

A Clinical Study of Edentulous Patients Rehabilitated According to the “All on Four” Immediate Function Protocol

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Purpose: The aim of this study was to compare definitive acrylic resin prostheses with or without a cast metal framework that were immediately loaded and supported by axial and tilted implants in completely edentulous patients after 3 years of function. **Materials and Methods:** Patients who were completely or partially edentulous in one or both arches with severe atrophy of the posterior regions were selected for this study. All patients immediately received prosthetic rehabilitations, each supported by four implants (two axial and two tilted). The patients were randomized to receive a definitive prosthesis with a cast metal framework or one made of acrylic resin only. Follow-up visits were performed up to 36 months after implant insertion and included radiographic assessments of bone levels around the implants. **Results:** Thirty-six patients participated, and 44 complete-arch immediately loaded prostheses (24 maxillary and 20 mandibular), each supported by four implants (in total 176 implants), were placed. In all, 21 screw-retained full-arch acrylic resin prostheses and 23 cast-metal-framework prostheses were delivered to the patients. The 3-year overall implant survival rate was 100% for axially positioned implants and 96.59% for tilted implants. Implant survival rates were 98.96% in the maxilla and 97.5% in the mandible. None of the 44 fixed prostheses were lost during the observation period, representing a prosthetic survival rate of 100%. No statistically significant differences were seen in crestal bone loss between tilted and axial implants at 12, 24, and 36 months in either arch. **Conclusions:** The same clinical outcome was seen for patients treated with the so-called All on Four protocol, regardless of whether the acrylic resin restorations were reinforced with metal. INT J ORAL MAXILLOFAC IMPLANTS 2012;27:428–434

Key words: acrylic resin prostheses, All on Four, metal-reinforced prostheses, tilted implants

The rehabilitation of an edentulous maxilla with implants loaded immediately after placement with a full-arch prosthesis represents a valid treatment option that has shown a high rate of survival.^{1–3} However, bone resorption and anatomical structures such as the maxillary sinus or the mandibular nerve represent limitations in the reconstruction of edentulous patients

and often lead to bone augmentation procedures, which are associated with high costs, high morbidity, and poor patient acceptance.

Clinical implant dentistry is orienting itself toward lower-cost treatment approaches using simple protocols that are well supported by scientific data⁴ and provide immediate function through immediate restoration and loading of dental implants.^{5–7} A new protocol, the so-called All on Four concept, which employs tilted implants to restore edentulous patients, has been proposed as an alternative to bone augmentation procedures. The placement of four implants—two posteriorly and two anteriorly—makes it possible to avoid bone augmentation procedures when rehabilitating a completely edentulous arch with minimal bone volume.^{8,9} The use of fewer and/or tilted implants has been encouraged by the results of implant load analyses¹⁰ demonstrating that four implants are sufficient to support a complete-arch prosthesis. Longer implants may be optimally placed in areas with good cortical anchorage to increase prosthetic support and reduce the length of cantilevers. This procedure supports a simpler,

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less expensive, and less time-consuming treatment compared to maxillary sinus elevation¹¹ or bone grafts.

Krekmanov et al¹² treated 47 consecutive patients with implants placed in tilted positions. Cumulative success rates in the maxilla at 5 years were 98% for tilted implants and 93% for axially positioned implants. Analysis of the load distribution in one mandibular case showed no significant difference between tilted and nontilted implants, and improved prosthesis support was confirmed. Several authors have reported promising clinical outcomes when placing immediate fixed reconstructions in edentulous patients supported by four splinted implants; immediately loaded full-arch fixed prostheses supported by two axial and two tilted implants in both arches have proven to be a successful long-term treatment option.^{3,8,9,13}

Because the immediate loading of tilted implants with a provisional restoration has been proposed as a simpler, more predictable, less expensive, and less time-consuming method to treat the atrophic maxilla,^{14,15} the aim of the present prospective study was to compare a definitive cast-metal-framework prosthesis with a definitive all-acrylic resin prosthesis, both of which were immediately loaded and supported by axial and tilted implants in patients with completely edentulous jaws, after 3 years in function.

