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# Factors Influencing the Incidence of Severe Complications in Head and Neck Free Flap Reconstructions



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**Background:** Complications after head and neck free-flap reconstructions are detrimental and prolong hospital stay. In an effort to identify related variables in a tertiary regional head and neck unit, the microvascular reconstruction activity over the last 5 years was captured in a database along with patient-, provider-, and volume-outcome–related parameters.

**Methods:** Retrospective cohort study (level of evidence 3), a modified Clavien-Dindo classification, was used to assess severe complications.

**Results:** A database of 217 patients was created with consecutively reconstructed patients from 2009 to 2014. In the univariate analysis of severe complications, we found significant associations ($P < 0.05$) between type of flap used, American Society of Anesthesiologists classification, T-stage, microscope use, surgeon, flap frequency, and surgeon volume. Within a binomial logistic regression model, less frequently versus frequently performed flap (odds ratio [OR] = 3.2; confidence interval [CI] = 2.9–3.5; $P = 0.000$), high-volume versus low-volume surgeon (OR = 0.52; CI = −0.22 to 0.82; $P = 0.007$), and ASA classification (OR = 2.9; CI = 2.4–3.4; $P = 0.033$) were retained as independent predictors of severe complications. In a Cox-regression model, surgeon ($P = 0.011$), site of reconstruction ($P = 0.000$), T-stage ($P = 0.001$), and presence of severe complications ($P = 0.015$) correlated with a prolonged hospitalization.

**Conclusions:** In this study, we identified a correlation of patient-related factors with severe complications (ASA score) and prolonged hospital stay (T-stage, site). More importantly, we identified several provider- (surgeon) and volume-related (frequency with which a flap was performed and high-volume surgeon) factors as predictors of severe complications. Our data indicate that provider- and volume-related parameters play an important role in the outcome of microvascular free-flap procedures in the head and neck region. *(Plast Reconstr Surg Glob Open 2016;4:e1013; doi: 10.1097/GOX.0000000000001013; Published online 27 October 2016.)*

The reconstruction of head and neck defects is of major importance in the complex treatment of head and neck cancer patients, allowing not only for an aesthetic closure of large defects after ablative surgery but also more importantly for functional recovery of swallowing, mastication, and speech.[1] The use of microvascular anastomosed free flaps has gained wide acceptance within the last decades, based on the variety of donor sites and as a consequence of multitude of tissue compositions, allowing for a defect-specific approach of reconstruction.[2–4]

Currently used free flaps in the head and neck are fasciocutaneous, musculocutaneous, and bone flaps.[2] The most commonly used fasciocutaneous flap in Europe is the radial forearm free flap,[5] followed by the anterolateral thigh flap, which belongs to the family of perforator flaps.[3,6–8] Other soft-tissue flaps are the rectus and latissimus dorsi flaps.[9,10] For bony reconstructions, a fibular flap,[11] an iliac crest, or a scapula flap can be used.[12–14] For facial reanimation surgery, a free gracilis

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flap is the primary choice.[2] In case of a complete pharyngeal reconstruction, a jejunum free flap is an option.[15]

Predictors of complications of free-flap surgeries in head and neck cancer patients have recently been delineated in a group of 185 patients and are found to be age, smoking status, American Society of Anesthesiologists classification, preoperative hemoglobin, and perioperative fluid management.[16] A more recent study on 304 patients reports only stage of disease and pharyngoesophageal reconstruction to be associated with severe complications. A convincing association with flap type and indication was not found, neither with preoperative radiation nor with chemoradiation therapy.[17]

There is accumulating evidence that head and neck cancer is better treated in larger centers, in particular academic centers, and there is an evolving body of evidence for a volume–outcome association in the care of head and neck cancer patients, with high-volume hospitals and high-volume surgeons providing significantly better survival.[18–22] In that sense, patients surgically treated in high-volume head and neck cancer centers have a 44% lower odds of mortality from acute complications than their counterparts treated in low-volume centers. Positive margins in the resection of oral cavity cancer are also associated with hospital case volume.[18,23]

Although there is ample evidence that surgeon volume, for example, in case of oral cavity cancers reconstructed with various pedicled and free flaps, impacts the survival of these head and neck cancer patients,[24] data on how volume- and provider-related factors might influence complications and/or duration of hospitalization after microvascular tissue transfer procedures are lacking. An explanation for this lack of data is the fact that as of now, no or few databases exist that gather follow-up data on complications associated with free-flap procedures, and volume–outcome association studies are best performed based on population-based administrative databases that neither exist.

