Five-Year Results of a Randomized Controlled Trial Comparing Patients Rehabilitated with Immediately Loaded Maxillary Cross-Arch Fixed Dental Prosthesis Supported by Four or Six Implants Placed Using Guided Surgery

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ABSTRACT

Purpose: To compare the 5-year clinical and radiological outcomes of patients rehabilitated with four or six implants placed using guided surgery and immediate function concept.

Materials and Methods: Forty patients randomly received four (All-on-4) or six (All-on-6) immediately loaded implants, placed using guided surgery, to support a cross-arch fixed dental prosthesis. Outcome measures were survival rates of implants and prostheses, complications, peri-implant marginal bone loss, and periodontal parameters.

Results: No drop-out occurred. Seven implants failed at the 5-year follow-up examination: six in the All-on-6 group (5%) and one in the All-on-4 group (1.25%), with no statistically significant differences ($p = .246$). No prosthetic failure occurred. Both group experienced some technical and biologic complications with no statistically significant differences between groups ($p = .501$). All-on-4 treatment concept demonstrated a trend of more complications during the entire follow-up period. A trend of more implant failure was experienced for the All-on-6 treatment concept. Marginal bone loss (MBL) from baseline to the 5-year follow-up was not statistically different between All-on-4 (1.71 ± 0.42 mm) and All-on-6 (1.51 ± 0.36 mm) groups ($p = .12$). For periodontal parameters, there were no differences between groups ($p > .05$).

Conclusion: Both approaches may represent a predictable treatment option for the rehabilitation of complete edentulous patients in the medium term. Longer randomized controlled studies are needed to confirm these results.

KEY WORDS: atrophic maxilla, atrophy, CAD/CAM technology, clinical research, computer-assisted, cone beam CT, edentulous atrophic maxilla, edentulous maxilla, immediate function, immediate loading

INTRODUCTION

Nowadays, no consensus has been reached on the most advantageous number of implants to be used to support a fixed dental prosthesis (FDP).[1] In the 1980s, Branemark and colleagues suggested a minimum of six implants in the mandible as the gold standard for complete edentulism rehabilitations,[2] whereas up to 14 implants have been used to anchor a cross-arch FDP in the edentulous maxilla.[3–5] Malò and colleagues[6,7] presented data following the rehabilitation of edentulous jaws with four immediately loaded implants (All-on-4®; NobelBiocare AG, Kloten, Switzerland). This treatment concept benefits from tilting the two distal implants, which allows to minimize cantilevers, despite minimal bone height and nerve or sinus proximity,[7] decreasing the overall treatment times.[8] Lower patient morbidity and a higher patient quality of life were reported up to 10 years.[9–12] As an alternative, Agliardi and colleagues[13] reported that six implants could be considered a predictable and cost- and time-effective option for the immediate restoration of the edentulous maxilla, avoiding

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bone grafting procedures. Computer-guided implant protocols may help clinicians to perform successful implant therapy minimizing or avoiding flap elevation,[14,15] although no statistically significant differences were found if compared with freehand implant placement.[14,16] Additionally, minor three-dimensional deviations between virtual planning and final implant position, and technique-related peri-operative complications, were demonstrated.[17–20]

The aim of the present randomized controlled trial was to compare clinical and radiological outcomes of maxillary implant-supported cross-arch FDP delivered on four or six implants, immediately loaded and inserted with computer-assisted procedures. The present study was undertaken according to the CONSORT statement to improve the quality of reports of parallel-group, randomized trials (http://www.consort-statement.org/).

MATERIALS AND METHODS

The present study is a parallel group, randomized controlled trial, aimed to evaluate patients with maxillary edentulism, or with failing dentitions, requiring implant-supported cross-arch FDP and immediate loading. Private patients were selected and treated in a consecutive order between June 2007 and December 2009. The investigation was conducted according to the principles embodied in the Helsinki Declaration of 2008. After being duly informed about the nature of the study, patients were asked to provide written consents.

