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Surgical and health related quality of life outcomes following treatment with zygomatic implant perforated (ZIP) flaps

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Abstract

Background: The zygomatic implant perforated (ZIP) flap is a novel approach to the challenge of reconstructing the maxilla. We report on our experience using the ZIP flap technique for patients undergoing infrastructure maxillectomy at Chris O'Brien Lifehouse, Sydney, Australia.
Methods: Thirteen patients who underwent a ZIP flap reconstruction between August 2019 and August 2021 were identified. Demographic, surgical, and histopathological information was collected. Health Related Quality of Life (HRQOL) was assessed using the FACE-Q Head and Neck Cancer module, the M.D. Anderson Dysphagia Inventory, and the Speech Handicap Index.
Results: A total of 44 zygomatic implants were placed, of which 42 (95%) survived. The median time from surgery to dental rehabilitation was 35 days. HRQOL data was available for nine patients over 24 months, demonstrating improved speech and swallowing outcomes over the follow up period.
Conclusions: The ZIP flap is a reproducible surgical technique that facilitates rapid dental rehabilitation post infrastructure maxillectomy.

Introduction

The complex three-dimensional morphology of the maxilla, combined with its essential functional and aesthetic roles, make it one of the most challenging regions of the human body to reconstruct. Furthermore, adjuvant radiation therapy is often required to maximize disease control.[1] Dental rehabilitation should be considered a fundamental goal in maxillary reconstruction after ablation.

Maxillary reconstruction has evolved from routine prosthetic obturation towards microvascular reconstruction. The zygomatic implant perforated (ZIP) flap, described by Butterworth in 2017, is a novel approach.[2] The technique combines fasciocutaneous free flap repair with zygomatic implants, facilitating both separation of the oral and nasal/paranasal cavities, along with fixed dental rehabilitation in a single surgical procedure. Traditionally, composite free flaps such as the osteocutaneous fibula or myo-osseous iliac crest have been combined with conventional dental implants to meet these objectives.[3] These flaps are more technique-sensitive and prone to complication compared with fascio-cutaneous reconstructions, risking delayed delivery of adjuvant therapy. Furthermore, dental implant loading is usually staged or delayed. The simplicity of the ZIP flap may provide predictable dental rehabilitation for more patients, and translate to better quality of life, whilst improving surgical efficiency and resource allocation.

This paper reports on our experience using the ZIP flap technique for patients undergoing infrastructure maxillectomy at Chris O'Brien Lifehouse, a specialized integrated cancer treatment centre in Sydney, Australia. In addition, Health Related Quality of Life (HRQOL) outcomes are assessed.

Methods

After obtaining institutional ethics approval (Protocol No 2020/ETH02415), all patients who had ZIP flap reconstruction during a two-year period from August 2019 to August 2021 were identified from the *Integrated Prosthetics and Reconstruction* database at Chris O'Brien Lifehouse. All patients provided written informed consent to participate in the study. No patients were excluded. Patient demographics, disease presentation, Okay classification,[4] surgical management, and dentoalveolar outcomes were extracted from the database. Enrolled patients were subsequently asked to complete the following HRQOL questionnaires: the FACE-Q Head and Neck Cancer (FACE-Q) module,[5] the M.D. Anderson Dysphagia Inventory (MDADI),[6] and the Speech Handicap Index (SHI).[7]

Surgical technique

Preoperative planning

All patients underwent preoperative combined clinical assessment with ablative and reconstructive surgeons and a maxillofacial prosthodontist. ZIP reconstructions were undertaken with either the radial forearm free flap (RFFF) or anterolateral thigh (ALT) flap based on defect and patient-specific donor site considerations. ZIP reconstruction was considered for unilateral or bilateral infrastructure maxillectomy defects involving a considerable dental component, but not involving the orbital rim or orbital floor, and with sufficient zygomatic bone for placement of the implants. Uninvolved teeth with poor prognoses were removed. Fine slice (<1 mm) computed tomography (CT) imaging and intra-oral surface scans were obtained, with DICOM data imported to our preferred dental implant planning software (see Fig. 1a,b) (Implastation, ProDigiDent, Illinois, USA). Zygomatic implants (Southern Implants) were planned so screw access exited via the occlusal aspects of the dental prosthesis in the lateral incisor and second premolar sites. If severe trismus was anticipated, screw access was planned to exit via the labial aspects for ease of access to prosthetic screw channels. Southern Zygomatic and Oncology Implants have been utilized for ZIP reconstruction at our Institution, with four available options: Conventional, Zygan, Oncology, and Zygex™. The Oncology and Zygex implants allow for a smooth surface to penetrate the soft tissue flap.[8] The narrower Zygex, with a 3.4 mm apex, was employed where the volume of zygoma was reduced. The Zygan and conventional zygomatic implants were employed where the alveolus remained intact.

