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Outcomes of microvascular head and neck reconstruction in solid organ transplant patients: A single institution experience and meta-analysis

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Summary *Background:* Solid organ transplant recipients are at increased risk of developing head and neck squamous cell carcinoma (HNSCC). These patients often require free flap reconstruction; however, data on outcomes in this immunosuppressed population remain limited and formal management guidelines are lacking.
Methods: We conducted a systematic review and pooled proportions meta-analysis, and a retrospective institutional database review, to compare outcomes of head and neck free flap reconstruction in transplant versus non-transplant patients. Cancer-related mortality and time from surgery to death were also assessed.
Results: The systematic review yielded four eligible studies. Kidney transplantation and anterolateral thigh flaps were the most common. Prednisone was the predominant immunosuppressant. The pooled flap success rate was 97%, with recipient and donor site complication rates of 21% and 16%, respectively. Our database had 14 transplant patients who underwent head and neck reconstruction for oral SCC (n = 12) or osteoradionecrosis (n = 2). Tacrolimus was the most common immunosuppressant. Recipient/donor site dehiscence, skin graft loss, and reoperation were significantly higher in transplant patients. Rates of infection,

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salivary leak, hardware exposure, or hematoma were similar. Overall mortality was significantly higher in transplant patients (64% vs. 23%; $p < 0.001$), although the 2-year mortality did not differ on Kaplan-Meier analysis.
Conclusion: Although free flap survival in transplant patients is comparable to non-transplant patients, postoperative complication rates are higher. Given their distinct risk profile and poorer prognosis, transplant patients with HNSCC may benefit from dedicated treatment guidelines.

In 2003, a total of 46,629 organ transplants were performed in the United States alone, a 9.2% increase from 2022.[1] Solid organ transplant (SOT) patients require life-long immunosuppressive therapy, which predisposes them to infections, metabolic complications, and considerably increases their cancer risk.[2] SOT patients are up to 200 times more likely to develop squamous cell carcinoma (SCC), which tends to exhibit more aggressive biological behavior and poorer outcomes.[3] In immunocompetent individuals, basal cell carcinoma outnumbers SCC by a ratio of 4:1; however, in immunosuppressed patients, this ratio is reversed to 1:4 in favor of SCC.[4] The head and neck region is the most common site of SCC in this population and advanced disease can require surgical resection followed by free flap reconstruction.[5] With the rising prevalence of organ transplantation, a growing number of SOT recipients require complex head and neck microvascular reconstruction. However, data on the outcomes of free flap reconstruction in this unique patient population are limited, with existing studies often pooling data from broader immunocompromised cohorts or focusing on reconstructions outside the head and neck region. These limitations hinder the development of evidence-based perioperative protocols tailored to transplant recipients. To address this knowledge gap, we conducted a two-pronged investigation. A systematic review and pooled proportions meta-analysis of the existing literature was performed to assess complication and success rates of head and neck free flap reconstruction in SOT patients. We also conducted a retrospective analysis of our institutional head and neck reconstruction database to directly compare clinical outcomes between transplant and non-transplant patients undergoing free flap reconstruction.

Methods

Systematic review and pooled proportions meta-analysis

A systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines and the checklist was followed.[6] We searched the PubMed, EMBASE and Medline databases supplemented by a manual review of relevant bibliographies. The detailed list of keywords and operators used in the literature review along with the date is provided in Supplementary Table 1.

Two independent reviewers (HO and FBB) screened all articles for eligibility in a three-stage process: title review, abstract review, and full-text evaluation. Discrepancies were resolved by consensus. Articles were included if they reported clinical outcomes and complications of head and neck microvascular free flap reconstruction in solid organ transplant patients, were original human studies, and were published in English. Review articles, technique papers, case reports, animal and non-human studies, cadaveric studies, non-English papers, papers including immunocompromised individuals other than solid organ transplant patients, and studies that did not report detailed complications, were excluded.

For each included study, we recorded sample size, type of transplant, type of free flap, type of immunosuppression, complications, and free flap success rates. Included studies were independently assessed using the Cochrane Methods revised version 2 tool of Risk Of Bias In Non-Randomized Studies- of Interventions (ROBINS-I). A pooled proportions meta-analysis was performed to identify the pooled flap success rates, donor and recipient site complication rates using a random effect restricted maximum likelihood (REML) model to account for inter-study heterogeneity.[7-9] Analysis was performed by using Stata v18.

