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ORIGINAL ARTICLE

Primary vs secondary zygomatic implant placement in patients with head and neck cancer—A 10-year prospective study

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Abstract

Background: Zygomatic implants can provide excellent remote anchorage to support the prosthetic rehabilitation of patients treated for maxillary and midfacial tumors.

Methods: Patients who underwent zygomatic implant placement by the author between 2006 and 2016 as part of their oncology treatment were followed prospectively.

Results: Forty-nine consecutively treated patients received 131 zygomatic implants of which 9 failed and were removed from 4 patients; 24 patients (49%) received radiotherapy either before or after implant insertion. The overall 12-month survival estimate was 94% and the 60-month estimate was 92%.

Conclusions: The use of zygomatic implants in the management of maxillary and midfacial malignancy is a predictable prosthetic treatment modality to support complex oral and facial prostheses. Their use with or without free tissue transfer can provide effective prosthetic rehabilitation with high implant survival irrespective of the timing of placement or the need for adjuvant radiotherapy.

Clinical Significance: Zygomatic Implants provide an excellent platform for the restoration of the dentition and facial structures affected by maxillary and midfacial malignant disease.

KEYWORDS

facial prosthesis, maxillectomy, oral cancer, primary osseointegrated implants, rhinectomy, zygomatic implants, zygomatic oncology implants

1 | INTRODUCTION

Malignant diseases of the maxilla and midface, although relatively rare, require radical and often combined treatment modalities to affect cure for the patient. The location, nature, and size of the primary tumor dictate the margins of the resection and the potential functional and cosmetic effect that the patient will subsequently have. Functional problems for such patients are all too common due to the central location of the maxilla and midface with potential for significant disturbance for speech, swallowing, and chewing as well as dental and facial appearance. The use of classifications such as those by Brown[1] and Okay[2] are helpful tools to assist with surgical planning and decision-making regarding surgical reconstruction, prosthetic obturation, and dental rehabilitation in this very complex area, but there are a wide variety of treatment approaches reported in the literature. The use of microvascular free tissue transfer has significantly advanced the management of this patient group, especially for larger tumors (Brown class III/IV) with a greater vertical component, which have the ability to significantly impact the facial appearance and/or require orbital enucleation. Although the

use of composite flaps in the maxillectomy patient has been well reported,[3,4] there is still much debate about the best flap to use in a specific circumstance, and this often comes down to patient fitness as well as the preference and experience of the surgical team. The use of composite flaps can provide much needed bony support for cosmetic facial support[5] and also provide bone for subsequent or immediate osseointegrated implant insertion to facilitate dental rehabilitation.[6]

The subsequent provision of a dental prosthesis in these high-level maxillectomy cases, although possible, is often not provided due to the difficulties in tolerating a conventional dental prosthesis after such surgeries, lack of prosthodontic expertise or funding for dental implants, or lack of patient suitability with the result that very few patients ultimately receive an implant-based rehabilitation.[7] When any type of prosthesis is required in this group of patients, the use of osseointegrated implants provide a much-needed foundation for its retention, stability, and overall patient acceptance. The use of conventional osseointegrated implants in maxillectomy patients have been reported for the support of oral and facial prostheses for some years,[8] and in recent years the use of zygomatic implants have been gaining more acceptance in the management of patients with complex maxillary and midface tumors.[9,10]

The use of conventional zygomatic implants inserted in a horizontal manner across the face to support nasal prostheses was first described by Bowden[11] and has subsequently been more widely adopted with reports of larger case series[9] demonstrating high survival and predictability with a low complication rate. Figure 1 demonstrates the use of this technique in a patient requiring total rhinectomy for an intranasal squamous cell carcinoma. The use of zygomatic implants to support maxillary obturator or fixed dental prostheses are more limited, with mainly case reports[12–16] being presented involving the secondary placement on patients with maxillary defects with a varying survival rates being reported (from 79% to 100%). The most significant report to date is by Boyes-Varley et al.[17] who presented a protocol using modified zygomatic (Oncology) implants specifically developed by a South African Implant company (Southern Implants Ltd, South Africa) for use in maxillary defect situations (Figure 2). The implant used had a roughened thread length of approximately 20 mm with the rest of the implant surface being polished to minimize the attachment of debris and maximize cleaning when used in oncology defect situations. Their protocol involved the primary placement of oncology implants on the maxillary defect side together with the placement of modified dental or standard zygomatic implants on the nondefect side with the subsequent provision of an early-loaded fixed dental prosthesis and separate acrylic palatal obturator prosthesis within 1-2 weeks of surgery. They reported the successful treatment of 20 patients

