Prevention of Mechanical Failures in Implanted Spinal Cord Stimulation Systems

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ABSTRACT

Introduction. Spinal cord stimulation (SCS) is an effective procedure for the treatment of neuropathic extremity pain, with success rates approaching 70%. However, mechanical failures, including breakage and migration, can significantly limit the long-term effectiveness of SCS. A systematic analysis of surgical techniques was undertaken by a consensus group, coupled with extensive in vivo and in vitro biomechanical testing of system components.

Methods. A computer model based on morphometric data was used to predict movement in a standard SCS system between an anchored lead and pulse generator placed in various locations. These displacements were then used to determine a realistic range of forces exerted on components of the SCS system. Laboratory fixtures were constructed to subject leads and anchors to repetitive stresses until failure occurred. An in vivo sheep model also was used to determine system compliances and failure thresholds in a biologically realistic setting. A panel of experienced implanters then interpreted the results and related them to clinical observations.

Results. Use of a soft silastic anchor pushed through the fascia to provide a larger bend radius for the lead was associated with a time to failure 65 times longer than an anchored but unsupported lead. In addition, failures of surgical paddle leads occurred when used with an anchor, whereas without an anchor, no failures occurred to 1 million cycles. Based on these findings, the panel recommended a paramedian approach, abdominal pulse generator placement, maximizing bend radius by pushing the anchor through the fascia, and anchoring of the extension connector near the lead anchor.

Discussion. Several factors are important in longevity of SCS systems. We discovered that technical factors can make a large difference in SCS reliability and that strict attention to these "best practices" will provide the best chance for maintaining the integrity of SCS systems over the long term.

KEY WORDS: mechanical complications, pain, spinal cord stimulation, surgery
INTRODUCTION

Spinal cord stimulation (SCS) was first described in 1967 as a potential treatment for intractable neuropathic pain (1). Over nearly four decades, surgical techniques and hardware have been refined to the point that SCS is now widely used throughout the United States and Europe with success rates approaching 70% (2-12). However, mechanical failures, including breakage and migration, can significantly limit the long-term effectiveness of SCS. In an analysis of 289 patients with implanted spinal cord stimulators, Rosenow et al. found a 32% failure rate for the most common system configuration, using cylindrical percutaneous-type leads placed in the thoracic spine and attached to a pulse generator placed in the gluteal region for the treatment of lower extremity pain (13). A systematic review of the SCS literature for failed back surgery syndrome and complex regional pain syndrome found 22 articles out of 583 that addressed complication rates. A mean of 10.2% of patients had some type of equipment failure, with 23.1% of patients undergoing revision of the stimulator for reasons other than battery change and 11.0% of patients undergoing removal of the stimulator for any reason (5). In another series of 102 patients with varying pain etiologies, 64 patients underwent revision surgery for various reasons. Eleven revisions were for lead migration, ten for inappropriate paresthesia coverage, and eight for "replacement due to failure" that presumably represent unrecognized lead breakages. Three revisions were for fracture of the "connecting lead" (14). This study also noted a higher rate of revision in cervical leads (5/35 or 14.3%) than in thoracic leads (6/67 or 9.0%). In another literature review, Cameron found a 13.2% incidence of lead migration and a 9.1% incidence of lead breakage, following analysis of 2972 patients from 51 papers (6).

Mechanical failures are thus a common cause of re-operation in patients with implanted SCS systems, costing hundreds of thousands of dollars and exposing patients to the additional risk and discomfort of revision surgery.

Faced with these high rates of mechanical failure, a systematic analysis of surgical techniques was undertaken to provide recommendations for implanting surgeons to minimize mechanical stresses and decrease failure rates for both percutaneous and surgical (paddle) leads. Extensive in vitro and in vivo biomechanical testing was carried out to better characterize failure modes of SCS systems in a controlled setting. A consensus group consisting of five experienced implanters was convened to discuss the results of this testing, with attention to technical details of the procedure that might be expected to decrease mechanical failures.

Mechanical failures can be classified into two main categories: migration and breakage. Vertical migration of a percutaneous lead in the epidural space can result from two major mechanisms. The lead can slip through its anchor when the tension on the lead exceeds the anchor's retention ability, or the anchor can be pulled away from its initial anchor point due either to breakage of the suture holding it in place or to disruption of the tissue to which it is anchored. The mechanical load exerted on an anchor is dependent on both the stiffness of the overall system, and the displacement between the anchor and the implantable pulse generator (IPG). A stiffer lead/extension combination will produce more force on the anchor, whereas a "springier" or more compliant system will transmit less force. The second factor, displacement, depends on the movement of the IPG in relation to the anchor. The combination of stiffness ("spring rate" in engineer terminology) and displacement determines overall force on the anchor. The higher the force, the more likely it is that the anchor will fail and the lead will migrate. Thus, decreasing either the stiffness or the displacement of a SCS system would be expected to lower the incidence of cranio-caudal lead migration.

