Study Title: The effect of clear masks on patient satisfaction with physician communication during awake brain surgery

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Background, Rationale and Context

When the coronavirus became a pandemic in early 2020, wearing masks became mandatory in all public places. This lead to certain challenges such as difficulty communicating among hearing-impaired individuals who may rely lip reading, and the use of clear masks has been shown to alleviate this challenge.(Atcherson et al) In the operating room, masks have been worn to reduce the risk of surgical site infections. Surgical masks are currently being worn in the operating room during placement of deep brain stimulators (DBS) in awake patients for the treatment of medically refractory movement disorders, including Parkinson's disease and Essential Tremor. During DBS surgery, a series of questions and assessments are carried out by a neurologist in the operating room to confirm location and appropriate placement of the stimulator, requiring patients to be awake and participatory. As the neurologist traditionally wears a surgical mask that prevents patients from lip reading, a surgical mask without a clear window has the potential to hinder the communication between the neurologist and the patient. It is of vital importance that the patient understands and accurately answers the neurologist's questions to facilitate optimal placement of the DBS electrode while maximizing operative efficiency.

Since the availability of clear masks has increased in the wake of the COVID-19 pandemic, surgeons have found improved satisfaction among patients whose surgeons use clear masks when discussing or explaining surgery in the outpatient setting. (Kratzke et al) One example of a clear mask is The Communicator (Safe'N'Clear, Inc., Davidson, NC, USA), which is the only FDA-approved, ASTM Level 1 surgical mask. It has a 4.75 x 1.35 inch clear window that allows for clear visibility of the mouth.

Clear masks have not been evaluated in the intraoperative setting. Our hypothesis is that the utilization of clear surgical masks in the operating room will lead to improved satisfaction and enhance communication for patients undergoing DBS surgery.

Objective

To evaluate patients' experience during awake brain surgery when the communicating neurologist wears a clear face mask compared with a standard surgical mask.

Methods and Measures

Design

Single-center prospective randomized controlled study

Setting

Wake Forest Baptist Medical Center

Subject selection criteria

Study participants who meet the below criteria will be approached for potential participation prior to surgery.

- **Inclusion Criteria**
  - Age ≥18 years
  - Patients electing to undergo deep brain stimulator placement
  - Patient in whom general anesthesia is not planned for stimulator target localization

- **Exclusion Criteria**
  - Patients who do not give consent
  - Patients who do not undergo DBS placement
  - Patients who are blind or have a severe visual impairment
  - Non-English speaking patients (i.e., patients for whom an interpreter would be needed to conduct the intra-operative assessment)

- **Sample Size**
  - Based on statistical calculations and projections, the target sample size will be 60 patients.

Interventions and Interactions

Patients who both elect to undergo DBS surgery and agree to participate in this study will have a record created in the study database. All patients scheduled for a DBS phase I surgery will be contacted via telephone in the days prior to their scheduled surgery to discuss the possibility of study participation. This will be done to give the patient time to consider study participation in order to avoid delays the morning of surgery. The morning of surgery the patient will be approached in pre-operative holding room to discuss participation in the study and if amenable sign consent for participation. This discussion will inform the patient that minor changes are being made in an attempt to improve the patient experience, but limited information regarding what steps exactly will be provided so as to reduce potential bias that might result from the patient knowing we are studying a new mask type. If the patient agrees to participation, a consent form will be signed and as a baseline will undergo the Hearing Handicap Inventory for the Elderly (HHIE-S) questionnaire before the operation (Appendix 1). The patient's record in the electronic study database will then be created and randomized to one of two groups. Group A will experience the neurologist wearing a clear mask, and group B will experience the neurologist wearing a standard covered mask. The patient and all other intra-operative personnel will wear a covered surgical mask.

Following standard surgical protocol, the DBS surgery will proceed with the patient awake. First, a stereotactic frame is securely attached to the patient's head and the patient is positioned appropriately. Local anesthetic is used for the neurosurgeon to obtain access through the scalp and skull. A microelectrode is then stereotactically placed using headframe coordinates. The neurosurgeon sets up the motor apparatus to allow the neurologist to advance the microelectrode to the appropriate deep brain target, operating the motor from a non-sterile station arranged next to the patient. The microelectrode will stimulate and record neuronal activity, during which time the neurologist will ask the patient questions to assess for changes in symptoms. These questions typically are of the following nature:

- Do you notice any tingling or pulling of the mouth or face?
- Do you see any flashes of light in your vision?
- Do you feel any tingling or heaviness of an arm or leg?
- Do you notice any metallic or strange taste?
- Can you draw a spiral on this piece of paper?
- Can you hold your arm out in front of you and keep it still?