FIGURE 1 The use of horizontally placed zygomatic implants to support a bar-magnet-retained nasal prosthesis in a patient requiring total rhinectomy for malignant disease [Color figure can be viewed at wileyonlinelibrary.com]

FIGURE 2 Zygomatic oncology implant; note the polished portion of the implant designed to allow use in maxillary or facial defects

with no reported loss of the oncology zygomatic implants. Certainly, the use of zygomatic oncology implants placed at the time of primary surgery offers significant benefits to the retention and support of obturator prostheses, and their use has also been documented by the author in a pediatric patient more recently[18] (Figure 3).

In an attempt to maximize the benefit to patients and to reduce the burden of hygiene and prosthetic maintenance, the treatment paradigm for low-level maxillary malignancy has continued to advance to encompass fixed dental rehabilitation together with the use of microvascular soft tissue flap closure. The zygomatic implant perforated flap procedure[19] combines the advantages of autogenous soft tissue reconstruction with those of an early-loaded zygomatic implant-supported fixed dental prosthesis (Figure 4), which can be delivered in the first 4-6 weeks after surgery irrespective of the subsequent need for radiotherapy.

The placement of osseointegrated dental implants at the time of primary cancer surgery is certainly gaining popularity across many centers[20,21] as the potential for more rapid rehabilitation is a clear advantage together with the avoidance of subsequent surgical trauma in the event that the patient requires radiotherapy for disease control. However, with respect to the timing of zygomatic implant placement in oncology patients, there is no comparative published data to assess the performance and survival of zygomatic implants placed either at the time of surgery or at a later point in the patient's cancer journey. This study attempts to address these questions.

2 | MATERIALS AND METHODS

The use of zygomatic and modified zygomatic (oncology) implants placed between 2006 and 2016 was studied in the Department of Maxillofacial Surgery, Aintree University Hospital, Liverpool, UK, and the Liverpool University Dental Hospital. Institutional approval was gained for data collection to facilitate the evaluation of the zygomatic implant service for patients with head and neck cancer. The aims of the study were to evaluate the survival of these implants utilized in the prosthetic rehabilitation of patients with maxillary and midface tumors and to ascertain whether the timing of placement had any bearing on zygomatic

