An up to 7-Year Retrospective Analysis of Biologic and Technical Complication With the All-on-4 Concept

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The aim of this study was to evaluate retrospectively biologic and technical complications as well as clinical and radiographic outcomes of patients treated with 4 implants according to the All-on-4 protocol and followed up to 7 years of function. Data from 56 consecutive patients presenting complete edentulous jaw, aged 18 years or older, treated between January 2008 and December 2013, were evaluated. The outcomes were implant and prosthetic survival and success rates, any complications, and marginal bone loss (MBL). Two-hundred twenty-four implants were placed in 56 patients. During the entire follow-up, 1 maxillary implant but no prosthesis failed during the healing process. Fourteen patients experienced 1 complication each (10 technical, 4 biologic). The overall implant and prosthetic success rate was 98.2% and 82.1%, respectively. All complications were considered as minor and successfully resolved chairside. A mean MBL of 1.30 $\pm$ 0.63 mm was observed at the last follow-up. Statistically significant difference was found for postextractive implants (0.79 $\pm$ 0.26) vs implants placed in healed sites (1.03 $\pm$ 0.46; $P = 0.024$). Within the limits of the present study, the All-on-4 concept may be a valuable surgical and prosthetic option for the treatment of complete edentulous jaws. However, minor technical and biologic complications can occur. Further long-term prospective data with primary outcomes focused on success rates are needed.

Key Words: All-on-4, complete edentulism, dental implants, complete-arch prosthesis, tilted implants, implant complications

Introduction

Several prosthetic treatment options exist for the treatment of complete edentulous patients, such as conventional complete dentures, removable implant-retained or -supported prostheses, or fixed implant-supported prostheses. Malò et al[1,2] in 2 pilot retrospective studies, presented a treatment option for the rehabilitation of the edentulous jaws by combining 4 implants, 2 straight medially and 2 tilted distally. Tilting the 2 distal implants allows maximum use of the existing bone placing posterior fixed teeth with minimum cantilevers, even in regions where bone height and nerve or sinus proximity would not allow the placement of axial implants. The All-on-4 treatment concept was demonstrated to be a cost-effective treatment concept in the treatment of complete edentulous jaws after 10 years of function,[3,4] decreasing the overall treatment times with a lower patient morbidity and a higher patient quality of life.[5] However, these results should be interpreted with caution since literature presents a lack of long-term data about the incidence of potential technical and biologic complications and their implications.

The purpose of this retrospective study was to evaluate the biologic and technical complications as well as clinical and radiographic outcomes of complete fixed dental prosthesis (FDP), delivered on 4 implants placed according to the All-on-4 protocol. This study followed the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines.

Materials and Methods

This retrospective study evaluated data collected from 56 consecutive patients (31 females, 25 males) aged 18 years or older (mean: 66.2 years). The patients presented with a sufficient amount of bone to place 4 implants of at least 10 mm in length in healed or extraction sites. The patients were treated between January 2008 and December 2013 according to the All-on-4 protocol (Nobel Biocare, Göteborg, Sweden). A total of 224 implants were placed and patients were followed clinically for up to 7 years (range: 1 to 7 years, mean: 39.3 months). The investigation was conducted according to the principles embodied in the Declaration of Helsinki for biomedical research involving human subjects. All patients were duly informed about the nature of the study and gave their written consent. Exclusion criteria evaluated before implant placement were: general medical (American Society of Anesthesiologists Class III or IV) and/or psychiatric contra-