During a routine DBS surgery, the neurologist is positioned in view of the patient while operating the electrode motor and asking the above questions. Microelectrode stimulation and recording will conclude

when the appropriate target has been reached; that is, when simulation achieves both symptom improvement without new neurologic symptoms. At that point, the microelectrode is withdrawn and the macroelectrode is placed. The macroelectrode is stimulated in the determined position to again confirm symptom improvement without new neurologic symptom or deficit, and when confirmed the neurosurgeon will secure the macroelectrode in place. At this point, the neurologist's testing portion is complete, and the neurologist exits the operating room while the neurosurgeon completes the implantation.

For patients who agree to study participation, the neurologist will wear the mask type assigned by the randomization group for the duration of involvement in the surgery. At the conclusion of the neurologist's interaction with the patient, the patient will be asked a series of questions (presented in Appendix 2, Data collection form) to evaluate the communication experience. This step will be performed by another member of the study team (not the participating neurologist) who will read from the questionnaire and record the patient's responses using the Likert scale (defined in Appendix 2). During questioning, the neurologist will step out of the operating room to reduce potential bias from the patients answering subjective questions in front of the neurologist.

At the conclusion of the questionnaire, the patient will undergo a short debriefing regarding the aims of the study, specifically the revelation that the purpose of the study is to evaluate the use of a clear surgical mask on the patient's experience, as assessed by the questionnaire.

At the conclusion of the neurologist's assessment, as is typical, the patient will be placed under sedation for the completion of the DBS implantation. In the event a patient is having bilateral DBS implantation in one operation, only the first DBS implantation will be included in the study. For these patients, the procedure will be carried out as stated above, but following the first DBS implantation the neurologist will continue to interact with the patient for the second DBS implantation. The second implantation will not be included in the study data collection.

A retrospective chart review will be conducted for the 30 day post-operative period to evaluate for surgery-related infection. Evaluating for rates of infection between mask groups will help to ensure there is no harm associated with use of a non-covered mask during the operation. The patients will not need to be contacted or otherwise actively participate in the study during this period; information will be obtained via medical record review only. For such a chart review, a waiver of consent will be completed in the IRB application. Such a waiver is necessary in order to answer the study question regarding mask safety and surgery-related infection, as it would be difficult to retrospectively re-consent every patient already enrolled in this nearly-complete study.

Outcomes and Statistical Plan

Data will be gathered based on the attached Data Collection Form (Appendix 2). Answers to the questionnaire will be deidentified.

Power calculations will be performed considering the primary endpoint of a dichotomous response to question #1 of the CG-CAHPS. Thirty subjects per group will be needed to achieve 80% power to detect a difference of 26% or more between proportions (hypothesized standard of care mask positive response rate of 73% versus clear mask positive response rate of 99%) with alpha of 5% using conservative two-sided Fisher's Exact Test. Therefore the enrollment goal will be 60 subjects total.

Secondary outcomes will include differences in response to the remaining quantitative questions of the CG-CAHPS and free text responses to the final question. As the quantitative question responses are on a Likert scale, responses 1-3 will be considered negative and 4 will be considered positive thereby converting the outcome to binary according to the top box method. Fisher's Exact Test will be used to investigate a difference between the standard of care mask and the clear mask for all dichotomous outcomes. P-values < 0.05 will be considered statistically significant. A content analysis will be performed on the free responses to investigate distinct themes.

Human Subjects Protection

Subject Recruitment Methods

Selection of potential study participants will be based upon screening all patients who elect to undergo DBS placement during the enrollment period. The decision to undergo DBS placement will be made on an individual patient basis between patient/family and treating neurologist and neurosurgeon, without regard to consideration or participation in this study. These potential study participants will then be screened using inclusion and exclusion criteria above and approached for interest. If amenable, the purpose and steps of the study will be further explained, but without divulging the clear mask as the topic of study to avoid introducing bias with regard to mask type. If the participant gives consent, the consent form will be signed prior to any data collection or randomization. At the conclusion of the patient's study participation (i.e., the completion of the questionnaires intra-operatively) the purpose of the study will be fully explained to the patient.