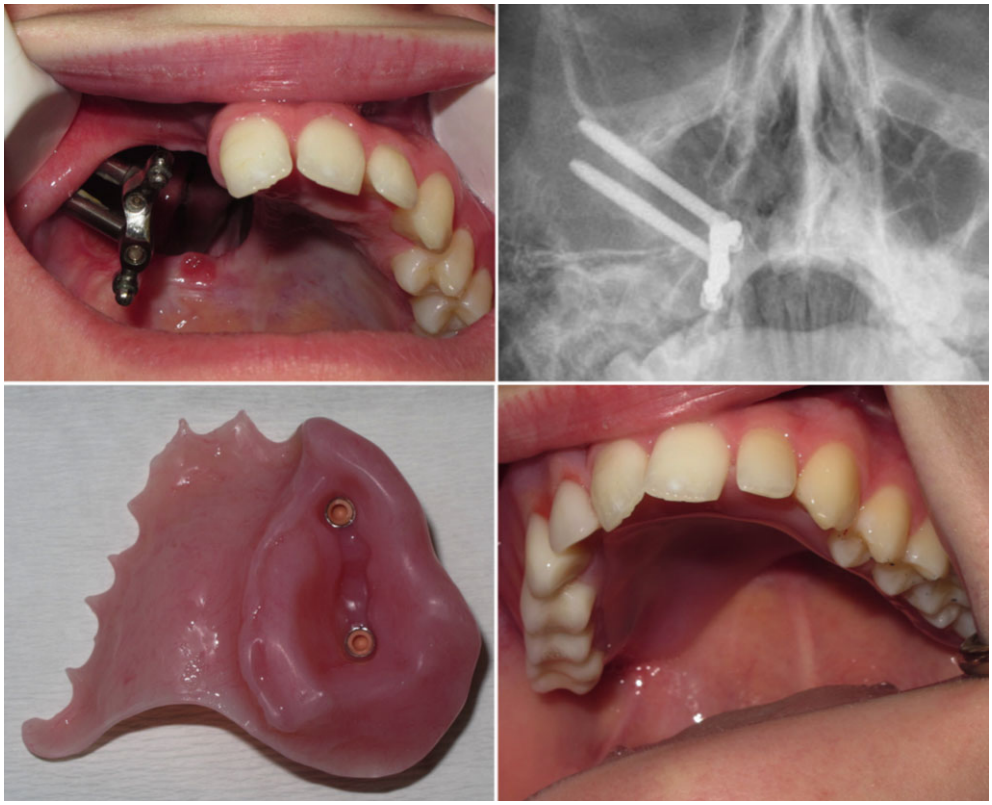

FIGURE 3 The use of oncology zygomatic implants in the support of a maxillary obturator prosthesis [Color figure can be viewed at wileyonlinelibrary.com]

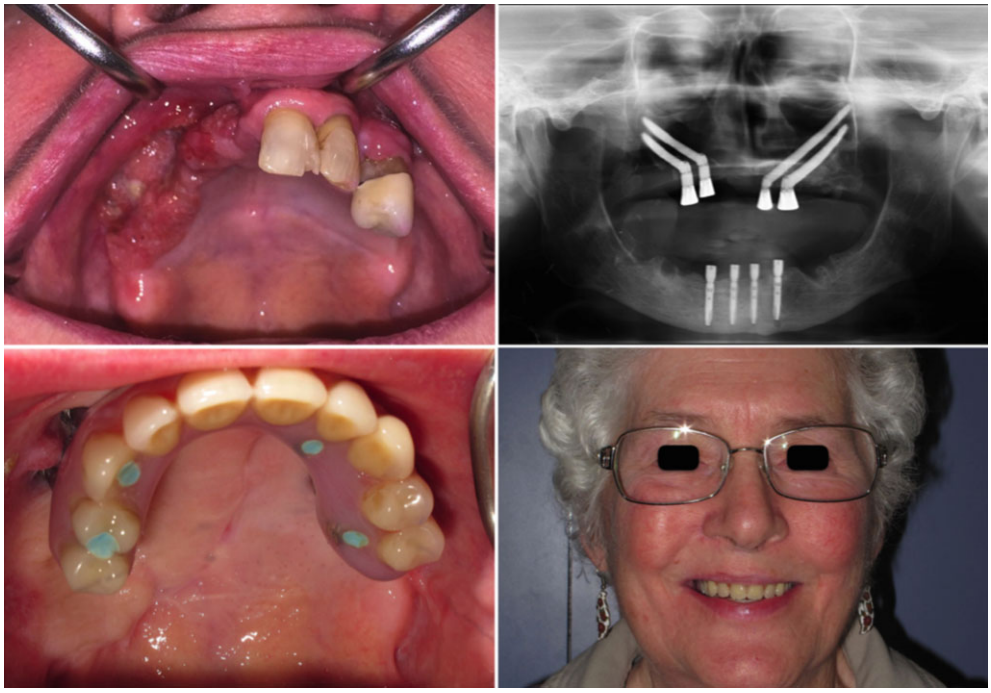

FIGURE 4 Zygomatic implant perforated flap procedure for the management of a low-level maxillary tumor [Color figure can be viewed at wileyonlinelibrary.com]

