Insertion of Zygomatic Implants with a Technical Modification of the Extrasinus Protocol: A Retrospective Case Series

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Purpose: The aim of this retrospective clinical case series report was to evaluate the outcomes of patients who underwent zygomatic implant surgery with a recent technical modification of the extrasinus surgical protocol. Materials and Methods: The implant system presented in this study had a novel designed unthreaded body with a 12.5-mm sharp threaded apical end for obtaining maximum retention to the zygomatic bone. A total of 92 patients with severely atrophic maxillae were included in this study. All the patients were treated with a modification of the extrasinus protocol for insertion of 261 zygomatic implants. The mean follow-up of the patients was 34.5 ± 17.1 (SD) months (range: 6 to 72 months). The implant survival rate was the primary outcome. The intraoperative and postoperative complications were evaluated as additional criteria for success. Results: The cumulative implant survival rate was 97.99%. Definitive or provisional prostheses were delivered on the same day of surgery, which resulted in an improvement in the quality of life of the patients. Five implants failed in four patients. No sinusitis or mucositis was seen in any of the patients. Eleven postoperative complications occurred in seven patients. Conclusion: The novel zygomatic surgery protocol introduced in this study can be an effective alternative to augmentation procedures and conventional implants, especially in cases of extremely atrophic posterior maxillae. Int J Oral Maxillofac Implants 2020;35:974–981. doi: 10.11607/jomi.8328

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Oral rehabilitation of patients with edentulous and severely resorbed posterior maxillae represents a special challenging condition for maxillofacial surgeons. The posterior maxillary ridge undergoes a rapid and progressive atrophy following tooth loss, and quantity of bone decreases dramatically. In addition to poor bone volume, this region usually presents poor bone quality, excessive occlusal forces, and hyperpneumatization of the sinus, which consequently may increase the risk of implant failures.1 As a solution for this compromised situation, many treatment modalities have been proposed in the literature, such as sinus elevation operation, onlay bone augmentation, angled implants, short implants, or zygomatic implants.2–5 Zygomatic implants were introduced by Brånemark in the 1990s6 as a major breakthrough in the rehabilitation of the atrophic posterior maxilla for eliminating or minimizing the need for bone grafting6,7 and for obtaining a steady anchorage in the zygomatic bone in cases when rehabilitation by conventional oral implants is unfeasible.8,9 Even in complicated cases, such as large maxillary defects due to oncologic resections, trauma, and congenital diseases, the complete rehabilitation of the total maxilla can be possible with the insertion of zygomatic implants.1,10

Since their first introduction, the main indication for zygomatic implants is the rehabilitation of a severe edentulous atrophic maxilla after tumor resection or trauma. However, indications for zygomatic implants also include failure of previous bone grafts and/or implants and failure of sinus augmentation. Contraindications for the use of zygomatic implants include acute infection in the maxillary sinus and uncontrolled systemic diseases. Special attention should always be paid to eliminate any existing acute infection of the maxillary sinus before placement of the zygomatic implants in order to prevent possible future complications.11–14

Zygomatic implants were proposed as a valid alternative to bone augmentation procedures considering the reduced cost and time.6,13–16 Zygomatic implants...
can provide the surgeon the possibility of obtaining a firm anchorage to the zygomatic bone,13–16 and the overall operating and office time decreases, with lower costs and high success rates.5,8,9,12,16–18

The additional anchorage on the zygomatic bone plays an important role in the high percentage of successful results for this procedure, and the quality of life of patients dramatically increases.15–19 Insertion of a zygomatic implant is a major surgical procedure, which should be performed by a properly trained surgeon. The main disadvantages of zygomatic implants include the risk of soft tissue complications around the abutments, sinusitis, and the risk of damage to surrounding complex anatomical structures.19,20 In recent publications on zygomatic implants, the importance of reducing the therapeutic time is frequently emphasized by comparing zygomatic implants and conventional methods, with the conclusion of an advantage for zygomatic implants.21 Overall, the unsatisfactory results of any therapy, in fact, do not just depend on inadequate surgical skills but on the excessive and incorrect demands that might have been placed on the technique itself as incorrect indications.

