

Technical Report

 **Cephalad Lead Migration Following Spinal Cord Stimulation Implantation**

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Lead migration (LM) is the most common complication after spinal cord stimulation (SCS). Although multiple reports of caudad LM have been described, cephalad LM has not been reported. Here we describe a case in which a stimulator lead migrates in the cephalad direction. A 60-year-old male with failed back surgery syndrome underwent SCS lead implantation via a dual lead approach to the top of vertebral body (VB) T9. A standard strain relief loop was used for each lead in the paramedian pocket. Postoperative testing revealed 100% paresthesia coverage of the painful areas. For the first 4 days, the patient continued to have excellent coverage; however, by the seventh day, the paresthesias ascended to above the nipple line. At the 2-week follow-up, cephalad migration of the left lead to the top of VB T1 was confirmed on fluoroscopy. The patient underwent successful lead revision in which a single paramedian incision technique was used to place extra sutures and a "figure-of-eight" strain relief loop. We provide the first case report of significant cephalad LM following SCS lead implantation. This migration can occur despite the use of current standard anchoring techniques. Additional investigation into the mechanism of such LM and lead-securing techniques is warranted.

Key words: spinal cord stimulation, lead migration, lead revision, strain relief loop

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Spinal cord stimulation (SCS) has emerged as an efficacious and cost-effective treatment modality for various neuropathic pain conditions, such as failed back surgical syndrome (FBSS) (1-5) and complex regional pain syndrome (6-9). Randomized controlled trials have supported its use for these conditions and have shown that it leads to improved quality of life, increased activities of daily living, and reduced health care costs (1,9). As additional research evolves, SCS will continue to be utilized for other chronic neuropathic pain states (10-13).

Complications of SCS have been reported at a rate of 30–40% (14). Lead migration (LM) is among the most

common complications of SCS, with reported incidences ranging from 13.2% (15) to 22.6% (14). LM is defined as displacement of the wire from its original desired location; it is caused by mechanical stress on an SCS component and results in the loss of effective stimulation. Such a complication leads to an increased risk of infection with each operative lead revision, in addition to increased costs. In an era when cutting health care expenditures is becoming increasingly important, current complication rates could curtail future acceptance and utilization of SCS.

We report a case of unusual LM to highlight the importance of technical pitfalls despite the current

standard of care, to provide insights into the possible mechanisms of failure, and to discuss a proposed technique for SCS revision.

CASE REPORT

SCS Lead Implantation

A 60-year-old man with a history of FBSS had intractable chronic low back and bilateral lower extremity pain for approximately 10 years. Upon evaluation in our clinic, the patient had clinical evidence for the diagnosis of FBSS and lumbar radiculopathy. Multiple trials of medication, including antidepressants, anticonvulsants, and opioids; physical therapy; and conservative interventional pain management therapies, including epidural steroid injections and facet blocks, had failed to relieve his pain. Since the pain syndrome continued to progress, interfered with daily living activities, and decreased his quality of life, the patient agreed to undergo an SCS trial. He obtained more than 50% relief of his bilateral low back and leg pain. He subsequently underwent SCS lead implantation without complication.

For the implantation procedure, a standard paramedian thoracolumbar approach was used. Dual lead placement was planned. Tuohy needles were placed into the epidural space at the level of the L1-2 interspace from both sides. The epidural space was en-

tered by using the loss of resistance technique to lead blank. Each Medtronic octad spinal column stimulator lead, model 37712 (Medtronic, Minneapolis, MN) was advanced on the contralateral side under live fluoroscopy and threaded cephalad just paramedian to the anatomical midline to the top of vertebral body (VB) T9 (Fig. 1). Excellent paresthesia coverage of the bilateral low back and legs was obtained with lead settings that were identical to the trial (2 negative and 2 positive at contacts 4-7, amplitude 10.2 V, pulse width 550 microseconds, and rate 60 pulses/s). The Tuohy needles were then safely removed under live fluoroscopy, confirming no change in lead tip placement. One nonabsorbable suture was applied to the middle groove of the Titan anchor, and cinched down to deform the anchor insert, thereby securing the anchor to the respective lead. Two nonabsorbable sutures were applied to flanking grooves of the Titan anchor to secure the lead-anchor complex to the lumbodorsal fascia. A strain relief loop (SRL), consistent with current standard recommendations (16), was used for each lead in the paramedian pocket. The leads were drawn to the implantable pulse generator (IPG) by standard tunneling and secured to it. Normal impedance values were subsequently obtained. The wounds were then irrigated with copious antibiotic solution. The IPG was placed in the battery pocket with standard SRLs beneath. The wounds were then closed in the usual fashion. In recovery, confirmation of appropriate paresthesia coverage was obtained before the patient was discharged.