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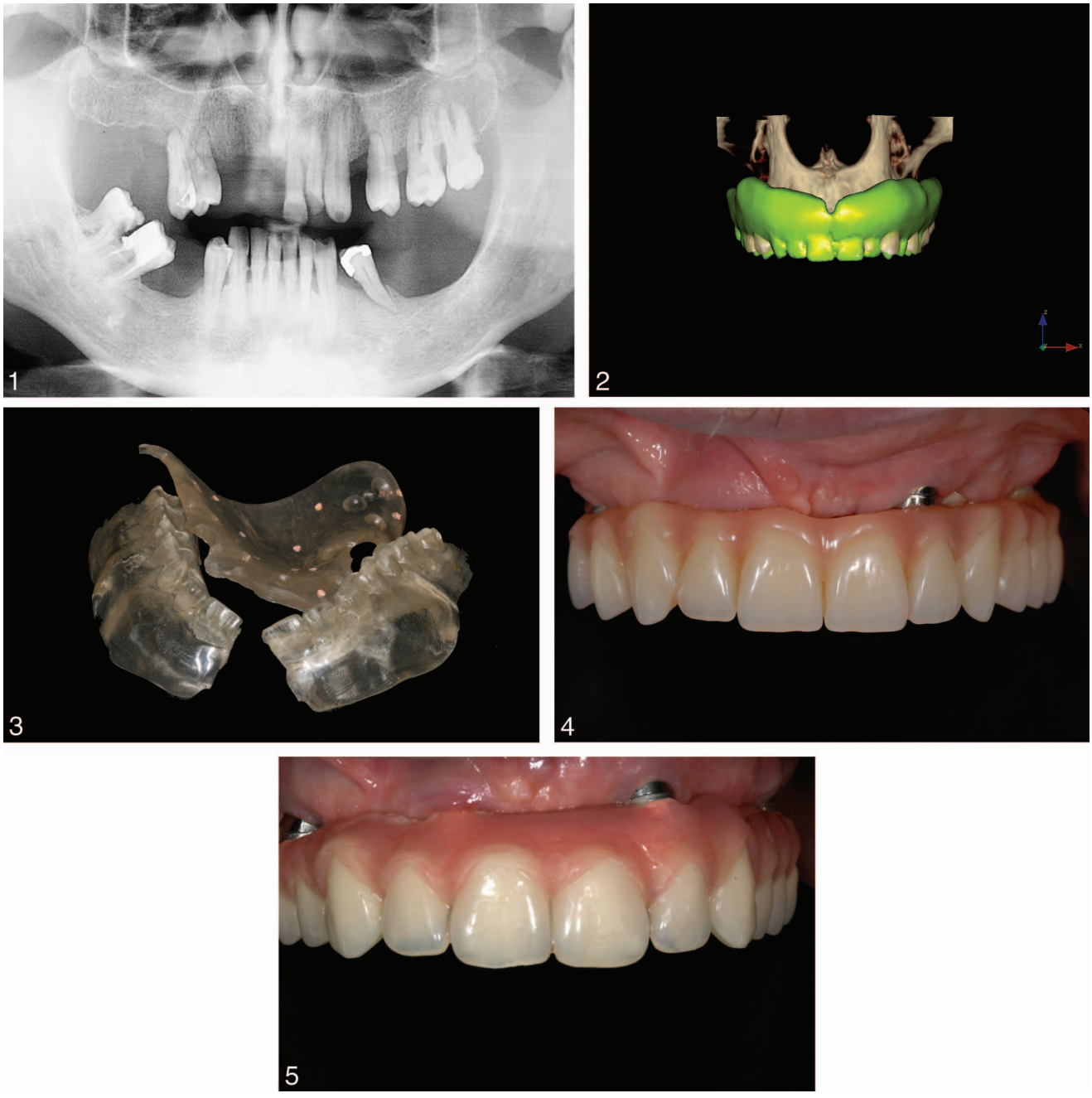
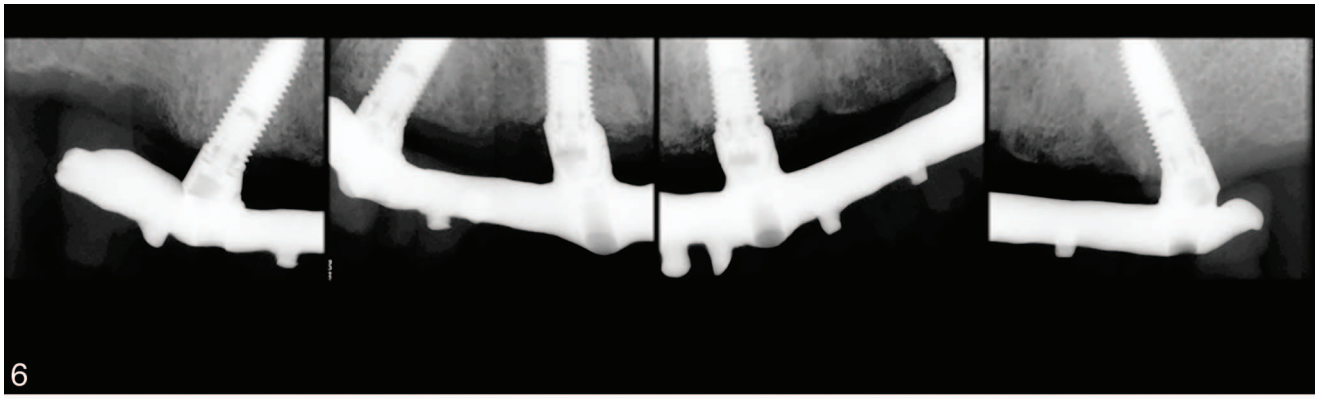
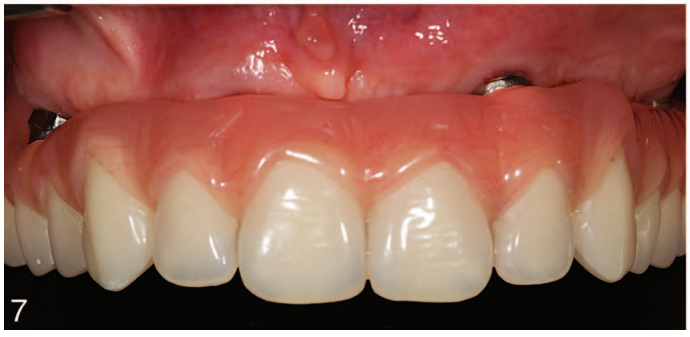