Institutional retrospective database review

We retrospectively reviewed all patients who underwent head and neck free flap reconstruction following SCC resection between September 2012 and December 2023. A retrospective database was used to review patients before 2019 and a prospectively maintained departmental database, along with electronic medical records, was used to review patients between 2019 and 2023. Patients without any history of solid organ transplant or immunocompromised status served as the control group. As all solid organ transplant patients had SCC in our cohort, patients in the control group who underwent reconstruction for any indication other than SCC were excluded to ensure homogeneity. The protocol was approved by the institutional review board (STUDY20050058).

Demographic and comorbidity data including patient age, gender, and medical co-morbidities (diabetes, thyroid disease, renal disease, cardiac disease, and pulmonary disease) were collected. Type of solid organ transplant and immunosuppressive medications were also recorded. Surgical data included the type of free flap, and surgical complications including dehiscence, skin graft loss/incomplete take, infection, salivary leak, hardware exposure, skin necrosis, and bleeding. All-cause mortality and time from surgery to death was also collected. Attempts to discern cause of death were made, however, reporting was inconsistent in the EMR and therefore this information was not collected.

The primary outcome assessed was the rate of complications and time until death. Descriptive statistics were performed for all variables. Univariate analysis, including Fisher's X^2 and Wilk's G^2 analyses, were performed to compare cohorts. Distribution fitting was used for all continuous variables and parametric tests, such as Student's *t*-test, or non-parametric tests, such as Mann-Whitney *U* test, were performed based on their distribution. Kaplan-Meier curve was used to assess time from surgery to death between the cohorts. All tests performed were two-sided and p-value of 0.05 was considered statistically significant. Analysis was performed using SPSS v29.

Results

Systematic review and pooled proportions meta-analysis

The literature search returned 154 unique articles after screening for duplicates. Manuscripts were independently reviewed by two reviewers, first by title, abstract, and finally full article—resulting in the inclusion of 4 articles (Figure 1). All articles were retrospective cohort studies with high heterogeneity among results. The risk-of-bias assessment was performed as summarized in the Supplementary Table 2 and no study achieved low risk across all domains. The total transplant patient population in these articles was 50. Among these patients, kidney transplantation was the most common, accounting for 52% of cases. Most of the patients were treated with prednisone as part of their immunosuppressive regimen, with 72% receiving prednisone, most commonly in combination with other agents (Table 1). The most common free flap type was anterolateral thigh flap (ALT) (44.6%), followed by radial forearm free flap (32.1%) (Table 1). All included studies assessed vascular thrombosis, flap loss, recipient site complications, and donor site complications (Table 2). The study by Perry et al. was excluded owing to lack of detailed data regarding free flap outcomes, despite meeting the initial inclusion criteria.[10]

The limited available literature and the resulting limited number of patients substantially limited the ability for further analysis. The pooled analysis demonstrated a flap success rate of 97%. The overall complication rate at the recipient site was 21%, whereas donor site complications occurred in 16% of patients. These findings were further

