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The Zygomatic Implant Perforated (ZIP) flap reconstructive technique for the management of low-level maxillary malignancy - clinical & patient related outcomes on 35 consecutively treated patients

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Abstract

Background: The zygomatic implant perforated (ZIP) flap technique provides immediate reconstruction and rapid dental rehabilitation for low-level malignant tumors.

Methods: Patients who underwent ZIP flap reconstruction between December 2015 and February 2021 were followed prospectively.

Results: Thirty-five consecutively treated patients were studied with 16 undergoing surgery alone and 19 undergoing surgery followed by radiotherapy. The median time to fit the prosthesis was 29 days with all patients requiring adjuvant radiotherapy receiving their fixed dental prosthesis prior to its commencement. Vascularized flap (100%), zygomatic implant (98.4%), and prosthesis (97%) survival were excellent and the ZIP flap protocol was highly rated by patient-related outcome measures especially for the chewing domain.

Conclusions: The ZIP flap technique provides an excellent means of providing an autogenous oronasal seal and a foundation for immediate cortically anchored fixed dental rehabilitation.

Clinical Significance: This technique provides rapid and robust rehabilitation for patients presenting with low-level maxillary malignancy despite the use of radiotherapy.

KEYWORDS

dental rehabilitation, health-related quality of life, maxillectomy, ZIP flap, zygomatic

1 | INTRODUCTION

The low-level Brown¹ Class 2 maxillary tumor is the most common presentation of maxillary and midfacial malignant disease but in itself is still relatively uncommon with these tumors still making up less than 6% of all head and neck tumors. The resulting Class 2 surgical defects produce oronasal communications, loss of teeth, and supporting alveolus and in some cases can reduce facial support where defects are extensive. The prognosis for patients presenting with malignant tumors in this area is potentially reduced compared to other oral sites² and many patients presenting with these lesions in our unit are often in their seventh decade and beyond. Definitive

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treatment requires surgical resection with or without adjuvant radiotherapy/chemoradiotherapy in order to effect cure. The low-level maxillary defect can vary in its dimensions depending on tumor location and horizontal extent but essentially does not involve the orbital floor or contents and should preserve the zygoma. Tumors which invade more posteriorly necessitating the removal of the pterygoid plates often result in significant trismus which can severely compromise patient quality of life, eating ability, and prosthodontic success. In terms of rehabilitation, these Class II defects can be managed with a variety of approaches including prosthetic obturation³ of the resulting defect or utilizing free-flap transfer to close the defect and to separate the mouth from the nasal and antral cavities. A wide variety of fascio-cutaneous and composite flaps have been described to treat maxillary defects with good success and there are several reconstructive algorithms in the published literature.^{1,4} However, resection and reconstruction alone do not address the significant tooth loss which patients experience with the resulting loss of cosmesis and function. Chewing and oral function are key aspects for patients and must be borne in mind when choosing a treatment approach for patients with malignant maxillary tumors.⁵ Prosthetic obturation can deliver dental rehabilitation relatively easily together with an attempt at sealing the maxillary defect from air, liquid, and foodstuffs. Patient-reported outcomes after prosthetic obturation vary when compared to patients managed with free tissue transfer.⁶ However in the larger studies reporting on low level maxillary defects,³ the outcomes are broadly similar although the patient experience after obturation is more difficult especially for larger more horizontal defects, in the irradiated patient and especially for those with postoperative trismus. On the other hand, surgical reconstruction also brings with it significant challenges in terms of providing support for dental rehabilitation and its immediacy. Soft tissue only flaps provide very limited support for a removable prosthesis and if a more bulky flap is employed, the prosthodontic space can be obliterated. Composite flaps can be employed successfully in maxillary reconstruction⁷⁻⁹ with the positioning of the bone more predictably employed using virtual surgical planning techniques. In benign cases, the "jaw-in-a-day technique"10 might even be employed, whereby the fibula reconstruction is based on the dental rehabilitation plan with the installation of a temporary implant supported prosthesis at the same time as the tumor resection. Its adoption for malignant cases where the use of adjuvant radiotherapy is common has not been reported in any great numbers, presumably due to the concerns that the bony union between the fibula and the native maxilla/ midface could be disrupted.

