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Bispectral EEG (BSEEG) to assess arousal after electro-convulsive therapy (ECT)

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ABSTRACT

Objectives: Postictal confusion is encountered among most patients following electro-convulsive therapy (ECT). This study aimed to test the capabilities of a point-of-care electroencephalography (EEG) method to quantitatively measure and monitor postictal confusion immediately following ECT. We evaluated whether a two-channel frontal EEG device may provide a purely quantitative measure of the postictal state that could aid in the continuous, clinical monitoring of patients following ECT.
Methods: 50 patients receiving ECT at the University of Iowa Hospitals and Clinics were recruited for this study. Subsequently, we obtained 5 min of frontal bispectral EEG (BSEEG) recording from a hand-held EEG device at baseline and 10–20 min following ECT. We performed power spectral density analysis to yield a "BSEEG" score and to capture the difference between patients at baseline and after ECT.
Results: The BSEEG score was demonstrated to be a significant indicator of postictal confusion compared to baseline. For 5 patients, we also obtained continuous EEG recordings following ECT to determine the time course required for a patient's BSEEG score to return to baseline. In this subset of patients, it took between 2 and 3 h in duration for the BSEEG score to return to the baseline range.
Conclusions: In this pilot study, we showed that BSEEG score was able to distinguish between baseline condition and postictal confusion in patients treated with ECT, and assess the duration for recovery from postictal confusion following ECT. BSEEG may provide a more sensitive measure of arousal in patients following ECT compared to traditional survey-based methods.

1. Introduction

Electro-convulsive therapy (ECT) is a commonly used treatment for patients with treatment-resistant psychiatric conditions (Kikuchi et al., 2009; Kerner and Prudic, 2014; Leiknes et al., 2012; Weiner and Prudic, 2013; Sackheim, 2017). Some consistent phenomena observed during ECT is a period of somnolence and confusion hours immediately following ECT, referred to as postictal confusion. The postictal period is highly variable between individuals as it is influenced by a number of factors including the parameters of the ECT stimulation protocol (Datto, 2000; Krauss and Theodore, 2010; Linton et al., 2002; Pogarell et al., 2005; Reti et al., 2014) and anesthetic procedure. Postictal confusion is different from postictal delirium, the latter of which is more prolonged and does not rapidly resolve, severe in terms of symptoms, and observed over an extended time-frame beyond the multi-hour interval following ECT (Krauss and Theodore, 2010).

Postictal confusion or postictal delirium are prevalent, can be hypoactive or hyperactive in nature, and can be dangerous if not appropriately monitored (Datto, 2000; Krauss and Theodore, 2010; Linton et al., 2002; Pogarell et al., 2005; Reti et al., 2014). Patients receiving ECT require close supervision in the postictal period as they are at risk for falling or becoming delirious, agitated, or combative (Datto, 2000; Krauss and Theodore, 2010; Linton et al., 2002; Pogarell et al., 2005; Reti et al., 2014). Currently, continuous monitoring and supervision by hospital staff is the only way to assess for patient recovery, which requires time and effort from limited resources in a busy hospital (Datto, 2000; Krauss and Theodore, 2010; Linton et al., 2002; Pogarell et al., 2005; Reti et al., 2014). Most hospitals monitor for cognitive recovery by asking orientation questions periodically over the course of recovery, but to date, no quantitative and objective measures are used that could complement these less precise measures of recovery.

Electroencephalography (EEG) is a potentially promising modality to

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monitor postictal confusion or delirium. EEG is historically useful in detecting delirium, particularly by capturing diffuse slowing of brain waves which are characteristic of delirium (Engel and Romano, 1959; Jacobson and Jerrier, 2000; Jacobson et al., 1993). The term 'diffuse slowing' indicates that across all 20 leads (diffusely), the brain wave signals show low frequency activity ('slowing') (Jacobson and Jerrier, 2000; Jacobson et al., 1993). However, a regular EEG has not been practical or timely for screening the high volume of patients with any form of delirium or postictal confusion. A regular 20 lead EEG is traditionally not portable for high-throughput hospitals or clinics, requires an experienced technician to place all EEG leads upon a patient's head, and needs a neurology specialist to interpret EEG data, which can all delay decision making for clinical care. However, our recent work was the first to show the utility of a simplified, portable, automated EEG with bispectral density analysis suitable for delirium mass screening in both general medicine and emergency room settings (Shinozaki et al., 2018; Lee et al., 2019).

