Immediately loaded zygomatic implants: a 5-year prospective study

Key words  dental implants, edentulism, prospective study, zygomatic implants

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Introduction

Rehabilitation with dental implants improves the quality of life of edentulous patients. However, adequate bone volumes are necessary for proper implant anchorage. In subjects with insufficient alveolar bone support, the use of bone augmentation procedures, short, tilted and zygomatic implants have been proposed.

Although autogenous bone has long been considered the gold standard for grafting, there is a need of two surgical sites, one to harvest the bone and another to perform the graft. Usually, major bone grafting procedures have to be performed under general anaesthesia requiring in-patient care. Recently, promising results have been reported with the introduction of bone substitutes. However, up to three surgical interventions may be needed before implants can be functionally loaded.

Short implants have been successfully used to restore edentulous atrophic maxillae but long-term outcome data are scarce. The use of tilted implants to support immediately loaded fixed prostheses for the rehabilitation of edentulous maxillae is...
a predictable technique, with an excellent prognosis in the short and medium term\textsuperscript{11}. Satisfactory long-term results have been recently reported\textsuperscript{12}.

Patient acceptance is an important issue in implant dentistry\textsuperscript{1-3}. One of the main factors that may explain lack of patient acceptance of rehabilitative procedures is the length of the treatment\textsuperscript{1,3,13}. In this respect, early/immediate loading protocols for jaws with different degrees of bone resorption have been associated with an increased patient acceptance rate\textsuperscript{1,3,13}.

Zygomatic implants were developed by Professor Brånemark and high long-term success rates have been published using a classic two-stage protocol\textsuperscript{14-17}. However, the effectiveness of zygomatic implants as compared to conventional dental implants in augmented maxillae has not been assessed in randomised clinical trials\textsuperscript{18}. Different clinical studies of immediately loaded zygomatic implants with machined and oxidized surfaces have shown 96 to 100\% short-term survival rates\textsuperscript{19-21}. Long-term results have recently been reported\textsuperscript{22}.

The possibility of anchoring more than one implant to the zygomatic bone has been presented\textsuperscript{13,23,24}. Moreover, modifications to the original protocol allowing an extra-sinus placement of the implants and a new implant design have been published, with 98.5 to 100\% survival rates for immediately loaded zygomatic implants\textsuperscript{25-28}. In addition, the tip of the implant is inserted in a zygomatic area with a wider and thicker trabecular bone, which allows for the attainment of primary stability and the possibility to load the implant immediately\textsuperscript{3,29,30}.

Sinusitis has been described as a complication in various clinical studies. Considering the literature in English, the probability of sinusitis seems to be 5 to 6\% (range 0–26.6\%)\textsuperscript{31}. Most cases of sinusitis have been associated with machined-surface zygomatic implants using a two-stage protocol, and the presence of oroantral fistulas was often associated with this complication\textsuperscript{31}. In most studies, sinusitis was treated with antibiotics and/or meatotomy with no further consequences\textsuperscript{16,17,20,31}. Extra-maxillary placement of the implants has also been proposed as a way to reduce the risk of sinusitis\textsuperscript{20,25-28}. Sinuscopy has shown that zygomatic titanium implants in sinuses were totally or partially covered with a normal-looking respiratory membrane\textsuperscript{31}.

There is little information on the long-term results of immediately loaded zygomatic implants. The present study was therefore conducted to assess the outcome of immediately loaded zygomatic implants 5 years post-loading. The STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines have been followed for presenting this prospective study\textsuperscript{32}. Shorter follow-ups of the same patient material were published previously\textsuperscript{3,20}. A preliminary study performed in the first 18 patients with 36 immediately loaded zygomatic implants and 68 immediately loaded conventional implants provided encouraging results\textsuperscript{3}. This initial clinical series (‘development group’) was completed with data of 24 patients with 45 immediately loaded zygomatic implants and 72 immediately loaded conventional implants (‘routine group’\textsuperscript{20}).

### Materials and methods

#### Patients

This prospective study included 42 consecutive patients (23 women and 19 men) with a mean age of 57.5 years (range 34–79 years) treated between June 2004 and December 2006 at the Department of Maxillofacial Surgery and Implantology of Medimar International Hospital in Alicante, Spain. Patients were followed until December 2011, with a follow-up of 5 years. Data at 5 years for all patients are presented. Approval from the review board of the hospital to use human data was obtained. Written informed consent was obtained from all participants.

