Combined Strain Relief Loop Failure and Lead Stiffness as a Cause of Lead Retraction In the St. Jude Infinity System: A Technical Note

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Figure 1

Guardian DBS Locking Device

Introduction

Deep brain stimulation efficacy and longevity is intimately related to accurate location of the brain electrode. Lead retraction over time has been noted in a subset of DBS patients(**1**). The mechanisms of upward lead migration are poorly understood. The St. Jude Guardian commercial locking device (**Figure 1**) is designed to withstand acute tension of up to ~0.5 pounds. The pressure limit of this commercial locking device is low compared to average human strength during routine movement. As such, a strain relief loop is crafted around each burr hole to act as a safety net in the event distal tension is applied to the brain lead after closure. The performance of the strain relief loop is dependent on its conceptual ability to tighten and loosen (e.g.-alter its radius) as needed in response to distally applied tension. However if a strain relief loop is enveloped by significant scar and cannot uncoil, then that force will be transmitted along the lead itself to the proximal tip, or to a point of least resistance. In the case of DBS, this is the area at which the proximal brain lead enters the commercial locking device. Lead composition may also play a role in the amount of tension transmitted to the locking device exit point—Stiffer leads will transmit more tension to the proximal lead exit point while elastic leads will transmit less tension due to elongation in response to applied tension. Failure of the strain relief loop due to scarring combined with the increased lead stiffness of the St. Jude Infinity System may be one possible mechanism of lead retraction after movement near the connection point between lead and the lead extender.

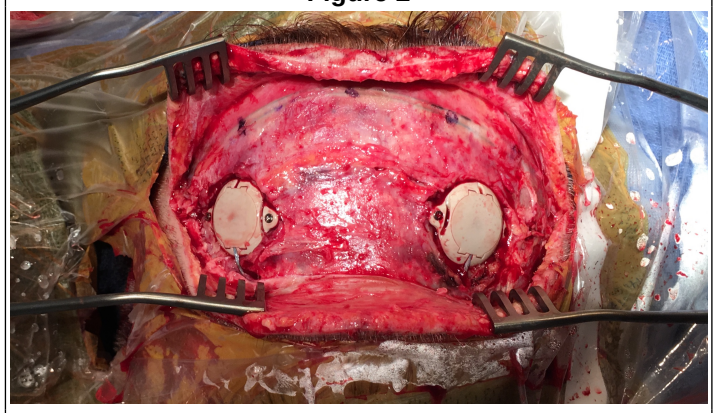
Methods

A case report of simultaneous lead migration, and subsequent lead revision, is presented in a Parkinson's patient treated with bilateral STN DBS using the St. Jude Infinity System.

Results

71M underwent bilateral DBS STN lead placement using interventional MRI(**2**). Immediate postoperative scans demonstrated leads in excellent position. Two weeks later, patient underwent routine dissection of the distal leads with connection to lead extenders/generator. No excessive manipulation occurred. Postoperative head CT demonstrated ~8 mm retraction of the lead tips. X-ray showed no change in the shape/radius of the strain relief loop for leads. DBS leads were revised. Severe scar had encased the extra-cranial brain leads (**Figure 2**). Lead retraction was confirmed by examining a black mark on each lead made at the original surgery immediately above the burrhole exit; at revision, these marks were several millimeters beyond the edge of the locking device rim despite intact locking devices.

Figure 2



Retracted leads encased in pericranium

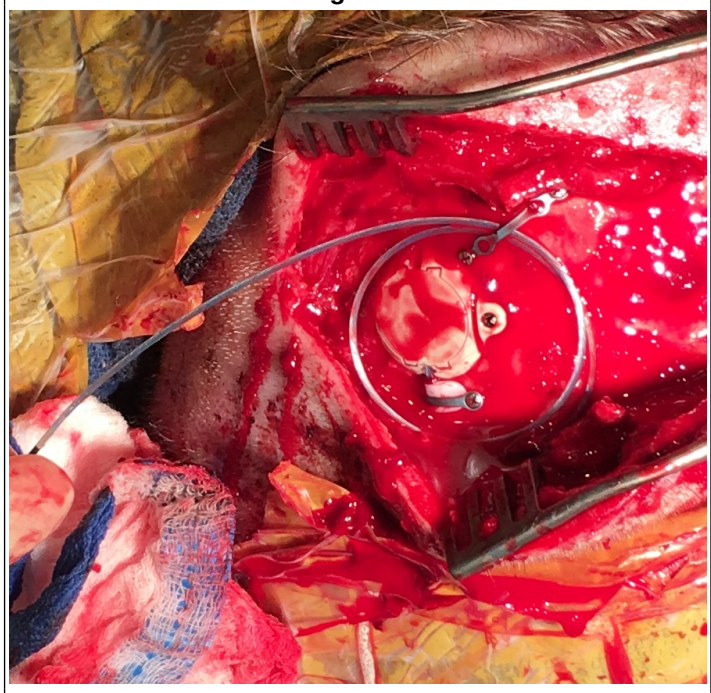
Technical Note

New St. Jude Infinity 0.5 mm spaced brain leads were placed successfully into the bilateral STN using the Clearpoint stereotactic system in the interventional MRI suite using the following improved technique (**Figure 3**): The Guardian locking devices are initially used to secure the brain leads. 10 mm from the exit point on the Guardian rim, a small plastic tab, to minimize erosion into the bone, was placed around each lead followed by placement of a 12mm flat microplate for additional security. A strain relief loop is then created around each burr hole. A break point for the loop is created using a curved second microplate or the Guardian groove. However the prefabricated strain-relief groove can become difficult to use if the Guardian flexes with the curve of the skull.

Conclusions

Scar formation may occur around strain relief loops following DBS lead placement. Envelopment of leads by pericranium may prevent loops from tightening with distal pressure during surgical manipulation or patient movement, which may transmit any distal pressure directly to the locking device exit point. The St. Jude Infinity lead is stiffer than the Medtronic lead to reduce its likelihood of in vivo damage; this reduced elasticity may make it more prone to movement from mild connector site manipulation. Technical adaptations can mitigate this risk.

Figure 3



Technical adaptations to promote lead accuracy over time

References

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