The use of zygomatic implants in the management of maxillary and midface malignancy has been well documented and shown to provide excellent remote anchorage for prosthodontic and prosthetic reconstruction^{11–13} even where postoperative radiotherapy has been used. The use of secondary zygomatic implant placement in two maxillectomy patients previously treated with a radial forearm soft tissue flap has also been previously described.¹⁴

The zygomatic implant perforated (ZIP) flap for the immediate reconstruction and rapid dental rehabilitation of the low-level maxillectomy defect was first published in 2017¹⁵ and combines the use of soft-tissue free flap reconstruction of the oral defect combined with the early loading of zygomatic implants whose abutments perforate the flap at the time of primary surgery. This technique has emerged as a useful option following reflection on difficulties and deficiencies of other techniques. The aim of this paper is to present the clinical characteristics, oral rehabilitation details, long-term outcomes, and health related quality of life (HRQOL) at around 1 year in a consecutive series of 35 ZIP flaps performed over a 5-year period.

2 | METHODS

Patients presenting to the Department of Maxillofacial Surgery, Aintree Hospital, Liverpool, UK with malignant low-level (Brown Class 2) tumors treated with the ZIP flap technique between December 2015 and February 2021 were evaluated in this study. Institutional approval for ongoing data collection was granted for this study by the Hospital Clinical and Audit Management Department (No. 7474). The aim of this prospective observational study was to evaluate the clinical and patient related outcomes of a cohort of consecutively treated patients to help improve the evidence base for this innovative technique. In summary, patients were managed in accordance with the published operative and prosthodontic protocol¹⁵ with two-team operating. Following the initial low-level maxillary resection and neck management, two teams continued the surgical procedure with one team placing the zygomatic, oncology zygomatic, and dental implants as required and the other team raising the soft tissue flap in parallel. In some patients, additional residual teeth not involved in the tumor resection were removed in order to provide additional implant sites with the aim for suitable cross-arch prosthetic fixation. Once the implants had been placed, prosthodontic impression and jaw registration procedures were undertaken to fabricate the fixed dental prosthesis in the early postoperative period. Finally, the soft tissue BUTTERWORTH ET AL.

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FIGURE 1 Low level maxillary malignant tumor requiring a Brown Class 2c resection [Color figure can be viewed at wileyonlinelibrary.com]

flap was inset to the maxillary defect and perforated by the abutments on the defect related zygomatic implants prior to or following the pedicle vessel anastomoses. In some patients where bulkier anterolateral thigh (ALT) flaps were used, the flap was often perforated a few weeks later with simultaneous fitting of the prosthesis. Following recovery, the patient was seen in the outpatient clinic 1–3 weeks later to try-in and subsequently fit the fixed dental prosthesis. Figures 1 to 5 illustrate the step-wise clinical protocol involved in a single case requiring a Class 2c low-level maxillary resection. Where postoperative radiotherapy was required, this was subsequently delivered, and the patients were then followed up on a 6–8 week basis during the first year post-treatment.

Information was collected from theater logs and patients' electronic records. Data collected included patient age, gender, smoking status at surgery, maxillary jaw status, pathology, maxillary defect classification, soft tissue flap utilized, number of zygomatic, oncology and dental implants placed, primary flap perforation, hospital stay, time to fit the dental prosthesis, postoperative radiotherapy, recurrence, survival as well as any complications reported or observed.

Patient-reported outcome measures (PROMs) were obtained from patients at 1-year postsurgery who were

sent paper-based questionnaires (UW-QOL v4 and LORQv3) to complete and return. Postal reminders were sent where required. The UW-QOL v4 questionnaire comprises 12 single item domains, with between 3 and 5 response options scaled evenly from 0 (worst) to 100 (best) according to response hierarchy. 16 UW-QOL domains are presented within two subscales, physical function and social-emotional function¹⁷ with each subscale score being the mean of six domain scores. Criteria derived from earlier work was used to highlight domains in which patients have a significant problem or dysfunction¹⁸; these criteria involve domain scores and whether patients select the domain as one of three most important to them in the previous week. There is also a single item overall quality of life (QOL) question on the UWQOL v4 for which patients are asked to consider not only physical and mental health, but also other factors, such as family, friends, spirituality, or personal leisure activities important to their enjoyment of life. There is also a similar question about health-related QOL within the past week and another asking about health-related QOL compared with 1 month before the cancer. The LORQ v3¹⁹ consists of 40 items. The first 17 items assess issues of oral function, orofacial appearance, and social interaction. Remaining items deal with prostheses and patient 4 WILEY———

