sEEG for expansion of a surgical epilepsy program: Safety and efficacy in 152 consecutive cases

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Abstract

Objective: Stereoelectroencephalography (sEEG) is an intracranial encephalography method of expanding use. The need for increased epilepsy surgery access has led to the consideration of sEEG adoption by new or expanding surgical epilepsy programs. Data regarding safety and efficacy are uncommon outside of high-volume, well-established centers, which may be less applicable to newer or low-volume centers. The objective of this study was to add to the sEEG outcomes in the literature from the perspective of a rapidly expanding center.

Methods: A retrospective chart review of consecutive sEEG cases from January 2016 to December 2019 was performed. Data extraction included demographic data, surgical data, and outcome data, which pertinently examined surgical method, progression to therapeutic procedure, clinically significant adverse events, and Engel outcomes.

Results: One hundred and fifty-two sEEG procedures were performed on 131 patients. Procedures averaged 10.5 electrodes for a total of 1603 electrodes. The majority (84%) of patients progressed to a therapeutic procedure. Six clinically significant complications occurred: three retained electrodes, two hemorrhages, and one failure to complete investigation. Only one complication resulted in a permanent deficit. Engel 1 outcome was achieved in 63.3% of patients reaching one-year follow-up after a curative procedure.

Significance: New or expanding epilepsy surgery centers can appropriately consider the use of sEEG. The complication rate is low and the majority of patients progress to therapeutic surgery. Procedural safety, progression to therapeutic intervention, and Engel outcomes are comparable to cohorts from long-established epilepsy surgery programs.

Keywords:
invasive encephalography, sEEG, stereoelectroencephalography, surgical epilepsy
1 | INTRODUCTION

In 2016, Engel strongly argued epilepsy patients who failed two appropriately selected and trialed antiseizure medications should be referred to tertiary epilepsy centers. His argument was grounded in the comprehensive diagnostic and treatment options, including surgery, available at tertiary epilepsy centers. This approach pursues Engel’s stated goal for epilepsy treatment: “no seizures, no side effects, as soon as possible.”

Though a sometimes challenging process, surgical treatment of drug-resistant epilepsy provides opportunities for seizure freedom or meaningful seizure reduction in appropriately selected patients. While many patients can achieve sufficient diagnostic concordance and safety data for epilepsy surgery with non-invasive methods, some patients require more precise localization of seizure foci and eloquent tissue that can be achieved only with invasive electroencephalogram (EEG) recording and cortical stimulation. Unfortunately, access to centers with the ability to perform invasive monitoring remains a barrier to treatment.

Stereoelectroencephalography (sEEG) is an invasive method of encephalography that makes for an attractive candidate to increase invasive monitoring capacity due to its safety and efficacy profile. sEEG is noted to have equal, if not improved outcomes with regard to morbidity and mortality. Recent data have shown that use of sEEG results in improved Engel outcomes in both lesional and nonlesional cases when compared to subdural grids and strips. Despite this evidence, overall adoption of sEEG in the United States has been delayed relative to other developed regions such as Europe and Canada.

New surgical therapies for drug-resistant epilepsy, such as responsive neurostimulation (RNS) and thalamic deep brain stimulation (DBS), are now approved and widely available for use in the United States. These new options expand consideration to patients previously not considered due to eloquent or multifocal seizure onset. Thus, the number of patients who proceed to therapeutic surgery after sEEG may be increased compared to previous cohorts studied prior to availability of these treatments.

sEEG represents an opportunity for new or growing centers to expand utilization of invasive monitoring and better attend to the needs of drug-resistant epilepsy patients. However, prior to any expectation of non-surgical or expanding epilepsy surgery programs adopting sEEG, the literature must show safety and efficacy from centers with a similar clinical profile. This is key to demonstrating generalizability of sEEG in terms of feasibility and success outside of long-standing epilepsy surgery programs. Furthermore, sEEG efficacy in the context of new technologies such as RNS and DBS therapies has not been reported. This manuscript provides safety and efficacy data for sEEG at The University of Kansas Comprehensive Epilepsy Center from 2016 to 2019. During this time, there was a significant expansion of the epilepsy program utilizing sEEG with availability of DBS and RNS as treatment modalities.

