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Trends of Microsurgical Head and Neck Free Flap Reconstruction and Safety During the COVID-19 Pandemic

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Abstract:
Background: The COVID-19 pandemic poses unprecedented challenges among patients with head and neck (HN) cancer that require oncologic and reconstructive surgeries. This study aims to identify differences in postoperative outcomes for patients who underwent microsurgical HN free flap reconstruction prior to vs. during the COVID-19 pandemic.
Methods: A retrospective observational study using the ACS-NSQIP 2019-2020 database to identify patients with HN cancer who underwent a vascularized free tissue transfer was undertaken. Two cohorts were created: pre- and during COVID-19. Fisher's exact test and the unpaired student's t-test were used to evaluate differences in sociodemographic and clinical characteristics between the cohorts. Multivariable logistic regression was used to assess differences in reoperation rates between groups, as well as to identify potential risk factors for reoperation.

Results: A total of 763 patients were analyzed. The mean age of patients in the overall cohort was 63.6 SD 11.5 years. Most patients were white (62.7%). Overall, no statistically significant difference was evidenced between cohorts in terms of immediate postoperative outcomes. Similarly, reoperation rates were similar between groups($p>0.05$). Dependent functional status($p=0.021$) and postoperative infection($p<0.001$) were found to be risk factors for reoperation after holding other factors constant.

Conclusion: HN flap reconstruction can be performed safely during the COVID-19 era. Standardized protocols for patient selection must be strictly followed to avoid disease progression and optimize surgical outcomes. Further studies assessing long-term outcomes during the pandemic are of utmost importance to elucidate the true impact of the COVID-19 pandemic on this population.

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Supplemental Data

Supplementary Table 1. *CPT codes for head and neck vascularized free tissue transfer*

Soft tissue flap CPT codes	15756 15757 15758 49906 15842
Osseous flap CPT codes	20955 20956 20957 20962 20969 20970 20972 20973

Supplemental Table 2. *ICD-10 codes for head and neck malignancies at different locations*

Location	ICD-10
Oral Cavity	C00.0- C00.9 C01, C02.1-C02.4, C02.8, C02.9 C07, C08.0, C08.1, C08.9 C03.0, C03.1, C03.9 C04.0, C04.1, C04.8, C04.9 C06.0, C06.1, C05.0, C05.1, C05.2, C05.8, C05.9, C06.2, C06.89, C06.80, C06.9
Pharynx	C09.8, C09.9, C09.0, C09.1, C10.0, C10.1, C10.2, C10.3, C10.4, C10.8, C10.9 C11.0, C11.1, C11.2, C11.3, C11.8, C11.9 C13.0, C12, C13.1, C13.2, C13.8, C13.9 C14.0, C14.2, C14.8 C32.0, C32.1, C32.2, C32.3, C32.8, C32.9
Mandible	C41.0, C41.1
Maxilla	C30.0, C30.1, C31.0, C31.1, C31.2, C31.3, C31.8, C31.9
Surface Structures	C43.0, D03.0, C43.111, C43.112, C43.121,

	C43.122, C43.10, D03.10, D03.111, D03.112, D03.121, D03.122, C43.21, C43.22, C43.20, D03.20, D03.21, D03.22, C43.30, C43.31, C43.39, D03.30, D03.39, C43.4, D03.4 C44.40, C44.41, C44.42, C44.49 C44.00, C44.01, C44.02, C44.09 C44.1021, C44.1022, C44.1091, C44.1092, C44.101, C44.1191, C44.1192, C44.111, C44.1121, C44.1122, C44.1221, C44.1222, C44.1291, C44.1292, C44.121, C44.131, C44.1321, C44.1322, C44.1391, C44.1392, C44.1921, C44.1922, C44.1991, C44.1992, C44.191 C44.202, C44.209, C44.201, C44.212, C44.219, C44.211, C44.222, C44.229, C44.221, C44.292, C44.299, C44.291

Supplemental Table 3. *Type of Procedures for Unplanned Reoperation*

CPT	Historical Control	COVID-19
Incision and drainage (10140, 10180, 21501, 27603, 41008)	**12 (18.46)**	**11 (20.36)**
Debridement (11012, 11042, 11043, 11044, 11046, 97587)	**15 (23.08)**	**3 (5.55)**
Repair (12001, 12051, 13160, 42953)	**3 (4.62)**	**2 (3.7)**
Adjacent Tissue Transfer or Rearrangement (14041, 14060, 14301)	**3 (4.63)**	**3 (5.55)**
Skin replacement surgery (15271, 15272)	**1 (1.54)**	**1 (1.85)**
Flaps (15736, 15757)	**2 (3.08)**	**3 (4.54)**
Repair blood vessel other than for fistula, with or without patch angioplasty (35201, 35231)	**4 (6.16)**	**3 (5.56)**
Excision, Exploration, Repair, Revision (35800, 35860, 35875, 35876)	**10 (15.39)**	**14 (27.77)**
Others (15824, 20100, 15851, 31525, 31600, 31603, 31647, 34201, 43246, 43653, 43830, 43840, 44120, 44120, 44146, 44300, 47562, 61518, 41899, 92502)		
Others		
Rhytidectomy; forehead **(15824)**	1 (1.54)	0
Exploration of penetrating wound (separate procedure); neck **(20100)**	1 (1.54)	0
Removal of sutures under anesthesia (other than local), other surgeon **(15851)**	0	1 (1.85)
Laryngoscopy direct, with or without tracheoscopy; for Aspiration - diagnostic, except newborn **(31525)**	1 (1.54)	0
Tracheostomy, planned (separate procedure); **(31600)**	1 (1.54)	1 (1.85)
Tracheostomy, emergency procedure; transtracheal **(31603)**	1 (1.54)	1 (1.85)
Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure) with balloon occlusion, when	1 (1.54)	0 (0)

performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe **(31647)**		
Embolectomy or thrombectomy, with or without catheter; carotid, subclavian or innominate artery, by neck incision - femoropopliteal, aortoiliac artery, by leg incision **(34201)**	1 (1.54)	0
Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure) with directed placement of percutaneous gastrostomy tube **(43246)**	2 (3.08)	1 (1.85)
Laparoscopy, surgical; transection of vagus nerves, truncal gastrostomy, without construction of gastric tube (eg, Stamm procedure) (separate procedure) **(43653)**	0	3 (5.56)
Gastrostomy, open; without construction of gastric tube (eg, Stamm procedure) (separate procedure) **(43830)**	2 (3.08)	2 (3.70)
Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury **(43840)**	1 (1.54)	0
Enterectomy, resection of small intestine; single resection and anastomosis **(44120)**	0	1 (1.85)
Colectomy, partial; with anastomosis **(44146)**	0	1 (1.85)
Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure) **(44300)**	1 (1.54)	0
Cholecystectomy **(47562)**	1 (1.54)	0
Craniectomy for excision of brain tumor, infratentorial or posterior fossa; except meningioma, cerebellopontine angle tumor, or midline tumor at base of skull **(61518)**	0	1 (1.85)
Other procedures on dentoalveolar structures **(41899)**	0	1 (1.85)
Otolaryngologic exam under general anesthesia **(92502)**	1 (1.54)	0
Total	15 (23.1)	13 (24.1)

Table 1. *Patient Demographics based on time of operation*

	Historical Control N= 462	COVID-19 N= 301	Total Cohort N= 763	p-value
Age *mean (SD)*	63.6 (11.8)	63.6 (11.0)	63.6 (11.5)	0.9786
BMI *mean (SD)*	27.0 (6.4)	27.1 (6.7)	27.0 (6.5)	0.7374
Race *n (%)*				
White	286 (62.6)	189 (62.8)	475 (62.7)	0.056
African American	22 (4.8)	14 (4.7)	36 (4.8)	
Asian	19 (4.2)	17 (5.7)	36 (4.8)	
American Indian	0 (0)	2 (0.7)	2 (0.3)	
Native Hawaiian or Other Pacific Island	0 (0)	4 (1.3)	4 (0.5)	
Other/ Unknown	130 (28.5)	75 (24.9)	205 (27.0)	
Functional Status *n (%)*				
Independent	451 (97.6)	296 (98.3)	747 (97.9)	0.879
Partially Dependent	9 (2.0)	4 (1.3)	13 (1.7)	
Totally dependent	1 (0.2)	1 (0.3)	2 (0.3)	
Unknown	1 (0.2)	0 (0)	1 (0.1)	
ASA Classification *n (%)*				
1-2	95 (20.6)	61 (20.3)	156 (20.5)	1.000
3-5	367 (79.4)	240 (79.7)	607 (79.6)	
Current Smoker *n (%)*	126 (27.3)	85 (28.2)	211 (27.7)	0.804
Comorbidities *n (%)*				
Diabetes Mellitus	25 (5.4)	21 (7.0)	46 (6.0)	0.437
COPD	30 (6.5)	30 (10.0)	60 (7.9)	0.098
Hypertension	235 (50.9)	147 (48.8)	382 (50.1)	0.605
Disseminated Cancer	30 (6.5)	10 (3.3)	40 (5.2)	0.0670
Preoperative Steroids	16 (3.5)	18 (6.0)	34 (4.5)	0.108
Bleeding Disorder	7 (1.5)	6 (2.0)	13 (1.7)	0.776
Preoperative Weight Loss	48 (10.4)	17 (5.7)	65 (8.5)	**0.024***

ASA, american society of anesthesiologists; BMI, body mass index; COPD, chronic obstructive pulmonary disease; n, frequency; SD, standard deviation; %, percentage

Table 2. *Surgical Characteristics*

	Historical Control N= 462	COVID-19 N= 301	Total Cohort N= 763	p-value
Surgical Team				
Otolaryngology	345 (74.7)	230 (76.4)	575 (75.4)	0.676
Plastic Surgery	105 (22.7)	66 (21.9)	171 (22.4)	
Other	12 (2.6)	5 (1.7)	17 (2.2)	
Location of Reconstruction *n (%)*				
Oral Cavity	247 (62.1)	149 (59.6)	396 (61.1)	0.761
Pharynx	79 (19.9)	56 (22.4)	135 (20.8)	
Mandible	21 (5.3)	9 (3.6)	30 (4.6)	
Maxilla	15 (3.8)	10 (4.0)	25 (3.9)	
Surface Structures	36 (9.1)	26 (10.4)	61 (9.6)	
Surgery Setting *n (%)*				
Inpatient	457 (98.9)	297 (98.7)	754 (98.8)	0.745
Outpatient	5 (1.1)	4 (1.3)	9 (1.2)	
Wound Classification *n (%)*				
Clean	127 (27.5)	88 (29.2)	215 (28.2)	0.685
Clean/Contaminated	310 (67.1)	201 (66.8)	511 (67.0)	
Contaminated	13 (2.8)	8 (2.7)	21 (2.8)	
Dirty/Infected	12 (2.6)	4 (1.3)	16 (2.1)	
Operation Time (minutes) *Mean (SD)*	561.8 (206.0)	554.3 (196.5)	558.8 (202.2)	0.6178
Length of Hospital Stay (days) *Mean (SD)*	6.0 (24.1)	5.6 (22.0)	5.9 (23.3)	0.8213

n, frequency; SD, standard deviation; %, percentage

Table 3. *Post-operative complications following head and neck free flap reconstruction (Total)*