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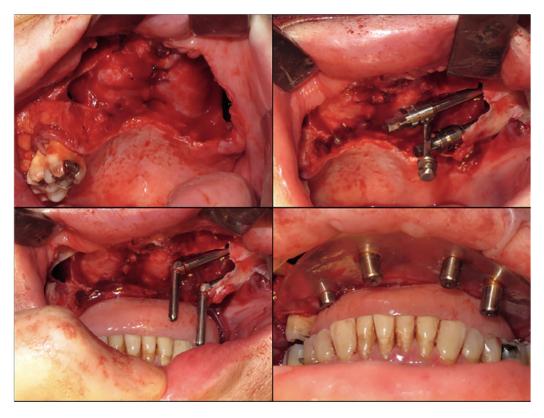


FIGURE 2 Resective maxillary defect together with the positioning of immediate zygomatic oncology implants [Color figure can be viewed at wileyonlinelibrary.com]

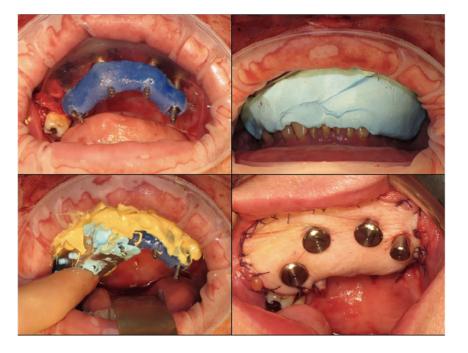


FIGURE 3 Immediate prosthodontic procedures and perforation of the microvascular radial forearm free flap soft tissue palate reconstruction [Color figure can be viewed at wileyonlinelibrary.com]

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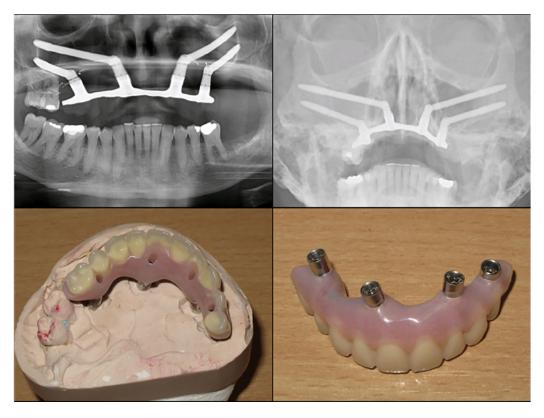


FIGURE 4 Postoperative radiographs demonstrating implant positioning and laboratory stages of fixed dental prosthesis construction [Color figure can be viewed at wileyonlinelibrary.com]

denture/prosthetic satisfaction. Items refer to problems or symptoms experienced during the previous week and are scored on a 1-4 Likert scale, from "never" (1) to "always" (4).

3 | STATISTICAL

The results were descriptive of the whole group and were comparative in regard to whether or not patients had received radiotherapy as part of the primary treatment. Given the very small numbers in statistical terms and the unlikelihood of achieving statistical significance at p < .05, the results section mainly comments on any interesting observed differences. The Mann–Whitney test was used to compare subgroups in regard to time to fitting prostheses, UWQOL subscale scores and the number of UWQOL domains indicating a significant problem or dysfunction. SPSS v25 was used for the analyses.

4 | RESULTS

The sample comprised 35 consecutive surgical patients from December 16, 2015 to February 10, 2021, with

median (inter-quartile range, IQR) 73 (69-77) years at surgery, range 49-89 years, 60% (21) of whom were male. The maxillary dental status was edentulous for 17% (6), part dentate for 66% (23), and dentate for 17% (6). Other clinical details for the sample are given in Table 1. The two patient subgroups, surgery plus radiotherapy (n = 19) or surgery alone (n = 16), had similar clinical profiles apart from the time taken to fit the prosthesis, which was shorter for those requiring radiotherapy (median 23 days) than for those without (median 37 days), Mann-Whitney test p = .04. In total, 125 zygomatic implants were placed in this patient cohort (standard zygomatic n = 56; oncology zygomatic n = 69) with a small number of additional dental implants (n = 19). The majority of patients were treated entirely with a quad zygomatic approach with only 10 patients receiving one more dental implants. Four patients were reconstructed with an ALT flap while the rest were treated with either fascio-cutaneous (n = 27) or a composite (n = 4) radial forearm flap. There were no free flap failures with one flap being salvaged at Day 2 due to venous compromise. Every patient had a maxillary fixed dental prosthesis fitted in the early postoperative period (range, 14-63 days) with those patients requiring radiotherapy being rehabilitated before the onset of adjuvant