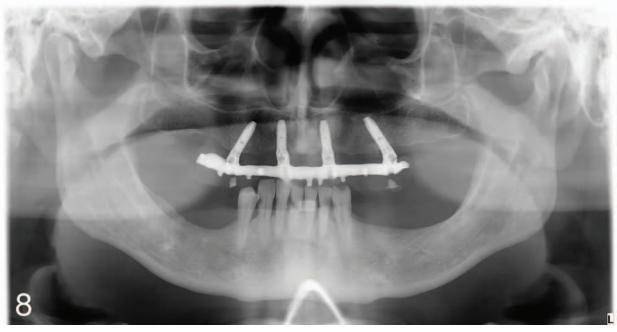
Figures 1–5. Figure 1. Pretreatment panoramic radiograph. **Figure 2.** Tridimensional software showing the virtual planning. **Figure 3.** Base and teeth setup portions of the disassembled maxillary radiographic guide. **Figure 4.** Temporary restoration screwed to the implants at abutment level. **Figure 5.** Screw-retained complete-arch restoration.

indications; pregnancy or nursing; any interfering medication (steroid or bisphosphonate therapy); alcohol or drug abuse; heavy smoking (>10 cigarettes/day); radiation therapy to head or neck region within 5 years; parafunctional activity; untreated periodontitis; poor oral hygiene and motivation defined as a full-mouth bleeding on probing and full-mouth plaque index ≥25%; subject has known allergic or adverse reactions to the restorative material; and unavailability for regular follow-ups.

