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Clinical outcomes of fully and partially threaded zygomatic implants in a cohort of patients with minimum 7.5-year follow-up

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Abstract. – OBJECTIVE: The aim of this retrospective case series report was to evaluate the results of oral rehabilitation with extra-sinus zygomatic implant surgery with a minimum follow-up of 7.5 years.

PATIENTS AND METHODS: A total of 35 patients with 87 zygomatic implants were included. The mean follow-up period of the patients was 93 months. The zygomatic implant survival and complications were evaluated as criteria for success.

RESULTS: There were no implant failures. Overall success rate without complications for zygomatic implant was 88.5%. Complications developed in 4 patients (1 cutaneous fistula and 3 mucositis). According to the results on an implant basis, patients with previously failed conventional implants had greater probability of complications. Patients with quad zygomatic implants had higher incidence of complications than those with two zygomatic implants. Fully threaded implant design was associated with higher incidence of mucositis than partially threaded design. No relation was found between implant success and smoking, prosthesis type, and antagonist dentition. When conducting the analysis using the patient as unit, only the antagonist dentition showed significant difference, the worst outcome being associated with the Toronto resin prosthesis.

CONCLUSIONS: Zygomatic implants can be considered as a safe alternative to conventional implant insertions and bone grafting procedures in oral rehabilitation of patients with severely atrophic maxillary bone.

Key Words:
Zygomatic implants, Maxillary atrophy, Oral rehabilitation, Dental implants, Extra-sinus zygomatic implants.

Abbreviations

ZI: Zygomatic implant; I: Conventional implant; CBCT: Cone Beam Computed Tomography
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology; SD: Standard Deviation.

Introduction

Zygomatic implant (ZI) was presented by Brånemark as an alternative to grafting procedures for patients with severe atrophy of the maxilla[1,2]. Initially, ZI was introduced for the prosthetic rehabilitation of patients with large maxillary bone defects caused by trauma or tumor resections[3]. Today, ZI is considered as a successful treatment modality in patients with edentulous atrophic maxilla for rapid improvement in function and esthetics[3-5]. Insertion of zygomatic implants can make the use of bone grafts unnecessary. Consequently, the treatment time and donor site morbidity can be reduced. However, the considerable length (30-60 mm) of zygomatic implants can make this type of surgery quite challenging[6,7].

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Since its introduction, interest in zygomatic implant surgery is growing constantly. Several surgical guidelines and protocols were proposed by various authors[8] for ZI insertions. Today, a diversity of zygomatic implantation protocols exists, such as "the Brånemark technique[9]", "the sinus slot technique[10]", "the extra-sinus/extra-maxillary technique[11,12]". Furthermore, there are minimally invasive modalities that use "custom-made drill guide", or "computer-aided surgical navigation system[13]", or "endoscopically-assisted[14]" zygomatic implant placement approaches. Each technique can offer certain advantages and disadvantages; however, a consensus regarding the most suitable method has not yet been reached.

According to a finite element analysis of zygomatic implant techniques for the severely atrophic edentulous maxilla by Wen et al[15], there is no significant difference among the techniques for the amount and distribution of stress on the external craniofacial bones. However, long-term clinical observations with extensive sampling and systemic comparisons among the different techniques is currently lacking in literature[15,16]. There is a limited number of scientific reports[17-20] in literature evaluating long term results (with at least 5 years of follow-up) of zygomatic implants insertions. The technique used in the present study is "the extra-sinus technique", according to which implants are placed externally to the maxillary bone and anchorage is obtained through the zygomatic bone, which can make this technique a promising alternative for all types of atrophic maxilla patients.

The purpose of this retrospective study is to report the clinical outcome of patients treated with zygomatic implants having either a full-threaded or a partially threaded body and followed-up for at least 7.5 years.

Patients and Methods

This article was written following the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (available at: http://www.strobe-statement.org)[21].

The study was designed as a retrospective clinical case series study in the unit of Maxillofacial Surgery of the IRCCS Orthopedic Institute Galeazzi, Milan, Italy. A retrospective research of the maxillofacial surgery unit database of patients undergoing reconstruction and zygomatic implant placement was undertaken after the approval from the institutional review board.