To understand parameters influencing the perioperative rate of severe complications and length of hospitalization, we constructed a database consisting of 217 consecutively performed free-flap procedures. Besides typical patient-related factors, we also analyzed factors related to the provider and to the volume of activity.

Toward the end of this study, we confirmed an association between severe complications and comorbidities measured via the ASA classification, but more interestingly, we found a correlation between severe complications and the frequency with which a flap was performed and moreover the operative volume of the surgeon.

## METHODS

From 2009 to 2014, 217 consecutive patients, of whom 202 were treated for a primary malignancy of the head and neck and 15 patients for secondary reconstructions and various head and neck traumas, underwent reconstruction with a free microvascular anastomosed flap. The reconstruction was performed by 6 microvascular head and neck surgeons. Data on the patients were retrospectively collected from the electronic patient charts, and a database was generated (Table 1). Given that immediate postoperative variables (severe complications and length of hospitalization) were assessed as primary endpoints, no patient was lost to follow-up. The study was approved by the institutional review board. One surgeon worked in 2 institutions, and this activity was included in the database. Patient- (T-stage, overall stage, ASA score, sex, prior radiation therapy, localization of the reconstruction, type of flap, and age) and provider-related (surgeon and microscope vs loupe use) variables and volume-sensitive variables (surgeon volume and flap frequency) were included. Volume-sensitive variables were derived from surgeon activity and frequency of flaps performed within the observation period of 5 years (Fig. 1).

**Table 1. Patient Characteristics**

| Characteristics | Value, n/% |
|---|---|
| Average age, y | 60 ± 14.5 |
| Sex | |
| Male | 156/72.0 |
| Female | 61/28.0 |
| ASA classification | |
| 1, 2 | 169/78.2 |
| 3, 4 | 46/21.8 |
| Reconstruction type | |
| Cancer | 202/93.1 |
| Noncancer | 15/6.9 |
| Type of flap | |
| Radial forearm | 149/68.7 |
| Fibular | 35/16.1 |
| Anterolateral thigh | 15/6.9 |
| Scapula | 3/1.4 |
| Rectus abdominis | 5/2.3 |
| Jejunum | 1/0.5 |
| Gracilis | 2/0.9 |
| Iliac crest | 7/3.2 |
| Microscope use | |
| Yes | 137/64.3 |
| No | 80/35.7 |
| Surgeon | |
| AA | 40/18.4 |
| BB | 2/1 |
| CC | 8/3.7 |
| DD | 37/17.1 |
| EE | 21/9.7 |
| FF | 109/50.2 |
| Site | |
| Oropharynx | 42/19.4 |
| Oral cavity | 90/41.5 |
| Hypopharynx/larynx | 24/11.1 |
| Maxilla and others | 51/23.5 |
| Mandible | 10/4.6 |
| T-stage | |
| 1, 2 | 82/42.9 |
| 3, 4 | 109/57.1 |
| N-stage | |
| 0, 1 | 113/59.2 |
| 2+ | 78/40.8 |
| Stage | |
| Early | 39/20.4 |
| Advanced | 152/79.6 |
| Prior radiotherapy | |
| Yes | 38/17.6 |
| No | 178/82.4 |

Values are provided in total (n) and as percentage (%). Flaps performed (within observation period) refer to frequently (>100) and less frequently (<100) used flaps; radiotherapy type has been not further defined.