Patients' medical histories were collected and study models were made. Preoperative photographs and radiographs (Figure 1) were obtained for initial screening and evaluation. Patients received professional oral hygiene prior to surgery and were instructed to rinse chlorhexidine mouthwash 0.2% (1 minute, twice a day, starting two days prior to the intervention). Two grams of amoxicillin and clavulanic acid (or clindamycin, 600 mg, if allergic to penicillin) was administered prophylactically 1 hour prior to surgery and continued for 6 days. Local anaesthesia was induced using a 4% articaine solution with epinephrine 1:100 000 (Ubistein; 3M Italy SpA, Milan, Italy). A flapless or a flap approach was performed depending on width







Figures 6–8. Figure 6. Periapical radiographs of the definitive restoration. **Figure 7.** Definitive restoration at 5 years after insertion. **Figure 8.** Panoramic radiograph at 5 years after insertion.

of the available keratinized mucosa. Implant placement was performed using either computer-guided template-assisted (NobelGuide, Nobel Biocare) implant placement (28 patients, 112 implants, Figure 2) or conventional freehand surgery (28 patients, 112 implants). All the implants were placed according to the surgical and prosthetic protocols recommended by the manufacturer (IFU 73494 Manual 2 / All-on-4 and IFU 71286). In case of immediately postextractive implants, a two piece radiographic guide was used (Figure 3).[6] Four different implants types were used (92 NobelReplace Conical Connection implants, 64 NobelSpeedy Groovy, 8 Brånemark System MKIII Groovy, and 60 NobelReplace Tapered Groovy implants). All the implants had the same moderately rough, phosphate-enriched titanium oxide surface (TiUnite, Nobel Biocare). The drilling sequence was chosen according to manufacturer's instructions in relation to the bone quality, achieving an insertion torque ranging from 35 Ncm to 55 Ncm at implant insertion (OsseoCare Pro Drill Motor Set, Nobel Biocare). Angled multi-unit abutments (17° or 30°, Nobel Biocare) were immediately connected to the distal implants, while, straight multi-unit abutments were used in the anterior implants, if needed. A metal-reinforced or fully acrylic, screw-retained provisional restoration without cantilever was prefabricated in case of immediate loading (40 patients, 160 implants, Figure 4). Onto the other implants (64) healing abutments (straight implants) or healing caps (distal implants) were connected. All patients received oral and written recommendations regarding medication (ibuprofen, 600 mg, administered every 8 hours per 1 day, and later on if needed), oral hygiene maintenance, and diet.

After 2 to 6 months a definitive impression was made at the implant or abutment level with plaster (Snow White Plaster no. 2, Kerr, Orange, Calif) and vinyl polysiloxane material (Flexitime dynamic putty and Light Flow; Heraeus Kulzer GmbH, Hanau, Germany), according to a previously reported protocol.[7] Definitive CAD/CAM titanium or zirconia frameworks were screwed either at the implant or abutment level according to the manufacturer's instructions. The veneering material was ceramic (n = 18), acrylic (n = 4), or composite (n = 34). The

Table 1

Patients' and interventions' characteristics

Outcomes	Number (%)
Males	25 (41.6%)
Females	31 (55.4%)
Mean age at implant insertion	66.2±8.5
Smokers (<10 cigarettes/day)	3 (60.0%)
Patients treated in the maxilla	22 (39.3%)
Patients treated in the mandible	34 (60.7%)
Patients treated using guided surgery	28 (50.0%)
Patients treated using conventional surgery	28 (50.0%)
Immediately loaded implants	160 (71.4%)
Conventionally loaded implants	64 (28.6%)
Implants placed in post-extractive sites	40 (17.8%)
Implants placed in healed sites	184 (82.2%)
10-mm implant length	24 (10.7%)
11.5-mm implant length	60 (26.8%)
13-mm implant length	104 (46.4%)
15–16-mm implant length	36 (16.1%)
Narrow implants	14 (6.3%)
Regular implants	210 (93.7%)

TABLE 2

Summary of the main results presented at implant level at the last follow-up examination