FIGURE 5 Intraoral and facial views of patient 3 months after ZIP flap reconstruction. ZIP, zygomatic implant perforated [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Patient and clinical characteristics, stratified by treatment modality

		Treatment mod	dality	
		Surgery + RT	Surgery alone	Total
Patients		19	16	35
Age at surgery (years)	Mean (IQR)	73 (69–76)	70 (68-81)	73 (69–77)
Sex	Male	7	7	14
Smoking status at surgery	Yes	3	2	5
Maxillary jaw status	Dentate	3	3	6
	Partially dentate	13	10	23
	Edentulous	3	3	6
Pathology	SCC ^a	18	15	33
Defect classification	Brown 2b	14	10	24
	Brown 2c	1	2	3
	Brown 2d	4	4	8
Flap	ALT	2	2	4
	Composite RFFF	4	0	4
	RFFF	13	14	27

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TABLE 1 (Continued)

		Treatment m		
		Surgery + RT	Surgery alone	 Total
Zygomatic implants placed (total $= 56$)	0	4	3	7
	1	1	1	2
	2	12	12	24
	3	2	0	2
Zygomatic oncology implants placed	1	4	4	8
(total = 69)	2	13	10	23
	3	0	1	1
	4	2	1	3
Dental implants placed (total = 19)	0	14	11	25
	1	2	3	5
	2	1	1	2
	3	1	1	2
	4	1	0	1
Flap perforated at surgery	Yes	18	14	32
Implants re-exposed	Yes	2	4	6
Opposing dentition	Complete denture	2	0	2
	Dentate	16	12	28
	$\begin{array}{c} \text{Dentate} + \text{partial} \\ \text{denture} \end{array}$	0	1	1
	Implant bridge	0	1	1
	Implant overdenture	1	2	3
Failed zygomatic implants	0	19	16	35
Failed oncology implants	0	18	16	34
	2	1	0	1
Failed dental implants	0	18	16	34
	2	1	0	1
Died	Yes	4	2	6
	Months: surgery to death	6, 13, 14, 32	11, 12	6, 11, 12, 13, 14, 32
Hospital stay (days)	4–7	6	5	11
	8–14	8	10	18
	15–23	4	1	5
	Median (IQR)	8 (7–14)	9 (6-11)	8 (7–12)
	Mean	10.5	9.3	10.2
Time to fit prosthesis (days)	14–20	4	3	7
	21–34	13	4	17
	35–63	2	9	11
	Median (IQR)	23 (21-30)	37 (25–44)	29 (21–37)

Abbreviations: ALT, anterolateral thigh; IQR, inter-quartile range; RFFF, radial forearm free flap; RT, radiotherapy; SCC, squamous cell carcinoma. a Adenoid cystic carcinoma (1) in surgery + RT group, carcinoma ex-PSA (1) in surgery alone group.

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TABLE 2 UWQOL results by treatment modality