MATERIALS AND METHODS

Patient Selection

This clinical study was performed in the Department of Dentistry, San Raffaele Hospital, Milan, Italy. All patients had to be in good health and edentulous (in one or both arches) or with only a few hopeless teeth, and all presented with severe atrophy of the mandible or maxilla in posterior regions. Exclusion criteria were any active infection or severe inflammation in the areas intended for implant placement, presence of chronic systemic disease, smoking more than 15 cigarettes per day, a bruxism habit, and poor oral hygiene.

Diagnoses were made clinically and radiographically (preoperative panoramic radiograph and computed tomographic scans). All patients gave their written informed consent for immediate implant loading.

Surgical Procedure

One hour prior to surgery, patients received 1 g amoxicillin (Zimox, Pfizer Italia), which they continued to take (1 g twice a day) for a week after the surgical procedure. Surgery was performed under local anesthesia (optocain 20 mg/mL with adrenaline 1:80,000; Astra).

In edentulous mandibles, incisions were made on the top of the alveolar crest, from the first molar on one side to the first molar on the contralateral side, with

Table 1 Diameters and Lengths of Implants Placed in the Maxilla and Mandible

| | Implant diameter | Implant length | |
|--------------------------|------------------|----------------|-------|
| | | 13 mm | 15 mm |
| Maxilla (n = 96) | | | |
| Axial (n = 48) | 4 mm | 22 | 0 |
| | 3.75 mm | 26 | 0 |
| Tilted (n = 48) | 4 mm | 20 | 28 |
| | 3.75 mm | 0 | 0 |
| Mandible (n = 80) | | | |
| Axial (n = 40) | 4 mm | 15 | 0 |
| | 3.75 mm | 25 | 0 |
| Tilted (n = 40) | 4 mm | 22 | 18 |
| | 3.75 mm | 0 | 0 |

bilateral releasing incisions. Subperiosteal dissection on the lingual and buccal surfaces was carried out, and the mental foramina were visualized. The most posterior implants were placed close to the anterior wall of the mental loop and were tilted distally about 30 to 35 degrees relative to the occlusal plane. The posterior implants, which were 4 mm in diameter and 15 or 13 mm in length, typically emerged at the second premolar position (PAD System, Sweden-Martina; Table 1). After the posterior implants were placed bilaterally, additional implants were placed in the anterior mandible. Anterior implants were either 3.75 or 4 mm in diameter and 13 mm in length (PAD System, Sweden-Martina). When necessary, bone shaping was performed with a round bur to level the bone crest and to achieve crestal positioning in the posterior arches, bone recontouring was performed distal to the angled implants.

In edentulous maxillary patients, incisions were made on the alveolar crest from the first molar on one side to the first molar on the contralateral side, with bilateral releasing incisions. Subperiosteal dissection was carried out. The most posterior implant was placed close to and parallel with the anterior sinus wall. Thus, these implants were tilted distally approximately 30 to 35 degrees. The lower corner of the implant neck was positioned level with the bone. Then implants were placed in the anterior maxilla, again with the implant necks positioned at the bone level. The posterior implants were 4 mm in diameter and 15 or 13 mm in length, and the anterior implants were either 4 or 3.75 mm in diameter and 13 mm in length (PAD System, Sweden-Martina).

Underpreparation was performed in soft bone to obtain high primary stability. If implants did not achieve the desired insertion torque, immediate loading was avoided and at least 3 months were allowed to elapse prior to loading.



Fig 1a Maxillary edentulous ridge.