The study population was composed by patients with 1-4 zygomatic implants that were placed between September 2012 and December 2014. Presurgical protocol included the assessment of the patients by cone beam computed tomography (CBCT) scans and/or panoramic radiographs for the assessment of the maxillary and zygomatic bone anatomy, and for the maxillary sinus pathologies.

Inclusion Criteria

- Patients presenting severely atrophic edentulous maxilla (Class IV-V Cawood and Howell);
- Extra-sinus zygomatic implant insertion;
- A minimum follow-up of 7.5 years.

Exclusion Criteria

- Active acute infection in oral maxillofacial region at the time of the surgery;
- Patients suffering from any major illness such as: immuno-compromised patients, patients with organ failures, AIDS, and oncologic patients;
- Patients with clefts;
- Patients that had incomplete documentation during their follow-up period;
- Zygomatic implant insertion with follow-up less than 7.5 years.

The decision of the number of zygomatic implants to be inserted for each patient depended on the patient specific anatomical features and of the biomechanical demands. All the zygomatic implants were inserted with "extra-sinus technique". The protocol adopted (pre/post-surgical medications, surgical approach, prosthetic procedures, and the follow-up) was previously described in more details in an article by the same team[22].

The zygomatic implants used in this study were either partially threaded (18 patients, 48 unthreaded long body implants with 12.5 mm apical thread, Noris Medical Ltd., Israel), or fully threaded (17 patients, 39 ICX Zygoma implants, Medentis medical GmbH, Ahrweiler, Germany).

Pre-Surgical Medication Protocol

One week prior to surgery patients underwent a professional oral hygiene session with 0.2% chlorhexidine digluconate oral rinses.

One day prior to dental surgery the patients started taking 1 g Augmentin (amoxicillin and

clavulanate potassium, Roche) for 6 days. Azithromycin 500 mg for 3 days was prescribed to the patients who were allergic to penicillin.

Surgical Protocol

The surgery was performed by the same surgeon (Fr.G.) under general anesthesia, or conscious sedation with local anesthesia (4% articaine with 1:100,000 adrenalin). All the zygomatic implants were inserted with "extra-sinus technique". Briefly, after the muco-periosteal flap reflections, all the implant site surgeries were performed using drills and burs. The ZIs were carefully inserted at a low speed (20-40 rpm) with a torque of 40-80 Ncm, and the final stabilization was performed manually. Additional standard dental implants were inserted, when needed and possible. Finally, after the placement of all implants (Figure 1), the flaps were repositioned and sutured using continuous resorbable sutures (Vicryl, Ethicon FS-2, Johnson & Johnson, USA).

Prosthetic Procedure and Follow-Up Protocol

Final or provisional prosthesis was delivered on the same day of surgery, and ZIs position/angulation was checked by Cone beam computed tomography (CBCT) scans and/or panoramic radiographs on the same day of surgery after insertion of zygomatic implants (Figure 2 and 3). The decision for final prosthesis delivery timing was also determined according to the financial availability of each patient. The occlusal emergence of the ZIs were 10-15 mm medial to the ridge, and the prosthetic superstructures were designed to enable proper oral hygiene in the area. The head of the implant with abutment in length and angulation were crucial factors for positioning the screw emergence on the occlusal surfaces and for determining the final thickness of the prosthesis. Most of the patients (29 patients) had Toronto prosthesis (with screws), while 6 had fixed cemented bridges, as final prosthesis.

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 function of prosthesis/occlusion/oral health status was clinically examined carefully at each appointment. CBCT scans and/or panoramic radiographs were obtained at follow-up appointments, whenever needed.

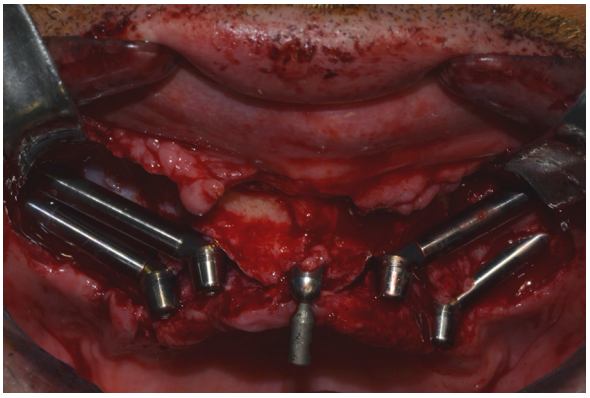

Figure 1. The intra-operative and intraoral view of one of the patients with partially threaded quad zygomatic implants inserted.