Leads also can move transversely within the spinal canal, leading to a change in the pattern of stimulation. This type of migration is believed to be relatively less common than vertical migrations, and its mechanism is less well-understood.

Breakage or fracture of the wires within the lead can occur with repeated bending or buckling. Some lead designs, known as "cable leads," incorporate conductor wires that run parallel to the axis of the lead that are contained within a flexible polymer outer jacket. A compressive load on the lead can result in buckling, producing a reduction of the cross-section of the lead at the location of the buckle that becomes a hinge point during movement of the spine. This hinge effect
causes localized stress in the wires that can cause fatigue failures.

Some leads are designed using conductor wires that are coiled into a helical shape and contained within a flexible polymer jacket ("coil leads"). This design minimizes localized failure by redirecting forces along the helical coil. However, fractured wires are occasionally observed just proximal to the distal end of rigid plastic anchors in returned products (Fig. 1). It was theorized that spinal movement in the sagittal plane could cause the lead to be periodically pulled around the end of the rigid plastic anchor, inducing localized stress in the wires that would eventually cause fatigue fractures.

**MATERIAL AND METHODS**

A systematic approach was used to develop appropriate testing paradigms for evaluation of various factors that might contribute to SCS failure. Analysis of the root causes of mechanical failures was performed in a four stage process as follows:

1. investigation of failures through analysis of returned products and clinical observations during surgical revision;
2. understanding of environmental factors involved in SCS failure, including expected movement of the relevant anatomy (based on published anthropometric data and computer modeling) and estimation of the mechanical properties of tissue surrounding implanted SCS systems (based on a chronic animal study);
3. estimation of mechanical loads on leads, anchors, and other parts of the system using calculations based on displacements and total system stiffness; and
4. construction of bench-top mechanical test fixtures to simulate the environmental conditions and loads that could recreate the migrations and fractures observed in clinical practice.

Based on the aforementioned observations and hypotheses, a number of biomechanical tests were designed to simulate conditions that could lead to the types of failures observed. Three different methods, providing complementary information, were utilized: 1) biomechanical modeling to determine the normal range of spinal motions, so that leads could be tested throughout a realistic range of displacements, 2) *in vitro* measurement of stiffness of various materials (spring rates), and 3) *in vivo* measurement of spring rates as well as anchor retention using quasi-static and cyclic loading.

In order to evaluate the forces exerted on SCS hardware due to movement, a computer model representing the geometry of the spine based on the dimensions of the thoracic and lumbar vertebrae (14,15) as well as average disc thickness (15-17) was developed. Mechanical properties of the model included spring rate, adherence, and displacement. Flexion and extension in the sagittal plane were simulated by rotating each vertebra about centers of rotation (pivot points) for each segment (18). As an example, the angular displacement between T12 and L1 from full extension to full flexion was 12 degrees, as predicted by the model. An example of the graphical display produced by the model is shown in Figure 2, which illustrates the typical situation where the lead is anchored on the fascia at point A and enters the spinal canal beneath the lamina at point B. This path length increases when the spine moves from extension to flexion. The change in lead path length from point A to point B, with a paddle lead at T12 and an anchoring point at approximately L2, was determined to be 2.1 cm.

This computer model of the spine, torso, and surrounding structures was then used to calculate possible lead displacements caused by normal body motions in the case of abdominal (Fig. 3)
and buttock (Fig. 4) IPG placements. The biomechanical effects of walking, bending, and twisting on the lead anchor point, lead, and IPG were simulated. These analyses provided information that helped determine typical displacements at various points within the system.

The in vitro spring rates (stiffness) for each of the different components, including extensions as well as both cable leads and coil leads, were assessed using an Instron tensile testing machine. The results of these spring rate assessments are presented in Figure 8.

Determination of in vivo spring rates was performed using an animal model. A 4-month chronic study included five sheep. Each animal was implanted with an IPG and extension on one flank, and a percutaneous lead and anchor on the contralateral side, all placed in the subcutaneous tissue. A soft silicone anchor was bonded to the lead with silicone adhesive, and the anchor was attached to the underlying fascia with 2-0 silk suture tied in a figure-of-8 configuration. The extension was implanted with a single loop immediately under the IPG. Each lead also was implanted with a single 3 cm diameter strain relief loop. A fixture was built to measure the force required to achieve a specific displacement, as described for the in vitro testing.

Figure 2. Computer model display of a typical anchoring configuration for a surgical paddle lead. Note the increase in the distance between point A (anchor attachment to fascia) and point B (entry of lead body beneath lamina) in flexion compared to extension.

