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Zygomatic implants for rehabilitation of patients with oncologic and congenital defects: A case series

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Title: Zygomatic implants for rehabilitation of patients with oncologic and congenital defects: a case series

Running Title: Zygomatic implants for oncologic patients

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ABSTRACT:
This case series aimed to assess the clinical outcomes of oncologic patients rehabilitated with a zygomatic implant-supported prosthesis. Ten oncologic patients who underwent upper jaw resections due to cancer were enrolled in the study. Zygomatic implants were utilized for rehabilitation according to specified inclusion criteria. Surgical and prosthetic procedures were standardized, and implant and prosthetic survival rates, along with complications, were evaluated. The study cohort comprised 10 patients with a mean age of 66.5 years. A total of 35 implants were placed, with a survival rate of 94.29% at the mean follow-up of 5.78 years. Biological complications affected 40% of patients, while prosthetic complications occurred in 40% of patients, necessitating modifications but with no outright failures. Zygomatic implants offer a viable solution for oncologic patient rehabilitation, particularly in cases where bone grafting is contraindicated or impractical. However, they present medium- to long-term complications that warrant careful consideration. Future research should focus on larger studies and meta-analyses to provide more robust evidence.

Keywords: zygomatic implants, oncologic, prospective study, atrophic jaws

INTRODUCTION

The integration of state-of-the-art 3D technology is indispensable for optimizing reconstructive surgery post-cancer resection. This is generally true in all major surgeries including head and neck treatments (Antúnez-Conde et al., 2021). Within maxillofacial surgery, a digital approach holds promise in streamlining procedures through Computer-Aided Design and Computer-Aided Manufacturing (CAD/CAM) techniques for restorative plates (Tarsitano et al., 2021), alongside the utilization of cutting guides and real-time navigation to execute surgeries as planned digitally. Moreover, the application of these technologies extends to dental arch restoration, facilitating the restoration of masticatory function and aesthetics.

This allows the surgeon to achieve the best position for the bone graft and place the dental implants in an optimal position (Felice et al., 2022) (King et Al, 2017). Nonetheless, long-term studies reveal that standard implants placed within fibula-free flaps are predisposed to greater inflammatory issues compared to those situated in normal bone (Pellegrino et al., 2018) (Kumar et Al, 2016).

Despite the established gold standard of bone reconstruction and standard implant-supported prosthetics (Soardi et al, 2013), various impediments such as overall health conditions or complications during bone graft healing may preclude such procedures (Stacchi et al, 2017). In cases where bone grafting is contraindicated or not feasible, alternatives to traditional implants must be explored. Customized subperiosteal implants have been proposed as one such alternative, particularly for patients with severe maxillary atrophy. These implants are custom-designed and tailored using advanced 3D imaging and CAD/CAM technology to fit the patient's specific bone anatomy, ensuring precise adaptation and optimal support, making them suitable for complex or compromised cases. (Onică N et, 2024).

To treat severe maxillary bone atrophy, zygomatic implants also have been used as an alternative to bone grafting. (Varghese et al, 2023) (Pellegrino et al, 2020) (Grecchi et al, 2022) While existing literature predominantly focuses on upper jaw treatment for bone atrophy (Vaira et al, 2024), recent data have begun to explore its applicability in oncologic patient restoration, boasting high success rates across both atrophic and oncologic case (Martens et al, 2016).

The potentiality of oncologic rehabilitation sans bone grafting using zygomatic implants heralds manifold benefits, particularly in scenarios involving elderly or health-compromised patients where bone grafting may pose contraindications. Moreover, the advent of new technology facilitates a comprehensive three-dimensional assessment of patients and preoperative implant planning with a complete visualization of residual bone.(Gallo et al, 2023) (Pellegrino et al, 2020)

While some authors have proposed zygomatic implant-based rehabilitation post-cancer resection as an alternative to reconstructive surgery, the extant literature is marked by a paucity of data, with most available evidence being retrospective.

In light of this, our prospective study aims to assess the clinical outcomes of oncologic patients rehabilitated with a zygomatic implant-supported prosthesis.

