Spinal Cord Stimulation and Implanted Intrathecal Drug Infusion

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The human experience of chronic pain is a complex bio-psychosocial disorder and effective management requires concerted effort from multiple sources. Implanted pain therapy devices have gained significant popularity as useful adjuncts in managing severe chronic pain. Spinal cord stimulator and implanted intrathecal drug delivery devices are particularly successful when used in conjunction with other therapy services, procedures, counseling, surgical interventions, and medications.

The use of spinal cord stimulation and implanted intrathecal drug infusion for managing chronic pain and spasticity offers distinct advantages and challenges. Both therapies are considered reversible and minimally invasive. Sufficient surgical skill and clinical knowledge required for successful implantation and long-term management by the skilled physician can be learned in a proctored environment with diligent study and dedication. This chapter will discuss spinal cord stimulation and implanted intrathecal drug infusion devices and offer some guidance on patient selection, trial processes, permanent implantation, operative procedures, and postimplant patient management.

Spinal Cord Stimulation

Passing an appropriately configured low voltage alternating current through the dorsal spinal cord can induce a tingling or “pleasant paresthesia”. When this generated paresthesia covers or overlays areas of pain, the paresthesia it is said to be “concordant” with the pain. This concordant paresthesia may substantially reduce the perception of pain and is the goal of spinal cord stimulation (SCS) therapy. This reduction in pain perception is often maintained for prolonged periods lasting years if appropriately managed.

The use of electricity to mitigate the experience of pain is long and varied in human history. After Melzack and Wall’s 1965 publication in *Science*, in which they proposed the gate control theory of pain reduction, there appears to have been renewed interest in electricity as an adjunct in pain management. Transcutaneous nerve and muscle stimulation has enjoyed a long history of use. The effectiveness of these devices for managing chronic pain is debated.3,4

Spinal cord stimulation as a modern pain management practice was introduced by Shealy and colleagues in 1967.5,6 Shealy reported reduced pain in a patient by placing electrodes in the intrathecal space adjacent to the dorsal column of the spinal cord. Various mechanisms of spinal cord stimulation have been proposed and remain an area of ongoing research. Likely, multiple mechanisms play a role.7,8-15

Current spinal cord stimulator systems consist of an epidural array of contacts and a power source or “pulse generator.” Typically patients are afforded a trial period during which the pulse generator is an external device connected to percutaneously inserted epidural electrodes. When the system is permanently implanted, the power source is surgically implanted into a subcutaneous pocket and is called an implanted pulse generator (IPG). Various stimulating parameters are adjustable on both external and internal power sources and represent the “programming” aspect of spinal cord stimulator management. For both trial and permanent implantation, electrode arrays are implanted into the epidural space as either “catheter-” or “paddle”-shaped devices. The catheter-shaped electrode or “percutaneous lead” is inserted through a specially configured needle-type introducer. The introducer is advanced into the epidural space utilizing fluoroscopic guidance and typically with a loss of resistance technique. The introducer may be inserted through the skin (percutaneous) or placed after an incision is made. One or more percutaneous leads are implanted to create the epidural array of metal electrode contacts. “Paddle” electrodes or laminotomy leads are much larger plastic substrate devices to which multiple metal electrode contacts are attached in various configurations. Figures 41-1 and 41-2 are images of current Medtronic and St. Jude Medical (Advanced Neuromodulation Systems, Inc. [ANS]) percutaneous and laminotomy leads. Because of their size, paddle electrodes require laminotomy or laminectomy for placement. Early electrode arrays were 2 or 4 contacts and available power sources contained only non-rechargeable batteries or required an inductive coil held over an implanted receiver coil for continuous power. At this writing, implanted power sources are capable of connecting up to 16 contacts and contain rechargeable or non-rechargeable batteries. Figures 41-3 and 41-4 are images of Medtronic and St. Jude Medical (ANS) implanted pulse generators.

Often, two and on occasion three percutaneous leads are implanted to create an array of contacts, whereas paddle leads have 4, 8, or 16 contacts arranged in various configurations of columns and rows.

Electrode arrays are most commonly placed in the epidural space between the second cervical and the eleventh thoracic vertebra levels over the middle portion of the cord. Retrograde electrode placement to stimulate sacral and lower lumbar nerve roots, lateral lead placement to stimulate nerve roots within the spinal canal, peripheral nerve stimulation, and subcutaneous “field” stimulation are all areas of ongoing investigation.17,18 This discussion is limited to traditional “dorsal column” stimulation, which represents the most common current usage of the SCS equipment.
Spine

Indications

Appropriate patients for SCS would include those whose pain is not acceptably managed with less invasive therapies and those for whom a definitive surgical procedure is not offered or is not desired. Often reserved for use later in a pain management continuum, spinal cord stimulation may be offered early in some cases, especially in the management of predominantly neuropathic and complex regional pain. Spinal cord stimulation has FDA indications in the management of pain of the trunk and or limbs. This somewhat nonspecific indication reflects the broad array of painful conditions that have been helped using spinal cord stimulation. Good to excellent long-term pain relief has been obtained in multiple chronic pain syndromes including failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), postherpetic neuralgia, and radicular pain secondary to central and foraminal stenosis in the nonoperated patient.

Several other painful conditions have been successfully managed with SCS including: pain secondary to inoperable ischemic cardiac pain, diabetic peripheral neuropathy, peripheral vascular ischemic pain, and Raynaud syndrome. Thoracic, abdominal and pelvic pain coverage with SCS has enjoyed only limited success but clinical efforts continue to afford SCS benefits to these patients. Early in its history, but rarely today, SCS has been used for spasticity management.

The application of spinal cord stimulation in primarily somatic pain conditions is often less successful than when used for radicular or neuropathic pain. Effective long-term axial low back and neck paresthesia coverage is an area of research and significant clinical efforts. Axial pain may often be somatic, neuropathic, or a combination and, as such, is more difficult to capture long term with dorsal column stimulation. However, because the causes of pain can be greatly varied and unknown, patients with a lower probability of success using SCS may derive considerable benefit. The opportunity to place a trial stimulator consisting of percutaneously placed electrodes connected to an external pulse generator is a tremendous advantage and is what allows the less-than-optimal patient to be considered.

Contraindications

The following situations would generally contraindicate SCS:

- Known systemic bacterial infection or infection in the proposed implant region
- Patients with an untreated or undiagnosed psychiatric condition
- Posterior surgical interventions that obliterate the epidural space where the lead array needs to be placed or along the required implant path of the lead
- Patients unwilling or unable to comprehend using the device
- Anticoagulated patients where the anticoagulated state cannot be stopped for the trial and implant process
- Pregnancy
- Previous DREZ lesions at or above the level of lead placement
- Deafferentation or CNS damage such that paresthesia generation is not possible
Significant canal stenosis along the proposed lead location contraindicates percutaneous lead placement and would make laminotomy lead placement in the area of stenosis a concern. Posterior spine surgeries most often obliterate the epidural space and lead placement through the surgical area typically is not possible. Magnetic resonance imaging (MRI), or if MRI is contraindicated, computed tomography (CT) scan of the proposed lead placement regions are often warranted to screen for significant canal stenosis or other intraspinal anomalies.

**Equipment**

At time of this writing, three companies manufacture and support the majority of spinal cord stimulator equipment: Medtronic Neurological, St. Jude Medical (ANS), and Boston Scientific. Each company has product sales and support personnel. Generally, these companies provide a variety of lead or electrode packages containing the electrode, introducer needle, various stylets, and anchors. Percutaneous leads typically have four or eight electrodes secured to a solid plastic catheter through which wires pass to connect the electrodes to metal contacts on the other end to connect to the power source. A trialing cable to connect the leads to a trial pulse generator may be included in the lead kit, or supplied as a separate item. The various implanted pulse generator packages contain a tool for securing the lead to the IPG. Many items are individually packaged and available when needed such as: various anchors, additional stylets, wrenches for the set screws on the IPG or extension, lead extensions, and others. When connecting electrodes placed in the cervical region and many laminotomy leads to an IPG located in the upper buttock or abdominal region, lead extensions are typically required.

The basis for all SCS systems is essentially the same: Various forms of a low voltage alternating current are passed from the generator to an array of electrode contacts in the epidural space to generate an electric field within the spinal cord. This electric field affects a change in the central nervous system and, when effective, the experience of pain. Each company has claims to unique benefits, programmability, battery life, stimulation parameters, constant voltage versus constant current and various equipment features. Implanter experience with the various products, individual bias, possibly geographic location due to product support issues, and experience of the manufacturers support personnel are important when choosing which company or companies to choose.

Each manufacturer’s trial and implanted generator is designed to connect only to that particular company’s leads. A battery powered external pulse generator is programmed to match those settings found to be most beneficial during the trialing process and is sent with the patient for the trial period. Trial leads are not appropriate or intended for permanent implantation.

Implanted pulse generators are used as the power source for permanent SCS systems. At this writing, IPG power sources are either rechargeable or non-rechargeable (primary cell). An inductive coil IPG was marketed by Medtronic and ANS (St. Jude Medical), but these are generally not used or are out of production. The decision to implant a primary cell powered versus a rechargeable device is made based on expected power requirements as determined during trialing of the array at time of implant, patient cognitive abilities, and implantor preference and experience. Power requirements for a trial implant array do not necessarily predict requirements for an array placed during a permanent implant.

Current Medtronic rechargeable IPGs will stop functioning after 9 years of usage and require replacement at that time. Boston Scientific and St. Jude Medical rechargeable IPGs do not have specific time limits. The actual life of the rechargeable devices is dependent on the type of battery technology, the number of battery recharge cycles, and the efficiency of the device. As the battery life depletes, the frequency of required recharges increases. A primary cell, non-rechargeable IPG battery under typical usage is expected to last approximately 6 years. Less maintenance from the patient (in the form of recharges) is required with a non-rechargeable IPG. When choosing between rechargeable or non-rechargeable power sources, battery recharging requirements must be weighed against the advantage of the battery’s expected increased life. When power requirements were high during trialing for the permanent electrode placement, then a rechargeable device may be more appropriate. Laminotomy leads tend to have considerably lower power requirements and therefore non-rechargeable power sources may be adequate. In general, however, the greater the power usage, the more likely it will be for a practitioner to choose a rechargeable option.