		Treatment moda	Treatment modality	
Patients		Surgery + RT	Surgery alone	Total
Patients		12	11	23
Overall QOL ^a	Fair/poor/very poor	3	0	3
	good/very good/outstanding	8	11	19
Health-related QOL ^a	Fair/poor/very poor	5	3	8
	Good/very good/outstanding	6	8	14
Health-related QOL compared to	Somewhat/much better	4	3	7
month before developing cancer ^a	About the same	1	6	7
	Somewhat/much worse	6	2	8
UWQOL social-emotional	<60	3	0	3
subscale score	60–79	5	1	6
	80-100	4	10	14
	Median (IQR) score	75 (63–87)	88 (83-96)	83 (74–
UWQOL physical function	<60	5	1	6
subscale score	60–79	4	1	5
	80–100	3	9	12
	Median (IQR) score	72 (42–84)	85 (81–96)	81 (55–
Social-emotional subscale				
• Pain	Best possible response	6	9	15
	Somewhere in-between	4	2	6
	Dysfunction	2	0	2
• Activity	Best possible response	4	7	11
	Somewhere in-between	5	2	7
	Dysfunction	3	2	5
• Recreation	Best possible response	2	5	7
	Somewhere in-between	6	6	12
	Dysfunction	4	0	4
• Shoulder	Best possible response	7	8	15
	Somewhere in-between	3	3	6 14 83 (74-96) 83 (74-96) 6 5 12 81 (55-8) 15 6 2 11 7 5 7 12 4
	Dysfunction	2	0	
• Mood	Best possible response	5	8	13
	Somewhere in-between	5	3	8
	Dysfunction	2	0	2
• Anxiety	Best possible response	8	6	14
	Somewhere in-between	2	5	7
	Dysfunction	2	0	2
Physical function subscale				
Appearance	Best possible response	1	5	6
	Somewhere in-between	9	6	15
	Dysfunction	2	0	2
Swallowing	Best possible response	4	8	12
	Somewhere in-between	5	2	7
	Dysfunction	3	1	4

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TABLE 2 (Continued)

		Treatment moda	Treatment modality	
Patients		Surgery + RT	Surgery alone	Total
• Chewing	Best possible response	5	8	13
	Somewhere in-between	5	3	8
	Dysfunction	2	0	2
• Speech ^a	Best possible response	2	4	6
	Somewhere in-between	7	7	14
	Dysfunction	2	0	2
• Taste	Best possible response	5	6	11
	Somewhere in-between	4	5	9
	Dysfunction	3	0	3
• Saliva	Best possible response	3	6	9
	Somewhere in-between	5	3	8
	Dysfunction	4	2	6
Number of domain	0	3	7	10
Dysfunctions (range 0–12)	1	3	2	5
	2	0	1	1
	3, 4, 11	3	0	3
	Median (IQR)	2 (0-4)	0 (0-1)	1 (0-3)

 $^{^{}a}$ Number of responses = 22.

Abbreviations: QOL, quality of life; RT radiotherapy.

radiotherapy. A small number of patients required reexposure of the implant abutment at the time of prosthesis fitting, and this was carried out under local anesthesia where required. Three patients treated with an ALT flap had their prosthesis fitted under general anesthesia together with debulking of the flap at a secondary timepoint.

Only one irradiated patient experienced implant failure with the progressive loss of two oncology implants and two dental implants which ultimately led to the loss of his fixed prosthesis. He was subsequently successfully restored with a removable prosthesis retained by his remaining zygomatic implant. This resulted in an overall zygomatic implant survival of 98.4% and a prosthesis survival of 97%.

Of the 35 patients, eight had undergone surgery less than 1 year ago and so were yet to complete a patient-reported outcome questionnaire. There were 27 patients having surgery with opportunity for 1 year patient-reported outcomes. Two of these died at 12 and 13 months postsurgery and were not sent a HRQOL questionnaire. Two other patients who had a recurrence of their cancer (at 4 and 7 months after surgery) were excluded from the analyses. All 23 patients completed the PROMs at a median (IQR) of 14 (13–16) months after surgery, 12 having had adjuvant radiotherapy and 11 who

did not. Table 2 (UWQOL) and Tables 3 and 4 (LORQ) show the HRQOL results.

The radiotherapy group tended to have more dysfunction and less best responses across the domains of the UWQOL (Table 2). There was a significant difference in the total number of domains with dysfunction (Mann-Whitney test p=.03); the range was 0–4 domains, apart from with one radiotherapy patient with dysfunction on 11 of the 12 domains. These observed trends were reflected within lower (worse) physical and socialemotional UWQOL subscale scores for the radiotherapy group, with a difference between subgroups of 13 units in median scores, Mann–Whitney test: physical (p=.02), social–emotional (p=.03).

