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Surgical Neurology International

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SNI: Epilepsy

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Original Article

Early case series with placement of NeuroOne Evo stereoelectroencephalography depth electrodes and review of other Food and Drug Administration-approved products

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Received: 10 April 2024
Accepted: 15 November 2024
Published: 06 December 2024

DOI
10.25259/SNI_277_2024

Video available on:
https://doi.org/10.25259/SNI_277_2024

Quick Response Code:

ABSTRACT

Background: Stereoelectroencephalography (SEEG) is a common diagnostic surgical procedure for patients with medically refractory epilepsy. We aimed to describe our initial experience with the recently released NeuroOne Evo SEEG electrode product (Zimmer Biomet, Warsaw, IN) and review technical specifications for other currently approved depth SEEG electrodes.

Methods: We performed a record review on the first five patients implanted with NeuroOne Evo SEEG electrode product using the robotic stereotactic assistance robot platform and described our surgical technique in detail. We recorded technical specifications of all currently Food and Drug Administration-approved SEEG electrodes for comparison.

Results: Our initial 5 surgical patients were reviewed. The average total time of operation was 92 min, with an average of 16.8 electrodes. The estimated time per electrode insertion was <2 min. There were no intracranial hemorrhages or hardware complications noted during monitoring. Monitoring provided diagnostic information in all patients, and removal and incision healing proceeded without issues.

Conclusion: NeuroOne SEEG electrodes can be implanted with efficiency and provide a valuable additional tool for the epilepsy surgeon. A tapered drill bit prevents the bolt from being placed beyond the inner cortex and may reduce the risk of brain contusion or inadvertent advancement of anchor bolts, and the electrode internal stylet also affords the potential to reduce the number of trajectory passes.

MeSH Terms: Epilepsy, EEG, Drug-resistant Epilepsy, Intracranial EEG
Keywords: AdTech, DiXi, NeuroOne, Positron emission tomography (PMT), Stereoelectroencephalography

INTRODUCTION

Stereoelectroencephalography (SEEG) is a widely utilized technique in invasive monitoring for medically refractory epilepsy when less invasive techniques are unable to distinguish potential epileptogenic areas effectively. In this procedure, multiple electrodes are surgically implanted into the brain using one of several targeting methods. Stereotactic head frames and surgical robots are common tools used for insertion. Robotic insertion has been shown to lower average

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operative time and perhaps improve accuracy.[3,5,6,9,11] The procedure is generally considered to have a low complication rate, with hemorrhage being the most common adverse event at 1–3%.[1,2,6,10] Electrode design and placement techniques have been relatively unchanged to date, and most electrode manufacturers recommend similar steps for the placement of each electrode. These include accessing the cranial vault, placement of a fixed skull bolt, opening of the dura, creation of a tract for the electrode to traverse, and placement of the electrode, which is subsequently fixed to the skull bolt.

Currently, Food and Drug Administration-approved SEEG electrode products include those from AdTech (Oak Creek, WI), PMT (Chanhassen, MN), DiXI (Chaudefontaine, France), and NeuroOne (Zimmer Biomet, Warsaw, IN, USA) companies. NeuroOne is the most recently approved of these, and little has been published about this electrode system to date.[4]

SEEG is becoming a more and more prevalent method of intracranial monitoring when advanced diagnostics are required to localize a patient's epilepsy. Due to the minimally invasive nature of SEEG, our center frequently employs this technique in refractory epilepsy that scalp electroencephalography (EEG) is unable to categorize confidently. The NeuroOne electrode design provides for reduced steps during implantation and makes the process of implantation more efficient. The authors report our initial experience and the technical specifications of the NeuroOne electrodes, with the goal of making the reader aware of new devices in epilepsy surgery, which could enhance safety and reduce steps involved in the implantation process.