2 | METHODS

2.1 | Data collection

After obtaining Institutional Review Board approval, a retrospective chart review of all patients who underwent sEEG implantation from January 2016 to December 2019 was performed. All patients from that period were included in the safety analysis. Patients with at least one year documented follow-up post-therapeutic intervention were analyzed for seizure outcome utilizing the Engel classification system. A limited chart review was done to determine case numbers for sEEG and grid placement from 2011 to 2015 to provide context for the case volume from 2016 to 2019.

2.2 | Clinical course

Patients seen at the University of Kansas Comprehensive Epilepsy Center with drug-resistant epilepsy, failure of two appropriate antiepileptic drugs, are considered for surgical evaluation and subsequently discussed at epilepsy surgery conference. The conference is comprised of
epileptologists, neurosurgeons, neuropsychologists, diagnostic radiologists, nuclear radiologists, fellows, residents, and nursing staff. The data reviewed include seizure semiology, magnetic resonance imaging (MRI), inpatient video EEG monitoring, functional MRI, and neuropsychology testing. Additional data in selected patients include fluorodeoxyglucose-positron emission tomography (FDG-PET), ictal single-photon emission computed tomography (SPECT) with Subtraction Ictal SPECT Co-registered to MRI (SISCOM), and Wada testing. The decision for sEEG is based on consensus agreement. Consensus agreement for sEEG indicates diagnostic uncertainty regarding the epileptogenic zone and thus, more practically, uncertainty for an obvious therapeutic surgery. Our group thus utilizes sEEG to ascertain specific epileptogenic zone localization(s) in situations such as but not limited to dual pathology; multifocal epilepsy (ie, bitemporal epilepsy with or without neuroimaging finding such as MTS); discordance between semiology, EEG, and neuroimaging; or most commonly MRI-negative scenarios. The patient’s semiology, electrophysiology, and radiology findings are utilized to formulate an implantation strategy that confirms an epileptogenic zone hypothesis while excluding alternate possibilities.17,18

Specific electrode trajectory planning is done by the neurosurgeon with input from the epileptologist. Identification of surface and deep vasculature is done with contrasted T1 3D magnetization-prepared rapid acquisition with gradient echo (MPRAGE) MRI. Trajectories are planned to avoid vessels and sulci.

Intraoperatively, the electrodes were initially placed using free arm optical navigation (Varioguide, Brainlab, Munich, Germany) and frame (CRW, Integra, Princeton, NJ) followed by Robot (ROSA ONE®, Zimmer Biomet, Warsaw, IN) when it became available at our institution in August 2018. All electrodes are secured with bolts and individually tested with intraoperative electrocorticography to ensure adequate interpretability. Bolts are dressed with xeroform, cotton gauze, and full head wrap. Patients are sent to the intensive care unit (ICU) for the first 12-24 hours and subsequently monitored in the Epilepsy Monitoring Unit. Patients remain on prophylactic antibiotics, while electrodes are in place. Head computerized tomography (CT) is obtained intraoperatively post-placement and immediately after the removal procedure.

The primary epileptologist reviews patient sEEG data daily during the inpatient stay. Once an adequate number of seizures have been captured to proceed with therapeutic decision making, functional mapping and seizure induction are done for appropriate patients.19,20 Cases are then presented again at the epilepsy surgery conference by the primary epileptologist and neurosurgeon with the surgical plan evaluated by the epilepsy group. Patients considered appropriate for surgical intervention are further counseled on risks and benefits for a given procedure prior to intervention.

After a therapeutic procedure, patients are seen in follow-up by neurosurgery at two and four weeks for postsurgical evaluation. The primary epileptologist will begin follow-up with the patient at two to four months post-op for an evaluation of the patient’s epilepsy and continue indefinitely with frequency based on patient need.

