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ORIGINAL ARTICLE

Hygienic maintenance in patients with maxillae atrophy and in oncological patients with maxillary resection rehabilitated with zygomatic implants: A nested monocentric prospective cohort study

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Abstract

Objective: To assess peri-implant soft tissues condition, comparing clinical parameters of implants placed in patients with atrophic upper jaws and patients who underwent maxillary resection for oncological reasons.

Background: Zygomatic implants (ZIs) in oncologic patients could be affected by more complications compared to implants placed in atrophic maxillae. The soft tissue condition is an essential requirement for implant success, but few studies have investigated this topic.

Methods: A nested monocentric prospective parallel cohort (atrophic vs. oncological patients) study was performed. Clinical visits and professional hygiene sessions were performed every three months, and bleeding on probing (BOP), probing pocket depth (PPD), gingival index (GI), plaque index (PI) and implant mobility were recorded by a blind outcome assessor.

Results: In total, 77 ZIs placed in 21 patients were evaluated: 54 (70.1%) ZIs were inserted in patients belonging to the atrophic cohort (PAM) and 23 (29.9%) ZIs in the oncologic cohort (OP). The probability of having BOP at the considered mean follow-up (27 months) was 24.8% (95% CI 19.0–31.9) for PAM and 22.9% (95% CI 15.1–33.9) OP. The mean PPD values were 2.78 ± 1.28 (range 1–8) in PAM and 2.91 ± 1.98 (range 0–10) in OP. None of the implants showed mobility. No associations between group belongingness and the entity of PPD, PI, GI and the risk of BOP were found, adjusting for the considered confounding factors (age, smoking and implant position).

Conclusions: Under a strict supportive hygiene therapy protocol ZIs in oncologic patients showed similar peri-implant tissue conditions to that of patients with maxillary atrophy.

KEYWORDS
atrophy, hygiene maintenance, oncologic resection, oral hygiene, peri-implant soft tissues, zygomatic dental implants

1 | INTRODUCTION

In patients with severely atrophic maxillae, zygomatic implants (ZIs) represent an alternative to conventional bone augmentation and implant rehabilitation with the advantage of rapid functional restoration.[1] ZIs in the rehabilitation of severe maxillary atrophies and defects showed a >95% survival rate after nearly 13 years of follow-up.[2] The high success rate reported in patients with atrophic maxillae has promoted the use of this technique to rehabilitate patients who have undergone maxillary resection for oncologic reasons.[3]

Some authors reported a lower success rate of ZIs placed in oncologic patients rather than implants placed in atrophic maxillae.[4,5] Moreover, ZIs appeared associated with more complications such as soft tissue problems,[1,6,7] like gingival hyperplasia, and BOP.[8] Plaque retention and consequent onset of mucositis and peri-implantitis could be facilitated by threads and the rough surface of the coronal portion of the zygomatic implant.[9] Another risk factor affecting the success of ZIs placed in resected patients could be represented by the implant emergences often placed in a palatal position and still bound by the residual bone. The palatal implant emergences position often causes a prominent prosthetic profile, creating food impaction and difficulties in plaque removal. A preoperative implant planning guided by the prosthetic plan[10] and based on anatomical landmarks,[11] or static surgical guides[12] or dynamic[11] navigation systems could address this problem but not completely solve it due to the limited residual bone.[13] The soft tissue condition is an essential requirement for implant success, but few studies investigate this topic. The present study, by monitoring over time soft tissue clinical parameters, could suggest if a systematic hygiene maintenance program guarantee high zygomatic implant success in oncologic patients.

The present study aimed to assess the peri-implant soft tissues condition of patients rehabilitated with ZIs, comparing clinical and hygienic parameters of implants placed in patients with atrophic upper jaws and patients who underwent maxillary resection for oncological reasons.

2 | MATERIALS AND METHODS

2.1 | Study design and participants

The study was designed as a nested monocentric prospective parallel cohort study.