MATERIALS AND METHODS

We performed a case series review of our first five consecutive patients with Zimmer NeuroOne EVO SEEG electrodes inserted at the University of California, Irvine Douglas, over approximately 6 months in 2023. The clinical, radiographic, and surgical history of each epilepsy patient was reviewed retrospectively through medical record review [Table 1]. No identifiable information was maintained for our report. The total operative time recorded was based on nursing operative documentation. The senior surgeon (Author SV) performed all procedures. Technical specifications of currently approved electrode products are listed in Table 2. Images of NeuroOne electrode insertion equipment are displayed in Figure 1. To be selected for SEEG implantation, each patient care plan was agreed upon at a multidisciplinary care conference. SEEG was performed to clarify the localization of epilepsy when focal epilepsy was suspected but not diagnosed with noninvasive methods, when bilateral epileptiform activity was suspected, and in other instances.

Surgical and medical device photographs were collected without any identifying features or patient identifiers, and, as is standard practice at our institution, each patient has consented before surgery to the possibility of publishing any photographs or videos obtained in connection with their clinical and surgical information in a de-identified fashion. This study was performed in line with the principles of the Declaration of Helsinki. Local Institutional Review Board Approval was granted before study initiation. This case series has been reported in line with the PROCESS guideline.

Figure 1: Various equipment components used with NeuroOne stereoelectroencephalography electrodes.

Surgical procedure

1. Procedures were performed under general endotracheal anesthesia. After preprocedural time-out and clipping of hair, the head was fixed into place with a Leksell stereotactic frame (Elekta Solutions, Sweden) or Mayfield skull clamp system (Integra Neurosciences, Plainsboro, NJ) and then attached to the robotic stereotactic assistance (ROSA) robot (Zimmer Biomet, Warsaw, IN, USA). Facial registration was performed using the built-in robotic software and laser capabilities, utilizing both preoperative computed tomography (CT) and double-contrast magnetic resonance imaging. This registration process takes between 20 and 40 min. Once the robot is calibrated, the patient is prepped and draped. Electrode trajectories were preplanned and loaded onto the robot.
2. Variable-length NeuroOne electrodes were inserted with ROSA assistance through previously planned trajectories as described in the following text. Systolic arterial pressure was maintained below 130 mmHg for the duration of electrode insertion time. Antiplatelets and anticoagulants were held for multiple days before each procedure.
3. Drilling into the skull was accomplished with a 2.1 mm tapered drill bit aimed through a robotic attachment piece along the trajectory for each electrode. The width of the bone at each entry point was measured on preoperative images, and the robotic attachment for drill guidance was used as a safety stop and positioned 3–5 mm beyond the anticipated bone width. With each increase in the depth of drilling, the surgeon would move the robot drill guide several millimeters along the trajectory and then advance the drill. In doing so, the surgeon was able to maintain manual feedback upon drilling through the inner table of the calvarium and perform one final 1–2 mm advancement of the drill guide (and subsequently, drill bit) with the intent to perforate through the dura mater with the drill tip. These drilling steps are illustrated in our associated surgical

Table 1: Patient demographics from initial cases with NeuroOne electrode product.

Variable	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Age/Gender	41/Female	47/Female	42/Male	29/Female	23/Female
Epilepsy duration (years)	40	10	26	20	18
Semiology	Oral automatism, bilateral arm flexion/extension, generalized	Deja-vu. Staring, hand automatisms, then generalized convulsions	Dyspnea, facial flushing, generalized convulsions	Fear, staring spell, head version, clonic activity	Staring, hand and oral automatisms, generalized clonic motor
Scalp EEG	No clear lateralization	Bitemporal spikes	Bitemporal ED (L>R)	L frontocentral spikes, fast activity	L temporal seizure
Imaging	L MTS, PET-negative	L MTS, PET-positive	MRI negative	L frontal surgical cavity and cystic change	MRI negative
Surgical history	VNS 4 years prior	None	None	L frontal resection (>10 years prior). Corpus callosotomy 18 months prior)	None
SEEG locations	Bi-frontotemporal, including orbitofrontal, cingulate, and premotor/motor	Bi-frontotemporal, including orbitofrontal, cingulate, and premotor/motor	Bi-frontotemporal, including orbitofrontal, cingulate, and premotor/motor, operculum	Left frontal, temporal, opercular, cingulate, around surgical cavity	Left frontal, temporal, opercular, cingulate
Number of electrodes (R: L)	10:10	10:10	10:10	0:14	0:10
Total operative time (min)	82	84	119	93	83
Monitoring duration (days)	3	3	5	2	2

ED: Epileptiform discharges, MRI: Magnetic resonance imaging, MTS: Mesial temporal sclerosis, PET: Positron emission tomography, VNS: Vagal nerve stimulator, SEEG: Stereoelectroencephalography, EEG: Electroencephalography

Table 2: Comparison data from each currently FDA-approved SEEG depth electrode product.