Post-Operative Complication	Historical Control N= 462	COVID-19 N= 301	Total Cohort N= 763	p-value
Wound-related *n (%)*				
Superficial skin infection	42 (9.1)	27 (9.0)	69 (9.0)	1.000
Deep incisional infection	15 (3.3)	8 (2.7)	23 (3.0)	0.829
Organ space infection	14 (3.0)	14 (4.7)	28 (3.7)	0.245
Wound dehiscence	25 (5.4)	15 (5.0)	40 (5.2)	0.869
Pulmonary *n (%)*				
Pneumonia	28 (6.1)	13 (4.3)	41 (5.4)	0.328
Pulmonary embolism	4 (0.9)	1 (0.3)	5 (0.7)	0.653
Renal/ Genitourinary *n (%)*				
Renal insufficiency	0 (0)	0 (0)	0 (0)	-
Acute renal failure	0 (0)	0 (0)	0 (0)	-
Urinary tract infection	2 (0.4)	7 (2.3)	9 (1.2)	**0.033***
Cardiac *n (%)*				
Cardiac arrest	8 (1.7)	3 (1.0)	11 (1.4)	0.541
Myocardial infarction	4 (0.9)	4 (1.3)	8 (1.1)	0.719
Hematologic *n (%)*				
Bleeding Complication	92 (19.9)	66 (21.9)	158 (20.7)	0.523
DVT	13 (2.8)	5 (1.7)	18 (2.4)	0.341
Systemic *n (%)*				
Shock/Sepsis	22 (4.8)	8 (2.7)	30 (3.9)	0.182
Unplanned reoperation *n (%)*	73 (15.8)	61 (20.3)	134 (17.6)	0.120

DVT, deep vein thrombosis; n, frequency; %, percentage

Table 4. *Post-operative complications following head and neck free flap reconstruction Q2*

Post-Operative Complication	Historical Q2 N= 79	COVID-19 Q2 N= 107	Total N= 186	p-value
Wound-related *n (%)*				
Superficial skin infection	9 (11.4)	4 (3.7)	13 (7.0)	0.077
Deep incisional infection	2 (2.5)	4 (2.8)	5 (2.7)	1.000
Organ space infection	4 (5.1)	7 (6.5)	11 (5.9)	0.762
Wound dehiscence	4 (5.1)	5 (4.7)	9 (4.8)	1.000
Medical-related Complications				
Pulmonary *n (%)*				
Pneumonia	4 (5.1)	5 (4.7)	9 (4.8)	1.000
Pulmonary embolism	0 (0)	0 (0)	0 (0)	-
Renal/ Genitourinary *n (%)*				
Renal insufficiency	0 (0)	0 (0)	0 (0)	-
Acute renal failure	0 (0)	0 (0)	0 (0)	-
Urinary tract infection	0 (0)	3 (2.8)	3 (1.6)	0.263
Cardiac *n (%)*				
Cardiac arrest	0 (0)	1 (0.9)	1 (0.5)	1.000
Myocardial infarction	0 (0)	0 (0)	0 (0)	-
Hematologic *n (%)*				
Bleeding Complication	14 (17.7)	25 (23.4)	39 (21.0)	0.369
DVT	2 (2.5)	1 (0.9)	3 (1.6)	0.575
Systemic *n (%)*				
Shock/Sepsis	1 (1.3)	0 (0)	1 (0.5)	0.425
Unplanned reoperation *n (%)*	14 (17.7)	19 (17.8)	33 (17.7)	1.000

DVT, deep vein thrombosis; n, frequency; %, percentage

Table 5. *Differential post-operative complications following head and neck free flap reconstruction*

Location of Reconstruction *n (%)*	Differential in Medical Complications*	p-value	Differential in Wound Complications*	p-value	Differential in Reoperation*	p-value
Oral Cavity	(+)0.68%	0.903	(+)1.38	0.787	(+)7.3	0.085
Pharynx	(+)0.05%	1.000	(+)0.43	1.000	(+)6.24	0.369
Mandible	(-)41.27%	**0.049***	(-)1.59	1.000	(-)17.46	0.393
Maxilla	(-)36.67%	0.111	(+)3.33	1.000	(+)33.33	0.121
Surface Structures	(+)5.77	0.774	(+)4.91	0.567	(-)6.2	0.689

*Refer to at least one complication within those groups were present.