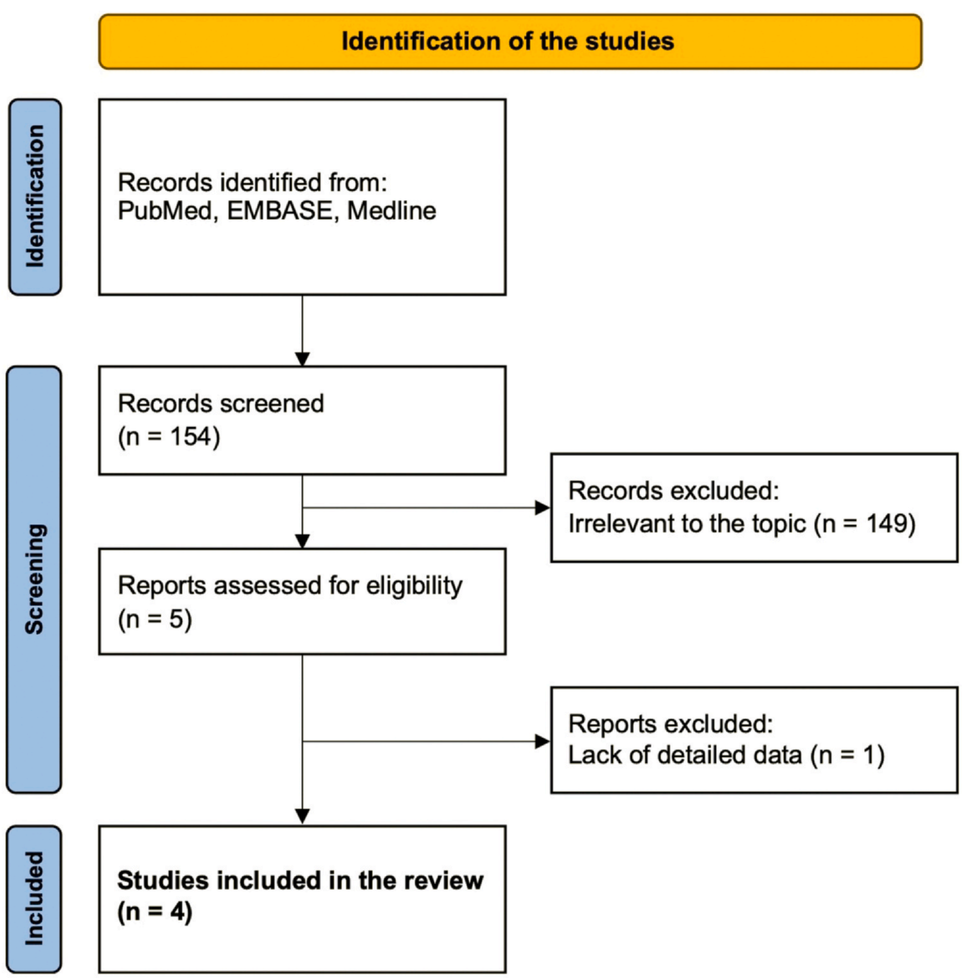


Figure 1 Protocol followed for systematic review and selection process of the papers included in this study.

Table 1 Summary of the papers included in pooled proportions meta-analysis.

Study	Sample size	Transplant type	Immunosuppressants	Type of free flap
Lee[11]	3	2 Kidney 1 Heart	2 CyA/Prednisone 1 FK506	2 RFFF 1 DCIA
Sbitany[12]	5	2 Kidney 3 Liver	1 FK506 1 FK506/MMF 1 CyA/Prednisone 1 FK506/Prednisone 1 FK 506/Sirolimus	4 RFFF 1 ALT
Miller[a,2]	17	11 Kidney 4 Liver 2 Heart 1 Lung	15 Prednisone 7 CyA 6 FK506 4 MMF 3 AZT 2 Sirolimus	8 RFFF 7 ALT 3 LD 2 FFF 1 RA 1 Lateral arm
Schaverien[5]	25	13 Kidney 1 Pancreas 4 Liver 2 Heart 2 Stem cell 6 Lung	5 Prednisone/ FK506 4 FK506 3 Prednisone/ FK506/MMF 3 Sirolimus/MMF 2 Prednisone/FK506/AZT 2 Prednisone/Sirolimus 2 Prednisone/Sirolimus/CyA 2 FK506/MMF 1 Prednisone/FK506/Sirolimus 1 Prednisone/MMF/CyA 1 Sirolimus 1 Prednisone/CyA 1 Sirolimus/MMF	17 ALT 4 RFFF 2 LD 2 FFF 1 TAP 1 Lateral arm
Total	50	Kidney 28 (52%) Liver 11 (20%) Lung 7 (13%) Heart 5 (9%) Stem cell 2 (4%) Pancreas 1 (2%)	Prednisone 36 (72%) FK506 28 (56%) MMF 15 (30%) CyA 14 (28%) Sirolimus 13 (26%)	ALT 25 (45%) RFFF 18 (31%) LD 5 (9%) FFF 4 (7%) Lateral arm 2 (4%) RA 1 (2%) TAP 1 (2%)

CyA, Cyclosporin; FK506, Tacrolimus; MMF, Mycophenolate Mofetil; AZT, Azathioprine; RFFF, Radial forearm free flap; DCIA, Deep circumflex iliac artery flap; ALT, Anterolateral thigh flap; LD, Latissimus dorsi flap; FFF, Free fibula flap; RA, Rectus abdominus flap; TAP, Thoracodorsal artery perforator flap.
[a] Reports percent of patients on each immunosuppressant, but does not report medications in combination.