**Preoperative Considerations**

Preoperative evaluation and preparation of a patient are critical to optimizing outcomes. Most implanters and payers will require a pre-implant psychological evaluation. This evaluation is best accomplished by a licensed psychologist or psychiatrist who has a clear understanding of issues associated with chronic severe pain and spinal cord stimulation. This evaluation helps the implanting physician identify psychological factors that invariably are present in patients with chronic severe pain. Occasionally, psychological issues are identified that require treatment prior to further consideration of spinal cord stimulator therapy. Good collaboration between the psychologist or psychiatrist and implanting physician is important and that all involved understand and address psychological issues. Long-term psychological needs may also be identified during this evaluation. Mostly the evaluation is an attempt to identify psychological issues that would preclude a patient from being considered for implantation. It is important that this evaluation be obtained before placement of the trial and incorporated in the overall pre-implant decision-making process.

An accurate and timely history and physical examination appropriate for a surgical patient is reasonable. This would include past surgeries, surgical complications, bleeding problems, drug allergies, current medications—with specific attention to those affecting coagulation, and appropriate review of systems. A physical examination related to the proposed procedure would include a focused neurologic examination, auscultation of the heart and lungs, abdominal palpation, and inspection of the proposed surgical sites for evidence of infection. A discussion with the patient and significant others regarding external wires and the trial pulse generator for a trial placement, expected incision locations for permanent implant, expected increased pain, and activity restrictions is prudent. Preoperative laboratory testing may be appropriate to rule out infections, bleeding problems, and chemical abnormalities. Chest radiographs and ECG may also be appropriate in patients with significant cardiac or pulmonary history. Specific tests and studies obtained are determined by individual patient considerations, facility requirements, and anesthesia needs.

Identification of possible immune deficiencies and, when indicated, evaluation of the immune status of patients is important. Patients with a history of recurrent infections, especially those known to have antibiotic-resistant organisms, are at particular risk. Diabetics, patients with poor personal hygiene, unsanitary living conditions, or other intraspinal anomalies.
conditions, chronic renal failure, long-term steroid exposure, the elderly and/or debilitated, and most obviously, those with known immunoglobulin deficiencies require careful considerations. When in doubt, consulting an internist and/or infectious disease specialist is appropriate. Maximize immune function in those patients identified to be at risk when possible. Appropriate perioperative antibiotics in the at risk patient and possibly all patients are important in reducing operative infections. Most preoperative antibiotics are best given within 30 minutes prior to incision.

**Facility**

Surgical implantation of permanent SCS systems is a surgical procedure requiring adherence to the usual surgical precautions and needs. Implantation of trial percutaneous spinal cord stimulator leads is generally also considered a surgical procedure requiring similar surgical precautions. C-Arm fluoroscopy is most typically used in addition to an x-ray translucent table, free of metal components which might interfere with appropriate x-ray imaging. Monitoring equipment appropriate for specific patient needs would typically include noninvasive blood pressure, pulse oximetry, and ECG. As with all surgical interventions, a surgery suite meeting local Life Safety Code, conditioned and filtered air, and backup electric power suitable for a surgery suite would be expected. Appropriate monitoring and resuscitation equipment to care for the surgical patient is also required. This would include airway management equipment and supplies, resuscitation drugs, cardiac defibrillator, as well as personnel trained in airway management and patient resuscitation.

**Surgical Considerations**

Typically, for both trial lead placement and permanent system implantation, patients are positioned supine with or without a pillow under the abdomen as needed to reduce lumbar lordosis for lumbar entry. Padding the upper chest will allow the neck to flex under the abdomen as needed to reduce lumbar lordosis for cervical entry when cervical placement is planned. Skin preparation is tailored to patient requirements and may be accomplished by washing the area, shaving when needed with an electric shaver, and final prepping with an applied iodine or chlorhexidine surgical prep. Plastic barrier drapes impregnated with iodine or chlorhexidine applied over the incision and introducer insertion areas will reduce local skin bacterial contamination. Appropriate draping of the patient and equipment including the C-arm is important.

Adherence to strict aseptic techniques by all personnel is critical to reducing infections. All room personnel must wear clothing appropriate for an operating room environment with surgical masks and hair caps. As in all implant surgeries, minimizing the handling of the sterile implanted devices lessens the chance of contamination. Liberal antibiotic irrigation may reduce the incidence of infection. Electrocautery is cautiously used by many implanters during the permanent implant process. Never cauterize near the introducer needle because severe shock and damage to the spinal cord may occur. Avoid cauterizing near any component leads or wires because the current may be transmitted down the wire and shock or damage neural structures. Heat from cautery will damage leads, extensions, and other components possibly causing failure. Cautery current has the potential to damage the electronic components of implanted pulse generators. Some implanters prefer using bipolar cautery to mitigate, but not eliminate, cautery risks. Heat from cautery damages surrounding tissues, which must go through a healing process. Increased seroma formation, wound healing complications, and infections are noted with excessive cautery usage.

Good surgical techniques, with proper wound closures in layers when needed, will reduce wound-healing complications. Additionally, local skin flaps when needed, creation of a generous IPG pocket, and closure of deeper fascial planes will help reduce tension across wound closures, thereby lessening wound healing complications. The use of absorbable suture in deeper layers is typical. A less reactive suture material such as PDS II (polydioxanone) may reduce the incidence of stitch abscess and superficial wound complications. Final skin closure with staples, nylon, or tissue glue such as DERMABOND adhesive may also provide an added level of skin approximation. Unlike nonimplant surgical procedures, superficial skin infections and wound healing complications may lead to involvement of deeper layers, exposing the implanted devices to infection. When deeper layers of the back incision or the pocket become infected, very often the entire system must be explanted to appropriately treat the infection.

**Trial Process Considerations**

The implantation of electrodes on a trial basis offers the patient, caregivers, and managing physician an opportunity to evaluate the effects of spinal cord stimulation prior to permanent implant consideration. Meaningful application and evaluation of the trial process is a combination of patient expectations, physician and staff experience, proper lead placement, programming of the electrode array, and careful evaluation of the stated results.

As with many therapies, there is a substantial placebo response which must be considered when evaluating patient response to a trial of spinal cord stimulation. Concordant paresthesia generated over the area of pain, which is reported by the patient to significantly reduce pain perception, is the goal of the trial. The length of time the trial leads remain implanted varies among practitioners and mitigating issues such as the need for anticoagulation medications and immune status. Most generally, the trial period should be long enough to allow the patient to use the stimulator while engaging in their usual activities of daily living. Typically, the trial duration is 5 to 14 days. Some practices occasionally use an “on the table” trial where the system is permanently implanted if the patient reports good relief with initial lead placement. This practice is most appropriate in situations where percutaneous lead placement is not possible and a laminotomy is required. An experienced implantor assesses the reported paresthesia and considers the risks and benefits of immediately implanting the permanent system. Permanent implantation of a laminotomy lead connected to an extension passed through the skin and attached to a trial generator has been used. An IPG and new extension can later be implanted if the trial is successful.

Long-term success of spinal cord stimulation cannot be completely predicted by the trial process. Positive placebo response with a trial implant can lead to poor permanent implant results. A positive placebo benefit will lessen over time and may account for many early nonimplant-related failures that appeared to have initially functioned well. If the trial protocol requires a very high reported level of benefit before a permanent implant is offered, improved long-term success would generally be expected. For example, patients who report only a 40% reduction in pain may be experiencing significant placebo response, and may not be the best candidates for permanent implantation. Factors to consider in
the determination as to the effectiveness of the trial would include reported effects such as increase in activities of daily living; reduction in oral pain medication usage; family members reporting improvement in activities and mood; improved sleep pattern; and a reported decrease in level of pain during activities and at rest.

Unfortunately, even in the best of circumstances, placebo response cannot be completely controlled. Some permanent implantations will not be successful and will rapidly lose effectiveness secondary to waning placebo response. Keeping the expected level of benefit from the trial high and the duration long will help mitigate placebo response. However, consideration should be given that by using a strict protocol requiring a very high level of relief during the trial (i.e., greater than 80%), some patients will be denied spinal cord stimulation that could otherwise benefit.

The trial process has great impact on an individual patient and is the patient’s critical opportunity to gather information to make an informed decision whether to continue to permanent implant. Considerable care must be given to this very important process. Preprocedure education, expert psychological evaluation, and careful discussion with all concerned regarding the process and expectations will help reduce disappointment and failure. Poor lead placement and/or programming that fails to provide optimal paresthesia coverage is not acceptable and will doom the trial from the beginning. For the patient’s benefit, effort must be given to provide as good a trial as is reasonably practical.

Percutaneous trial leads are placed through needle type introducers inserted through the skin. Lead location is adjusted based on the patient’s reported paresthesia when the lead is connected to a trial generator. The trial leads may be secured using various techniques. Figures 41-5, 41-6, and 41-7 demonstrate one method whereby the leads are sutured to the skin with 0-silk, tincture of benzoin applied and Steri-Strips are placed to create a loop of lead to act as a strain relief. A 4 × 4 dressing is applied and secured with wide 3M Medipore H tape. The trialing cable is also secured with tape to reduce stress at the lead cable connection.

In the recovery area, final adjustments are made to the trial generator parameters when needed, and instructions are given to the patient and caregivers. Although use of the trial generator is straightforward, considerable time may be needed to assure and instruct the patient and caregivers in its use. The patient is most frequently discharged to home and given instructions including a contact number to call when questions arise. Patients are cautioned against twisting and bending movements which might cause the leads to move from their implanted location. However, the patient is encouraged to engage in usual activities of daily living as practical to best assess the stimulator’s effectiveness. Although a reduction in pain medication requirements is one indication of effectiveness, if pain medication is abruptly discontinued during the trial implant, confusion may arise as to effectiveness. Patients are asked not to get the dressings wet and to contact the physician for any dressing changes that may be needed.