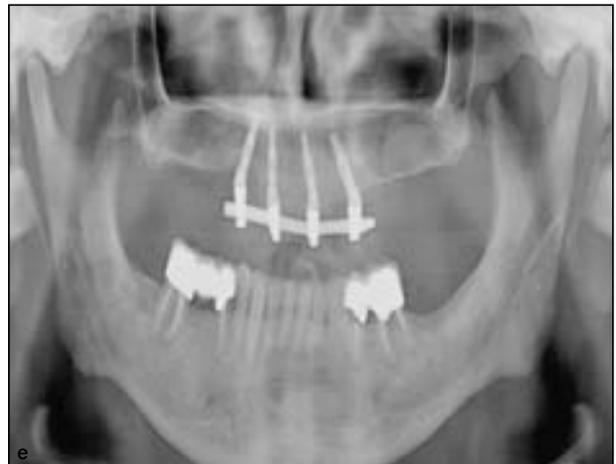
Fig 1b Preoperative panoramic radiograph.

Fig 1c The flaps were sutured and angulated abutments (PAD System) were placed.



Fig 1d The definitive metal-framework prosthesis.

Fig 1e Panoramic radiograph at 3 years.



Angulated abutments (PAD System, Sweden-Martina) for anterior implants were set at 17 degrees and those for posterior implants were set at 30 degrees to compensate for the lack of parallelism between implants. These abutment angulations were chosen so that the prosthetic screw access holes would be in an occlusal or lingual location.

Flap adaptation and suturing were performed in the usual manner with 4-0 nonresorbable sutures (Fig 1).

Prosthetic Protocol

A prosthesis was prepared prior to surgery in accordance with a diagnostic setup. The vertical dimension was established and corrected using facial reference marks recorded prior to surgery.

Pickup impressions (Permadyne, ESPE) of the implants were made at the conclusion of surgery. Then, an interocclusal registration was performed using the prefabricated prosthesis, and panoramic radiographs



Fig 2a Maxillary edentulous ridge.



Fig 2b Preoperative panoramic radiograph.



Fig 2c The flaps were sutured and angulated abutments (PAD System) were placed.



Fig 2d The definitive all-acrylic resin prosthesis.



Fig 2e Panoramic radiograph of patient, treated with "All on Four" in both arches, at 3 years.

were obtained. Twenty-four hours after implant placement, screw-retained full-arch definitive prostheses were positioned.

According to a random selection protocol, one group of patients received definitive prostheses made

of acrylic resin masticatory surfaces (Sinfony Resin, ESPE), with metal frameworks for increased strength and rigidity (Fig 1). The other group of patients received definitive prosthesis with acrylic resin frameworks (Res-in IVOCRON, Ivoclar Vivadent) (Fig 2).

Table 2 Dentate Ridges with Hopeless Teeth

| Patient no. | Hopeless teeth* | |
|-------------|--------------------|------------------------|
| | Maxilla | Mandible |
| 1 | 11, 12, 14, 21, 24 | Edentulous |
| 2 | 11, 12, 13, 21, 22 | Edentulous |
| 3 | Edentulous | 31, 32, 33, 41, 42, 43 |

*FDI tooth-numbering system used.

Cantilevers were typically extended to the first molar regions. Articulating paper (Bausch) was used to check the occlusion and adjust it, if necessary. Static occlusion consisted of central contacts established on all masticatory units. Dynamic occlusion included canine/premolar guidance, regardless of the opposite arch settings. The screw access holes were covered with provisional acrylic resin (Fermit, Ivoclar Vivadent).

Follow-up

All patients followed a soft diet (avoiding bread and meat) for 2 months.

Follow-up visits were performed by a dental hygienist at 3, 6, 12, 24, and 36 months after implant insertion. Success criteria for implant survival were: presence of implant stability, absence of radiolucent zone around the implants, no mucosal suppuration, no pain.

Restoration success, defined as the absence of fractures of the acrylic resin superstructure, even if one or more implants supporting the restoration have been removed. Implant survival was defined as the absence of implant mobility, swelling, or pain in the surgical site at the time of examination. Implant success was defined as implant survival plus marginal bone loss of less than 1.5 mm after 1 year of loading and no more than 0.2 mm of loss between each follow-up appointment after the first year of function.

