Clinical Evaluation of the Zygoma Implant: 3-Year Follow-Up at 16 Clinics

Karl-Erik Kahnberg, DDS, PbD,* Patric J. Henry, BDSc, MSD,† Jan-Mikael Hirsch, DDS, PbD,‡ Lars-Olov Öbrnell, DDS, PbD,§ Lars Andreasson, MD, PbD,¶ Per-Ingvar Brånemark, MD, PbD,‖ Matteus Chiapasco, MD,# Göran Gynther, DDS, PbD,** Kaj Finne, DDS,†† Kenji W. Higuchi, DDS, MS,‡‡ Sten Isaksson, DDS, MD, PbD,§§ Chantal Malevez, MD, DDS,¶¶ Friedrich W. Neukam, MD, DMD, PhD, at Edward Sevetz, Jr, DMD,## Juan P. Urgell, MD, DDS,*** Göran Widmark, DDS, PbD,††† and Pia Bolind, DDS, PbD‡‡‡

Purpose: The purpose of this clinical investigation was to evaluate the treatment outcome with zygoma implants with regard to implant survival, patient satisfaction, and function of prosthesis replacement after 3 years.

Patients and Methods: The treatment outcome of 76 patients treated with 145 zygoma fixtures at 16 centers was evaluated with regard to implant survival. Status of peri-implant mucosa and amount of plaque were registered annually. Patients’ and dentists’ evaluations of the functional and esthetic outcome of the treatment were assessed at delivery of prosthesis and thereafter at each follow-up visit.

Results: Sixty of 76 patients were followed for 3 years after prosthetic delivery. Five of 145 placed zygoma implants failed during the course of the study resulting in an overall implant survival rate of 96.3%. At the 3-year follow-up, 75% of the implants sites were registered with normal peri-implant mucosa and 68% with no visible plaque. The patients were fully satisfied with the esthetic and functional...
outcome of the treatment in 86% and 71%, respectively, at the 3-year follow-up visit. All reported data from dentists scored from acceptable to excellent.

**Conclusion:** The multicenter study showed a high predictability of the zygoma implant-supported rehabilitation.

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Patients with extreme resorption of the maxilla, or defects after tumor resection present complex problems for the restorative dentist. In the treatment of these patients, bone grafts have been used to re-establish osseous contours providing possibilities for a tooth anchorage system. The grafting procedures are demanding for the patients and usually require hospitalization. Many patients are unable or unwilling to undergo the rigors of these procedures.

By introducing the zygoma implant concept, Professor Brånemark presented a nongrafting alternative for the treatment of this group of patients. Treatment with zygoma implant does not require hospitalization and usually allows the patients to use their maxillary dentures after surgery. In addition, the zygoma implant procedure eliminates possible problems with donor site morbidity, concern for bone graft incorporation, and the number of implants required supporting fixed bridge prosthesis is reduced. There are few reports with follow-up data on the zygoma implant. A 100% survival rate was reported for the zygoma implants in a clinical report on 22 cases followed for 34 months. Supporting this finding, Malevez et al, in a retrospective study, reported a 100% survival rate of 103 zygoma implants in 55 patients after 6 to 48 months of loading. Bränemark et al followed 28 patients that had received 52 zygoma implants. The survival rate up to 5 years for the zygoma implants was 94%. Immediate loading of zygoma implants has been reported by Balshi and Wolfinger in 2 different case reports.

Because the long axis of the implant is outside of the bone tissue and only a short part of it is integrated in the bone tissue, it makes it necessary to combine the zygoma implants with conventional implants, preferably in a semicircular construction. In the recommendations by Professor Brånemark, it is not advisable to use the zygoma implant for only unilateral rehabilitation in the maxilla. In our clinical material, however, 1 patient has been treated with only 1 zygoma implant combined with conventional implants unilaterally.

The zygoma implant is a valuable technique for solving demanding cases of maxillary dentofacial reconstruction. Thus, it is a treatment option in cases with limited bone volume in the posterior maxilla and large sinus cavities but still some residual bone in the anterior region. The 1-year follow-up showed an implant survival rate of 97%. However, a longer follow-up period is required for evaluation of the treatment concept. Sixteen oral and maxillofacial surgical centers have evaluated the treatment outcome with the zygoma implants 3 years after prosthesis insertion. This study presents the clinical result of this multicenter study.

**Patients and Methods**

**INCLUSION AND EXCLUSION CRITERIA**

All patients with completed growth, scheduled for treatment with the zygoma implant at the 16 clinics during December 1997 to September 1999 were enrolled in a consecutive order. The therapy was decided by the responsible surgeon and prosthodontist. No further inclusion and exclusion criteria were applied.

**PATIENTS**

A total of 76 patients, 57 females and 19 males, (x = 58, range, 35 to 77 years) were treated with 145 zygoma implants. Serious previous or ongoing illness was registered for 29% of the patients. Any previous treatment in the maxillary molar region with implants or grafts was reported for 11% and 9% of the patients, respectively, and 5% of the patients were reported to have had radiotherapy in the head and neck region. Fifteen (20%) of the patients were reported smokers.