Surgery

Tumour resection, lymphadenectomy, and vessel access were undertaken prior to placement of zygomatic implants. The zygomatic bone, infraorbital nerve, and inferolateral orbital rim were exposed, followed by placement of implants. Straight multi-unit abutments (Southern Compact Conical Abutments) were inserted, followed by partial inset and microvascular anastomosis of the fascio-cutaneous flap. The flap was perforated with stab incisions, followed by completion of inset, placement of a silastic flange to prevent flap migration back over the implants, and fitment of a 'Sombrero' custom (Southern Implants) healing abutment for retention of the silastic (see Fig. 2).

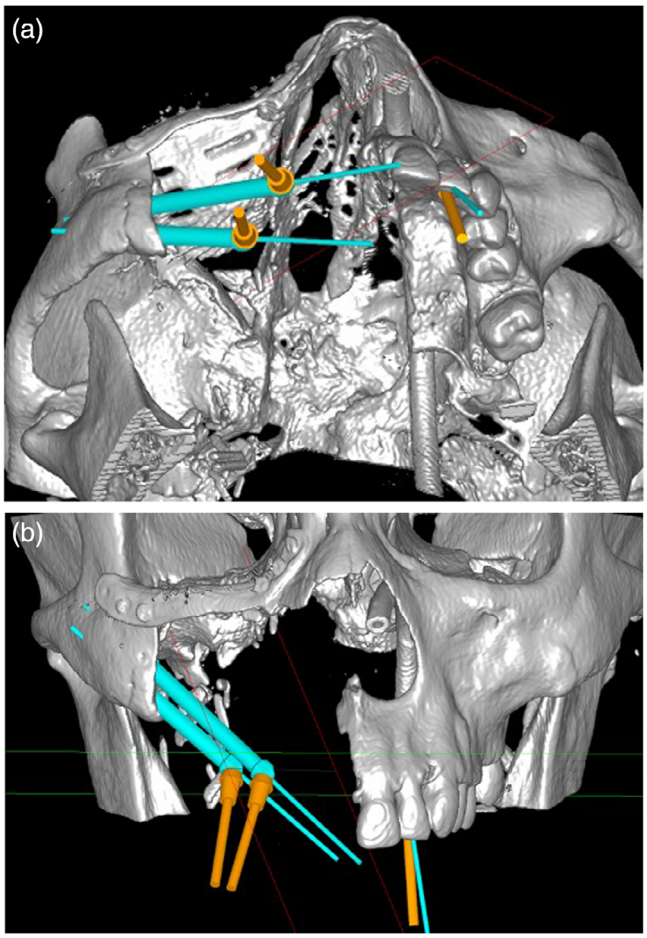

Fig. 1. (a) and (b) Planning scans demonstrating two oncology implants in the right zygomatic bone.

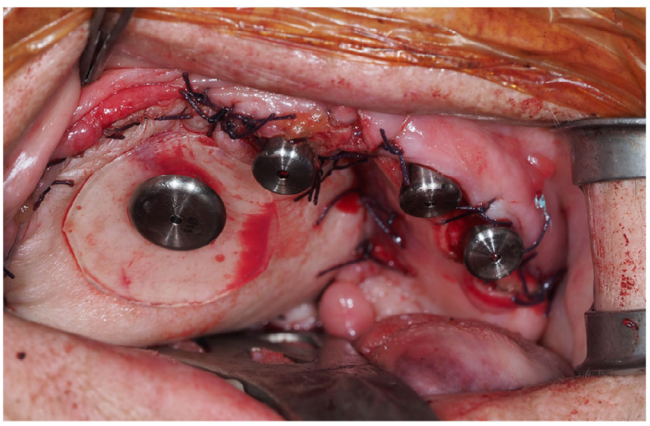

Fig. 2. One zygomatic implant (right second premolar site) can be seen perforating a RFFF with a 'Sombrero' style healing abutment over a silastic sheet, to prevent migration of the flap. Three other zygomatic conventional healing abutments are fitted to zygomatic implants that were not required to perforate the free flap.

