A Clinical Evaluation of the Zygoma Fixture: One Year of Follow-Up at 16 Clinics

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Purpose: To evaluate treatment outcome with Zygoma fixtures (Nobel Biocare, Göteborg, Sweden) with regard to fixture survival, patient satisfaction, and function of prosthesis replacement.

Materials and Methods: The treatment outcome of 76 patients treated with 145 Zygoma fixtures at 16 centers was evaluated. Patient’s and dentist’s evaluations of the functional and aesthetic outcome of the treatment were assessed at delivery of prosthesis and at the 1-year follow-up visit. At the 1-year follow-up visit, the status of the peri-implant mucosa around the abutments and the amount of plaque were registered.

Results: Sixty-six of the 76 patients, with 124 Zygoma fixtures supporting the prosthetic restorations, were evaluated at the 1-year follow-up. The overall survival rate for the Zygoma fixtures was 97.9% after 1-year of follow-up. Eighty percent of the patients were fully satisfied with both aesthetic and functional outcome at the time of prosthetic insertion and at the 1-year follow-up. All reported data from the dentists, with the exception of one restoration with several abutment screw loosening, scored from acceptable to excellent for the aesthetic and functional outcome of the treatment. The status of peri-implant mucosa was recorded as normal in approximately 60% of the sites. Plaque, when present, was more often detected on the palatal surfaces compared with the buccal surfaces.

Conclusion: This 1-year follow-up of Zygoma fixtures has shown good results with an acceptable number of minor complications and a majority of satisfied patients.

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Osseointegrated implant support for craniofacial prostheses was introduced in the 1980s. It was shown that an implant-supported prosthesis using custom-designed longer implants inserted into the zygomatic bone combined with the standardized Bränemark System could replace the traditional prosthesis. Patients with craniofacial and/or intraoral defects were rehabilitated with prostheses attached to osseointegrated implants. The improved method for rehabilitation of these patients has had a profound positive impact on their quality of life. The biological basis for this treatment modality was sufficient bone volume found for fixture installation in the zygomatic bone and the minimal loss of volume and bone quality over time.

The same method as used for patients with intraoral defects after partial or total maxillectomies was applied for specific intraoral conditions, such as severely resorbed maxilla with poor bone quality or other anatomic limitations.

The transsinusal fixture, the Zygoma fixture (Nobel Biocare, Göteborg, Sweden), was designed to be anchored apically in the zygomatic bone and marginally on the palatal side of a minimal residual alveolar crestal bone. Using this technique, bone grafts could be avoided from time to time and yet adequate mechanical stability was provided for teeth in the posterior regions.

The procedure reduces morbidity specifically in elderly persons or patients with compromised general health, where bone grafting would be hazardous.

Total treatment time and cost of the rehabilitation would also be lowered in comparison with the traditional rehabilitation with bone grafts.

This report comprises the 1-year follow-up results from patients treated with the Zygoma fixtures in a global multicenter study in 16 clinics. The centers represent a part of an ongoing open, prospective investigation performed where the patients will be followed for 3 years after rehabilitation with an implant-supported prosthesis.

The objectives of the present clinical investigation are to evaluate treatment outcome with Zygoma fixtures with regard to fixture survival, patient satisfaction, and function of prosthesis replacement.

Materials and Methods

Inclusion and Exclusion Criteria

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

Patients

A total of 76 patients (57 women; 19 men; \( x = 58 \); range, 35 to 77 years) were treated with 145 Zygoma fixtures. Sixty-one (80%) of the patients were reported nonsmokers and 15 (20%) smokers at the time of surgery.

Serious previous or ongoing illness was registered in 29% of the patients. 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. Information is unreported for 4% of the patients.

Radiologic Preoperative and Postoperative Examination

Conventional radiographic examinations and panoramic images supplemented with intraoral radiographs were used to determine the height of the remaining maxilla and to identify the anatomic structures and to detect the presence of pathology (Fig 1).

These investigations allowed for decision-making as to whether conventional implants could be installed anteriorly without a bone graft or not.

Lateral cephalograms were used to evaluate the sagittal relationship between the maxilla and mandible and also to estimate the width of the frontal bone.

Conventional or computed tomography was, when required, used to estimate bone volume.

To determine whether the anatomic situation would allow installation of Zygoma fixtures or not and to eliminate the risk of undiagnosed pathologic lesions, 2 optional radiographic techniques were recommended for the zygoma:

1) Computed tomography with axial scans parallel to the hard palate or coronal scans. Reformatted frontal images, produced perpendicular to the scan plane, allowed for identification of the
maxillary sinus extension into the zygoma and evaluation of the thickness and height of the zygomatic body and possible presence of sinus pathology.