Data points collected were designed to assess surgical procedural, safety, and efficacy outcomes. Procedural and demographic data included age, gender, preoperative imaging diagnoses, number of electrodes placed, laterality of electrodes, stereotactic tool, and operative time. Efficacy data included frequency of progression to therapeutic procedure, therapeutic procedure type, and Engel outcomes for patients with at least one year of follow-up. For Engel outcomes, a subgroup was created for palliative procedures defined as procedures not expected to produce seizure freedom (ie, RNS, DBS, vagal nerve stimulation (VNS), and radiofrequency ablation/thermocoagulation (RFA)). This allows separate analysis of potentially curative and palliative procedures. Safety data included radiographic findings after both electrode placement and removal as well as clinically significant outcomes. Clinically significant outcomes included symptomatic hematoma, electrode fracture, infection, neurological deficit, failure to collect data sufficient for surgical decision making, and mortality.

Data were analyzed using descriptive statistics in Excel (Ver 16.40). Case length comparisons were done using Welch’s t-test with F test to compare variances in Prism (Ver 8.4.3). 95% confidence intervals were calculated for Engel outcomes and major complications using the Wilson-Brown method in Prism (Ver 8.4.3).

3  |  RESULTS

3.1  |  Pre-2016 case volume

In the time period from 2011 to 2015, there was a median of one (range 0-7) sEEG case and zero (range 0-5) simultaneous sEEG and grids cases performed per year. Grids alone were placed a median of one (range 0-7) sEEG case and zero (range 0-5) simultaneous sEEG and grids cases performed per year. Please see Figure 1 for case depth electrode placement volume increase from 2011 to 2019.

3.2  |  Demographics

One hundred and thirty-one patients were treated from 2016 to 2019 for a total of 152 sEEG procedures. Of the
131 patients, 68 (52%) patients were female. Sixty-five of 131 patients (50%) were nonlesional. Lesional cases included 27 patients with mesial temporal sclerosis (MTS), of which 16/27 had dual pathology. Furthermore, imaging diagnoses are detailed in Table 1. Twenty-one patients had more than one sEEG implantation within the time period; 15 underwent additional electrode placement during the same hospital stay, while 6 underwent separate reimplantation. Average age was 39 years (range 19-69).

### 3.3 Procedural data

Average number of electrodes per patient were 10.5 (range 1-21) for a total of 1603 electrodes placed. Electrodes were placed bilaterally in 89 procedures, right side only in 31 procedures, and left side only in 32 procedures. Seven patients underwent placement of grids or strips at the same time as placement of depth electrodes. Three stereotactic strategies were used in this series: frame (91), robot (58), and free arm (3). Average length of implantation was 10.4 days (range 3-26 days).

### 3.4 Operative time

Average time from incision to closure for all cases was 186 min (range 23-467 min) with an average per electrode time of 20 min (range 5-138 min). When comparing stereotactic methods, the incision to closure time was longer for the frame (219 min, range 23-467 min) as compared to the robot (136 min, range 64-276 min) ($P<.0001$) with an average per electrode time of 24 min (range 5-111 min) and 11 min (range 6-30 min) ($P<0.0001$) for frame vs robot, respectively (Figure 2).

### 3.5 Results of investigation

One hundred and ten patients (84%) underwent a total of 124 therapeutic procedures defined as being performed with the intent to cure or palliate seizure burden. Twenty-five patients, whose initial sEEG plan did not provide adequate data to proceed with therapeutic intervention, underwent 27 procedures for further investigation (Figure 3). After initial investigation, 15 underwent additional electrode implantation during the same hospital stay (Phase IIB), seven underwent reimplantation at a later date (two following a definitive procedure), and three underwent subdural grid electrode implantation. Two patients required reinvestigation after phase IIB (1 subdural grid and 1 sEEG). Of these repeat procedures, 21 sEEG cases fell within the study window and were included in safety and efficacy analysis. Of the 15 phase IIB patients, 14 patients have undergone a definitive procedure, while one patient is being scheduled for a definitive procedure. Six of seven reimplantation patients and three of four grid investigation patients ultimately underwent a therapeutic procedure.