Nested studies hierarchically cocoon a proposed substudy into an existing parent study and are conducted concurrently and jointly with the parent study instead of after and/or separately. The initial eligible cohort was represented by patients treated in "Oncozygoma" and "Zygoma" studies[1,2] (Unit of Oral and Maxillofacial Surgery, Department of Biomedical and Neuromotor Science of the University of Bologna). Being a nested study, that is a study design in which participants are selected from a parent study focusing on new study questions and outcomes, a cohort of oncological patient from "Oncozygoma" study was selected and a cohort of atrophic patients from "Zygoma" study was selected Oncozygoma and Zygoma studies included, respectively, 11 and 17 patients.

These patients had severe maxillary atrophy or poor residual maxillary bone resulting from a neoplasia resection. In this nested study, the cohort of oncological patients included only patients which were affected by squamous oral cancer; the selection of patients in atrophic cohort was based on matching criteria (age and sex) with the oncologic group. All patients underwent ZIs placement and fixed prosthetic rehabilitation.

All consecutive patients attending the Unit of Oral and Maxillofacial Surgery (Department of Biomedical and Neuromotor Science of the University of Bologna) for the periodical follow-up visits were included. The patients were divided into two cohorts: one cohort included patients ($n = 14$) affected by severe atrophy of the upper jaw (PAM); the other included patients ($n = 7$) who underwent maxillary resection for oncologic reasons (OP). All the patients were rehabilitated with ZIs immediately loaded with fixed Toronto prosthesis for at least three months in January 2018.

Since the main indication for rehabilitation with ZIs is represented by maxillary atrophy, we used that group of patients as a control group. After the rehabilitation, all the patients received instructions for correct daily home hygienic maintenance.

The study was conducted following the principles of Good Clinical Practice [ICH Harmonized Tripartite Guidelines for Good Clinical Practice 1996 Directive 91/507/EEC; DM 15.7.1997], the Declaration of Helsinki, and national regulations on the conduct of clinical trials, and informed consent was obtained by all the participants.

The Ethics Committee of S. Orsola-Malpighi University Bologna approved the study protocol (093\2013\O\SPER). The study reporting followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

2.2 | Outcome definition and assessment

The outcomes were BOP, probing pocket depth (PPD), gingival index (GI), plaque index (PI) and implant mobility.

2.3 | Clinical examination

Patients were invited to follow a supportive therapy program with quarterly sessions during which clinical parameters were recorded. The clinical measurements were performed by a blind outcome assessor using a periodontal probe (PDT Sensor Probe Type Roy/STM 2-3-4-5-6-7-9, DenMat®). The mean follow-up from the insertion of the implants was 27.82 months (range: 6–40 months).

Clinical parameters were assessed at each zygomatic implant's mesial, distal, palatal and vestibular aspects, maintaining the

prostheses in situ. The prostheses were removed in 19 patients as the parameters assessment was difficult to perform. Only two prostheses (1 in PAM and 1 in OP group) were not removed.

PPD was measured, from the mucosal margin to the bottom of peri-implant pocket using a plastic probe. BOP was recorded as present/absent within 30 s after probing.

The presence of plaque was detected and recorded using the modified PI[14,15]: to each implant surface a value ranging from 0 to 3 was assigned.

GI score measures the severity of inflammation in the mucosa. The degree of inflammation was scored from 0 to 3.[14–17] Implant mobility was rated as absent or present (Figure 1).[6]

2.3.1 | Statistical analysis

A descriptive analysis was performed, presenting continuous variables as mean ± standard deviation (SD); categorical variables were presented as absolute and relative frequencies. BOP, PI and GI probability over time were assessed using Kaplan–Meyer curves and life tables. Inferential analysis with a mixed-effects Cox regression model, and a multilevel linear regression model was performed to compare the two cohorts in terms of BOP risk, PPD, GI and PI.

The levels of the hierarchical models were patients and implants. The models were adjusted for the following confounding factors: age, smoking and implant position (anterior or posterior emergence). The significance level was set at 0,05. All the analyses were performed using Stata, version 15 (Stata Corp LP).

FIGURE 1 Clinical assessment of bleeding on probing (BOP) with removed prosthesis.