SCS LEAD MIGRATION

For the first 4 days after implantation, the patient reported consistent coverage of the desired painful areas, more than 80% pain reduction, and improved daily functioning and quality of life. However, by the fifth day, he experienced paresthesias up to the level of the umbilicus, to the epigastrium on the sixth day, and above the nipple line on the seventh day. The resultant paresthesias and loss of low back and leg coverage led the patient to turn off the SCS system.

Based on the literature and on our own clinical experience with SCS, the leads most often are reported to migrate caudally, resulting in the loss of desired stimulation coverage and possibly causing the patient to experience undesired stimulation in other areas. This patient's LM pattern, however, was atypical. The differential diagnosis at this time included lead breakage and subsequent migration, or lead dislodgement at the level of the anchor or the IPG connection. Surgi-

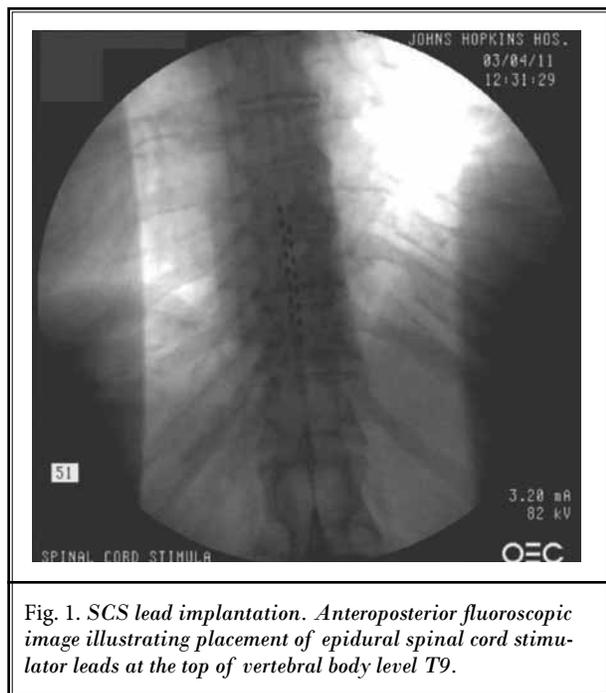


Fig. 1. SCS lead implantation. Anteroposterior fluoroscopic image illustrating placement of epidural spinal cord stimulator leads at the top of vertebral body level T9.

cal planning took into consideration that the patient's lead may have completely fractured and migrated in the cephalad direction, leading to paresthesias in the anterior thoracic region, but not in the low back or legs. However, scenarios involving open or short circuit, disconnection, dislodgement, fracture, and other forms of structural compromise were essentially ruled out because normal impedances and continued stimulation paresthesias were obtained while the SCS system was turned on.

At the 2-week follow-up, fluoroscopic imaging confirmed cephalad LM of the left lead tip to VB T1 (Fig. 2) and caudad migration of the right lead to VB T10. Lateral views confirmed dorsal lead placement. Lead integrity and connection with the IPG appeared to be contiguous as assessed by scanning fluoroscopy and was confirmed upon interrogation, ruling out physical compromise to the lead itself. The patient was subsequently scheduled for lead revision.

SCS Lead Revision

After the patient provided written informed consent, he was transferred to the operating room. A time-out was conducted, and the operative side was initialized. After induction of modified anesthesia care, the patient was placed in the prone position and monitored by a separate anesthesiology team with a noninvasive blood pressure cuff, an electrocardiogram monitor, and pulse oximetry. He received cefazolin 2 g IV < one hour before incision. The thoracolumbar spine was prepped and draped in the usual sterile fashion.

Fluoroscopy was used to locate the indwelling hardware in the region of the paramedian incision before surgical approach was attempted. Fluoroscopic images revealed the lead tip on the left at the top of VB T1. The lead tip on the right was at the top of VB T10.

