Review Article

The impact of volume and surgical throughput on outcomes in head and neck reconstruction: a systematic review

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Background: Microvascular free tissue transfer is the standard of care for head and neck reconstruction. It is suggested that the volume of cases/surgical throughput might be linked to better free flap outcomes, following the pattern of other surgical disciplines. However, the literature evidence is unclear.

Methods: I performed a PRISMA-guided systematic review (PROSPERO CRD206975). Reports were identified using a search algorithm in MEDLINE/EMBASE. I have included articles in English, irrespective of the study design. I compared the free flap success rate between high-volume units (>50/year) and low-volume units (<50/year). An attempt to record secondary outcomes (mortality, readmissions, complications, return to theatre) was also made. Eligible studies were assessed for quality using the GRADE method.

Results: I identified 27 eligible studies. Distribution between high and low volume units was equal (12 *vs.* 11 studies). The remaining 4 studies were multicenter and revealed no difference between included units. Flap cases/year ranged from 8 to 280. Free flap success rate ranged from 89% to 100% (average 95%) with no differences between units. Very limited data were available on the secondary outcomes (mortality, readmissions, complications, return to theatre). The quality of the eligible studies was suboptimal, and the threat of selective reporting bias was present.

Discussion: This systematic review revealed that the reported free flap success rate is similar between high and low volume units. Despite suboptimal study quality, this review calls for caution when outcomes are used as a justification for centralizing H&N services, as literature doesn't seem to support this as strongly is in other surgical disciplines.

Keywords: Free flaps; reconstruction; cancer; volume; outcomes; free tissue transfer

Received: 13 September 2021; Accepted: 28 February 2022; Published: 10 September 2022.
doi: 10.21037/fomm-20-60
View this article at: https://dx.doi.org/10.21037/fomm-20-60

Introduction

Microvascular free tissue transfer is the gold standard of head and neck (H&N) reconstruction. Surgical techniques around free flap surgery have evolved enormously over the last few decades; we now live in the era of patient-specific 3D-aided H&N free flap reconstruction (1,2).

The general belief is that this kind of complex surgery should be carried out in high volume centers, with high numbers of cases/surgical throughput, in order to achieve the best possible outcomes for the patients. Many other factors favoring H&N centralization have been cited, including teaching, education, training, cost reduction and efficient health economy, teamwork building, research, audit and governance monitoring (3). In reality, most of these benefits can be achieved anywhere, without centralization of services, as long as clinical outcomes are favorable for patients. Other proposals to improve outcomes (such as dual attending surgeon operating, minimize junior doctors operating) are yet to prove their efficiency (4).

Literature from other specialties suggests that the relationship between volume and outcomes is not always

linear, but often follows a bell distribution. This of course means that outcomes might improve up to a certain volume level, after which any further increase has a detrimental effect (5). On other occasions, achievement of acceptable outcomes might plateau after a certain case volume and remain unchanged thereof (6).

Recent systematic reviews and meta-analyses suggest an acceptable average free flap success level for H&N reconstruction of 95% (7). This is somehow lower than breast and limb reconstruction (8), which can partly be explained by the general fitness and performance score of the H&N patients. Taking into account salvage cases and ORN cases, one can safely consider a free flap success rate of over 90% as the minimum acceptable outcome in H&N reconstruction.

Unfortunately, free flap outcomes reporting isn't universally mandatory. In the UK, the UKNFR registry is a step towards the right direction (9), but until it becomes a practice requirement, the scene of the free flap H&N reconstruction will remain vague at best.

Here, I conduct a systematic review of all available published evidence, in an attempt to establish a correlation between surgical throughput and clinical outcomes in H&N free flap reconstruction. I discuss the pitfalls of data collection and reporting, and I debate the pros and cons of centralization of H&N services. I present the following article in accordance with the PRISMA reporting checklist (available at https://fomm.amegroups.com/article/view/10.21037/fomm-20-60/rc).

Methods

Protocol and registration

I performed a systematic review of all available literature in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and the guidance set out by the Cochrane Handbook of Systematic Reviews of Intervention (10,11). The systematic review was submitted to the International Prospective Register of Systematic Reviews (PROSPERO) (CRD206975).