2.4 | Sample size calculation

The estimated sample size for a two-sample proportions test, with a power of 0.80, an alpha error of 0.05, an estimated effect size of 0.25 (delta) and expecting a 10% dropout, was 75 implants. The outcome used for the sample size calculation is BOP. In this calculation that considers proportion of 2 groups, p1 and p2, ds is not used, but parameters like delta between the two values, that is, in this case, an estimate obtained from our pilot studies, the critical value of the normal distribution at $\alpha/2$ and the critical value of the normal distribution at β.

3 | RESULTS

3.1 | Participants

Twenty-one patients with 77 ZIs placed who met the previously mentioned inclusion criteria were included in the study: 7 oncologic patients and 14 patients with maxillae atrophy. Patients' and implants' baseline characteristics are summarized in Table 1. For OP treated with radiotherapy, the dose of radiation ranged from 60 to 63 Grey, and intensity-modulated radiation therapy was used. Smoker patients reported a frequency of fewer than ten cigarettes per day. No patient with diabetes was enrolled in this study. In 17 patients (80.95%), 4 implants were placed; in 3 (14.29%) patients, the inserted implants were 2 and in one patient (4.76%), 3 implants were placed.

3.2 | Bleeding on probing (BOP)

Results are summarized in Table 2.

The probability of having BOP 6 months after implant placement was 5% for PAM, while for OP was 0%; at the considered mean follow-up (27-months) and at 40-months follow-up, for PAM this probability rose, respectively, to 24.8% and 39.8%, and 22.9% for OP (Figure 2).

The risk of BOP was not associated with the group variable (oncologic/atrophic, adjusting for the confounding factors age, smoking and position).

3.2.1 | Probing pocket depth (PPD)

The mean PPD values were 2.78 ± 1.28 (range 1–8) in PAM and 2.91 ± 1.98 (range 0–10) in OP. Adjusting for the considered confounding factors, no association between the entity of PPD and groups was found.

3.2.2 | Plaque Index (PI) and Gingival Index (GI)

All the patients in both groups presented adequate keratinized mucosa surrounding the implants.

	Total	Oncologic	Atrophic
Patients (*n*)	21	7	14
Age (years ± SD)	65.9 ± 13.3	67.4 ± 12.7	65.2 ± 14.1
Males, %	11 (52.4)	4 (19.1)	7 (33.3)
Smokers, %	9 (42.8)	3 (42.8)	6 (42.8)
Radiotherapy, %	5 (71.4)	5 (71.4)	0
Implants (*n*, %)	77	23 (29.9)	54 (70.1)
Posterior position %	60 (77.9)	9 (39.1)	51 (94.5)
Mean follow-up range (6–40 months)	27.82	26.92	28.72

TABLE 1 Baseline characteristics of the total study population and by groups. Continuous variables are presented as mean ± standard deviation; categorical variables are expressed as numbers (percentage).

	Atrophic		Oncologic	
PI				
0	0.0%		17.7%	(95%CI 11.7–26.4)
1	48.8%	(95% CI 41.8–56.3)	5.4%	(95%CI 2.3–12.6)
2	17.1%	(95% CI 12.3–23.6)	2.8%	(95%CI 0.9–8.4)
3	33.0%	(95% CI 26.2–41.6)	10.8%	(95%CI 5.8–19.8)
GI				
0	31.3%	(95% CI 24.9–38.8)	20.6%	(95%CI 14.0–29.5)
1	19.7%	(95% CI 13.9–27.6)	4.5%	(95%CI 1.-11.6)
2	32.7%	(95% CI 26.3–40.4)	11.7%	(95%CI 6.4–20.6)
3	20.8%	(95% CI 15.1–28.4)	0.0%	

TABLE 2 Comparison of the two patients' cohorts different gingival index (GI) and plaque index (PI) scores expressed as percentage.

Note: GI scores: 0: normal gingiva; 1: mild inflammation: slight change in colour, slight oedema, no bleeding on probing; 2: moderate inflammation: redness, oedema and glazing, or bleeding on probing; 3: severe inflammation: marked redness and oedema, ulceration with a tendency to spontaneous bleeding. PI scores: score 0: no detection of plaque; score 1: plaque only recognized by running a probe across the smooth marginal surface of the implant; score 2: plaque can be seen by the naked eye; score 3: abundance of soft matter.

