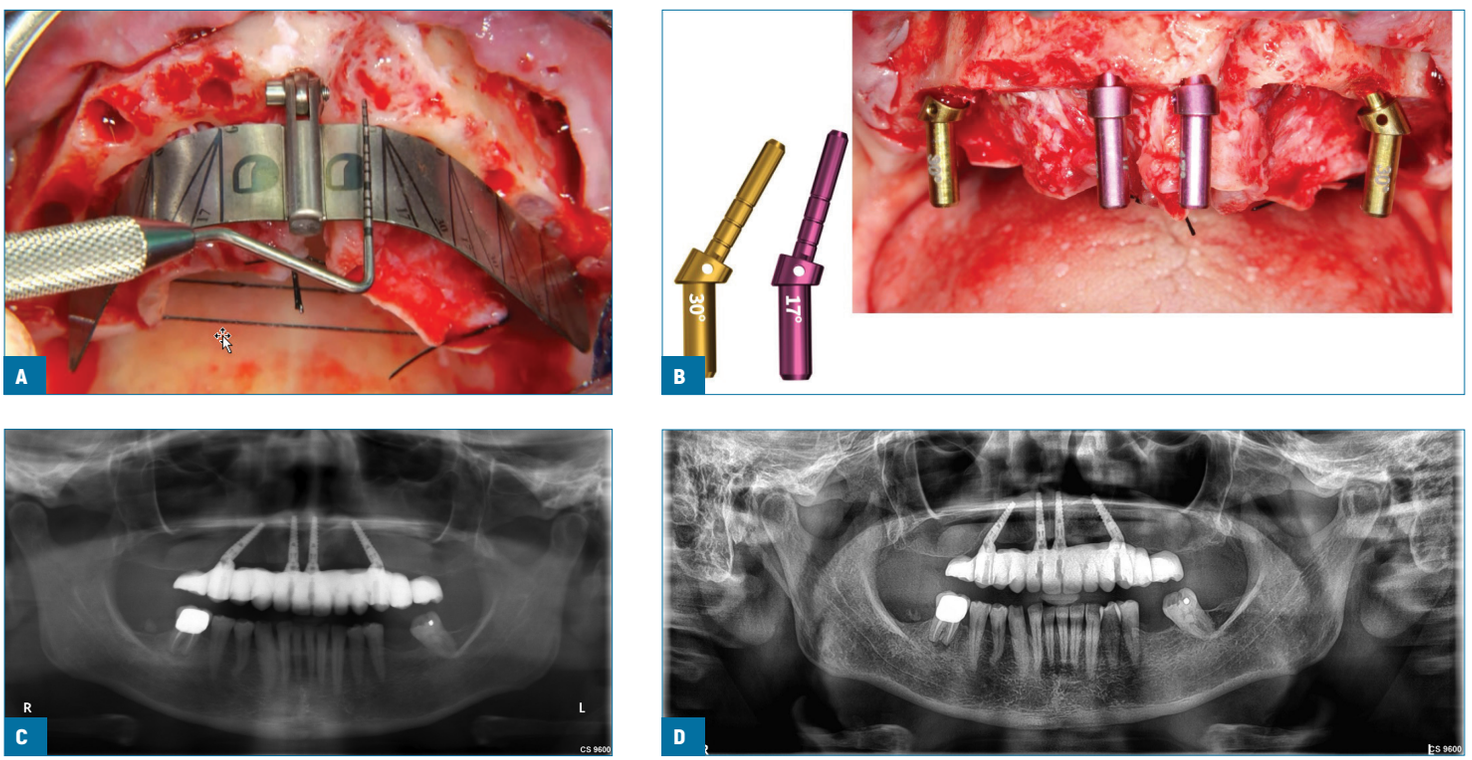
TABLE 1 BASELINE PATIENT CHARACTERISTICS

Number of patients	112
Age (years)	64.0±9.2 (range 44-81 years)
Gender (male)	48 (42.8%)
Smoking	
Non smokers	68 (60.7%)
Smoking <10 cigarettes/day	32 (28.5%)
Smoking 11 to 20 cigarettes/day	12 (10.7%)
Bruxism	22 (19.6%)
Initial situation	
Edentulous	33 (29.4%)
Terminal dentition	79 (70.6%)
Comorbidities	
Hypertension	35 (31.3%)
Diabetes	18 (16%)
Hyperthyroidism	6 (5.3%)
Osteoporosis	12 (10.7%)
Opposing dentition	
Fixed prostheses on implants	36 (32.1%)
Natural teeth	28 (25%)
Overdentures on implants	8 (7.1%)
Fixed prostheses on teeth	29 (25.9%)
Others	11 (9.8%)