Inclusion criteria were total or partial maxillary edentulism, feasibility of placement of conventional implants in the premaxilla, and impossibility to treat the posterior maxilla without grafting procedures or with 5 or 6 mm-long implants, or pterygoid implants\textsuperscript{3}. Tilted posterior implants were used when the implant could emerge at the level of the second premolar\textsuperscript{3}. Patients with enough maxillary bone to be rehabilitated with conventional implants were excluded as were patients with acute sinusitis, bruxism, poorly controlled diabetes, metabolic disorders that may compromise the functionality of the implant and those declaring to smoke more than 10 cigarettes a day\textsuperscript{3}.
Study protocol

Patients included in the study were rehabilitated either by using one or two zygomatic implants together with standard implants (40 patients), or four zygomatic implants (2 patients). Complete arch rehabilitation was accomplished in 37 patients, 22 of which were totally edentulous, and partial arch rehabilitation in 5 (1 zygomatic implant in combination with 2 conventional implants). In 33 patients, 2 zygomatic implants in combination with conventional implants were used as follows: 6 implants in 2 patients, 5 implants in 3 patients, 4 implants in 16 patients, 3 implants in 5 patients and 2 implants in 7 patients. In 2 patients, 1 zygomatic and 5 conventional implants were inserted. In 2 patients, 4 zygomatic implants (2 in each side) were inserted.

Preoperative assessment included panoramic radiographs and a computed tomography (CT) scan up to the zygoma to obtain information on the osteomeatal complex, characteristics of the Schneiderian mucosa and the antrum. All patients were free of sinus symptoms and none of them had been diagnosed with chronic sinusitis.

Surgical and prosthetic procedure

A total of 81 zygomatic implants were placed (Brånemark System, Nobel Biocare, Gothenburg, Sweden). The distribution of the lengths of the implants is shown in Table 1. The implants had an apical diameter of 4 mm and a neck diameter of 4.5 mm, as well as a 45-degree pre-tilted head that emerges at the occlusal level. The implant surfaces were either commercially pure titanium (machined) (44 implants) or porous titanium oxide (37 implants).

The conventional implants used were Brånemark or Replace (Nobel Biocare). A total of 140 conventional implants were placed (108 Brånemark and 32 Replace). The length of the implants was between 10 and 15 mm, with a porous titanium oxide surface (Table 2).

Surgery was performed under general anaesthesia. To decrease bleeding and the amount of analgesics needed intra-operatively, local anaesthesia in the maxillary vestibulum, in the area of the zygomatic bone and 1 cm palatal to the bone crest was used. The zygomatic area was exposed via an incision in the posterior maxilla followed by vertical releasing incisions along the posterior part of the infra-zygomatic crest and anterior to the surgical site. In order to improve the visibility of the drilling direction and the starting point at the crest, a small lateral bone window was made with spherical burs, which also allowed the careful dissection of the sinus membrane. Zygomatic implants were directed towards the zygomatic bone, anchoring them at the level of the maxillary alveolar process and in the zygomatic bone itself, following the standard protocol.

Different approaches were used in the present study, including the ‘classic approach’, a modification of ‘sinus-slot technique’ with extra-sinus placement of the zygomatic implant and a third procedure.

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<th>Length (mm)</th>
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<td>40</td>
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<td>42.5</td>
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<td>45</td>
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<td>47.5</td>
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<td>52.5</td>
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<td><strong>Total</strong></td>
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<td>4.3 × 16</td>
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<td><strong>Total</strong></td>
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<td><strong>Total</strong></td>
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that can be called a ‘minimally invasive approach’\textsuperscript{20}. The modification of sinus-slot was accomplished when crestal emergence of the implant was a priority, particularly in patients with a well-preserved alveolar process and a very concave lateral wall of the maxilla. In this way, part of the implant runs out of the maxillary sinus (extra-sinus approach) before entering the zygomatic bone (Fig 1).

If patients were edentulous for a long period (10 of the 22 edentulous patients), a long crestal-palatal incision was avoided to keep the integrity of the palatal mucosa in order to facilitate the establishment of a soft tissue barrier at this level. In these patients, a soft tissue punch was used at the level of the palatal mucosa and a small incision was made at the sulcus, at the level of the zygomatic buttress, which was large enough to ensure a good visualisation of the entire lateral wall of the maxilla and the zygomatic area after degloving in order to allow the design of the lateral window. The position of the implants inside or outside the sinus was dictated by the anatomic characteristics of the individual patients, especially on the curvature of the lateral wall of the maxilla.

The drilling and placement of the implants were performed following the standard protocol\textsuperscript{15}. Ideally, each implant should be supported by surrounding bone, seeking an anchorage in the body of the zygomatic bone and in the ridge at the rim of the maxilla. Care was taken to test the anchorage of the tip of the implant in the most superior cortical portion of the zygomatic bone, and to obtain crestal emergence of the zygomatic implant. Abutments were connected during the same implantation procedure using standard or straight/angled multiunit Bränemark definitive abutments (Multi-unit Abutment System, Nobel Biocare).