**RADIOLOGICAL EXAMINATION**

Preoperative radiographic examinations were carried out to identify anatomic structures, detect presence of pathology, evaluate the sagittal relationship, and estimate bone volume. See Hirsch et al for details (Fig 1).

**SURGICAL TECHNIQUE**

The palate and the maxilla up to the infraorbital foramina, the infrazygomatic crest, and the body of the corpus zygomaticum were exposed using a vestibular or crestal incision. A window was opened in the lateral aspect of the maxillary sinus wall enabling a direct view into the sinus. Considering the local anatomy of the alveolar crest, lateral sinus wall, and the area between the dorsal part of the infraorbital margin and the zygomatic arch, the implant site was
prepared. The preparation was carried out with a sequence of specially designed burs. Usually the entrance in the maxilla was located in the second bicuspid area slightly palatal of the alveolar crest and the apex of the implant penetrated approximately 1 mm through the zygomatical body. The implant with its angulated head was turned in accordance to prosthetic demands. After insertion of cover screws, the mucoperiosteal flap was repositioned and sutured in layers. Postoperative recommendations followed the standard procedures after insertion of dental implants. After approximately 6 months, the implants were exposed and abutments, healing or permanent, were placed in an ordinary manner with special care to thinning and trimming of the tissues around the zygoma implant (Fig 2).

PROSTHODONTIC TECHNIQUE AND FOLLOW-UP VISITS

The prosthodontic protocol has been presented previously in the 1-year follow-up report of this study. After prosthetic insertion, the patients were scheduled for review after 1 and 2 weeks and thereafter on a regular basis with annual follow-ups.

Patients’ and dentists’ evaluations of the functional and esthetic outcomes were assessed at delivery of the prosthesis and at the follow-up visits.

Any complication in relation to the treatment was registered and symptoms from maxillary sinus; including fistula formation and stability of the prosthetic restoration were carefully noted throughout the follow-up period.

The status of the peri-implant mucosa around the abutments was registered according to a modified version of Löe and Silness gingival index and the amount of plaque present on the abutments was registered using a modified version of Silness and Löe plaque index at all follow-up visits.

Results

Of 76 patients, 73 received prosthetic restorations supported by 137 zygoma implants. One patient, with 2 zygoma implants, withdrew from the study due to economic reasons before prosthetic delivery. In 2 patients, the zygoma implants were not used as support for the restorations due to implant failure (2 zygoma implants) and sleeping implant (1 zygoma implant). At prosthetic delivery, 1 additional zygoma implant failure had occurred in a patient receiving a prosthetic restoration on the remaining implants and 1 zygoma implant in 2 patients, respectively, were left “sleepers.”

Of 73 patients, 60 with prosthetic restorations supported by zygoma implants were followed for 3 years after prosthetic delivery. From prosthesis insertion to the final 3-year follow-up, 12 patients withdrew from the study due to serious illness in 2 patients, poor compliance of 3 patients, and 7 patients moved during the follow-up period. One patient lost the last remaining zygoma implant at the 3-year follow-up.

One additional failure of a zygoma implant occurred at the 2-year follow-up.

During the course of the entire study period, 5 of 145 zygoma implants failed giving an overall survival rate of 96.3% after 3 years of functional load.

During the study, removal of the prosthesis was undertaken for repair or modification as required. Removal of the prosthesis for a period greater than 2 weeks occurred in 8 patients. In 2 cases this was for laboratory repair of fractured tooth sections and in 1 case for modification of the prosthesis due to failed conventional implants. In this third case, the bridge was modified after loss of conventional implants placed as part of a pre-existing anterior partially edentulous implant anchored bridge but subsequently incorporated into a full arch prosthesis with zygoma implants. Two patients were converted from a fixed...
bridge prosthesis to an implant-supported overdenture situation, one electively and the other due to lost conventional implants associated with an anterior bone graft. The overdenture in the latter was supported by magnets on the zygoma implants. One patient had prosthesis modification after loss of 1 conventional and 1 zygoma implant with subsequent successful installation of a further implant. Another patient had a remake of the fixed bridge prosthesis after loss of a conventional implant associated with abutment screw loosening and prosthetic gold screw fracture. One patient had the fixed bridge removed for longer than 2 weeks in association with revision soft tissue surgery for removal of inflammatory hyperplastic tissue around the zygomatic abutments in relation to inadequate plaque control. These 8 patients formed part of a group of 10 patients classified as having clinically unstable prosthetic results because the prosthesis required removal for remedial purposes. Of the additional 2 patients, 1 was classified as unstable because of loosened ball attachment caps that were replaced with simultaneous reline of the overdenture prosthesis. The final patient was classified as clinically unstable but reasons were not specified.

All prosthetic complications and modifications were considered to be within the usual level of maintenance requirement as experienced with traditional maxillary osseointegrated implant-supported prostheses.

Normal peri-implant mucosa and no visible plaque were registered for an increasing number of sites over the study period. Seventy-five percent of the sites were registered with normal peri-implant mucosa and 68% of the sites were registered with no visible plaque at the 3-year follow-up. Infection, redness, and swelling around zygoma abutments were reported for 2 of 60 patients.