MATERIALS AND METHODS

From October 2013, the study enrolled nine patients who had undergone upper jaw resections due to cancer, alongside one patient with a congenital malformation requiring rehabilitation in a prospective cohort study approved by the ----- ----- ---- ------ (approval number093/2013/O/Sper), ----, ------. The study was conducted according to the principles outlined in the Declaration of Helsinki on experimentation involving human subjects. Each patient gave his informed consent to participate in the study.

All patients were in good general health and had been cancer-free for at least one year at the time of enrolment.

Inclusion criteria were specified as a necessity for zygomatic implants due to the lack of native bone capable of supporting standard implants, and for individuals undergoing cancer resection surgery resulting in soft tissue only reconstructions without the use of bone grafting. This also extended to patients who experienced unsuccessful outcomes from previous reconstructive attempts where bone grafting was either contraindicated or declined. A declaration of good general health was required for participation.

Exclusion criteria encompassed the availability of alternative treatments involving bone grafting and standard implants, ongoing drug therapies that contraindicated surgery, and health conditions deemed insufficient to withstand the proposed surgical interventions.

Functional defects were classified based on criteria established by Brown (Brown et al, 2000) and Pellegrino (Pellegrino et al, 2015).

The resection, reconstruction type, radiation therapy, and smoking habits were recorded.

Prior to surgery, all patients underwent Cone Beam Computed Tomography (CBCT) and surgical planning utilizing specialized implant planning software (Implanav, Bresmedica, Australia). For some patients, dynamic navigation systems were employed during implant placement.

Surgical procedure

The surgeries were performed under general anesthesia, supplemented by the local administration of an anesthetic with a vasoconstrictor (mepivacaine+adrenaline 1:100,000).The surgical procedure involved creating a full-thickness flap up to expose the anterior malar bone skeletonisation, followed by the implant site preparation. This preparation involved the use of rotary drills in a sequence recommended by the implant's manufacturer.In some cases, an ultrasonic tip was also used to prepare the implant site's initial part. Alternatively, some procedures utilized a guided implant site preparation technique with the aid of a navigation system. This system facilitated real-time tracking of the drill, ensuring adherence to the pre-planned trajectory.

Then the zygomatic implant (Oncology and Zyg, Southern Implants, Irene, South Africa) was screwed using a handpiece driver, and the positioning was completed manually. After the positioning of the conical abutments, the sutures were carried out.

Prosthetic procedure

Two customized impression trays reproducing the dental arch were preventively prepared. The design of the first tray featured an open palatal section resting on the median palatal mucosa, which

facilitated the accurate positioning of transfer abutments.. The transfer abutments were splinted using photo-luting hard DuraLay resin (Reliance Dental Manufacturing, Worth, Ill) with the tray and together. Then, a polyvinyl siloxane material (3M, Two Harbors, Minnesota, United States) was injected into the free space above the dental tray. The second tray, reproducing the patient's denture and maintaining a stand onto the palatal mucosa only in the median part, was used for taking a second impression of occlusion on the healing abutments.

Within 72 hours, a screw-retained prosthesis was delivered and functionally checked. In case of doubt on the correct occlusion check, an intermediate proof was made after 48 hours.

Outcomes

The implant and prosthetic survival and clinical success rate were evaluated. The implant and prosthetic success were evaluated according to the clinical criteria proposed for the zygomatic implant (Pellegrino et al. 2020) (D'Agostino et al, 2021). Implant survival was defined as the absence of failure and the maintenance of the implant function. In case of implant failure during the follow-up, the failure time was recorded, and the event was considered a censored event.

Clinical success for the implant was defined based on several key criteria: the implant had to remain intact and in position without causing pain, exhibiting rotation, inducing bleeding or pus formation, or causing soft tissue inflammation. Any inflammation that persisted despite enhanced oral hygiene practices and the application of local disinfectants was considered as unsuccessful.

Prosthetic survival, meanwhile, was determined by the ongoing functionality of the prosthesis. A prosthesis was considered successful if it remained fully supported by all implanted fixtures, extended to at least the first molar without any need for reduction in prosthetic extension from the initial day of delivery to the final follow-up evaluation.