Immediately after wound closure by suturing, an impression was made using stock trays (Megatray, Megadenta Dentalprodukte, Radeberg, Germany), standard impression copings (Nobel Biocare) screwed on the abutments and silicone impression material (Aquasil Monophase Ultra, Dentply DeTrey, Konstanz, Germany). Complete arch
(37 patients) or partial arch acrylic resin (5 patients) fixed prostheses (Lucitone, Dentsply, Addlestone, United Kingdom) reinforced with metal wire (Remanium, Dentaurum, Ispringen, Germany) were delivered within 24 hours. Postoperatively, all patients were treated with amoxicillin/clavulanate (2 g daily) and dipyrone (575 mg every 8 hours for 7 days) for pain relief. Chlorhexidine gluconate mouthwash 0.2% (1 min b.i.d. for 2 weeks) was recommended. Mutually protected occlusion (MPO) with canine guidance was used in 40 patients. In 7 patients with only 2 anterior implants placed, MPO with a group function occlusal scheme was used. Patients were instructed to be on a soft diet for 1 month.

Assessments

Once the provisional prostheses were loaded, patients were scheduled for control visits after 1 week and 1, 3 and 6 months. Hygiene instructions, plaque control and small occlusal adjustments were made at each visit. Six months after loading, the provisional restorations were removed, and individual implants were tested for stability, pain and infection. Impressions were taken for manufacturing the definitive prostheses (Fig 2). After delivery of definitive prostheses, patients were controlled every 6 months during the first year and annually thereafter. Prostheses were removed and cleaned at each visit and oral hygiene was reinforced if needed. Panoramic radiographs were obtained for all patients after surgery, at the 6- and 12-month follow-ups, and once a year thereafter. Anteroposterior (A-P) cranial radiographs were obtained after surgery to better visualise the zygomatic implants. All patients were followed up for at least 5 years.

Outcome measures

Outcome measures were:

- Prosthesis failures: a successful prosthesis was a prosthetic restoration that functioned as intended and was clinically stable and had not been removed for a substantial period of time (2 weeks or more) during the investigation.
- Implant failures: a successful implant (either zygomatic or conventional) was a stable implant as confirmed by a stability test. A slight

Fig 2 Patient with atrophic maxillary bone rehabilitated with zygomatic implants. a) CT scan showing resorption of maxillary bone. b) Axial CT view showing narrow crestal bone. c) Postoperative panoramic radiograph showing 2 zygomatic implants and 4 conventional implants in place. d) Intraoral view of the patient showing the anteroposterior distribution of implants. e) Frontal view of the definitive prosthesis.
lateral mobility was accepted only for zygomatic implants while rotating implants were considered as failed and removed. Implant stability was examined by tightening the abutment screws at 15 Ncm torque. A failed implant was a mobile implant, or one that had to be removed for infection or other reasons or was fractured.

- Any complications.

Descriptive statistics were used in the analysis.

## Results

At the end of the study in December 2011, 36 of the 42 patients had been followed up for 5 years. Twelve zygomatic and 22 conventional implants in 6 patients were not reviewed as patients were lost to follow-up. Three of the patients moved to another country, 1 of them died and the remaining 2 patients could not be contacted. Therefore, the outcomes of 68 zygomatic implants and 112 conventional implants were evaluated.

Continuous stability of the definitive prosthesis was achieved in all patients except 1 throughout the study. One patient having a fixed dental prosthesis on 2 zygomatic and 4 conventional implants had the prosthesis changed after the failure of 1 zygomatic and 1 conventional implant.

One zygomatic implant was lost. The success rate of zygomatic implants was 98.5% (68/69). The failed implant had a machined surface, and was found to be mobile after prosthesis removal at the 3-year follow-up, and was accompanied by disturbances in the zygomatic region. This case was diagnosed as implant failure; the implant was removed and not replaced.

A slight bending movement was observed at 5 zygomatic implants: 3 implants out of 4 in 1 patient, and 2 implants in 1 patient having 2 zygomatic implants combined with 2 conventional implants.

Six conventional implants were lost in 4 patients, with a success rate of 94.9% (112/118). One anterior implant in 2 patients and 2 implants in another patient were removed due to mobility at the 3-month control visit. They were not replaced. Another anterior implant failed 4 years after placement in the same patient who lost the zygomatic implant. In this case, the conventional implant was replaced and immediately loaded and the definitive prosthesis changed to an overdenture. Another anterior implant failed at the 4-year follow-up in a patient with only 2 conventional implants, and was replaced and immediately loaded by adapting the definitive prosthesis.