### 3.6 Engel outcomes

Of the 110 patients who underwent a therapeutic procedure, 42 patients had at least one year of follow-up (average 24 months; range 12-46 months). Thirty patients underwent procedures meant to be curative, while the remaining 12 had palliative surgeries. Including all therapeutic
procedures, 22 (52.4%; 95% CI (37.7-66.6)) patients were Engel I, 12 (28.6%; 95% CI (17.2-43.6)) were Engel II, 5 (11.9%; 95% CI (5.2-25.0)) were Engel III, and 3 (7.1%; 95% CI (2.5-19.0)) were Engel IV. When examining the 30 patients undergoing curative procedures with one year of follow-up (average 25 months; range 12-46 months), 19 (63.3%; 95% CI (45.5-78.1)) patients were Engel I, 7 (23.3%; 95% CI (11.8-40.9)) were Engel II, 3 (10.0%; 95% CI (3.5-25.6)) were Engel III, and 1 (3.3%; 95% CI (2.5-19.0)) was Engel IV (Figure 4).

### 3.7 sEEG-related imaging abnormalities

Imaging abnormalities included findings of blood, pneumocephalus, or fluid collections regardless of clinical significance. CT imaging is done immediately after 152 implantations revealed 29 (19.1%) with pneumocephalus, six (3.9%) with subdural hematomas (SDH), and one (0.7%) with intraparenchymal hemorrhage (IPH). Five of the SDHs were clinically insignificant while one required surgical evacuation. The IPH was clinically significant and resulted in permanent neurologic deficit.

The 15 patients who underwent Phase IIB surgeries only underwent a single removal procedure; therefore, of the 152 implantations, there were only 137 electrode removal procedures. CT performed immediately after electrode removal demonstrated 60 (43.8%) with tract pneumocephalus, 46 (33.6%) with blood along electrode tracts (tractoma), five (3.6%) patients with edema, five (3.6%) patients with SDH, and seven (5.1%) patients with other intracranial blood. All five SDH were present on the post-placement scan, while the seven with other intracranial blood were de novo on post-removal scan. None of these findings were clinically significant. Three (2.2%) patients were noted to have retained electrodes on follow-up CT.

### 3.8 Clinical complications

The complication rate for clinically significant events (two hemorrhages, three retained electrodes, one status epilepticus, and one complication causing inability to complete analysis) were 3.94% (95% CI 1.82%-8.34%) per procedure and 0.37% (95% CI 0.17%-0.81%) per electrode. All retained electrodes were removed without clinical effect: One was removed with enlargement of the burr hole during the electrode removal procedure. The other two patients had the retained electrode removed at the time of therapeutic procedure on 111 and 145 days post-implantation without complication. For hemorrhagic events (1 SDH and 1 IPH), the rate was 1.36% (95% CI 0.23%-4.67%) per procedure and 0.13% (95% CI 0.02%-0.45%) per electrode. There was a single complication with permanent deficit, ongoing contralateral hemiparesis after IPH, for a rate of 0.66% (95% CI 0.04%-3.6%) per procedure and 0.06% (95% CI 0.003%-0.35%) per electrode.

### 4 DISCUSSION

The safety and efficacy of sEEG has been demonstrated initially by European centers, which was followed by Canadian and then major US epilepsy centers in prior publications. Despite those positive studies and the need for tertiary epilepsy care expansion including invasive monitoring, sEEG adoption in the United States remains slow. The most recent data from Abou-Al-Shaar demonstrated growth using a data set from Centers for Medicare and Medicaid Services (CMS) Part B. This demonstrated an overall increase in the proportion of sEEG cases from 2010 to 2016; however, SDE procedures continued to outnumber sEEG. Thus, slow sEEG adoption may be related to generalizability concerns despite the safety and efficacy profiles demonstrated by larger and more established high-volume centers. Furthermore, Englot et al. reported outcomes data from the National Inpatient Sample database, which questioned the role of low or mid-volume centers (<5 or 5-15 lobectomies per year, respectively) due to increased adverse events after lobectomy. Prior to 2016, our institution had a median of one (range 0-12) intracranial investigation using depth electrodes correlating with seven (range 4-19) resective procedures per
Based on National Association of Epilepsy Centers (NAEC) data, this volume is consistent with the majority of levels 3 and 4 epilepsy centers in 2019 where roughly two-thirds of centers perform 10 or less resective procedures per year. From 2016 to 2019, our group averaged 38 (range 18-56) depth electrode placement procedures per year, which resulted in 110 therapeutic procedures. Given this growth, we sought to demonstrate a similar safety and efficacy profile as seen in prior publications at a center that grew from a surgical volume representative of the majority of NAEC level 3 and 4 centers, which can be part of the strategy for increasing epilepsy surgery usage.

