

SINUSOUTCOMES.ORG

# FESS WITH SHAVER GUIDANCE STATEMENT

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## AUTHORSHIP AND EDITING

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## STATES COVERED BY CASE SUBMISSIONS BY DATE

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

## CASE DATA REVIEWED BY DATE

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

129 FESS WITH POWERED SHAVER 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

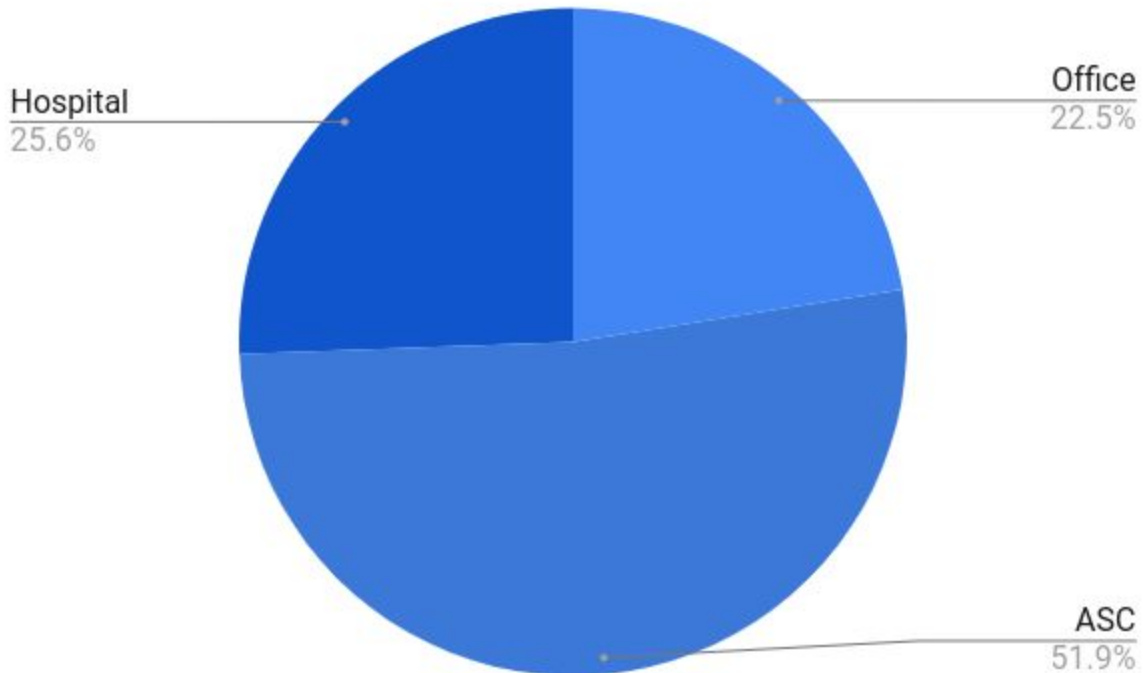
## PRIMARY FINDINGS

### Data submitted up to June 16, 2020 Primary Outcomes:

- Number of FESS with Shaver Cases Reviewed: 129 cases
- COVID-19 infections reported in the dataset: none 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