	Immediate Loading (n = 160)	Conventional Loading (n = 64)	*P* Value
Number of patients with implant failures	1 (1.8%)	0 (0.0%)	1.0
Number of patients with prosthesis failures	0 (0.0%)	0 (0.0%)	NA
	Postextractive (n = 40)	Healed Sites (n = 184)	*P* Value
Number of patients with implant failures	0 (0.0%)	1 (1.8%)	1.0
Number of patients with prosthesis failures	0 (0.0%)	0 (0.0%)	NA

TABLE 3

Summary of the main results presented at patient level

	Immediate Loading (n = 40)	Conventional Loading (n = 16)	Odds Ratio (95% CI)	*P* Value
Number of technical complications during healing	7	-		
Number of biological complications during healing	1	0		
Overall complications during healing	8	0	8.6 (0.4–158.9)	0.056
Number of technical complications after definitive prosthesis delivery	1	2		
Number of biological complications after definitive prosthesis delivery	3	0		
Overall complications after definitive prosthesis delivery	4	2	0.77 (0.1–6.9)	1.0
Overall complications during the entire follow-up	12	2	3.0 (0.5–22.4)	0.172

occlusion was adjusted avoiding any premature contacts (Figures 5 and 6). Mutually protected occlusion with anterior guidance or balanced occlusion was used in cases of opposing natural dentition or a FDP and complete removable denture, respectively. Follow-up visits were scheduled at 1, 3, and 6 months and then annually up to 7 years of function (Figures 7 and 8). At every follow-up visit, occlusal adjustments were performed if needed. The patients underwent a professional cleaning every 4 to 6 months. Periapical radiographs were obtained annually.

Primary objectives: Implant and prosthetic survival and success were defined according the criteria suggested by Van Steenberghe,[8] as amended by Papaspyridakos in 2012.[9]

Secondary objectives:

- Any technical (fracture of the framework or the veneering material, screw loosening, etc) and/or biologic (pain, swelling, or suppuration) complications were recorded.
- Distance from the most coronal margin of the implant collar and the most coronal point of bone-to-implant contact was taken as the marginal bone level (MBL), and evaluated on intraoral digital radiographs taken with the paralleling technique using a film holder (Rinn XCP, Dentsply, Elgin, Ill) at implant placement (baseline) and then yearly up to 7 years. The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads. The software was calibrated for every single image using the known distance of the implant threads pitch. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.1 mm.

An independent and fully blinded dentist (LC) evaluated the implant and prosthetic survival and success rate. Complications were assessed and treated by the treating clinicians (MT

TABLE 4

Marginal bone loss [mm ± SD (95% CI)] between groups taken at the 1-year follow-up examinations

Immediate Loading (n = 160)	Conventional Loading (n = 64)	*P* Value
0.90 ± 0.37 (0.75–1.11)	1.0 ± 0.45 (0.84–1.12)	0.354
Postextractive Implants (n = 40)	Implants Placed in Healed Sites (n = 184)	
0.79 ± 0.26 (0.66–0.94)	1.03 ± 0.46 (0.85–1.11)	0.024*

*Statistically significant

TABLE 5

Life table analysis: implant survival rate

Interval in Years (t_i)	Implants at Start of Interval (a_i)	Failures During Interval (n_i)	Survival Rate Within Period (%) (S_i)	Cumulative Survival Rate (%) (CS_i)
0–1	224	1	99.6	99.6
1–2	212	0	100.0	99.6
2–3	140	0	100.0	99.6
3–4	116	0	100.0	99.6
4–5	64	0	100.0	99.6
5–6	48	0	100.0	99.6
6–7	24	0	100.0	99.6

Table 6

Life table analysis: prosthetic survival rate

Interval in Years (t_i)	Patients at Start of Interval (a_i)	Failures During Interval (n_i)	Survival Rate Within Period (%) (S_i)	Cumulative Survival Rate (%) (CS_i)
0–1	56	0	100.0	100.0
1–2	53	0	100.0	100.0
2–3	35	0	100.0	100.0
3–4	29	0	100.0	100.0
4–5	16	0	100.0	100.0
5-6	12	0	100.0	100.0
6–7	6	0	100.0	100.0