Placing only two channels (i.e., bispectral EEG [BSEEG]) on the head (Fp1 and Fp2 electrode positions) is an attractive approach because it allows for non-experts to use the technology, meeting a critical need by removing the necessity of specialized neurologists and technicians, thus permitting mass adoption of the technology. The concept of bispectral brain wave monitoring is not unique, and has been used to monitor depth of anesthesia and, during ECT, to monitor seizure quality and length (Doi et al., 1997; Liu et al., 1997; Powers et al., 2005; Schmidlin et al., 2001). Thus, although EEG is not currently used in screening for delirium or postictal confusion, obtaining EEG signals from limited channels is a well-established technology.

Regarding ECT, it is also essential for patients' safety to monitor their cognitive level in the process of recovery following ECT and postictal confusion (Datto, 2000; Krauss and Theodore, 2010; Linton et al., 2002; Pogarell et al., 2005; Reti et al., 2014). In this study, we build upon previous work including our own (Shinozaki et al., 2018; Lee et al., 2019), to assess whether the BSEEG method with a two-channel frontal EEG device may provide a reliable and objective measure of confusion and cognitive recovery during the postictal state after ECT and could be monitored continuously and aid in the clinical monitoring of patients following ECT.

2. Methods

2.1. Participants

Study subjects were recruited from patients who were admitted to the University of Iowa Hospitals and Clinics between May 2018 and December 2018. We recruited patients scheduled to receive ECT to compare features of brain wave signals, before and after ECT, obtained using a simplified EEG device. The human subjects research conducted in this study followed the tenets of the Declaration of Helsinki, with University of Iowa institutional review board (IRB) approval. Informed consent was obtained from the subjects after explanation of the nature and possible consequences of the study. The parameters of the ECT protocols (electrode placement, intensity of stimulation, number of stimulation, duration of crisis, etc.) and anesthetic procedures (anesthetic agents used, doses, time between injection and stimulation, etc.) used varied across patients. 70% of the subjects received bilateral ECT electrode placement (while the rest received unilateral electrode placement), and 64% of the subjects received index ECT treatments with the remaining subjects receiving maintenance ECT. Anesthetic agents commonly used included some combination of methohexital, succinylcholine, glycopyrrolate, ketorolac, etomidate, esmolol, and hydralazine. Only 18 subjects received propofol over the course of their ECT treatment, and only 3 subjects received a benzodiazepine following ECT.

2.2. Clinical assessment

We screened for patients with potential cognitive impairment who may lack capacity to consent using the Montreal Cognitive Assessment (Nasreddine et al., 2005), and obtained consent from subjects as appropriate. For baseline dementia, we reviewed hospital records for past diagnosis of dementia, although no patients in our study had a previous diagnosis of dementia. We also screened for the presence of postictal confusion by administering the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) (Ely et al., 2001; Kuczmarska et al., 2016; Nishimura et al., 2016; van Eijk et al., 2011).

2.3. EEG device

Following those clinical evaluations, we placed EEG leads on each patient's left and right side of the forehead (Fp1 and Fp2, respectively) with one ground on the center of the forehead (Fpz), with references on the left and right earlobes (A1 and A2, respectively) to obtain two-channel signals as described previously (Shinozaki et al., 2018), which were recorded for 5 min at baseline, and a second recording over 10–20 min immediately following ECT. For 5 subjects, we also obtained continuous EEG recordings following ECT to determine the required time for a patient's BSEEG score to return to baseline. For data capture, we used a commercially available, handheld EEG device (CMS2100, Contec, Qinhuangdao, China). For disposable electrodes, we used alligator clips with disposable electrode patches (Item #602924, Alligator Clip Lead; Item #388007, Nutab Disposable Electrodes, Rochester Electro-Medical, Lutz, FL, USA). The maximum electrode impedances allowed for recordings was 10 MOhms.

2.4. EEG measurements

For baseline and postictal measurements, we asked patients to close their eyes and relax their jaws, then to sit still during recording as much as they could. Data was transferred to a secure server for subsequent signal processing. In a previous study (Shinozaki et al., 2018), we compared the quality of the brain wave signal from our limited-lead EEG device with the brain wave signal obtained from a traditional 20-lead EEG machine from the same patients at the same time. Through this comparison, we established that the EEG from the limited-lead device was fully functional with respect to its ability to measure brain waves derived from two EEG channels attached to patients' foreheads (Shinozaki et al., 2018).

