Immediate function of four zygomatic implants: a one-year report of a prospective study

Key words    atrophic maxilla, immediate loading, zygomatic implants

Purpose: To evaluate the clinical outcome of maxillary prostheses supported by four immediately loaded zygomatic implants after one year of function.

Materials and methods: Seventeen patients were consecutively included and followed up to one year after prosthetic loading. Patients had severely atrophic maxillae (Cawood and Howell classification C-VI and D-V or D-VI) and were rehabilitated using four zygomatic immediately loaded implants, two in each zygoma bone. Outcome measures were success rates of the prostheses, of the zygomatic implants, complications and oral health-related quality of life (OHRQoL).

Results: No patients dropped out. No zygomatic implants were lost, although one implant could not be used because it was placed in an unfavourable position. The orbital cavity was penetrated during the drilling procedure in one patient with no relevant clinical consequences. One patient experienced an infection followed by a fistula in one zygomatic implant, which was successfully treated. The average score from the OHIP-14 questionnaire was 3.4, which is similar to that of the general population.

Conclusions: The present study suggests that four immediately loaded zygomatic implants can be used to rehabilitate patients with severely atrophied maxillae.

Introduction

Edentulism is an individual concern, a professional responsibility and a prominent public health issue. Although prevalence of edentulism is diminishing in some parts of the world, the longevity of populations worldwide and other factors contribute to sustain the actual number of edentulous patients.

Edentulism affects quality of life (functional, psychological and social aspects), and has been associated with increased risk for systemic chronic disease, alterations in nutritional state, and death. Rehabilitation with dental implants has been demonstrated to be a good tool to improve the quality of life of edentulous patients. Furthermore, early/immediate-function protocols have been documented for mandibles and maxillae with different degrees of resorption, and have been associated with an increase in the acceptance rate by patients.

Rehabilitation of extremely atrophic totally edentulous maxillae by insertion of standard implants is very challenging. Traditionally, they have been treated with dentures, but this approach may not meet the functional, psychological and social needs of the indi-
Many types of bone-augmentation procedures, including sinus lifts, have been proposed to increase the bone volume for implant insertion\textsuperscript{10-17}. These are widespread techniques, but the frequent need to use delayed protocols in which the grafts are placed first, and the risk of potential intraoral and/or extraoral complications could decrease patient acceptance\textsuperscript{1,16,18}. It has been demonstrated that there is a discrepancy between the high success rate of standard implants and their acceptance rate by patients. The length of the treatment process could be one of the main factors\textsuperscript{1,18}.

The use of four zygomatic implants to treat the totally atrophied maxilla has been proposed. This alternative has been described in different clinical studies\textsuperscript{19-22}. A 96\% to 100\% survival rate for zygomatic implants has been reported for this treatment modality\textsuperscript{19-22}.

Zygomatic implants have been mainly used for patients with available bone at the level of the anterior maxilla. The present technique consists of the combination of two zygomatic implants, one in each side, with two to four standard implants at the level of the premaxilla\textsuperscript{23-32}. The use of immediately loaded zygomatic implants has also been documented\textsuperscript{19,21,22,33-36}. Sinusitis has been described as a complication in various clinical studies: considering the English literature, the probability of sinusitis seems to be 5\% to 6\% (range 0\% to 26.6\%)\textsuperscript{23,37}. The majority of sinusitis has been associated with machined-surface zygomatic implants using a two-stage protocol, and the presence of an oroantral fistula has been advocated as the main explanation for this complication\textsuperscript{37}. Immediate function protocols and extra-maxillary placement of the implants have also been proposed as ways to reduce the risk of sinusitis\textsuperscript{19,21,33}.

Several anatomical studies have validated the excellent quality of zygomatic bone and have stressed the importance of the cortical portion of zygomatic bone for anchoring implants\textsuperscript{38,39}. It has also been documented that the area of zygomatic bone used for implant insertion has wider and thicker trabecular bone, and this may explain the good initial primary stability of zygomatic implants, and the suitability for immediate loading\textsuperscript{38,39}.

Clinical trials have shown that four implants can be as effective as six or more for complete rehabilitation of the maxilla according to the two-stage protocol\textsuperscript{40,41}.

