

SINUPLASTY GUIDANCE STATEMENT

AUTHORSHIP AND EDITING

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STATES COVERED BY CASE SUBMISSIONS BY DATE

JUNE 16, 2020: CALIFORNIA, CONNECTICUT, FLORIDA, INDIANA, TEXAS

JULY 13, 2020: CALIFORNIA, CONNECTICUT, FLORIDA, GEORGIA, MICHIGAN, NEW JERSEY, NEW YORK, INDIANA, TEXAS

CASE DATA REVIEWED BY DATE

JUNE 16, 2020: Total Cases Submitted 221, Total Procedures 467

110 SINUPLASTY CASES REVIEWED (DATABASE USED: SINUS SURGERY RESPONSES LOCKED 6-16-20-12-45)

JULY 13, 2020: Total Cases Submitted 2458, Total Procedures 2919

272 SINUPLASTY CASES REVIEWED (DATABASE USED: SINUS SURGERY RESPONSES LOCKED 07-13-20-12-38)

PRIMARY CONSIDERATIONS

- Individual procedures on sinusoutcomes.org are considered for review after approximately 100 cases of the particular procedure have been submitted. Previously reviewed procedures are considered for additional review after every 100 subsequent procedures have been submitted. Each review attempts to determine safety considerations based on data related to the primary outcomes reported.
- Since the onset of the pandemic, the United States has seen different disease characteristics for the virus, state by state, based on multiple factors. Each review of the data will show the size of the data set and the states included in the data set. Results from one set of state specific data or report cannot necessarily be extrapolated to states that have not yet reported data.
- The primary outcomes reported are:
 - Was there any COVID-19 infections reported in the dataset
 - Was there any presumed transmission of COVID-19 to patients
 - Was there any presumed transmission of COVID-19 to surgeons
 - Was there any presumed transmission of COVID-19 to staff

PRIMARY FINDINGS

Data submitted up to June 16, 2020 Primary Outcomes:

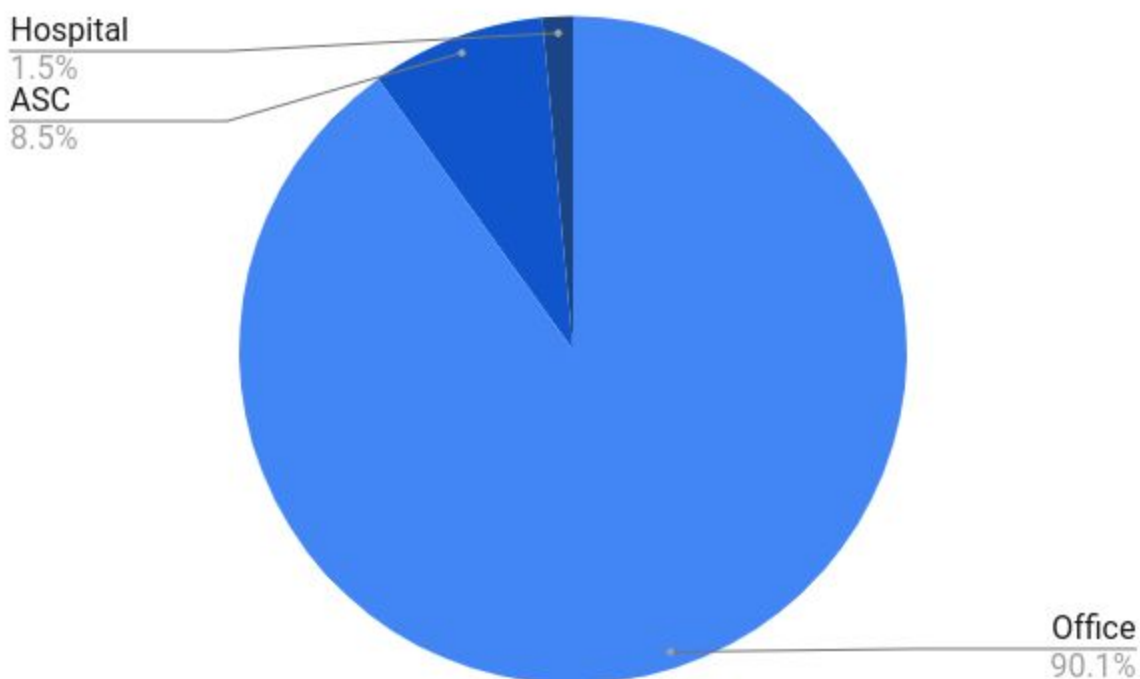
- Number of Sinuplasty Cases Reviewed: 272 cases
- COVID-19 infections reported in the dataset: 1 case reported
- Presumed transmission of COVID-19 to patients: none reported
- Presumed transmission of COVID-19 to surgeons: none reported
- Presumed transmission of COVID-19 to staff: none reported