2.5. EEG signal processing and analysis

As previously described (Shinozaki et al., 2018), recorded EEG data were exported in European Data Format for further analysis. Each channel of EEG data was extracted and subsequently filtered for excessive noise. As EEG, particularly at frontal electrode sites, are prone to artifact signals, such as those caused by eye blinks, facial muscle activities, surrounding electronics, and simple body movements, and these signals can compromise quality, several filtering strategies were applied. A low-pass filter was first applied to the EEG signals, which were then portioned into four-second windows which were excluded from analysis if they contained abnormally high amplitudes from eye blinks or similar artifact events. The power spectral density (PSD) of the remaining partitioned signals were obtained via fast Fourier transformation. A PSD ratio (PSDR) of low-to-high frequency activity, specifically 3–10 Hz activity was used to obtain a BSEEG score where the activity in each partitioned window was integrated into a single value. The computed ratio was reported as the average of both channels for further analysis before and after ECT, and during an extended time window following ECT in a subset of patients. To demonstrate whether BSEEG changed significantly between baseline and immediately following ECT during postictal confusion, a paired *t*-test was performed with R software (version 3.5), with p values of 0.05 or less considered to indicate statistical significance.

3. Results

50 subjects were recruited for the present study, and their demographics are listed in Table 1. All subjects were assessed to be negative for delirium and postictal confusion at baseline, and positive for postictal confusion following ECT. Our initial PSDR analysis showed that while the individual low (3 Hz) and high (10 Hz) frequency bands used for the computation of the PSD ratio did not differ between the baseline and postictal recordings, our EEG device differentiated conditions between baseline and postictal confusion states using the measure of the ratio of the 3–10 Hz activity. Thus, the PSDR analysis detected the presence and absence of postictal confusion in the same patient at different time points.

3.1. Comparison of BSEEG between baseline and postictal delirium states

There was a significant difference ($P < 0.0001$, df = 49) when comparing BSEEG at baseline (mean = 1.22, SD = 0.071) and immediately following ECT during postictal confusion (mean = 1.45, SD = 0.087), with an average increase of BSEEG score by 18.8% from baseline to postictal (Fig. 1). In all cases, BSEEG score increased without exception and differences in BSEEG score between pre and post were in average = 0.23, SD 0.067, Min = 0.085 and Max = 0.45.

3.2. Analysis of time required for BSEEG to return to baseline following ECT

For 5 patients, we also obtained continuous EEG recordings following ECT to determine the required time for a patient's BSEEG score to return to baseline (Fig. 2). For these patients, on average it took over 2 h for their BSEEG scores to return to their baseline range. Contrastingly, all subjects were determined to be alert and oriented to person, place, and time within the first 30 min postictal.

4. Discussion

Our results show the utility of a simplified, portable, automated EEG with bispectral density analysis (BSEEG method) for quantifying arousal following ECT. Using such a strategy, our approach showed significant intra-individual differences before and after developing postictal confusion due to ECT. We show that bispectral frontal EEG is a potentially practically useful marker of arousal following ECT with a unidirectional increase across all 50 participants, and a gradual return to baseline that showed inter-individual variability, but took more than two hours on average to be achieved.

While changes in BSEEG cannot be correlated with postictal confusion in the present data set, we believe BSEEG method could provide an innovative clinical tool easy to implement for monitoring patients' recovery and arousal following ECT. Compared to traditional EEG, which requires >20 leads placed all over the head of patients by a trained EEG technician, our system requires only a few leads placed on the forehead, thus requiring minimal training. Screening can be achieved in minimal time (i.e. minutes), and extended monitoring can also be performed, even dynamically, with recordings of longer duration. This is a significant advantage compared to a traditional EEG reading interpreted by specialists, which introduces significant delays. The BSEEG method is also an improvement over numerous screening instruments currently used in practice, such as questionnaire-style methods, which are prone to interpretive variation by examiners, require extensive training, and prolonged time to conduct.