Eligibility criteria

Study designs and report characteristics

All human experimental (randomized control trials and trials) and observational studies (case series, case reports, case control and cohort) were eligible for inclusion. There was no limitation on the sample size. Review papers and eligible studies were screened for papers not detected by the search algorithm. Animal studies were excluded. Language was restricted to English literature.

Participants

All adult (over 18 years) patients undergoing H&N autologous free tissue transfer were included. There were no limitations on the type of flap or reconstruction indication (tumor ablation, ORN, etc.) however trauma cases were excluded.

Interventions

I included all publications reporting surgical outcomes in H&N free flap reconstruction whilst offering information about the institutional volume/number of cases/surgical throughput. I accepted reports comparing outcomes from the same institute but different time periods (thus indicating a change in numbers treated *vs.* outcomes). I have also included multicenter studies where the comparison between units was clearly made based on volume/number of cases.

Comparators

Any study that directly reported and/or compared surgical outcomes in H&N free flap reconstruction with total number of treated patients was included. The treating units were classified as large (>50 cases/year) based on the BAHNO recommendations for double team consultant operating and recommended volume per consultant (12). Even if this direct comparison wasn't made, I attempted to extract this information from the available data and documented whether this was unclear or impossible based on the available information.

Outcomes and definitions

The primary outcome was free flap success rate (N/%). Flap failure was defined as a non-surviving free flap, requiring debridement and/or removal, and/or further reconstruction (further free flap and/or further pedicled flap and/or further dressing).

Secondary outcomes included:

(I) Perioperative mortality (30 days);
(II) Clavien-Dindho grade III–IV complications;
(III) 28-day unplanned hospital re-admission;

(IV) Return to theatre for exploration and flap salvage.

Information sources and search strategy

I performed a comprehensive literature review using the advanced search in MEDLINE (OVID interface), EMBASE (OVID interface), and PubMed from its origin till August 2020.

The following terms (MeSH) were used: "microvascular free tissue transfer" OR "free flap" OR "head and neck reconstruction" AND "number" OR "outcomes" OR "free flap salvage" OR "success rate". Each term was exploded prior to being combined. Initial results were screened based on titles and abstracts. The references of all eligible papers were screened, and any missed studies were included. If unable to extract data from the literature, I contacted the corresponding author. If there was no response, the study was excluded, and documented in the PRISMA flow chart below. I also screened ClinicalTrials.gov for any ongoing trials.

Data extraction and management

All data extracted were tabulated in a predefined sheet. I recorded the type of study, number of flaps, type of flap used, number of cases per year in that particular institute, and all the primary and secondary outcomes.

Quality assessment

I assessed for publication bias as previously described (13). The quality of evidence was assessed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.

Statistical analysis

I aimed to record the free flap success rate (%) in all included studies and compare it to the number of cases performed per year within the same institution or team (denominator). Should data quality allowed, I aimed to calculate the relative risk ratios with 95% confidence intervals using the Cochran-Mantel-Haenszel test. I expected significant between-study heterogeneity; therefore, a random-effects model was applied. Heterogeneity was measured using the I^2 statistic (claiming significance at $P<0.05$). Publication bias was assessed using the established funnel plot method.

Results

PRISMA flow diagram (Figure 1)

My initial search strategy generated a large volume of titles [2,134]. After screening for duplicates, titles and abstracts, I analyzed 52 full text articles. Twenty-five were excluded, including two reviews, 7 with overlapping data, 8 with selective presentation of data, 5 with no available data at all and 3 non-English literature papers. Therefore, a total of 27 articles were included and fully assessed.

Primary outcome (Table 1)

All 27 papers were retrospective case series (*Table 1*). There were no randomized controlled trials. Eleven articles came from low volume centers, 12 from high volume centers and 4 were multicenter studies including both high and low volume units. The number of H&N flaps/year ranged from 8 to 280. The reported free flap success rate ranged from 89% to 100% (with the vast majority of studies reporting results between 93–96%). There was no association between unit volume and free flap success rate; this was further emphasized in the 4 studies presenting results from various centers. All studies but two have used a variety of free flaps. Only 8 studies provided data on pre-op radiotherapy. Data synthesis was unnecessary as all studies reported overlapping outcomes.