Figure 3. Computer modeling of lead displacements caused by normal body movements with the implantable pulse generator (IPG) implanted in an abdominal location. During walking (A), the distance between anchor and IPG shortens and elongates by 0.2 cm, whereas during maximal twisting of the torso (B), this distance changes by 1.7 cm.
Distance between anchor and IPG location elongates by 9 cm.

Figure 4. Computer modeling of lead displacements caused by normal body movements with the implantable pulse generator (IPG) implanted in a hip/buttock location. Flexion of the spine causes elongation of the distance between anchor and IPG of 9 cm compared with neutral position. A = spine in neutral position; B = spine in flexed position.

Once the spring rates of individual system components were determined, the mechanical tension (load) exerted on the anchor could be estimated by multiplying the effective spring rate of the entire system by the expected displacement (Fig. 5). Using displacement estimates from the computer model described above, a graph of anchor load vs. displacement could be generated for various system configurations (Fig. 6).

Finally, these data were used to design tests of anchor retention ability, both in a quasi-static and cyclic loading environment. Quasi-static loading mimics a sustained pull on an anchor, whereas cyclic loading mimics the repeated stresses that would be placed on an anchor during normal body movement. A variety of anchor configurations were evaluated by attaching the anchor to the lead and then suturing the moving portion to a tensile testing machine. The anchors were sutured to an elastomeric sheet that mimicked the lumbodorsal fascia. The opposite end of the lead was attached to the stationary portion of the machine. The displacement rate of the anchor was 5.0 inches per minute. All samples were preconditioned by soaking in Ringer's solution at 37°C for a minimum of 4 days. Before placing the lead in the testing machine, a thin layer of animal fat was applied to the lead to mimic the presence of intraoperative body fluids. Load vs. displacement data were collected, and the leads were observed directly to determine the point at which the lead began to slide through the anchor.

Cyclic loading of the anchor was investigated using a test fixture that moved back and forth a particular distance (stroke length), smoothly varying the tensile load between a peak value of 0.75 pounds and 0 pounds in deionized water at 37°C. The anchor was attached to the moving portion of the fixture and the opposite end of the lead was attached to a spring that was held stationary. The spring stiffness was selected to approximate the calculated stiffness of an implanted SCS system, and the peak load was achieved by adjusting the fixture's stroke length.

Different fixtures were constructed to evaluate bending around a rigid plastic anchor, and buckling of the lead as might occur between an anchor and the fascia. Failure testing in the lead buckling condition was performed with both a small radius of bend/buckle (0.5 mm) and a large radius (1.5 mm). These two conditions are represented in Figure 7.

RESULTS

Measured spring rates of the various system components are summarized in Figure 8. Spring rates for cable and coil conductor lead types were determined in vitro, whereas the other spring rates were determined in the chronic sheep implant model described above. Using these spring rate measurements, the effective spring rate of a typical thoracolumbar SCS system was calculated as 0.57 lbs/inch (10.18 kg/m). Figure 6 shows the calculated loads as a function of displacement for different implant and component configurations. Note that the configuration that places the least amount of mechanical strain on the anchor is a coil lead with strain relief loops, whereas a cable lead without strain relief loops produces more than three times the load on the anchor.

The buckling fatigue test produced the first fractured conductors at an average of 5457 ± 2877 cycles (mean ± standard deviation) (N = 9), using a bend radius of 0.5 mm. The failures of the lead conductors were similar to those found in leads that fractured in vivo (Fig. 1). After adjusting the bend radius to 1.5 mm (simulating the presence of...
Force (F) = (K_{eq})(Displacement (X))

Figure 5. Illustration of the method for determining the composite spring rate (K_{eq}) of the entire spinal cord stimulation (SCS) system. (A) Simplified diagram of the composite spring rate. The force (F) on the anchor equals the spring rate (K_{eq}) of the entire system times the displacement (X) generated by body movement. (B) Diagram of the individual components of an SCS system and their anatomical locations. Pt. 1, IPG; Pt. 2, anchor; Pt. 3, extension connector; Pt. 4, attachment of connector to tissue. (C) Detailed mechanical model representing the spring rates of each individual component: K_1, attachment of IPG to fascia; K_2, adherence between tissue and extension; K_3, extension jacket; K_4, extension wires; K_5, lead jacket; K_6, lead wires; K_7, adherence between tissue and lead; K_8, attachment of anchor to fascia; K_9, adherence between tissue and connector.

a silicone anchor pushed through the fascia as illustrated in Figure 7), fractures were observed at 330,113 ± 181,350 cycles (N = 5). This represents a 60-fold improvement in the number of cycles to failure when compared to the lead without the support of the silicone anchor.

The bending fatigue test using the rigid plastic anchor produced fractured conductors at an average of 42,398 ± 15,081 cycles (N = 4). This test also produced fatigue failures of the lead conductors that were typical of those found in leads that fractured in vivo (Fig. 1). When the test was repeated using the silicone anchors, keeping the angular displacement and stroke constant, four samples were tested to 1 million cycles without failure.