implant usability or survival. All patients treated by the author with conventional or oncology zygomatic implants during the study period were included in the analysis. Patients were followed regularly during the study period to monitor their overall disease control as well as any issues with their implants and prostheses. When patients died with their implants and prosthesis intact, their date of death was taken as the final data point for implant survival and prosthesis follow-up. The University of Washington Quality of Life (UW-QOL) questionnaire was sent out to many of the patients in this cohort as part of our routine quality of life data collection within the center. A further posting was carried out to long-term survivors at the end of the study period to gain a long-term picture of the outcome of these treatments. When multiple questionnaires had been completed by the patient, the latest questionnaire was used for the QOL analysis. Version 4 of the UW-QOL questionnaire consists of 12 single-question domains; these have between 3 and 6 response options that are scaled according to the hierarchy of the response. The domains are pain, appearance, activity, recreation, swallowing, chewing, speech, shoulder, taste, saliva, mood, and anxiety. Another question asks patients to choose up to three domains that have been the most important to them. In regard to their overall QOL (six response options), patients are asked to consider not only physical and mental health but also many other factors, such as family, friends, spirituality, or personal leisure activities, that were important to their enjoyment of life. The whole questionnaire focuses on current patient health and quality of life within the past 7 days. By comparing UW-QOL responses with responses to more in-depth questionnaires collected at the same time, algorithm trigger cutoffs have been derived[22] that define a "significant problem" on each UW-QOL domain. It is also informative to know the other extreme, that is, those giving the best possible response. Logically, there is middle ground between these extremes, and by creating three categories we present a simple summary of variation within each domain.

2.1 | Statistical method

Kaplan-Meier curves were constructed for the survival time of implants to failure and then separately for conventional zygomatic vs oncology implants and for primary vs secondary implants. These require the assumption of independence of each implant in regard to failure. Cox regression was used to make these comparisons after adjusting for clustering within patients. A separate patient-level Kaplan-Meier analysis was made of the time to (first) failure.

3 | RESULTS

During the study period, 53 patients with head and neck cancer were treated with 140 zygomatic and/or zygomatic oncology implants as part of their oral and/or facial prosthetic rehabilitation. Implants were placed either at the time of initial resective surgery or at a secondary time point after successful oncological treatment. Of the initial patient cohort, four patients subsequently died of their disease without completing their prosthetic rehabilitation. These patients and their 9 zygomatic implants were excluded from the study leaving a study cohort of 49 patients and 131 zygomatic implants. The

majority of the patients (35/49) had been diagnosed with squamous cell carcinoma within the maxilla/midface. The other patients were seen mainly with a number of other less-common malignant tumors although one patient with a previous maxillary ameloblastoma, two patients with pleomorphic salivary adenoma, and one patient suffering with maxillary osteoradionecrosis were also included (Table 1).

The patients were divided into two main groups (primary implant group [n = 27 patients] vs secondary implant group [n = 22 patients]) depending on the timing of zygomatic implant placement. The two groups were comparable in terms of age, gender, and smoking status (Table 2). The secondary implant group was disadvantaged in terms of preoperative irradiation with eight patients (36%) having been irradiated before implant placement. However, 15 patients (56%) of the primary implant group subsequently received radiotherapy following their resective surgery and implant placement with radiotherapy usually commencing about 6 weeks postoperatively. In total, 24 of the 49 patients in the study (49%) received radiotherapy either before or after implant insertion.

The primary implant group received 75 zygomatic implants of which 39 were of the oncology subtype, whereas the secondary group received a total of 56 zygomatic implants of which 19 were of the oncology subtype. In both groups, a small number of additional standard dental implants were used in the support of the final prosthesis for some patients (primary group, n = 14 implants; secondary group, n = 16 implants). The majority of implants were loaded in a conventional manner after osseointegration had taken place with the primary group having a tendency for earlier loading (median 1.7 months [interquartile ratio {IQR}, 0.9-3.9] months vs 9.3 [IQR, 5.2-12.2] months) due to the introduction of earlier loading protocols within the later years of the study. The zygomatic implants were subsequently used to retain and support a different range of oral and facial prostheses including maxillary obturators, fixed dental prostheses, maxillary overdentures, and facial prostheses (Table 3). All patients were followed up on a regular basis with the overall surgical follow-up ranging from 2 to 110 months.