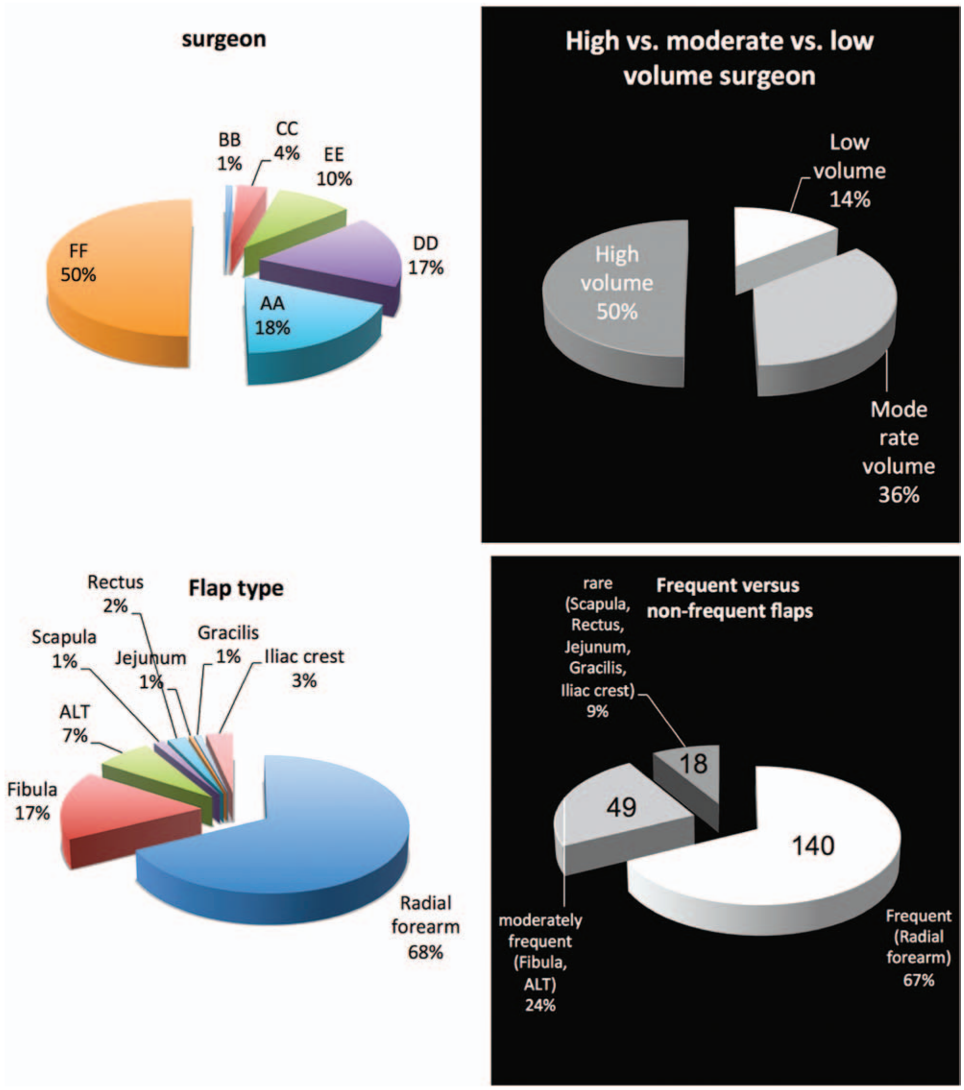


**Fig. 1.** Volume-sensitive variables. A, Surgeons were grouped according to their activity in percent free flaps performed within the observation period and then assigned to the "high-volume" (FF), the "moderate-volume" (AA, DD), and the "low-volume" (BB, CC, EE) group of surgeons. B, Free flaps were grouped according to their frequency of use during the observation period and then assigned to the "frequent" (radial forearm), the "moderately frequent" (fibula, antero-lateral thigh), and "rare" (scapula, rectus, jejunum, gracilis, iliac crest) groups.

Every cancer patient was discussed in a multidisciplinary tumor board of the medical centers for treatment decision making. Staging was performed via a triple endoscopy with biopsy and imaging. Imaging modalities consisted of either computed tomography with contrast or magnetic resonance imaging. The stage of the disease was determined after the surgical resection of the tumor according to the TNM system of the International Union against Cancer (7th edition). The indication for adjuvant treatment was based on nodal status and margins. In case of positive permanent margins, the patient received adjuvant chemoradiation.