In our previous work, we have already shown the usefulness of a small, portable, bedside, point-of-care BSEEG device with simplified lead placement in differentiating delirium in a general hospital setting (Shinozaki et al., 2018) as well as in an emergency room setting (Lee et al., 2019). In this study, we applied our approach to a new patient population: patients with post-ictal confusion following ECT, who did not show post-ictal delirium. Our intention with BSEEG is not to discriminate the condition of post-ictal confusion. Rather, we aimed to show that BSEEG perhaps provides a more quantitative, objective assessment of post-ictal confusion, compared to questionnaire-style methods which are subjective and provide binary classifications. This pilot study provides encouraging results that BSEEG can be used to provide objective and quantifiable measure of the severity of post-ictal confusion in patients, which is difficult, if not impossible, by a questionnaire-based method like CAM-ICU. The BSEEG method can perhaps provide an automated, fine-grained assessment and quantification with further validation.

That there is a change in frontal BSEEG in the post-ictal period is no surprise, nor is that all patients experienced post-ictal confusion. The two variables may not necessarily be related, and correlating post-ictal confusion with other measures is difficult given the subjective, non-quantitative assessments largely used in clinical practice (which are not always documented by healthcare workers). All patients were alert and oriented to name, location, and date within 30 min post-ictal, but the BSEEG only returned to baseline after over 2 h. While no case can be made that BSEEG is any kind of measure of post-ictal confusion, in clinical practice, the BSEEG method may have the potential to be used as an additional metric to specifically monitor the level of arousal, and hence recovery following ECT. Multiple studies have examined disorientation and recovery of orientation after ECT up to 120 min postictal (Daniel and Crovitz, 1982; d'Elia, 1974; Gottlieb and Wilson, 1965; Lancaster et al., 1958; Lunn and Trolle, 1949; Mowbray, 1954, 1959; Valentine et al., 1968; Wilcox, 1956). Postictal disorientation experienced after ECT reportedly lasts for 1–2 h following ECT (Kranaster et al., 2012; Tzabazis et al., 2013), while cognitive side effects have been noted to persist for 90 min following seizure termination (Perera et al., 2004). Our study continued on the work of these previous studies, and thus we examined over 120 min of postictal EEG. However, these previous studies have all relied on asking orientation questions, which leaves opportunities for methodological improvement. Our BSEEG method provides a continuous measurement, which is quantifiable and thus more informative than traditional mental status exam questions.

Furthermore, the effects of ECT on EEG activity, and the clinical significance of these effects, has been investigated for decades. One study of patients with different types of depression showed that ictal EEG activity is mostly in the Delta and Theta frequency range, with activity greater than this range almost equal to zero (Wahlund et al., 2009; Weiner et al., 1991). Ictal EEG characteristically starts with a high-voltage "sharp waves and spikes" phase, followed by a second phase consisting of rhythmical "slow-waves." The last phase of the ictal EEG is characterized by low amplitude and higher frequency. This EEG pattern is called postictal suppression, after which the patient's clinical status gradually recovers to baseline (Wahlund et al., 2009; Weiner et al., 1991). Perturbations in EEG measures persist even as individuals appear to be awake in the postictal period (Gunawardane et al., 2002; Palanca et al., 2018; Soehle et al., 2014; Thimmaiah et al., 2012). Persistent slow theta and delta oscillations have been observed in EEG following ECT, sometimes requiring weeks after treatment to resolve (Volavka et al., 1972; Kolbeinsson et al., 1988; Sackheim et al., 1996,

Table 1
Demographics of study subjects.

	Test subjects ($N = 50$)
Median age (years, SD)	56.0, 15.0
Female (*N*, %)	30, 60%
White (*N*, %)	48, 96%
CAM-ICU negative at baseline (*N*, %)	50, 100%
CAM-ICU positive postictal (*N*, %)	50, 100%