Nine zygomatic implants (three conventional and six oncology) were removed from four patients, six within 4 months of placement, another two by 1 year and another after 3 years of function. Implant survival was examined using Kaplan-Meier calculations (Figures 5–7), and these suggest 5-year survival rates of 90% or better, with slightly better results for conventional zygomatic implants and for primary implants emerging within the first couple of years. The overall 12-month survival estimate was 94% and the 60-month estimate was 92%. However, the failure data implies some clustering within patients of which Figures 5–7 do not allow for. Cox regression methods were used to compare the type of implant (zygomatic vs oncology) and timing (secondary vs primary) with respect to survival time of the implant, after adjusting for clustering of implantation within patient. The hazard ratios (HR) obtained suggested a doubling (HR = 2.25) of risk of failure with secondary timing relative to primary and for a halving (HR = 0.56) for zygomatic conventional implants relative to oncology implants. Two methods (robust and bootstrap) of estimating standard errors (SE) after adjusting for clustering gave different but large estimates, but neither of these HR results achieved statistical significance ($P \geq 0.42$). A separate patient-level analysis (49 patients) was made of the time to (first) failure with an overall 12-month survival estimate of 94% (SE, 4%) and a 60-month estimate of 90% (SE, 5%).

TABLE 1 Patient diagnoses (n = 49 patients)

Patient diagnoses	Number of patients
SCC	35
Adenoid cystic carcinoma	4
Rhabdomyosarcoma	1
Sarcoma	1
Ameloblastoma	1
Pleomorphic salivary adenoma	2
ORN maxilla	1
Verrucous carcinoma	1
Langerhans histiocytosis	1
Adenocarcinoma	1
Melanoma	1

Abbreviations: ORN, Osteoradionecrosis; SCC, squamous cell carcinoma.

TABLE 2 Study patient demographics

	Primary implant group	Secondary implant group
Number of patients	27 (13 male; 14 female)	22 (12 male; 10 female)
Age, median (range), y	70 (13-92)	68 (23-79)
Smokers	14 (52%)	10 (45%)
Radiotherapy: postop	15 (56%)	1 (5%)
Radiotherapy: preop	0	8 (36%)

TABLE 3 Implant and prostheses follow-up data

	Primary implant group	Secondary implant group
Conventional zygomatic implants	36	37
Oncology implants	39	19
Additional dental implants	14 (oral) 3 (nasion)	16 (oral)
Median time till loading (IQR), mo	1.7 (0.9-3.9)	9.3 (5.2-12.2)
Prostheses		
Facial prosthesis	13	2
Obturator	10	10
Fixed dental prosthesis	4	7
Overdenture	2	3
Median prosthetic follow-up (IQR), mo	21.6 (12.4-39.9)	44.9 (29.0-68.9)
Median surgical follow-up, mo	42.7 (IQR 21.7-66.4; overall range 2-110)	

Abbreviation: IQR, interquartile range.

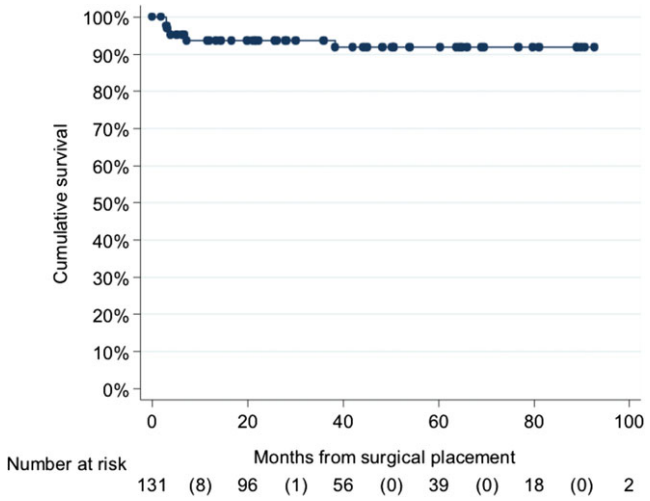

FIGURE 5 Kaplan-Meier survival estimate of all zygomatic implants placed. The numbers in parentheses show the number of failures between the stated time points, eight failures within 20 months, one failure within 21-40 months, and no failures thereafter [Color figure can be viewed at wileyonlinelibrary.com]