COVID-19 Infection Breakdown

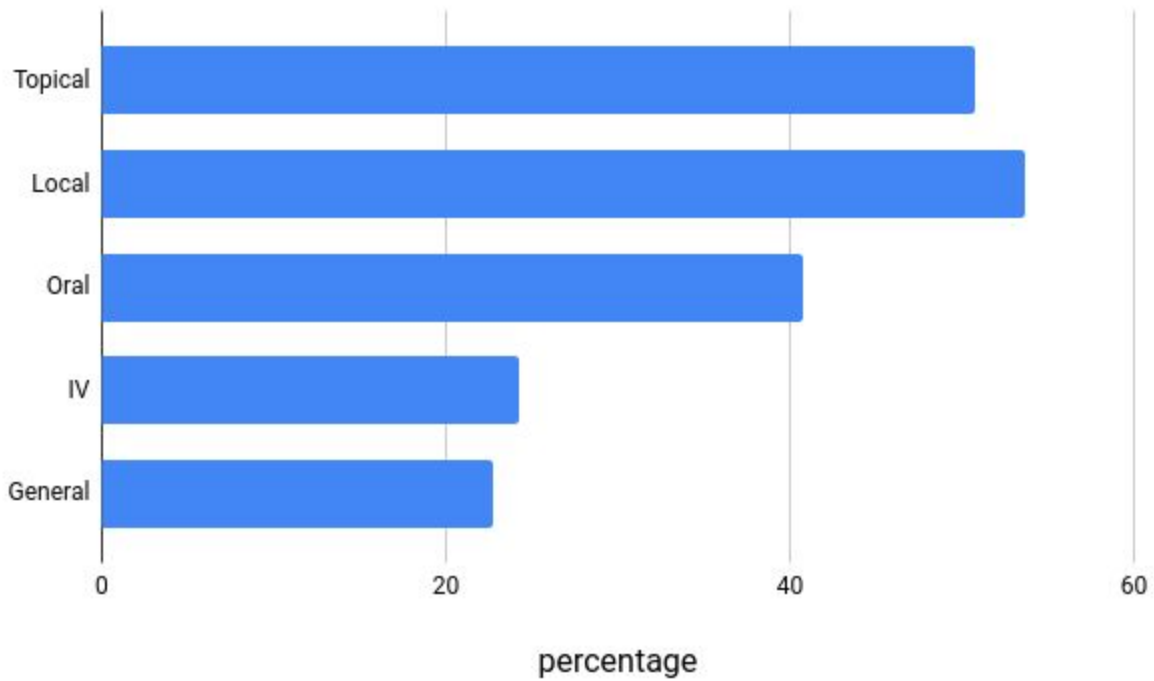
Case DOS	COVID-19 Status	Procedures Performed	Location and Anesthesia	PPE Information	Additional Measures	Additional Info	Outcomes*
May 5, 2020	Positive on date of procedure	Sinuplasty	Office, Topical, Local, Oral	Doctor used N95, Eye, Gloves, Gown - Staff used Surgical Mask, Eye, Gloves, Gown - Patient used no PPE	No additional measures were used	Patient was symptomatic but had a negative COVID-19 lab result on pre-op testing. The case was performed as scheduled. One week later the lab contacted the patient and ENT office notifying them that an error had occurred and that the original test was actually positive.	Patient made Full Recovery - there was no disease transmission to doctor, staff or to other patients