No randomised clinical trials have been performed to assess the possible advantages of zygomatic implants over grafting procedures\textsuperscript{42}. Advantages may include improved predictability, lower morbidity, and better treatment acceptance by patients\textsuperscript{43}.

The purpose of the present prospective study was to evaluate the outcome of immediately loaded prostheses supported by four zygomatic implants in severely atrophic maxillae after one year of function.

## Materials and methods

### Study design

The study was designed as a prospective case series. In total, 17 fully edentulous patients were consecutively included (10 females and 7 males), with a mean age of 57.7 years (range 41 to 78 years). Four patients smoked fewer than 10 cigarettes per day. One patient had renal insufficiency and hypothyroidism, one had hypercholesterolemia, and another patient had undergone surgical intervention due to sinusitis 2 years previously; nevertheless, this patient was clinically free of sinus-related symptoms before the surgery. A single experienced operator treated all patients from May 2006 to September 2009 at the Department of Implantology and Maxillofacial Surgery at Medimar International Hospital, Alicante, Spain. The principles outlined in the Declaration of Helsinki on clinical research were adhered to, and approval from the review board of the hospital to use human data for the study was obtained. Signed written informed consent was obtained for each patient.

### Patient population

The criteria for inclusion in the study were:

- Fully edentulous in the maxilla.
- Able to sign an informed consent.
- Posterior maxilla that could not be treated without using grafting procedures including sinus grafting or pterygoid implants (classes D and E according to the Lekholm classification\textsuperscript{44}).
- The anterior maxilla had insufficient width to place implants of at least 3.3 mm diameter and/
or insufficient height to allow the placement of implants shorter than 8.5 mm.

The exclusion criteria for the study were:
- The patient was not able to give his/her informed consent to participate.
- Health conditions that did not permit the surgical procedure (including general anaesthesia).
- Patients with uncontrolled systemic contraindications to surgery.
- Uncontrolled diabetes.
- Patients who were treated with IV bisphosphonates (at any time)
- Alcohol or drug abuse as noted in patient records or in patient history.
- Heavy smokers (> 10 cigarettes/day).
- Reason to believe that the treatment might have a negative effect on the patient's health (psychiatric problems), as noted in patient records or in patient history.
- Any disorders in the planned implant area such as previous tumours, chronic bone disease, or previous irradiation in the head/neck area.
- Severe bruxism or other destructive habits.

### Outcome measures

The success criteria for zygomatic implants were:
- The implant acted as an anchor for the prosthesis.
- No suppuration, pain or ongoing pathologic process at the maxillary sinus and the zygomatic bone.
- Individual implant stability, considering that, when the zygomatic implant is not connected to another implant, a slight bending movement at the coronal aspect of the implant can be expected in some cases. Implant stability was examined (with the prosthesis removed) manually at 6 months of loading, by individual tapping or application of light force to the implant with a dental instrument or tightening of the abutments.

A failed zygomatic implant was an implant that presented increased mobility, had to be removed, was fractured, or failed to meet the aforementioned success criteria.

A successful prosthesis was defined as a prosthesis that was functioning as intended, was clinically stable, and had not been removed for a substantial period of time (2 weeks or more) during the study period. A prosthetic failure was registered as a prosthesis lost due to implant failure or a prosthesis that could not be placed due to implant failure(s).

Oral health-related quality of life (OHRQoL) was measured by means of the self-filled questionnaire OHIP-14 (oral health impact profile), at least 6 months after loading of the definitive prosthesis. This was done by an independent assessor (EC). The OHIP measures people's perceptions of the social impact of oral disorders on their well-being. By means of 14 questions, it explores seven different dimensions including functional, psychological and social aspects. Each particular item can be scored between 0 and 4 by the patient, considering that 0 corresponds to no impairment and 4 to the highest degree of impairment. The final score (0–56) for each patient results from the sum of all the particular items (Table 1).