Table 6. *Multivariable Analysis of Risk Factors for Reoperation*

	COVID-19 Group*	
	OR (95% CI)	**P-value**
Potential Risk Factors for Reoperation		
Reconstruction During COVID-19	1.51 (0.89 – 2.57)	0.127
Age >55	0.65 (0.32 – 1.30)	0.221
BMI ≥30	0.74 (0.38 – 1.45)	0.387
African American race	0.80 (0.26 – 2.48)	0.704
Hispanics	1.24 (0.36 – 4.29)	0.737
Dependent Functional Status	6.92 (1.34 – 35.74)	**0.021***
ASA Classification >2	1.04 (0.49 – 2.20)	0.919
Smoker	1.51 (0.82 – 2.80)	0.189
Diabetes	0.36 (0.09 – 1.49)	0.158
Hypertension	1.26 (0.70 -2.25)	0.441
COPD	0.84 (0.31 – 2.29)	0.728
Disseminated Cancer	1.19 (0.39 – 3.60)	0.756
Bleeding Disorder	2.80 (0.47 – 16.71)	0.256
Pre-operative weight loss >10% of body weight	0.89 (0.38 – 2.09)	0.789
Pre-operative steroid use	1.70 (0.46 – 6.22)	0.423
Post-operative wound infection	5.41 (2.98 – 9.81)	**<0.001*** **
Wound Classification > 2 (Contaminated)	0.77 (0.38 – 1.54)	0.457
Hematocrit < 30	0.67 (0.28 – 1.62)	0.378
Albumin < 3.5	0.78 (0.45 – 1.38)	0.395
Operative time in top 25% (>679 minutes)	1.55 (0.85 – 2.84)	0.156
Length of hospital stay in top 25% (>13 days)	4.56 (2.56 – 8.12)	**< 0.001 *** **

Trends of Microsurgical Head and Neck Free Flap Reconstruction and Safety During the COVID-19 Pandemic

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Abstract

***Background*:** The COVID-19 pandemic poses unprecedented challenges among patients with head and neck (HN) cancer that require oncologic and reconstructive surgeries. This study aims to identify differences in postoperative outcomes for patients who underwent microsurgical HN free flap reconstruction prior to vs. during the COVID-19 pandemic.

Methods: A retrospective observational study using the ACS-NSQIP 2019-2020 database to identify patients with HN cancer who underwent a vascularized free tissue transfer was undertaken. Two cohorts were created: pre- and during COVID-19. Fisher's exact test and the unpaired student's t-test were used to evaluate differences in sociodemographic and clinical

characteristics between the cohorts. Multivariable logistic regression was used to assess differences in reoperation rates between groups, as well as to identify potential risk factors for reoperation.

Results: A total of 763 patients were analyzed. The mean age of patients in the overall cohort was 63.6 SD 11.5 years. Most patients were white (62.7%). Overall, no statistically significant difference was evidenced between cohorts in terms of immediate postoperative outcomes. Similarly, reoperation rates were similar between groups($p>0.05$). Dependent functional status($p=0.021$) and postoperative infection($p<0.001$) were found to be risk factors for reoperation after holding other factors constant.

Conclusion: HN flap reconstruction can be performed safely during the COVID-19 era. Standardized protocols for patient selection must be strictly followed to avoid disease progression and optimize surgical outcomes. Further studies assessing long-term outcomes during the pandemic are of utmost importance to elucidate the true impact of the COVID-19 pandemic on this population.

Keywords: Reconstruction; microsurgery; head and neck; COVID-19

Introduction:

The COVID-19 pandemic has had far-ranging effects on every healthcare system in the world. Hospitals and clinics have been overwhelmed by the deluge of patient care needs directly resulting from COVID-19 infections, while many other patients have been unable to access other

types of healthcare.[1] The toll of this pandemic, which includes widespread difficulties in providing healthcare for a myriad of reasons, has led to a need for resource stewardship. This has resulted in some patients not receiving timely and critical care, particularly patients with cancer.[2] Reconstructive surgery has been no exception to this strain, where temporary holds on elective surgery have delayed care for many patients.[3,4]

Many surgeons have devised innovative safety protocols to help these patients receive necessary procedures.[5–7] Studies have examined the effects of these altered protocols on patient course and complication rates, specifically in the context of microsurgical head and neck (HN) reconstruction.[8] Preliminary center-specific studies have demonstrated that, with adjusted safety protocols and careful patient selection, there has been significant difference in complications when these measures to mitigate viral exposure are taken.[8,9] To further these efforts and protect access to care for HN malignancy, specifically that of free tissue transfer reconstruction, there is a need to assess the efficacy and safety of these new protocols comprehensively.

Using data from the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database, this study aims to identify any differences in postoperative outcomes for patients who underwent microsurgical HN free flap reconstruction prior to the COVID-19 pandemic compared with those who underwent reconstruction during the pandemic.

Methods

Patient Identification

After obtaining approval from our institution's IRB (Protocol # 2021D001052), we performed a retrospective study using the ACS-NSQIP database. All patients undergoing HN free flap reconstruction from the ACS-NSQIP 2019-2020 were prospectively collected and analyzed.[10–12] Current Procedural Terminology (CPT) codes were first used to identify patients who underwent a vascularized free tissue transfer (***Supplementary Table 1***). Identified cases were then cross-referenced with patients with an ICD-10 code associated with a HN malignancy (***Supplementary Table 2***).

Aims and Outcomes of Interest

The primary aim of this study was to compare differences in 30-day postoperative outcomes in patients who underwent HN free flap reconstruction during the COVID-19 pandemic (Q2-Q4 of 2020) compared to a those who underwent HN free flap reconstruction in the year prior to the pandemic (Q1-Q4 of 2019 and Q1 of 2020). Furthermore, we compared the percentage of unplanned reoperations for each day through the first post-operative month (POD 30) to provide a detailed post-operative timeline for the two groups in an effort to capture potential delays in care linked to the COVID-19 pandemic. We also aimed to analyze potential risk factors for reoperation.