Informed Consent

Written informed consent will be obtained prior to data collection or randomization. The risk of harm or discomfort is expected to be negligible, as the intraoperative questionnaire is short and not expected to extend the length of surgery more than 15 minutes. In addition, the clear mask has been approved for use in the operating room by the Food and Drug Administration and is not expected to increase the risk of infection compared to the standard covered mask. The rights and welfare of study participants will be protected by using measures to maintain the confidentiality of study information. Study results will be presented or published in lieu of providing individual subjects additional information regarding the study.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, stored separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection, subject identifying information will be destroyed in three years (consistent with data validation and study design), producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, and any computer data will be password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations, or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

References

1. Atcherson SR, Mendel LL, Baltimore WJ, et al. The effect of conventional and transparent surgical masks on speech understanding in individuals with and without hearing loss. *J Am Acad Audiol*. 2017;28 (1):58-67. doi:10.3766/jaaa.15151
2. Kratzke IM, Rosenbaum ME, Cox C, Ollila DW, Kapadia MR. Effect of Clear vs Standard Covered Masks on Communication with Patients During Surgical Clinic Encounters. *JAMA Surg.* 2021;156(4):372-378.

Appendix

1. Hearing Screening Questionnaire
2. Data collection form

Appendix 1. Hearing Screening

Patient ID: _____ **Date:**_____ **Rater:** _____

Hearing Handicap Inventory in the Elderly – Screening Questionnaire

Instructions: Answer Yes, No, or Sometimes for each question. Do not skip a question if you avoid a situation because of a hearing problem. If you use a hearing aid, please answer according to the way you hear with the aid.

1. Does a hearing problem cause you to feel embarrassed when you meet new people?	Yes (4)	No (0)	Sometimes (2)
2. Does a hearing problem cause you to feel frustrated when talking to members of your family?	Yes (4)	No (0)	Sometimes (2)
3. Do you have difficulty hearing when someone speaks in a whisper?	Yes (4)	No (0)	Sometimes (2)
4. Do you feel handicapped by a hearing problem?	Yes (4)	No (0)	Sometimes (2)
5. Does a hearing problem cause you difficulty when visiting friends, relatives, or neighbors?	Yes (4)	No (0)	Sometimes (2)
6. Does a hearing problem cause you to attend religious services less often than you would like?	Yes (4)	No (0)	Sometimes (2)
7. Does a hearing problem cause you to have arguments with family members?	Yes (4)	No (0)	Sometimes (2)
8. Does a hearing problem cause you difficulty when listening to TV or radio?	Yes (4)	No (0)	Sometimes (2)
9. Do you feel that any difficulty with your hearing limits or hampers your personal or social life?	Yes (4)	No (0)	Sometimes (2)
10. Does a hearing problem cause you difficulty when in a restaurant with relatives or friends?	Yes (4)	No (0)	Sometimes (2)

Total Score:_____

Interpretation of Total Score: 0-8 = no handicap; 10-24 = mild to moderate handicap; 26-40 = severe handicap.

Adapted from: Ventry I, Weinstein B. Identification of elderly people with hearing problems. ASHA. 1983; 25:37-42.

Appendix 2. Data collection form

Patient ID: _____ **Neurologist:** _____

Group Assignment: □**A** – Clear □**B** – Covered

Mask type used: Clear / Covered

CG-CAHPS Questions	*1 = Not at all* *4 = Completely*			
* Did this provider explain things in a way that was easy to understand?	1	2	3	4
* Did this provider listen carefully to you?	1	2	3	4
* Did this provider seem to know the important information about your medical history?	1	2	3	4
* Did this provider show respect for what you had to say?	1	2	3	4
* Did this provider spend enough time with you?	1	2	3	4
Additional Questions				
* Did this provider demonstrate empathy?	1	2	3	4
* How comfortable do you feel trusting Dr. (Neurologist)'s decisions?	1	2	3	4
* Did you understand what you were being asked to do?	1	2	3	4
* How satisfied are you with the procedure thus far overall?	1	2	3	4
	1 = Strongly disliked *4 = Strongly liked*			
† What was your impression of the Neurologist's mask?	1	2	3	4

§ What comments do you have about the Neurologist's mask(s)?_____

_____

_____

** 4-point Likert scale (1=not at all, 4=completely; †4-Likert scale (1=strongly disliked, 4=strongly liked; § Free response; Abbreviations: CH-CAHPS, Clinician and Group Consumer Assessment of Healthcare Providers and Systems*