Discussion

This study started in the late 1990s and represents the early experience and follow-up of the zygoma
implant in a multicenter approach. The number of enrolled patients varied among the participating centers but reflected the current demand and possibility for providing the treatment with zygoma implants at each center. Although all centers followed a common study protocol, minor variations in the surgical or prosthetic treatments carried out cannot be excluded when conducting a multicenter study. The multicenter approach offers the potential to gather substantial follow-up data in a limited time period and, in addition, gives an indication of the reliability for the method used in several different centers.

A total of 145 zygoma implants were placed in this study. During the course of the study, 5 zygoma implants failed and 3 zygoma implants were never abutment connected, ie, left “sleeping.” Two of these “sleeping” implants were reported unstable. Of 76 patients enrolled in the study, 73 received a zygoma implant-supported restoration. In a number of cases (14%), the patients had previous sinusitis problems that could possibly affect the zygoma implant insertion. Some patients had also been exposed to radiation of the head and neck before implant treatment (5%). Due to patient withdrawal (n = 12) and 1 patient who lost the remaining zygoma implant during the follow-up period, prosthetic restorations of 60 patients were followed for the entire study period. The esthetic and functional assessment of the implant rehabilitation showed good results at the 3-year follow-up. Considering the originally difficult rehabilitation situation in these patients, the results are very encouraging. The 96% survival rate of the zygoma implants after 3 years of prosthetic loading corresponds to reported survival rates for conventional implant treatment of the upper jaw.10

The withdrawn patients constitute 15% of the total patient population in this study. For all patients, the reasons for withdrawal have been reported and, in some cases, with the notification that the treatment works well. It cannot be taken for granted, however, that all these patients would have been reported as successful with no complications providing they had fulfilled the study course.

The advantages with the zygoma implant procedure compared with bone grafting techniques include time saving and an equal number of required surgical interventions, as is customary for conventional 2-stage implant treatment. However, the zygoma implant has to be combined with conventional implants to secure stability for the restorations. The ideal cases for zygoma implants are patients with a sufficient remaining bone volume in the anterior region but severely resorbed posterior parts with pneumatization of the crestal bone by the sinus allowing implant stability marginally.

The reaction of the sinus mucosa to the zygoma implant penetrating the maxillary sinus cavity has been studied by Petruson.10 He followed patient cases with an endoscopic technique. Mucosa covered the implants in some cases, whereas in other cases, the implants were partly covered. At visual inspection, the mucosa was normal with no signs of increased secretion or infection around the implants.

The 2-point anchorage in the zygomatic bone and the maxillary alveolar process of the zygoma implant is a prerequisite for the implant stability. The weakest point in the zygoma implant bone anchorage is the crestal bone. In most cases, the bone tissue at the entrance through the palatal bone is extremely thin. The thin palatal bone in combination with a widening of the drill hole during the surgical procedure as well as possible micro movement of the zygoma implant after loading may be factors having an impact on sinus-related symptoms and complications.

Limited maxillary bone volume may have had an impact in this study and cannot be excluded as a possible cause of the reported implant failures.

During the course of the follow-up in this study, sinus-related symptoms and complications were reported for 14 patients. At the final 3-year follow-up, 1 patient had reported sinusitis but no persisting fistula formation was reported.

Drainage of the maxillary sinus is a constant problem in sinus infections. Bråemark4 described a protocol to improve ventilation and drainage in cases of recurrent sinusitis. A new ostium to optimize the nasal passage from the sinus was reported for 4 patients, resulting in no recurrence of the sinusitis. This approach, applied with the zygoma procedure for patients at risk, might reduce sinus-related symptoms and complications.

In extreme cases of maxillary resorption, more than 1 zygoma implant placed unilaterally has been reported by Balshi et al.12 Bothur et al.13 and Brånemark.4 The anterior zygoma implant in these cases can sometimes involve the wall of the orbit. Special attention is advocated to protect the orbit content.

In 2 case reports by Balshi and Wolfinger,5,6 an immediate loading protocol including zygoma implants was described. In these cases, clinical circumstances and patient needs had called for a modified protocol. However, more experience of an immediate loading protocol would be needed before a modified protocol could be recommended.

Although the zygomatic implants have been shown to have a number of advantages, the technique may have some limitations. The demanding surgery requires trained surgeons experienced in maxillofacial procedures. There is a risk for orbital injuries or postoperative sinusitis in connection with surgery. Due to the palatal location of the implants a more complex
restorative design is needed. Implant failure may also require more complicated treatment compared with the nonzygomatic procedures. Whether the zygoma implant procedure can be made using local anesthesia combined with sedation or using only general anesthesia is a decision for the surgeon and patient together. General anesthesia is recommended normally.

Future aspects of the zygoma implant may include modification of the surface structure possibly enhancing the osseointegration over time. Other measures could include modifications of the palatal design of the implant to avoid potential risks for fistula formation leading to sinus infections or peri-implant tissue problems.

In a multicenter study of zygoma implant rehabilitation in severe cases of maxillary resorption, the 3-year result showed a high predictability of the method definitely securing its position in implant reconstruction and rehabilitation procedures of the upper jaw.

References