The safety comparisons of sEEG vs SDE in the literature demonstrate a mildly increased safety profile for sEEG. Specifically, when comparing systematic reviews of sEEG and subdural grids, sEEG has lower rates of infection, hemorrhage, and neurologic deficit while mortality rate was slightly higher for sEEG. A systematic review comparing sEEG and SDE by Yan et al. revealed SDE had significantly higher rates of overall complications including: SDH/EDH, infection, CSF leak, transient neurologic deficit, medical complications, and mortality. sEEG demonstrated higher rates of ICH; however, all-cause hemorrhage and permanent neurologic deficit were not significantly different. In a single institution comparison of SDE and sEEG, Schmidt et al. found significantly more abnormal imaging findings for SDE. While clinically significant complications were lower for sEEG, the finding was not significant. The data presented in this article continue to demonstrate low rates of clinically significant complications.

**FIGURE 3** Procedures from sEEG. Demonstrating the procedures performed subsequent to sEEG monitoring. To add detail, neocortical resections (seven frontal, four parietal, two temporal, two insular, and two occipital), LITT (12 hippocampal/amygdala ablations, two amygdala remnant, two parietal, two occipital, one frontal, one insular), and other (one encephalocele repair, one meningioma removal, one callosotomy). DBS ATN, Deep Brain Stimulation to the Anterior Thalamic Nucleus; IIB, additional electrodes placed during the same hospitalization; LITT, Laser interstitial thermal therapy; RNS, Responsive neurostimulation; VNS, Vagal Nerve Stimulation.
hematomas and permanent neurologic deficits, including no infections or mortality. Our data found all significant hematomas were evident on post-placement CT head, which is consistent with prior reports.\(^7\)\(^,\)\(^25\) The post-removal CT data reflect that while common, tractomas and pneumocephalus are not clinically significant. Post-placement pneumocephalus and post-electrode removal CT abnormalities have not been reported previously in the literature. In sum, though both techniques generally have low complication rates, the literature and our experience support a safe sEEG profile (please see Table 2 for detail).

Robotic technology has been increasingly utilized for sEEG due to its efficiency in the OR. Kim et al. compared targeting with a free arm (Vertek\(^8\), Medtronic, Minneapolis, MN) vs Robot (ROSA ONE\(^8\), Brainlab, Munich, Germany). They found shorter operative time for robot as compared to free arm (126 min vs 173 min, \(P = 0.02\)), while finding no differences in ability to localize the seizure onset zone or seizure outcomes.\(^29\) Gonzalez-Martinez reported their experience using the robot (ROSA ONE\(^8\))\(^23\) in which they compared to their prior series using a frame-based approach.\(^10\) They found no accuracy difference with the benefit of markedly reduced operative times for the robot method (130 min vs 352 min, \(P < 0.001\)). In our series, the difference in operative times between techniques was not as drastic with 136 vs 218 min for robot and frame, respectively. It is also noteworthy that 70 of the first 72 cases of our expansion were completed using the CRW frame. We report one clinically significant hematoma with each modality, the IPH with the frame and the SDH with the robot. This is in contrast to Cardinale et al. who had no significant hemorrhagic complications after transitioning to the robot-based protocol.\(^25\) Though the robot offers a significant advantage with regard to operative efficiency, the difference may not be as large as previously reported, with frame-based stereotaxis offering an effective option for centers wishing to start or expand an sEEG program.