GUIDANCE ON THE SAFETY OF PERFORMING SINUPLASTY

Data submitted up to July 13, 2020 General Case Data on Site of Service

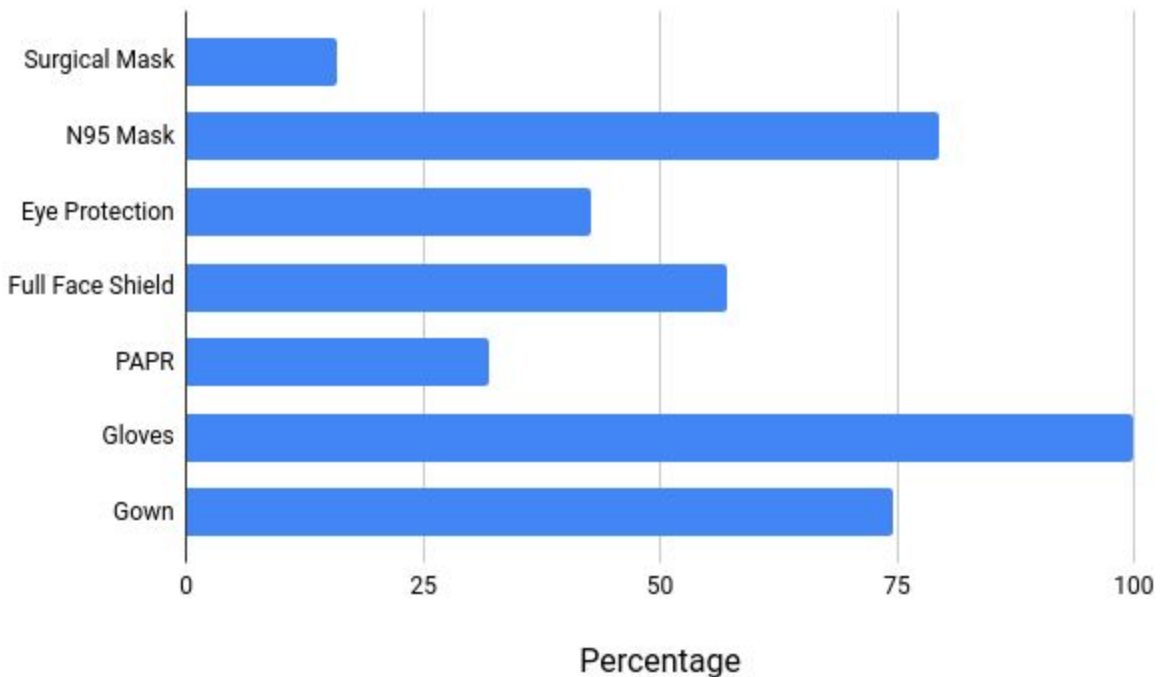


Data Submitted up to July 13, 2020 General Case Data on Anesthesia Used

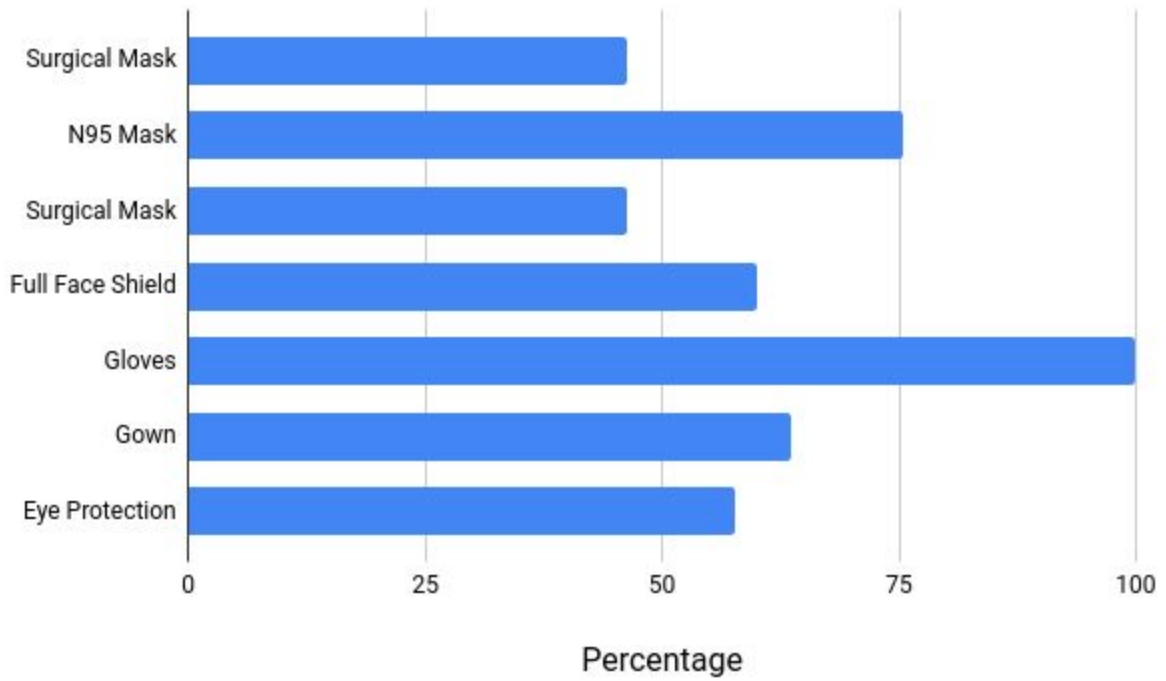


Discussion: The data set reviewed showed that the majority