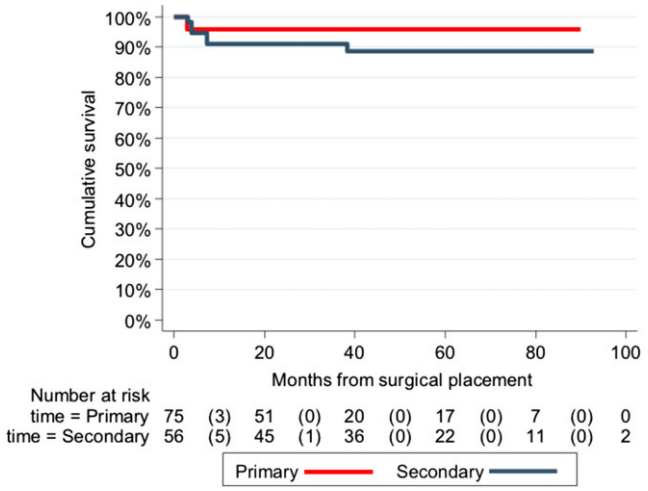

FIGURE 7 Kaplan-Meier survival estimate comparing primarily vs secondarily placed zygomatic implants. The numbers in parentheses show the number of failures between the stated time points [Color figure can be viewed at wileyonlinelibrary.com]

The four (first) failures occurred at 2.9, 3.1, 3.9, and 38 months after surgery.

There were no significant postoperative surgical complications in the primary implant group; but in the secondary implant group, two patients experienced a short-lived episode of infection in the skin overlying the zygomatic body within 6 months of placement which subsequently resolved. A further two patients developed chronic infections some years after placement: one associated with bone loss around the apex of an oncology implant used to support a removable obturator and the other associated with a horizontally placed implant to support a nasal prosthesis in a previously irradiated patient. Both patients continue to function with limited symptoms, and the associated implants remain in function to date. Prosthodontic complications were also limited to a small number of patients who experienced episodes of screw loosening and screw fracture, with one particular patient who was treated early in the study requiring significant prosthodontic maintenance, partly because the patient's large obturator prosthesis was retained by only two zygomatic implants and opposed by natural dentition in the mandible.

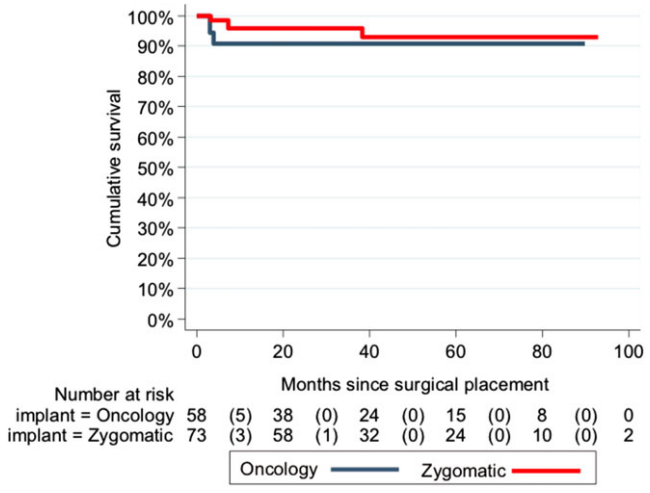

FIGURE 6 Kaplan-Meier survival estimate comparing zygomatic vs oncology implants. The numbers in parentheses show the number of failures between the stated time points [Color figure can be viewed at wileyonlinelibrary.com]

Twenty patients died during the course of the study either of their disease or for other reasons. Of the patients who died, their median postsurgical survival time was 23.8 months (IQR, 12.0-52.2 months), and their time with their implant-retained prosthesis was 18.2 months (IQR, 9.8-44.9 months).

UW-QOL data were available for 51% (25/49) of the patients. A summary of responses to the single question domains is shown in Table 4, and these responses were a median (IQR) of 35 (16-54) months after the fit of the prosthesis. Most patients (60%) were able to swallow as well as ever, and none had significant problems in regard to swallowing; most (72%), however, did recognize a change in appearance although only one patient had a significant problem with this. In regard to the overall QOL, 72% (18) said it was "good," "very good," or "outstanding" (2 "outstanding," 7 "very good," 9 "good," 6 "fair", 1 "poor", 0 "very poor").

