



Bony encapsulation of a NeuroPace subdural electrode



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To the Editor

In 2013, NeuroPace, Inc., obtained approval from the U.S. Food and Drug Administration for a brain-responsive neurostimulation system, known as RNS, to treat medically refractory partial-onset seizures. Since then, brain-responsive neurostimulation has been used to treat a wide variety of epileptic foci originating in the mesial temporal lobe, insula, and other cortical areas [1–4].

In the NeuroPace primary clinical trial, adverse events noted over a 2-year post-implant period included infection, device damage or revision, increased seizure frequency, intracranial hemorrhage, and death. Lead damage was noted in 5 of the 191 subjects. Most damage occurred at the site at which the lead was secured at the burr hole (4 of the 5 subjects); however, one patient incurred damage to one lead as it was sheared between the skull and an anchoring titanium plate and (in the same patient) a second lead was inadvertently severed [4]. We describe here an additional complication of bony encapsulation of the NeuroPace lead.

Case report

History and examination

A 44-year-old woman with a history of focal right-sided seizures with secondary generalization underwent placement of a NeuroPace device with two strip electrodes. On the basis of prior seizure monitoring including the use of both stereotactic depth electrodes and subdural electrode grid placement, one electrode strip was placed over the right sensorimotor cortex corresponding to the grid leads maximally involved in ictal onset. The second electrode strip was placed at the level of the right middle temporal gyrus as this was an area of significant interictal activity that was thought to be in the epileptogenic zone. Continuous electrocorticography (ECoG) monitoring over the ensuing 2 years revealed that the ictal onset zone involved the frontal strip only and no seizures originated from the temporal leads. RNS ECoG review also revealed the ictal onset EEG pattern in the frontal strip likely represented the lagging edge of the ictal onset zone, which involved a region more lateral and inferior. This correlated with the original diagnostic subdural grid. Despite this, the patient experienced a significant reduction

in her focal seizures as reported in her seizure diary. This led to the decision to place a second strip along the inferior and lateral edge of the frontal ictal onset zone when it was time for battery replacement and to use strip-to-strip stimulation to modulate a larger region. The temporal strip was to be disconnected. This revision surgery was planned for when the RNS pulse generator was at the end of its life span and required replacement. This was approximately 25 months after initial Neuropace implantation.

Surgery

The patient's prior craniotomy incision was opened to reveal the RNS pulse generator. As the prior frontotemporal craniotomy was opened, resistance was noted upon lifting the bone flap. Further inspection showed that the temporal electrode had become encased in bone as it neared the ferrule (Fig. 1A). By using a curette, the lead was freed from bony encasement and allowed to rest atop the dura. Visual inspection of the lead did not find obvious damage, nor did subsequent impedance checks via the RNS system.

Next, a dural incision approximately 1 cm inferior to the frontal lead was made, and a third strip electrode was inserted. Its position was confirmed with intraoperative fluoroscopy. The dura was reapproximated and the bone flap was secured. The NeuroPace ferrule and new generator were positioned and secured, and the electrode leads were coiled away from the incision. The galea and superficial tissues were closed. A stereotactic noncontrast head computed tomography (CT) scan with 0.6-mm slices and scout film (Fig. 1B) were obtained to confirm appropriate electrode positioning.

Discussion

Calvarial bone growth is not uncommon, although it is normally associated with specific diseases such as en plaque meningioma, Van Buchem disease, Paget disease, hyperostosis frontalis, or fibrous dysplasia [5–10]. In the current case, it is unclear whether the electrode entrapment represents true bony remodeling or bone erosion by the electrode. To date, bony encapsulation of a lead involving the inner cortex of the craniotomy flap is an undocumented complication of NeuroPace lead implantation. This unexpected outcome makes any revision of the system that requires removal of the craniotomy flap more precarious as it stands to be a possible point of lead damage if not recognized early. Additionally, it is unknown whether any forewarning of this complication is visible on standard medical imaging as many patients do not get serial imaging beyond the immediate postoperative period after initial implantation. Therefore, preoperative CT may be warranted

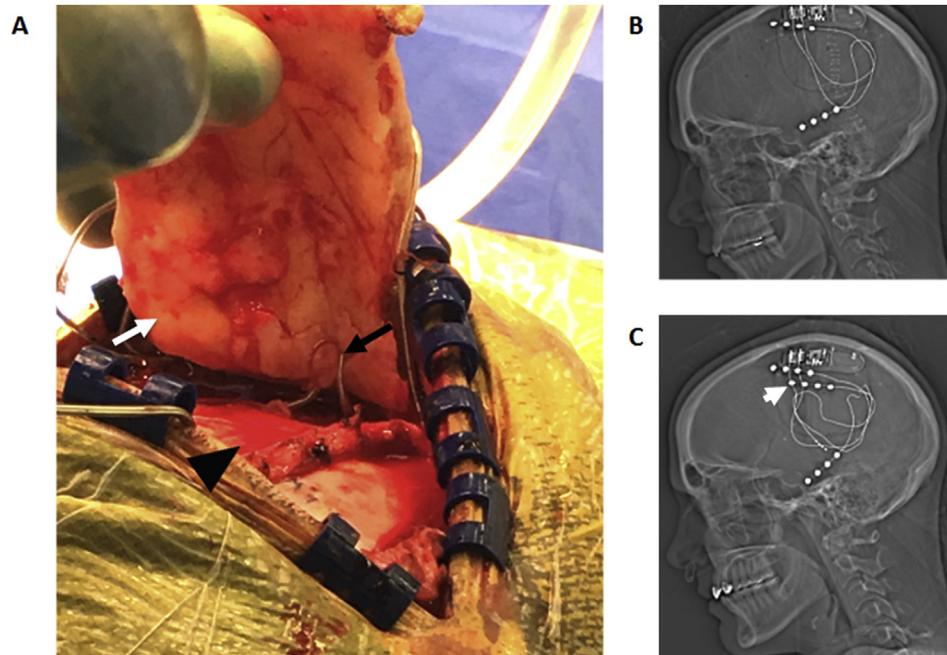


Fig. 1. **A.** Intraoperative photo of the temporal electrode lead encased in bone. The lead was noted to exit the dura (black arrow head) and travel a short distance before becoming encased in bone (black arrow) within the craniotomy flap (white arrow). It then exited the bone and continued to the lead–stimulator junction. **B.** Scout film from the postoperative CT scan after initial NeuroPace implantation showing the original electrode configuration. **C.** Scout film from the postoperative CT scan showing the location of the new 4-contact strip electrode (white arrow).

in an attempt to observe such encapsulations in revision surgeries where the craniotomy flap will be removed.

The RNS system is a proven therapy for epilepsy, with a median reduction in seizure frequency of >50% at 2 years [3,4] and 66% at 6 years [3]. Because the device continuously records electrocorticographic activity, the RNS system allows the treating team to learn more about the patient as time goes on. This continuous stream of new information may sometimes prompt the placement of additional subdural electrodes; however, reopening dura in such cases can be difficult given prior scarring. Furthermore, the current case shows that encapsulation of the wires may occur in the epidural space. We therefore recommend several preemptive steps. First, if there is uncertainty regarding the optimal placement of strip electrodes, multiple electrodes should be placed during the initial operation when feasible, reserving the unconnected electrodes for future use should they be necessary. Second, the distance the electrode wires run between the dura and skull should be minimized. Finally, if the bone flap is to be removed, caution should be taken to ensure the leads separate easily from the skull to avoid electrode damage.

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Disclosure of interest

The authors report no conflicts of interest.

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