Fatigue testing of paddle leads simulating the use of an anchor failed at an average of 16,098 ± 6960 cycles (N = 4). The failures were all fractures of the conductors between the anchor and paddle portion of the lead. The test was repeated without the anchor and after addition of a strain relief loop, lowering the effective stiffness of the system and thereby the peak load. The test ran without failure to over 1 million cycles (N = 4) at which time the test was terminated.
**DISCUSSION**

An expert panel of five experienced implanters was convened to discuss the results of the biomechanical testing and their application to clinical practice. Lead placement technique, anchoring technique, surgical lead placement, and IPG placement were discussed in detail. Those techniques that had led to successful reduction in lead failures, especially those which correlated with the results found on biomechanical testing, were formulated as "best practices" recommendations from the group.

The panel recommended that percutaneous leads should be introduced by a paramedian rather than a midline approach. A shallower angle of introduction is beneficial for lead steering and

![Image](image_url)

**Figure 7.** Simulated lead buckling configurations. (A) Small bend radius simulating the clinical situation of anchoring at the point of exit of the lead from the fascia. (B) Large bend radius simulating the clinical situation of pushing the tip of the anchor through the fascia.

![Image](image_url)

**Figure 8.** Measured spring rates of various system components. Cable conductor lead and coil conductor lead spring rates were measured in vitro; all other values were measured in the *in vitro* sheep model described in the text.
helps minimize the potential for compression of neural structures due to bending of the relatively stiff lead. In addition, anchoring of the lead with the technique recommended below is facilitated by the paramedian approach.

Lateral migration of the lead in the epidural space may be decreased by using techniques that maximize friction on the lead body and minimize mechanical factors that might act to displace the lead. The panel recommended that leads be introduced as close as possible to the midline and that lateral movement of the lead within the epidural space be minimized as much as possible. The shape of the vertebral arch tends to force the lead toward the midline and may decrease the tendency for lateral migration. Bends or curves in the lead may have a tendency to straighten, potentially leading to migration. In addition, injection of fluid or air into the epidural space should be discouraged, as this serves to decrease friction and may promote lateral migration.

The group discussed anchoring techniques for percutaneous leads, given the following observations from biomechanical testing:

1. Use of a silicone anchor with percutaneous leads improved average time to failure compared to using a rigid plastic anchor (> 1,000,000 cycles vs. ~42,000 cycles).

2. Increasing the bend radius of percutaneous leads by supporting them with the tip of the anchor as they entered the simulated lumbodorsal fascia improved average time to failure by 60-fold compared to the nonsupported condition.

3. Of the methods investigated, bonding the lead to the silicone anchor with silicone adhesive was the only method that reliably prevented slippage of the lead through the anchor during cyclic loading.

The panel recommended the use of a soft silicone anchor, attached to the lead using silicone medical adhesive and nonabsorbable suture. The anchor should then be attached to the lumbodorsal fascia using a figure-of-8 suture to minimize tissue trauma. The tip of the anchor should be pushed through the fascia in order to maximize the bend radius of the lead with flexion and extension of the spine. In addition, the group recommended that patients be positioned during implantation with the spine in a neutral position to minimize extremes of flexion or extension. The anchor should be placed as near as possible to the spinous process to avoid lead movement generated by muscle contractions.

Regarding techniques for placement of surgical paddle leads, biomechanical testing showed that the use of an anchor without a strain relief loop caused failures at between 8000 and 23,000 cycles, whereas no failures occurred at > 1,000,000 cycles when no anchor was used and a strain relief loop was added. The panel therefore recommended that no anchor be used when implanting surgical leads and strain relief loops should be placed in the epifascial plane. In addition, if an extension is used, the connector should be placed either near the lead or near the pulse generator in order to prevent the formation of a third point of fixation within the system.

Placement of the IPG in the buttock region may produce up to a fivefold increase in tensile loading compared with placement in the abdomen or midaxillary line. The panel therefore recommended that buttock IPG placement be reserved for special clinical situations and should not be routinely performed.

Biomechanical testing revealed a number of potential areas for minimizing mechanical stress related to spinal cord stimulator implant procedures. In many cases, these biomechanical tests confirmed the clinical experience of the expert panel, whereas in other cases the test results caused a rethinking of some previously recommended and widely used procedures.

Spinal cord stimulation is an effective therapy for the treatment of neuropathic extremity pain. However, mechanical complications remain a significant challenge to long-term success. A structured approach to the analysis of these mechanical complications, coupled with a clinical strategy for minimizing potential adverse tensile loads on the system components, should lead to improved long-term performance of SCS systems.

REFERENCES