Any possible adverse event or complication was also recorded.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Distribution of OHIP items, ranking from 0 (never), 1 (hardly ever), 2 (occasionally), 3 (very often) to 4 (fairly often)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OH1</td>
<td>Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH2</td>
<td>Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH3</td>
<td>Have you had painful aching in your mouth?</td>
</tr>
<tr>
<td>OH4</td>
<td>Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH5</td>
<td>Have you felt self conscious because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH6</td>
<td>Have you felt tense because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH7</td>
<td>Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH8</td>
<td>Have you had to interrupt meals because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH9</td>
<td>Have you found it difficult to relax at meals because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH10</td>
<td>Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH11</td>
<td>Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH12</td>
<td>Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH13</td>
<td>Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>OH14</td>
<td>Have you been totally unable to function because of problems with your teeth, mouth or dentures?</td>
</tr>
</tbody>
</table>
General anaesthesia. The maxillary sinus wall was exposed from the nasal aperture to the orbital rim and posteriorly onto the zygomatic arch via a mid-crestal incision and vertical releasing incisions along the posterior part of the infrazygomatic crest and anterior to the surgical site. The vertical ridge/anterior rim of the zygomatic arch was identified. The infraorbital nerve was carefully identified and special care was taken to avoid the orbital rim and orbital floor. Mucoperiosteal flap elevation and exposure of the central/posterior part of the zygomatic complex, avoiding interference with the orbit, the lateral wall of the maxillary sinus, and the alveolar crest, were carried out using the lower border as an anatomic guideline. To obtain visual control of the drills, a small lateral window was made in the bone. Sinus mucosa was laterally displaced from the area where the implants would pass. A series of drills was used to penetrate the alveolar process and a depth indicator was used to assess the correct length of the implant. The drilling sequence included only three burs: a 2.9-mm spherical bur and cylindrical burs of 2.9 mm and 3.5 mm diameter. The drilling was performed under constant water irrigation to prevent overheating. Zygomatic implant positions were determined during surgery according to the anatomy of the zygoma and surrounding structures (Fig 1).

All implants were engaged bicortically at the level of the zygomatic bone, with a preset torque of at least 35 Ncm. The most anterior implant was placed first: the maxillary entrance was made in the canine/lateral incisor region. The second implant was placed at the level of the second premolar/first molar running along the infra-zygomatic crest. The position of the implants was inside or outside the sinus, depending on the anatomic circumstances of the patient, especially the curvature of the lateral wall of the maxilla19,21,33 (Fig 2).

Care was taken to place the tip of the implant in the most superior cortical portion of the zygomatic bone, and to obtain crestal emergence of the zygomatic implant. Ideally, each implant should be supported by surrounding bone, at both the neck and the apex.

<table>
<thead>
<tr>
<th>Length of zygomatic implant (mm)</th>
<th>Number of implants placed</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>35</td>
<td>3</td>
</tr>
<tr>
<td>40</td>
<td>13</td>
</tr>
<tr>
<td>42.5</td>
<td>11</td>
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<tr>
<td>45</td>
<td>12</td>
</tr>
<tr>
<td>47.5</td>
<td>8</td>
</tr>
<tr>
<td>50</td>
<td>12</td>
</tr>
<tr>
<td>52.5</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>68</td>
</tr>
</tbody>
</table>

**Table 2** Lengths of the zygomatic implants placed in 17 patients
The abutment connection was made just after implant placement, using standard or straight/angled multiunit Brånemark definitive abutments (MultiUnit Abutments; 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; Dentsply DeTrey, Konstanz, Germany). The provisional prostheses were fabricated using acrylic resin (Lucitone; Dentsply DeTrey) and reinforced with metal wire (Remanium; Dentaurum, Ispringen, Germany), and were placed between 24 and 48 hours after surgery (Fig 3).
All patients received antibiotic treatment (2 g of amoxicillin with clavulanic acid per day) from 1 day before surgery until 7 days after, and analgesics (magnesic metamizol) to minimise post-operative pain. Chlorhexidine gluconate mouthwash 0.2% was prescribed for 1 minute twice a day for 2 weeks and a soft diet was recommended for 1 month.

Fourth visit: delivery of the full-acrylic provisional prostheses and occlusal adjustments (Fig 4).