We included HN free flap patients from the entire year of 2019 and the first quarter of 2020 as the pre-pandemic control in this study for several reasons. First, most institutional practices regarding surgical logistics, surgeon technique, and post-operative enhanced recovery pathways were likely most similar between these two years. Utilizing data from years prior to 2019 may have introduced important differences related to these factors, which could confound

the data. Therefore, we surmised that comparing these two cohorts offers the best opportunity to elucidate the potential effects of the COVID-19 pandemic on patient selection, hospital course and severity, and postoperative outcomes.

Risk Adjustment/ Statistical Analysis

Patient demographics and clinical characteristics were summarized. Rates of wound-related, pulmonary, cardiac, renal/genitourinary, hematologic, and systemic complications were compared between the two years. For descriptive analysis, frequencies and percentages were used to present categorical variables. Following the Central Limit Theorem, the data were considered normally distributed, and therefore, means and standard deviations were used to present continuous variables.

For inferential analysis, the Fisher's exact test and the unpaired t-test were used to assess differences in sociodemographic, clinical characteristics, and complications between groups in categorical and continuous data, respectively. A multivariable logistic regression was used to assess differences in reoperation between groups, as well as to identify potential risk factors for reoperation. Statistical significance was set up for a p value less than 0.05. Analysis was performed using STATA statistical software (STATA Corp., College Station, TX version 16.1).

Results

Demographics: Pre-pandemic and COVID-19 Cohorts

A total of 763 HN free flaps were analyzed between 2019 and 2020. The mean (SD) age of patients in the overall cohort was 63.6 (11.5) years, and the mean (SD) BMI was 27.0 (6.5).

Among patients in the study, 62.7% of patients were White, 4.8% Black or African American, and 32.5% represented other races (Asian, American Indian, Alaska or Hawaiian native, Pacific Islander) or were unknown. Overall, 27.7% of patients were smokers at the time of surgery, and 79.6% had an American Society of Anesthesia (ASA) physical status classification between 3 and 5. Almost all (97.9%) of patients were of independent functional status. This study's most common patient comorbidity was hypertension (50.1%). When divided into their respective groups based on time of surgery, there were significantly more patients who lost >10% body weight in the six months prior to surgery (p=0.056) in the pre-pandemic group. Though not significant, there was a trend toward overall differences in the race among patients based on time of surgery (p=0.06). A summary of the population demographics for both groups is presented in ***Table 1.***

Surgical Characteristics

A statistically significant difference was evidenced in HN flap reconstruction trends between the cohorts ***(Figure 1)***. The majority (98.9%) of patients had their surgery performed in the inpatient setting. 'Clean' or 'clean contaminated' wound classification was present in 95.2%. The length of hospital stay was 6.0 days for those who underwent HN free flap reconstruction prior to the pandemic and 5.6 days for those during the pandemic. When comparing the operative time between the COVID-19 and pre-pandemic groups, the COVID-19 group had a shorter operative time of only 7.5 minutes, which was not statistically significant. When stratified by location of reconstruction in the total cohort, 61.1% of patients had reconstruction of the oral cavity, 20.8% had reconstruction of the pharynx, and the remaining 18.1% had reconstruction of the mandible (4.6%), maxilla (3.9%), and surface structures (9.6%). The surgical specialty

performing HN free flap reconstruction cases was otolaryngology (75.4%), with plastic surgery performing 22.4%. Surgical characteristics for both groups can be found in ***Table 2.***

Postoperative Complications

The most common postoperative complications for the cohort were hematologic complication and unplanned reoperation, with 23.1% and 17.6% during the first 30 post-operative days, respectively ***(Table 3).*** The next most common complication was surgical wound-related complication in 20.9% of the cases. The rates of pulmonary (6.1%), cardiac (2.5%), renal/genitourinary (1.2%), and systemic complications (3.9%) were overall low in this cohort. On univariate analysis, the only significant difference in complications between the groups was the higher rate of urinary tract infections in the COVID-19 group.

Furthermore, there were no significant differences between the two groups on subgroup analysis of those who underwent HN free flap reconstruction during the second quarter of the year (April- June) (***Table 4***). After stratifying cases by the location of reconstruction, we found that those who had free flap reconstruction of the mandible were significantly more likely to have a medical complication ($p<0.05$) (***Table 5***).

Risk Factors and Timing of Unplanned Reoperation

Similar type of surgical procedures for unplanned reoperation were evidenced between the two groups except for debridement procedures, in which pre-COVID-19 group had 23.08% cases vs 5.55% in the during COVID-19 group **(*Supplemental Table 3)***. When controlling for sociodemographic and clinical risk factors, no differences were found between the pre-COVID-

19 and during COVID-19 groups concerning unplanned reoperation (p=0.127) (***Table 6***). Additionally, dependent function status (p 0.021) and post-operative wound infection (p <0.001) were found to have increased odds of undergoing unplanned reoperation after HN flap reconstruction after adjusting other cofactors constant (***Table 6, Figure 2***).