of cases were performed in the office setting using a combination of topical, local, oral, general, and IV anesthesia. No particular type of anesthesia showed any increased risk profile for the covered period.

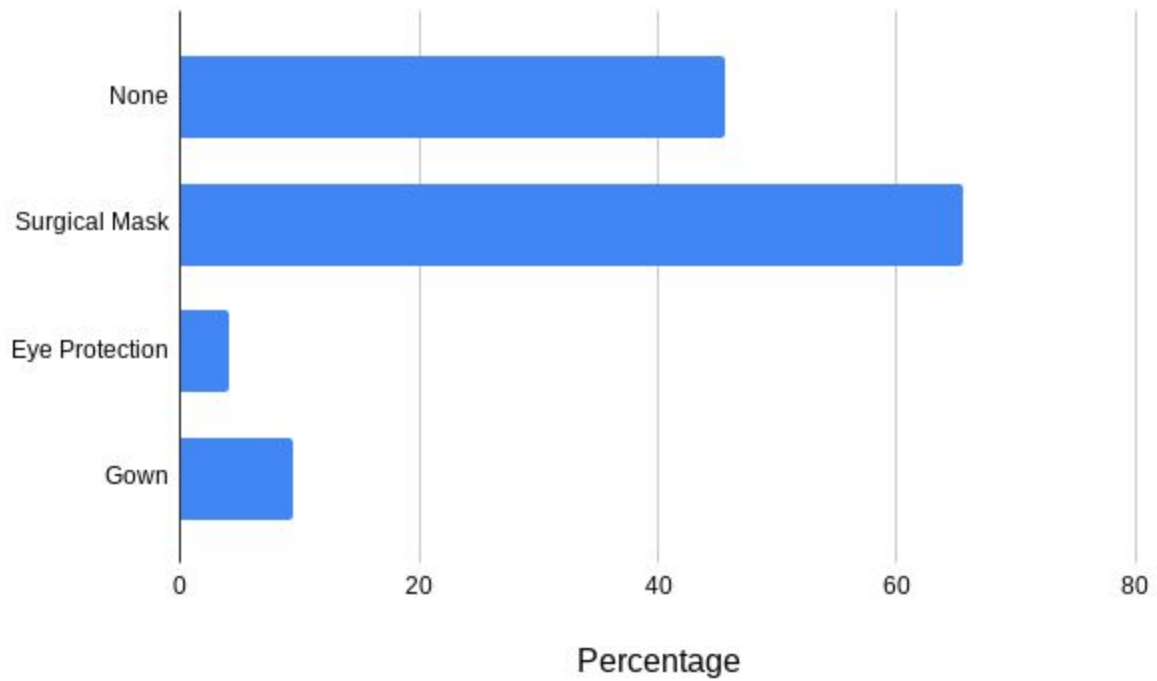
Data submitted up to July 13, 2020 PPE used during the procedure by the Doctor