The skin and deeper tissues were anesthetized by administering approximately 20 mL of 1% lidocaine with epinephrine 1:200,000 kelvin via a 25-gauge, 3.5-inch needle. A skin incision was made with a #10 blade over the old paramedian scar, and the tissue was carefully dissected by electrocautery down to the level of the lead-anchor-fascial complex. Careful hemostasis was obtained throughout with electrocautery. The incision was undermined in the medial and lateral directions, creating a pocket. The Titan anchors already in place were exposed without compromising the leads by using careful, blunt dissection. Upon exposure of the indwelling anchor, it was evident that the prior SRL had unraveled (Fig. 3A) and that at least one suture was not

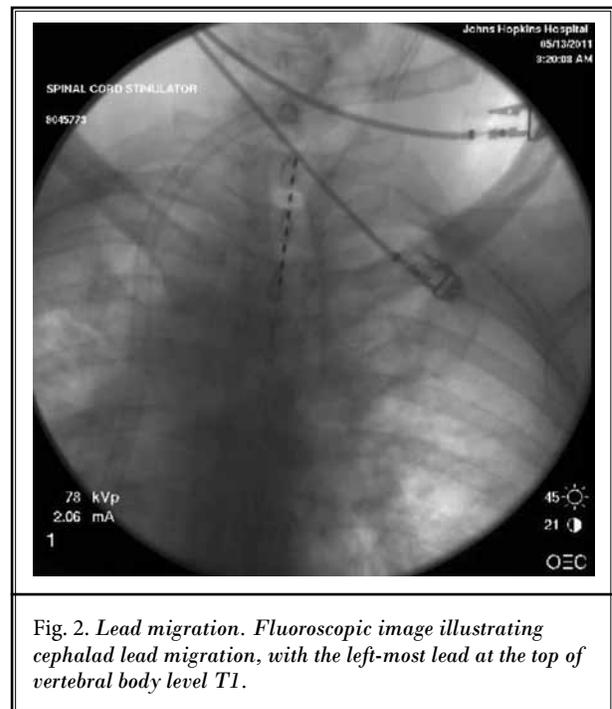


Fig. 2. Lead migration. Fluoroscopic image illustrating cephalad lead migration, with the left-most lead at the top of vertebral body level T1.

secured to the anchor (Fig. 3B). The lead on the left was found to move freely within the anchor when it was gently pulled inferiorly through the anchor. Under live fluoroscopy, the lead was carefully pulled down the midline from the top of VB T1 to the top of VB T8 (Fig. 4). We stopped at T8 instead of T9 to ensure better capture of axial low back pain. The other lead remained at the top of T10. Intraoperative stimulation testing revealed excellent paresthesia coverage corresponding to the bottom 4 contacts of the revised lead.

Next, 2 nonabsorbable sutures were used to secure the anchor onto the lead (Fig. 5a). Thereafter, gentle tugging of the lead inferiorly produced no slippage through the anchor. Then, 2 nonabsorbable sutures were used to secure the anchor-lead complex to the lumbodorsal fascia. Again, gentle tugging of the lead produced no slippage through the anchor, as confirmed under live fluoroscopy.

Next, our attention was directed to the other anchor in the same paramedian incision pocket. Upon full exposure of that anchor, it was clear that at least one suture was not secured to the anchor. Two nonabsorbable sutures were used to secure the anchor onto the lead. Gentle tugging of the lead produced no slippage through the anchor. Then, 2 nonabsorbable sutures were used to secure the anchor-lead complex to the



Fig. 3. SCS revision. A) Photograph illustrating how the strain relief loop uncoiled after the initial implantation. B) The loosened suture was identified upon exposure of the anchor during SCS revision. The loose suture enabled the lead to move freely within the anchor. Note that the anchor-fascial complex is secure.

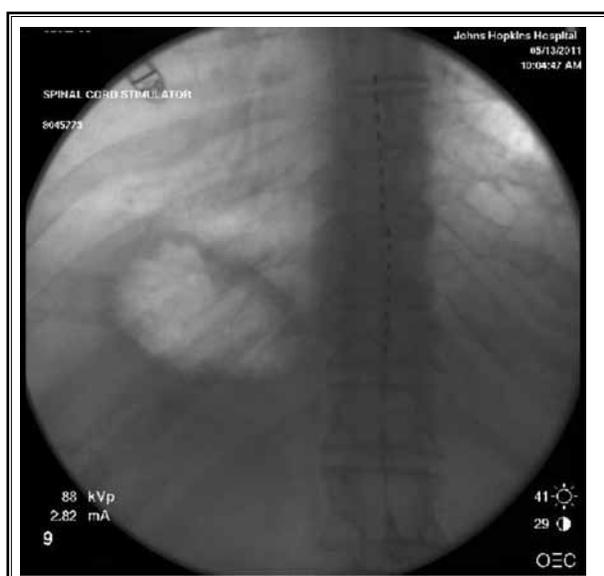


Fig. 4. Fluoroscopic image illustrating final lead position at the top of vertebral body level T8 after lead adjustment.

lumbodorsal fascia. Again, gentle tugging of the lead produced no slippage through the anchor, as confirmed under live fluoroscopy.