Once the provisional prostheses were loaded, patients received oral hygiene instructions 1 week post-operatively and were recalled at 1 week, 1 month, 3 months and 6 months. Six months after loading, provisional restorations were removed, and individual implants were checked for stability, pain and infection. Impressions were taken for manufacturing the definitive prostheses. Fifteen patients received a fixed, screw-retained prosthesis whereas two patients received an overdenture retained by a bar splinting all the zygomatic implants. One overdenture was designed on just three zygomatic implants. Mutually protected occlusion with canine guidance was used in all patients.

After definitive prostheses were placed, patients were recalled every 6 months for maintenance, up to the first year after implant placement. Prostheses were removed and cleaned at each visit (Fig 5).
Fig 4 Patient with extremely narrow remnant of maxillary bone rehabilitated with the four zygomatic implant technique. (a) CT scan showing severe resorption of the maxillary bone. (b) Clinical photo showing two zygomatic implants on each zygomatic bone after its installation. (c) Occlusal view of definitive prosthesis in place. Note the emergence of the zygomatic implants that are close to the crest. (d) Anterior view of definitive prosthesis.
Fig 5  Patient with full atrophy of the maxillary bone after failure of a previous implantological rehabilitation. (a) Preoperative CT scan with failed conventional implants. (b) Intraoral view of the surgery: two zygomatic implants placed at the same zygomatic bone. (c) Post-operative cranial radiograph showing four zygomatic implants. (d) Definitive prosthesis (anterior view).
Results

No patients dropped out from the study, and all were followed up to 1 year. Individual implant stability was confirmed, although six implants were characterised by a slight bending movement at the maxillary level.

One implant could not be used to hold the prosthesis because it was placed in an unfavourable position. In this implant, the minimal implant stability (>30 Ncm) was not obtained at placement, and it was unstable. It was left unloaded and was not used for supporting the prosthesis.

All prostheses functioned as intended, were clinically stable, and had not been removed for a substantial period of time (2 weeks or more) during the study period.

During the surgical procedure, one orbital cavity in one patient was penetrated by the 2.9-mm drill. This was due to the exceptionally complicated anatomy of the patient, who had a very narrow zygomatic bone. The surgeon immediately stopped the drilling procedure to look for another drilling direction. The penetration was followed by a conjunctival haematoma, which spontaneously resorbed in 1 week with no further consequences. One patient experienced an infection followed by a fistula at one zygomatic implant. The problem was solved with systemic antibiotics and minor surgery to drain and clean the affected area. No patient suffered from sinus-related complications or sinusitis during the follow-up period.

The average score from the OHIP-14 questionnaire was 3.4 (Table 3), which is similar to scores of the general population (scores of between 4 and 5)\textsuperscript{46}.

Discussion

The preliminary results suggest that zygomatic implants could be a predictable method for the treatment of very atrophic maxillae, confirming previous findings\textsuperscript{20,22}. With immediate occlusal loading, an immediate improvement in quality of life could be expected\textsuperscript{1,2,5}. Furthermore, treatment time and patient discomfort could be substantially reduced and patient acceptance increased\textsuperscript{19,36}.

Traditionally, extremely and totally atrophied maxillae, when standard implants cannot be inserted because of severe bone resorption, have been treated with dentures or fixed prostheses supported by implants placed in augmented bone\textsuperscript{1,10-17}. Dentures, especially in atrophic jaws, are associated with different kinds of morbidity (stomatitis, traumatic ulcers, and irritation-induced hyperplasia), psychological alterations (depression), and social problems (reduced social interactions, educational opportunities and job opportunities)\textsuperscript{1,47}. Grafting procedures, including sinus lift, onlay graft, and apposition graft with or without Le Fort I osteotomy, are commonly used, showing success rates between 60% and 90%\textsuperscript{10-16}. Nevertheless, the need for a staged approach, the increased risks of potential intraoral and/or extraoral complications, and increased costs could reduce patient acceptance\textsuperscript{1,36}. Furthermore, in a recent study, a grafting procedure or four zygomatic implants was offered to patients with a totally atrophied maxilla and all the patients chose zygomatic implants\textsuperscript{22}. For these reasons, the development of treatment alternatives would be well received by these patients especially if immediate function is possible\textsuperscript{20,22}.