The surgical technique reported in the present study is a modification of the extrasinus protocol, which utilizes implants of a specific design with an unthreaded long body and a 12.5-mm apical thread (Fig 1). A bypass of the maxillary sinus prevents any possible additional postoperative complications caused by damage to the sinus membrane. The prosthetic platform being shifted more buccally allows for a more appropriate position of the emergence close to the alveolar crest, a less bulky restoration, and a better design for the prosthesis.22 The aim of this retrospective study was to evaluate the clinical outcome of zygomatic implants inserted in severely resorbed maxillae using a recent technical modification of the extrasinus protocol.

MATERIALS AND METHODS

The study was designed as a retrospective clinical case series with 92 patients, who were referred to the Department of Dentistry and Maxillofacial Surgery at the University of Milano (section of Galeazzi Hospital, Italy). All the patients signed an informed consent form, and the study protocol was in compliance with the principles of the Declaration of Helsinki on medical protocol. Institutional review board approval was obtained for retrospective studies on implants, with protocol number 2552377-L2058 (“Riabilitazione implantare del paziente parzialmente o totalmente edentulo: Valutazione delle tecniche e dei materiali per migliorare la predicibilita’ e il mantenimento”—“Implant rehabilitation of the partially or totally edentulous patient: Evaluation of techniques and materials to improve predictability and maintenance”).

All the patients presented in this study were treated with a modification of the extrasinus protocol with a specially designed zygomatic implant (Noris Medical). Seventy-nine of the patients received immediate loading of the prosthesis, while 13 of the prosthetic rehabilitations were functionalized in a delayed approach. The decision for immediate loading was not based on a scientific indication but was given upon the request of each patient, mostly due to economic reasons, independent of the primary stability of the zygomatic implant, which was present in all the cases.

The inclusion criterion was total edentulism in severely atrophic maxillae Class IV-V Cawood and Howell.23 The exclusion criteria were: major systemic health conditions (Patients ASA-3 and 4 according to the American Society of Anesthesiologists), active infection in the oral and maxillofacial region, radiotherapy or chemotherapy in the 12 months prior to surgery, and inability or unwillingness to follow the instructions for the follow-up. The population of the patients presented some systemic conditions, which can be listed as follows: two depression, one Sjogren syndrome, one pulmonary embolism, one osteoporosis, two arthrosis, one heavy smoker, two hypothyroid, two hypertension, and four patients with ectodermal dysplasia. All these conditions were under control, so they were not accepted as major obstacles to performing surgical operations. There were two bruxist patients, and one of them lost an implant due to this condition.

The patients were radiologically evaluated with preoperative panoramic radiographs and CBCT scans for the form and dimensions of the maxillary and zygomatic bone and for any infections or pathologies in the maxillary sinus. A blood test, electrocardiography, and chest radiography for all the patients were obtained in order to evaluate general health status. A week before surgery, a professional session of oral hygiene was provided to each patient with oral rinses (chlorhexidine di-gluconate 0.2% mouthwash, which was started 3 days prior to the surgery). The patients were prescribed with preoperative and postoperative antibiotics: augmentin

Fig 1 Conical bur with nonworking tip.
were convergent and did not interfere between them. The preparation of the distal implant was done as posteriorly and vertically as complicated and dangerous one. The preparation of the zygomatic implant is always advisable since it is the more meticulous implant with the correct length of the zygomatic implant with the final conical bur. In cases of quad-zygoma surgery, the mucoperiosteal flap reflection reached the lower orbital rim. Special attention was paid to the emergence of the infraorbital nerve during the whole surgical operation, in order to position the anterior zygomatic implant at a safe distance. The implant site preparation was performed with drills and burs that were mounted on a contra-angle handpiece, which allowed easier positioning of zygomatic implants distal to the maxillary second premolar region. After the reflection of the mucoperiosteal flap, corticotomy of the anterolateral wall of the sinus was prepared with a round (4 mm in diameter) diamond bur.