2) Conventional tomography with frontal tomo-grams, 2 to 4 images some mm apart, perpendicular to the hard palate. These images showed the extension of the maxillary sinus and presence of sinus pathology.

When available, Scanora system (Soredex-Finndent; Orion Corporation, Helsinki, Finland) was used, with sinus tomographic programs or maxillo-dental tomographic programs.

For postoperative radiographic examination of Zygoma fixtures, tomography as above was performed, as well as panoramic views and sinus projections (Fig 2).

SURGICAL TECHNIQUE

Surgery was performed in general anesthesia or local anesthetics with conscious sedation following the routine of each clinic. A vestibular incision from second molar to second molar was performed similar to the Le Fort I procedure or, alternatively, a crestal incision with releasing incisions in the midline and/or posteriorly in the second molar area. A palatal mucoperiosteal flap was raised to the level of the first molar area bilaterally. The nasal apertures were exposed as well as the lateral and anterior part of the sinus walls up to the level of the infraorbital foramina. To prevent involvement of the orbital floor during fixture installation, the exposure was extended in the posterior-superior direction to the lateral surface of the zygomatic bone, localizing the fossae (incisura) between the zygomatic arch and the lateral and medial surface of the frontal process of the zygomatic bone. A small window, approximately 5 × 10 mm, was created on the sinus wall for a direct view into the sinus. The sinus mucosa was penetrated and removed from the sinus roof, enabling a fixture pathway through the sinus. A retractor was placed in the incisura to facilitate a correct 3-dimensional orientation and to ensure direct visualization of drill penetration during site preparation. The site preparation for the Zygoma fixture was designed to place the fixture as posteriorly as possible, with the fixture head close to the alveolar crest.

A round bur was used to penetrate the maxillary bone into the sinus, making an entrance mark in the posterior-superior roof of the sinus. The site preparation was continued with a twist drill (diameter 2.9 mm), penetrating the outer cortical layer of the zygomatic bone at the incisura. The site of the alveolar crest and the entrance into the zygomatic bone were further widened with a pilot drill (diameter 3.5 mm), followed by a 3.5 mm twist drill to complete the preparation all the way through the zygoma complex. When required, a pilot drill (diameter 4 mm) was used to enlarge the fixture entrance into the alveolar bone.

The Zygoma fixture was inserted using low speed on the drilling unit until the tip of the fixture engaged the zygomatic bone. Installation was finalized manually until the fixture was properly seated with a desired fixture head position. The conventional implants placed anteriorly were inserted according to standard clinical procedures for the Brånemark System.5 Cover screws were placed on the implants and the wound was closed in 2 layers. The postoperative care followed the normal routines.

Abutment connection was performed after an appropriate healing time in accordance with standard Brånemark System procedures.

PROSTHODONTIC TECHNIQUE

The clinical sequences and implant componentry used were those routinely advocated in the prosthodontic protocol ad modum Brånemark.5

The common prosthetic guidelines were followed, which dictated that the occlusal design minimized torque and bending moments, with adequate access at the mucosal interface to fulfill hygienic demands and facilitate home care maintenance. The prosthetic treatment plan aimed for an optimal balance between functional, aesthetic, and hygienic requirements.

Following initial healing and suture removal, the preoperative denture was relined as necessary during the interval between stage 1 and stage 2 surgery in accordance with standard protocol for implant treatment of the edentulous jaw. Following abutment connection, a transfer registration was taken, if indicated, to fabricate a rigid bar system designed to prevent adverse forces on individual implants. The denture was generously relieved around the abutment areas and relined with a soft tissue conditioner ensuring minimization of transverse and torque-like forces.
The design of the final prosthetic bridge construction was rigid to provide stabilization. The fit of the bridge was absolutely passive to prevent load transfer to individual implants, and the final reconstruction was completed as soon as possible (Figs 3, 4).

After prosthetic insertion, patients were scheduled for review after 1 and 2 weeks, and were followed on a regular basis thereafter. The recall schedule was established based on an individual evaluation of each patient’s needs and circumstances.

Patient’s and dentist’s evaluations of the functional and aesthetic outcome of the treatment were assessed at delivery of the prosthesis and at the 1-year follow-up visit (Fig 5).