Next, great care was taken to manage the excess lead spanning the difference in length of 7 vertebral levels within the paramedian pocket (Fig. 5a). Since one SRL would be too large for the paramedian pocket, several technical considerations were made.

It was possible that this excess lead originated at the IPG pocket site from SRLs that became uncoiled after implantation and ultimately migrated through the tunnel into the paramedian anchor site, and distally upon compromise of the anchor-lead complex. It was not possible to move the excess lead from the paramedian pocket through the tunnel toward the IPG site. Although application of an additional anchor in the paramedian pocket for the excess lead might provide a “backup system” for preventing migration (17,18), this procedure would have likely required another incision to access the IPG site and disconnect the lead to apply the second anchor. Surgical opening of the buttock IPG pocket site was considered, but before acting on this premise, we attempted to spare another incision and reduce infection risk by managing the excess lead within the paramedian pocket. We decided to manage the excess lead by creating a “figure-of-eight” loop (Fig. 5b), effectively reducing the medial-to-lateral cross-sectional area. We subsequently tied down one nonabsorbable suture to the fascia using an airknot at the intersection of the figure-of-eight loop, taking care not to strangulate the lead with forces that could compromise lead integrity. This figure-of-eight loop was intended to reduce the likelihood of the excess lead unraveling and possibly reduce the chance of effective LM by serving as a pseudoanchor point in the system. A fluoroscopic image showed no further migration of the leads.

Finally, the wound was irrigated copiously 3 times, each time with 50 mL of bibiotic-containing solution.

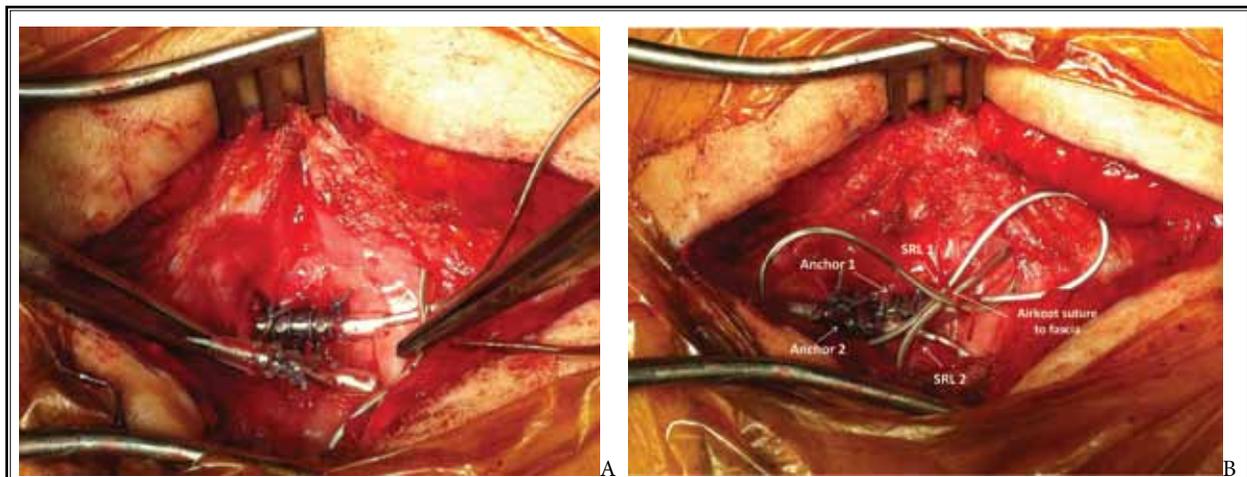


Fig. 5. A) Photograph illustrating excess lead in the paramedian pocket after pull-down of SCS lead to desired location. Note the placement of extra sutures securing the anchor onto the lead. B) Figure-of-eight strain relief loop. Note the airknot suture around intersection of loops.