The first 17 items of the LORQv3 assessed issues relating to oral function, orofacial appearance, and social interaction and applied to all patients (Table 3). For all but one of these items, the mean score was worse in the radiotherapy group and this is reflected also in greater numbers of patients experiencing the issue/problem either "often" or "always." The second part of the LORQv3 assesses the social impact of prostheses as well as patient denture satisfaction (Table 4). For patients having dentures/implant retained teeth, the radiotherapy group appeared to have greater problems regarding soreness or ulceration of gums. Both groups had some

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TABLE 3 The first 17 LORQ items assessing issues related to oral function, orofacial appearance, and social interaction, at 12 months with results stratified by whether or not patient had primary adjuvant radiotherapy (RT)

	Surgery and RT $(n = 12)$		Surgery alone $(n = 11)$		All patients $(n = 23)$	
	Mean	N	Mean	N	Mean	N
1. Did you experience difficulty with chewing?	2.4	5	1.5	1	2.0	6
2. Did you have pain when you chew? ^a	1.7	3/11	1.2	1	1.5	4/22
3. Did you experience difficulty with swallowing solids?	2.4	5	1.7	2	2.1	7
4. Did you experience difficulty with swallowing liquids?	1.7	3	1.1	0	1.4	3
5. Did food particles collect under your tongue?	2.1	4	1.2	1	1.7	5
6. Did food particles stick to your palate?	2.8	7	1.7	1	2.3	8
7. Did food particles stick inside your cheeks? ^a	2.2	4	1.8	2/10	2.0	6/22
8. Did you have mouth dryness?	2.8	7	1.7	1	2.3	8
9. Did you have problems with drooling?	2.7	5	1.3	1	2.0	6
10. Did you experience problems with speech?	2.3	5	1.9	2	2.1	7
11. Were you upset by your facial appearance?	2.3	4	1.2	1	1.7	5
12. Were you upset by the appearance of your mouth?	2.4	4	1.4	1	1.9	5
13. Were you upset by the appearance of your lips?	2.5	5	1.0	0	1.8	5
14. Were you upset by the appearance of your teeth?	1.2	0	1.3	1	1.2	1
15. Did your chewing ability affect your social life? ^a	2.5	5	1.5	1	2.0	6
16. Did your chewing ability influence your choice of foods?	3.0	7	1.8	3	2.4	10
17. Did you experience difficulty with opening your mouth?	2.2	4	1.3	0	1.7	4

Abbreviations: LORQ, Liverpool Oral Rehabilitation Quality of Life.

Note: Each item was scored as 1 = never, 2 = sometimes, 3 = often, 4 = always. The table gives mean score and number of patients who said "often" or "always."

problems finding food particles collecting underneath the denture or implant but apart from this there were no obvious differences across the rest of Table 4.

The overall mean postsurgical follow-up of the group was 25 months (range, 2–60 months). Apart from issues associated with disease recurrence referred to above, a small number of patients experienced some complications ranging from minor prosthodontic issues (screw loosening, acrylic tooth fracture) to the development of an oronasal fistula in three patients. Of these, one was reclosed surgically in an nonirradiated patient with the other two patients being treated with an obturator prosthesis retained by the implant supported fixed bridgework. Three patients experienced some tethering/contracture of the upper lip.

5 | DISCUSSION

This is the first prospective cohort study to report longer term outcomes including patient-reported outcomes following use of the ZIP flap technique for low-level maxillectomy in a series of consecutively treated malignant cases. The results are encouraging and demonstrate the potential benefit of this technique in the management of low-level maxillary malignancy. The high implant and prosthesis survival rates confirm that the use of zygomatic implants with their remote anchorage provides robust support for early loaded fixed dental prostheses and this seems not be significantly reduced by postoperative radiotherapy. While the follow-up is still limited, our initial surviving cases are now around the 5-year mark with very little implant or prosthesis loss. The soft tissue component of the reconstruction has also performed well despite being perforated by the implant abutments on the day of surgery for the vast majority of patients, something that many microvascular surgeons would fear might lead to flap compromise. We have shown that this is not the case and that free flap survival is not affected. The speed of oral rehabilitation is the main key advantage of the ZIP flap technique with all patients being restored within

^aNumber of responses = 22.