Table 1 Clinicopathological data

	Sex	Age	Histopathology	Maxilla OKAY classification	Flap	Radiotherapy	Number of implants	Implant failure	Time to loading of implants (days post-operative)	Complications	Clavien-Dindo classification
Patient 1	M	49.5	SCC	Ib	ALT	No	4	1	27	Orbital floor breach	IIIb
Patient 2	F	63.9	SCC	II	ALT	Post-operative	5	1	220	Marginal flap necrosis	I
Patient 3	M	54	Invasive fungal rhinosinusitis	III	ALT	No	4	0	12	Orbital floor breach (asymptomatic) Marginal flap necrosis	I I
Patient 4	F	60	Osteoradionecrosis	Ib	ALT	Pre-operative	8	0	18	Nil	N/A
Patient 5	M	57.3	SCC	II	ALT	Pre-operative	2	0	29	Lip contracture	IIIb
Patient 6	M	50.7	Ameloblastoma	II	RFFF	No	5	0	62	Nil	N/A
Patient 7	M	71.9	Angiosarcoma	Ib	RFFF	Post-operative	8	0	11	Nil	N/A
Patient 8	F	49.6	Phosphaturic Mesenchymal Tumour	II	RFFF	No	8	0	106	Total flap failure	IIIb
Patient 9	F	81.4	SCC	II	ALT	No	4	0	35	Post-operative haemorrhage	IIIb
Patient 10	F	90.8	SCC	Ib	RFFF	Post-operative	4	0	54	Silastic sheet requiring modification	IIIb
Patient 11	M	70.4	Defect following previous reconstruction	Ia	RFFF	No	2	0	127	Local collection or infection	II
Patient 12	F	81.8	SCC	II	RFFF	Post-operative	4	0	55	Nil	N/A
Patient 13	F	76.2	SCC	Ib	RFFF	Pre-operative	4	0	6	Local collection or infection Excess granulation tissue	II IIIa

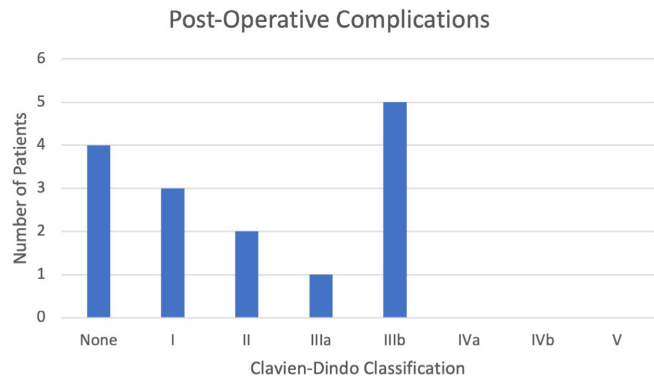

Fig. 3. Post-operative complications. Note two patients suffered two complications: both complications have been documented in the graphic.

Prosthetic fabrication and installation

Pre-operative digital scans of the dentition and/or removable dentures were imported into planning software. Clear duplicates of the dentition or diagnostic removable dentures were prepared as surgical guides. Following placement of the implants and attachment of the multi-unit abutments, abutment level impressions were obtained by luting titanium cylinders to surgical guides or impression trays. Both digital and analogue laboratory processes were used to design and produce a prosthesis. A soft diet was prescribed for the 8-week post-operative period. In addition to aesthetic concerns, adjustments to the prosthesis were made to accommodate for tongue space, cleaning access, and the occlusion.

Measurement of HRQOL

The HRQOL questionnaires were selected for their strong psychometric properties and high test–retest reliability. Eligible patients were mailed or emailed an invitation letter with a copy of the questionnaires or provided the materials at their follow-up appointment. Patients who did not respond within 4 weeks of the initial contact were followed up by phone.

(1) The FACE-Q module consists of 14 independently functioning scales that measure healthcare experience and outcomes of treatment following head and neck cancer procedures.[5] All 14 scales were used in this study. The raw scores for items that make up each scale are added to provide a total score and converted to 0 to 100, with higher scores for all scales but one (cancer worry) reflecting a better outcome.

(2) The MDADI evaluates how patients view their swallowing ability following treatment and the impact of swallowing dysfunction on HRQOL.[6] It consists of a global assessment, and emotional, functional, and physical subscales. The global assessment is scored individually whereas all other assessments are summed, and a mean score is calculated before being multiplied by 20 to obtain a score between 0 and 100, with higher scores reflecting higher functioning.