Radiographic assessments were made using panoramic images obtained immediately after surgery and at each follow-up visit (Fig 1). Bone levels were measured on the mesial and distal aspects of each implant, using the implant-abutment junction as a reference point. To adjust for dimensional distortion and enlargement on the radiographs, the actual known lengths of the implants were compared to the measured implant dimensions on the radiograph.^{4,16} A radiologist measured the changes in marginal bone height over time twice, marking the reference points and measuring lines on the screen interactively; the numeric value of measurements was recorded by software (CDR, Schick Technologies). The radiographic measurements were compared to the measurements obtained immediately after surgery.

Statistical Analysis

A dedicated software program (SPSS 11.5.0, SPSS) was used for all statistical analyses. Bone level measurements were reported as means \pm standard deviations at 12, 24, and 36 months. Bone loss around the axial and tilted implants was compared with the Student *t* test at a significance level of $P = .05$.

RESULTS

Between January 2007 and July 2007, 36 patients, 22 women and 14 men with a mean age of 54.6 years (range, 41 to 81 years), were randomly selected for this study and were treated with 44 immediately loaded complete-arch prostheses (24 maxillary and 20 mandibular), each supported by four implants (in total 176 implants) (Table 1). Eight patients were treated with both maxillary and mandibular prosthetic rehabilitations. In all, 21 screw-retained full-arch definitive acrylic resin prostheses and 23 definitive cast-metal-framework prostheses were delivered to the patients. Cantilevers extended to the first molar regions in all but three cases, in which they reached only the second premolar area.

All implants in immediate function had a final insertion torque of at least 40 Ncm. In three patients, the anterior implants were immediately positioned in fresh extraction sockets. These patients had presented with partially edentulous ridges (residual hopeless teeth are reported in Table 2) and underwent extraction of residual teeth on the same day that implants were positioned. The granulation tissue was removed from the extraction sockets. Postextraction implants were positioned in central incisor sites: in the maxillary central incisors in two patients and the mandibular central incisors in the third patient.

During the first 4 months after implant placement, three implants failed (one maxillary and two mandibular), all as a result of pain (Table 3). All failed implants were tilted and were replaced immediately without compromising prosthetic function.

One patient, a 76-year-old nonsmoking woman, reported severe discomfort, pain, and swelling in the anterior maxilla 3 months after surgery. The restoration was removed, and subsequent examination revealed that mucositis was present around an axial implant in the right lateral incisor area. Curettes were used along the implant surface and amoxicillin was delivered locally to the peri-implant mucosa. The restoration was repositioned, and the patient received a cycle of 500 mg amoxicillin (Zimox, Pfizer Italia) twice daily for 5 days.

The 3-year overall implant survival rates were 100% for axially positioned implants and 96.59% for tilted implants. The implant survival rates were 98.96% in the maxilla and 97.5% in the mandible.

Table 3 Failure Analyses for Axial and Tilted Implants

| Location/type | Placed | Failed | Survival rate (%) |
|--------------------------|--------|--------|-------------------|
| Maxilla (n = 96) | | | |
| Axial | 48 | 0 | 100 |
| Tilted | 48 | 1 | 97.97 |
| Mandible (n = 80) | | | |
| Axial | 40 | 0 | 100 |
| Tilted | 40 | 2 | 95.00 |

Table 4 Crestal Bone Loss Values (Mean ± SD) for Maxillary and Mandibular Tilted and Axial Implants

| | Time | | |
|-------------------|-------------|-------------|-------------|
| | 12 mo | 24 mo | 36 mo |
| Axial | | | |
| Maxilla (n = 48) | 1.02 ± 0.35 | 1.08 ± 0.41 | 1.10 ± 0.45 |
| Mandible (n = 40) | 1.04 ± 0.30 | 1.04 ± 0.35 | 1.06 ± 0.41 |
| Tilted | | | |
| Maxilla (n = 48) | 1.05 ± 0.29 | 1.07 ± 0.46 | 1.11 ± 0.32 |
| Mandible (n = 40) | 1.05 ± 0.32 | 1.09 ± 0.29 | 1.12 ± 0.35 |

None of the 44 fixed prostheses were lost during the observation period, representing a prosthetic survival rate of 100%. Only two all-acrylic resin prosthetic reconstructions displayed fractures of the acrylic resin material. Occlusal screw loosening was observed in only 3% of sites within 6 months of follow-up.