Any healthy edentulous patient, or patients presenting a failing dentition, aged 18 years or older, with Class II to V according to Cawood & Howell,[21] required a maxillary implant-supported cross-arch FDP were considered for inclusion in this study. Failing dentitions were noted when two or more of the following characteristics were present: loss of more than 75% of supporting bone, probing pocket depths ≥ 8 mm, class III furcation, hypermobility,[22] and nontreatable endodontic issues.[23] Exclusion criteria were: patients with uncontrolled diabetes, history of radiation to the head and neck, pregnancy or nursing, intravenous bisphosphonate therapy, smoking more than 10 cigarettes a day, and inability to comply with annual implant and maintenance schedules. Immediate postextractive implants could be placed if the alveolus presented a buccal wall up to 2 mm lower than the most coronal bony peak, and at least 5 mm of bone below the tooth apex. If the operator decided to wait for the post-extractive socket healing, the implant sites were left to heal for at least 3 months.

Preoperative photographs, periapical radiographs or panoramic x-rays, and model casts were obtained for initial screening and evaluation. Patients underwent a computed tomography (CT) or cone beam CT (CBCT) scans according to a double-scan protocol,[24] in order to assess the possibility of placing four or six implants in healed bone or at the same time of tooth extraction. In case of immediate postextractive implants, a two-piece radiographic guide was used for the diagnostic study and the virtual implant planning.[25] The Digital Imaging and Communication in Medicine (DICOM) data of the two sets of scans were transferred to three-dimensional software planning program (NobelGuide, Nobel Biocare AG). Prior to implant planning, patients were randomly allocated to receive four (All-on-4 group) or six (All-on-6 group) implants according to a parallel group design. Once the randomization lists were created, envelopes with random codes were sequentially opened by a staff member not involved in the study. All implants were planned according to the allocated interventions. In case of post-extractive sockets, implant insertion was planned along the palatal socket wall, 1.5 mm below the coronal vestibular alveolar crest. After careful functional and aesthetic evaluation and final verification, the virtual plan was approved, and a stereolithographic surgical template was ordered (Nobel Biocare AG).

Patients underwent professional oral hygiene prior to the surgery and received prophylactic antiseptic and antibiotic therapy. After local anesthesia, residual teeth were extracted as atraumatically as possible. The surgical templates were placed intraorally in relation to the opposing arch using the silicon surgical index derived from the mounted casts and stabilized with three to four preplanned anchor pins. Flapless or a miniflap approach, with or without tissue grafting was performed as needed. NobelSpeedy Groovy implants (Nobel Biocare AG) were placed following the drilling protocol recommended by the manufacturer, according to bone density.[26] Final insertion torque ranged from 35 to 45 Ncm. Seventeen degree or 30° angled multi-unit abutments were connected to the tilted implants for proper screw access hole orientation. If needed, straight multi-unit abutments were used in the anterior implants. A prefabricated, screw-retained, fully acrylic or metal-

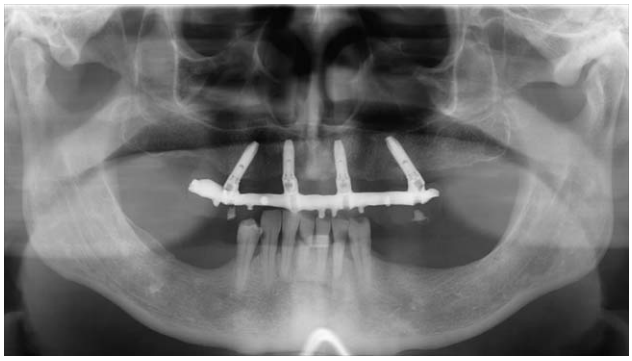

Figure 1 Ortopantomograph at 5-year follow-up of a cross-arch rehabilitation in the All-on-4 group.

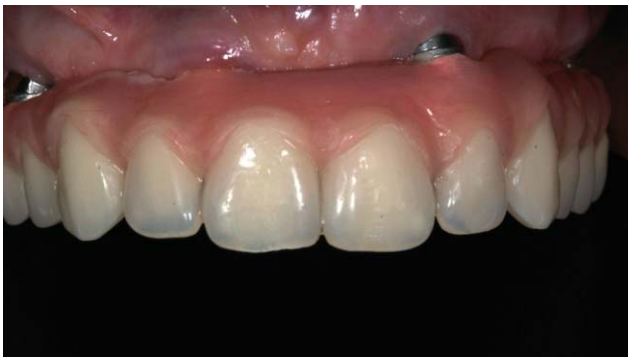

Figure 3 Definitive cross-arch restoration at 5-year follow-up delivered in the All-on-4 group.

reinforced acrylic resin provisional restoration, without any cantilever was immediately delivered to the patient. Postsurgical analgesic was controlled with ibuprofen 600 mg after surgery, and later on if needed.