The surgical approach was dependent on the location of the disease and the reconstructive needs. For oral cavity malignancies requiring a free-flap procedure, either a fasciocutaneous flap was used or a bone flap in case of mandible involvement. For oropharyngeal and laryngeal/hypopharyngeal reconstruction, fasciocutaneous flaps were used. For maxillary reconstruction bone flaps, fasciocutaneous and musculocutaneous flaps were used. Microvascular anastomosis was performed either with an operation microscope (Leica OH5, Leica Microsystems, Wetzlar, Germany; Zeiss S8, Carl Zeiss Meditec AG, Jena, Germany) or with magnifying loupes (3.5-fold). Arteries and veins were both sewn using either 8.0 or 9.0 Prolene sutures.

Surgical complications were rated using a *modified* Clavien-Dindo (CD) grading system.[25,26] The modified grading system adds 1 additional category distinguishing between patients requiring a surgical, endoscopic, or radiological intervention for *hematoma evacuation without wound-healing complications, minor wound dehiscence, or vascular complication with complete functional salvage of the flap* and those requiring intervention for *fistulas, or complete or partial flap loss result-*

**Table 2. Modified Clavien-Dindo Classification for Perioperative Complications of Head and Neck Free-flap Procedures**

Grade I: Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions.
Acceptable therapeutic regimens are drugs as antiemetics, antipyretics, analgetics, diuretics, and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II: Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions are also included.
Grade III: Requiring surgical, endoscopic, or radiological intervention for hematoma evacuation without wound-healing complications, minor wound dehiscence, vascular complication with complete functional salvage of the flap.
Grade IV: Requiring surgical, endoscopic, or radiological intervention for fistulas, complete or partial flap loss resulting in additional procedures.
Grade V: Life-threatening complication (including central nervous system complications)* requiring IC/ICU management.
Grade V-a: Single organ dysfunction (including dialysis).
Grade V-b: Multiorgan dysfunction.
Grade VI: Death of a patient.

In bold letters, the modifications made to the original Clavien-Dindo classification system; grades I–III are considered nonsevere complication; grades IV–VI are considered severe complication.
*Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding TIA, IC, and ICU.
IC indicates intermediate care; ICU, intensive care unit; TIA, transient ischemic attacks.



*ing in additional procedures* (Table 2). A severe complication according to this novel classification is a complication requiring a surgical, endoscopic, or radiological intervention for *fistulas or complete or partial flap loss resulting in additional procedures* (ie, fistula formation or flap losses/partial losses requiring additional major interventions, ie, additional [regional] flaps or repetitive wound dressings including vacuum-assisted systems), in case of single- or multiorgan failure or in case of death. An additional grouping according to late complications indicated by the suffix "d" in the original CD classification was not considered.

All statistical analysis was performed using SPSS statistical software for Windows, version 20 (SPSS, Inc, an IBM Company, Chicago, Ill., USA). Pearson $\chi^2$ tests were used to determine the association between categorical variables. Binary logistic regression was used to identify independent predictors of increased severe complication rate with an inclusion threshold of $P \leq 0.05$. To determine variables predicting length of hospitalization, a Cox-regression model was used with an inclusion threshold of $P \leq 0.05$. Cases with covariate data missing or unknown were excluded from the multivariate analysis. Effects of categorical variables were reported as odds ratios (ORs). In all cases, a $P \leq 0.05$ was considered statistically significant.

## RESULTS

### Rates and Type of Complications

The overall rate of complications in this group of 217 patients based on the modified classification was 42%: 14.7% severe and 27.3% minor complications. Twelve patients (5.5%) were found with complete flap losses and 15 patients (6.9%) with fistulas requiring additional major interventions prolonging the length of hospitalization. Additional complications were death in 2 patients due to multiorgan failures as a consequence of a sepsis and hemorrhagic shock, a myocardial infarct, and a superinfected hematoma (Table 3).

**Table 3. Severe Complications According to the Modified CD Classification System**

| | |
|---|---|
| Severe Complications (Modified CD) | 32/217 (14.7%) |
| Complete flap losses | 12 (5.5%) |
| Fistulas | 15 (6.9%) |
| Death (sepsis and multiorgan failure, shock and multiorgan failure) | 2 (0.9%) |
| Myocardial infarct | 1 (0.5%) |
| Hematoma with wound infection | 1 (0.5%) |

Severe complications in total numbers and percentage.