(3) The SHI is comprised of 30 items evaluating speech-related problems in daily life in patients with oral or oropharyngeal cancer.[7] Each item is scored on a five-point scale (0–4) to

Table 2 HRQOL outcomes

	Radiotherapy	Months	MDADI	SHI	FACE-Q domains													
					Facial appearance	Eating and drinking	Oral competence	Salivation	Smiling	Speaking	Swallowing	Appearance distress	Drooling distress	Eating distress	Smiling distress	Speaking distress	Cancer worry	Information satisfaction
Patient 1	No	3	31	91	89	34	87	87	44	18	58	100	100	26	57	0	0	100
		6																
		12																
		24																
Patient 2	Post-operative	3	86	3	75	46	75	78	78	50	100	60	100	62	68	90	37	60
		6	88	8	53	34	66	78	64	82	100	46	58	32	48	69	45	74
		12	97	1	100	42	66	87	71	75	100	90	100	44	57	90	47	77
		24																
Patient 3	No	3	63	63	50	22	49	46	44	57	88	0	0	0	24	21	0	81
		6	73	77	47	34	25	87	64	31	100	0	48	19	68	42	0	71
		12	89	41	56	38	66	49	59	50	100	30	39	32	15	38	0	100
		24																
Patient 4	Pre-Operative	3	61	27	50	34	49	62	59	50	88	22	32	38	39	45	42	100
		6																
		12																
		24																
Patient 5	Pre-operative	3																
		6	76	26	75	38	33	78	100	50	67	100	90	62	100	77	37	85
		12																
		24	86	25	75	53	41	72	88	50	67	100	81	74	100	82	16	85
Patient 6	No	3																
		6																
		12	52	85	20	57	57	78	16	18	100	0	100	81	24	31	53	20
		24																
Patient 7	Post-operative	3																
		6																
		12	100	4	75	57	87	57	78	75	100	100	100	89	100	90	6	100
		24	87	5	81	53	100	72	78	90	100	68	100	74	100	90	37	100
Patient 8	No	3																
		6																
		12																
		24			100	78	87	87	39	50	45	90	100	100	57	63	71	81
Patient 9	No	3																
		6			70	46	16	38	39	43	49	57	39	Incomp.	Incomp.	Incomp.	Incomp.	Incomp.
		12																
		24																
Mean		3	60	46	66	34	65	68	56	44	84	46	58	32	47	39	20	85
		6	79	37	57	38	35	70	67	52	79	51	59	38	72	63	27	77
		12	85	33	63	49	69	68	56	55	100	55	85	61.5	49	62	27	74
		24	87	15	85	61	76	77	68	63	71	86	94	83	86	78	41	89
Median		3	61	45	63	34	62	70	52	50	88	41	66	32	48	33	19	91
		6	76	26	62	36	29	78	64	47	84	52	53	32	68	69	37	74
		12	93	23	66	50	66	68	65	63	100	60	100	63	41	64	27	89
		24	86	15	81	53	87	72	78	50	67	90	100	74	100	82	37	85

Note: The gray shade was to indicate that the patient in question had not answered at that time point.