Discussion:

The COVID-19 pandemic has impacted patient care significantly due to its unprecedented nature. The health care system had to adapt in a sensible and timely manner to consistently provide the best service conceivable. Patients with HN malignancies were not the exception to the burden generated by the COVID-19 pandemic.[13–18] This study's findings highlight from a national standpoint that, in general, patients who underwent HN flap reconstruction during the pandemic were not statistically significantly different from patients before the pandemic in regard to clinical outcomes. In other words, the health care system was able to overcome surgical challenges among the HN population, which translated into similar post-operative clinical outcomes between before and during pandemics cohorts. This likely included COVID-19 screening, management of treating COVID-19 positive patients perioperatively, and following these patients after discharge.

HN surgeons were forced to triage patients based on their disease, (1) urgency, and (2) probability of improved outcome with surgery.[13] This contingency measure was due to the fact that these type of procedures pose a unique risk compared to other specialties, as they work with the upper airway.[13] Thus, both patients and health care providers are specifically vulnerable to SARS-CoV-2 transmission.[19] It has been described that patients with SARS-CoV-2 disease

who undergo surgical procedures suffer worse surgical outcomes than those without the disease.[20–23] Therefore, much-needed recommendations and new protocols rapidly emerged to decrease virus spread whilst preventing patients' disease progression and surgical complications.[14,15,24–27] In fact, patients with indolent neoplastic diseases were shifted to undergo nonsurgical alternatives more than before the pandemic.[13] Indisputably, long-term studies assessing the true impact of this first-time shift are needed to expose not only changes in clinical outcomes, but also in patient-reported outcomes.

Our study results showed that HN flap reconstruction for malignant diseases could be performed safely during COVID-19. Overall, no major differences in terms of sociodemographic characteristics, clinical profile, operative time, length of hospital stay, and 30-day postoperative outcomes between before and during the COVID-19 pandemic were evidenced in this cohort. Of note, we found statistically significantly higher rates of urinary tract infection in the COVID-19 group. However, we believe that overall complication rates were very low; therefore, this finding is not clinically relevant. Similar findings were demonstrated by Wai et al., where the authors presented in 2020 their COVID-19 pandemic experience among this population.[9] In 63 operations during COVID-19 and 84 operations during pre-COVID-19, the authors found similar perioperative outcomes with no recorded viral transmission within both health care providers and patients.[9] This might be a reflection of proper pre-operative screening protocols. In fact, studies have shown that with an appropriate screening process and post-operative care, these elective procedures can be performed safely during the current pandemic while minimizing delays in treatment.[28–31]

Furthermore, it could be then reasonable to infer that due to the massive elective surgeries' cancellations secondary to the COVID-19 pandemic, delays in diagnosis and treatment, as well as a surge of advanced HN cancer are anticipated.[32–34] Moreover, Kiong et al., in a retrospective review, evidenced an increased tumor burden in patients with HN malignancies, despite having similar time of diagnosis.[32] Not surprisingly, Rygalski et al. described that delays in surgical treatment significantly increased the risk of death.[35] Even pre-pandemic, the hazard of death increases by 4.6% for every 30-day delay in time-to-surgery among this population.[35] However, the long-term impact of the pandemic, in relation to organic and mental burden among HN patients who suffered from delays is yet to be elucidated.[36] Until now, lessons learned to maximize outcomes have been described in the current literature. During the pandemic, Han et al. proposed a paradigm shift in HN cancer management.[26] The authors suggested the use of a multidisciplinary team to define "essential surgery" that require immediate life or function-threatening diseases that necessitate surgeries, as well as to identify those patients that might benefit from nonsurgical options.[26] Therefore, a multidisciplinary approach might play an important role in maximizing patient outcomes. If this approach is implemented in the future, this could potentially (1) avoid delays and (2) improve clinical and patient-reported outcomes.[26]

Additionally, HN surgeons focused on reconstruction must be aware of the potential risk factors increasing the likelihood of undergoing unplanned reoperations. This study's results demonstrate that dependent functional status, and postoperative wound infection were found to be risk factors for unplanned reoperation after conducting an adjusted analysis. Undergoing unplanned reoperations increases the burden placed not only on the patients, but also surgeons

and the health care system.[37] Sangal et al. findings aligns with ours; they found that total operative time, surgical site infection, and wound dehiscence were significantly associated with reoperation in major HN surgeries.[37] Moreover, they also identified further risk factors for reoperation not evidenced in our cohort, such as being African American, having disseminated cancer, and being ventilator dependent for more than 48 hours after surgery.[37] Therefore, proper control of the modifiable risk factors in the postoperative setting is critical to avoid reoperation among this population.

Limitations of a big database should be taken into consideration when assessing the internal and external validity of this study. This study used a national database with pre-determined data collection points that limit the assessment of other variables that might be of interest for patients who underwent HN flap reconstruction, such as type of anesthesia medications, recovery protocols, cancer stage, and history of radiation. Also, long-term complications cannot be evaluated with this database. Lastly, surgical techniques, surgical decisions, and specific patient preoperative details were not able to be ascertained.

Conclusions:

HN flap reconstruction can be performed safely during the COVID-19 era. Similar profile status on immediate post-operative outcomes were evidenced between the cohorts. Standardized and rigorous protocols for surgical candidates must be strictly followed to avoid disease progression and optimize surgical outcomes. Lastly, further studies assessing long-term outcomes during the pandemic are of utmost importance to elucidate the true impact of the COVID-19 pandemic on this population.

Ethical statement: The authors are 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. This study was IRB approved (#2021D001052) at the Beth Israel Deaconess Medical Center.