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TABLE 4 Remaining LORQ items dealing with prostheses and patient satisfaction with these, at 12 months with results stratified by whether or not patient had primary adjuvant radiotherapy (RT)

	Surgery and RT (n = 12)	,	Surge (n = 1	ery alone 11)		All pa (n = 2	
18. Do you have any natural teeth in the UPPER jaw?	4		2			6	
19. Do you have any natural teeth in the LOWER jaw?	10		8			18	
24. Do you have an upper denture? ^a	0/11		1			1/22	
25. Do you have upper implant retained teeth? ^a	11/11		10			21/22	
32. Do you have a lower denture? ^a	0		1/10			1/22	
33. Do you have lower implant retained teeth? ^a	1		4/10			5/22	
		Mean	N	Mean	N	Mean	N
If dentures or implant retained teeth (YES to question	n 24 25 32 or 33):	(n = 11)		(n = 11)		(n = 22)	
20. Were you embarrassed about conversing because retained teeth?	of your dentures/implant	1.8	3	1.5	1	1.6	4
21. Did you refuse dinner invitations because of embadentures/implant retained teeth? ^b	ırrassment about your	1.7	2/10	1.4	1	1.5	3/21
22. Did you feel loss of self-confidence because of emdentures/implant retained teeth?	barrassment about your	1.5	2	1.4	1	1.5	3
23. Did you find it difficult to open your mouth becau implant retained teeth?	se of your dentures/	1.4	1	1.0	0	1.2	1
If upper dentures or implant retained teeth (YES to q 25):	uestion 24 or question	(n = 11)		(n = 11)		(n = 22)	
26. Were you dissatisfied with your upper denture/im	plant retained teeth? b	1.6	1	1.0	0/10	1.3	1/21
27. Did you upper denture/implant retained teeth cau of the gum?	ise soreness or ulceration	2.0	4	1.1	0	1.5	4
28. Did you find food particles collecting under your retained teeth?	upper denture/implant	2.7	7	2.2	3	2.5	10
29. Did you take out your upper denture/implant reta	ined teeth for eating?	1.0	0	1.0	0	1.0	0
30. Did you feel insecure with your upper denture/im	plant retained teeth?	1.3	1	1.1	0	1.2	1
31. Were you worried that you upper denture/implanfall out?	t retained teeth might	1.0	0	1.0	0	1.0	0
If lower dentures or implant retained teeth (YES to quality 33):	uestion 32 or question	(n=1)		$(n=4^{\rm c})$		(n = 5)	
34. Were you dissatisfied with your lower denture/im	plant retained teeth?	2.0	0	2.3	2	2.2	2
35. Did you lower denture/implant retained teeth cau of the gum?	se soreness or ulceration	1.0	0	1.8	1	1.6	1
36. Did you find food particles collecting under your leatined teeth?	ower denture/implant	4.0	1	1.5	0	2.0	1
37. Did you take out your lower denture/implant reta	ined teeth for eating?	1.0	0	1.8	1	1.6	1
38. Did you feel insecure with your lower denture/im	plant retained teeth?	1.0	0	1.8	1	1.6	1
39. Were you worried that you lower denture/implan fall out?	t retained teeth might	1.0	0	1.0	0	1.0	0

Note: Each item was scored as 1 = never, 2 = sometimes, 3 = often, 4 = always. The table gives mean score and number of patients who said "often" or "olympis".

Abbreviation: LORQ, Liverpool Oral Rehabilitation Quality of Life; RT, radiotherapy.

 $^{^{}a}n = 22.$

 $^{^{}b}n = 21.$

^cFifth patient did not complete questions 34–39.

a very short time span (weeks) following surgery and certainly before radiotherapy where this was required. This is extremely important for a number of reasons, the most important being the restoration of patient cosmesis and function, minimizing the period of dysfunction and pathological adaptation to a modified and unrestored state which many patients undergoing composite flap reconstruction and eventual dental rehabilitation suffer from with many waiting years until they eventually receive their implant supported prosthesis.²⁰ In addition, survival in maxillary and midfacial malignant disease has been shown to be reduced compared to other oral cancer sites and so time to rehabilitation becomes even more important in this group. Alternative treatment approaches such as the Alberta-reconstructive-technique incorporates occlusally driven digitally planned fibula flap reconstruction together with primary dental implant placement but despite this their published reported mean time to dental restoration is in excess of 1 year²⁰ with only a few cases being reported in the maxilla. There is some momentum to restorative immediacy together with the use of the "jaw-in-a-day" technique in some centers²¹ but their use in malignant cases requiring postoperative radiotherapy is in its infancy with very small numbers presented so far with limited follow-up at this point. In addition, most of such cases involve the mandible with very few maxillary cases reported. This may reflect the additional complexities of composite free flap reconstruction in the maxilla where the remaining native bone is thin, the pedicle length can be difficult and where union of the bone flap to the residual bone is often compromised especially if radiotherapy is to be used post-surgically. Certainly, the authors are convinced that the use of zygomatic implants into native cortical bone provide the best possible anchorage for fixed dental rehabilitation in this compromised and often irradiated group. The use of standard dental implants in this group was limited and increasingly the authors prefer to utilize the quad zygoma approach often with the sacrifice of a few residual teeth on the nondefect side if necessary to facilitate this approach. Post-treatment trismus certainly plays a part in the compromise often seen in terms of dental rehabilitation for this group of patients and this underlines the importance of early rehabilitation where possible with a definitive prosthesis. While it would be possible to fit a provisional prosthesis on the day of surgery, the authors feel that taking a few weeks to produce and fit a definitive metal-based acrylic or porcelain prosthesis in the early postoperative phase serves the patient better especially if trismus subsequently worsens and makes access for treatment difficult or impossible. Monitoring of the soft tissue flap in the first 48 h is also not impeded by a prosthesis and in the unfortunate situation where the