### Univariate Analysis of Factors Associated with Severe Complications

To identify variables significantly associated with the occurrence of severe complications, a univariate analysis was performed. This analysis returned the variables type of flap ($P < 0.0001$), ASA classification ($P = 0.045$), frequently versus less frequently performed flap ($P < 0.0001$), microscope use for the anastomosis ($P = 0.039$), surgeon ($P = 0.024$), high- versus low-volume surgeon ($P = 0.007$), and T-stage ($P = 0.009$) as significant (Table 4).

### Logistic Regression Analysis of Factors Associated with Severe Complications

To identify factors independently associated with the occurrence of severe complications, a binomial logistic regression model was created. The model returned 3 variables independently associated with the occurrence of severe complications. Those were frequently versus less frequently performed flap (OR = 3.2; confidence interval [CI] = 1.7–5.8; $P < 0.001$), high- versus low-volume surgeon (OR = 0.52; CI = 0.29–0.93; $P = 0.007$), and ASA classification (OR = 2.85; CI = 1.1–7.5; $P = 0.045$) (Fig. 2) (Table 4).

### Predictors of Length of Hospitalization

To identify predictors of a prolongation of hospitalization, a Cox-regression model using a forward likelihood ratio strategy was employed. The 4 variables retained in the model found to independently correlate with the length of hospitalization were T-stage ($P = 0.001$), complication status ($P = 0.015$), site of the reconstruction ($P < 0.001$), and surgeon ($P = 0.011$) (Table 5).

## DISCUSSION

Within this series of 217 patients, we found a total of 42% complications, of which 14.7% were severe and 27.3% minor. Although these numbers may seem initially quite high, they actually compare favorably with currently

**Table 4. Univariate and Multivariate Analyses of Factors Impacting on Severe Complications According to the Modified Clavien-Dindo System**

| Characteristics | Severe Complication (%) | *P* (Univariate) | OR (95% CI), *P* (Multivariate) |
|---|---|---|---|
| Sex | | | |
| Male | 16 | NS | NS |
| Female | 11.5 | — | — |
| Type of flap | | | |
| Radial forearm | 8.7 | **0.000** | NS |
| Fibular | 25.7 | — | — |
| Anterolateral thigh | 20.0 | — | — |
| Scapula | 0.0 | — | — |
| Rectus abdominis | 60.0 | — | — |
| Jejunum | 0.0 | — | — |
| Gracilis | 0.0 | — | — |
| Iliac crest | 57.1 | — | — |
| ASA classification | | | |
| 1, 2 | 11.8 | **0.045** | **2.85 (1.1–7.5) 0.033** |
| 3, 4 | 23.4 | — | |
| Frequently vs less frequently performed flap | | | |
| Rare | 38.9 | **0.000** | **3.2 (1.7–5.8) 0.000** |
| Moderately frequent | 24 | — | |
| Frequent | 8.7 | — | — |
| Microscope use | | | |
| Yes | 10.9 | **0.039** | NS |
| No | 21.2 | — | — |
| Surgeon | | | |
| AA | 17.5 | **0.024** | NS |
| BB | 0 | — | — |
| CC | 25 | — | — |
| DD | 29.7 | — | — |
| EE | 19.0 | — | — |
| FF | 7.3 | — | — |
| High- vs low-volume surgeon | | | |
| High | 7.3 | 0.007 | 0.52 (0.29–0.93) 0.028 |
| Moderate | 23.4 | — | |
| Low | 19.4 | — | — |
| Site | | | |
| Oropharynx | 11.9 | 0.627 | NS |
| Oral cavity | 15.6 | — | — |
| Hypopharynx/larynx | 16.7 | — | — |
| Maxilla and others | 11.8 | — | — |
| Mandible | 30.0 | — | — |
| T-stage | | | |
| 1, 2 | 7.3 | 0.009 | NS |
| 3, 4 | 21.1 | — | — |
| Overall stage | | | |
| Early | 7.7 | 0.144 | NS |
| Advanced | 17.1 | — | — |
| Prior radiotherapy | | | |
| Yes | 12.9 | 0.194 | NS |
| No | 21.1 | — | — |

Percentage of severe complications is provided; *P* values are recorded only if significant.
NS indicates not significant.