In order to determine the correct intraoral emergence of the zygomatic implant, these holes were then connected, creating grooves by using diamond cylindrical body burs with no working tips and with three different levels of grits (fine, medium, coarse). The conical bur with a nonworking tip provided a valid point of support and fulcrum for the subsequent bone preparation (Fig 1). In fact, this procedure, when correctly performed, also protects the integrity of the sinus membrane. Small possible accidental perforations of the sinus mucosa in the region of the zygomatic recess are not of significant importance in terms of sinusitis sequelae. The preparation of the zygomatic implant site was continued using a sequence of drills (2.5 cm long and 2 to 3.2 mm in diameter) with the final conical cutting tips. A depth indicator was then used to determine the correct length of the zygomatic implant with its tip located on the external cortical zygomatic bone. Starting the preparation from the most anterior zygomatic implant is always advisable since it is the more complicated and dangerous one. The preparation of the distal implant was done as posteriorly and vertically as possible so that the apexes of the zygomatic implants were convergent and did not interfere between them. Finally, the zygomatic implants were positioned with an extraoral screwdriver, or with the standard protocol of screwing that is used with conventional implants. The flaps were repositioned and sutured using resorbable sutures.

The patients were recalled for clinical follow-up after 10 days, 1 month, and every 3 months for the first year, and then twice a year. The occlusion was examined carefully at the delivery of the definitive prostheses and at each follow-up. In the first year following zygomatic implant insertion, the follow-up criteria for the patients with Toronto prostheses (a permanent prosthesis that is fixed on implants by screws) included additional interventions that can be described as follows. Every 6 months, the Toronto prostheses were unscrewed to check the status of the surrounding tissues. Implant success and survival rates were evaluated based on the clinical and radiologic criteria as a primary outcome. Complications were evaluated as additional criteria for success. Zygomatic implants were considered to be successful according to the criteria described by Aparicio et al as follows.15

**Successful:**

- Stable zygomatic implant with no mobility and no pain
- No associated sinus pathology
- Healthy peri-implant tissue condition

**Unsuccessful:**

- Clear clinical mobility with evidence of disintegration of the apical part of the implant
- Rotation of the implant
- Persistent pain
- Sinus pathology
- Recession of the tissues with more than seven exposed threads of the implants

**Statistical Analysis**

Descriptive statistics were done using mean values and SD for quantitative variables normally distributed. Normality of distributions was assessed using the d’Agostino and Pearson omnibus test. The cumulative implant survival rate was assessed using the Kaplan-Meier analysis, and the results were presented with a life table analysis. The effect of the different variables (sex, reason for zygomatic implant, number of zygomatic and conventional implants, loading, prosthesis type, and zygomatic implant location) on implant survival was evaluated using the Fisher exact test, given the low incidence of failures in each subgroup. The implant was the unit of analysis. $P = .05$ was considered
as the significance threshold. Statistical analysis was performed using GraphPad Prism 5.03 (GraphPad Software).

RESULTS

The study population was composed of patients aged from 21 to 76 years (mean: 58.2 years; SD: 9.28) who had at least one zygomatic implant placed between January 2014 and January 2020. The intraoperative view and postoperative panoramic radiograph of a representative case can be seen in Figs 2 and 3.