4 | DISCUSSION

The use of zygomatic implants to assist in the prosthetic rehabilitation of patients following resections of the maxilla and midface provides another significant tool to the multidisciplinary teams managing these most complex groups of patients. Although the use of dental implants made tremendous strides forward in the management of these patients, zygomatic and modified zygomatic implants provide another tier of advantages for clinicians providing oral and facial

TABLE 4 Quality-of-life analysis of treated patients

UW-QOL domain	Number of patients	Percent with best response (n)		Percent scoring between the two extremes (n)	Percent with significant problem/ dysfunction (n)
Pain	25	*I have no pain*	60% (15)	28% (7)	12% (3)
Appearance	25	*There is no change in my appearance*	28% (7)	68% (17)	4% (1)
Activity	25	*I am as active as I have ever been*	32% (8)	60% (15)	8% (2)
Recreation	25	*There are no limitations to recreation at home or away from home*	28% (7)	64% (16)	8% (2)
Swallowing	25	*I can swallow as well as ever*	60% (15)	40% (10)	0% (0)
Chewing	25	*I can chew as well as ever*	48% (12)	52% (13)	0% (0)
Speech	25	*My speech is the same as always*	40% (10)	52% (13)	8% (2)
Shoulder	25	*I have no problem with my shoulder*	60% (15)	32% (8)	8% (2)
Taste	25	*I can taste food normally*	48% (12)	36% (9)	16% (4)
Saliva	25	*My saliva is of normal consistency*	52% (13)	40% (10)	8% (2)
Mood	25	*My mood is excellent and unaffected by my cancer*	32% (8)	60% (15)	8% (2)
Anxiety	25	*I am not anxious about my cancer*	60% (15)	28% (7)	12% (3)

Abbreviation: UW-QOL, University of Washington Quality of Life.

rehabilitation in the cancer setting. Insertion of these long implants into the highly cortical bone of the zygoma provides very high and predictable initial stability in a position remote to the resection of the tumor. The high initial stability promotes immediate and early prosthetic loading of these implants, which can result in full implant-supported dental and/or facial rehabilitation within a matter of weeks.[19] This is highly desirable for any patient but especially in this cohort of patients with cancer whose survival may be limited or even reduced compared to other oral tumor sites.[23] In addition, rapid secure prosthodontic rehabilitation provides much needed facial and lip support, especially in the edentulous patient, as well as improving overall facial and dental appearance, facilitating restoration of speech, and allowing a faster return to social interactions and overall recovery. Patient-reported quality-of-life outcomes in this study appear to be favorable, with the majority of surviving patients reporting an overall quality of life several years after treatment as good, very good, or outstanding. In addition, the number of patients reporting a significant dysfunction with chewing, swallowing, speech, and appearance was extremely low indeed. The literature on quality-of-life outcomes for patients with head and neck cancer treated with zygomatic implants is very sparse indeed although a recent paper by Wang[24] suggested that patients receiving an implant-supported obturator had comparable quality of life and function to a patient provided with a fixed dental bridge supported by implants in a vascularized bony reconstruction. Certainly, the use of osseointegrated implants provides much needed stability for dental and facial prostheses, and clinically patient acceptance is much higher.

The "remote anchorage" concept is invaluable to prosthetic restoration in the maxillectomy situation with the apical end of the implant providing the necessary mechanical anchorage into the residual facial skeleton, the body of the implant traversing through the space previously occupied by the resected maxilla, and the angled head design allowing subsequent prosthetic restoration (see Figure 3). When used to support maxillary obturator prostheses, the use of zygomatic implants provides much needed "in-defect" support and retention, which is impossible to achieve through standard dental implant-retained restorations. In-defect support allows the patient to function on the defect side of the obturator prosthesis and prevents the prosthesis from being displaced superiorly into the maxillectomy cavity, which is a real problem for conventional obturator prostheses. The oncology zygomatic implant provides the added advantage of a polished midsection for such circumstances, and this is designed to improve the patient's ability to clean the implants as they emerge into the defect.

