LETTER TO THE EDITOR

Catastrophic Failure of a Boston Scientific Artisan Spinal Cord Stimulator

To the Editor:

INTRODUCTION

The most common reasons for revision or removal of permanent spinal cord stimulator leads are infection and mechanical failure. Most mechanical failures involve displacement of an intact lead or a fracture of the wires within one or both electrodes. This is the report of a case of catastrophic failure of a paddle lead. The implications regarding certain fixation techniques and the information that is lacking in the literature will be discussed.

CASE REPORT

A 43-year-old white male developed neck and back pain with radiation to the left lower extremity after helping a neighbor move a refrigerator in September 2004. He underwent a transforaminal lumbar interbody fusion at L5-S1 by another spine surgeon on June 30, 2008, without improvement in his pain. At the time of presentation, his back pain radiated to the left posterolateral thigh, leg, and foot. His pain increased with all activities. He obtained relief from lying down. He had numbness and paresthesias along the lateral aspect of the left thigh, leg, and foot, and weakness in his left knee. He had been treated with anti-inflammatories, muscle relaxants, pain medications, epidural blocks, and physical therapy without improvement. A computed tomography (CT) myelogram of his lumbar spine showed no evidence of herniated disc or stenosis at any level. He had a spinal cord stimulator trial with greater than 50% improvement in his pain. On March 16, 2010, he underwent implantation of a Boston Scientific Artisan spinal cord stimulator through a laminectomy at T8 and placement of a rechargeable battery over the left hip. The lead was secured to the spinous process of T9 with two sutures of 2-0 Ethibond tied over silastic anchor sleeves, which had displaced from the epidural space into the muscular layer. The silastic anchor sleeves were still sutured to the spinous process of T9, although they were both empty. Consistent with the x-ray, the electrodes were found wrapped around the IPG in the subcutaneous pocket over the left hip. A new Boston Scientific Artisan lead was inserted through a laminectomy at T8 and was connected to the original IPG.

One week later, the stimulator was programmed, and the patient reported satisfactory coverage and pain control. Figure 3 shows his final x-ray.

DISCUSSION

Mechanical failure of the permanent spinal cord stimulator device has been reported in most series of neuromodulation. Kemler (1) implanted permanent percutaneous spinal cord stimulators in 24 patients. One patient had a “defective lead” and five others had “complications related to unsatisfactory position of the electrode.” Kumar (2) implanted various leads into 121 patients and noted electrode displacement or fracturing among the notable complications. North’s (3) analysis of 298 permanent spinal cord stimulator implants revealed that clinical and technical failures were significantly less when multichannel devices were substituted for single-channel implants. Cameron (4) culled 68 studies on spinal cord stimulation and found that the most common form of mechanical failure was lead migration at 13%. The incidence of lead breakage was 9%

The technique manuals for the Boston Scientific and Medtronic stimulators recommend creating a strain relief loop in the electrode. Kumar (5) reported an expert panel opinion stating, “A strain relief loop should be considered after anchoring the lead…Biomechanical testing has shown that, with surgical leads, a strain relief loop should be created.” Henderson (6) performed fatigue testing of paddle leads. The leads fixed with an anchor failed at an average of 16,000 cycles. Removing the anchor and adding a strain relief loop “decreased the effective stiffness of the system and thereby the

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peak load.” The test ran for 1,000,000 cycles without failure. Although anchors were used in this case, strain relief loops were added at each end of the electrodes. This did not protect the system from a catastrophic failure when the patient fell. Since the fall and the implant failure occurred four weeks post-op, it is unlikely that there was enough scar to negate the electrode motion at both loops.

To the author’s knowledge, no one has reported the catastrophic failure of a stimulator as described in this case report. Since this was an acute event (a fall in the bathtub) that resulted in the destruction of the lead, one would assume that a great deal of force was involved. The author was surprised to learn from the manufacturer that no tensile failure testing has been performed on this brand of lead. To get a general idea of the failure strength of these leads, the author contacted St. Jude Medical. Such failure testing has been performed by this manufacturer on their leads, but the data are considered proprietary. They would not share the information, and internet searches proved unsuccessful.

CONCLUSION

Although this is an isolated case report, falls are not infrequent, especially in patients taking chronic narcotic medications. The author believes that mechanical testing of these implantable devices deserves further attention. At the very least, the tensile strength of the implants should be known as this might affect decisions related to the fixation of these devices.

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REFERENCES


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