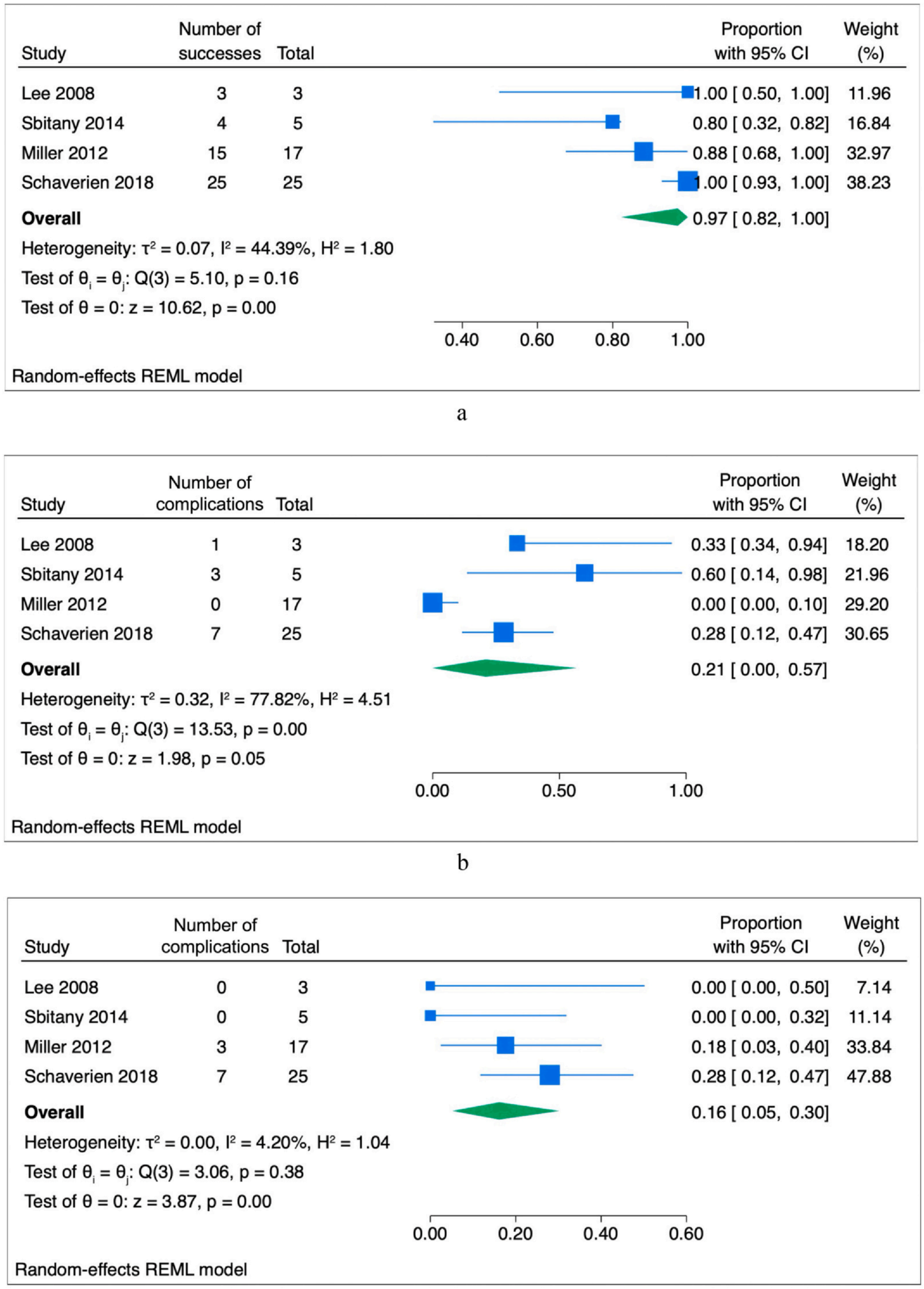
validated by a pooled proportions meta-analysis using a random-effects REML model, which confirmed consistent rates of flap success and complications across all included studies (Figure 2a-c).