A macroscopic oroantral communication was found in a patient (a smoker) just after placement of an oxidized zygomatic implant. It was followed by an episode of sinusitis 4 months later. Sinusitis was successfully treated with amoxicillin/clavulanate (1 g every 8 hours for 10 days) and meatotomy. The oroantral communication closed spontaneously 1 month later.

Another patient complained of swelling and pain at the zygomatic level in the early postoperative period and was successfully treated with antibiotics (amoxicillin/clavulanate 875 mg, t.i.d. for 10 days) without further complications.

Resin teeth were replaced by 4 definitive acrylic fixed dental prostheses after 4 years of function due to extreme tooth wear.

## Discussion

Zygomatic implants allow for immediate occlusal loading as well as an early improvement in quality of life. Also, treatment time and morbidity can be substantially reduced, which in turn increases patient acceptance. The main finding of the study is that only 1 immediately loaded zygomatic implant out of 69 placed failed up to 5 years after loading, which corresponds to a success rate of 98.5%. This finding is clinically relevant as it demonstrates the good 5-year outcome of this type of implant in the rehabilitation of patients with severely atrophic maxillae. To our knowledge, only one previous study provided data on the long-term results of immediately loaded zygomatic implants.

The present success rate of 98.5% is consistent with 96 to 100% short-term survival rates of immediately loaded zygomatic implants reported in different studies. The possibility of a tetracortical anchorage of the zygomatic implant as well as the insertion of its apex in a zygomatic area with a wider and thicker trabecular bone, as has been validated.
by several anatomical studies, could be the reason for the high success rate\textsuperscript{3,29,30}. Furthermore, due to the density of the zygomatic bone, it was possible to achieve primary implant stability and implants could be loaded immediately\textsuperscript{3,29}. It should be noted that the single case of zygomatic implant failure and the 6 failures of conventional implants occurred in patients of the ‘development group’.

There are a few studies about placement of more than 1 implant in the same zygomatic bone\textsuperscript{13,23,24}. The results obtained seem to be promising, even with immediate function protocols\textsuperscript{13,23,24}. Two patients in the present study were successfully treated using 4 immediately loaded zygomatic implants, 2 at each side (Fig 3). In these aforementioned clinical studies, 98 to 100\% survival rates were reported for this implant combination using an immediate function protocol\textsuperscript{13,23,24}.

There are currently no clinical studies reporting on the use of unilateral zygomatic implants to achieve partial arch rehabilitation. Five patients in the present study were partially rehabilitated by means of 2 conventional implants and 1 zygomatic implant. Further investigations are needed to evaluate this treatment procedure.

Slight mobility of the coronal part of the implant with no further consequences was observed in 5 implants of 2 patients when the anchorage at the level of the maxillary bone was probably not optimal.

The present study showed a very low rate of complications. There was only 1 case of sinusitis. In this case, just after implant placement and with a conventional flap approach, macroscopic oroantral communication was found and sinusitis developed 4 months later. Sinusitis was successfully treated with antibiotics and meatotomy, and the oroantral communication spontaneously closed 1 month later. Furthermore, the infection of the antrum did not cause the failure of the implant. After 3 years of follow-up, the patient had not experienced any further complications.

In all patients, a one-stage procedure was accomplished with connection of the definitive abutments immediately after the surgery, avoiding multiple connections/disconnections of the transmucosal component. It has been hypothesised that it could lead to a better establishment of the soft tissue barrier and a decreased risk of a communication between the oral and sinus cavities\textsuperscript{13,20,31}. For this reason, although it has not been proven, immediate
function protocols and extramaxillary placement of the implants have been suggested to decrease the risk of oroantral communication and sinusitis. A classic intra-sinus approach for placement of zygomatic implants has been associated with an emergence more palatal than natural dentition. Although the majority of the zygomatic implant heads were emerging slightly palatal, no problems for the prosthesis construction or from a soft tissue health point of view, including discomfort for the patient or difficult oral hygiene, were found in the present study.

The present findings should be interpreted taking into account the limitations of the study, including the small number of patients, the different types of implants used and the lack of a peri-implant marginal bone level evaluation. A randomised controlled trial of patients with atrophic maxillae treated with immediately loaded zygomatic implants as compared with grafting procedures could provide useful information about the effectiveness of these therapies, helping patients and clinicians to choose the best option.

Conclusions
The rehabilitation of severely atrophic maxillae by means of immediately loaded fixed implant-supported prostheses supported also by zygomatic implants provided excellent medium-term results.

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References