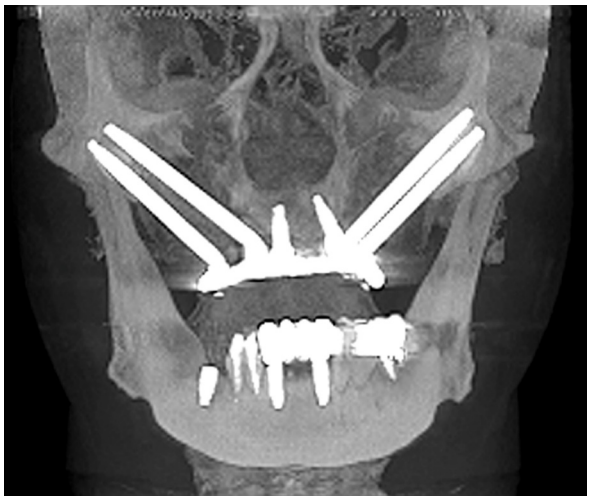

Figure 2. The post-operative radiographic frontal image of the patient showing quad ZIs.

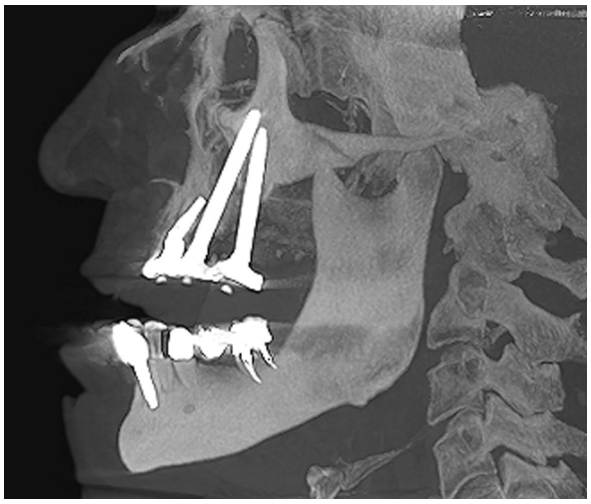

Figure 3. The post-operative radiographic profile image of the patient showing quad ZIs.

Zygomatic Implant Success Evaluation

The implant survival and intra-/post-operative complications were evaluated and recorded at each appointment as criteria for success, according to the clinical parameters, which are listed on Table I. A zygomatic implant presenting any of these clinical signs was considered as a non-successful implant.

All possible intra-operative/post-operative complications, such as neurosensory deficits, bleeding, infection, the condition of peri-implant soft tissues, and adverse events, were evaluated. The treatment applied to solve such issues was reported. Peri-implant mucositis was characterized by soft tissue inflammation surrounding implants, and bleeding on probing. Peri-implantitis was considered as a progressive loss of supporting marginal bone and infection around implants.

Prosthesis complications consisted of two main categories. The first included defects in chewing and speech, difficulties in maintaining oral hygiene, and problems with prosthesis design that involved discomfort for the patient. The second was about mechanical complications affecting prosthetic components, such as broken abutments or connecting screws or loosening of screws, usually due to prosthetic overload situations.

Statistical Analysis

Descriptive statistics of the data was done using mean values and standard deviation (SD) for variables normally distributed. Normality of distributions was evaluated through the d'Agostino and Pearson omnibus test. The relationship between gender, reason for ZI, number of zygomatic and conventional implants, prosthesis type, ZI location, and complications were all assessed. The effect of each variable (gender, reason for ZI, type of antagonist dentition, number of zygomatic implants per prosthesis, ZI location, prosthesis type, implant design, smoking habits) on complications was evaluated by using the Fisher's exact test, given the low incidence of complications in each subgroup. The distribution of complications in the two groups of implants was assessed using a time-to-event analysis. Cumulative complication rate was estimated through Kaplan-Meier analysis. The cumulative incidence of complications in fully threaded and partially threaded implants was compared using log-rank (Mantel-Cox) test. The patient and the zygomatic implant numbers were evaluated separately as units of analysis for success. p=0.05 was considered as the significance threshold. Statistical analysis was performed using GraphPad Prism 5.03 (GraphPad Software, Inc., La Jolla, CA, USA).