Institutional retrospective database review

In our institutional review, 14 solid organ transplant patients who underwent head and neck free flap

Table 2 Complications reported in the papers included in pooled proportions meta-analysis.

Study	Sample size	Thrombosis	Flap loss	Recipient site complications	Donor site complications
Lee[11]	3	0	0	1 fistula	0
Sbitany[12]	5	1 (arterial)	1 partial	1 seroma 1 wound dehiscence	0
Miller[2]	17	0	1 total 1 partial	0	3 infection and hematoma
Schaverien[5]	25	0	0	4 hematoma 2 wound dehiscence 1 infection	4 wound dehiscence 1 hematoma 1 infection 1 skin graft loss
Total	**50**	**1**	**3**	**10**	**10**



c

Figure 2 Pooled proportions meta-analysis of the literature showing an overall free flap success rate of 97% in solid organ transplant patients (a), recipient site complication rate was 21% (b), and donor site complication rate was 16% (c).

reconstruction were identified between September 2012 and December 2023. All patients underwent reconstruction owing to oral SCC (n = 12), or osteoradionecrosis secondary to treatment of oral SCC (n = 2). The most frequently transplanted organ was the liver, accounting for 46.6% of patients, followed by the kidney in 26.6% of cases (Table 3). Nearly all patients (93%) received tacrolimus as their primary immunosuppressive agent, either as monotherapy or in combination with mycophenolate, prednisone, or hydrocortisone.

The anterolateral thigh flap was the most commonly used flap in this cohort, applied in 62.5% of reconstructions.

Table 3 Summary of patients from institutional database.

Patient	BMI	M/F	Transplant type	Immunosuppressants	Comorbidities	Type of free flap	Complications
1	23.2	M	liver	FK506, MMF	CAD, GERD, Afib	ALT	Recipient site hematoma and dehiscence
2	25.7	M	kidney	FK506	CAD, CKD, lung Ca	ALT	
3	17.8	M	liver	FK506	CAD, COPD, GERD, HCV, HCC, CKD	ALT, FFF	
4	29.6	M	heart	FK506	CAD, COPD, DM, GERD, gastric lymphoma, prostate ca, thyroid ca, CKD	ALT	Incomplete skin graft take in donor site, donor site dehiscence, recipient site skin necrosis
5	25.7	M	liver	FK506	hypothyroidism, GERD	ALT	
6	20.7	M	lung, liver	FK506, prednisone	CAD, COPD, hypothyroidism, GERD, paroxysmal Afib, SS, HTN, CKD,	ALT	Recipient site skin necrosis
7	24.2	M	liver	FK506	DM, hypothyroidism, GERD, HCC	FFF	Infection, hardware exposure
8	21	M	lung	CyA, MMF	CAD, COPD, blood disorders, GERD, CKD, OSA, nephrolithiasis, pseudogout, HLD	ALT	Donor site dehiscence
9	18.6	M	lung	FK506, prednisone	CAD, COPD, GERD, CKD, anxiety, depression, osteopenia	FFF	
10	21.1	M	kidney	FK506	CAD, DM, CKD, gout, HLD	ALT	
11	27.8	M	kidney	FK506	CAD, DM, blood disorders, GERD, CKD, HLD, gout	ALTx2	Recipient site dehiscence
12	25.77	M	liver	FK506	CAD, GERD, CKD, HTN, HCV	FFF	Skin graft loss in donor site
13	27.38	F	kidney	FK506/hydrocortisone	CKD, HCV, adrenal insufficiency, BrCa, HCV	RFFF	
14	32.9	M	liver	FK506, prednisone	CAD, COPD, DM, paroxysmal Afib, UC, PSC	Vastus lateralis	
Total			Liver 7 (46%) Kidney 4 (27%) Lung 3 (20%) Heart 1 (7%)	FK506 13 (93%) Prednisone 3 (22%) MMF 2 (13%) Hydrocortisone 1 (7%)		ALT 10 (63%) FFF 4 (25%) RFFF 1 (6%) Vastus lateralis 1 (6%)	