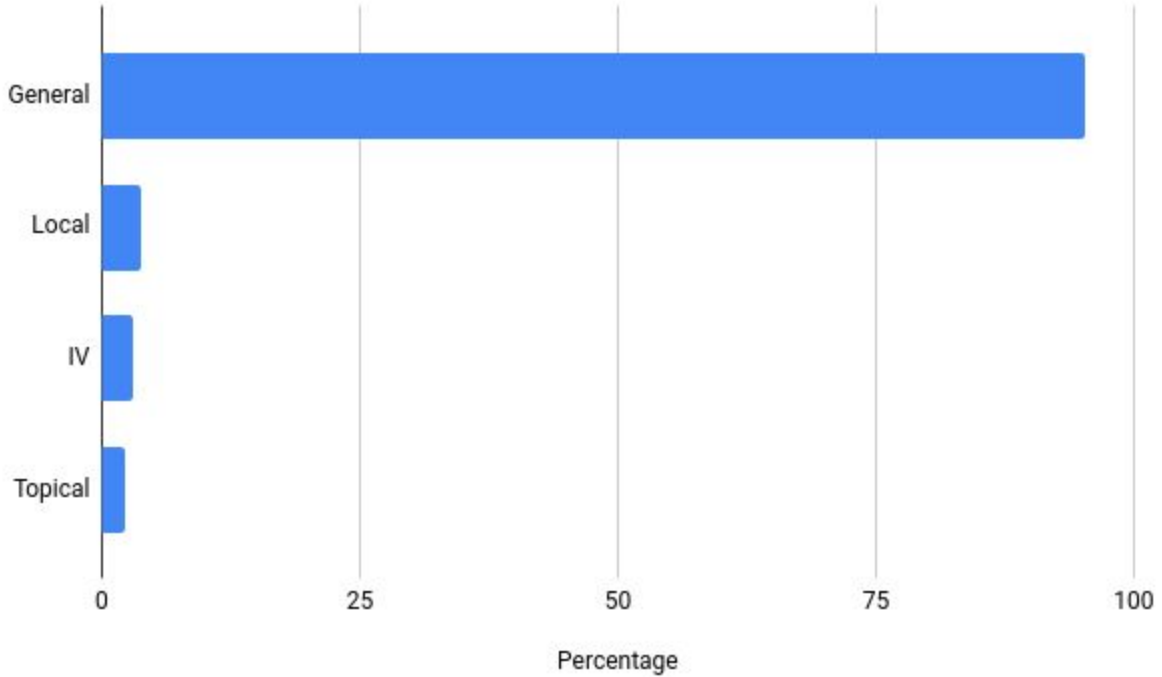
## GUIDANCE ON THE SAFETY OF PERFORMING FESS w/ SHAVER

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



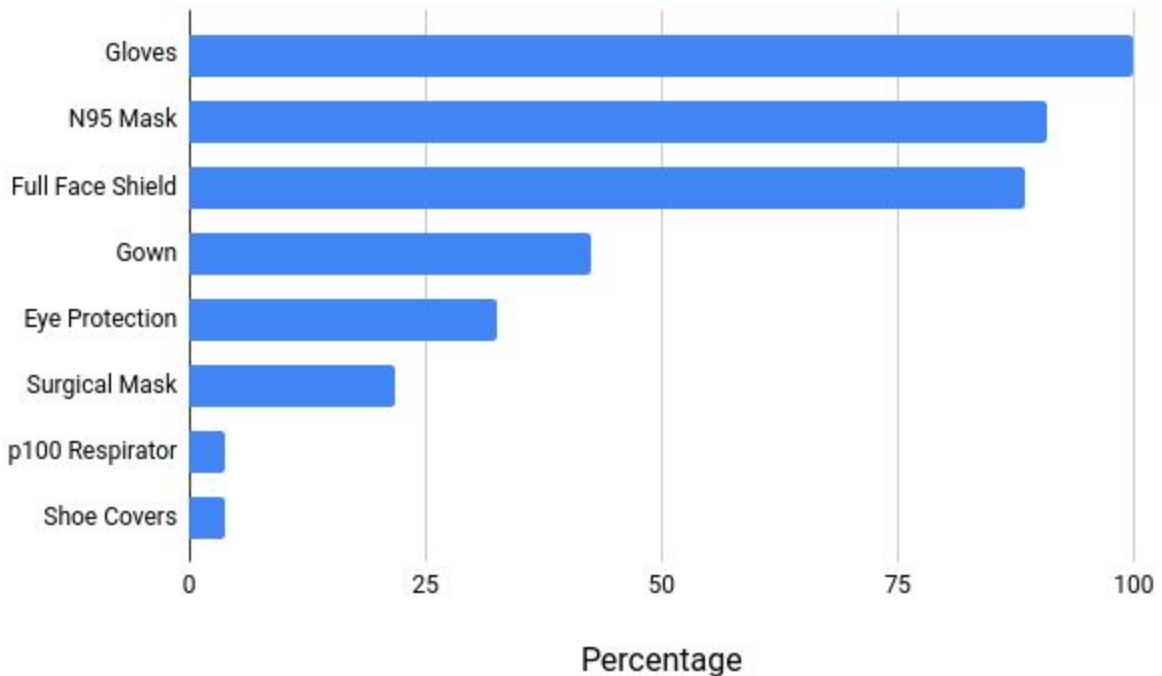
**Discussion:** The data set reviewed showed that the majority of cases were performed in ASC's with the remainder being performed in the office or hospital setting. No particular site of service showed any increased risk profile for the covered period.