Secondary outcomes (Table 2)

There was great variability on the available results for the secondary outcomes. Mortality data were available in 9 studies (33%) with a perioperative mortality rate ranging from 0–3.4%. Only two studies reported readmission rates (5% *vs.* 7%). Unfortunately, data on return to theatre for re-exploration and Clavien-Dindho surgical complications weren't available in the majority of the studies. Information on preop RTX was available in 9 studies (14-16,18,19,22-24,32); in one of them (15) the flap success rate was 90% with 26% of the study population being post RTX patients.

Quality of evidence

Figure 2 shows the GRADE summary of findings to assess for bias risk. As expected, the overall study quality was low or very low. Bias was serious in many outcomes due to lack of direct comparisons. There was also heterogenicity

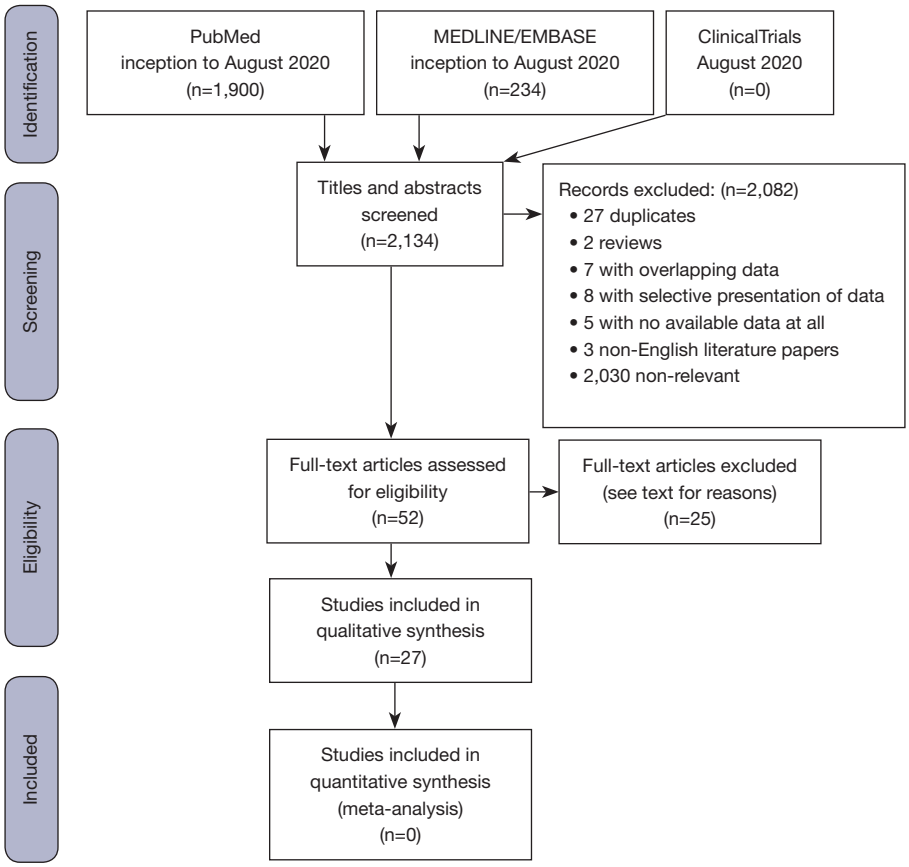

Figure 1 PRISMA flowchart for identification of eligible studies.

in the results from earlier literature with higher rates of complications (I^2 P<0.05). Selective reporting bias (40) is assumed, as units with failure rates higher than the perceived maximum (i.e., 10%) do not publish their outcomes. The author is aware that these units exist (at least in the UK) via RCS external reviews (data not shown).

Discussion

The current systematic review, first of its kind in the medical literature, revealed a somehow unexpected finding: That surgical throughput and number of free flap cases/year is not clearly and directly related to the free flap success rate, based on the data available on the published eligible papers. This of course comes as a surprise, as one of the main arguments supporting the centralization of H&N services is the need to improve all of patients' outcomes, including flap success rate. In other specialties, the association between volume and outcomes is very clear and has already led to reconfiguration of services (i.e., vascular surgery) (6).