At the 1-year follow-up visit, the status of the peri-implant mucosa around the abutments was registered according to a modified version of Löe and Silness gingival index,6 and the amount of plaque present on the abutments registered using a modified version of Silness and Löe plaque index.7

SUCCESS AND FAILURE CRITERIA

In evaluating treatment outcome, the following success and failure criteria were applied:

- **Successful subject** was a patient who had received the oral rehabilitation he or she required and the rehabilitation was functioning as intended.
- **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) during the investigation.
- **Successful Zygoma fixture** was when:
  - The fixture remained in the jaw and was stable, and the treatment was functionally successful.
  - No signs of infection, pain, or ongoing pathologic processes, such as fistula formation and...
Results

Sixty-six of the 76 patients, with 124 Zygoma fixtures supporting the prosthetic restorations, were evaluated at the 1-year follow-up. The remaining 21 fixtures were not reviewed following 1 year of loading because of 3 fixture failures, 3 fixtures left uncovered, 12 fixtures placed in 6 patients withdrawn from the study, and 3 fixtures placed in patients who had not passed 1 year of loading of the permanent prosthetic restoration in place.

The overall survival rate for the Zygoma fixtures was 97.9% after 1-year of follow-up.

Sixty-four of the 66 restorations followed for 1-year of functional loading complied with the treatment plan at delivery and represented 58 fixed bridges and 6 implant-supported overdentures. During the first year of functional loading, 2 fixed bridges had been replaced with implant-supported overdentures, 1 because of failed conventional implants and 1 upon patient request. Gold alloy was the most frequently used framework material in 71% of the restorations, followed by titanium in 15% of the frameworks. The most commonly used occlusal surface material was composite resin, reported for 45% of the restorations, followed by acrylic resin in 35% and porcelain in 17% of the restorations. Eighty-eight percent of the patients had a bilateral support and 12% had a unilateral support with Zygoma fixtures. A majority of the restorations, 88%, were supported with 4 to 6 implants. In a few patients, 7 or 8 implants were used.

In addition to the 2 bridges replaced with implant-supported overdentures, another 3 prosthetic restorations had been removed for more than 2 weeks during the follow-up period; 1 restoration was modified because of failure of a conventional supporting implant and 2 restorations required dental laboratory repair.

Aesthetic and functional evaluation of the prosthetic restoration according to the patient’s and dentist’s assessment was available in 85% of the cases. The patients were fully satisfied with both the aesthetic and functional outcome in 80% of the treatments at the time of prosthetic insertion and at the 1-year follow-up. All reported data from the dentists, with the exception of 1 restoration with several occasions of abutment screw loosening that was judged functionally unacceptable at 1-year follow-up, scored from acceptable to excellent for the aesthetic and functional outcome of the treatment.

Information of the status of the peri-implant mucosa and plaque at the 1-year follow-up is unreported for 20% of the Zygoma fixtures. The status of the peri-implant mucosa was recorded as normal peri-implant mucosa in approximately 60% of the sites. Bleeding after superficial probing or discoloration and spontaneous bleeding were more often found on the palatal compared with the buccal surfaces. The registration available showed no visible plaque around 60% of the sites. Plaque, when present, was more often detected on the palatal surfaces compared with the buccal surfaces.

ADVERSE EVENTS/REPORTED COMPLICATIONS IN 76 PATIENTS

The previously stated failures of 3 Zygoma fixtures were lost in 2 patients before prosthetic restoration. One patient lost both the Zygoma fixtures and 1 patient had 1 remaining Zygoma fixture which was used as support for the prosthetic restoration.

Excessive bleeding was reported in 3 patients in connection with implant surgery and 1 of these patients also developed a postoperative infection. Exposure of the Zygoma cover screw was reported for 1 patient.

Pain and/or impaired nerve function was reported in 6 patients. In 1 patient, a unilateral paresthesia was still present at 1-year follow-up. In 2 other patients, the paresthesia spontaneously resolved. One patient at 1-year follow-up continued to experience pain in inclement weather. Because of a prominent Zygoma fixture apex, a sensitive skin reaction was reported in 1 patient. One additional patient experienced pain from the sinus 2 months after surgery, which persisted at the 1-year follow-up as pain at night. Vague symptoms, such as sensation when jumping or feeling of stuffiness in the sinus area, were reported in 2 patients.

During the follow-up period, fistula formation was reported in 5 patients as single occurrences. Three were detected before or at abutment connection. In 2 patients, a fistula formation was reported following prosthesis insertion.