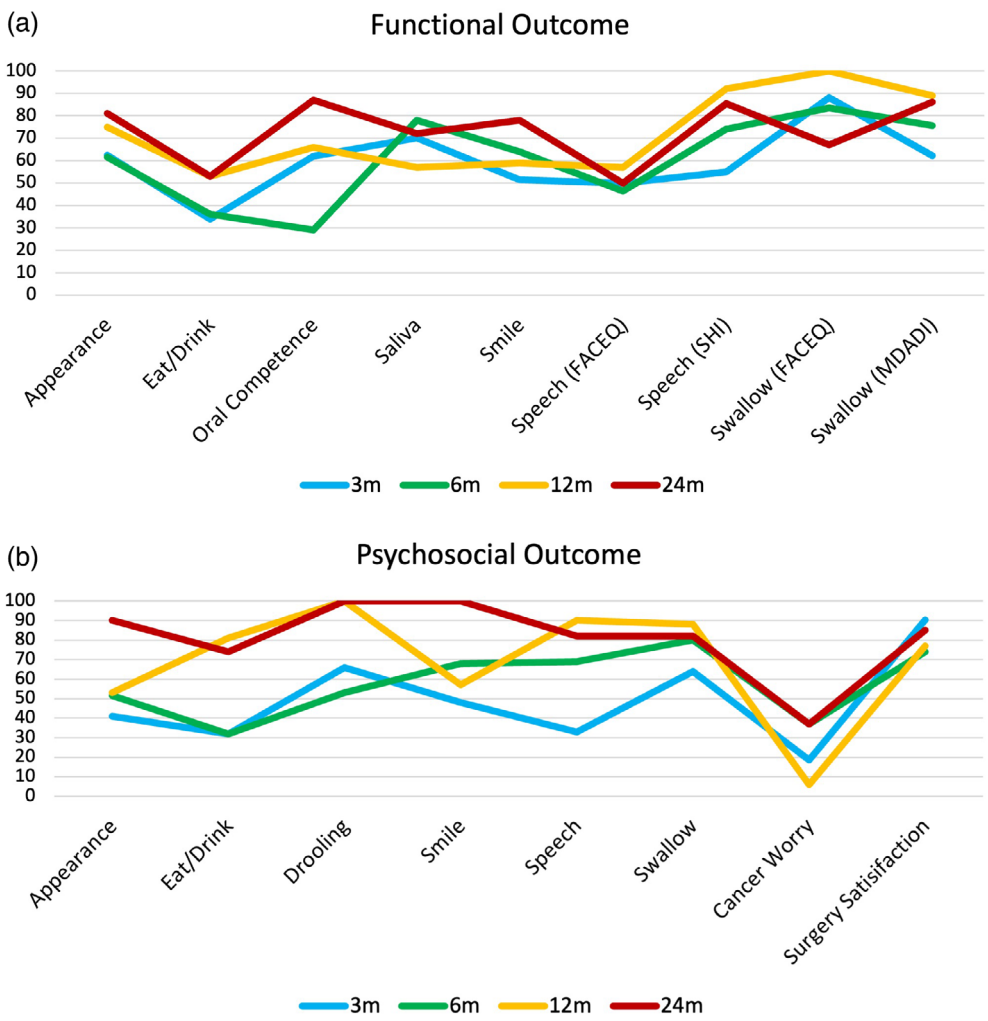

Fig. 4. (a) Functional outcome. Composite graph combining mean scores of functional outcomes from the MDADI, SHI and FACE-Q questionnaires at 3, 6, 12, and 24 months. (b) Psychosocial outcome. Composite graph combining mean scores of psychosocial outcomes from the MDADI, SHI and FACE-Q questionnaires at 3, 6, 12, and 24 months.

reach a total score between 0 and 120, with a lower score indicative of better HRQOL.

Statistical analysis

Data was exported from a REDCap database to Microsoft Excel for analysis. Descriptive statistics are provided as medians and ranges. Statistical differences between groups were not analysed due to the small sample size.

Results

Thirteen patients who underwent maxillectomy and zygomatic implant placement were included with a median age of 63.9 years (range 49–91 years). The most common indication for surgery was malignancy ($n = 8$) and all patients underwent immediate reconstruction, except two patients who had undergone maxillectomy 108 and 3 months prior to reconstruction. A RFFF was used in seven patients and an ALT in six patients. Four patients required post-operative radiotherapy, of which one received concurrent chemotherapy, and three patients had prior (pre-operative) radiotherapy. One patient died during follow up 10 months after surgery from disease progression. There were 44 zygomatic implants (Zygomatic $n = 1$, Zygan $n = 15$, Zygex $n = 18$, and Oncology $n = 10$) and 18 dental implants placed. The clinicopathological and surgical features are summarized in Table 1.

Surgical outcomes

The mean operative time was 637 min (range 510–822 min) and average length of postoperative stay was 15 days (range 9–32 days).

There were six major complications (Clavien-Dindo III and above) (46%) (see Fig. 3). One patient had a total flap failure, due to a previously undiagnosed thrombophilia. The flap was removed and the defect closed using a buccal fat flap and a local advancement flap. The patient was discharged with a temporary implant-borne obturator on anticoagulation and referred to haematology. One patient required removal of a zygomatic implant due to a breach of the orbital floor causing diplopia, which resolved on removal, and a replacement zygomatic implant was inserted. Two further patients required a return to theatre; for evacuation of a haematoma, and adjustment of the silastic supports around the abutments due to impingement on the soft palate. One patient

underwent correction of a lip contracture 13 months after flap inset. One patient had excess granulation tissue around an implant requiring debridement under local anaesthetic.