Without dismissing the possibility of strong selective reporting bias (40), it seems as if the medical evidence doesn't support the argument of a link between surgical throughput and free flap success outcomes. Furthermore, there was scarcity of available data to draw a clear correlation between volume and the secondary outcomes. Admittedly, the search algorithm used on this occasion was targeted to flap survival outcomes, and some studies looking specifically at the secondary outcomes might have been missed. I am aware of studies specifically looking at these secondary outcomes from large units in UK and Europe (41,42); these studies report complications towards the upper end of what is recorded in this systematic review. Although speculative, it seems like larger units might report higher complication rates. This of course could be linked to a stronger data collection mechanism and a more robust clinical governance, and M&M processes.

The main limitation of the current systematic review and the available data is that they are not fully representative

Table 1 Characteristics and primary outcome of eligible studies

Study	Country/ region/area	Total number flaps	Time period	Number cases/year	Large unit (yes/no)	Types of flap	Flap success rate	Post RTX	Grade certainty
Al-Dam, *J Craniomaxillofac Surg*, 2014 (14)	Germany	103	2011–2012	103	Yes	Fibula, RFF, LD, ALT, DCIA, Scapula, MSAP	98/103 (95.15%)	23 (24.4%)	Low
Spoerl, *Oral Maxillofac Surg*, 2020 (15)	Germany	494	2009–2018	50	Yes	Fibula, RFF, LD, ALT, DCIA, Scapula, MSAP, lateral arm, pec major	443/494 (90%)	129 (26%)	Low
Marttila, *Br J Oral Maxillofac Surg*, 2018 (16)	Finland	191	2005–2010	38	No	RFF, ALT, DCIA, Scapula, Rectus, Fibula	181/191 (95%)	0 (0%)	Very low
Kovatch, *Laryngoscope*, 2019 (4)	USA	NA	NA	Mean 83	Yes	All types	95.7% (reported)	NA	Very low
Kessler, *J Craniomaxillofac Surg*, 2012 (17)	Netherlands	81	2007–2011	Mean 20	No	RFF, Fibula, ALT, Scapula	100%	0 (0%)	Low
Rendenbach, *Int J Oral Maxillofac Surg*, 2018 (18)	Europe	NA	NA	NA	Mixture of units	All types	Majority over 90%. Authors mention no difference between centres or specialties	NA	Moderate
Salama, *Int J Oral Maxillofac Surg*, 2009 (19)	USA	71	2002–2005	23	No	RFFF, Fibula ALT, rectus	67/71 (94%)	0 (0%)	Low
Eckardt, *J Craniomaxillofac Surg*, 2003 (20)	Germany	500	1982–2000	28	No	Jejunum, RFFF, Scapula, LD, Fibula, Gracilis, Rectus, DCIA, Lat Arm	470/500 (94%)	Unclear but less than 10%	Low
Pohlenz, *Int J Oral Maxillofac Surg*, 2012 (21)	Germany	1,000	1987–2010	75	Yes	LD, RFFF, ALT, Fibula, DCIA, Jejunu	870/100 (92.4%)	NA	Very low
Lou, *Int J Oral Maxillofac Surg*, 2019 (22)	China	1,038	2006–2017	103	Yes	Fibula, DCIA, Scapula	1,024 (99%)	187 (18%)	Very low
Wang, *Br J Oral Maxillofac Surg*, 2018 (23)	China	169	2011–2016	33	No	RFFF	168 (99%)	8 (3.5%)	Low
Sugiyama, *Head Neck*, 2016 (24)	Japan	773	1995–2006	35	No	Jejunum	750 (97%)	218 (29.5%)	Low
Nouraei, *J Plast Reconstr Aesthet Surg*, 2015 (25)	UK	11,841	2003–2013	118	Mixture of units	All flaps	11,345 (95%)	Unclear	Very low
Ho, *Br J Oral Maxillofac Surg*, 2012 (26)	UK	1,278	1992–2009	70	Yes	All flaps	1,214 (96%)	Unclear	Moderate
Sweeny, *Laryngoscope*, 2020 (27)	USA	2,890	2007–2017	280	Mixture of units	All flaps	2,757 (95.1%)	Unclear	Low