Throughout the study, both minor and major complications, along with any adverse events, were closely monitored and recorded by a blinded operator, ensuring an unbiased assessment. This comprehensive recording included both biological and mechanical complications, as well as any radiographic signs of pathology that emerged, providing a thorough evaluation of the implant and prosthetic outcomes.

RESULTS

The study cohort consisted of 10 patients with a mean age of 66.5 ± 13.61 years, ranging from 48 to 88 years, including seven males and three females. The diagnoses varied: five patients presented with squamous cell carcinoma (SCC), one with osteoblastic osteosarcoma, two with adenoid cystic carcinoma, one with mucoepidermoid carcinoma, and one patient had a cleft outcome, included in the study due to the related anatomical defect.

Functional defects were classified based on criteria established in a previous research by Pellegrino: one patient was categorized as class I, two as class IIa, four as class IIb, two as class IIc, and one as class III.

According to the Brown classification system for maxillectomy defects, the distribution was four type 2a defects, two type 3a, one type 2b, and one type 1. Additionally, two patients exhibited maxillary atrophy resulting from radiotherapy. **(Table 1)**

Primary reconstruction aimed to achieve oro-nasal communication closure in seven patients, utilizing various techniques: three patients underwent reconstruction with a temporalis muscle flap,

three with an anterolateral thigh microvascular flap, and one with a microvascular fibula flap. One instance of fibula free flap failure due to venous thrombosis occurred in the first postoperative week, necessitating a secondary reconstruction with an anterolateral thigh flap.

The mean follow-up period after implant surgery was 5.78 ± 2.87 years, ranging from 13 to 120 months. During this period, five patients died: one at 13 months, one at 48 months, two at 60 months, and one at 76 months after implant placement. The causes of death were a relapse in one case and other general pathologies in the remaining four cases.

Across the 10 patients, a total of 35 implants were placed, averaging 3.5 implants per patient. The implant survival rate at the mean follow-up was 94.29%, with two noted failures **(Graph 1).** The first failure occurred at 8 months but did not affect the final prosthetic outcomes, while the second, removed at 60 months due to infection likely stemming from the zygomatic implant, which did affect the final prosthetic outcomes, resulting in the prosthesis being shortened. This infection caused a biological complication, resulting in an extra-oral fistula with minor exposure of a reconstructive mesh in the orbital floor.

In total, 5 biological complications ensued, affecting 4 out of the 10 patients (40%). Specifically, 3 instances of mucositis were recorded, two arising at the 3-year juncture and one at the 5-year mark, all successfully managed with 0.20% chlorhexidine mouth rinses, resulting in complete regression. An oro-antral communication occurred post-surgically, spontaneously resolving within the initial 6 months. Lastly, at the 5-year follow-up, peri-implantitis with cutaneous fistula was observed, the etiology of which remains uncertain, whether originating from the orbital floor mesh or the implant-associated infection. (**Fig.2**)

Prosthetic complications were recorded in 7 instances across 4 out of 10 patients (40%), necessitating prosthetic modifications, specifically a reduction of the occlusal plate to less than the first molar. These complications included 1 prosthetic fractures, 1 shortened prosthesis, 1 chipping at the incisor level, 3 instances of screw loosening, and 1 flattened screw, resulting in a 60% success rate at the patient level for prosthetic outcomes. Notably, no prosthetic failures were observed.

DISCUSSION

The rehabilitation of oncologic patients with zygomatic implants remains under evaluation. Published studies lack uniform data, and the types of prosthetic rehabilitation vary significantly. Standardizing treatment for these patients is challenging due to the diverse extent of surgical resections and patient anatomies. Factors such as the choice of reconstructive technique, healing processes, scarring, and postoperative complications add layers of complexity to the decision-making process.

The adoption of mobile obturator prostheses for younger patients is debated among professionals, with follow-up durations typically spanning short to medium terms. Notably, long-term follow-up data, are few, with the literature comprising mainly case reports, retrospective studies, and a limited number of prospective studies (Hackett et Al, 2021). The absence of randomized controlled trials (RCTs) makes it difficult to generate robust scientific evidence. Due to the small number of patients treated in this study making strong or generalized conclusions is challenging.