The definitive impression was made at implant or abutment level 4 months after implant placement, according to a previously reported protocol.[27] Five months after healing, the definitive prosthesis with Computer-Aided-Design/Computer-Aided-Manufacturing (CAD/CAM) titanium or zirconia frameworks was screwed. Definitive implant-supported complete FDP was fabricated with pink material in the cervical region (hybrid design), or with a conventional crown design. The occlusion was adjusted avoiding any premature contacts. Mutually protected occlusion with anterior guidance or balanced occlusion was used in cases of opposing natural dentition ($n = 23$) or opposite implants ($n = 11$) and complete removable denture ($n = 6$), respectively. Follow-up visits were scheduled 1, 6 months and then annually up to 5 years of function (Figures 1–4).

The primary outcome measures were implant and prosthetic survival rates, and any biologic (pain, swelling, mobility, suppuration) and/or technical complications (framework and/or veneering material fracture, screw loosening). Marginal bone loss and soft tissue parameters represented the secondary outcome measures. The distance from the most coronal margin of the implant collar and the most coronal point of bone-to-implant contact was taken as marginal bone loss (MBL). It was evaluated on intraoral digital radiographs taken with the paralleling technique using a film-holder (Rinn XCP, Dentsply, Elgin, IL, USA) at implant placement (baseline) and then yearly up to 5 years on function. All readable radiographs were displayed in an image analysis program (DFW2.8 for windows, Soredex, Tuusula, Finland) calibrated for every single image using the known distance of two consecutive implant threads pitch. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.05 mm and averaged at patient level.

Soft tissue parameters around the implant-abutment interfaces were assessed at the 5-year examination. The sulcus bleeding index (SBI) was evaluated at four sites around each implant according to the

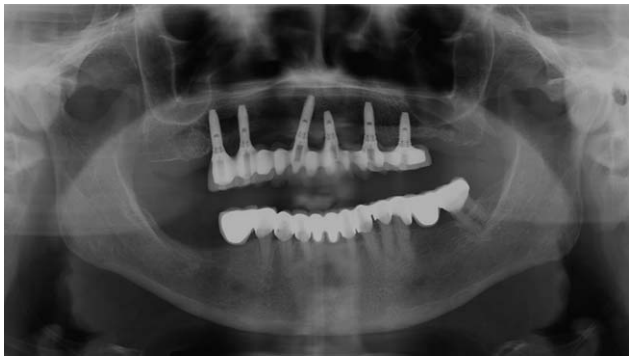

Figure 2 Ortopantomograph at 5-year follow-up of a cross-arch rehabilitation in the All-on-6 group.

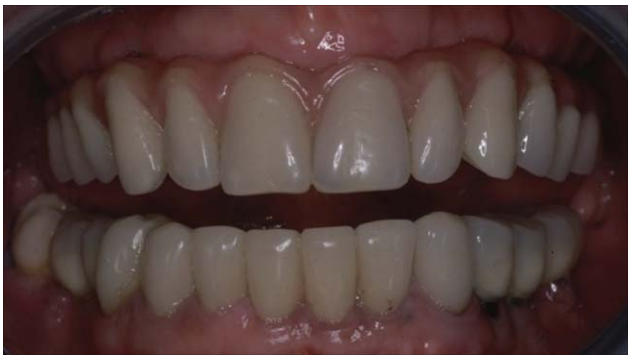

Figure 4 Definitive cross-arch restoration at 5-year follow-up delivered in the All-on-6 group.