Table 1 (*continued*)

Table 1 (*continued*)

Study	Country/ region/area	Total number flaps	Time period	Number cases/year	Large unit (yes/no)	Types of flap	Flap success rate	Post RTX	Grade certainty
Weckx, *Oral Surg Oral Med Oral Pathol Oral Radiol*, 2017 (28)	Belgium	100	2011–2015	25	No	ALT, Fibula	96 (96%)	NA	Very low
Klosterman, *Otolaryngol Head neck Surg*, 2015 (29)	USA	136	1993–2013	8	No	RFF, Fibula	124 (92.6%)	NA	Low
Liang, *Br J Otorhinolaryngol*, 2018 (30)	Brazil	98	2007–2015	12	No	RFF, Fibula, ALT, Jejunum	75 (90%)	NA	Very low
Zhang, *Int J Oral Maxillofac Surg*, 2015 (31)	Taiwan	4,640	1979–2013	136	Yes	All flaps	4404 (97%)	139 (3.1%)	Moderate
Farquhar, *Otolaryngol Head Neck Surg*, 2018 (32)	USA	170	2007–2014	25	No	NA	151 (89%)	NA	Low
Brady, *Am J Otolaryngol*, 2017 (33)	USA	1,417	2015–2013	170	Yes	All flaps	Data for 582 (95%)	NA	Moderate
Thomas, *JAMA Facial Plast Surg*, 2018 (34)	USA	1,115	2012–2014	Multiple centres	Mixture of units	All flaps	Unclear	NA	Moderate
Kucur, *Eur Arch Otorhinolaryngol*, 2016 (35)	USA	260	2006–2010	65	Yes	All flaps	249 (96.5%)	NA	Low
Husso, *J Reconstr Microsurg*, 2016 (36)	Finland	594	1995–2012	33	No	All flaps	578 (97%)	NA	Moderate
Smith, *Br J Oral Maxillofac Surg*, 2005 (37)	Aystralia	263	1987–2002	18	No	RFFF	254 (96.6%)	NA	Very low
Dassonville, *Eur Arch Otorhinolaryngol*, 2008 (38)	France	213	2000–2004	52	Yes	RFFF, Fibula, Scapula	1,999 (93.4%)	Unclear	Low
Ross, *J Reconstr Microsurg,* 2008 (39)	UK	584	1993–2003	58	Yes	All flaps	550 (94%)	Unclear	Moderate

RFF, radial forearm flap; LD, latissimus dorsi flap; ALT, anterolateral thigh flap; DCIA, deep circumflex iliac artery flap; MSAP, medial sural artery perforator flap; RFFF, radial forearm free flaps; NA, not applicable.

of all the units performing microvascular free flaps for H&N reconstruction worldwide. Registration mechanisms do not exist in many countries and in those that have one, recording of data and outcomes is not always mandatory. Therefore, the threat of selective reporting bias is real. However, one cannot dismiss what is clearly shown in the literature, which is comparable outcomes between low and high-volume units.

There are a number of ways to interpret these results. From my point of view, I see them as equipoise-generating highlighting the importance of outcome reporting. We live in the era of data clarity, and this was emphasized recently with the covid19 pandemic (43). This unfortunate situation showed us how easy and quick can be to collect reliable and robust worldwide data, if there is universal will (44). I do not see why we cannot do the same for free flap H&N reconstruction. A worldwide database is feasible and welcomed; internet and digital technology can make this happen in virtually no time. The UKNFR (9) is a prime example of what a free flap registry should look like; a worldwide database like that will resolve the ambiguity around outcomes in less than a year.