Variable	AdTech	DiXi	PMT	NeuroOne EVO
Diameter (mm)	0.86–1.96	0.8	0.8	0.8
Contact size (mm)	1.27 or 2.41	2	2	2
Intercontact spacing (mm)	3–3.73	1.5	1.5	1.5–3.2
Depth and Grids?	Yes	Yes	Yes	Yes
# of contacts	4–16	5–18	8–16	5–16
Internal stylet	Yes	Yes	Optional	Yes
Outer coating material	Polyurethane with barium	Iridium polyimide	Silicone	Polyimide
Connection cables	Single-use. Sterile	Re-usable. Nonsterile	Re-usable. Sterile.	Single-use. Sterile

FDA: Food and Drug Administration, SEEG: Stereoelectroencephalography, PMT: Positron emission tomography, DiXi: Dixi Medical, USA, PMT: PMT Medical Corporation, Chanhassen, MN

video [Video 1]. Unlike the design of other drill bits, the NeuroOne drill provides a tapered tip which prevents the bolt from being placed too deep within the skull and also reduces the risk of causing intracranial injury.

4. An alternative to using the drill tip to perforate the dura is to use a separate probe with a tapered sharp endpoint combined with a cautery device to open the dura. With this method, the surgeon can also palpate the dura and use monopolar electrocautery periodically to transmit electricity through the palpation probe and create a small opening within the dura.
5. Varying length bolts (20–35 mm) were placed into the predrilled hole based on the measured soft-tissue thickness at each location. Once into the bone, approximately 5 turns

were performed to anchor each bolt.

6. After dural perforation, each electrode was inserted. No preinserting stylet pass was used, as the NeuroOne Evo SEEG electrode has an incorporated internal stylet, which provides adequate rigidity for placement. Electrodes were planned and placed with an orthogonal trajectory whenever possible.
7. Each electrode was anchored to a metal bolt fixated in the skull by tightening the electrode cap until finger tight.
8. Each electrode had between 10 and 16 contacts. After insertion, electrodes were labeled, and sterile bandages were dressed along each exit site. Postoperative X-rays were obtained before leaving the operating room (OR) [Figure 2]. After each surgery, a fine-cut, noncontrast head CT was obtained to record electrode position and rule out obvious hemorrhage. Inpatient monitoring was performed in a specialized unit for EEG patients.

RESULTS

Our initial five cases with NeuroOne EVO electrodes proceeded without any apparent technical issues. It is reasonable to expect an average time of <2 min per electrode insertion with this system. We did not have any intracranial hemorrhage on immediate postoperative CT scans. Monitoring yielded diagnostic information in all patients, and there were no apparent hardware complications. Surgical removal of the electrode and anchor bolt systems after monitoring proceeded without any complications, and incisions (closed with staples) were well healed at 2-week follow-up appointments for each patient.

DISCUSSION

There are several small alterations to surgical techniques utilized in our series that make electrode insertion more efficient. The use of a robot to aid in the efficiency and accuracy of electrode insertion has been documented previously.[3,5,6,11] Our technique to use the drill-guide attachment on the robot arm as a drill safety stop reduces time with each burr hole and reduces the inadvertent advancement of the drill. The tapered design of the NeuroOne drill bit is uniquely designed to prevent the anchor bolt and the drill from extending into the cranial vault or excessively deep placement of the anchor bolt. This appears to be a useful safety feature during drill use for both experienced surgeons and those in training. In our institutional-specific practice, we utilize the ROSA robot drill attachment as a safety stop for the drill. With the separate attachable safety stop, the surgeon must use a flathead screwdriver to adjust the safety stop on the drill bit; each time, more length of the drill bit needs to be exposed. Using the robot drill-guide attachment, the surgeon can easily move the drill guide several millimeters further along the robotic trajectory each time the drill needs to be advanced, and with less chance of the safety-stop unintentionally moving. A final nuance with the potential to reduce operative time is the absence of a preelectrode pass through the brain with a stylet to create a tract for the electrode to traverse. The NeuroOne electrodes have a built-in stylet that provides significant rigidity to obviate the need for the creation of a tract. Once the dura has been perforated adequately, the risk of errant placement of electrodes is significantly reduced.