Table I. Clinical parameters for ZI evaluation for success.

Intra-operative complications
• Perforation of the orbital cavity • Persistent bleeding • Infraorbital or zygomatic facial nerve injury • Fracture of the zygomatic bone
Post-operative complications – Early:
• Persistent nasal bleeding in the first 3 days • Malar cutaneous emphysema • Facial or periorbital hematoma • Temporary neurosensory deficits (Infraorbital and zygomatic facial nerve)
Post-operative complications – Late:
• Sinusitis • Infection of peri-implant soft tissues • Mucositis • Oroantral or cutaneous fistulas • Periorbital abscesses • Peri-implantitis • Loss of the implant

Results

The selected dataset had a total sample of 317 zygomatic implants. 215 implants with less than 7.5 years of follow-up and 15 implants placed in cleft patients were excluded, according to the exclusion criteria. The study population fulfilling the inclusion criteria consisted of 35 patients with 87 zygomatic implants aged 23-74 (mean age 56, SD=10.9) years at the time of surgery, and who had at least one zygomatic implant placed.

According to the results, there were 7 ectodermal dysplasia patients, 7 patients with atrophic maxillary bone with previous conventional implant failures, and 21 patients with atrophic maxillary bone due to aging and/or edentulous ridge. The mean follow-up period of the patients was 93 months (range 90-117 months, SD=10.3 months). 25 of the patients had two ZIs, 9 patients had quad (4) ZIs, one patient had one ZI inserted. Details on number of zygomatic and conventional implants inserted for each patient and outcomes are listed on Table II. There were no ZI failures.

Complications were seen in 4 patients (all post-operative, since no intra-operative complication was seen in any patient):

Table II. Implant-based ZI complication rates according to different characteristics.

Variable	Characteristics	Complications/Total number of implants	Success %	*p*-value
Gender	Male Female	2/45 8/42	95.5 80.9	0.03*
Reason for ZI	Severe atrophic maxilla Previous implant failure	4/63 6/24	93.6 75.0	0.02*
Antagonist dentition	Toronto Resin Fixed bridge/implant and/or natural teeth Removable prosthesis Toronto zirconium	6/48 4/29 0/6 0/4	87.5 86.2 100 100	0.07
Number of ZI+I	1ZI+1I Total result for1ZI 2ZI+0I 2ZI+2I 2ZI+3I 2ZI+4I Total result for 2 ZI 3ZI 3ZI+1I 3ZI+2I Total result for 3 ZI 4ZI 4ZI+1I 4ZI+2I 4 ZI + 3I Total result for 4 ZI	0/1 0/1 0/12 4/12 0/6 0/20 4/50 - - - - 6/24 0/4 0/8 - 6/36	100 100 100 66.6 100 100 92.0 - - - - 75.0 100 100 - 83.3	0.04*
ZI location	13 or 23 (canine) 16 or 26 (first molar)	3/19 7/68	84.2 98.7	0.23
Type of prosthesis	Toronto Zirconium Toronto Resin Ceramic Bridge	0/4 10/72 0/11	100 86.1 100	0.13
Implant design	Full threaded ZI Partialy threaded ZI	8/39 2/48	79.4 95.8	0.02*
Smoking	yes No	0/4 10/83	100 87.9	0.61
Total		10/87	88.5	

ZI: Zygomatic implant, I: Conventional implant, *$p < 0.05$.

– Peri-implant mucositis in three patients (involvement of eight ZIs) at 3 months of follow-up. Treatment: debridement with ultrasonic devices and Diode laser applications (Doctor Smile Dental laser, Lambda S.p.A., Brendola, Italy) as treatment modality for mucositis around the zygomatic implants. Chlorhexidine rinses for at least two weeks. All the mucositis cases were resolved without any further complications.
– Unilateral cutaneous fistula in one patient (involvement of two ZIs) after 8 months. Treatment: surgical intervention which included fistulectomy and simultaneous lipofilling.

No peri-implantitis was seen in any of the patients. There were no additional prosthetic complications. Percentage of ZI without complications was 88.5%. Details of the data including gender, reason for ZI, number of zygomatic and conventional implants, prosthesis type, ZI location, and complications are listed in Table II and Table III. No relation was found between implant success and smoking, prosthesis type, ZI location and antagonist dentition.