This systematic review could not address the main argument favoring centralization of H&N services and H&N free flap reconstruction. This is cost and health economics. Without a doubt, collecting manpower and recourses in large centers creates several opportunities for money saving exercises (oncall rotas, fewer MDT clinics, less junior residences in one site, etc.). However, this should be weighted against potential disruption for patients, as

Table 2 Eligible studies and secondary outcomes

Study	Mortality	Index side of cancer	Readmissions (%)	Return to theatre (%)	Clavien III–IV
Al-Dam, *J Craniomaxillofac Surg*, 2014 (14)	4 (3.8%)	Oral	NA	24 (23.3%)	Not mentioned but over 25%
Spoerl, *Oral Maxillofac Surg*, 2020 (15)	NA	Oral (91%); extraoral (9%)	NA	51 (10%)	Not mentioned but over 30%
Marttila, *Br J Oral Maxillofac Surg*, 2018 (16)	0 (0%)	Oral	14 (7%)	48 (25%)	20 (12%)
Kovatch, *Laryngoscope*, 2019 (4)	NA	All H&N	NA	NA	7.5% (mean)
Kessler, *J Craniomaxillofac Surg*, 2012 (17)	NA	Oral	NA	6 (7.5%)	Not mentioned but over 10%
Kessler, *J Craniomaxillofac Surg*, 2012 (17)	NA	All H&N	NA	NA	Authors mention no difference between centres or specialties
Salama, *Int J Oral Maxillofac Surg*, 2009 (19)	2 (3.5%)	Oral	NA	Unclear but more than 6 (8%)	Unclear but over 21 (25%)
Eckardt, *J Craniomaxillofac Surg*, 2003 (20)	NA	All H&N	NA	Unclear but over 8%	Unclear but over 10%
Pohlenz, *Int J Oral Maxillofac Surg*, 2012 (21)	8 (0.8%)	All H&N	NA	Unclear but over 150 (8%)	Unclear but over 200 (20%)
Lou, *Int J Oral Maxillofac Surg*, 2019 (22)	1 (0.1%)	Oral	NA	Unclear but over 54 (7%)	112 (11%)
Wang, *Br J Oral Maxillofac Surg*, 2018 (23)	NA but possibly 0	Oral	NA	8 (3.5%)	20 (9%)
Sugiyama, *Head Neck*, 2016 (24)	NA	Oral	NA	Unclear but over 3%	Unclear but over 3%
Nouraei, *J Plast Reconstr Aesthet Surg*, 2015 (25)	399 (3.4%)	All H&N, oral 63%	NA	Unclear but over 15%	Unclear but over 20%
Ho, *Br J Oral Maxillofac Surg*, 2012 (26)	NA	Oral	NA	Unclear but over 5%	Unclear but over 5%
Sweeny, *Laryngoscope*, 2020 (27)	NA	All H&N	NA	Unclear but over 5%	Unclear but over 5%
Wecks, *Oral Surg Oral Med Oral Pathol Oral Radiol*, 2017 (28)	NA	All H&N	NA	Unclear but over 5%	Unclear but over 5%
Klosterman, *Otolaryngol Head neck Surg*, 2015 (29)	1 (0.5%)	Oral	NA	>10%	20%
Liang, *Br J Otorhinolaryngol*, 2018 (30)	NA	All H&N	NA	>10%	>20%
Zhang, *Int J Oral Maxillofac Surg*, 2015 (31)	NA	All H&N	NA	Unclear but over 5%	Unclear but over 5%
Farquhar, *Otolaryngol Head Neck Surg*, 2018 (32)	NA	All H&N	NA	>10%	44%
Brady, *Am J Otolaryngol*, 2017 (33)	11 (1.9%)	All H&N	5%	15%	45%
Thomas, *JAMA Facial Plast Surg*, 2018 (34)	Unclear	All H&N	Unclear	225 (20%)	54%
Kucur, *Eur Arch Otorhinolaryngol*, 2016 (35)	NA	All H&N	NA	44 (17%)	78 (32%)
Husso, *J Reconstr Microsurg*, 2016 (36)	NA	All H&N	NA	NA	25%
Smith, *Br J Oral Maxillofac Surg*, 2005 (37)	4 (1.8%)	Oral	NA	44 (18%)	>20%
Dassonvile, *Eur Arch Otorhinolaryngol*, 2008 (38)	NA	All H&N	NA	>5%	>5%
Ross, J *Reconstr Microsurg*, 2008 (39)	NA	All H&N	NA	>5%	>5%

H&N, head and neck; NA, not applicable.