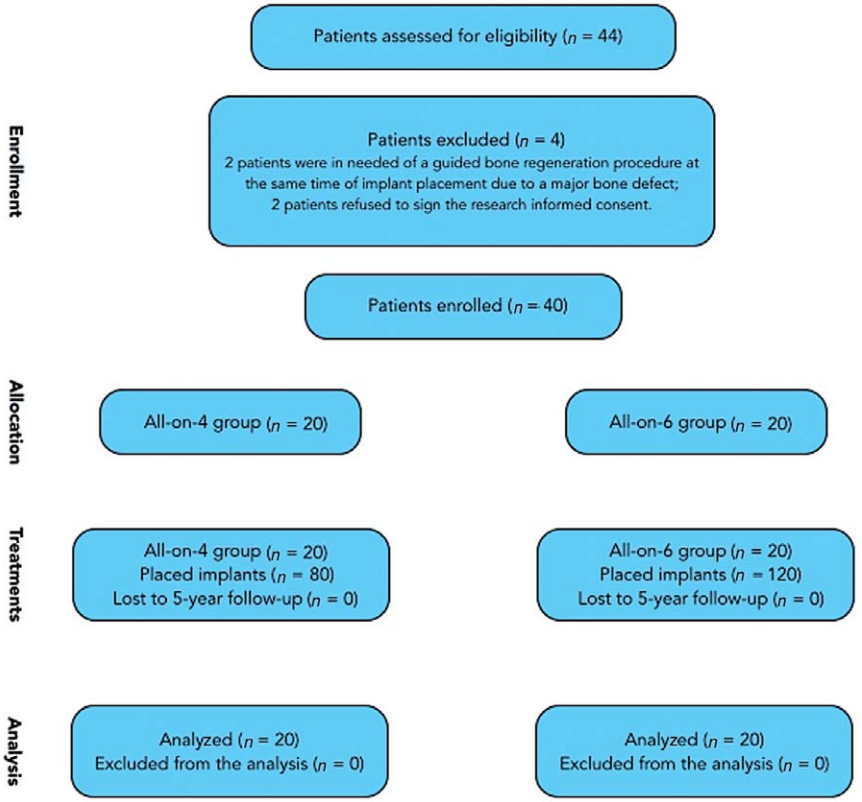

Figure 5 CONSORT flow diagram.

Mombelli Index,[28] whereas the plaque index (PI) was evaluated at one site for implant according to the same author.[28]

Two independent dentists (MC and LC) evaluated the implant and prosthetic survival and success rates. Complications were treated by the treating clinician (MT) who was nonblinded. Marginal bone level changes were evaluated by an independent radiologist not previously involved in this study (EX). An independent dental hygienist (RI) who was otherwise not involved in the study performed all periodontal measurements.

A bio-statistician with expertise in dentistry analyzed the data using SPSS software for Mac OS X (version 22.0; SPSS Inc., Chicago, IL, USA) for statistical analysis. Descriptive analysis was performed for numeric parameters using mean ± standard deviation and median with confidence interval (95% CI). Implants and prostheses were used as the statistical unit of the analyses. Comparison between each follow-up within groups was performed using paired *t*-test to detect any change in mean marginal bone levels (continuous outcomes) during the entire follow-up. Differences of means at patient level between groups were compared by independent sample *t*-tests. Periodontal parameters as well as differences in the proportion of patients with prosthetic failures implant failures and complications (dichotomous outcomes) were compared between groups using the Fisher's exact probability test and the Yate's corrected chi-square test. All statistical comparisons were conducted at a 0.05 level of significance.

RESULTS

A total of 200 implants were placed in 40 consecutive edentulous patients (21 males and 19 females, mean age of 63 years, range 42–87). All patients were treated according to the allocated interventions and followed-up with a minimum period of 5 years (mean 63.8 months, range 60–84), with no patient dropped-out. A flow diagram of the activities through the phases of the trial is shown in Figure 5. There were no apparent baseline imbalances between the two groups apart from the presence of more postextractive and short implants placed in the All-on-6 group. Patients and interventions characteristics are summarized in Table 1.

Seven implants failed at the 5-year follow-up examination: six in the All-on-6 group (5%) and one in the

TABLE 1 Patients' and Interventions' Characteristics

	All-on-4 ($n = 20$)	All-on-6 ($n = 20$)
Males ($n = 21$)	10 (47.6%)	11 (52.4%)
Females ($n = 19$)	10 (52.6%)	9 (47.4%)
Mean age at implant insertion (years)	66.8	60.2
Smokers (<10 cigarettes/day) ($n = 2$)	1 (50.0%)	1 (50.0%)
Implants placed in post-extractive sites ($n = 32$)	9 (28.1%)	23 (71.9%)
Implants placed in healed sites ($n = 168$)	71 (42.23%)	97 (57.7%)
10-mm implant length ($n = 80$)	8 (10.0%)	72 (90.0%)
11.5-mm implant length ($n = 54$)	36 (66.6%)	18 (33.4%)
13-mm implant length ($n = 66$)	36 (54.5%)	30 (45.5%)
Narrow (3.3 mm) diameter implants ($n = 4$)	0 (0.0%)	4 (100.0%)
Regular (4 mm) diameter implants ($n = 196$)	80 (40.8%)	116 (51.2%)

All-on-4 group (1.25%), with no statistically significant differences ($p = .246$). No prosthesis failed. The main results and statistics are summarized in Table 2.