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

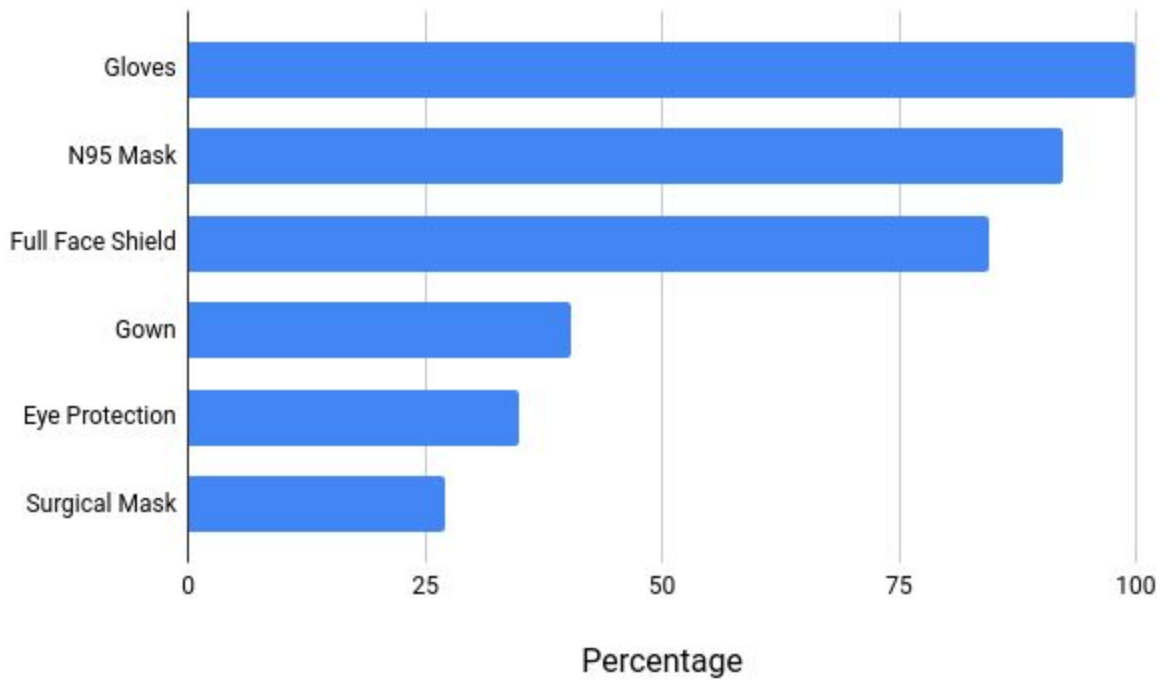


**Discussion:** The data set reviewed showed that the majority of cases were performed in ASC's using a combination of general, local, IV or topical anesthesia. No particular type of anesthesia showed any increased risk profile for the covered period.

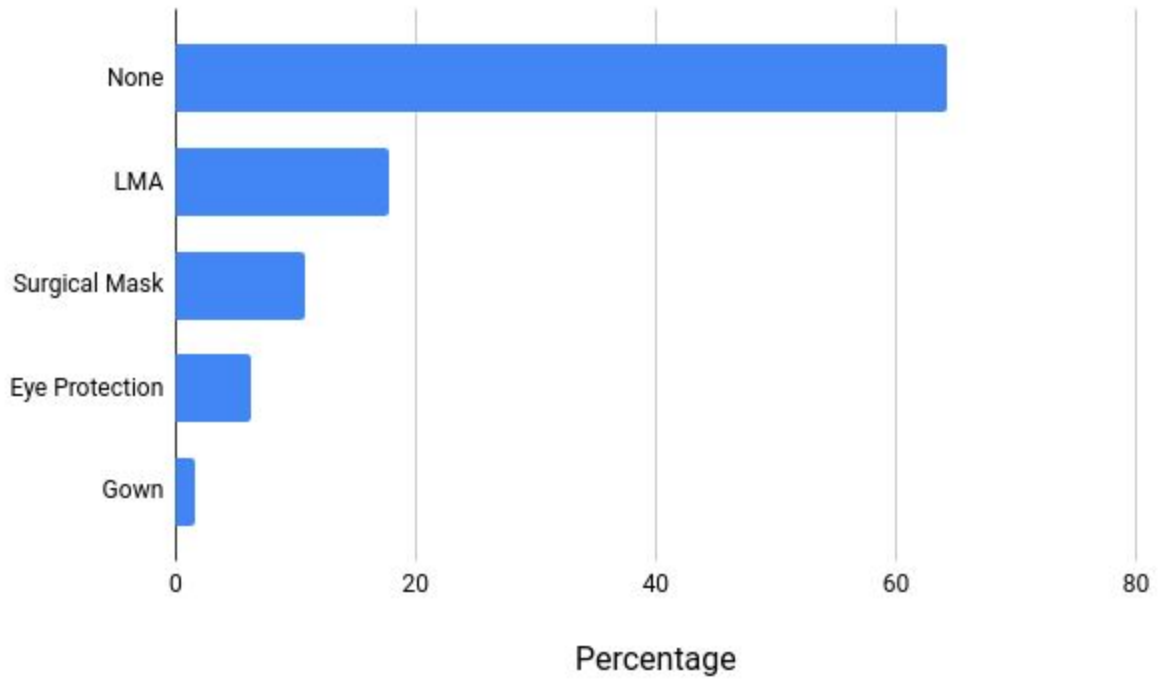
Data submitted up to July 13, 2020    PPE used during the procedure by the Doctor