After completion of the trial, the patient and caregivers are questioned regarding perceived benefits, and if a pain diary was kept, it is reviewed. The percutaneous trial leads are most generally removed by gentle traction on the lead with the patient in a slightly flexed sitting position. If unusually severe or radicular pain
is experienced when attempting removal, the patient is repositioned prior to further attempts.

A successful trial is defined differently by various physicians. Most physicians consider at least a 50% reduction in pain, improvement in activities of daily living, and some medication reduction to be important. The determination to proceed with permanent implant may best be delayed for several days following removal of the trial. This period without the SCS effect allows time for comparison and gives the patient and physician additional information. It is important that the patient, family members, and medical teams have reasonable long-term expectations. Clear understanding of the surgical implant process including short and long-term risks as well as postimplant requirements is important. The patient is made aware of the possible need for further surgeries for lead revision, equipment failure, and eventual IPG replacement.

**Percutaneous Lead Placement**

Lead placement whether for trial or permanent system implantation is preformed using minimal, if any, conscious sedation with appropriate amounts of local anesthetic. Moderate or heavy sedation is discouraged to lessen complications associated with introducer placement and lead advancement. Reported paresthesia location, quality, and benefit by overly sedated patients are suspect and difficult to interpret. Paresthesia qualities will often change as the level of sedation lessens. Clear verbal communication with the patient is critical during the lead placement process. Lingering sedation given for local infiltration, incision, introducer placement, and lead advancement can significantly affect the patient’s perception and reported paresthesia. Reassuring words along with slow infiltration of reasonable quantities of local anesthetic solutions into the appropriate region will greatly reduce sedation requirements. In permanent implantation, when the leads are anchored and trialed to ensure an appropriate stimulation pattern, patient communication becomes less important and increased sedation, if needed, can be given.

Percutaneous leads are inserted through a specially designed large-bore (approximately 14 gauge) introducer needle. These introducers allow leads to emerge from the tip, to be advanced and carefully manipulated during the placement process. Leads can be damaged and even sheared while withdrawing through the introducer. When there is resistance to withdrawal, slight advancement and rotating the lead may allow the lead to be successfully withdrawn. When there is concern that damage to the lead may occur, removal of the introducer and lead together with subsequent reinsertion of the introducer is indicated. For lumbar radicular pain, the expected region of the spinal cord best stimulated typically will reside between the sixth and eleventh thoracic vertebral level. Needle entry would be at T12-L1 or L1-2 when practical. Motion within lower lumbar segments may increase lead failures such as fracture and dislodgment. For cervical lead placement, introducer insertion at C7-T1 or below is best—again due to motion and typically a more generous epidural space. Cervical lead tips are positioned somewhere below the C2 level.

The spinal area being considered for placement of the introducer needle is imaged most generally with C-arm fluoroscopy. The C-arm is adjusted in oblique and tilted projections to provide an optimal view of the intended entry interspace. Inspection of the interspace may reveal boney changes that could make introducer placement or subsequent lead advancement difficult. Often, declining the fluoro beam to more closely match the needle entry angle can demonstrate obstruction or anatomic variations. Paramedian insertion of the introducer needle is preferred starting approximately one spinal level below. The entry angle of the introducer relative to the spine should be approximately 45 degrees when practical to allow for the lead to optimally emerge from the tip. This angle also improves the ability to “steer” or to control the lead tip as it is advanced. The introducer tip target is slightly ipsilateral and below the spinous process. Figure 41-8 shows a left paramedian introducer placement at T12-L1. Air or saline loss of resistance technique is most often used along with anterior-posterior and lateral fluoroscopy imaging as the needle is advanced to identify the epidural space. Nonionic contrast may also be employed if needed to help confirm epidural space placement.

Most introducer placements are at spinal levels where the spinal cord is present. Great care is exercised to have exacting needle control as the introducer is advanced so as not to cause damage to the spinal cord. Figure 41-9 demonstrates one technique of holding the syringe and needle. Notice the operator’s left thumb and index fingers grasping the needle at the skin level while the right hand gently “bounces” the syringe plunger providing pressure for the loss of resistance. The introducer is advanced only by the fingers pinching the needle while the right hand assists in directing the introducer. Using this technique, the introducer is less likely to be accidentally advanced into the dural space possibly causing spinal cord or nerve root injury.

Once the introducer is in place, an electrode or lead is inserted through it and advanced staying midline or slightly off midline to a level above the expected final implant level. When practical, it is best that the electrode emerge from the introducer directly cephalad and not angled to either side. Fig. 41-10 demonstrates the lead emerging from the introducer directed cephalad. Lumbar and thoracic leads can easily stray laterally when advanced and pass laterally and then into the anterior epidural space where paresthesia is not pleasant. Depending on implanter experience and.

**Figure 41-8** Proper introducer placement using a left paramedian approach at the T12-L1 interspace. This patient has a fusion of L3 and below.
the desired paresthesia, the lead may be placed directly midline or slightly off midline.

Once the lead is initially placed, it is connected to a trial generator using a cable passed from the sterile field. Some of the lead contacts are selected, for example, three in the middle portion on an eight contact electrode, in a +,−,+ configuration. The power is increased on the trial generator until the patient reports tingling or paresthesia, which they are asked to describe. The lead is slowly withdrawn while the patient reports changes in the quality and location of the paresthesia. If in this process a very good paresthesia is obtained, which the patient assuredly reports to be beneficial, the lead may be left at that location. When the lead is withdrawn to a spinal level at which useful paresthesia is no longer reported, the lead is advanced back into a position where the most optimal paresthesia was reported. These position adjustments are made slowly and in cooperation with the person controlling the trial generator to minimize unpleasant or very strong stimulation. This “trolling” technique can reduce the number of adjustments required for optimal final lead placement. Trial generator parameters may be adjusted as needed to improve paresthesia coverage, but fine-tuning of the parameters for optimal coverage is generally undertaken at a later time. Generator parameters include pulse width, frequency, power (voltage or current), and lead contact configuration (each contact can be set to +, −, or off).

If on initial trialing, the patient reports a sharp biting pain at a very low power setting, the lead may be intrathecal. The lead is withdrawn and an attempt may be made to reinsert at this or a different level. On occasion, CSF in the epidural space from a dural puncture by the introducer may make trialing the lead difficult because the CSF interferes with the conductance. In this situation, the procedure is best abandoned and again tried at a later date. If the lead is being placed in the thoracic region, and the patient reports sharp pain within the chest wall or abdomen, the lead may be in the anterior epidural space or lateral in the posterior epidural space stimulating the nerve roots. A lateral fluoroscopic image is often useful in diagnosing these placements. Stimulation of the ligamentum flavum may be reported as a sharp or biting posterior sensation as the power is increased. Repositioning of the lead may reduce this undesired stimulation. Implantation of laminotomy leads in lieu of percutaneous leads is thought to reduce this ligamentum stimulation.

Many implanters repeat this lead implantation process with additional leads to provide optimal paresthesia coverage and afford more programming flexibility. With changes in pain patterns, electrode movement, and scar formation, reprogramming with multiple contacts is generally more successful. Two percutaneous leads are generally placed in this fashion to provide an electric field across the spinal cord. Occasionally, three electrodes are implanted and are thought to possibly offer some advantage from a “tri-pole” electrical field. Fig. 41-11 is an AP radiograph showing

Figure 41-9 Exact needle control during introducer placement. Advancing only with the left thumb and index finger.

Figure 41-10 Lead emerging from introducer directed cephalad slightly left of midline.

Figure 41-11 Anteroposterior (AP) radiograph of a dual percutaneous lead array prior to introducer removal.
the electrode positions following trialing but before the introducers were removed and Figure 41-12 shows a lateral projection of the same leads after one introducer was removed.

The epidural space contains nerve roots, fat, connective tissue, lymphatics, venous vessels, and small arteries. These small arteries supply posterior spinal structures and do not supply the spinal cord. Tissue adhesions within the epidural space may make passage of the electrode more difficult. When a patient is in the prone position, contact between the ligamentum flavum and the dura may be less consistent. Tissues contained within the epidural space may reduce effective contact between the dura and the electrode. Often stimulation is stronger when the patient lies supine owing to improved electrode contact and the spinal cord’s posterior movement secondary to gravity.

**Surgical Implantation of Percutaneously Placed Leads**

When permanent percutaneous leads are placed, a midline incision at the expected lead implant spinal level may be made prior to placing the needle introducer(s). The advantage of this technique is that good exposure of the spine and hemostasis using cautery can more easily be accomplished prior to introducer placement. The disadvantage is that the incision may need to be extended when placement at the expected level cannot be accomplished or when a more lateral introducer insertion is required. Incisions may be made following placement of the leads through the skin. If the leads are placed in a bilateral paramedian approach, the incision is made between them. If they are placed on the same side, the incision is made alongside both introducers. Some implanters make a separate incision at each introducer location. When making two or more incisions, consideration must be given to wound healing complications owing to impaired blood supply to the skin areas between incisions. The dissection is made to the fascia overlying the spinous process and developed as needed for exposure. Dissection to the entry point of the introducer into the spinal fascia or ligament is required when the leads are placed percutaneously prior to incision. Following careful removal of the needle, the lead is drawn back-wards through the skin puncture into the incision and anchored. When the incision is made prior to introducer placement, cautery may be used before introducer placement.

Lead movement from the initial implant location is the most common cause of lead failure. This typically arises from failure at the anchor. Leads can move laterally or medially without failure at the anchor site. Device companies have made good progress in developing new anchors that securely hold the lead with minimal circumferential pressure. Proper use of anchors, referencing manufacturer technique recommendations, and suturing to appropriate structures are critical to long- and short-term success. The anchor is generally sutured along the posterior lateral aspect of the spine, such that the leads are not sharply bent. This reduces stress points that can cause failure of the internal wires. Anchors are applied as close as practical to the point where the lead enters the interspinal ligament or fascia. Figure 41-13 shows an anchor sutured at each end and a tie being passed around the anchor to apply circumferential pressure securing the lead to the anchor. Leads may pull back with spinal flexion-extension movement and emerge between the fascia entry point and the anchor, especially if this distance is great. A nonabsorbable, purse-string suture placed around the introducer needle prior to removal and tightened after final verification of lead position may reduce this complication.