Both group experienced some technical and biologic complications with no statistically significant differences between them ($p > .05$). Two prosthetic screws loosening were experienced in the provisional restorations of two patients treated according to the All-on-4 concept, resolved by retightening a new screw and stabilizing the occlusion. Both groups experienced one fracture of the fully acrylic provisional prostheses that were repaired chairside. Fracture of the veneering material of the definitive implant-supported complete FDP occurred in four patients (three All-on-4 group and one All-on-6 group). All of these situations were fixed chairside, restoring the prosthesis and stabilizing the occlusion. Pain and swelling without suppuration were reported in one patient of both groups during osseointegration, around distal implants. In both cases, the temporary abutments were replaced with healing abutments. The temporary prostheses were shortened, and the implants were left to heal for 4 months. The other three biologic complications were experienced in three patients (one into the All-on-4 group and two into the All-on-6 group) after the definitive prosthesis delivery, within the first year of loading, and were classified as peri-implantitis. All 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. After the treatment, the bone stopped receding, and the soft tissue remained stable during the entire follow-up.

Generally, the All-on-4 treatment concept showed a slightly risk of complications during the entire follow-up period ($p = .661$; Relative Risk (RR) = 1.39; 95% CI 0.64–2.45), whereas the All-on-6 group experienced a higher risk of implant failure ($p = .246$; RR = 1.4; 95% CI 0.70–1.70). The main results and statistics are summarized in Table 3.

Mean marginal bone level changes from baseline to the 5-year follow-up were not statistically different between groups (difference = 0.20 ± 0.06 mm; 95% CI 0.08–0.18; $p = .117$). The main results and statistics are summarized in Table 4.

At the 5-year follow-up examination, in the All-on-4 group, positive SBI was reported around five implant/abutment complexes (6.25%) of three patients,

TABLE 2 Summary of the Main Results Presented at Implant Level at the Last Follow-Up Examination

	All-on-4 ($n = 80$)	All-on-6 ($n = 120$)	Relative Risk (95% CI)	*p* Value
Implant failures	1 (1.25%)	6 (5.0%)	1.4 (0.70–1.70)	.246
Prosthesis failures	0 (0.0%)	0 (0.0%)	–	NA

TABLE 3 Summary of the Main Results Presented a Patient Level During the Entire Follow-Up Examination

	All-on-4 ($n = 20$)	All-on-6 ($n = 20$)	Relative Risk (95% CI)	p Value
Number of technical complications during healing	3	1	1.6 (0.43–2.21)	.605
Number of biological complications during healing	1	1	1.0 (0.05–2.05)	1.0
Overall complications during healing	4	2	1.4 (0.47–2.22)	.661
Number of technical complications after definitive prosthesis delivery	3	1	1.6 (0.43–2.21)	.605
Number of biological complications after definitive prosthesis delivery	1	2	0.6 (0.03–1.86)	1.0
Overall complications after definitive prosthesis delivery	4	3	1.2 (0.38–2.09)	1.0
Overall complications during the entire follow-up	8	5	1.39 (0.64–2.45)	.501

whereas in the All-on-6 group, positive SBI was detected around nine implant/abutment complexes (7.5%) of five patients. No difference was founded between groups ($p = 1.0$). Positive PI was reported around 16 implant/abutment complexes (20%) of eight All-on-4 restorations, whereas in the All-on-6 group, positive PI was detected around 11 implant/abutment complexes (9.2%) of six patients. No difference was founded between groups ($p = .064$).

DISCUSSION

The purpose of this study was to investigate the most advantageous number of implants to support a cross-arch screw-retained FDP in maxillary edentulous patients. Treatment options were four (two axial and two tilted, All-on-4 protocol) or six (axial, All-on-6 protocol) implants. All implants were placed once the intervention was planned with a dedicated three-dimensional software, loaded immediately and controlled for 5 years. The null hypothesis that no difference exists between the two tested procedures was confirmed.