According to the results on an implant basis (Table II), female patients (p=0.03) and patients with previously failed conventional implants had greater probability of complication. Fully threaded design ZI had higher incidence of complications (all mucositis) than partially threaded design (p=0.02). The cumulative incidence of

Table III. Patient-based complication rates according to different characteristics.

Variable	Characteristics	Complications/Total number of patients	Success %	*p*-value
Gender	Male Female	1/19 3/16	94.7 81.2	0.20
Reason for ZI	Severe atrophic maxilla Previous implant failure	2/28 2/7	92.8 71.4	0.15
Antagonist dentition	Toronto Resin Fixed/ implant and/or natural teeth Removable prosthesis Toronto zirconium	3/8 1/23 0/3 0/1	62.5 95.8 100 100	0.02*
Number of ZI + I	1 ZI 2 ZI 3 ZI 4 ZI	0/1 2/25 None 2/9	100 92.0 - 77.7	0.21
Type of prosthesis	Toronto Zirconium Toronto Resin Ceramic Bridge	0/1 4/28 0/6	100 85.7 100	0.39
Implant design	Fully threaded ZI Partially threaded ZI	3/18 1/17	83.3 94.1	0.26
Smoking	yes No	0/2 4/33	100 87.8	0.79
Total		4/35	88.6	

ZI: Zygomatic implant, I: Conventional implant, *$p < 0.05$.

complications, evaluated by Kaplan-Meier analysis, was significantly higher in fully threaded as compared to partially threaded implants (p=0.015), being respectively 20.51% and 4.17% (Figure 4).

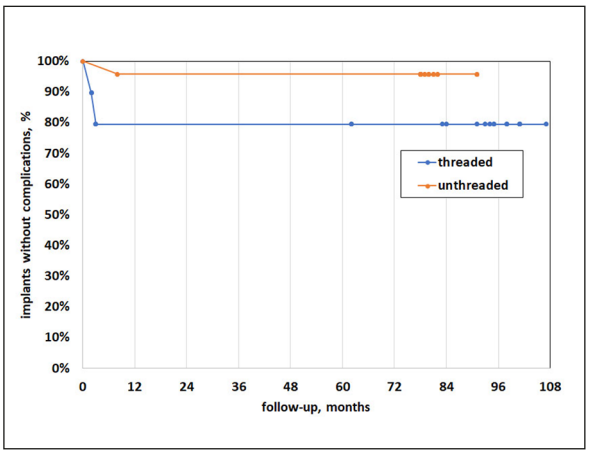

Figure 4. The cumulative incidence of complications estimated with Kaplan-Meier analysis, showing implants without complications and follow-up period.

When number of ZIs were compared among patients, it was seen that quad ZIs had higher incidence of complications than 2 ZIs (p=0.04). Additionally, there was just one case with 1 ZI and there were no cases with 3 ZIs inserted in the study, so those numbers were not included in the evaluation. When conducting the analysis using the patient as unit (Table III), only the antagonist dentition showed significant difference, the worst outcome being associated with the Toronto resin prosthesis (p=0.02).

Discussion

Zygomatic implants are considered advantageous especially for patients with failures of previous and repeated bone augmentation procedures and for patients wishing to avoid a bone graft procedure[14,17,23]. In literature, ZIs are reported to have high success rates with low incidence of complications. However, the complication rate associated with ZI insertions is not negligible, and this kind of surgery can be highly demand-

ing and can be associated with serious complications[19]. Possible critical postoperative complications of ZIs include fracture of zygomatic bone, sinusitis, soft tissue infection around the implants, paresthesia of the infraorbital or zygomatic facial nerves, formation of oroantral fistula, and implant failures[13].