Symptoms in relation to the penetrating Zygoma implant pillar; hyperplasia (Fig 6), mucositis/gingivitis, pain, or infection were reported for 8 of the patients at a total of 10 occasions during the follow-up period.

Complications relating to the prosthetic restoration were reported for 9 patients, including abutment screw loosening, abutment screw fracture, frame-
work fracture, occlusal surface fracture, and incompletely seated abutment.

**Discussion**

Two to 4 conventional implants, in the anterior maxilla, as support for a fixed bridge in cases with compromised bone quantity and quality is not considered to fulfill the requirements for an acceptable long-term prognosis. In addition, such a limited number of implants usually does not meet the patients’ expectations in terms of aesthetics and occlusal support. Nevertheless, in cases with less acceptable anatomy and bone quality, 4 implants can sometimes work in a 5- to 10-year perspective. Thus far, the standard methods for rehabilitation with implants in posterior regions of severely atrophic maxilla have involved inlay and/or onlay bone grafting procedures.

Based on the excellent results with implants placed in the zygomatic region for rehabilitation in complex cases such as maxillectomies, Brånemark proposed and treated patients with skeletal continuous maxillae using a modified procedure and special implants (ie, Zygomaticus fixtures) with good results.

The Zygoma fixture was used as an alternative to bone grafting in the area of the maxillary sinus in the advanced resorbed maxilla.

In the present study, a successful Zygoma fixture was defined as a fixture remaining stable in the jaw functioning without signs of pain or pathologic processes. Because the prosthesis was not routinely removed at the 1-year follow-up visit, the stability of each individual fixture was not elucidated. Therefore, according to the stated criteria, this report is composed of data on survived Zygoma fixtures.

Of the patients enrolled in the present study, 11% had already experienced implant failures and 9% were failures with previous attempts to rehabilitate the molar regions in the maxilla with bone grafts. For placement of the conventional supporting implants in the anterior part of the maxilla, bone grafts were required in 25 patients (33%).

These figures reflect the challenging patient population enrolled in the study. The overall survival rate after 1 year for the Zygoma fixtures was 97.9%.

Brånemark et al reported the overall survival rate of Zygoma fixtures as 94.2% after a more extensive follow-up period of 5 to 10 years of 52 fixtures in 28 patients.

Survival rates for a group of grafted patients varying between 60% to 86% after follow-up periods from 19 to 95 months have been reported.

Esposito et al identified 73 follow-up investigations that provided detailed information on the Brånemark System implant with regard to frequencies of early and late failures (ie, before and after loading). An important confirmation of a clinical impression was the general trend of maxillae having almost 3 times more implant losses than in mandibles. In addition, it was seen that severe cases requiring bone grafting resulted in 14.9% failed implants. Detailed analysis of the Brånemark System implants inserted in bone grafts in sinus and nasal lift procedures in the atrophic maxilla have, over different time periods up to 80 months, showed a failure rate of 9.1%.

The standard method for rehabilitation of posterior regions in severely atrophic maxillae before the introduction of the Zygoma fixture has been inlay bone grafting (the augmentation of the maxillary sinus with autogenous bone grafts). Long-term experience with autogenous onlay bone grafting and simultaneous placement of osseointegrated fixtures, where the patients were followed for 2 to 15 years, resulted in a survival rate of originally installed fixtures of 80% to 85.8%.

Focusing specifically on inlay bone grafting (sinus procedures comparing 1- and 2-stage sinus inlay bone grafts after 1 year) in a prospective randomized study a cumulative success rate of 79% for 1-stage and 89.2% for 2-stage procedures was reported by Wannfors et al. The 3-year results presented were for 1-stage (77.7%) and 2-stage procedures (86.5%) indicating additional losses after loading. For the 1-stage procedure, the success rates after 3 years in use were significantly lower compared with the nongrafted reference group.

In a short-term perspective study, similar results have been obtained using autogenous bone grafts plus hydroxyapatite or hydroxyapatite alone for maxillary floor augmentation and delayed placement of implants.

Therefore, it can be concluded that rehabilitation with the Zygoma fixture as reported in the present 1-year results and previous results by Brånemark et al indicate a promising implant outcome.

All but 2 of the 66 patients were at the 1-year follow-up fitted with the originally planned fixed prosthetic restoration (97%). Two patients had received implant-supported overdentures as a replacement for their fixed bridges, 1 because of patient request and 1 because of the failure of conventional supporting implants. This is a satisfying result considering the difficult group of patients treated. Brånemark et al reported continuous fixed prosthesis function achieved for 23 of the patients (82.1%) and 96.4% including overdenture rehabilitation.