CyA, Cyclosporin; MMF, Mycophenolate Mofetil; FK506, Tacrolimus; CAD, coronary artery disease; GERD, Gastroesophageal reflux disease; Afib, Atrial fibrillation; CKD, Chronic kidney disease; Ca, Cancer; COPD, Chronic obstructive pulmonary disease; HCV, Hepatitis C virus; HCC, Hepatocellular carcinoma; DM, Diabetes Mellitus; SS, Systemic sclerosis; HTN, Hypertension; OSA, Obstructive sleep apnea; HLD, Hyperlipidemia; BrCa, Breast cancer; UC, Ulcerative colitis; PSC, Primary sclerosing cholangitis; RFFF, Radial forearm free flap; ALT, Anterolateral thigh flap; FFF, Free fibula flap.

Table 4 Complications in the transplant and non-transplant groups in the institutional database.

Complications	Transplant group (n = 14)	Control (n = 1047)	
Reoperation within 30-days	5 (35.7%)	163 (15.6%)	**p = 0.04**
Donor site complications			
Incomplete skin graft take	1 (7.1%)	38 (3.7%)	p = 0.418
Donor site dehiscence	4 (28.6%)	53 (5.1%)	**p = 0.026**
Graft loss	2 (14.3%)	1 (0.3%)	**p < 0.001**
Recipient site complications			
Bleeding	1 (7.1%)	60 (5.7%)	p = 0.82
Necrosis of neck and face skin	2 (14.3%)	122 (11.7%)	p = 0.76
Infection	2 (14.3%)	112 (10.7%)	p = 0.67
Dehiscence	3 (21.4%)	56 (5.3%)	**p = 0.038**
Salivary Leak	0 (0%)	25 (2.4%)	p = 0.59
Hardware Exposure	1 (7.1%)	30 (2.9%)	p = 0.36

The second most frequent was the free fibula flap, used in 25% of cases.

Demographic information differed between the control (n = 1047) and transplant free flap patients. Transplant patients were more likely to be men ($p = 0.046$), have a blood disorder ($p = 0.028$), and have a gastrointestinal, renal, or vascular comorbidity ($p < 0.001$, $p < 0.001$, $p = 0.031$, respectively). Transplant patients were also more likely to have undergone prior radiation or surgery (p = 0.049, 0.011, respectively) (Table 3).

In terms of surgical outcomes, transplant patients demonstrated significantly higher rates of recipient and donor site dehiscence ($p = 0.038$, $p = 0.026$). Transplant patients were also more likely to have total skin graft loss ($p < 0.001$) and undergo re-operation within 30 days of the index procedure ($p = 0.04$). However, there were no statistically significant differences in the rates of recipient site infection, salivary leak, hardware exposure, skin necrosis, or bleeding/hematoma between the two groups (Table 4).

Mortality analysis revealed that the transplant cohort experienced a significantly higher overall mortality rate compared to the non-transplant group (64% vs. 23%; $p < 0.001$). However, 2-year mortality was not statistically significant ($p = 0.130$). Nonetheless, when stratified by time using the Kaplan-Meier survival analysis, the difference in two-year overall survival between the two cohorts was not statistically significant (Figure 3).

Discussion

The population of immunocompromised patients continues to grow owing to advancements in transplant medicine and the widespread use of immunosuppressive therapies.[1,13] Although these therapies are critical for graft survival, they impair tissue regeneration and wound healing, introducing new challenges in surgical care.[14] Among these patients,