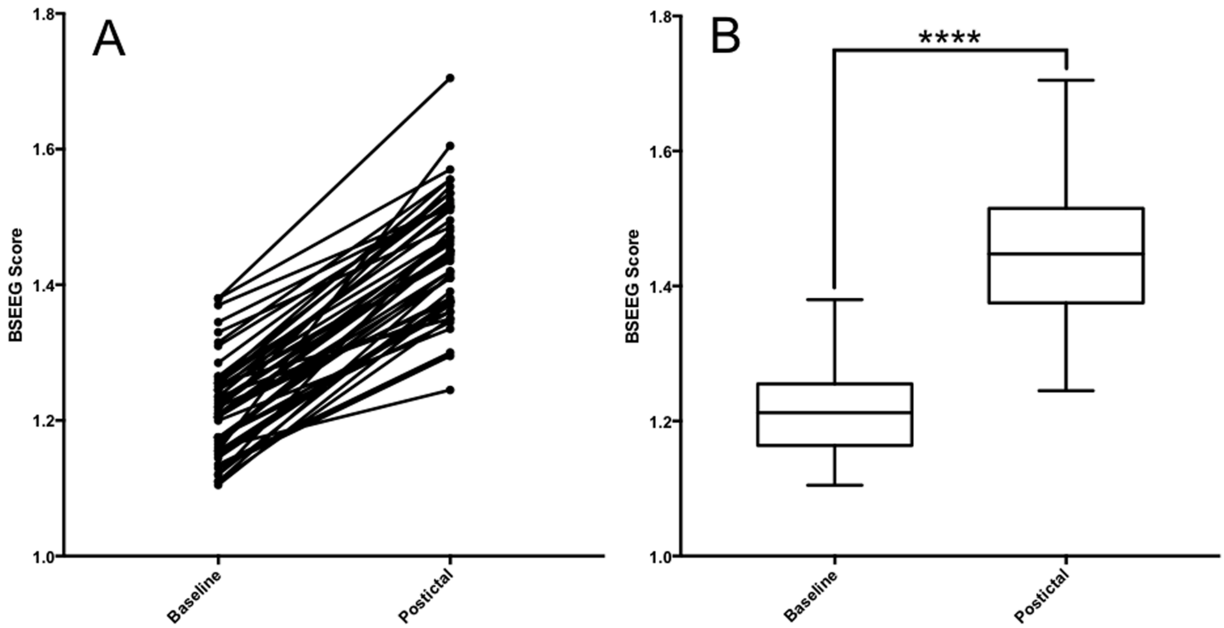

Fig. 1. BSEEG comparison at baseline and during postictal confusion. Bispectral frontal EEG is a reliable marker of the postictal confusion state with a unidirectional increase across all 50 participants (A) and a significant group difference ($P < 0.0001$, df = 49) when comparing BSEEG at baseline and immediately following ECT during postictal confusion (B).

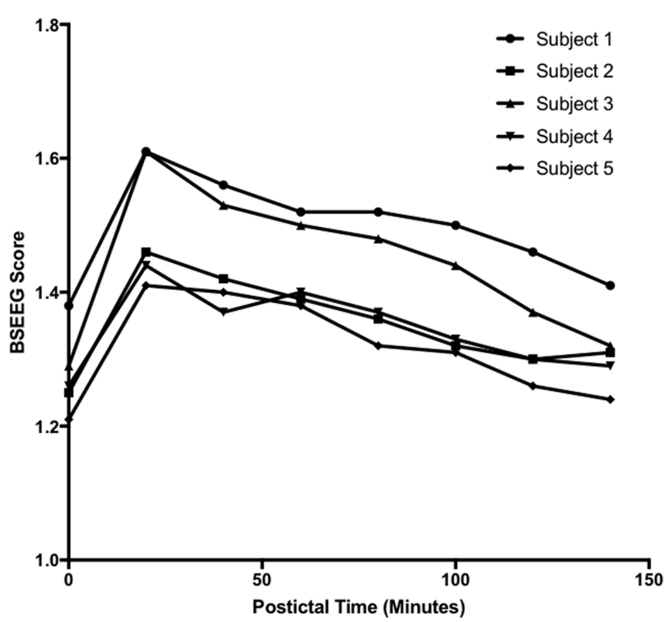

Fig. 2. Monitoring postictal recovery with BSEEG. BSEEG scores were calculated over multiple hours of recording, illustrating that the approximate return to baseline occurs between 2 and 3 h in these 5 patients.

2000). These effects of ECT with respect to changes in low and high frequency EEG power are well-established, and are consistent with our results which showed an increase in the ratio of low frequency to high frequency EEG activity.