Meticulous hemostasis was maintained with electrocautery. The figure-of-eight strain relief anchoring loop was tucked below as the fascial layer was closed with interrupted 0-Vicryl sutures (Ethicon, Inc. Somerville, NJ). Then the dermal-subdermal layer was closed with interrupted 3-0 Vicryl sutures, followed by skin closure with staples. Impedances were subsequently confirmed on repeat testing. Dressings consisted of xeroform, sterile gauze, op-site, and ioban.

The patient tolerated the procedure well and was transferred to the recovery area in stable condition where appropriate postoperative paresthesia mapping was confirmed. The patient was discharged home in stable condition with no complications.

Follow-up

At 2 and 6 weeks postrevision, the patient continued to report excellent paresthesia coverage and pain relief over the low back and bilateral legs, identical to the benefit received from the initial implantation. Confirmation of the absence of LM was obtained on surveillance fluoroscopic imaging at 6 weeks postrevision (Fig. 6).

Discussion

We believe that this represents the first report of significant cephalad LM following SCS lead implantation and should be observed in order to prevent injury. For example, cephalad migration at the cervical level could have led to significant spinal cord injury. LM is

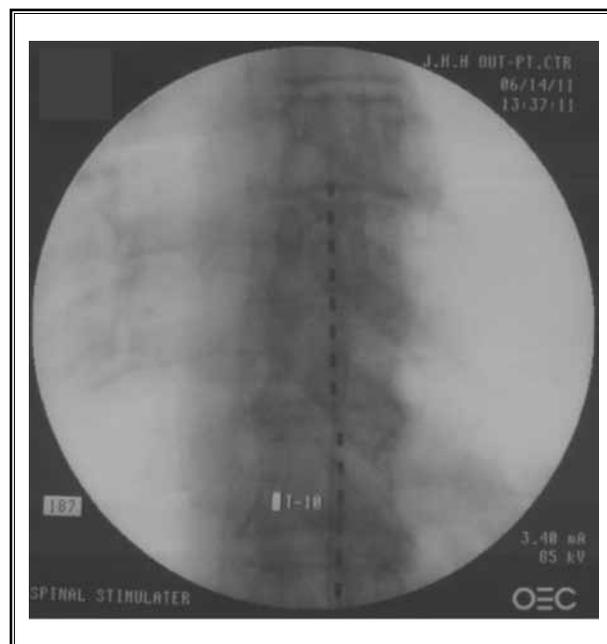


Fig. 6. Follow-up. Fluoroscopic image confirming the absence of lead migration at 6 weeks postrevision. Note the lead tip at the top of vertebral body level T8.

among the most common complications of SCS. Such a complication usually necessitates operative revision, which carries additional risks and costs. In addition, few SCS revision techniques have been described (18,19).

Hence, the need exists for a better understanding of LM and lead revision techniques.

Our patient developed LM approximately 4 days after implantation, well before scar formation could enable security of the lead-anchor-fascial complex. Upon open revision, the lead was found to move freely within the anchor, indicating compromise of the suture-anchor-lead complex. The excess lead is hypothesized to have originated from the IPG pocket site. Although standard SRLs were provided during the initial implantation, the loops had uncoiled, and the excess lead followed the path of least resistance, resulting in unusual LM in the cephalad direction.

The underlying etiology of LM in our case was not entirely clear, as spine trauma, infection, and muscle spasm did not appear to precede loss of capture. The usual safeguards as proposed by previous technical assessments with SCS were followed (20). Perhaps of significance, our patient reported repetitive vigorous bending and rotational movements about the waist, and sleeping with arms extended above the head, despite our precautions. The literature shows that LM is most likely to occur during the first several weeks of the implant, before tissue encapsulation of the system has fully formed, and if the patient has subjected the system to large displacements from vigorous activity (14,20).

Mechanisms of LM have been described (14,20). Security of the lead-anchor complex relies heavily on the bond created between the anchor and lead. Several strategies for enhancing this bond have been described, including the use of medical-grade silicone glue, although prospective evaluations of such technical considerations are lacking. Careful attention to suture technique to enhance knot tightness, particularly with the first throw of a surgeon's knot, cannot be overstated. As seen in our case report, the placement of more than one suture for lead-anchor security may produce a backup system for the prevention of LM, such that if one of these sutures fails, the other suture is still viable. More recently, novel approaches to lead security have gained FDA approval and include mechanical locking anchors using a twist-lock mechanism (Swift-Lock Anchor, St. Jude Medical, Plano, TX) and a torque-wrench mechanism (Clik Anchor, Boston Scientific, Valencia, CA) that does not require the use of sutures. Prospective trials are indicated to ascertain which lead anchoring approaches, if any, are superior.