The placement of zygomatic implants requires a careful three-dimensional awareness on the part of the surgeon to ensure that the head of the implant is in a suitable position to support the prosthesis while being firmly anchored within the bone of the zygoma. Ideally, two implants should be placed on the resected side if at all possible, and this

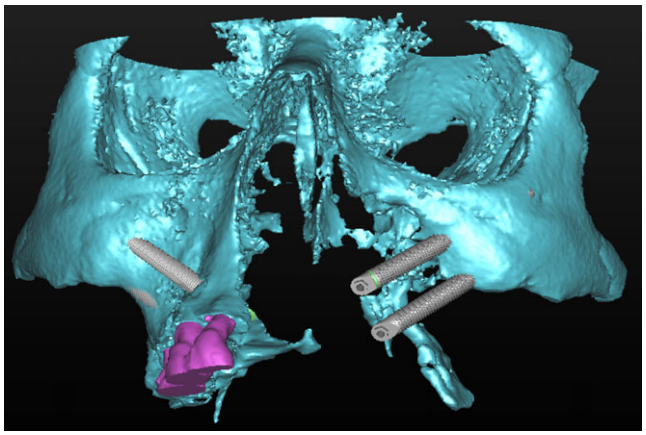

FIGURE 8 3D surgical simulation of the placement of remotely anchored zygomatic implants into the left residual zygoma following a previous left low-level maxillectomy [Color figure can be viewed at wileyonlinelibrary.com]

provides technical challenges to the inexperienced surgeon and may affect survival and usability. Figure 8 illustrates the approximate trajectory and spacing required in the placement of two remotely anchored zygomatic implants into a patient following a previous low-level maxillectomy. The angle of insertion is flatter than the contralateral native maxilla, and the heads should be angulated slightly anteriorly to provide adequate access postoperatively depending on the patient's mouth opening and planned restoration.

Certainly, the zygomatic implant survival rates in patients with cancer reported in the literature to date tend to show worse results in general than those reported in the normal population, especially when secondary placement was undertaken. In many respects, this is understandable when the challenges of treating these cases are fully understood and when only a small number of patients have been managed in a single unit. The effects of smoking, radiotherapy, and significant cantilevering forces must also be considered as negative predictors as they are in patients receiving conventional dental implant treatment. The current study brings together a long-term view on the management of maxillary and midfacial tumor patients treated with zygomatic and modified zygomatic oncology implants. It demonstrates high implant survival rates and confirms that this type of treatment can be applied safely and effectively in the overall prosthetic management of this patient group. It has been shown that, even in a range of complex circumstances, zygomatic implants can be satisfactorily placed to always allow their effective use in supporting a subsequent prosthesis. The advantages of primary placement of osseointegrated implants in patients with head and neck cancer are increasingly being realized, and this study confirms that this approach in the maxilla and midface provides the highest survival rate and reduces the overall time to rehabilitation, even when postoperative radiotherapy is required. In fact, this study demonstrated primary zygomatic implant survival rates only slightly lower to those reported in the management of non-cancer patients.[25] Certainly, access for zygomatic implant placement is much improved at primary resective surgery, and this approach, in the view of the author, should be the gold standard in the management of patients requiring implant-based prosthetic rehabilitation for malignant disease of the maxilla and midface together with early prosthesis construction.

There was a nonsignificant trend towards worse implant survival outcomes for patients treated secondarily rather than primarily at the time of tumor resection, and this is in line with what has been reported already in the literature. In addition, there was a trend for higher failure rates for zygomatic oncology implants used for remote anchorage compared to conventionally placed zygomatic implants. The use of Cox regression analyses to look for significance in any of these findings is frustrated by the nine implant failures clustering within only four patients. This may be a relatively large sample of patients with head and neck cancer, and the small number of failures is good news clinically. However, from the statistical perspective, the small number of failures inhibits the precision of any analysis. The only pragmatic way to confirm these potential observations would be a multicenter collaborative study. This study, however, does go a long way to provide long-term data regarding the successful use of zygomatic implants in patients with maxillary and midfacial malignant disease.

5 | CONCLUSIONS

The use of zygomatic implants in the prosthetic management of the patient with head and neck cancer provide excellent remote anchorage for the support and retention of oral and facial prostheses with high patient acceptance and resulting quality-of-life outcomes. They demonstrated high survival and usability even in highly complex situations where radiotherapy was used in the postsurgical phase of the patient's oncology treatment. There was a trend towards improved survival when implants were placed at the time of primary surgery compared to at a later date although this was not statistically significant in this large study.

6 | CLINICAL SIGNIFICANCE

The use of zygomatic and modified zygomatic implants provides predictable support and retention for complex oral and facial prostheses for patients being treated for head and neck cancer. High levels of implant survival are achievable even in a cohort of patients subjected to radiotherapy as part of disease control measures.

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