The survival rate of zygomatic implants in oncologic patients is generally high and aligns with findings from other studies. This rate, alongside the nature and frequency of complications, appears comparable to those reported in patients with atrophic jaws. This study highlights specific complications, such as peri-implant soft tissue inflammation, which were effectively managed with topical chlorhexidine applications. Notably, one implant failure was attributed to prosthetic issues, underscored by a patient's report of an unscrewed prosthesis over several months. In another instance, a subocular fistula developed five years post-operation in a patient who had undergone orbital floor reconstruction with a custom titanium mesh, raising questions about the infection's origin, but the implant, while osseointegrated, was removed.

The observed prosthetic success rate is lower than that typically seen with standard zygomatic implants, likely due to the impact of scar tissue on masticatory function, leading to mucosal trauma. Modifications to the prosthesis post-delivery were often required to address these issues. This variability makes it difficult to standardize cases and highlights the significant reliance on the expertise of the surgical-prosthetic team.

CONCLUSIONS

This study highlights the challenges in long-term follow-up of these types of rehabilitations due to the advanced age of the patients, their systemic comorbidities, and the risk of relapse. Given the limited data and the small number of patients treated, definitive conclusions are challenging to draw. While the technique shows promise, it is not without its medium- to long-term complications.

Consequently, the zygomatic implant approach should be considered a secondary option in case of bone grafting failure, or particularly when bone grafting is not viable or in elderly patients who are not candidates for major reconstructive surgery. For younger patients or those with non-malignant conditions, the latest reconstructive techniques using CAD/CAM technology may offer more sustainable rehabilitation options, yielding better aesthetic outcomes and reducing the immediate need for zygomatic implants. Further research, including more studies and meta-analyses, is essential to validate these findings.

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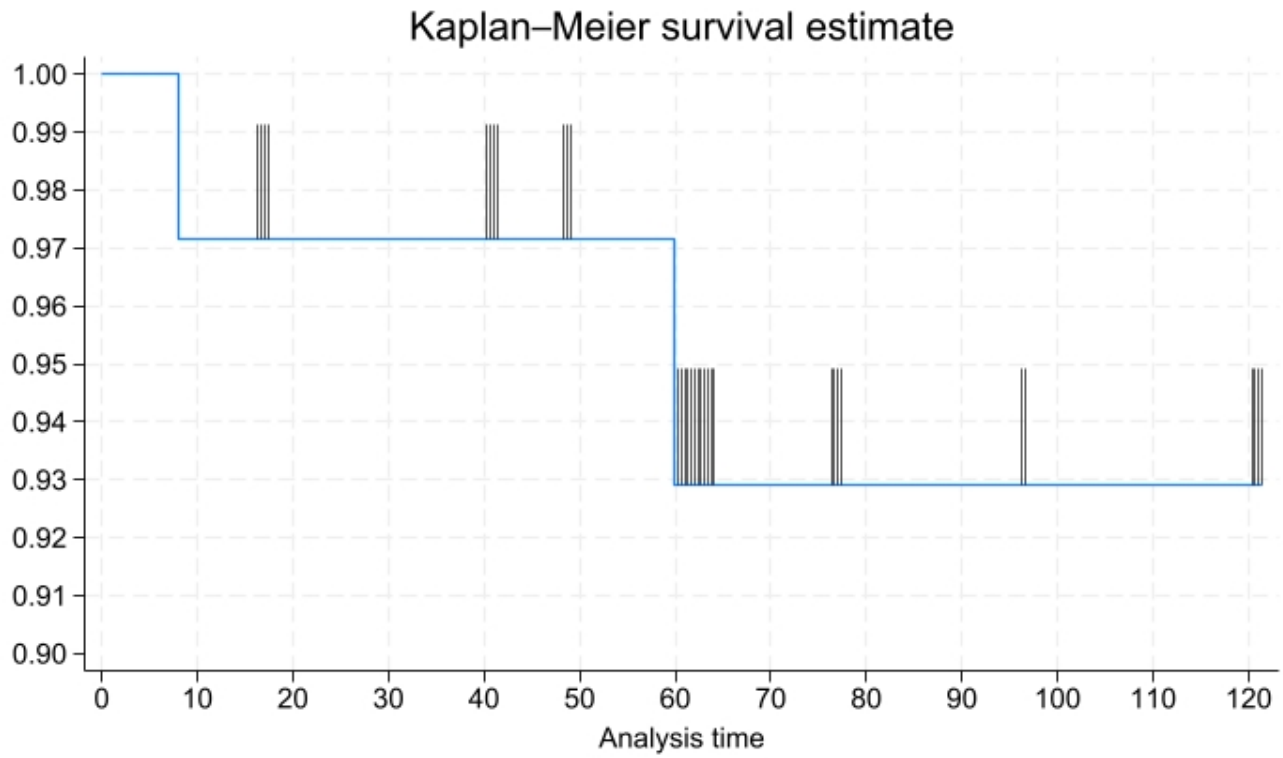
FIGURES AND LEGENDS