There were five minor complications (Clavien-Dindo I-II) including two partial flap necroses adjacent to the perforating implants, managed conservatively (see Fig. 3). Both cases of partial flap necrosis were observed between an implant perforation site and a closely adjacent flap margin. In both cases the small and self-resolving necrosis was attributed to implant perforation mispositioning. Two patients developed postoperative collections that were aspirated on the ward and treated with intravenous antibiotics. Routine postoperative CT of another patient demonstrated breach of the orbital floor by one zygomatic implant: this patient was asymptomatic and did not require intervention.

Dental outcomes

In total, 42 of 44 zygomatic implants integrated giving a survival rate of 95%. One patient had a zygomatic implant replaced due to placement in the orbit, and one patient had a loose posterior zygomatic implant removed 8 months after placement, which was not replaced.

All patients have received a dental prosthesis. The median time to loading of the dental implants with a provisional prosthesis was 35 days (range 6–220 days) as summarized in Table 1. One patient received a temporary obturator prior to discharge due to flap failure. This was replaced with an interim prosthesis 2 weeks later, 1 month after the initial placement of the implants. There were three minor prosthodontic issues, including two fractured interim prostheses and a fractured acrylic tooth. One patient is being considered for flap revision due to the flap encroaching upon the prosthodontic space.

Patient reported outcomes

HRQOL data was available for nine patients: four patients at 3 months, four patients at 6 months, five patients at 12 months, and three patients at 24 months. Three patients answered questionnaires at 3, 6, 12, and 24 months, two patients answered at 3, 6, and 12 months, and four patients answered at one time point only. FACE-Q, MDADI, and SHI scores are shown in Table 2. MDADI scores increased from a median of 61 (range 31–86) at 3 months to a median of 93 (range 52–100) at 12 months postoperatively, indicating improvement in the perceived impact of swallowing dysfunction. Scores decreased slightly at 24 months (median 87, range 86–87), however only two patients returned responses. SHI scores also improved over time from a median of 45 (range 3–91) at 3 months to a median of 15 (range 4–25) at 24 months. Two patients completed the SHI at 24 months indicating that speech was not impacting their everyday life (SHI score < 6).[7] Median FACE-Q scores improved over time in all domains, other than swallowing at 24 months, which was consistent with the MDADI scores (see Fig. 4).

Discussion

The goals of maxillary reconstruction are restoration of facial form, separation of the oral and nasal cavities, and dental rehabilitation to facilitate functions such as speech, mastication, and swallowing. Restoration of maxillary dentition is traditionally one of the most challenging and neglected aspects of treatment,[2] however the ZIP flap technique has been shown to provide early successful dental rehabilitation.[3] This series of 13 patients confirms the utility of the ZIP flap for achieving dental rehabilitation, but also highlights some of the challenges associated with this approach.

Traditional prosthodontic obturation post maxillectomy has several disadvantages including discomfort, especially in delicate irradiated tissues, difficulties achieving an adequate oro-nasal seal, and extensive prosthodontic follow up.[2] Hirsch *et al.*[9] addressed these difficulties in 2009 with a staged procedure involving maxillectomy and RFFF reconstruction, with insertion of zygomatic implants 4 months later, and dental restoration at 6 to 7 months. In 2017 Butterworth and Rogers combined maxillectomy, free flap reconstruction and insertion of zygomatic implants into a single operation—the ZIP flap—which facilitated rapid dental rehabilitation.[2] Thereafter, Hackett *et al.*[10] describe a 'paradigm shift' in maxillectomy reconstruction towards primary implant placement. A 10-year prospective study comparing primary and secondary zygomatic implant placement found primary placement to be the gold standard due to the advantages of early dental rehabilitation.[11]

In 2021, Butterworth *et al.*[12] described surgical and quality of life outcomes for 35 consecutive ZIP flap patients. Butterworth *et al.*[12] used 144 implants, comprising 56 conventional zygomatic, 69 zygomatic oncology, and 19 dental implants, with a zygomatic implant survival rate of 98.4%. In our cohort the zygomatic implant survival rate was 95%. We had one total flap failure: this patient had an undiagnosed thrombophilia, but it is uncertain whether the implants may have also contributed by causing pressure on the perforators or the pedicle. This highlights the importance of minimizing technical errors, as they can have substantial repercussions for patients, particularly in oncology practice where timely delivery of postoperative radiotherapy is an important goal of free flap reconstruction. Butterworth *et al.*[12] described a 100% flap survival rate demonstrating that the ZIP-flap technique can be done safely with appropriate planning and expertise.