In the present study, the overall implant survival rate was 98.08%. The cumulative implant survival rate according to Kaplan-Meier analysis was 97.99%. Table 1 shows the life table analysis for the zygomatic implants, up to the 6-year follow-up. Detailed data concerning sex, reason for zygomatic implant, number of zygomatic and conventional implants, loading, prosthesis type, and zygomatic implant location are listed in Table 2. No statistically significant difference in implant survival rate was found among the groups for any of the factors evaluated. The significance resulting for the number of zygomatic implants placed is not relevant, as there were very few patients with an odd number of zygomatic implants. Definitive or provisional prostheses were delivered on the same day of surgery, and all the patients benefited from improvements in their quality of life following surgery. There was one intraoperative complication (fracture of the zygomatic bone). Five implants were lost in four patients (2 in the first week, 1 in 3 months; the other 2 implants were lost after 11 and 19 months due to occlusal overload caused by heavy bruxism). No sinusitis and no peri-implant mucositis were seen in any of the patients. Eleven postoperative complications developed in 7 patients: 3 oroantral sinus communications, 1 cutaneous fistula, 1 abscess around zygomatic bone, 1 infection around the apical part of the zygomatic implant (due to apical overinstrumentation of the implant site), 1 permanent paresthesia, 3 temporary neurosensory deficits (3 hypoesthesia), and 1 fracture of the abutment screw.

DISCUSSION

Zygomatic implants are currently one of the outstanding popular options in which the stable retention of the prosthesis can be achieved by the insertion of two to four implants with reduced costs and time for the patient.9,10 The classical approach for zygomatic implant

<p>| Table 1 Life Table Analysis |
|----------------------------------|----------------|----------------|------------------|--------------------|---------------|</p>
<table>
<thead>
<tr>
<th>Implants at risk</th>
<th>Lost to follow-up</th>
<th>Failed implants</th>
<th>Implant survival %</th>
<th>CSR%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–12 mo</td>
<td>261</td>
<td>51</td>
<td>4</td>
<td>98.47</td>
</tr>
<tr>
<td>12–24 mo</td>
<td>206</td>
<td>39</td>
<td>1</td>
<td>99.51</td>
</tr>
<tr>
<td>24–36 mo</td>
<td>166</td>
<td>30</td>
<td>0</td>
<td>100.0</td>
</tr>
<tr>
<td>36–48 mo</td>
<td>136</td>
<td>88</td>
<td>0</td>
<td>100.0</td>
</tr>
<tr>
<td>48–60 mo</td>
<td>48</td>
<td>28</td>
<td>0</td>
<td>100.0</td>
</tr>
<tr>
<td>60–72 mo</td>
<td>20</td>
<td>15</td>
<td>0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

CSR = cumulative implant survival rate; mo = months.
surgery introduced by Brånemark was a pioneering technique that has been used by several clinicians worldwide with successful results. The zygomatic implants ranging from 30 to 52.5 mm in length are placed in the second premolar region through the palatal bone and are fixed into the zygomatic bone. Since its introduction, several protocol alternatives have been specified for zygomatic implant surgery by
other authors with variations. The sinus slot technique was the first to be introduced as a safer option.\textsuperscript{25} In this technique, a lateral guide window is made directly through the buttress wall of the maxilla, which allows a direct view to the base of the zygomatic bone and implant position. In comparison with the classical protocol, the dissection used is narrower and less than half the amount of implant is exposed, which allows a greater bone-to-implant interface and more buccal position of the implant and results in better alignment with the definitive prosthesis.\textsuperscript{20,25} Boyes-Varley et al later critized this technique due to the lack of direct visualization of the entrance of the implant into the zygomatic bone, which is crucial to minimize complications.\textsuperscript{18}

Another alternative to the classical protocol is the extrasinus technique.\textsuperscript{26} In this approach, most of the implants are placed externally to the maxillary sinus, and anchorage is obtained through the zygomatic bone, which makes this technique an alternative for all types of atrophic maxilla patients. With the use of the extrasinus technique, the need for maxillary antrostomy or the creation of a slot is eliminated, which results in improved direct visualization.\textsuperscript{20} The emergence of the zygomatic implant is on the alveolar crest, which permits better biomechanics for prosthesis design. This technique also offers the advantages of fewer surgical steps, reduced surgical time, and a shorter cantilever, and it is less invasive than the other methods.\textsuperscript{20,27}