Graph 1: Kaplan-Meier survival estimate of the 35 implants. Time (in months) is represented on the x-axis, while cumulative survival is depicted on the y-axis. Vertical tick marks are present to indicate censoring.

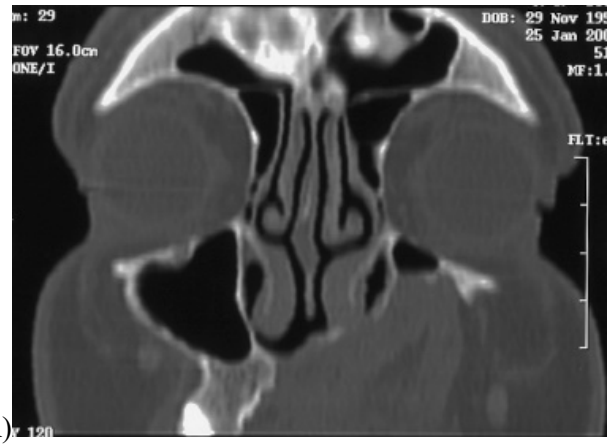
Patient number	Age (yr)	Diagnosis	Brown's classification	Zygomatic Implants	Bone defect classification
1	59	OSCC	2b (left)	3	IIA
2	74	ACC	1 (left)	4	IIC

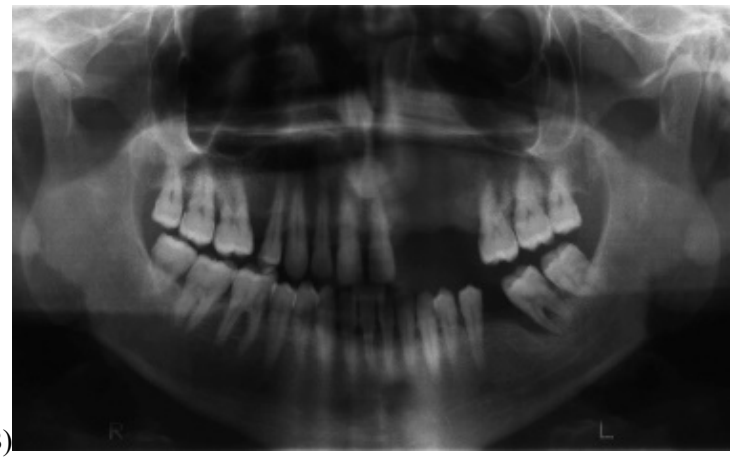
3	52	cleft	/	4	III
4	69	Osteoblastic osteosarcoma	2a left)	4	IIB
5	87	OSCC	2a (left)	4	IIB
6	65	OSCC	2a (right)	4	IIB
7	88	OSCC	2a (left)	4	IIB
8	67	OSCC +RT		4	IIC
9	48	ACC	3a (left)	2	I
10	56	Mucoepidermoid carcinoma	3a (left)	2	IIA

Table 1: This table provides an overview of patient characteristics and details regarding zygomatic implants. Patient data includes age in years, diagnosis, Brown's classification of maxillectomy defects, and bone defect classification. Zygomatic implant information includes the number of implants placed per patient. Abbreviations: ACC, adenoid-cystic carcinoma; OSCC, oral squamous cell carcinoma; RT, Radiotherapy.

Figure 1: Example of a clinical case of zygomatic implant placement.