published literature on complications after free-flap procedures for the head and neck region. A previously published study on 185 patients reconstructed with free flaps for head and neck defects reports 53% overall complications and 40% severe complications,[16] whereas a similar study on 304 patients reconstructed with similar techniques reports an overall complication rate of 32.5% and a severe complication rate of 20%.[17] Although seemingly favorable, the rates of severe complications in this study need to be considered in the context of the modified CD classification that reports complications only as severe that are rather prolonging hospital stay. It is likely that if the original CD classification would have been used, the results would have been similar to the published literature. A severe complication rate of nearly 15%, which is also associated with a high risk of prolongation of the hospitalization, has to be considered seriously. It means that major efforts are needed to reduce this number, not only to improve the quality of treatment for our patients but also to reduce the costs that are associated with the prolongation of hospitalization.

It is interesting to compare this rate of severe complications with the chemoradiation literature. However, there are difficulties to be considered, comparing the Radiation Therapy Oncology Group acute toxicity rating with the modified CD classification. One could assume that a grade IV acute toxicity in a patient treated with chemoradiation likely results in a prolongation of the hospitalization and thus could be considered a severe complication, at least comparable with a surgical severe complication. Considering this, the reported rate of 15% severe complications in this study does not compare unfavorably with the reported incidence of grade IV acute toxicity of 18% in the chemoradiation group in the RTOG 99-11 trial.[27]

The multivariate analysis of severe complications in this study returned 3 variables to be independently associated. Although 1 variable (ASA classification) belonged to the group of the patient-related variables, the other 2 variables are volume-sensitive variables: high-volume surgeon versus low-volume surgeon and frequently versus less frequently performed flap. The 2 latter parameters could be interpreted as volume–outcome indicators. They show that a surgeon who performs fewer than 20 flaps a year should probably either try either to increase his/her activity or to quit this activity. They also show that within the armamentarium of a free-flap surgeon, rarely used flaps should be rather avoided, because if performed seem to bring an additional risk of complication with them. Again, the surgeon can choose to either increase the frequency of this rare flap or abandon it and choose a flap he/she is more acquainted with. In summary, this type of surgery should not be done “occasionally” by surgeons. A steady volume throughout the year should be maintained.

But the analysis of these data should trigger additional measures with regard to training young free-flap surgeons and surgeon–surgeon collaboration. Young head and neck surgeons, who start out doing free flaps in smaller volume centers, should probably be supervised by experienced surgeons throughout their gaining of independence. This period of surveillance could eventually last until a solid activity of >20 free flaps per year for the younger surgeon is achieved. Adequate selection of patients “appropriate” to be taken to surgery by the younger colleague should be made by the more experienced supervisor. Other measures to take into consideration consist of early surgical simulation/training for surgeons in microvascular free-flap procedures. This might include training of flap harvest on cadavers before the interventions and comput-