In a recent systematic review, Wang et al[24] evaluated the reliability of ZI supported prostheses for the rehabilitation of the atrophic maxilla and reported mean survival rate of 96.7%. According to this report[24], orbital perforation was the most frequent complication. In another study, Maló et al[25] observed patient-specific and zygomatic implant-specific cumulative survival rates between 96.7% and 97.9%, with a follow-up between 6 months and 7 years[25]. Biological complications were rare (22.7%), and mostly resolved without major problems. Mechanical complications were more frequent (44%) and one third of the mechanical complications were seen in patients that were diagnosed with bruxism. In a similar study, Yates et al[18] reported 5-10-year survival rate of ZI as 86%. They concluded zygomatic implant insertion as viable and successful option when trying to restore the atrophic maxilla, with the potential to avoid additional augmentation/grafting procedures[18]. In a more recent study, D'Agostino et al[19] assessed complications related with ZI placement with 5 years of follow-up and found 97.41% cumulative survival rate with moderate prevalence of implants with altered conditions of the peri-implant tissues. In this present study, the follow-up period was minimum 7.5 years, and according to the results, there were no ZI failures. Additionally, the rate of complications was 12% (4 complications out of 35 patients). No relationship was found between location, prosthesis type, smoking status and implant success. Consequently, the results of this present study are in accordance with the high survival and low complication rates that are reported in literature by various authors[18,19,24,25].

According to a report by de Araújo Nobre et al[26], the most frequent biological complications for zygomatic implants are sinusitis, soft tissue infections, paresthesia, and oroantral fistula. Additional interventions are needed during the recall phase to resolve these situations[26]. In this work, no sinusitis, soft tissue infections, paresthesia, and oroantral fistula was seen as a complication. The surgical procedure performed was "the extra-sinus technique" and the advantages of this protocol include the elimination of maxillary antrostomy or the creation of a slot, which can result in improved direct visualization during the whole procedure. Furthermore, it is favorable for better biomechanics in terms of superstructure prosthesis design and have shorter cantilevers due to implant positions[12,25]. Another advantage of this technique is the decreased risk of perforation of the maxillary sinus membrane. Even in such cases, sinus perforations would be at higher and more posterior point in the maxillary sinus, when compared to the classical technique. Since the main part of implants' body is positioned outside of the sinus, the risk of sinusitis can decrease dramatically[11,13,27,28]. In this study, none of the patients had sinusitis and, according to the opinion of the authors, "the extra-sinus technique" that was utilized had an important role in this result.

Several authors had investigated the effect of conventional implant design and surface properties on peri-implantitis and peri-implant mucositis. Jokstad et al[29] in a recent systematic review, evaluated the role of implant design in the rehabilitation of the edentulous maxilla with conventional implants and reported the lack of compelling data to state that a particular implant system or design feature stands out amidst others[29]. Reports[30-32] on conventional implants show no evidence that implant surface characteristics or design can have a significant effect on the initiation of peri-implantitis. In literature, there is a lack of reports evaluating ZI design. In this study, ZI design was evaluated and, according to the results, 3 of the patients (out of 35 patients) had manifestations of mucositis (3 months after surgery) around 8 zygomatic implants with fully threaded design. There was no peri-implant mucositis seen in the implant design that utilized partially threaded design (unthreaded crestal long body with 12.5 mm apical threaded part). The difference was statistically significant. Fully threaded design ZI had higher incidence of mucositis than partially threaded design (p=0.02). The cumulative incidence of complications was significantly higher in fully threaded as compared to partially threaded implants (p=0.015), being respectively 20.51% and 4.17%. Initially, due to the higher frequency of the peri-implant tissue problems associated with the patients that received fully threaded design ZIs, partially threaded design was utilized as an alternative solution. However, this choice of application was based on a clinical observation

and had no scientific basis. Additionally, this type of partially threaded design utilized "the extra-sinus technique". According to the opinion of the authors of this work, unthreaded crestal long body might be an important factor for prevention of peri-implant tissue complications, such as mucositis and/or peri-implantitis, and sinusitis. However, further studies are needed to confirm this statement.

Ashnagar et al[33], in a recent literature review, evaluated the effect of lasers on conventional implants and reported positive outcomes after 6 months of follow-up[33]. In this study, the peri-implant mucositis manifestations were all treated by Diode laser applications (Doctor smile dental laser, Lambda S.p.A., Brendola, Italy) without any major efforts and with success. No further peri-implantitis was seen in any of the patients.