A) B) C) Pre-operative imaging and clinical photographs of the underlying pathology, including CT scan, panoramic radiograph (OPT), and clinical photos. D) E) F) Clinical photographs, including facial photos and post-resection panoramic radiographs of the upper maxilla reconstructed using a pedicled temporalis muscle graft. G) Placement of three zygomatic implants (Southern Implants, ONC). H) I) J) One-year clinical and radiographic follow-up after immediate prosthetic loading, including facial photographs. K), J) Ten-year clinical and radiographic follow-up after prosthetic loading

A) 

B) 

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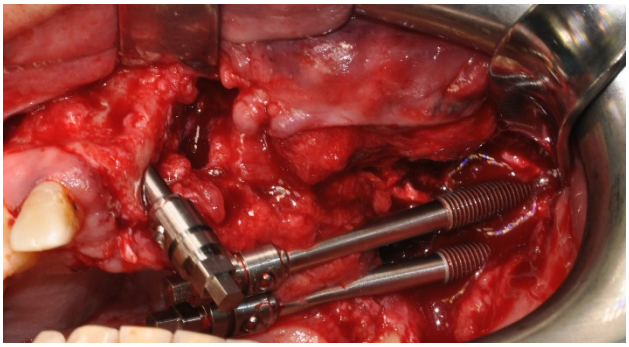
G) 

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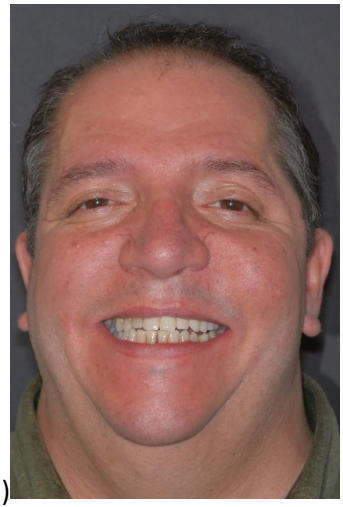
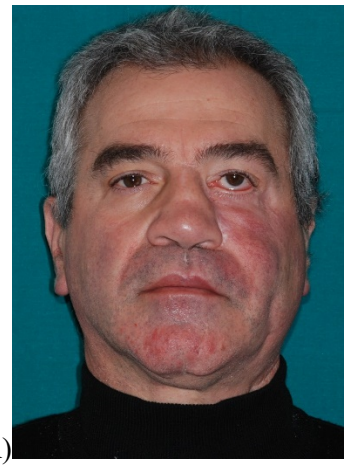
J) 

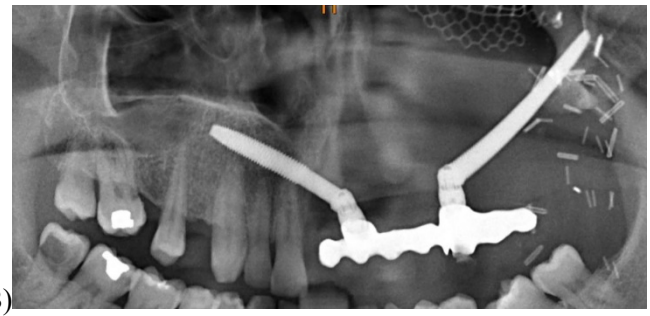
K)

L)

Figure 2: Case of complication

A-C) Clinical photographs of the face, panoramic radiograph, and intraoral photograph at 3 years of follow-up. D) Presence of cutaneous fistula at 5-year follow-up. E) Clinical follow-up photograph of the face at 10 years. F) Intraoral follow-up photograph at 10 years showing the distally shortened prosthesis. G) Panoramic radiograph at 10-year follow-up showing the residual zygomatic implant.