Stress points along the leads are reduced by providing room for them to coil and to lie flat within tissue planes. Generally, a flap of skin or deeper tissue is developed in the inferior aspect of the incision to allow the lead to curl in this area and provide strain relief.

**Permanent Laminotomy Lead Implantation**

Laminotomy or surgical leads are also referred to as *paddle leads* because of their shape. A laminotomy or laminectomy is generally required to provide enough room for insertion into the epidural space. Electrode contacts reside on the surface toward the spine and are, therefore, insulated on the posterior surface. Generated electric fields with these leads are unidirectional toward the dura and spinal cord. The posterior surface against the ligamentum flavum
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is insulated, so stimulation of the ligament is unlikely. These leads tend to be more efficient and require less power to produce paresthesia. Current laminotomy leads have 4 to 16 contacts arranged in various configurations of contact size, spacing, and orientation. It is likely that their larger size makes them less prone to movement when implanted.

The placement of paddle electrodes may be accomplished using minimally invasive spinal retractors and access systems or via a traditional open laminotomy. Figure 41-14 shows a laminotomy lead being implanted using a minimally invasive technique. To confirm useful concordant paresthesia, the patient is questioned during trial stimulation whenever a lead array is being implanted. Intraoperative questioning requires the laminotomy be performed using spinal or epidural block and local anesthesia infiltration with sedation when required. Spinal and epidural block anesthesia along with local anesthesia infiltration can be used when correct paresthesia reported. The location of optimal laminotomy lead placement can often be well approximated by a previously performed percutaneous trial. When the laminotomy lead is placed under general anesthesia at the level as determined by the trial, a risk is taken that, upon patient awakening, less than optimal coverage will be afforded. Figure 41-15 shows a tripole laminotomy lead implanted slightly right of midline.

Radiation Safety

Considerable radiation exposure may be had by the implanting physician during introducer placement and lead manipulation. This is especially true during the early phases of learning. Techniques used to reduce radiation exposure include using a modern C-arm fluoroscopy machine in the pulse and low-dose modes when appropriate; using collimation to view only those areas needed to be imaged; using AP imaging with the x-ray source under the patient; keeping hands out of the x-ray beam; positioning the image so that the area of interest is at the bottom of the image screen; lowering the image intensifier as practical; and proper lead shielding of the surgeon. Proper lead shielding includes leaded goggles to protect the eyes; thyroid shield; full lead apron; and lead batons hanging from the side of the table. A piece of lead sheeting may be fashioned to provide an area of minimal radiation to protect the hands. This shield is sterilized and laid over the drapes. All these maneuvers play a role in reducing lifetime radiation exposure. With practice and experience, typically radiation exposure becomes much less. Figure 41-16 shows fluoroscopy positioning, lead apron, thyroid shield, lead eye protection, and the use of a sheet of lead to protect the hands. Some of these efforts will also reduce radiation exposure to the patient.

Pocket Creation and IPG Implantation

After placement of the epidural lead array, a subcutaneous area or pocket is created to accommodate an IPG. Following infiltration of the proposed pocket area with local anesthetic containing epinephrine to reduce bleeding, a horizontal incision is made to the subcutaneous fat layer. Blunt finger dissection and electrocautery is used inferior to the incision to develop a pocket. Pockets are most often
developed in the upper buttocks just lateral to the upper sacrum. This area typically is below the belt line and pressure against a chair is minimal. Smaller power sources may allow for a suitable pocket to be developed adjacent to the lead implant spinal incision. Recharging may be more difficult with the IPG in these areas and should be considered when planning pocket location. Other IPG pocket sites include the abdomen or infraaxillary region. Placement under muscle or a fascial layer may be needed in extremely thin patients.

The pocket is usually developed inferior or below the incision such that the incision does not overlie the IPG. Rechargeable IPG pockets are best created under less subcutaneous tissue to reduce the distance between the IPG device and the recharging coil placed over it. Device company recommendations are followed in regard to pocket configuration and depth. If a non-rechargeable device is implanted, pocket depth can generally be greater—but not so great as to make communicating with it difficult.

A tunneling device is inserted through the subcutaneous tissues and passed between the pocket and the spine incision. The leads or lead extensions when required are passed or drawn into the pocket. Figure 41-17 shows tunneling between the spinal incision site and the IPG pocket. Connections are carefully dried and secured to the IPG using a special tool.

Most IPGs have two suture holes along the upper edge where nonabsorbable sutures are used to secure the IPG to a fascial plane. These sutures keep the IPG from turning in the pocket. Rotation and movement of the IPG in the pocket over time will stress the lead wires causing fracture and lead dislodgement. These sutures are best placed through a deep fascia layer and tied with 2 to 3 cm of slack. Figure 41-18 shows the IPG with silk sutures being placed. Figure 41-19 shows how placing an instrument into the loop of tie will allow the knots to be tied tightly while leaving slack in the loops to reduce failure. If these sutures are tied tightly, they tend to “saw” through the tissues over time and fail. The spinal incision and the pocket are closed with absorbable sutures in layers when appropriate.

**Postoperative Measures**

Postoperative instructions include antibiotic coverage, dressing changes, wound care, pain medications, symptoms and signs for the patient to be vigilant of and for which the physician should be notified. For trial placements, the dressing may be left in place until the trial leads are removed. If a trial lead dressing becomes soiled or wet, dressing change by the physician or staff would reduce incidence of damage or lead dislodgement.

After surgical interventions, including permanent implants, system removal or revisions, dry gauze type dressings taped in place with nonplastic tape works well. Over time, occlusive dressings may hold moisture and become sites for bacterial entry. Patients implanted with permanent devices are instructed not to get the dressing wet; no soaking in water for a period of at least four weeks is recommended. Wrapping plastic kitchen wrap circumferentially around the low abdominal and midback regions will allow patients to shower without compromising the dressing. Otherwise, sponge bathing may be best. If the dressing becomes wet or soiled, it is to be changed. Wounds are cleansed only with mild soap and water or dilute hydrogen peroxide. Antibiotic ointments are avoided as this may introduce ointment into deep layers, impairing skin approximation and healing.

Antibiotics are provided during the trial period and after permanent system implantation or revision according to the implanting physician’s experience, patient needs, and type of surgery. For the average-sized adult, an antibiotic such as Keflex (cephalexin), 500 mg PO, q 6 to 8 hours unless patient is allergic or allergic to a
frequency in hertz (Hz), and pulse width (microseconds) can be
may be individually programmed to positive (+), negative (−), or
for a trial or for permanent implantation. Each contact on the lead
the trialing of leads. This is the case whether the lead is being placed
of a cable passed from the sterile field, is used intraoperatively for
stimulation pattern substantially changes.
are expected in permanent systems due to minor lead movements,
external and can be directly programmed. Often programming and
IPG is programmed
therof the general pain management regimen.
Activity is limited following permanent lead placements. Aggressive spine twisting and bending motions are discouraged for
6 to 8 weeks after which the leads are thought to be held in position
by scar forming around the lead in the epidural space. Trial
leads are left in place only days and during this brief period, signifi-
cant scarring of the leads will not develop. Part of the trial process,
however, is to encourage patients to engage in their usual activities.
These activities may, of course, cause leads to move from their
implanted locations and patients are counseled regarding this pos-
sibility. If trial leads move after sufﬁcient time has elapsed, such that
the patient can make a reasonable determination of effectiveness,
then the trial need not be repeated. However early lead movements
to a point where reprogramming is unable to regain paresthesia,
may necessitate repeating the trial. Patients often report signiﬁcant
increased stimulation during acceleration in automobiles owing to
improved contact and the cord moving closer to the electrodes.
Therefore patients are advised not to drive with the stimulator
powered on.

Postoperative instructions include some counseling regard-
ing possible adverse events. Epidural hematoma occurs most often
early with epidural abscess occurring somewhat later after implant
and developing more slowly.87

Programming
The trial generator and implantable pulse generator (IPG) have
multiple programmable parameters. The IPG is programmed
through the skin using a wireless device where the trial generator is
external and can be directly programmed. Often programming and
reprogramming of the IPG by the physician is assisted by a repre-
sentative of the device company or other knowledgeable staff. After
initial IPG parameter settings are programmed, future adjustments
are expected in permanent systems due to minor lead movements,
scar formation, or pain proﬁle changes. During the trial period,
reconﬁguration of the trial generator settings may be required if
stimulation pattern substantially changes.

Each device company has their individual programming sys-
tem to communicate with the IPG for this programming or repro-
gramming. A trial generator connected to the lead array by means
of a cable passed from the sterile ﬁeld, is used intraoperatively for
the trialing of leads. This is the case whether the lead is being placed
for a trial or for permanent implantation. Each contact on the lead
may be individually programmed to positive (+), negative (−), or
(off) to not be used. The voltage or current range (amplitude), pulse
frequency in hertz (Hz), and pulse width (microseconds) can be
modified to generate the most effective paresthesia. At time of this
writing, pulse generators can control as many as 16 contacts, which
when adjusted with these various parameters, can create a nearly
endless number of possible combinations. Experienced and knowl-
edgeable physician and personnel are needed to optimally program
these devices. Various electrode contact conﬁgurations along with
other parameters are selected and the power is slowly increased
while the patient reports speciﬁc paresthesia for that particular
combination. Based on the location and quality of the reported par-
esthesia, changes are made to the programming and the power is
again slowly increased. This process is repeated until the optional
coverage is reported. This process may be time consuming to opti-
mize all reasonable combinations, but with experience it is often
manageable.