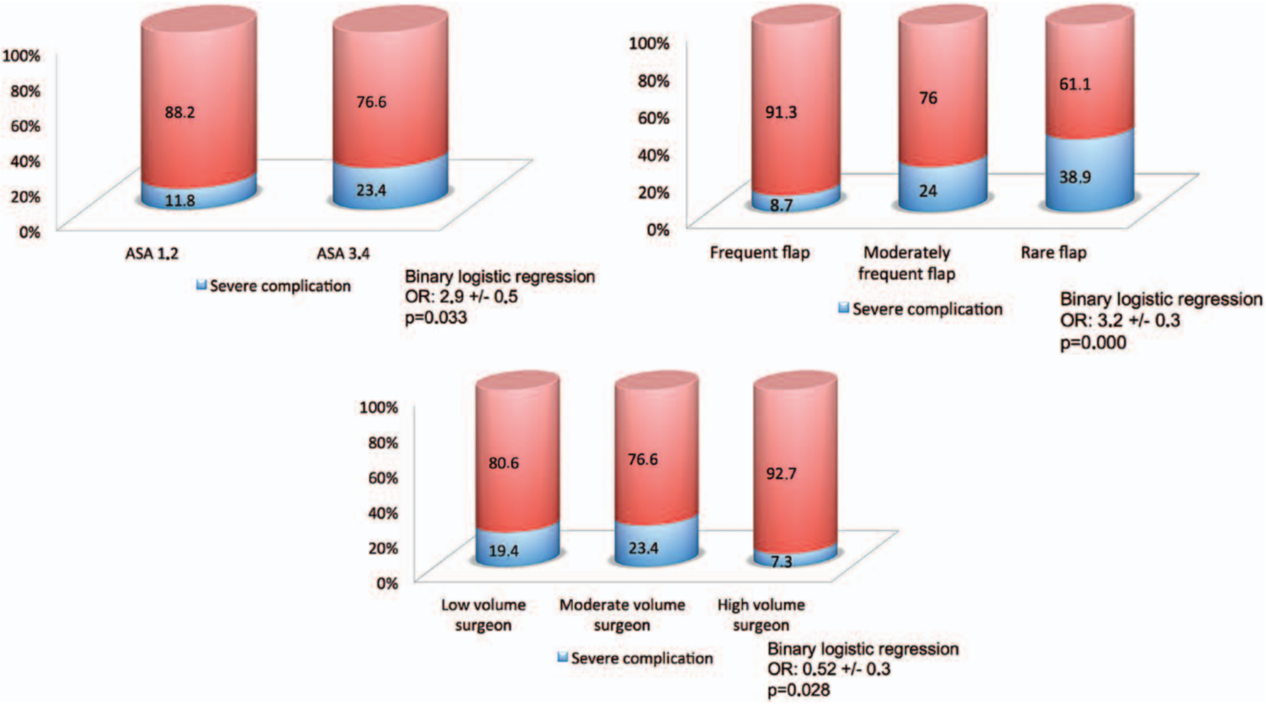


**Fig. 2.** Rates of severe complications. A, Percentage of severe complications in low- versus moderate- versus high-volume surgeons. B, Percentage of severe complications in the group of patients reconstructed with a frequent, moderately frequent, and rare flap. C, Percentage of severe complications depends on ASA classification.

**Table 5. Cox-regression Analysis of Factors Impacting on Length of Hospital Stay**

| Characteristics | HR (95% CI) | *P* |
|---|---|---|
| Surgeon | — | **0.011** |
| AA vs FF | 1.2 (0.7–1.9) | NS |
| BB vs FF | 8.8 (1.1–68.7) | 0.037 |
| CC vs FF | 0.7 (0.3–1.5) | NS |
| DD vs FF | 0.6 (0.3–0.97) | 0.037 |
| EE vs FF | 0.6 (0.4–1.1) | NS |
| FF | — | — |
| Site | — | **0.000** |
| Oropharynx vs mandible | 4.2 (1.1–16.3) | 0.041 |
| Oral cavity vs mandible | 5.9 (1.5–22.5) | 0.009 |
| Hypopharynx/larynx vs mandible | 3.0 (0.8–11.4) | NS |
| Maxilla and others vs mandible | 12.2 (3.1–48.4) | 0.000 |
| Mandible | 30.0% | — |
| T-stage (T1, 2 vs T3, 4) | 0.52 (0.35–0.77) | **0.001** |
| Complication (modified Clavien-Dindo) (minor vs severe) | 0.56 (0.35–0.9) | **0.015** |

HR indicates hazard ratio; NS, not significant.

er-based surgical simulations making use of "virtual reality" environments.

The multivariate analysis in this study on duration of hospitalization returned the parameters "T-stage," "severe complication," "surgeon," and "site of reconstruction" as independent predictors. The influence of larger T-stage on duration of hospitalization can be easily explained by the fact that larger tumors require more demanding reconstructions and thus a longer hospitalization for rehabilitation. Severe complications are logically associated with prolonged hospitalization. In the comparison of sites, mandibular reconstructions had the worst outcome. It is of great interest to note that 1 of the 4 variables related to the length of hospitalization in this study is provider related; in other words, the surgeon who performs the procedure has an impact on the length of the hospitalization likely through the quality of the surgery provided.

In summary, we provide evidence that besides typical patient-related factors such as comorbidities, volume-related parameters such as the frequency with which a flap is performed and the activity of a surgeon impact the outcome of microvascular free-flap procedures.

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