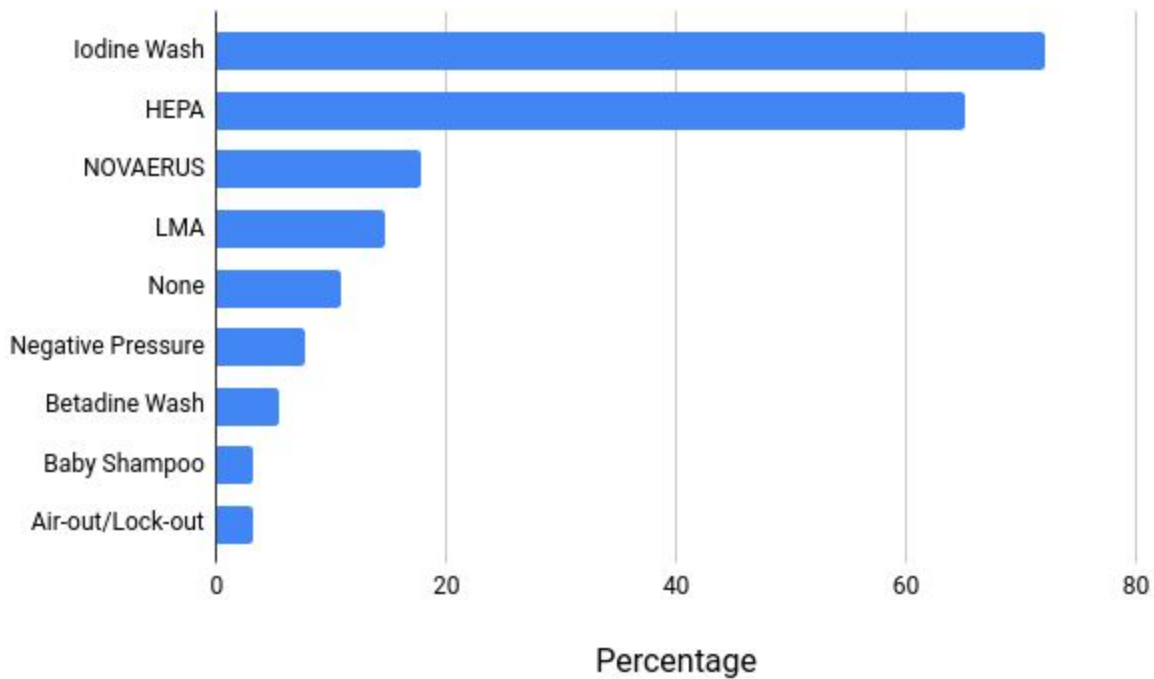
Data submitted up to July 13, 2020 PPE used during the procedure by the Staff



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, full face shields/eye protection, gloves and gowns by both the surgeon and staff. A small percentage of surgeons reported use of a P100 respirator during the case, however this did not correlate with a change in risk profile for case transmission.

Over 60% of respondents did not have the patient use any PPE or use any additional safety measures for the case. PPE use by patients was low for all other types of protective equipment with reported use at less than 20% for any other type of PPE. Iodine wash and HEPA filtration were the two highest reported additional safety measures used. Each of these was reportedly used over 60% of the time. Despite the high prevalence of use, in this data set there does not appear to be any change in risk profile based on any additional safety measures used in the procedure room.

**Safety Opinion:** As of July 13, 2020 FESS w/ Shaver is safe to perform using reasonable precautions in all settings in the states of California, Connecticut, Florida, Georgia, Michigan, New Jersey, New York, Indiana, Texas.

## NEXT REVIEW

WHEN FESS w/ SHAVER CASES EXCEED 300 SUBMISSIONS on SINUSOUTCOMES.ORG