Other benefits of a built-in stylet model are the lack of need for a separate stylet, which adds cost to the procedure, and the avoidance of potential deformation or bending of a stylet with repeated use. A disposable stylet can be opened for each case should the surgeon desire to create an additional trajectory pass before inserting the SEEG electrode. As we accumulate experience with NeuroOne electrode insertion, we anticipate that high accuracy of placement will eliminate the need for utilizing this (or multiple) additional stylets and perhaps reduce cost.

Another potential benefit of not using a separate stylet is a reduced rate of intracranial hemorrhage due to a reduced number of trajectory passes. Multiple authors cite a relationship between the number of electrode passes in deep brain stimulation and hemorrhage risk, and one could assume a similar correlation in SEEG.[12] The overall hemorrhage rate in SEEG has been quoted at 1–3% and is likely escalated with an increasing number of electrodes and frontal lobe location.[2,10] This reduced number of trajectory passes with an internal stylet may, of course, be offset as the total number of electrodes for each procedure increases. The most common

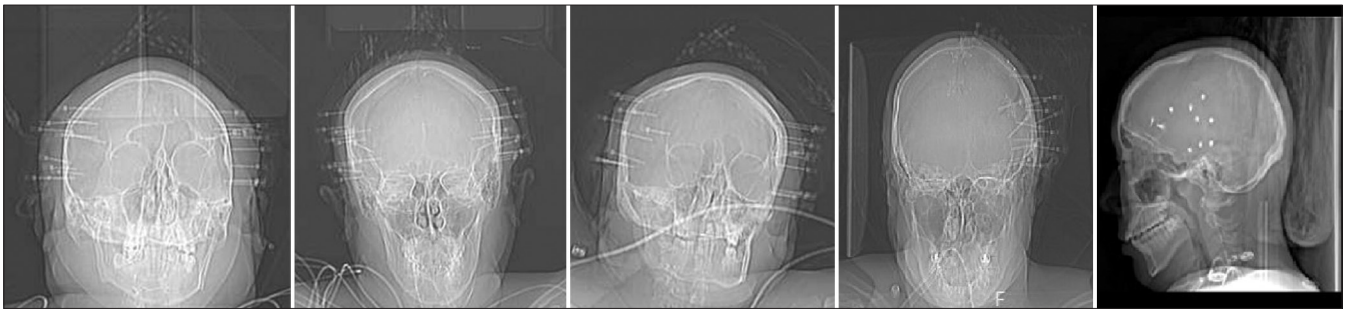

Figure 2: Postoperative X-rays on each patient after stereoelectroencephalography placement.

Video 1: Numbered steps for insertion of NeuroOne Evo Stereoelectroencephalography electrode. The video demonstrates the utilization of a robotic stereotactic assistance robot drill-guide as a depth-stop to increase the safety of drilling.

type of hemorrhage after SEEG is intraparenchymal, which would not be easily detected intraoperatively.[10] For the surgeon, electrode diameter is important when planning the site of brain entry and reducing the chance of surface vessel contact. NeuroOne has a relatively thin electrode profile, which may reduce the chance of a vascular collision in either circumstance. McGovern *et al*. demonstrated that hemorrhage risk in SEEG is related to the total number of electrodes, underlying the importance of establishing a focused monitoring hypothesis when possible.[8] They demonstrated a 2.2% symptomatic hemorrhage risk after SEEG but a 19.1% radiographic hemorrhage risk for all types of intracranial bleeding.[8] Worthy of mention is a very recent publication from Lee *et al*., which showed a larger radial error in trajectory targeting when using an internal-stylet technique as opposed to an external, manually measured stylet pass before inserting the final SEEG electrode with robotic assistance.[7] In addition to the internal-stylet method, greater trajectory entry angle and greater target depth were also correlated with greater targeting error.[7] It will be of great interest to see if we find similar results and acceptable accuracy in our future experience with NeuroOne electrodes and their internal stylet feature.