Complications
As with any surgical procedure, even in the most competent of
hands, complications will and do occur. The frequency and sever-
ity of complications will vary depending on multiple factors, some
of which can be mitigated. Severe complications are rare, but can
include death, spinal cord injury, or nerve root injury that may
occur during the placement of the introducer needle and passing
the lead. Short-term complications tend to be related to, and asso-
ciated with, the implant surgical procedure.

Wound healing complications include subcutaneous infec-
tion, wound dehiscence, stitch abscess formation, and deep infec-
tions. Most infections related to the surgical implant will develop
in the ﬁrst 4 weeks following surgery. If at any time the wound
breaks down (dehisces) such that implanted components are visi-
ble, aerobic and anaerobic wound cultures must be obtained to help
guide antibiotic coverage and to determine if the wound is infected
or if mechanical factors led to the dehiscence. Typically, some skin
contamination in a dehisced wound is cultured. If the wound is
infected, most generally the system is explanted, the infection is
cleared, and the patient is later evaluated for possible reimplan-
tation. If wound dehiscence is caused by failure of the closure and the
wound is not infected as determined by cultures, surgical excision
of the affected skin margins, vigorous irrigation with antibiotic or
dilute Betadine (povidone—iodine) solution, and secondary wound
closure with PDS-type suture may be attempted. Local skin ﬂap
development will reduce the stress across an incision and lessen
the incidence of dehiscence. Figure 41-20 shows a dehisced wound
being marked for excision of the margins for secondary closure. The
cultures and Gram stain along with clinical impressions suggested
that this pocket was not infected. Abscess formation around suture
material may remain limited to the subcutaneous tissue or can
extend and enter deeper layers. When the device capsule is involved
or if the deeper layers around a lead implant site are involved, reso-
lution in the presence of the implanted devices is difficult.

Epidural Abscess and Hematoma
Prompt recognition and treatment of these potentially devastating
complications are important. Pain (out of proportion of expected)
at or below the level of the lead placement, motor or sensory loss
significantly above preimplant level, fever, and chills will prompt
concern. If suspicion exists for epidural abscess or hematoma in
the trial patient, prompt removal of the trial leads and MRI of the
spine at the appropriate spinal levels is performed. In the per-
manently implanted patient, CT of the appropriate spinal levels
and if needed CT myelography may demonstrate an abscess or
Spine hematoma with cord compression. Currently, all device manufacturers do not approve of MRI scanning at the level of the leads. Medtronic has developed a protocol under which MRI of the head region may be performed in patients with leads placed in the thoracic area. If abscess is found, prompt surgical removal of the leads and decompression of the abscess is indicated along with antibiotic coverage. Removal of the generator may also be appropriate with lead infection complication but this is variable.

Epidural hematoma is a rare but potentially devastating complication of all epidural procedures. The introducer needle can lacerate epidural vessels and the passing of a lead out of the needle with subsequent manipulation of the lead during placement can traumatize vessels. Surgical paddle lead placement also has potential for vascular damage and bleeding. The incident of bleeding and subsequent hematoma formation would be expected to be greater in patients with delayed clotting. This complication would be expected to develop within hours of implant but may develop days later. Physical examination and CT or CT myelography most often lead to proper diagnosis. In evaluating patients with trial leads, removal of the trial leads and MRI is appropriate. Prompt neurosurgical decompression of the hematoma regions may significantly improve outcome.

**Lead Dislodgement**
Most commonly called lead migration is the displacement of a lead from its initial implant location. This complication occurs most often within the first 6 weeks after implant. Meticulous lead anchoring technique, lead location, and anchoring the lead with the lead under minimal stress will lessen the rate of lead dislodgement. Newer anchoring devices from the device companies will likely reduce the incidence of this complication. Movement of trial leads results in less-than-optimal data and may require repeating the trial. If trial or permanent leads have moved a minimal amount, reprogramming may be able to adjust for the changes. If reprogramming of a lead array is unable to recapture the desired paresthesia, often surgical lead revision is required. With trial leads, the trial may need to be repeated depending on sufficiency of data prior to lead movement.

**Tunneling Damage**
Damage to structures from tunneling can occur and would be expected more frequently when connecting cervical electrodes with generators located in the upper buttocks. The long tunneling distance and possible loss of positive control of the tip of the tunneling device may result in perforation of nearby structures. Pleural cavity and intrabdominal penetration as well as injury to vascular and neural structures is possible. Intrabdominal penetration is greater when the generator is placed in the anterior abdominal area requiring tunneling around the flank.

**Pain at the Pocket Site**
Chronic pain may develop within IPG pockets. Most often this pain is secondary to cutaneous nerve irritation at the outer margins of the pocket. Extending the pocket size 1 to 2 cm beyond the edge of the IPG dimensions during development of the pocket may reduce this unpleasant complication. Locating the IPG over bone may result in pressure pain over the periosteum. Over several months, a dense capsule surrounding the IPG may develop in some patients and become painful. Breaks in the insulation of leads or extension cables can cause a focal sharp burning pain when the stimulator is turned on.

**Conclusion**
The efficacy of stimulating the dorsal spinal cord with epidurally placed electrodes is well documented in helping to control severe chronic pain from multiple sources. When appropriately applied in the overall management of selected pain conditions, long-term pain reduction and quality of life improvements can be realized. As clinical and laboratory research efforts continue along with device improvements, these devices are expected to become even more useful. As anchoring and other device technologies improve and physician surgical training and experience improve, overall complication rate is expected to diminish.

**Intrathecal Pumps**
Implanted intrathecal drug infusion uses either an electric powered and programmable pump or a pressure infused delivery device. Both devices are connected to an implanted intrathecal catheter. The drug reservoir is contained within the pump and is periodically refilled by inserting a special non-coring needle through the skin into a port located within the middle portion of the pump body. Continuous intrathecal infusion of medications offers unique advantages in the management of severe spasticity as well as chronic severe malignant and nonmalignant pain.88-93

With intrathecal delivery, drugs are deposited within the CNS more directly to target receptors in the spinal cord and, to some extent, the brain. Intrathecal delivery bypasses gut or transdermal absorption limitations and first-pass drug metabolism. Because intrathecal delivery circumvents the blood brain barrier that affects
the distribution of medications into the central nervous system, much smaller doses of medications are needed to afford the desired benefits. In addition, fewer cerebral and peripheral effects are generally experienced. These benefits come at the price of system complexity, risks, and required refills.

**Indications and Patient Selection**

Implanted intrathecal drug infusion may be indicated for pain and spasticity with considerable overlap between the two groups. Spasticity arising from head and spinal cord injury, cerebral vascular accident, anoxic brain injury, drug or toxic CNS insults, or demyelinating conditions such as muscular sclerosis all have shown favorable response to intrathecal baclofen therapy. When spasticity is not well managed with oral medications or botulinum toxin injections, consideration may be given to implanted intrathecal baclofen infusion as a treatment adjunct.

Most patients being considered for intrathecal drug infusion are being treated with other medications and therapies that have not been adequate or have led to undesirable side effects or complications. These patients are often challenging in their overall medical management and psychological and social needs.

Patients suffering with chronic severe pain that is not well managed with oral or transdermal medications owing to medication side effects may also be offered an intrathecal drug trial and considered for system implantation if effective. Narcotic side effects tend to be less with continuous intrathecal administration compared to other methods of administration.94

**Contraindication**

Contraindications for implantation are the following: known allergy to any of the infused drugs; systemic and local infections at the proposed implant location; cachectic and severely debilitated patient not having suitable body mass; those on anticoagulant medications that cannot be stopped for placement of the intrathecal catheter; those patients very near end of life; and patients not showing a suitable response to the intrathecal trial.

**Pump Medications**

Currently the Food and Drug Administration (FDA) has approved morphine, baclofen, and ziconotide for intrathecal administration. These medications are commercially available in preservative-free formulations and are of sufficient concentration to be used alone or in combination. Many practitioners employ the services of an experienced compounding pharmacy to formulate mixtures of these and other medications that are not commercially available.95,96 Medications and mixtures not FDA approved are considered “off label” usage. Compounding pharmacies adhere to strict guidelines and test for sterility, potency, and pH, and they provide valuable feedback relating to the various medications being compounded. Considerations regarding drug concentrations, solubility, compatibility, and stability are important, and consultation with the compounding pharmacist is a necessity.97

Medications commonly used “off label” in intrathecal infusion include hydromorphone, clonidine, bupivacaine, fentanyl, and sufentanil. Other, less frequently utilize used “off label” medications include midazolam, meperidine, ropivacaine, neostigmine, adenosine, and ketorolac. Various drug combinations may be tried to provide optimal pain and spasticity control. Which drug or drugs to consider is often based on physician experience and the particular type of pain being managed. With the introduction of ziconotide, some treatment algorithms have changed. The reader is encouraged to research the literature and consult other physicians who are experienced in pump management when prescribing intrathecal mixtures.98,99-103

**Types of Infusion Pumps**

Implanted intrathecal infusion pumps are of two general technologies: electronic programmable with a motor-driven roller pump; and nonprogrammable constant flow pumps. Constant flow pumps do not require a power source. They use a fixed orifice outlet from the reservoir which is held under a constant pressure by a collapsible compartment containing a gas/liquid mixture of Freon.

As of this writing, two companies manufacture the majority of implanted infusion pumps: Medtronic and Johnson & Johnson. Medtronic currently manufactures only the SynchroMed II (Fig. 41-21). This device is programmable and uses a motor-driven roller pump. Johnson & Johnson’s device, the Codman 3000, is a constant flow pump and uses constant gas pressure from a liquid/gas mixture of Freon (Fig 41-22).

The electronic programmable intrathecal infusion pumps manufactured by Medtronic (SynchroMed II) are the most commonly implanted infusion devices for pain and spasticity in the United States. Medtronic pumps are currently manufactured in 20 mL or 40 mL capacities with a catheter access port. Older generation programmable Medtronic pumps had 10 mL or 18 mL capacities with or without catheter access ports, and with or without suture loops.