The cantilever was reduced by inserting the drill to obtain a more posterior implant position, just anterior to the mesial wall of the maxillary sinus. The implants in distal segments were tilted in order to achieve the second premolar position according to the surgical guide. The implant site was under-prepared in order to achieve insertion torques of between 30 and 80 Ncm before the final seating of the implants. Bicortical anchorage was established in cases where either high occlusal loads were foreseen, or the density of bone was too low to achieve high primary stability with immediate function. The final insertion torque was measured using a calibrated torque wrench (JDTorque, J Dental Care), able to measure torque within 5% of the target in the range of 15 to 80 Ncm.

Conical abutments (JDentalCare) were connected to the implants: 30° angled abutments were connected to the two posterior tilted implants, and straight (0°) or 17° angled abutments were connected to the anterior implants. After closing and suturing the flap with 4/0 non-absorbable sutures, the abutments were connected with a torque of 30 Ncm, and a 10-unit provisional acrylic fixed implant-supported prosthesis was placed the day after surgery. No cantilevers were used to minimise fracture risk and excessive stress over the distal implants. The prostheses had reduced occlusal surfaces and flat cusps; centric and lateral contacts were checked. A soft diet was recommended for the first month and oral hygiene instructions were given.

The definitive 12-unit screw-retained metal-composite prostheses were delivered 6 months after surgery. Oral hygiene instructions and diet indications were provided to all participants, and follow-up appointments were scheduled at 10 days and at annual intervals thereafter for the entire duration of the study. A long-term example clinical case is illustrated in **FIGS. 1A-D**.



FIGS. 1 A-D: *Clinical views and panoramic radiographs of a study participant. Clinical view of the surgical guide to tilted implant positioning (A). Clinical view of tilted pins used to check the correct implant inclination (B). Panoramic radiograph taken 1 year after implant placement (C). Panoramic radiograph taken 10 years after implant placement (D).*

Outcome measures

The primary outcome measures were prosthesis and implant success. Prosthesis success was based on function. The need to replace the prosthesis or insert more than four implants was considered as a failure.

Implant success was assessed according to the following criteria, defined by Maló et al.[25,26]

- implant fulfilled its function as support for reconstruction;
- implant was stable when individually manually tested;
- absence of signs of infection that could jeopardize the implant outcome;
- absence of radiolucency around the implant.

The removal of implants for any reason was classed as a failure.

The secondary outcome measures were:

- Marginal bone-level (MBL). On the day of surgery, and at 5 and 10 years, periapical radiographs were taken with a film holder (Super-Bite, Hawe Neos Dental, Bioggio, Switzerland) using the parallel technique. MBL measurements were performed on the mesial and distal sites, and average values were calculated. The MBLs at 5 and 10 years were compared with that at the day of surgery, and total marginal bone loss was calculated;
- Complications. Any biological or mechanical complications occurring during the entire follow-up period were recorded and reported.
  Examples of biological complications were:
  - peri-implant mucositis (heavily inflamed soft tissue without bone loss) and peri-implantitis (presence of periodontal pockets ≥5mm with bone loss and suppuration or heavily inflamed tissues),
  - fistulas,
  - numbness or paraesthesia (temporary or permanent),
  - abnormal or prolonged pain after implant insertion.

Mechanical complications included fracture or loosening of prosthodontic components, assessed clinically and radiographically.

Statistical analysis

Multivariate logistic regression analysis was used to investigate the risk factors associated with marginal bone loss >3.0 mm at the last follow up, as well as the occurrence of biological or mechanical complications, adjusting for confounding variables. Candidate variables were included if clinically relevant or significant on univariate analysis. The cut-off of 3 mm was decided according to the normal distribution of marginal bone loss recorded in the study: it corresponds to the 70th centile on the 10-year bone loss distribution.