Additionally, the overall stiffness of an implanted system, including the lead, extension and tissue, can

be calculated and used to predict forces imparted to the implanted system (Fig. 7a). Forces applied to the system, such as pulling the lead or extension taut, may result in a short or open circuit or in LM. Current recommendations include allowing enough slack in the lead or extension to accommodate patient movement. Coiling the excess lead body into a circular loop that is more than 2 cm (0.8 in) in diameter (16) reduces the risks of kinking, damage, or electromagnetic interference and its effects.

SRLs are used in a variety of other fields, including electrical engineering (21), where such configurations protect wires from damage in high-stress areas. A strain relief device not only absorbs the pushing and pulling forces exerted on the wire during use, but also increases its bend radius (16,22). An increase in the bend radius increases the force required to cause lead displacement (Figs. 7a and 7b). It is well appreciated that implanting SCS leads without SRLs may reduce the functional survival time of the lead; as a consequence, the SCS may require reprogramming and/or early replacement of the lead to restore effective therapy.

A paucity of literature exists for varying configurations of SRLs. Although data are unpublished, internal evaluations have been performed. We theorize that if the anchor-lead complex becomes dislodged or otherwise ineffective, the use of multiple SRLs (in our case, a figure-of-eight loop) might provide an additional buffer to the SCS system against potential effects of longitudinal forces, further minimizing LM potential.

When evaluating the figure-of-eight SRL, key elements of the on-label SRL can be observed. In fact, the figure-of-eight loop effectively provides the same amount of slack as 2 of the on-label SRLs (assuming the diameters are of equal size). The figure-of-eight loop does not violate current rules of strain relief for SCS; namely it exceeds a 2-cm radius and avoids a U-shaped configuration. However, according to unpublished, *in vitro* experimentation by Medtronic, this and other multiloop configurations constrained by one or more loose knots has shown a propensity for only one of the loops to absorb a given displacement, resulting in a tight bend radius being formed right before the slack is consumed from the loop (Fig. 8). Although the tight bend radius potentially could increase the risk of lead compromise, tissue encapsulation around the loops would likely prevent such an occurrence, thereby aiding recovery of the strain relief back to the starting diameter. Knot tightness and possible tissue in-growth may restrict the free movement of the loop

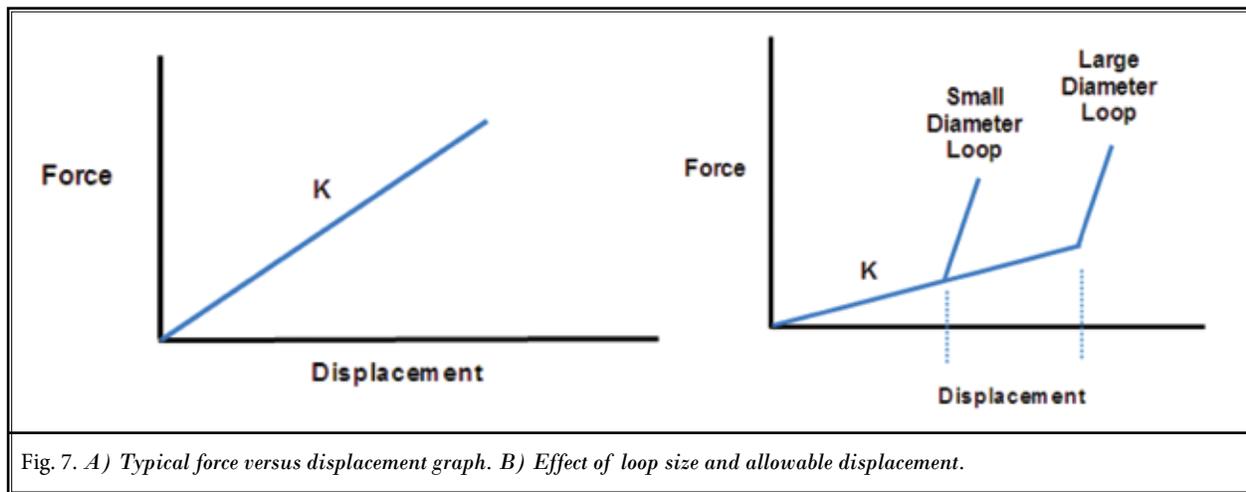


Fig. 7. A) Typical force versus displacement graph. B) Effect of loop size and allowable displacement.