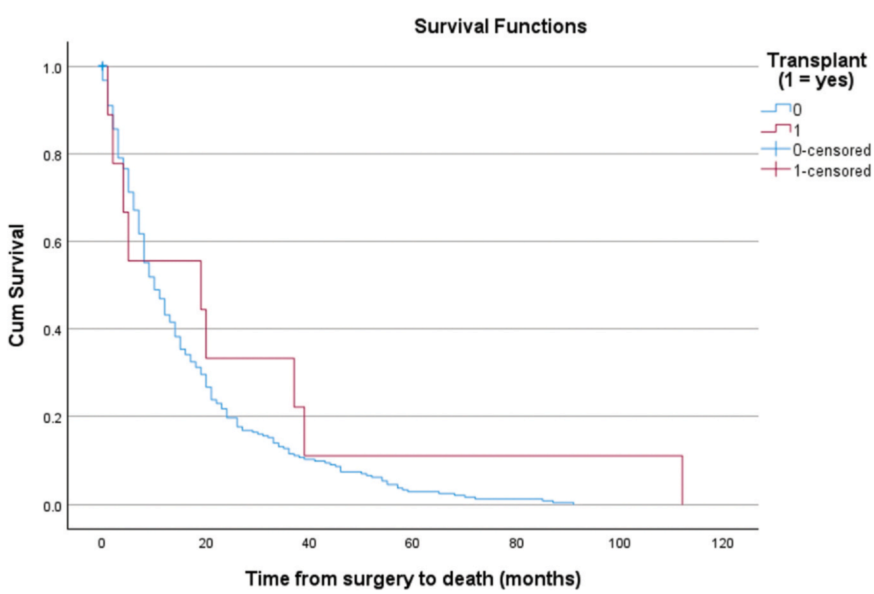


Figure 3 Kaplan-Meier survival analysis showing that mortality rate in the transplant patient population was significantly increased compared to the non-transplant population (64 vs. 23%; $p < 0.001$). However, the 2-year overall mortality was not significant.

those with solid organ transplants (SOT) face particularly complex reconstructive scenarios, especially in the head and neck region where the margin for complication is small. In this study, we hypothesized that head and neck free flap reconstruction in SOT patients would result in higher rates of complications owing to impaired wound healing from chronic immunosuppression. Our results support this hypothesis. Although flap survival rates were similar between transplant and non-transplant patients, the SOT cohort experienced significantly more complications, including dehiscence, skin graft loss, and a higher need for reoperation. These complications prolong recovery and severely impact quality of life, particularly in the head and neck region, where even minor wound issues can lead to functional impairment and aesthetic compromise.

The literature on this topic remains sparse and heterogeneous. The available literature significantly restricted the ability of our pooled proportions meta-analysis to reach strong conclusions, and the small number of patients substantially constrained the strength of inference. Some studies included all immunocompromised patients in addition to solid organ transplant patients,[12] whereas others included free flaps outside the head and neck region, limiting their generalizability.[11] Our systematic review identified only 4 papers that met strict inclusion criteria, with a combined cohort of just 50 patients. The largest series published by Schaverien et al., reported no increase in free flap loss in transplant patients.[5] However, the overall complication rate in this population was 60% compared to 34% in all head and neck free flap reconstruction patients (n = 3753) as reported by the same group.[15] This disparity aligns with our institutional findings.

The published NSQIP data places the overall complication rate for head and neck free flap reconstruction between 49% and 55%.[16-18] In our study, SOT patients had significantly more wound healing complications and were over three times more likely to require reoperation compared to controls. These findings reinforce that flap success alone is an insufficient metric of reconstructive success in this high-risk group. Instead, comprehensive outcome measures including complication rates, return to function, and patient quality of life are needed to guide management. Immunocompromised patients with SCC have more aggressive disease, characterized by multifocal early recurrence and metastases, and overall decreased survival, as observed in our study as well.[19-22] Risk of disease specific death is more than double compared to immunocompetent patients.[20] In our cohort, almost one-third of the patients died within the first year following surgery and all with recurrent disease. These results are consistent with those of prior studies, including those by Miller et al., who reported a median survival of 14.4 months and survival rate of 29.4% at the last follow-up.[2] However, the two-year mortality on Kaplan-Meier was not statistically significant in our study, highlighting the inherently high mortality of this patient population. Given the limited life expectancy observed in this population, the emphasis on management should shift toward maximizing quality of life. Wound complications and repeated surgeries can dramatically reduce functional outcomes and patient satisfaction. Thus, the risks of aggressive surgery should be carefully weighed against patient goals, particularly in the context of limited survival.

Emerging immunotherapies, such as PD-1 inhibitors (e.g., cemiplimab and pembrolizumab), have shown promise in treating advanced SCC, including in immunocompromised patients. The C.A.S.E. study, for example, reported that 47% of immunosuppressed patients achieved either a complete or partial response to cemiplimab.[23] These findings are promising particularly for patients at high surgical risk and further studies may be helpful to evaluate the oncologic efficacy and transplant safety of such agents.