In sinus bone graft procedures, 85% to 94.8% had functioning prosthetic constructions after 3 years. These results indicate that patients treated with Zygoma fixture-supported prosthesis were rehabilitated to a similar level as patients bone grafted with maxillary sinus inlays followed by fixture installation.
Eliminated or reduced donor site morbidity and reduction in treatment time are potential advantages of the Zygoma protocol. Using Zygoma fixtures reduces the preoperative risk, which suggests that older patients and patients with more severe general health-related problems can be rehabilitated compared with traditional surgical methods with bone grafts. The medical history of 29% of the patients enrolled in the present study showed previous or ongoing serious illness, and 37% of patients required ongoing medication. Still, the Zygoma procedure could be performed by well-trained oral and maxillofacial surgeons under general anesthesia or conscious sedation and local anesthetics.

In addition to general morbidity, adverse events related to fixture installation are of importance. The extent of surgical complications, such as extensive bleeding, infection and paresthesia, pain, and decreased nerve function reported in this study are, although unfortunate, within the range that must be considered acceptable. Bränemark et al.9 noted a few sensory nerve disturbances that resolved spontaneously and minor oozing from the nose and sinus during the first postoperative day. Fairly extensive swelling and bruising 10 to 14 days postoperatively was reported for most patients.

Bränemark et al.9 performed sinoscopy to examine possible reactions of the antral and sinus mucosa demonstrating the Zygoma fixtures to be completely or partly covered with normal mucosa. However, they reported 2 patients (3.5%) after 6 and 9 years with suppuration from the sulcus of the abutment because of sinus infection. Four additional patients were treated successfully for recurrent sinusitis with mental antrostomy. In this study, fistulas have been reported in 5 patients before as well as after abutment connection, and at 1-year follow-up. Three patients (4%) experienced symptoms from the sinus specified as night pain, pain unilaterally in bad weather, or blockage of the sinus.

In addition, problems well known from surgical and prosthodontic rehabilitation with osseointegrated implants were reported, such as too narrow interimplant distance and incomplete seating of abutment.

The problems reported so far that are related to the Zygoma procedure are not severe and are within the magnitude of what is experienced with other methods.

The aesthetic and functional evaluation of the prosthetic result, at prosthetic delivery and 1-year follow-up, was performed by the responsible prosthodontist and the patients. The result from an aesthetic point of view was in 3% acceptable and in 83% good or excellent; only 3 patients were not fully satisfied. From a functional point of view, a technical problem with repeated abutment screw loosening was reported in one case. Eight percent of the patients were not fully satisfied.

The functional and aesthetic results are considered excellent, considering the number of difficulties involved in these rehabilitations, converting, in fact, oral invalids into well-functioning persons.

Plaque was more frequently found on the palatal surface of the abutments, which also explains the discoloration of the soft tissue that was more frequently registered at these sites. Sulcus bleeding of the alveolar mucosa surrounding the implant abutment was registered in 22% on the palatal side and 11.5% on the buccal surface. Bränemark et al.9 reported that the palatal position of the Zygoma fixture created no discomfort and no speech problems. Using a meta-analytic approach, it has been shown that late failures caused by peri-implant infection is a rare occurrence in relation to the conventional Bränemark system implants.14 Corresponding data for the Zygoma fixture are currently not available. However, the registration of plaque indicates that cleaning is more difficult on the palatal side, requiring reinforcement and modification of plaque control and home care programs.

Prognostic factors both positive and negative are cumulative, and a thorough assessment is needed before treatment. Signs of bruxism were noticed in 15% of the patients. There is little evidence that parafunction (bruxism and clenching) are associated with increased late failure rates, but excessive loading may induce bone loss.

Experimental studies (for review see Hollinger et al.22) have shown the negative effect of nicotine on bone healing, and consensus has been reached that smoking has a negative influence on implant survival,22,23 though well-designed clinical trials focusing on the topic are not available. In general, smokers have shown approximately twice the number of failures compared with nonsmokers. In this study, smoking habits were reported for 20% of the patients. Based on the expected negative effect of smoking, a tobacco cessation program could be considered for this category of patients.

This 1-year follow-up of Zygoma fixtures has shown good result with an acceptable number of minor complications and a majority of satisfied patients.

Based also on previous data on this method, it can be concluded that the Zygoma fixture is an option for implant treatment of the compromised maxilla.

References

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