patient must return to theater for management of a compromised flap or postoperative hemorrhage, there is no impediment to treatment. Additionally, being able to try-in the prosthesis in a conscious patient often allows for improvements in tooth position, show, and occlusion to be made.

Our patient cohort was relatively elderly and a number of patients treated were in their eighties. Despite this, the use of twin operating teams and the avoidance of tracheostomy makes the ZIP flap approach suitable even for older patients with significant comorbidities. The donor site morbidity from a soft tissue flap is significantly less than that of a composite flap, especially in the older patient, and it's use can potentially reduce any delays to starting radiotherapy where this is required. Peripheral vascular disease can also preclude the use of the fibula flap for some patients whereas the vast majority of these arteriopaths can have a successful soft tissue flap undertaken.

In the medium term, we have experienced a few patients developing fistulae (n = 3) which we were able to manage either by reclosure (one case) or by the employment of an obturator prosthesis (two cases) retained by the implant supported fixed bridgework. Fistulae are a recognized and reported complication with the use of the radial forearm flap in the maxilla and midface and were reported in 14% of a recent case series.²² This complication only affected three patients in our cohort, two of which were heavily irradiated and one nonirradiated patient whose fistula we were able to reclose surgically. Despite this set-back, all three patients continued to function well following remedial treatment and continued with their implant supported fixed prosthesis. In order to reduce this potential problem, our aim is always to oversize the soft tissue flap to some degree and to ensure meticulous flap inset with suture margins over the palatal bone where possible. In terms of patient follow-up and maintenance, the ZIP flap reduces prosthodontic follow-up significantly compared to prosthetic obturation. As the oronasal seal is not provided by the prosthesis, there is no need for regular appointments for prosthetic modification, which are so often required even when obturators are supported by implants.23 This reduced maintenance requirement is advantageous for patients and reduces costs for health care institutions.

Patient-reported outcomes need to be central to the development of any new surgical technique hence their inclusion in this study. The overall quality of life reported by our cohort was excellent with 83% (19/23) reporting that their QOL was good, excellent, or outstanding following treatment. Key functional performance indicators of rehabilitation following maxillectomy such as speech, chewing, and swallowing proved to be highly rated especially the chewing domain. The surgery plus radiotherapy

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group reported slightly worse QOL outcomes generally which is well recognized.

Clearly the ZIP flap is one technique of several that can be used in the management of low-level maxillary malignancy and its outcomes should be judged alongside the options of prosthetic obturation as well as composite flap reconstruction with delayed or immediate dental implant placement and restoration. Currently it provides one of the most predictable means of treatment incorporating early fixed dental rehabilitation. It certainly requires a high degree of technical skill and teamwork to ensure good outcomes with the three dimensional placement of the zygomatic implants being a key part. The authors place the implants in a free-hand manner utilizing the available surgical and dental landmarks although the use of virtual planning with surgical guides may also figure in the future for some centers.²⁴ Further development and refinement of the ZIP flap technique with the use of virtual surgical planning, intraoral scanning as well as computer aided design - computer aided manufacturing (CAD-CAM)prosthesis construction may help to improve different aspects of the workflow. Additional multicenter evaluation and longer-term follow-up studies are also required to understand the reproducibility and resilience of the technique in the medium to long term in surviving patients.

CONFLICT OF INTEREST

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

DATA AVAILABILITY STATEMENT

Data are available on request from the authors.

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