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### Clinical Paper Dental Implants

# Immediate full-arch rehabilitation of the severely atrophic maxilla supported by zygomatic implants: a prospective clinical study with minimum follow-up of 6 years

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Abstract. The aim of this study was to evaluate the outcomes of immediate full-arch prostheses supported by zygomatic implants alone or in combination with standard fixtures after a minimum of 6 years of loading. From October 2008 to April 2010, 15 patients with severely atrophic maxillae were treated using four zygomatic implants or two zygomatic implants in conjunction with two conventional fixtures. All subjects received a fixed screw-retained prosthesis within 3 hours of surgery, while the final restoration was delivered after 6 months. Follow-up examinations were scheduled to evaluate zygomatic implant survival, conventional dental implant success, prosthetic success, plaque and bleeding scores, marginal bone loss for conventional dental implants, and patient satisfaction. Forty-two zygomatic fixtures and 18 standard implants were placed. Patients were followed up for a minimum of 79 months (range 79-97 months, average 90.61 months). No implant was lost, leading to implant and prosthetic survival rates of 100%. Bone loss for conventional implants averaged  $1.39 \pm 0.10$  mm after 6 years of function, leading to a 100% implant success rate. High levels of patient satisfaction were recorded. These medium-term results indicate that immediate full-arch rehabilitation supported by zygomatic implants could be considered a viable treatment modality for the severely atrophic maxilla.

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Key words: atrophic maxilla; dental implants; fixed prostheses; immediate loading; zygomatic implants.

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Long-term edentulism brings evident changes to the lower third of the face, due to modifications of the oral and facial tissues<sup>1</sup>. Sometimes, in the case of severely atrophic ridges, not even the support of the hard palate can guarantee adequate stabilization for a maxillary denture, and the presence of a loose mucosa can often increase patient discomfort. In this scenario, rehabilitation of the maxillary arch with an implant-supported prosthesis can be challenging.

Different techniques are used to gain sufficient bone volume before implant placement (sinus lift, intraoral and extraoral grafts, Le Fort I with inlay and onlay grafts, titanium meshes)<sup>2–6</sup>. Bone augmentation is usually recommended first, and delayed implant insertion is suggested to increase the success rate of the final restoration<sup>2–6</sup>. These procedures require long treatment times, sometimes with multiple surgical sites and interventions, possible severe complications, and high morbidity, thus reducing patient acceptance<sup>7,8</sup>. The success rates of these bone augmentation techniques range from 60% to 90%<sup>7</sup>.

Zygomatic bone is used to anchor implants placed for the retention of total prostheses in the case of maxillectomy or cleft palate<sup>9-11</sup>. In 1988, Brånemark introduced the use of zygomatic implants combined with conventional fixtures to support dental prostheses<sup>12</sup>. His technique included an entry point on the palatal side of the residual crest and an implant path through the sinus cavity that resulted in perforation of the sinus membrane. Twenty-eight patients were treated with a total of 52 zygomatic implants, and an implant success rate of 96.2% was achieved after 5 years of function<sup>12</sup>. However, the percentage of sinusitis was notable (14%). Furthermore, with this technique, the palatal emergence of the implant heads causes interference with phonetics and difficulty in the maintenance of hygiene.

New implant morphologies have since been developed and a different approach has been adopted to overcome the complications occurring with the Brånemark technique<sup>13</sup>. This approach consists of starting the osteotomy at the level of the residual crest and inserting the zygomatic implants external to the sinus membrane, preserving its integrity<sup>13</sup>.

The short- and medium-term survival rates of zygomatic implants look promising<sup>14–19</sup>. A review of the literature on 1541 zygomatic implants reported a survival rate of 97.86%<sup>20</sup>, and another review showed similar results<sup>21</sup>, but it should be pointed out that there was heterogeneity in the data in both of these

reviews as a result of study design, number of patients treated, follow-up times, and loading protocols.