Author: P Kyzas

Question: The impact of cases numbers and surgical throughput on outcomes in head and neck reconstruction

Certainty assessment							Certainty
No of studies (for the primary outcome)	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	
27	Observational studies-retrospective	Serious	Moderate	Serious	Serious	Strong association	⊕◯◯◯ VERY LOW

1. All studies were retrospective
2. Secondary outcome reporting was inconsistent
3. Pre-op risk factor (RTX) was under reported
4. Strong possibility of selective reporting bias

Figure 2 GRADE quality assessment of included studies. GRADE, Grading of Recommendations, Assessment, Development and Evaluation.

some will need to travel further to be treated in a specialist centralized unit. Often this is accompanied by promises of better care and better outcomes. Whilst this is not entirely degraded, the results of the current systematic review call for caution when discussing about flap success outcomes. According to the literature, small isolated units have the potential to offer equally good flap success outcomes to the local population. Whether this is financially sustainable or desirable is a different story, that falls outside the scope of this manuscript.

There are a number of reasons to look at large units with high throughput in a positive way. Teaching and training are one of the main ones. Rotating in such a unit gives trainees/residences an opportunity for a swift exposure in a variety of reconstructive options in a short period of time. It also allows involvement with cases with rarer pathologies and rarer anatomical variations (the more you do the more you see). It builds up a culture of teamwork and multidisciplinary approach. There might be better access to new technology and innovation (i.e., robotic surgery, 3D printing, financially sustainable only when shared between specialties and used very frequently in a tertiary hospital). There is possibly better support from other allied health specialties (ICU, anesthetics, interventional radiology) and clinical interdependencies are clearly defined and available. A large centralized unit has kudos and higher public profile which has a positive impact on recruitment, aka service resilience. A large center can easily recruit to clinical trials, thus supporting research.

My study has several limitations. Firstly, the systematic review was contacted by a single author. However, I have significant experience in contacting systematic reviews and meta-analyses (45-47) and have published widely on the methodology of these kind of studies (40,45). Therefore, the results of the current study are reliable, despite contradicting my expectations (and my personal beliefs/wishes). However, there is still a risk of selection bias and this should be taken into account when interpreting the results. Secondly, selective reporting might have influenced the results of my review; but this could have been done in either direction (i.e., favoring large or small units) as it is currently impossible to identify and control the denominator (total number of units and number of cases/year in each of them). Thirdly, factors influencing free flap success rate are multiple, and the one chosen to record for this review (preop RTX) was found to be significantly under-reported; this might have influenced the outcomes. Lastly, it is very possible that the vast majority of units and surgeons are happy with the (arbitrary) universally accepted 95% (+/–) free flap success rate and they won't report their results unless extremely good (i.e., approaching 100%) or forced to do so by their institution if extremely poor.

Conclusions

In conclusion, this systematic review revealed that the reported free flap success rate for H&N reconstruction is similar between units with large or small case volume. The quality of the identified studies was questionable, and the risk of selective reporting bias is lurking. This systematic review calls for caution when outcomes are used as a justification for centralizing H&N services, as literature does not seem to support this as strongly is in other surgical disciplines.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the Guest Editor (Michael Ho) for the series "Head and Neck Reconstruction" published in *Frontiers of Oral and Maxillofacial Medicine*. The article has undergone external peer review.

Reporting Checklist: The author has completed the PRISMA reporting checklist. Available at https://fomm.amegroups.com/article/view/10.21037/fomm-20-60/rc

Conflicts of Interest: The author has completed the ICMJE uniform disclosure form (available at https://fomm.amegroups.com/article/view/10.21037/fomm-20-60/coif). The series "Head and Neck Reconstruction" was commissioned by the editorial office without any funding or sponsorship. The author has no other conflicts of interest to declare.

Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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doi: 10.21037/fomm-20-60
Cite this article as: Kyzas P. The impact of volume and surgical throughput on outcomes in head and neck reconstruction: a systematic review. Front Oral Maxillofac Med 2022;4:23.