At the 36-month evaluation, peri-implant crestal bone loss averaged 1.10 ± 0.45 mm for axial maxillary implants (n = 48 implants) and 1.11 ± 0.32 mm for tilted maxillary implants (n = 48 implants) (Table 4). In the mandible, mean peri-implant crestal bone loss of 1.06 ± 0.41 mm for axial implants (n = 40) and 1.12 ± 0.35 mm for tilted implants (n = 40) was found (Table 4). No statistically significant differences ($P > .05$) in crestal bone loss were found in either arch between tilted and axial implants at 12, 24, and 36 months.

DISCUSSION

The data from the present prospective study have shown encouraging clinical results with this method of restoring edentulous arches with immediately loaded full-arch fixed prostheses supported by two anterior axial implants and two distal tilted implants. For this technique, survival rates between 96.7%⁸ and 97.6%⁹ have been reported.

Three patients each lost one implant, and all prostheses survived on the remaining three implants until the replacement implants were loaded. The use of three

loaded implants allows for the failure of one implant without failure of the prosthesis. All of the failed implants had been inserted with a torque of at least 40 Ncm.

In the current study, radiographs demonstrated that the bone resorption patterns for posterior angulated implants were similar on the mesial and distal surfaces and were in agreement with the findings of others.^{11,12,14,17,18} No statistically significant differences ($P > .05$) in crestal bone loss were detected between tilted and upright implants at the 12-, 24-, and 36-month follow-up evaluations in either arch. This finding is also consistent with the literature,^{9,17} confirming that tilted implants may achieve the same outcome as implants placed in an upright position. This positive result is associated with biomechanical advantages, since in this protocol implants are placed in strategic positions from a load-sharing point of view. Placement of the two well-anchored posterior tilted implants together with the anterior axially oriented implants can provide a predictable foundation for an implant-supported prosthesis. This surgical-prosthetic procedure also seems to validate the reduced length of the cantilevered segments of the prostheses. Implant placement and orientation provided effective cross-arch stabilization without the need for bone grafting procedures. The exclusion of maxillary sinus bone grafts resulted in significantly less morbidity and dramatically decreased the financial costs associated with those procedures. This treatment protocol allows the implant rehabilitation process to be simplified and

shortened for both the patient and the clinical team. The postsurgical period is more comfortable for patients, since they begin utilizing their fixed prosthesis right after implant placement.

In this study, only definitive prostheses were made—23 with cast metal frameworks and 21 with all-acrylic resin frameworks—but none of them failed. No fractures of prosthesis frameworks were reported, although two all-acrylic resin prosthetic reconstructions displayed fracture of the acrylic resin material. The immediate creation of the definitive restoration, which features a simple and repeatable prosthetic protocol, represents a major advantage for patients, providing less expensive and less time consuming treatment.

Some authors^{19,20} have stated that metal frameworks are significantly stronger than all-acrylic resin frameworks, since they may provide increased rigidity to the immediate prostheses as compared to all-acrylic resin prostheses, improving the survival of the implant-prosthetic rehabilitation. Likewise, Grunder,²¹ in a small pilot study, reported on the treatment of five patients with edentulous maxillae and found that five of seven failed implants occurred in patients with non-metal-reinforced provisional restorations. However, other authors^{9,14} have used all-acrylic resin prostheses without metal frameworks and have also reported high survival rates. Non-metal-reinforced acrylic resin restorations provide better shock-absorbing occlusal surfaces, resulting in reduced stress transmission to the bone-implant interface^{22–24} which decreases the risk of overload. This is particularly important in an immediate loading protocol.

Although the international literature is controversial on this point, the present study reported the same clinical results in patients with or without metal-reinforced acrylic resin restorations. However, more long-term prospective clinical trials are needed to confirm the effectiveness of the surgical-prosthetic protocols used in this study and whether a metal framework is necessary for the “All on Four” immediate prosthetic rehabilitation procedure.

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