Medtronic also marketed a constant flow infusion pump (IsoMed) which is not currently in production. The IsoMed pump was available in 20, 35, and 60 mL volumes, with flow rates of 0.05, 1.0, and 1.5 mL/day. The IsoMed pump carries FDA approval for morphine sulfate infusion.

Medtronic programmable infusion pumps (SynchroMed II) are FDA approved for morphine sulfate (Infumorph), baclofen (Lioresal Intrathecal) and ziconotide (Prialt). Johnson & Johnson’s Codman 3000 is FDA approved for morphine sulfate (Infumorph) and baclofen (Lioresal Intrathecal).
Intrathecal Catheters

Several different catheters are or have been marketed by Medtronic. Current catheters are either a one-piece design with the same catheter dimensions the entire length or a two-piece design wherein the intrathecal or distal segment has a smaller outside dimension than the pump or proximal segment. These two segments are spliced together at the back incision region. Figure 41-23 shows the Medtronic two-piece catheter. Both Medtronic one- and two-piece catheters have the same internal diameter and a catheter volume of 0.0022 mL/cm of length. Both catheters have a radiopaque tip and six side holes near the tip. Each design has advantages and disadvantages and implanter preference generally dictates which is used.

The Johnson & Johnson Codman offers the Flextip Plus catheter which is a 19 gauge one-piece design with a titanium-reinforced inner coil to resist kinking.

Direct access to the catheter is occasionally useful in the management of intrathecal infusion devices. Generally with the SynchroMed II programmable pump, the port aids in the diagnosis of pump system failure and is accessed at a location near the catheter connector. Access to the catheter with the Codman constant flow pump is by way of a specially designed needle inserted through the access port. With the Codman pump, this port may be used for bolus administration, but with intrathecal placement it may also be aspirated. Bolus delivery using the SynchroMed II can be accomplished by programming, and bolus through the access port is generally not needed unless diagnostic testing is being undertaken. These catheter access ports are unfiltered and solutions are injected directly intrathecally. When accessing the catheter port, care is taken to avoid accidental overdose by injecting the contents of the catheter. A catheter may contain approximately 0.19 mL of solution. If, for example, the pump medication is baclofen 2000 mcg per mL, then there is 380 mcg of baclofen in the catheter (2000 micrograms times 0.19 mL). This, injected as a bolus, is often an overdose.

Integral to all the implanted pumps is a submicron (.22 micron) bacterial filter. This filters the infused solution prior to entering the intrathecal catheter and reduces the risk of bacterial contaminated reservoir solutions being infused.

The Codman 3000 constant flow pump has no batteries and can function for prolonged periods. SynchroMed II pumps generally function 4 to 8 years before battery depletion, depending on infusion rate. The battery is sealed within the pump and cannot be replaced. Changing the battery requires removal with replacement of the pump. Near the end of battery life, the pump will indicate this condition when it is interrogated during refill. An audible tone from the pump can also be set to sound when the near end of battery life condition occurs. When end of battery life is indicated, it is advised to replace the pump prior to complete failure, which generally occurs within 4 weeks.

Preimplant Considerations

A wide range of patients are considered for intrathecal drug delivery, including pediatric patients for intrathecal baclofen. Extremes of health are encountered in the malignant pain population, many times undergoing concurrent radiation and chemotherapy. Each group will have specific needs and considerations. Varied issues arise when dealing with these diverse patient groups.

Close collaboration with managing neurologists, oncologists, internists, surgeons, and other health care providers and the patient’s support network is important for successful long-term outcomes. Careful discussion with the patient and care providers regarding the implant process, ongoing refill needs, and issues relating to catheter failure and other possible complications is required.

Patients with ongoing infections, bleeding dyscrasia or prolonged bleeding secondary to antplatelet medications or chemotherapy are closely evaluated. Body mass is important when considering pump size and pocket location.

Drug Trial

Trialing intrathecal medications prior to system implant is useful and often required by payers. Baclofen is most often trialed as a single intrathecal dose of 50 to 100 mcg injected into the spinal fluid at the lower lumbar spine. If adequate benefit is not obtained with a
changes to the definitions to increase the sensitivity. This is known added a “grade 1+” to make a six-point scale and made minor lower extremity spasm may do worse with some ADLs such as pain score, and changes in activities of daily living. Patients with period such as frequency of spasms, increased range of motion, in either score. Other factors may also be assessed during this trial is most often performed by experienced physical therapy practitio- ners prior to and at 30 minutes, 2, 4, and 6 hours after injection. This assists in documenting the patient’s response. The Ashworth Scale is a five-point scale (0, 1, 2, 3, or 4). Bohannon and Smith added a “grade 1+” to make a six-point scale and made minor changes to the definitions to increase the sensitivity. This is known as the Modified Ashworth Scale. Table 41-1 is a chart comparing the two Ashworth scales. A drop of at least two points is desired in either score. Other factors may also be assessed during this trial period such as frequency of spasms, increased range of motion, pain score, and changes in activities of daily living. Patients with lower extremity spasm may do worse with some ADLs such as pivot transfer where they depend on leg stiffness for support. These muscles often require long-term retraining if intrathecal baclofen infusion is instigated. A baclofen trial typically requires 6 to 8 hours to complete. Often, an initial phase of good benefit is followed by a period during which the baclofen effect is maximal and the patient is to “loose”. This is followed by another period of acceptable benefit as the baclofen effect begins to resolve and the patient returns to baseline tone.

From the trial results, an estimate of a starting baclofen dose is made. However, intrathecal baclofen is most generally infused using programmable pumps, and dose adjustments are expected as the optimal dose is sought over the weeks and months after implant.

Intrathecal drug trials of narcotics and other medications may be accomplished by single injections, sequential injections, or by placement of a catheter. An intrathecal or epidural catheter may be used and a continuous infusion of medications provided over several hours to days. The dose and mixture of medications may be adjusted during this period to assist in optimizing the desired effect. A wide range of patient responses may occur and can be delayed. Close observation of these patients is generally advised. Personnel experienced in managing spinal catheters and external spinal infusion pumps are important to reduce dosing errors and the incidence of catheter infections.

Pain medication trials are subjective in that the amount of pain reduction is reported by the patient and cannot be measured. Significant placebo effect in these trials may occur and is difficult to control and factor. Most often the patient is observed for drug reactions that may indicate the trialed drug is not appropriate. Some guidance as to the initial drug infusion rate can also be determined. When using a catheter, various mixtures of medications may be trialed rapidly and serve as a guide to the initial pump mixture.

### Implant Process

Implantation of an intrathecal pump and catheter is a surgical procedure requiring a surgical environment and techniques as described in the previous section on spinal cord stimulator implant. The pump is most generally implanted in the lower quadrant of the abdominal region, and the catheter is inserted in the lower lumbar region with the catheter tip advanced to an appropriate spinal level.Previous abdominal surgical procedure scarring or the presence of a suprapubic urinary catheter or gastrostomy feeding tubes will affect the planned pocket location. With the patient lying supine, the proposed pocket skin incision location is marked. In adults, typically a transverse incision slightly larger than the pump is made at the level of the lower portion of the umbilicus. Pumps and catheters may be implanted using general endotracheal anesthesia or local anesthesia with sedation. Communication with the patient is not required during implantation. Patients may report pain if the spinal cord or nerve roots are contacted during introducer placement or catheter manipulation. If there is increased concern for spinal cord or nerve damage, local anesthesia may be preferred so that the patient may report.

Patients are placed in the lateral position padded and secured using straps and wide tape as needed. An auxillary role is placed as customary for patents in this position. It is helpful to secure the patient in such a way as to not impede access to the lower spine and abdominal region. The proposed surgical areas are prepped using Betadine or chlorhexidine scrub followed by 3M™ DuraPrep, ChloroPrep, or other appropriate surgical prep. Complete draping of the surgical areas is required including the C-arm unit. Strict aseptic surgical technique is employed.

C-arm fluoroscopy is required to verify spinal structures and level and to verify appropriate introducer placement and catheter tip location. Posteroanterior (PA) fluoroscopy imaging is initially used and the image is adjusted so that the intended insertion level is visualized in a true PA projection. The introducer is inserted below the level of the conus medullaris which is typically above

<table>
<thead>
<tr>
<th>Score</th>
<th>Ashworth Scale</th>
<th>Modified Ashworth Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No increase in tone</td>
<td>No increase in muscle tone</td>
</tr>
<tr>
<td>1</td>
<td>Slight increase in tone giving a catch when the limb is moved in flexion or extension</td>
<td>Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion (ROM) when the affected part is moved in flexion or extension</td>
</tr>
<tr>
<td>1+</td>
<td>N/A</td>
<td>Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM</td>
</tr>
<tr>
<td>2</td>
<td>More marked increase in tone but limb is easily flexed</td>
<td>More marked increase in muscle tone through most of the ROM, but affected parts are easily moved</td>
</tr>
<tr>
<td>3</td>
<td>Considerable increase in tone, passive movement is difficult</td>
<td>Considerable increase in muscle tone, passive movement is difficult</td>
</tr>
<tr>
<td>4</td>
<td>Limb is rigid in flexion or extension</td>
<td>Affected part is rigid in flexion or extension</td>
</tr>
</tbody>
</table>

*Ashworth, 1964.
L2 in adults. Figure 41-24 shows a patient in the left lateral position with the C-arm providing a PA view for placement of the intrathecal introducer. A slight paramedian introducer approach is used with as flat of an entry angle to the spine as is practical. The needle tip target is midline below the spinous process. When the introducer needle is inserted through the dura with the bevel aligned in the longitudinal axis, fewer dural fibers are cut. This may reduce the incidence of postdural puncture headache. The introducer is advanced using lateral radiographic imaging and is stopped midway in the spinal canal. Figure 41-25 shows a lateral fluoroscopy image of the introducer and catheter projecting cephalad. The bevel position of the needle is indicated on the hub and after entry into the intrathecal space is rotated to point cephalad. Brief removal of the stylet will demonstrate copious CSF flow from the needle and is quickly replaced so as not to allow a large volume of CSF to escape. This is especially important in the pediatric patient where spinal CSF volume is minimal. The catheter tip is held near the needle hub and is inserted as soon as the stylet is removed. Gentle pressure only is required to pass the catheter and advancement is observed in the PA and lateral fluoroscopy projections until the radiopaque tip is at the intended spinal level. Occasionally as the catheter emerges from the introducer tip, it touches the anterior wall of the spinal canal. If this occurs, withdrawing the introducer slightly may allow the catheter to pass. Withdrawing a catheter from the introducer can result in sheering of the catheter. When a catheter fails to advance easily, remove the introducer and catheter together. The introducer can be reinserted at the same or different spinal level.