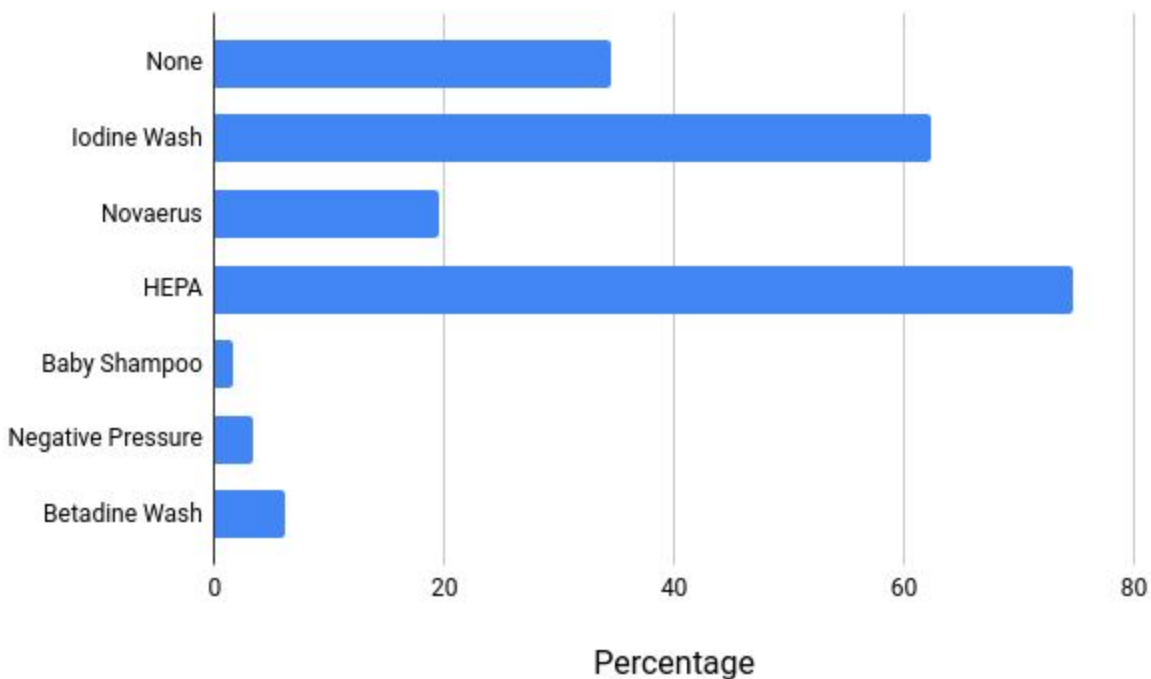
Data submitted up to July 13, 2020 PPE used during the procedure by the Staff



Data submitted up to July 13, 2020 PPE used during the procedure by the Patient



Data submitted up to June 16, 2020 PPE Additional Safety Measures Used



Discussion: The majority of cases performed in this data set showed use of N95 surgical masks, gloves, and gowns by both the surgeon and staff. A smaller percentage of respondents indicated PAPR use by the physician however this did not correlate with a change in risk profile for case transmission.

Surgical Mask use by the patient during the procedure ranked high at over 60%, with the majority of other respondents not requiring the patient to use any PPE for the procedure. About 35% of respondents did not use any additional safety measures for the case. HEPA filtration and Iodine wash ranked first and second in this data set when additional safety measures were studied. Both of these measures were used over 60% of the time with patients. In this data set, requiring the patient to use PPE during the procedure or using additional safety measures during the procedure does not appear to improve the safety or risk profile of sinuplasty.

Safety Opinion: As of July 13, 2020 Sinuplasty is safe to perform using reasonable precautions in the office setting in the states of California, Connecticut, Florida, Georgia, Michigan, New Jersey, New York, Indiana, Texas.

NEXT REVIEW

WHEN SINUPLASTY CASES EXCEED 300 SUBMISSIONS on SINUSOUTCOMES.ORG