Table 8

Life table analysis: mean marginal bone loss (MBL) ± standard deviation (mm) (95% CI)

Interval in Years (t_i)	Patients at Start of Interval (a_i)	Mean MBL ± Standard Deviation (mm) (95% CI)
0–1	56	0.97 ± 0.43 (0.83–1.05)
1–2	53	0.21 ± 0.11 (0.16–0.24)
2–3	35	0.16 ± 0.07 (0.12–0.18)
3–4	29	0.15 ± 0.07 (0.12–0.18)
4–5	16	0.14 ± 0.07 (0.09–0.17)
5–6	12	0.12 ± 0.04 (0.10–0.16)
6–7	6	0.13 ± 0.03 (0.10–0.16)
0–7	56	1.30 ± 0.63 (1.09–1.41)

and SMM), who were not blinded. The MBL was evaluated by an independent radiologist not involved in the study.

Statistical analysis

Descriptive analysis was performed for numeric parameters using means ± standard deviations (95% CI). Cumulative implants survival and success rates were reported with the implant as the statistical unit. Prosthetic success and survival rates, as well as complications and MBL were reported with the patient as the statistical unit of the analyses. Implant and prosthetic survival and success rates were calculated using actuarial life table analysis. Two subgroups (immediate versus conventional loading and postextractive vs implants placed in healed sites) were created. Differences in the proportions of patients with implant failures, prosthesis failures, and complications (dichotomous outcomes) were compared using the Fisher's exact test. Marginal bone loss between subgroups was compared using the Mann–Whitney U test. All statistical comparisons were conducted at a 0.05 level of significance.

Results

The main patients' characteristics were reported in Table 1. One out of 224 implants (0.4%) failed in a smoker patient before delivery of the final prosthesis. An infectious etiology with pain, swelling, and suppuration were recorded. The implant (distal implants in position 16) was removed 2 months after placement, and it was replaced 3 months later. The temporary prosthesis was shortened to the right canine. No definitive prostheses failed (Table 2). Fourteen patients experienced 1 technical or biologic complication each, resulting in 10 technical and 4 biologic complications reported during the entire follow-up. The overall implant and prosthetic success rate was 98.2% and 82.1%, respectively. All complications were considered as minor and successfully resolved as follows. Three prosthetic screws loosened in the provisional restorations of 3 patients. They were resolved by retightening the screws and stabilizing the occlusion. Four fractures of fully acrylic provisional prostheses occurred.

The temporary prosthesis was adjusted chairside, and the occlusion was stabilized. The first biological complication was reported 6 weeks after implant placement in an 80-year-old female patient with controlled diabetes, around a mandibular, distal, immediately loaded implant, placed in a healed site using guided surgery. The patient reported pain and swelling without suppuration. The temporary abutment was replaced with a healing abutment. The temporary prosthesis was shortened to the right canine, and the implant was left to heal for 4 months. The other 3 biologic complications were experienced after the definitive prosthesis delivery, and were classified as peri-implantitis, consisting of a mean mesio-distal peri-implant bone loss of 3.3, 3.1, and 2.8 mm, reported at 3, 5, and 3 years, respectively. Patients received nonsurgical therapy consisting of mechanical debridement with a glycine-based air-powder abrasive device and local application of antimicrobial agents followed by oral hygiene instructions and motivation.

Table 7

Life table analysis: technical and biological compilations after delivery of the final prosthesis

Interval in Years (t_i)	Patients at Start of Interval (a_i)	Technical Complications During Interval (n_i)	Biologic Complications During Interval (n_i)	Success Rate Within Period (%) (S_i)	Cumulative Survival Rate (%) (CS_i)
0–1	56	0	0	100.0	100.0
1–2	53	1	0	98.1	98.2
2–3	35	0	2	94.3	94.6
3–4	29	1	0	96.6	92.9
4–5	16	0	1	93.8	91.1
5–6	12	1	0	91.7	89.3
6–7	6	0	0	100.0	89.3

After the treatment the bone stopped receding and the soft tissue remained stable. Fracture of the composite or ceramic veneering material of the definitive implant-supported complete FDP occurred in 3 patients at the 2-, 4-, and 6-year follow-up examinations, most likely due to occasional parafunctional habits. These situations were resolved chairside, stabilizing the occlusion. Statistical comparisons were reported in Table 3.