A) 

B) 

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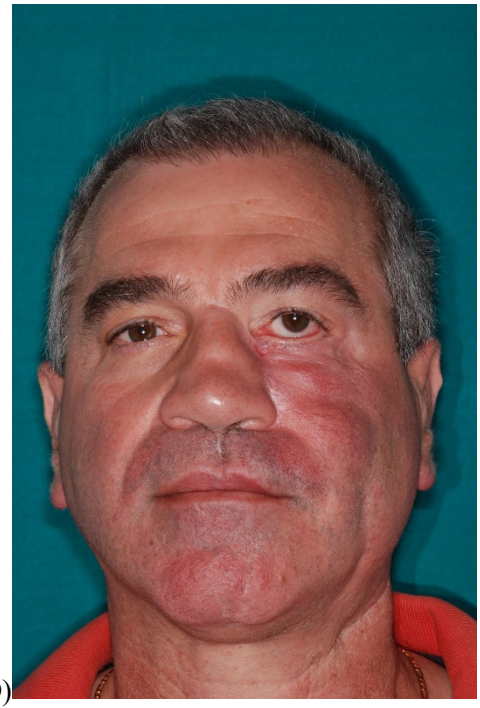
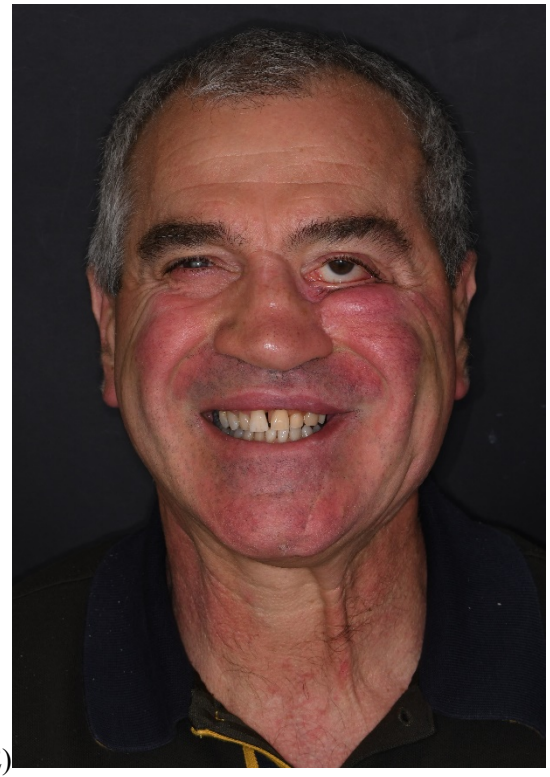
D) 

E) 

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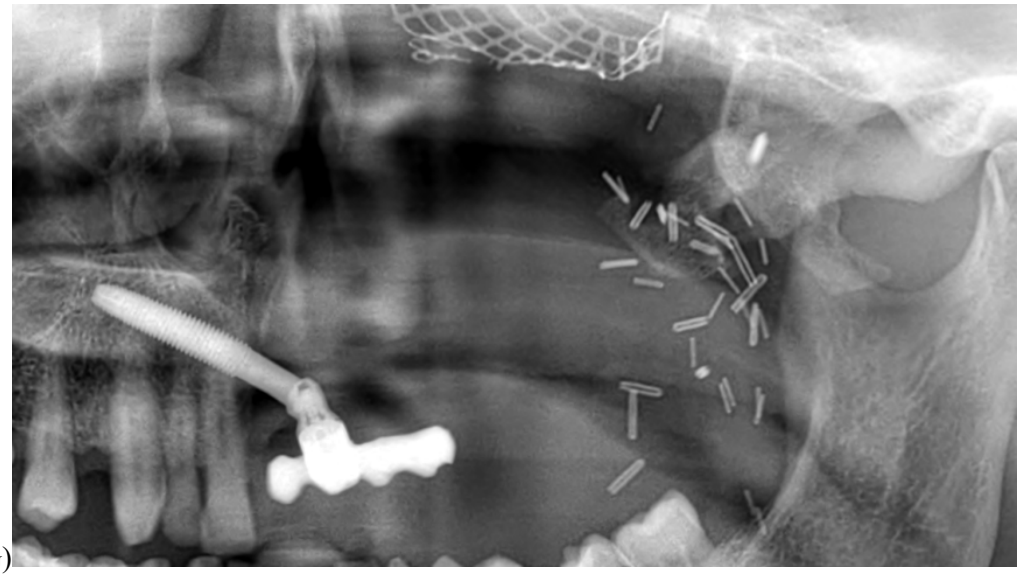
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