The main limitation of the present investigation was the recruitment of maxillary patients. Thus, the results may be generalized only to the upper jaw. Another limitation was the small sample size that may have hidden some differences. Finally, last limitation of the present study included the nonblinded status of outcome assessors. Nevertheless, this limitation was intrinsic in the study design itself, due to a different number and tridimensional position of the implants within groups. It is interesting to note that all patients included in this study were continuously monitored over the study period, with no patient dropped out. All patients were treated in private practices and were continuously seen for study follow-up and for periodontal and implant maintenance, willingly complied with the study protocol.

The present is one of the first studies comparing patients rehabilitated with four or six dental implants, making difficult to evaluate how the present results would fit with other comparable studies. First long-term results were reported in Sweden[26] and by the Toronto study,[29] which described prostheses supported by more than four implants, mostly by five or six. Conversely, Malò and colleagues,[30] in a retrospective study, concluded that using four implants to support a fixed prosthesis is a viable treatment option to rehabilitate completely edentulous maxillae. Analyzing cantilever length, it must be highlighted that they are obviously

TABLE 4 Summary of the Main Marginal Bone Loss During Each Follow-Up Examinations

	All-on-4 ($n = 20$)	All-on-6 ($n = 20$)	Difference ($n = 20$)	p Value
0–12 months	1.05 ± 0.35 (0.98–1.20)	0.96 ± 0.29 (0.78–1.02)	0.08 ± 0.05 (0.10–0.14)	.408
12–24 months	0.20 ± 0.10 (0.16–0.24)	0.21 ± 0.16 (0.11–0.23)	0.0 ± 0.07 (0.2–0.06)	.942
24–36 months	0.17 ± 0.08 (0.11–0.19)	0.14 ± 0.05 (0.13–0.17)	0.03 ± 0.03 (−0.02–0.02)	.186
36–48 months	0.15 ± 0.07 (0.12–0.18)	0.11 ± 0.04 (0.08–0.12)	0.03 ± 0.03 (0.03–0.07)	.085
48–60 months	0.14 ± 0.06 (0.10–0.16)	0.09 ± 0.04 (0.08–0.12)	0.05 ± 0.02 (0.02–0.04)	.006
0–60 months	1.71 ± 0.42 (1.45–1.83)	1.51 ± 0.36 (1.38–1.66)	0.20 ± 0.06 (0.08–0.18)	.117

longer in prostheses supported by less implants, although this parameter depends mostly on the anterior-posterior spread. Falk and colleagues investigated loading patterns of fixed cantilever prostheses and demonstrated maximum loading forces on the distal implants adjacent to the cantilevers.[31] Although higher stress in the cortical bone around the implants was registered in single cases, it was shown that with this treatment concept bone apposition could be observed underneath the cantilevers in the posterior zone of the mandibular jaw.[32] A recent systematic review reported good outcomes for this concept that mostly utilized only four, sometimes five (two axial and two to three tilted) implants, with distal cantilevers included in the prosthesis design.[33] This arrangement demonstrated to reduce the number of implants to a minimum, increasing the arch of extension and the support of cross-arch fixed prostheses. As a consequence, the cantilever length decreases. A meta-analysis found stable marginal bone levels with no difference between axial and tilted implants.[34]

In patients with Cawood & Howell class IV, V and VI,[21] the All-on-4 treatment concept seems to be a safe, effective, and efficient surgical-prosthetic protocol on both jaws to avoid technique-sensitive augmentation procedures.[34,35] Nevertheless, the current evidence on All-on-4 is limited by the quality of available studies and the paucity of long-term clinical outcomes.[8] Moreover, the hygienic maintenance of the hybrid designed All-on-4 FDPs can be challenging, particularly when extensive prosthetic flanges are needed.[36] For the aforementioned reasons, patient demand, compliance, dexterity, financial capability, skeletal maxillomandibular relationship, and residual bone anatomy have to be taken into consideration to customize the proper implant number, position, and dental prostheses.[37,38]

CONCLUSIONS

The results of the present study suggest that both treatment concepts could be a viable and predictable option for the rehabilitation of complete edentulous maxilla in the medium term. However, longer term randomized controlled trials are needed to confirm this results.

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