Neuromodulatory technologies such as RNS and DBS to the anterior nucleus of the thalamus (ATN) represent expanded options in the post-investigation treatment algorithm for surgical epilepsy.\(^14\)\(^,\)\(^15\) In some instances, our institution also performs radiofrequency ablations as a palliative treatment to disrupt seizure networks in patients who have been localized and are deemed not appropriate for resection. Prior large series report only resective surgeries following sEEG, likely due to the limited availability of neuromodulatory therapies at those times. The Cleveland Clinic group has three separate publications with rates of sEEG progressing to surgery ranging from 67% to 81%.\(^10\),\(^21\),\(^23\) McGonical reported a series of lesional cases that demonstrated resective surgery rate of 80% in 100 patients.\(^30\) A pediatric series from Taussig shows resection rate of 78% after sEEG. Our series of sEEG investigations reports 110 of 131 (84%) patients had undergone some form of intervention. If including 8 planned interventions, our intervention rate will be 90%. Our increased rate of intervention is attributed to the availability of new technologies in situations where a complete seizure focus

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**TABLE 2** Demonstrating key publications regarding the safety of sEEG

|                | SDE | sEEG |
|----------------|-----|------|
|                | Infection | Hemorrhage | Neuro Deficit | Mortality | Infection | Hemorrhage | Neuro Deficit | Mortality |
| Arya (2013)    | 2.3%  | 4.0%  | 4.6%  | 0.2%       | -         | -         | -           | -         |
| Mullin (2016)  | -    | -    | -    | -          | -         | 0.8%      | 1.0%        | 0.6%      | 0.3%      |
| Schmidt (2016) | 4.7%  | 1.9%  | -    | 0%         | 3.8%      | 0.6%      | -           | -         |
| Yan (2019)     | 1.6%  | 4.8%  | 5.7%\(^a\) | 0.4%      | 0.9%      | 3.0%      | 1.9%\(^a\)  | 0.2%      |
| Cardinale (2019)| -    | -    | -    | -          | 0.1%      | 0.7%      | 0.4%        | 0.1%      |
| Miller (2020)  | -    | -    | -    | -          | 0%        | 1.32%     | 0.66%       | 0%        |

Abbreviations: SDE, Subdural Electrodes; sEEG, Stereo-electroencephalography.

\(^a\) Transient neurodeficits.

\(^b\) 2/317 procedures resulted in permanent neuro deficit, however, unclear if related to SDE or sEEG.
resection is not possible (eg, eloquent focus, bilateral hippocampus, or multifocal onset). At our institution, sEEG is additionally used to optimize therapy selection through localization of eloquent areas or confirmation of multifocal onset. Though these interventions are less likely to result in seizure freedom, they do allow for meaningful improvement in seizure control, which can improve quality of life. Thus, expanding treatment options increases the pool of patients who can be considered for invasive seizure evaluation, as it provides the possibility of finding a resectable seizure focus, with neuromodulatory options available for those without a resectable focus such as multifocal or eloquent seizure foci.

4.1 | Limitations

Our series demonstrates safety and efficacy in a large number of patients. These study data are limited by a retrospective data collection. Additionally, since our institution does not have a significant number of SDE implantations, there is no opportunity for direct comparison. The data set includes patients who underwent sEEG from January 2016 to December 2019. In turn, Engel outcomes were taken only for patients with one year of follow-up to ensure adequate time for seizure outcomes. This significantly lowered the number of patients included for analysis of Engel outcomes. Review of these outcomes should be done at more delayed time points to determine durability of outcomes. Finally, our results demonstrate the experience at an institution with fellowship-trained epileptologists and functional neurosurgeons and thus limit the generalizability of the results.

5 | CONCLUSION

Addressing the unmet needs of drug-resistant epilepsy patients remains a complicated problem. The increased utilization of sEEG by new or expanding epilepsy centers represents one opportunity to move closer to the goal of “no seizures, no side effects, as soon as possible.” Although sEEG in the United States is increasing in utilization, it still has not reached levels noted in Europe and Canada, despite long-standing safety data and perhaps more importantly, new data showing improved Engel outcomes. Our sEEG experience demonstrates an increased intervention rate and similar safety profile compared to previously reported data. Our group found the frame an effective sEEG implantation method, while the robot did provide intraoperative efficiency gains once utilized. In sum, these data demonstrate success with sEEG for rapid growth of a surgical epilepsy program with multidisciplinary evaluation that offers generalizability to tertiary epilepsy centers interested in expansion.

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CONFLICTS OF INTEREST

Author Patrick X Landazuri has received payment for consulting services with Monteris Medical.

ETHICAL APPROVAL

We confirm that we have read the Journal’s position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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