RESULTS

A total of 112 patients (64 women and 48 men; mean age at intervention 64.0 ± 9.2 years, range 44-81 years) were included in the study. They were rehabilitated with 448 immediately loaded implants supporting 112 fixed full-arch maxillary prostheses. All participants (n = 112) were assessed at the first check-up after the intervention (100%), and every year thereafter, with a mean follow-up period of 8.3 years (3025 days, range 2508-3650 days). Comorbidities were frequently observed, the most common being hypertension (31.3%) and diabetes (16%). About 60% of participants were non-smokers, and 10.7% smoked 11-20 cigarettes/day. The main baseline features of study participants and the implants they received are shown in **TABLES 1, 2**, respectively. The opposing arch dentition was natural dentition in 28

TABLE 2 IMPLANTS CHARACTERISTICS AND INSERTION TORQUE

Diameters	Length	Insertion torque
3.2 mm: 28 (6.2%)	10 mm: 20 (4.4%)	30 Ncm: 10 (2.2%)
3.7 mm: 319 (71.2%)	11.5 mm: 64 (14.2%)	35 Ncm: 25 (5.6%)
4.3 mm: 101 (22.5%)	13 mm: 242 (54%)	45 Ncm: 97 (21.6%)
	15 mm: 85 (18.9%)	50 Ncm: 32 (7.1%)
	18 mm: 37 (8.2%)	60 Ncm: 67 (14.9%)
		70 Ncm: 102 (22.7%)
		80 Ncm: 115 (25.6%)

participants, implant-supported fixed prostheses in 36, and tooth-borne fixed prostheses in 29.

Thirteen patients (11.6%) were lost to follow-up: eight patients became unreachable and did not attend annual check-ups after a mean of 2.6 years, while five died of a heart attack, respectively 4 months and 2 and 4 years after implant placement. The last scheduled follow-up appointment was on 31st December 2021.

At the end of follow-up period, the implant success rate at patient level was 95.5%. A total of six implants failed in three patients. In one patient all four implants failed 3 months after placement, but the patient had not adhered to recommendations for a soft diet, and the implants failed due to overload. The remaining two failed implants were lost in two patients one year after placement, and were repositioned with both prostheses being replaced.

During the follow-up, biological complications occurred in 17.1% of patients: mucositis was observed in 13 patients (13.1%) at 4.3±0.8 years after the procedure, and peri-implantitis was observed in four patients (4%) at 4, 5 and 6 years respectively. Mechanical complications were reported in 18 subjects (18.1%).

Specifically:

- the provisional acrylic restoration fractured in five patients 2, 3 or 5 months after loading. The prostheses were unscrewed and repaired in the lab;
- final prosthesis screws loosened in two patients 4 and 6 years after loading, respectively;
- the definitive prostheses composite chipped in eleven patients 1, 2, 4, 6 and 7 years after loading, respectively. The prostheses were unscrewed and repaired in the lab.

The average marginal bone level at baseline was -0.02 mm. After 5 years it was 1.6 mm (95% CI: 1.3, 1.7; range: 0.4-2.3), and after 10 years it was 2.4 mm (95% CI:1.5, 3.1; range: 0.8-4.9) (**TABLE 3**). Binary logistic regression analysis was performed to evaluate the potential risk indicators for marginal bone loss >3.0 mm (**TABLE 4**), the incidence of biological complications (**TABLE 5**) and the incidence of mechanical complications (**TABLE 6**) at the last follow-up. Binary logistic regression analysis showed a significant association between marginal bone loss >3.0 mm and smoking (OR 11.1, 95% CI 3.5-45.1, P = 0.003). As expected, bruxism was significantly associated with the incidence of mechanical complications (OR 7.8, 95% CI 1.8-38.6, P = 0.01). Patients were considered affected by bruxism if they reported tooth grinding or clenching, and/or if their teeth were flattened, fractured or chipped.

TABLE 3 MARGINAL BONE LEVELS AT DIFFERENT TIME INTERVALS (0, 5 AND 10 YEARS).