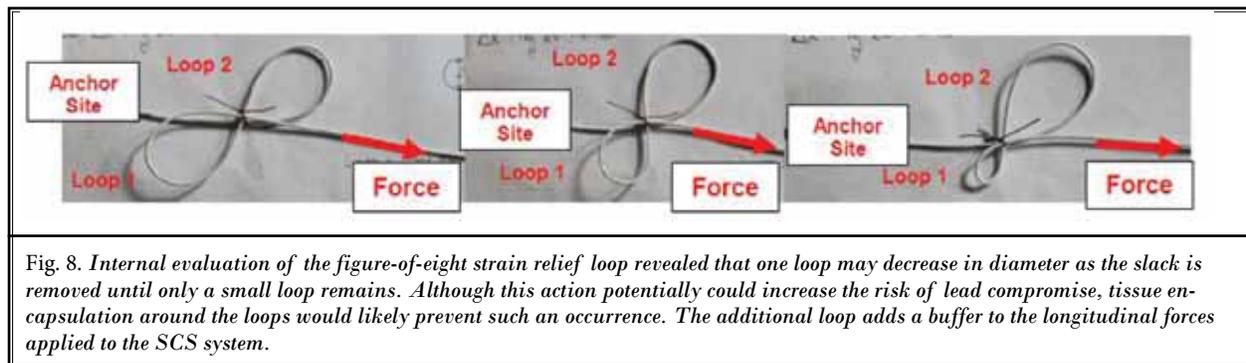


Fig. 8. Internal evaluation of the figure-of-eight strain relief loop revealed that one loop may decrease in diameter as the slack is removed until only a small loop remains. Although this action potentially could increase the risk of lead compromise, tissue encapsulation around the loops would likely prevent such an occurrence. The additional loop adds a buffer to the longitudinal forces applied to the SCS system.

during a patient's range of motion. It is important to mention that an airknot suture was tied around the lead to the fascia to reduce the risk of the SRL unraveling and was not cinched down onto the lead itself. Furthermore, a recent study demonstrated that lead integrity does not appear to cause substantial physical damage or electrical impairment when sutures are tied securely directly onto the lead (23). That study suggested that anchoring directly to the lead might produce minimal damage, but these preliminary data must be confirmed and expanded. Nevertheless, given the theoretical risks of the figure-of-eight SRL based on internal evaluation, Medtronic recommends the use of the SRL configuration documented in the SCS 1x8 Implant Manual (16).

Despite persisting with vigorous activity, our patient continues to derive significant benefit from SCS revision. He has stable paresthesia coverage and pain control, and the absence of LM has been confirmed by surveillance fluoroscopic imaging (Fig. 6). The

SCS revision was performed with only one incision, reducing the risk of infection that might occur with additional incisions. Additionally, although more hardware was effectively managed in the paramedian pocket, the patient reported no discomfort in this region after revision. We speculate that in addition to restabilizing the lead-anchor-fascial complex, extra SRLs in the figure-of-eight configuration may have provided further protection against uncoiling and subsequent LM.

CONCLUSION

This case is presented to: 1) remind readers of the challenges of LM faced by implanters; 2) illustrate the first report of significant cephalad LM following SCS lead implantation; 3) raise awareness that cephalad LM may occur despite standard techniques; 4) illustrate how to detect LM should it occur; 5) postulate why this LM might have occurred; 6) present troubleshooting that occurred while limiting revision to one incision; 7) suggest the po-

tential protective value of SRL on longitudinal lead migration in general; and 8) introduce an alternative SRL configuration that warrants further investigation.

Patients suffering from chronic neuropathic pain are often refractory to conventional medical and interventional treatments and experience significant pain and disability. While SCS may offer an alternative treatment, a technical learning curve remains. Lead migration, the most common complication of SCS, is a major barrier to success. In an era when cutting health care expenditures is becoming increasingly important, current complication rates could curtail future acceptance and utilization of SCS. This possibility underscores the importance of a continued push toward technological and technical advances, such that current techniques

for SCS are fine tuned, and complications associated with this important treatment modality are reduced. Further prospective investigation into the mechanism of action, mechanism of complications, optimization of surgical techniques, and long-term efficacy is warranted in order for SCS to become a widely accepted mainstay treatment.

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