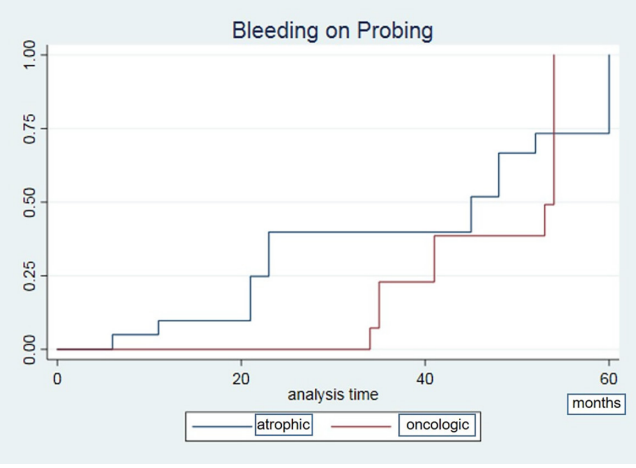

FIGURE 2 Kaplan-Meyer curve relative to bleeding on probing in atrophic and cancer patients.

Between PAM, the probabilities at the considered mean follow-up (27-months) to have a PI = 0 were 0%, 48.8% for PI = 1, 17.1% for PI = 2 and 33% for PI = 3.

Between OP, the probabilities to have a PI = 0 were 17.7%, 5.4% for PI = 1, 2.8% of OP had PI = 2 and 10.8% PI = 3.

Considering PAM, the probabilities to have a GI = 0 were 31.3%, 19.7% for GI = 1, 32.7% for GI = 2 and 20.8% for GI = 3.

Considering OP, the probabilities to have a GI = 0 were 20.6%, 4.5% for GI = 1, 11.7% for GI = 2 and 0% for GI = 3.

Adjusting for the confounding factors, no significant association between belonging to PAM or OP and PI.

3.2.3 | Mobility

None of the implants showed mobility.

4 | DISCUSSION

The present study aimed to assess and compare the clinical conditions of peri-implant tissues in patients affected by atrophy of the upper jaw and in patients who have undergone maxillary resection for oncological reasons.

The mean probing depth values recorded in both OP and PAM were lower than 3 mm. Prostheses have been removed when the clinical question regarding the state of health of the peri-implant tissues cannot be solved with a routine clinical visit alone or for the

need of prosthetic components restoration. Other studies found higher PPD values but did not report any difference between atrophic and oncologic patients. For example, Al-Nawas et al. found mean PPD values of 7.0 (±1.3) mm in patients with severe atrophy and 6.7 (±1.6) mm in patients with tumour resection between groups not statistically significant.[6] In the specific case of ZIs, it should be considered that soft tissue characteristics can also influence these values. Implants placed in resected maxillae could be surrounded by the alveolar mucosa, by tissue deriving from skin grafting or by temporal muscle which had been surgically rotated to cover a defect related to previous ablative surgeries [18]

Regarding mean GI values at the mean follow-up, the probability of having an index ≤1 was 51% for PAM and 25.1% for OP. PAM group had higher gingival superficial bleeding, being the probability to have GI = 3 equal to 20.8%, but the total evaluation of this parameter did not show a statistical difference between groups. Some authors found poor oral hygiene and inadequate hygienic parameters around ZIs,[20] while others reported good soft tissue conditions.[19] In fact, in the retrospective study of Davò et al.,[19] the evaluated sites demonstrated excellent health, with a GI score of 0 at 31 (79.5%) of implant sites and a GI score of 1 at the remaining 8 (20.5%) implant sites. However, it should be noted that this study had a follow-up of only ten months.

Another short-term follow-up (1 year) study, including oncological and patients with atrophy, reported GI values mostly between 1 and 2, indicating moderate inflammation.[21]

The PI values at 27-month follow-up indicated that both groups showed sufficient bacterial plaque control, considering that the probability of having a PI ≤ 1 between PAM was 48.8% and between OP was 23.1%.