The thin profile of NeuroOne electrodes provides an additional technical specification that might reduce hemorrhage risk. With a diameter of 0.8 mm, NeuroOne has a slim profile [Table 2]. A range between 5 and 16 contacts, each 2 mm in length, allows for sufficient recording coverage. Contact spacing ranges from 1.5 to 3.2 mm for larger electrodes to offer more customized surface contact per brain region. In comparison, DIXI Medical, USA (DIXI) SEEG electrodes (Chaudefontaine, France) have a similar diameter (0.8 mm) and a semi-rigid structure intended to allow the surgeon to choose between utilizing a preelectrode stylet and using the electrode alone to create the trajectory. The stylet is listed as a single-use item. DIXI electrodes exhibit a fixed distance of 1.5 mm between all contacts, and a nonsterile attachment cable is typically used [Table 2]. PMT Medical Corporation, Chanhassen, MN (PMT) offers the surgeon an option of selecting an electrode with or without internal stylet on order, which is unique among the existing companies. In theory, PMT electrodes (without a stylet) may be the least rigid of existing products, which may predispose to trajectory deflection; the exact incidence of this is unknown. AdTech (Oak Creek, WI) SEEG electrodes have a wide range of contact sizes and diameters, some of which are available through special order. Some of the special-order electrodes have a diameter over twice as large as their competitors, leaving a bigger trajectory footprint and a need for careful preoperative planning to avoid vascular structures if these models are used. The ideal number of contacts will be different depending on the area of tissue monitored and the suspected epileptogenic and irritative zones. Connection cables for AdTech are typically advertised as a sterile, single-use product.

With a learning curve for insertion considered, it would be reasonable to infer small cost savings from the shortened duration of anesthesia if the surgeon fully realizes the potential surgical time benefits of the NeuroOne tapered drill and internal stylet.

Although this series is one of the earliest reports of NeuroOne SEEG electrodes, it includes a very limited number of patients. Due to an overall low complication rate with SEEG, a larger number of electrode insertions would be necessary to compare operative times, technical issues, or hardware complications between these and other electrode models. The same statement could be made about the diagnostic capabilities of this electrode versus other available designs. This text is intended to be a review of some technical specifications of this new SEEG product and not a lengthy review of the indications for SEEG. There are many similarities between currently approved electrode models. The lack of a separate stylet for NeuroOne electrode insertion may prompt the concern of electrode deviation; the risk of this event is unknown and would be elicited with a large volume of consecutive cases. Finally, as the variable of cost is influenced by many factors – insurance, availability, and hospital contractual agreements, it may be difficult to generalize trends.

CONCLUSION

Our initial experience with NeuroOnc SEEG products gives us positive expectations for continued use in epilepsy surgery. Their low profile, variability in contact spacing, and

semi-rigid internal stylet design suggest that they can be both versatile and efficient for the surgeon in terms of OR time and cost. There are multiple similarities in design between the existing electrode companies, which will make studying some differences challenging, whether this may be hardware complications, successful use in monitoring data, or risk of complications in a procedure with already low complication rates.

Acknowledgments

We would like to recognize all surgical device company representatives who have worked at UCI in their efforts to provide accurate information and assist with patient care.

Author contributions

NW: Conceptualization, data curation, formal analysis, writing of original draft, review, and editing; AH: Conceptualization, review, and editing; SV: Conceptualization, formal analysis, review and editing, supervision.

Ethical approval

The research/study was approved by the Institutional Review Board at the University of California Irvine, number 3656, dated 10/01/2023.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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How to cite this article: Winslow NK, Himstead AS, Vadera S. Early case series with placement of NeuroOne Evo stereoelectroencephalography depth electrodes and review of other Food and Drug Administration-approved products. Surg Neurol Int. 2024;15:454. doi: 10.25259/SNI_277_2024

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