The present results are comparable to results of other similar trials\textsuperscript{20,22}.

The relationship between zygomatic implants and the maxillary sinus remains controversial; some

<table>
<thead>
<tr>
<th>Patient</th>
<th>Mean post-operative OHIP-14 result</th>
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<tbody>
<tr>
<td>1</td>
<td>1</td>
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<tr>
<td>2</td>
<td>0</td>
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<tr>
<td>3</td>
<td>0</td>
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<tr>
<td>4</td>
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<td>6</td>
<td>2</td>
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<td>7</td>
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<td>8</td>
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<td>16</td>
<td>3</td>
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<tr>
<td>17</td>
<td>4</td>
</tr>
<tr>
<td>Total (mean)</td>
<td>3.4</td>
</tr>
</tbody>
</table>

Table 3  Values of the OHIP-14 questionnaire for the 17 patients
authors have reported a low rate of sinusitis as a complication related to machined-surface zygomatic implants placed with a two-stage protocol. No sinusitis or sinus problems were registered in the follow-up period in the present series of patients. In all of these consecutive patients, a one-stage procedure was accomplished, with connection of the definitive abutments on the day of the surgery. By doing so, multiple connection/disconnection of transepithelial components associated with two-stage procedures has been avoided. It has been hypothesised that this could lead to a better establishment of the soft tissue barrier and a decreased risk of oroantral communication.

The surgical procedure demands good anatomical knowledge of the area involved, because the amount of bone available at the level of the zygomatic bone is limited. In a cadaver study, van Steenberghe et al. determined that the average width of the zygomatic bone is 20.5 mm. For this reason, penetration of the orbital cavity is a potential risk that must be controlled. This complication has been described in one clinical study, and also occurred in one of the patients in the present series. No relevant clinical consequences were found, since the surgeon rapidly stopped the drilling procedure and looked for another drilling direction.

All implants but one were stable, and had high primary stability at the time of placement. This was made possible by drilling to a diameter of only 3.5 mm diameter. Nevertheless, one implant was not stable at placement, and was not immediately loaded. The patient was immediately rehabilitated with an overdenture, splinting the remaining three implants. After 6 months, the provisional overdenture was changed to the definitive prosthesis using just three implants, because there was poor emergence of the implant, which had experienced some rotational movement leading to an unfavourable location of the implant head. Nevertheless, this zygomatic implant was osseointegrated.

In all patients, zygomatic implants were anchored both to the maxillary bone and to the zygomatic bone (classic approach) (Fig 1). However, when crestal emergence of the implant is a priority, especially in patients with a well-preserved alveolar process, and a very concave lateral wall of the maxilla, modification of the ‘sinus-slot’ is possible. In this way, part of the implant runs out of the maxillary sinus before entering the zygomatic bone, and promising results have been reported. A slight bending movement of the coronal part of the implant, with no further consequences, was observed in six implants. According to the authors’ experience, this slight mobility of the isolated zygomatic implant seems to be reduced by cross-arch stabilisation, and tends to decrease over time. It is necessary to develop tools to measure these movements and to establish acceptable limits.

All patients in the present study presented an atrophied maxilla: some had less than 4 mm of bone as a result of the resorption process of the maxillary bone (Fig 3). Other patients had a narrow crest, where an implant could not be inserted (Fig 4), and others had experienced failure of a previous implant rehabilitation with/without graft (Fig 5). In the latter group of patients, the alternative of four zygomatic implants seems to be of particular value, since the patients felt they had no options.

OHRQoL was evaluated by means of OHIP-14, 6 months after loading of the definitive prosthesis. The mean value of OHIP was 3.4, meaning that the actual oral health related quality of life level was satisfactory, and comparable with the normal population.

The limitations of the present study include the small sample size and the short follow-up. Further prospective studies and randomised controlled clinical trials are required to further evaluate four immediately loaded zygomatic implants.

Conclusions

The present study showed that four immediately loaded zygomatic implants can be used for the successful rehabilitation of patients with atrophic maxillae.

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References