The motivation and education of patients and improvement of patients' compliance in the home oral hygienic care should facilitate implant maintenance. Moreover, the prosthesis design plays an important role as prosthesis should be easily cleanable. The presence of vestibular flanges and a prosthetic body of considerable thickness greatly influence the hygienic results, with an abundant accumulation of plaque, especially on the vestibular side (Figures 3 and 4).

BOP mean value was low during the first months of follow-up; then, it increased with time. Regardless, both groups showed similar values of BOP (Figure 5). The worsening of this index over time could be explained by some factors that over time lead to a higher gingival inflammation: the prosthesis design that could limit the access of hygienic aids (e.g., implant floss, interdental brush), the decrease in patient compliance and the characteristics of the soft tissues surrounding implants, which could lack in keratinized tissue.[21]

In the present study, all patients were rehabilitated with fixed prostheses. Although many authors prefer removable prostheses, some studies reported fixed rehabilitations,[3,4] with very few complications.[22] All analysed implants were immediately loaded. Some other studies reported the immediate loading of ZIs with good clinical results.[19,23]

Among the limitations of the present study, there is the lack of radiographic images: the study aimed to monitor the parameters

FIGURE 3 Prosthesis should be easily cleanable. The presence of vestibular flanges and a prosthetic body of considerable thickness could influence the hygienic results. Prothesis was removed to score clinical data also at the buccal aspect of implants.

FIGURE 4 Plaque accumulation, especially on the vestibular side.

FIGURE 5 Bleeding on probing (BOP) value increases as the follow-up interval lengthens probably due to a higher gingival inflammation: the prosthesis design that could limit the access for hygienic manoeuvres.

detectable on clinical examination and radiological evaluation has not been introduced in dental follow-up to minimize patient exposure to ionizing radiation also for the presence of patients undergoing cancer treatment.

Other limitations included the variation of PI and GI depending on the hygienic compliance of the patient in determining periods, so their determination could be biased. Moreover, the compliance in respecting the planned follow-up visit and oral hygiene sessions was not always continuous.

5 | CONCLUSION

Despite the limitations of this study, it can be concluded that rehabilitation on ZIs performed in oncologic patients could achieve peri-implant tissue conditions similar to patients with maxillae atrophy. Periodic professional hygiene and specific home hygiene instructions to allow biofilm control in both OP and PAM rehabilitated with ZIs could contribute to the maintenance of peri-implant tissues and to the medium and, presumably, long-term success of implant-prosthetic rehabilitations.

6 | CLINICAL RELEVANCE

6.1 | Scientific rationale for the study

ZIs placed in oncologic patients have been reported to show a lower success rate rather than implants placed in atrophic maxillae.[4,5] ZIs, during the recall phase, appeared associated to soft tissue problems such as BoP in both oncologic and maxillary atrophy affected patients.[6] As peri-implant soft tissues condition could be considered a critical factor for implant success/maintenance over time, a systematic hygienic supportive program could improve zygomatic implant success rate also in oncologic patients.

6.2 | Principal findings

BOP was 24.8% for PAM and 22.9% for OP. The mean PPD values were 2.78 ± 1.28 in PAM and 2.91 ± 1.98 in OP. None of the implants showed mobility. No associations between group belongingness and the entity of PPD, PI, GI and the risk of BOP were found, adjusting for the considered confounding factors (age, smoking and implant position).

6.3 | Practical implications

The inclusion of oncologic patients who underwent maxillary resection in a systematic program of periodic professional hygiene with specific home hygiene instructions could allow to maintain comparable peri-implant tissues conditions as occurred in patients with maxillae atrophy.

AUTHOR CONTRIBUTIONS

All authors approved the final version of this manuscript before submission and agreed to be accountable for all aspects of the work ensuring that questions related to the accuracy or integrity of any part of the work were appropriately addressed and resolved. GP, AB and PF contributed to design, search and selection; AF, DR and FG to data analysis and interpretation and PF, GP and AB critically revised the manuscript.

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CONFLICT OF INTEREST STATEMENT

All authors declare that they have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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