The extrasinus technique uses a one-stage surgical approach, thus reducing the risk of peri-implantitis and mucositis, which is of paramount importance in cases with a two-stage protocol in implant dentistry (the two-stage implant dentistry approach includes two separate surgeries, one for bone augmentation and another for implant insertion).\textsuperscript{28,29} The technique used in the present study, which is a technical modification of the extrasinus protocol, implies the use of a special kit designed for zygomatic implant surgery (Fig 4). This kit is composed of a round diamond bur, three diamond cylindrical body burs with nonworking tips and different levels of grits (fine, medium, coarse), a depth indicator, and a sequence of drills (2.5 cm long and 2 to 3.2 mm in diameter). The zygomatic implant that was used has an unthreaded long body ending with a particular aggressive threaded 12.5-mm apical segment. The zygomatic site preparation and implant has a complete extrasinus path for preserving the sinus membrane and avoiding any postsurgical sinus sequelae. In addition to the optimal position of the implant, an ideal emergence of the implant on the alveolar crest is provided with the use of angled multiunit abutments from 17 to 60 degrees.

In zygomatic implants, the prosthesis plays a key role in success. In the present study, three failed implants were lost due to inappropriate prostheses for distribution of forces on the zygomatic implants. In one patient, two zygomatic implants were lost due to deep peri-implantitis (in this study, mucositis was considered to be a minor infection of the mucosal soft tissue, while oroantral fistula was considered to be the communication between the oral cavity and the maxillary sinus, and deep peri-implantitis represented a serious infection including soft and hard tissues around implants). Such peri-implantitis was caused by the overloading of the implants due to the incorrect positioning of the definitive prosthesis and poor oral hygiene of the patient, who did not come to the follow-ups. In particular, in patients with heavy bruxism, special care should be given to the prosthetic planning in order to distribute the forces equally on the supporting implants. In the present study, the other zygomatic implant was lost in a patient that presented heavy bruxism. The overloading of the forces by the prosthesis on the zygomatic implant from bruxism resulted in the loss of the implant. In more detail, in one of these bruxist patients, there was clear clinical mobility with evidence of disintegration of the apical part of the implant, which was removed with an additional surgical intervention. This patient had received four zygomatic implants, and as a solution, the definitive prosthesis was successfully adjusted to three zygomatic implants.

The postoperative complications seen in seven patients were treated and solved by additional interventions with success. Oroantral communications (oral cavity and maxillary sinus communications) of the three patients were treated by additional surgical operations with the use of local anesthesia. For this purpose, a Bichat fat pad flap was used to cover the unthreaded part of the zygomatic implant. The mucoperiosteal flap
extending over the Bichat fat pad was sutured over, in order to cover and securely close the previous oroantral sinus communication.

In cases of active sinusitis, an additional surgery was done under general anesthesia with a simultaneous functional endoscopic sinus surgery. In the present study, the cutaneous fistula was treated by a two-stage surgical approach. The first surgery was done under general anesthesia. Functional endoscopic sinus surgery, fistulectomy, and simultaneous lipofilling were performed at this stage. After 6 months, another lipofilling intervention under local anesthesia was done in order to adjust some remaining esthetic imperfections. Another complication seen in this study was zygomatic bone periostitis, due to the overpreparation of the zygomatic implant site by the final drill, which was inserted too deeply over the zygomatic cortical bone. Consequently, the zygomatic implant was inserted too deeply and the apex was located 1.5 mm over the zygomatic cortical bone. In this case, the periostitis was treated successfully by cutting the apex of the zygomatic implant under general anesthesia.

CONCLUSIONS

Oral rehabilitation of the maxilla with zygomatic implants significantly shortens the time of rehabilitation with a reduction of adverse effects and complications. However, the placement of zygomatic implants is a major surgical procedure that has risks because of the surrounding anatomical structures and should be performed in selected patients. Additionally, surgical and prosthetic planning experience is highly required in order to overcome the possible complications.

According to the data obtained from this study, insertion of zygomatic implants with a technical modification of the extrasinus protocol is an effective and safe alternative to conventional protocols in the literature with a high success rate and few complications, especially in patients with an extremely atrophic posterior maxilla.

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REFERENCES