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Figure 1. *Number of head and neck free flap reconstructions by quarter from 2019-2020*

Figure 2. *Percentage of reoperation over the first post-operative month*

Table 1. *Patient Demographics based on time of operation*

	Historical Control N= 462	**COVID-19 N= 301**	**Total Cohort N= 763**	**p-value**
Age *mean (SD)*	63.6 (11.8)	63.6 (11.0)	63.6 (11.5)	0.9786
BMI *mean (SD)*	27.0 (6.4)	27.1 (6.7)	27.0 (6.5)	0.7374
Race *n (%)*				
White	286 (62.6)	189 (62.8)	475 (62.7)	0.056
African American	22 (4.8)	14 (4.7)	36 (4.8)	
Asian	19 (4.2)	17 (5.7)	36 (4.8)	
American Indian	0 (0)	2 (0.7)	2 (0.3)	
Native Hawaiian or Other Pacific Island	0 (0)	4 (1.3)	4 (0.5)	
Other/ Unknown	130 (28.5)	75 (24.9)	205 (27.0)	
Functional Status *n (%)*				
Independent	451 (97.6)	296 (98.3)	747 (97.9)	0.879
Partially Dependent	9 (2.0)	4 (1.3)	13 (1.7)	
Totally dependent	1 (0.2)	1 (0.3)	2 (0.3)	
Unknown	1 (0.2)	0 (0)	1 (0.1)	
ASA Classification *n (%)*				
1-2	95 (20.6)	61 (20.3)	156 (20.5)	1.000
3-5	367 (79.4)	240 (79.7)	607 (79.6)	
Current Smoker *n (%)*	126 (27.3)	85 (28.2)	211 (27.7)	0.804
Comorbidities *n (%)*				
Diabetes Mellitus	25 (5.4)	21 (7.0)	46 (6.0)	0.437
COPD	30 (6.5)	30 (10.0)	60 (7.9)	0.098
Hypertension	235 (50.9)	147 (48.8)	382 (50.1)	0.605
Disseminated Cancer	30 (6.5)	10 (3.3)	40 (5.2)	0.0670
Preoperative Steroids	16 (3.5)	18 (6.0)	34 (4.5)	0.108
Bleeding Disorder	7 (1.5)	6 (2.0)	13 (1.7)	0.776
Preoperative Weight Loss	48 (10.4)	17 (5.7)	65 (8.5)	**0.024***

ASA, american society of anesthesiologists; BMI, body mass index; COPD, chronic obstructive pulmonary disease; n, frequency; SD, standard deviation; %, percentage

Table 2. *Surgical Characteristics*

	Historical Control N= 462	COVID-19 N= 301	Total Cohort N= 763	p-value
Surgical Team				
Otolaryngology	345 (74.7)	230 (76.4)	575 (75.4)	0.676
Plastic Surgery	105 (22.7)	66 (21.9)	171 (22.4)	
Other	12 (2.6)	5 (1.7)	17 (2.2)	
Location of Reconstruction *n (%)*				
Oral Cavity	247 (62.1)	149 (59.6)	396 (61.1)	0.761
Pharynx	79 (19.9)	56 (22.4)	135 (20.8)	
Mandible	21 (5.3)	9 (3.6)	30 (4.6)	
Maxilla	15 (3.8)	10 (4.0)	25 (3.9)	
Surface Structures	36 (9.1)	26 (10.4)	61 (9.6)	
Surgery Setting *n (%)*				
Inpatient	457 (98.9)	297 (98.7)	754 (98.8)	0.745
Outpatient	5 (1.1)	4 (1.3)	9 (1.2)	
Wound Classification *n (%)*				
Clean	127 (27.5)	88 (29.2)	215 (28.2)	0.685
Clean/Contaminated	310 (67.1)	201 (66.8)	511 (67.0)	
Contaminated	13 (2.8)	8 (2.7)	21 (2.8)	
Dirty/Infected	12 (2.6)	4 (1.3)	16 (2.1)	
Operation Time (minutes) *Mean (SD)*	561.8 (206.0)	554.3 (196.5)	558.8 (202.2)	0.6178
Length of Hospital Stay (days) *Mean (SD)*	6.0 (24.1)	5.6 (22.0)	5.9 (23.3)	0.8213

n, frequency; SD, standard deviation; %, percentage

Table 3. *Post-operative complications following head and neck free flap reconstruction (Total)*

Post-Operative Complication	Historical Control N= 462	COVID-19 N= 301	Total Cohort N= 763	p-value
Wound-related *n (%)*				
Superficial skin infection	42 (9.1)	27 (9.0)	69 (9.0)	1.000
Deep incisional infection	15 (3.3)	8 (2.7)	23 (3.0)	0.829
Organ space infection	14 (3.0)	14 (4.7)	28 (3.7)	0.245
Wound dehiscence	25 (5.4)	15 (5.0)	40 (5.2)	0.869
Pulmonary *n (%)*				
Pneumonia	28 (6.1)	13 (4.3)	41 (5.4)	0.328
Pulmonary embolism	4 (0.9)	1 (0.3)	5 (0.7)	0.653
Renal/ Genitourinary *n (%)*				
Renal insufficiency	0 (0)	0 (0)	0 (0)	-
Acute renal failure	0 (0)	0 (0)	0 (0)	-
Urinary tract infection	2 (0.4)	7 (2.3)	9 (1.2)	**0.033***
Cardiac *n (%)*				