However, to this day, reliable EEG measures that can be linked to underlying neurobiology and cognitive function have not been established for the recovery period following ECT (Palanca et al., 2018). One study examined whether EEG features are sensitive to treatment condition using a dosing range for right-unilateral (RUL) ECT or high-dose bilateral (BL) ECT, as well as predictive of clinical and cognitive outcomes. The authors found that BL ECT resulted in greater ictal power and postictal suppression than each RUL ECT condition, but EEG failed to discriminate the RUL ECT groups. Additionally, EEG measures, specifically greater ictal power and postictal suppression, were modestly associated with clinical outcome, but no EEG measures were associated with cognitive outcomes. Another study showed that greater suppression in EEG following ECT was more likely to be associated with prolonged memory impairment (Volavka et al., 1972). EEG measures that are perturbed for any period of time following ECT are believed to be linked to therapeutic efficacy, level of disorientation, or retrograde amnesia, but no clear relationships have been established to date, nor does this study make any possibility more probable.

One logistical limitation to the study included discontinuation of EEG data after no more than two hours of collection to allow the patient to rest and recover from ECT. However, even with this limitation in data collection, we can still capture the approximate return to baseline with BSEEG. Assessing the duration of postictal confusion with BSEEG is an exciting opportunity as such data can be difficult to collect with questionnaire methods, and BSEEG can potentially help determine the standard of care for monitoring of patients following ECT. In the age of digital phenotyping and computational psychiatry, the BSEEG score can be used as a guideline measurement and vital sign to assess confusion and cognitive recovery in an objective manner, and more efficiently guide staff operations. BSEEG may provide a physiological marker of ECT treatment adequacy, which is useful given that ECT can result in generalized seizures that lack efficacy, physiological markers of treatment adequacy are needed (Koitabashi et al., 2009; Perera et al., 2004). However, as previous studies have shown, the inability of EEG to differentiate between different forms of RUL ECT may suggest that EEG is limited in its ability to measure treatment adequacy, and rather reflects individual neuropsychopharmacological differences and biological variability (Koitabashi et al., 2009; Perera et al., 2004).

We acknowledge several limitations of the present study as a proof-of-concept study, including a relatively small sample size and confounding effects of anesthesia. For instance, given that ECT sessions require the administration of general anesthesia, further studies that account for anesthetic agents are needed. As mentioned, the parameters of the ECT protocols (stimulus parameters, etc.) and anesthetic procedures used varied across subjects, which potentially create variability in the degree of confusion and physiological response to ECT. While we did record the details on anesthetic procedure and ECT procedure used for each subject, the parameters vary across all subjects, and do not allow us to create balanced sub-groups to draw any meaningful, statistically-significant conclusions. No significant associations have been found with BSEEG and anesthetic or ECT procedure, as the sizes of individual sub-groups (grouped according to anesthetic or ECT procedure) in this dataset are too small to draw meaningful conclusions. Our study motivates the need for larger studies to be conducted to explore the effects of different anesthetic and ECT procedures.

Nevertheless, with the subjects in this study, our data demonstrates evidence of reliability as well as the ability to capture a range of variable postictal responses, with potential for the technology to mature to improve future patient care with more objective monitoring for the better assessment of patients' cognitive status. While we did not specifically look at post-ictal delirium in this study, BSEEG could have utility in identifying patients at risk for post-ictal delirium if their values had a greater rise than most patients or stayed high for longer following ECT. Our group has already shown the utility of BSEEG methods to detect delirium in general hospital (Shinozaki et al., 2018) and emergency room (Lee et al., 2019). Future work will evaluate how BSEEG values (relative to one's baseline) relate to functional improvement (orientation, responding to simple questions) as well as whether there are typical values associated with transferring from a post-ECT recovery area to the inpatient floor or discharging the patient when ECT is done as an outpatient.

CRediT authorship contribution statement

Kasra Zarei: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Writing – original draft. **Nicholas A Sparr:** . **Nicholas T Trapp:** Investigation, Validation, Writing – review & editing. **Elena D Neuhaus:** . **John W Cromwell:** . **Aaron D Boes:** Investigation, Resources, Supervision, Writing – review & editing. **Gen Shinozaki:** Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Writing – review & editing.

Declaration of Competing Interest

Gen Shinozaki and John Cromwell are co-founders of Predelix Medical LLC. They are the only authors with a conflict of interest. This work was supported by grants NSF1664364 and K23MH107654.

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