The relation between periodontal health status and ZI periimplantitis was assessed by Lombardo et al[34]. As a result, they reported no differences in crestal bone loss and periimplantitis between patients with periodontal problems and patients with no-periodontal problems' history[34]. The result of the present study was in accordance with this statement, since one of the patients in this study had a previous history of periodontal disease and, after a follow-up of 98 months, had no problems regarding either ZIs or prosthesis. No other soft tissue problems were seen in any of the patients. Strict oral hygiene training and careful prosthetic planning in the clinic might be the key factor in achieving this successful result.

In the present study, one patient had inflammation of the soft tissues with an external cutaneous fistula. The latter, which was seen after 8 months, was treated by fistulectomy and simultaneous lipofilling in two consequent surgeries. In the first surgery, under unconscious sedation, fistulectomy and lipofilling operations were performed with success and complete healing was achieved. However, due to some aesthetic concerns of the patient, an additional lipofilling was applied to the site in the following six months.

According to the results using the implant as unit, female patients (p=0.03) and patients with previously failed conventional implants had greater probability of complication. Additionally, it was seen that quad ZIs had higher incidence of complications than 2 ZIs (p=0.04). According to the results using the patient as unit, Toronto resin prosthesis (as antagonist dentition) showed a significant difference (p=0.02). However, according to the opinion of authors, it would be improper to declare this as statement. First, results are conflicting among them (as results for implant as unit and patient as unit are different). Secondly, the number of patients that was included was low. Controlled studies with larger groups are needed to assess the long-term prognosis for this technique.

According to the literature, maxillary sinus augmentation is a successful and predictable intervention with low complication rates, and the survival rate of dental implants has been reported to be above 90%[34]. However, the implant success can be affected by a variety of patient- implant-, surgery-, prosthesis-related factors like age, gender, implant size, implant shape, material of implant, length and diameter, location of implant, and bone quality. Studies evaluating long term results (with minimum 6 years of follow-up) are important to understand the critical factors that can influence the successful results[35,36]. The main reason for selection of zygomatic implant insertions among alternatives is mostly based on increasing demand from the patients for more economic options in less time. In this study, the survival rate of ZIs was found as 100% and percentage of ZIs without complications was 88.5%, which can make ZIs an attractive alternative.

The main rationale for this investigation is the minimum 7.5-year follow-up assessment of ZI surgical protocol to evaluate long-term ZI survival rate and the interrelation between complications and success for rehabilitation of extremely resorbed maxilla. According to the results of this study, high survival rate and low complications were found with ZIs. High success rate could mainly depend on the expertise of the single surgeon that had performed the interventions, careful planning (both surgical and prosthetic), and strict oral hygiene protocol. However, this extremely challenging procedure should never be underestimated.

Limitations

The limited sample number and retrospective design of this study can be considered as main limitations. Future studies should focus on longer follow-up periods with at least 10-year outcomes with comparison of implant designs and novel techniques, such as guided zygomatic surgery.

Conclusions

There is an increasing interest in literature for oral rehabilitation with zygomatic implants in

patients with extremely atrophic maxilla; however, there is currently still a limited number of reports evaluating this type of treatment modality with long follow-up periods and large groups of patients.

As a conclusion, insertion of zygomatic implants can be considered as an effective and safe alternative to conventional treatment modalities. However, further prospective randomized controlled studies with larger groups are needed to assess the long-term prognosis for this technique.

Conflict of Interest

The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

Ethics Approval

The study protocol followed the principles laid down in the Declaration of Helsinki on medical protocol and a signed informed consent agreement form was obtained from all the patients before the procedures. Institutional Review Board approval of the Orthopedic Institute Galeazzi was obtained for retrospective studies on implants, with number 2552377-L2058.

Informed Consent

All patients signed an informed consent form before being enrolled for this study.

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Authors' Contribution

F.Go., F.Gr., E.G., M.D.F., E.L.A., F.R.P.B., A.G.L., A.B.G. and C.M. conceived and designed the analysis. Databases were searched and data was collected by F.Go., F.Gr., E.G., and M.D.F. All the authors contributed on analysis and interpretation of data for the work. F.G. drafted the work and wrote the manuscript with input from all authors. F.Go., F.Gr., E.G., M.D.F., E.L.A., F.R.P.B., A.G.L., A.B.G. and C.M. revised the work critically for intellectual content. Integrity of the work was appropriately investigated and resolved by all authors. All authors contributed and approved equally to the final version of the manuscript.

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