Cardiac arrest	8 (1.7)	3 (1.0)	11 (1.4)	0.541
Myocardial infarction	4 (0.9)	4 (1.3)	8 (1.1)	0.719
Hematologic *n (%)*				
Bleeding Complication	92 (19.9)	66 (21.9)	158 (20.7)	0.523
DVT	13 (2.8)	5 (1.7)	18 (2.4)	0.341
Systemic *n (%)*				
Shock/Sepsis	22 (4.8)	8 (2.7)	30 (3.9)	0.182
Unplanned reoperation *n (%)*	73 (15.8)	61 (20.3)	134 (17.6)	0.120

DVT, deep vein thrombosis; n, frequency; %, percentage

Table 4. *Post-operative complications following head and neck free flap reconstruction Q2*

Post-Operative Complication	**Historical Q2 N= 79**	**COVID-19 Q2 N= 107**	**Total N= 186**	**p-value**
Wound-related *n (%)*				
Superficial skin infection	9 (11.4)	4 (3.7)	13 (7.0)	0.077
Deep incisional infection	2 (2.5)	4 (2.8)	5 (2.7)	1.000
Organ space infection	4 (5.1)	7 (6.5)	11 (5.9)	0.762
Wound dehiscence	4 (5.1)	5 (4.7)	9 (4.8)	1.000
Medical-related Complications				
Pulmonary *n (%)*				
Pneumonia	4 (5.1)	5 (4.7)	9 (4.8)	1.000
Pulmonary embolism	0 (0)	0 (0)	0 (0)	-
Renal/ Genitourinary *n (%)*				
Renal insufficiency	0 (0)	0 (0)	0 (0)	-
Acute renal failure	0 (0)	0 (0)	0 (0)	-
Urinary tract infection	0 (0)	3 (2.8)	3 (1.6)	0.263
Cardiac *n (%)*				
Cardiac arrest	0 (0)	1 (0.9)	1 (0.5)	1.000
Myocardial infarction	0 (0)	0 (0)	0 (0)	-
Hematologic *n (%)*				
Bleeding Complication	14 (17.7)	25 (23.4)	39 (21.0)	0.369
DVT	2 (2.5)	1 (0.9)	3 (1.6)	0.575
Systemic *n (%)*				
Shock/Sepsis	1 (1.3)	0 (0)	1 (0.5)	0.425
Unplanned reoperation *n (%)*	14 (17.7)	19 (17.8)	33 (17.7)	1.000

DVT, deep vein thrombosis; n, frequency; %, percentage

Table 5. *Differential post-operative complications following head and neck free flap reconstruction*

Location of Reconstruction *n (%)*	Differential in Medical Complications*	p-value	Differential in Wound Complications*	p-value	Differential in Reoperation*	p-value
Oral Cavity	(+)0.68%	0.903	(+)1.38	0.787	(+)7.3	0.085
Pharynx	(+)0.05%	1.000	(+)0.43	1.000	(+)6.24	0.369
Mandible	(-)41.27%	**0.049***	(-)1.59	1.000	(-)17.46	0.393
Maxilla	(-)36.67%	0.111	(+)3.33	1.000	(+)33.33	0.121
Surface Structures	(+)5.77	0.774	(+)4.91	0.567	(-)6.2	0.689

*Refer to at least one complication within those groups were present.

Table 6. *Multivariable Analysis of Risk Factors for Reoperation*

	COVID-19 Group*	
	OR (95% CI)	**P-value**
Potential Risk Factors for Reoperation		
Reconstruction During COVID-19	1.51 (0.89 – 2.57)	0.127
Age >55	0.65 (0.32 – 1.30)	0.221
BMI ≥30	0.74 (0.38 – 1.45)	0.387
African American race	0.80 (0.26 – 2.48)	0.704
Hispanics	1.24 (0.36 – 4.29)	0.737
Dependent Functional Status	6.92 (1.34 – 35.74)	**0.021***
ASA Classification >2	1.04 (0.49 – 2.20)	0.919
Smoker	1.51 (0.82 – 2.80)	0.189
Diabetes	0.36 (0.09 – 1.49)	0.158
Hypertension	1.26 (0.70 -2.25)	0.441
COPD	0.84 (0.31 – 2.29)	0.728
Disseminated Cancer	1.19 (0.39 – 3.60)	0.756
Bleeding Disorder	2.80 (0.47 – 16.71)	0.256
Pre-operative weight loss >10% of body weight	0.89 (0.38 – 2.09)	0.789
Pre-operative steroid use	1.70 (0.46 – 6.22)	0.423
Post-operative wound infection	5.41 (2.98 – 9.81)	**<0.001*** **
Wound Classification > 2 (Contaminated)	0.77 (0.38 – 1.54)	0.457
Hematocrit < 30	0.67 (0.28 – 1.62)	0.378
Albumin < 3.5	0.78 (0.45 – 1.38)	0.395
Operative time in top 25% (>679 minutes)	1.55 (0.85 – 2.84)	0.156
Length of hospital stay in top 25% (>13 days)	4.56 (2.56 – 8.12)	**< 0.001 *** **

Supplemental Data Legends:

Supplementary Table 1. *CPT codes for head*

Supplemental Table 2. *ICD-10 codes for head and neck malignancies at different locations*

and neck vascularized free tissue transfer

Supplemental Table 3. *Type of Procedures for Unplanned Reoperation*