The aim of this study was to evaluate the outcomes of immediately loaded fullarch restorations supported by zygomatic implants, alone or in combination with standard implants, for the immediate treatment of the severely atrophic maxilla (posterior maxilla of class 5 or 6 according to the classification of Cawood and Howell<sup>22</sup>). Clinical data after 6 years of follow-up are provided. This article was written following the Strengthening the Reporting of Observational Studies in Epidemiology guidelines (STROBE)<sup>23</sup>.

#### Materials and methods

#### Study protocol

This was a prospective observational clinical study on the treatment of patients with a severely atrophic maxilla. All subjects underwent surgical implant placement and immediate prosthesis delivery at a private dental office in Lisbon, Portugal, performed by one surgeon (EA) with experience in full-arch rehabilitations and immediate loading procedures. The final prostheses were made in Bollate, Italy, by a small group of clinicians with experience in full-arch rehabilitations and prosthetic protocols. The investigation was conducted in accordance with the principles of the Declaration of Helsinki, as revised in 2004, and was approved by an independent ethics committee (Ethics Committee for Health, Lisbon, Portugal).

At the preliminary visit, detailed information regarding the nature of the study and any possible alternative treatment was provided to all patients. Written informed consent was obtained before enrolment. A total of 15 patients (13 female and two male) were treated consecutively between October 2008 and April 2010. The mean age on the day of surgery was 62 years (range 46– 70 years). All patients were followed for a minimum of 6 years (range 73–91 months, average 85.04  $\pm$  7.23 months).

#### Inclusion and exclusion criteria

Inclusion criteria were the following: patient of any race and sex; fully edentulous maxilla with severe resorption of the posterior ridges preventing implant placement in the pterygoid area or conventional fixtures without prior sinus grafting (Cawood and Howell class 5 or  $6^{22}$ ); inadequate bone volume up to the canine region to place implants of at least 3.3 mm diameter and/or 10 mm in height; good general health condition; and physically and psychologically able to undergo a surgical procedure under general anaesthesia (American Society of Anesthesiologists (ASA) class 1 or 2) and subsequent restorative procedures chair-side.

The following exclusion criteria were applied: the presence of active infection or inflammation at the sites intended for implant placement, in the maxillary sinus or in the osteomeatal complex; presence of systemic disease (i.e. haematological disease, uncontrolled diabetes, serious coagulopathies, or disease of the immune system); irradiation to the head and neck region within 60 months before surgery; treatment with bisphosphonates at any time; heavy smoking habit (more that 20 cigarettes/day); severe bruxism or clenching; emotional instability or unrealistic aesthetic expectations; poor oral hygiene; and poor motivation to return for scheduled follow-up visits. Twelve subjects were excluded because of the presence of at least one of the aforementioned conditions.

#### Preoperative evaluation

Preliminary screening was performed using panoramic radiographs, radiography of the skull in lateral view, and a computed tomography (CT) scan, with imaging including the zygoma and osteomeatal complex. A clinical examination was conducted with particular attention to the amount of keratinized gingiva and to all prosthetic references, such as the occlusal vertical dimension, smile line, lip support, and inter-arch relationships (vertical and horizontal overlap). If an improper vertical dimension was noted, a denture with a new dimension was delivered for 6 months, and any sign of temporomandibular joint pathology or patient discomfort recorded.

Surgical planning was based on CT scan observations, although the final decision concerning the implant configuration was made intraoperatively. According to bone availability, two options were considered: four zygomatic implants (All-on-4 Extra-Maxilla, or All-on-4 Double-Zygoma; Nobel Biocare AB, Göteborg, Sweden) or two zygomatic implants in combination with two conventional fixtures in the anterior maxilla (All-on-4 Hybrid; Nobel Biocare AB), as described previously<sup>18</sup>. The zygoma implants used in this study had a straight head ending with an external hex, a 5-mm diameter body, and a narrow tip with active threads for the engagement of the zygomatic bone. The threads were not present in the coronal half of the

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