Other minor differences between series include Butterworth *et al.*[12] reporting three cases of oronasal fistula and three patients with tethering or contracture of the upper lip.[12] In our cohort there were no oronasal fistulae, however one patient required correction of contracture. Our lower rate of fistula may be due to the more liberal use of ALT flaps, which have more subcutaneous tissue. In our cohort there was an even distribution of flap donor sites. Butterworth *et al.*[12] preferred RFFFs due to the increased bulk of ALT flaps making the inset more challenging. Consistent with this observation, one patient in our cohort who received an ALT flap is being considered for revision due to flap bulk encroaching upon the prosthodontic space.

Loading of implants

The primary advantage of the ZIP flap technique is the facilitation of rapid dental rehabilitation with early loading of implants.

Loading of zygomatic implants is described as early as 72 h post insertion.[13] Butterworth *et al.*[12] reported a median time to fit a prosthesis of 29 days (range 14–63 days). Loading was prioritized for patients undergoing post-operative radiotherapy, with a median loading time of 23 days compared to 37 days for patients not requiring radiotherapy. Conversely, Salvatori *et al.*[14] delayed loading in two patients undergoing radiotherapy after a one-stage resection, loco-regional flap and zygomatic implant insertion: the rationale was to allow osseointegration of the implants prior to radiotherapy. The median time to loading in our cohort was 35 days, with a wide range from 6 to 220 days. The advantages of the ZIP flap were clearly demonstrated with two patients in the cohort undergoing dental restoration prior to discharge from hospital. Of the five patients loaded within 28 days, two patients had previous radiotherapy, one had post-operative radiotherapy and two had no radiotherapy. None experienced complications relating to stability or osseointegration of the implants. Three patients had delayed dental restoration over 3 months after their ZIP flap procedure. One of these patients, whose implants were loaded at day 220, received radiotherapy prior to loading and access was severely limited by trismus.

HRQOL

Butterworth *et al.*[12] measured quality of life using the UW-QOL v4 and LORQv3 questionnaires. Quality of life post-ZIP flap was better for patients in the surgery-only cohort, compared with those undergoing post-operative radiotherapy. HRQOL data was available for nine patients in our cohort using FACE-Q, MDADI and SHI scores. It is difficult to draw strong conclusions from a small cohort answering at singular time points. Three of the four patients responding at 3 months had received a prosthesis at the time of response, three of four at 6 months, and all five at 12 months. HRQOL pertaining to speech and swallowing was generally better in patients responding at 12- and 24-months post operatively compared to those at 3 and 6 months respectively. This may be due to improvement over time, or individual patient variation. SHI scores were varied: two patients felt they had excellent speech at all time points at which they were assessed, while others experienced significant difficulty. The two patients who answered at 3, 6, and 12 months showed improvement in all domains over the assessment period. One was fitted with a prosthesis day 12 post-reconstruction, and the other was fitted prior to the 12-month HRQOL assessment.

Conclusions

The ZIP flap allows concurrent resection of malignancy, immediate reconstruction of the midface, and early dental rehabilitation. It is a reproducible surgical technique with predictable outcomes. Additional investigation into the long-term HRQOL outcomes is needed.

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Author contributions

Antonia L. Watson: Data curation; formal analysis; investigation; writing – original draft; writing – review and editing. **Michael Hurrell:** Conceptualization; investigation; methodology; writing – review and editing. **Dale Howes:** Conceptualization; data curation; methodology; writing – original draft; writing – review and editing. **David Leinkram:** Conceptualization; data curation; investigation; writing – original draft; writing – review and editing. **Tsu-Hui (Hubert) Low:** Conceptualization; data curation; writing – review and editing. **Masako Dunn:** Conceptualization; data curation; formal analysis; investigation; methodology; project administration; writing – review and editing. **Jonathan R. Clark:** Conceptualization; data curation; formal analysis; methodology; project administration; supervision; writing – original draft; writing – review and editing.

Conflicts of interest

None of the listed authors have a conflict of interest to disclose.

Ethical approval

Institutional ethics approval was obtained for the study (Protocol No 2020/ETH02415).

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