	Implant placement N = 112	5 years after loading N = 99	10 years after loading N = 23	Difference placement - 10 years
	Mean±SD (95% CI)	Mean±SD (95% CI)	Mean±SD (95% CI)	Mean±SD (95% CI)
Average marginal bone level (mm)	0.02±0.06 (-0.07; 0.08)	1.60±0.74 (0.63; 1.51)	2.42±0.92 (1.48; 3.32)	2.40±0.88 (1.50; 3.26)

TABLE 4 RISK FACTORS FOR MARGINAL BONE LOSS >3.0 MM

Factor	OR (95% CI)	P-value	ORa (95% CI)	P-value
Gender (male)	2.1 (0.4-8.2)	0.23		
Age	1.0 (0.8-1.2)	0.95		
Smoking	7.3 (2.0-27.1)	0.002	11.1 (3.5-45.1)	0.003
Fixed opposing dentition	1.8 (0.6-5.7)	0.42		
Systemic conditions	0.4 (0.2-1.9)	0.39		

Multivariate logistic regression analyses used to investigate risk factors associated with the marginal bone loss >3.0 mm, adjusting for confounding variables. Candidate variables are included if clinically relevant or significant on univariate analysis. OR = odds ratio; a = adjusted.

TABLE 5 RISK FACTORS FOR BIOLOGICAL COMPLICATIONS

Factor	OR (95% CI)	P-value	ORa (95% CI)	P-value
Gender (male)	1.3 (0.4-3.2)	0.75		
Age	1.1 (0.8-1.2)	0.52		
Smoking	8.3 (3.2-25.2)	<0.0001	14.2 (3.7-40.9)	<0.0001
Fixed opposing dentition	1.5 (0.6-4.0)	0.76		
Systemic conditions	0.8 (0.3-2.6)	0.80		

Multivariate logistic regression analyses used to investigate risk factors associated with biological complications, adjusting for confounding variables. Candidate variables are included if clinically relevant or significant on univariate analysis. OR = odds ratio; a = adjusted.

TABLE 6 RISK FACTORS FOR MECHANICAL COMPLICATIONS

Factor	OR (95% CI)	P-value	ORa (95% CI)	P-value
Gender (male)	2.8 (1.0-6.9)	0.074		
Age	1.0 (0.8-1.2)	0.84		
Smoking	1.5 (0.7-4.8)	0.41		
Bruxism	9.2 (3.2-15.8)	0.002	7.8 (1.8-38.6)	0.01
Fixed opposing dentition	1.2 (0.5-4.2)	0.56		
Systemic conditions	1.4 (0.8-5.2)	0.40		

Multivariate logistic regression analyses used to investigate risk factors associated with mechanical complications, adjusting for confounding variables. Candidate variables are included if clinically relevant or significant on univariate analysis. OR = odds ratio; a = adjusted.

DISCUSSION

This retrospective study aimed to evaluate the long-term outcomes of all-on-four full-arch rehabilitation of the upper jaw. Outcomes monitored up to 10-year follow-up were implant and prosthesis survival and success rates, biological and mechanical complications, and marginal bone level changes. The data collected in showed that this technique yielded good clinical outcomes, which were maintained over the follow-up period. The implant success rate was 95.5% over a mean of 8.3 years. Biological complications, such as bleeding on probing and mucositis, and mechanical complications were reported in 17.1% and 18.1% of cases respectively, and marginal bone loss was 2.4 mm at 10-year follow up. Smoking habits did negatively affect the MBL and the occurrence of biological complications, but this damaging impact on dental implant therapy has previously been widely reported in the literature[27-30].

The values found in the present study were consistent with data provided in the aforementioned study by Maló et al.[25]. The high prosthesis survival, implant success and implant survival rates, and the moderate occurrence of biological and mechanical complications encountered in this study can be linked to several factors, including the accuracy of the preoperative planning and surgical procedure and the participants' compliance. The limitations of this study include the involvement of a single centre and the retrospective design. On the other hand, the outcomes were evaluated under real clinical conditions and the patient inclusion criteria were rather broad, so we would expect similar results in other patients with similar characteristics treated similarly by other clinicians.

CONCLUSIONS

Within the limits of this study, the high long-term implant and prosthesis survival rates, the low bone loss and the moderate incidence of biological and mechanical complications indicate that the all-on-four concept can be considered a viable option for immediate fixed prosthetic rehabilitation in edentulous maxillae. More clinical trials with follow-ups of at least 10 years and larger sample size are needed to provide further evidence of the long-term success of the all-on-four concept in maxilla, ideally taking into consideration a control group for comparison.

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