A longitudinal incision is made against the needle and carried down to the fascia overlying the spinous processes. Blunt dissection is carried out to expose the site where the needle pierces the spinal fascia. A purse-string of nonabsorbable suture such as 0-silk is placed around the needle barrel incorporating the fascia. Figure 41-26 demonstrates a purse-string of 0-silk being placed around an introducer. The introducer is removed with the catheter stylet in place. After radiographic verification of the location of the catheter tip is made, the purse-string is tightened. When the stylet is removed, clear CSF should easily drip from the catheter. Occasionally, the CSF may require aspiration using a "Luer-Slip" tuberculin syringe at the pump connector end. A suitable anchor is slid onto the catheter and secured to the fascia with nonabsorbable suture as per manufacturer recommendations. When using a two-piece catheter, the spinal segment is typically trimmed and a protective "boot" is slid onto the spinal segment. The spinal and pump segments are connected by a titanium pin from the thicker pump segment. Care is taken when making this connection because damage to the catheter may occur causing a hole and persistent CSF leakage with loss of benefit. Using a one-piece catheter does not generally require a splice at the spine but a pump connector is attached to the end of the catheter using nonabsorbable suture.

A pocket is developed following incision of the skin at the previously marked site down to the subcutaneous fat layer. Blunt finger dissection and electrocautery is used in the subcutaneous fat tissue plane. The pocket is often placed toward midline and lower in the abdomen and pelvis. It is best to anchor pumps to the deep fascia, however, in very obese patients it may not be practical to place the pump against the abdominal fascia. In some circumstances, a pocket is developed within the subcutaneous fat layer. Pumps placed within a thick fat layer deep to the skin may be difficult to refill, are at increased risk of flipping or turning, and if
programmable, they may be hard to communicate with because of the distance.

A hollow tunneling device is passed from the back incision to the pocket if using a two-piece catheter and from the pocket to the back incision when using a one-piece catheter. The tunneling device may be bent to conform somewhat to the intended path dimensions (Fig. 41-27) Alternately, the tunneling device may be passed to an intermediate incision located in the lower flank region using two separate passes.

Nonabsorbable sutures are used to anchor the pump in the pocket. Three or four, typically 0-silk, are placed into the deep fascia and passed through corresponding suture loops. These sutures prevent the pump from rotating, flipping, and migrating laterally. The catheter connector is secured to the pump as per manufacture recommendations. The catheter is coiled and held behind the pump and they are both gently placed into the pocket making sure the sutures do not directly touch the catheter. The ends of a pair of forceps may be placed into the loop of suture prior to tying several knots to create approximately 2 cm of slack. If these sutures are tied tightly, they tend to “saw” through the tissue with pump movements. Figure 41-28 shows a pump in the pocket ready for skin closure.

A small coil of catheter is desired at the back incision to act as a strain relief. A small subcutaneous flap is developed to allow the catheter to coil in this region. Incisions are observed for bleeding and cauterized appropriately. Wounds are irrigated with antibiotic irrigation and closed in layers to reduce tension across the incision. An interrupted closure of buried knots using a minimally reactive suture such as polydioxanone (PDS) may reduce wound healing complications. This material also tends to provide a longer lasting approximation force than does polyglactin 910 (Vicryl). Skin staples, running nylon, Steri-Strips or tissue glue may also be employed. Gauze dressing is taped into place.

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**Postoperative Complications**

When wound healing complications arise at the back surgical site, there is concern with the increased opportunity for bacteria to enter the intrathecal space resulting in meningitis. Wound dehiscence may result secondary to persistent CSF leakage or seroma formation. In this situation, it may be reasonable to correct the defect and, in the uncontaminated wound, close the skin secondarily. However, if there is any indication of deep wound infection, the catheter and all components are removed; the infection is cleared, and after the area has healed, a catheter is again placed. Infected wounds where catheter components remain rarely heal by primary or secondary intention. Because of the significant increased risk of CNS infection, it is not appropriate to place an intrathecal catheter at the level of a dehisced wound until the wound is completely healed.

Pump pocket wound healing complications are reduced by proper pocket creation, local flap development when needed, and closure with minimal stress at the incision. Even superficial infections may progress to involve deeper levels and the pocket. When infection of the pocket occurs, removal of the pump and catheter is warranted. An infection of the pump pocket can tract down the catheter path and involve the catheter implant site. Some reports of successful infection treatment “salvaging” the device have been given. These efforts are undertaken by experienced implant groups with knowledge of the risks and benefits of such attempts.107-111

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**Refilling the Pump Reservoir**

The computer within the Medtronic SynchroMed II calculates the expected pump volume based on the input volume at time of refill and the programmed infusion rate. The pump does not have a volume sensor. It will continue to infuse at the programmed rate until nearly empty. At a volume below 1.0 mL the infusion becomes gradually less and at a volume below approximately 0.6 mL, the infusion stops. There is a residual 1.4 mL within the pump that cannot be aspirated or pumped out. This residual drug
may be important when drug concentration changes are made and is the reason Medtronic advises that the reservoir be rinsed with the new drug prior to refill when a significant drug concentration change is made. The infusion will continue at the set rate until the reservoir is empty regardless of the calculated volume.

The SynchroMed II has a refill port within the center of the pump and is accessed with a 22 gauge noncoring Huber needle and a catheter access port is located toward the outer edge near the pump catheter connector. The Medtronic refill port is designed for 500 accesses using the 22 gauge Huber needle. Huber needles lessen damage to the port with repeated entry. The catheter port is accessed with a 24 gauge non-coring Huber needle. Accidental injection of medication into the catheter access port and thus directly into the intrathecal space may have disastrous consequences. Therefore, the use of a standard refill “kit” containing the appropriate needles and guide template is recommended.

The Johnson & Johnson, Codman 3000 will continue to infuse until the entire contents are depleted. Refill of the Codman pump is accomplished using a similar technique and again, use of the supplies available from the manufacturer is recommended. Access to the Codman catheter for bolus administration or aspiration of CSF is accomplished using a special needle also available from the manufacturer.

**Refill Complications**

The installation of the medication into an intrathecal pump and associated programming of the programmable pumps is a major source of medical error. Most serious complications, including death, related to intrathecal drug infusion systems occur as a result of these errors. Intrathecal pumps often contain concentrated medications. If, at time of refill, the medication is accidentally injected into the pump pocket or surrounding tissues instead of the pump reservoir, serious complications may arise. When the medication is a concentrated narcotic, acute narcotic overdose will occur. Immediate supportive care should be instituted including airway management and ventilatory support as needed. Prolonged infusion of naloxone (Narcan) in an ICU may be necessary where long-term respiratory support and monitoring can be provided. A prompt attempt may be made to aspirate the misplaced drug when practical.

Accidental injection of baclofen into the pocket is of much less concern. Subcutaneously placed baclofen has minimal direct consequences except, when unrecognized; it will result in early termination of benefit. Other compounded medications accidentally placed into the pocket will have varying effects peculiar to the drug.

If pump medications require compounding, concern is given as to the accuracy of the prescription and resultant compounded medication. It behooves the managing physician to understand the complexities of compounding intrathecal medications. Solubility limits, toxicity, pH, and incompatibilities of certain mixtures are considered. Intrathecal medications are prepared by compounding pharmacies using laminar flow hoods in a sterile environment practicing impeccable technique. Well trained and knowledgeable personnel with the utmost concern for accuracy, sterility, packaging, and validation of the product by appropriate testing using chemical assays, pH and toxicity measurement, and bacterial cultures will lessen complications. The managing physician is wise to know the details of this process and the people and processes involved to provide their patients optimal care.

**Managing Patients with Intrathecal Infusion Pumps**

There is considerable variation among practices managing intrathecal drug infusion and the “art” of pump management is developed with experience. Long-term management of patients with intrathecal pumps containing narcotics is not simply to increase the dose. Continuous dose escalation of narcotics will lead to tolerance. A “hyperalgesic” state may also develop when narcotic dosage is very high. As with any delivery route, chronic high-dose narcotic administration appears to inhibit the usual pain control mechanism. A few practitioners advocate using low doses of intrathecal morphine (less than 0.5 mg/day) to avoid some of the complications associated with dose escalation.

Tolerance problems appear to be less with intrathecal baclofen and ziconotide. After attaining a stable infusion rate, dose escalation is not typically required to provide the same clinical efficacy. Infusion rates of these medications require only occasional adjustment when disease or health state changes are thought to be long term in nature.

**Infusion System Failure**

Ongoing management of patients with intrathecal infusion systems by knowledgeable health care professionals is a valuable first source of information indicating there may be a malfunction. Between refills and especially at the time of refill, patients and patient care providers report or are questioned regarding symptoms and perceived benefits. If significant changes in benefit are reported, suspicion is raised and attention is given to the possibility of a system malfunction. Multiple factors will affect medication benefit and include patient illness, physical and psychological stress, medication changes, and disease progression or remission. Patient history and past issues at times of refills are also important. These are factored together with the physician’s personal knowledge of the patient to formulate an impression regarding how to proceed.