Our decision to focus solely on head and neck free flap reconstructions in SOT patients was deliberate. Complications in this region are uniquely consequential. For instance, a minor dehiscence in an extremity may heal with local care, whereas the same issue in the oropharynx can lead to salivary leak, fistula formation, infection, pneumonia, and death. In our cohort, over one-third of patients required surgical re-intervention owing to such complications, underscoring the need for specialized perioperative strategies.

Another area of ongoing debate is the perioperative management of immunosuppressive medications. Our sample size was not large enough to draw a correlation between the immunosuppressant medications and complications. However, prednisone was found to increase the rate of wound-related complications,[5,12] and it might have contributed to increased complication rates in our transplant patient cohort. However, Wang et al., did not find any significant correlation between the immunosuppressive regimen intensity (unchanged vs. reduced/held) and overall complications, although there was a trend toward increased complication rate.[24] mTOR inhibitor sirolimus is another immunosuppressant that increases wound-related complications after free flap reconstruction.[25,26] Interestingly, sirolimus is associated with a lower incidence of SCC in solid organ transplant patients.[27-31] This dual role presents a clinical dilemma, as agents that lower cancer risk may simultaneously impair surgical healing. Mycophenolate mofetil appears to have a more favorable profile in this regard, as it is less disruptive to wound healing and may reduce skin photosensitivity, thereby lowering the risk of SCC.[14,32] Future research should aim to define evidence-based immunosuppressive protocols tailored to surgical patients.[4]

This study is not without limitations. The retrospective nature of our institutional review introduces inherent biases, and the small sample size of transplant patients limits statistical power along with the ability to control for confounders such as comorbidity, prior radiation, and immunosuppressive regimen. During the institutional time span of more than a decade, our reconstructive techniques, perioperative care, and immunosuppressive strategies may have evolved and are a potential source of confounding in our analysis. Additionally, the lack of functional and patient-reported outcomes restricts the assessment of reconstructive outcomes beyond surgical morbidity. The studies included in our meta-analysis were limited in number and heterogeneous in design, which also restricted the possibility of comparative analysis and generalizability of pooled estimates. Our analysis primarily focused on the overall pooled effect estimate of flap survival rates, as the available evidence was insufficient to support reliable stratified analyses of other variables such as the

Table 5 Considerations for perioperative optimization.

Preoperative
Multi-disciplinary evaluation
Review of goals and quality of life expectations
Discussion of increased risk of wound healing complications
Review of the immunosuppressive regimen
Review of nutritional supplementation for optimal wound healing
Optimization of other comorbidities
Intraoperative
Optimal free flap size to minimize donor site comorbidities
Possible utilization of local tissues in conjunction with free flaps
Strategies to prevent donor dehiscence (such as negative pressure wound therapy and tension offloading devices)
Postoperative
Optimized hospital stay and in-house consultations as needed
Multi-disciplinary evaluation and follow-up
Close follow-up in the first 30 days
Early conservative management of wound complications

immunosuppressive agents. Nonetheless, by combining a rigorous literature review with real-world institutional data, we provide a comprehensive picture of the challenges facing this unique patient population.

In conclusion, solid organ transplant patients undergoing head and neck reconstruction with free flaps experience significantly higher complication rates and have a poorer overall prognosis than non-transplant patients. Although flap survival may be similar, the full scope of surgical morbidity must be considered. These findings highlight the urgent need for specialized perioperative guidelines and underscore the importance of shared decision-making that centers patient values and goals of care. Future guidelines can be formulated to enable optimization of perioperative elements (Table 5). Preoperatively, a thorough multi-disciplinary counseling, review of the immunosuppressive regimen, and optimization of comorbidities and the nutritional status can be considered. Surgical strategies to minimize wound healing complications can be implemented. Postoperative care can be adjusted to include close monitoring particularly in the early postoperative period to facilitate early conservative management for wound complications. A prospective, multicenter trial is warranted to develop evidence-based strategies for optimizing outcomes in this high-risk group.

Ethical approval

The protocol was approved by the Institutional Review Board (STUDY20050058).

Funding

None.

Declaration of Competing Interest

None declared.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.bjps.2026.02.032.

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