After an initial mean marginal bone loss of 0.97 ± 0.43 mm, all implants presented a mean of 0.15 ±0 .07 mm per year. At the last follow-up examination the mean marginal bone loss was 1.30 ± 0.63 mm (Table 4). All the data were analyzed during the entire follow-up using a life table analysis (Tables 5–8).

Discussion

The present retrospective study was developed to evaluate the 7-year biologic and technical complications as well as the radiographic outcomes of implant-supported complete FDPs delivered on 4 implants placed according to the All-on-4 protocol. The main limitations were the retrospective nature of the study and the lack of a control group. However, data from 56 patients with 224 implants followed up to 7 years on function may allow some preliminary and generalizable conclusions. The implant (99.2%) and prosthetic (100%) survival rates, as well as the mean bone loss of 1.52 ± 0.41 mm experienced at the last follow-up examinations, are consistent with other studies investigating the same topic. Postextractive implants showed lower marginal bone loss during the first year on function, rather than the implants placed in healed sites (mean difference 0.23 ± 0.20 mm). A possible explanation for these results could be the protective effect of the socket preservation technique.[10]

Babbush et al[11] retrospectively examined 165 patients treated according to the All-on-4 protocol. The cumulative implant survival rate was 99.6% (99.3% in maxilla and 100% in the mandible) for up to 29 months of loading. The definitive prosthesis survival rate was 100%. Recently, the same author retrospectively analyzed the patient-centred outcomes, including the cost of treatment, length of the treatment period, and comfort provided by the temporary prosthesis in patients treated according to the All-on-4 protocol, comparing the results with complete-arch FDPs supported by natural teeth or implants and implant-supported overdentures.[12] The costs, length of treatment and the comfort provided by the temporary prostheses significantly favoured the All-on-4 treatment modality.

Malò et al[3] retrospectively reported cumulative patient-related success rates of 93.8% up to 10 years of follow-up in the mandible. The prostheses survival rate was 99.2%. In the maxilla, a 5-year survival rate of 93% was reported.[4] The survival rate of the prostheses was 100%. The mean marginal bone loss was 1.52 ± 0.3 mm after 3 years.

A recent systematic review by Patzelt et al[5] that included 4804 implants demonstrated a mean cumulative implant and prosthesis survival rate at 3 years of 99.0 ± 1.0% and 99.9 ± 0.3%, respectively. The mean bone loss at 3 years amounted to 1.3 ± 0.4 mm.

In the present study, 14 complications (10 technical and 4 biologic) were experienced in 14 patients (25%) during the entire follow-up. Nevertheless, this result did not differ from those normally encountered in oral rehabilitation in which implants are used as support for a FDP (33.6% at 5 years).[13] Eight (57.1%) complications were reported during healing in patients wearing the temporary restorations (eg, all the fractured temporary prostheses were fully acrylic). After delivery of the final restorations, 3 technical and 3 biologic complications were experienced in 6 patients (10.7%). The 3 biologic complications seem to be ascribable purely to plaque accumulation in patients with "host susceptibility."[14,15] For the latter, delivery of a metal-reinforced temporary restoration during healing might be advisable, and patients should be placed in a well-structured hygiene and occlusal maintenance program after treatment.

Conclusion

The All-on-4 concept may be a valuable treatment modality for fully edentulous jaws. It may decrease overall treatment time and re-establish adequate function in a cost-effective way. However, technical and biologic complications can occur. Further long-term prospective data are needed.

Abbreviations

FDP: fixed dental prosthesis
MBL: marginal bone loss

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