Pump content volume discrepancy at time of refill may indicate a failure of the system to infuse the appropriate volume, indicating a catheter occlusion, or in rare situations, failure of the pump. Occasionally, lower than expected volume is found and may represent drug being diverted, internal failure of the pump, or most commonly, error at time of refill. When comparing expected pump volume and actual aspirated volume, several factors are considered. Syringe accuracy of ±5% is common. Syringe volume variance, along with differences in refill techniques, can produce significant variations when comparing actual with expected volumes. The expected pump volume is calculated by the internal computer of the programmable pumps and does not indicated actual volume. The volume expected in the Codman pump is calculated by multiplying the days of infusion by the pump infusion rate and subtracting this volume from the initial volume. Actual pump volume must be measured by aspiration of the entire reservoir contents at time of refill. This aspirated drug is discarded and not reused.

When a patient suffers a profound reduction in benefit, there are several considerations. Symptom onset shortly after refill may indicate pump programming or drug errors. The refill event is reviewed, and if the pump is programmable, it is interrogated and the programming is confirmed. Instilled medication prescription is reviewed and if compounded medication was used, the compounding pharmacy is contracted to verify the prescription and the compounded medication that was supplied. Supportive care is
instituted as indicated. This may include increased oral pain medication or oral baclofen. Patients will, on occasion, require hospitalization for parenteral antispasmodic or pain medications and on rare incidences, placement of a temporary intrathecal catheter to restart the intrathecal infusion. Often, prompt surgical correction of a catheter defect or replacement of a failed pump is best.

**Catheter Failure**

The ability to manage implanted intrathecal infusion pump and catheter system failure is important in the overall management of the patient. Most commonly, the spinal catheter fails and only in rare instances will the pump fail. Infused volume is small—as low as 0.3 mL/day in the Codman pumps and as low as 0.046 mL/day for the Medtronic SynchroMed II. Therefore, most generally, if a defect arises along the catheter, there is complete loss of benefit.

Currently manufactured catheters are difficult to kink or occlude but are susceptible to cutting or punctures. Small defects or microfractures may prevent the medication from reliably reaching the intrathecal space. Meticulous implant technique, careful anchoring of the catheter to a deep fascial layer or ligament, appropriate pocket creation, and anchoring of the pump in the pocket will help reduce catheter damage. If the distal end of a catheter is in the intrathecal space and a defect manifests along some portion of that catheter, CSF leakage most often occurs with accumulation of CSF within the area of the defect. Diagnosing the nature and location of the failure may require significant effort and medical decision making.

Plain AP and lateral radiographs of the pump and the entire catheter are useful to demonstrate if complete catheter fracture or dislodgement has occurred. Figure 41-29 shows a lateral radiograph whereon a catheter has pulled out of the intrathecal space and is coiled within the back implant region. This complication likely resulted from anchoring within the subcutaneous tissues and not at the spinal fascia. These radiographs cannot with certainty demonstrate catheter kinks or defects that do not cause complete catheter fracture.

Catheter fracture and defects most often occur at the inter-spinal ligament, at connectors or anchor sites and within the pump pocket. If indicated, a medication bolus may be programmed using a programmable pump and the patient should be observed for improvement which would suggest the catheter is intact. The catheter access port may be accessed and CSF attempted to be aspirated. If CSF is easily aspirated, nonionic contrast suitable for intrathecal administration may be injected and the flow of contrast followed and intrathecal spread confirmed. If CSF cannot be aspirated, contrast should not be injected because a bolus of medications contained within the spinal catheter segment is possible.

If contrast spread is intrathecal, then reasonable assurance is made that the catheter is continuous, but this study cannot rule out the presence of small catheter defects. With small defects, the contrast can pass down the catheter into the intrathecal space without enough contrast passing out the defect to be easily detected. In this situation, an indium DTPA In 111 study may be useful to demonstrate the defect. This nuclear medicine study uses radioactive indium DTPA 111 (0.5 to 2 mCi) placed into the pump reservoir. The pump is allowed to infuse at its usual rate and the flow of indium is documented by serial scans over a period of time depending on the pump flow rate. The indium DTPA In 111 study can be accomplished without interrupting normal medication delivery or alternately the pump contents can be emptied and the indium DTPA In 111 can be added to saline placed into the pump. Indium DTPA In 111 will collect at a site where pump contents exit the catheter. Figure 41-30 demonstrates a small collection of indium DTPA In 111 at the spinal implant site and a large amount being infused into the spinal canal. This was a very small defect and was positional. With an intact catheter the indium DTPA tracer will be seen within the spinal canal. It is useful to place a lead blank or shield over the pump to reduce the tracer count the camera sees to improve the signal-to-noise ratio. In special situations, and using great care, a very small aliquot (less than 0.05 mL) of indium DTPA has been injected directly into the catheter access port and the pump has been allowed to run at its usual rate. In doing this, the tracer is only present in the catheter which considerably reduces the background noise and provides improved resolution. The risk of this technique is that when the catheter access port is injected, contents of the catheter are displaced. This can result in significant overdosing. This technique can be useful in those situations where the catheter dye study is apparently normal but a catheter failure is still of concern. After the dye study, the catheter is free of medication and a small aliquot of indium DTPA 111 can more safely be placed into the catheter. Indium DTPA 111 half-life is 2.83 days or 67.9 hours and is predominantly excreted in the urine. Rapid appearance of counts in the kidneys and the bladder is noted after the indium DTPA exits the catheter.

Fluid accumulation at the spinal catheter insertion site or the pump pocket may indicate a CSF leak from a defect in the catheter. CSF pressure is transmitted down the catheter to the location of a defect. The flow rate from an intrathecal implanted pump is very small and if any defect along a catheter develops, CSF and pump
medications will flow out of the defect. This generally causes complete loss of benefit and often an accumulation of CSF at the site. CSF may track along the external surface of a catheter and accumulate at a distant site. Occasionally CSF leakage at the spinal insertion site or at a catheter splice or anchor in the back can track around the catheter tissue sheath and enter the pump pocket resulting in CSF collection.

Other considerations for fluid collection would include seroma and infection. Generally, seroma and CSF accumulations are not associated with redness or skin temperature elevation. Early after implant, seroma accumulation is common and generally of little consequence. Aspiration of seroma fluid is avoided because the procedure has the potential of introducing bacteria into the area. If an infection is suspected, prompt aspiration of the fluid with appropriate Gram stain and culture will help direct antibiotic care. When a deep infection is diagnosed, prompt removal of the pump and catheter is advised. Eradication of an infection in the presence of implanted devices is very difficult and in the presence of an intrathecal catheter additional risks of CNS spread are imparted.\textsuperscript{107,108,111,135-137} If a fluid collection is suspected to contain CSF, a beta-2 transferrin assay can be useful. Beta-2 transferrin is a protein found almost exclusively in the CNS and spinal fluid.\textsuperscript{138}

Persistent postural headache may arise as a result of CSF leakage around the catheter where it pierces the dura. This complication is reduced with the application of a purse-string suture placed around the introducer needle prior to its removal at time of implant.\textsuperscript{139} An x-ray-guided epidural blood patch may be helpful, understanding that this procedure carries some increased infection risk and the possibility of blood entering the intrathecal space.\textsuperscript{140,141} In persistent cases, surgical exploration of the implant area looking for possible catheter sources of the CSF leakage is recommended. This provides an opportunity to possibly witness CSF flow around the catheter where it enters the ligament or fascia. CSF leakage around the catheter may be accentuated by applying increased intrathoracic pressure by a Valsalva maneuver. On occasion, the solution is to remove the catheter, over-sew the area to close the site where the catheter pierced the ligament or fascia, and place another catheter.

Catheter dislodgement can occur if the catheter is not properly anchored to deep fascia or as a result of a traumatic event. Also, if the pump is not anchored in the pocket and it rotates, over time the catheter can coil to the extent that it pulls the entire catheter into the pocket. If the catheter remains in the spinal implant region, the back incision may be opened and that portion of catheter, along with the anchor and splices if any, is removed and a new spinal segment is implanted and spliced to the remaining pump segment. If the catheter has pulled back into the pump pocket, then the pocket is opened along with the back site with placement of a new catheter and tunneling.

When catheters fracture at the interspinal ligament, most often the fragment will migrate into the intrathecal space. Unless the fragment causes some neurologic sequela, it most frequently is left in the intrathecal space and attempts to retrieve it are not made. Antibiotic effectiveness may be reduced in CNS infections when retained fragments are present.\textsuperscript{142,143}

**Catheter Tip Inflammatory Mass**

Patients presenting with relatively sudden or unexplained decreased therapeutic response, pain, neurologic changes such as weakness and reflex changes should be evaluated for the presence of a mass at the catheter tip.\textsuperscript{144} These masses are not well understood but appear to be associated more with the infusion of highly concentrated narcotic preparations. The incidence is expected to be greater than 0.5% of all intrathecal catheters and has been reported with morphine and, to a lesser degree, with baclofen.\textsuperscript{147-151} Catheter granulomatous or inflammatory masses appear to develop over time and may compress the spinal cord. Diagnosis is best made using a high-resolution MRI scanner. Gadolinium contrast may demonstrate enhancement of the mass, suggesting its inflammatory nature. Where MRI is contraindicated or not available, CT myelography of the catheter tip region may be useful. Plain radiograph examination prior to MRI or CT is used to direct the scans to the area of most interest near the catheter tip. Scanning two spinal levels above and three levels below the catheter tip usually is sufficient. The proper management of a catheter tip mass, although debated generally, includes neurosurgical consultation. Cord compression resulting in significant neurologic compromise typically is treated by prompt neurosurgical removal of the intrathecal mass along with the catheter. When neurologic symptoms allow, pulling back the catheter to a location below the mass and changing the pump drug mixture may be enough to allow resolution.

**Conclusion**

Intrathecal drug delivery provides an opportunity to administer medication within the central nervous system very close to target receptors. When properly managed, these systems provide a long-term addition to overall successful patient management. Medications infused intrathecally have a different therapeutic profile than other delivery routes. Often greater drug efficacy is noted with fewer drug side effects. Intrathecal delivery systems are currently available and reliable but they require ongoing management and patient care decisions.

**REFERENCES**


