Intrathecal Procedures

Intrathecal Pump Catheter Study

Pump Type: Medtronic Synchromed II
Drug: ***
Total Daily Dose: ***

After confirming written and informed consent and discussing the risk, benefits and alternatives for the procedure, the patient had the correct site marked by the physician performing the procedure. The patient was taken to the procedure suite. A pulse oximeter was placed, and verbal and visual monitoring were maintained throughout the procedure.

The Intrathecal Pump was queried.

The physician's hands were cleaned with an alcohol-containing solution. A hat and mask were worn throughout the procedure. Sterile gloves were worn. The patient was placed in the supine position. The skin overlying the intrathecal pump was prepped with chlorhexidine gluconate. A sterile drape was then applied. The pump outline was assessed and palpated. Landmarks were utilized to determine its orientation.

The Medtronic catheter access kit was utilized. While employing sterile technique, a cather access needle was inserted into the catheter access port. The metal back plate was contacted. *** ml of fluid was easily aspirated from the pump. This exceeded the expected volume of the catheter, and was consistent with CSF.

*** ml of Omnipaque was injected, and a myelogram was obtained. The image was saved.

The needle was removed. A catheter priming bolus was performed. The pump was reprogrammed.

The patient was monitored, reassessed and discharged after an appropriate observatory period. No complications were noted.

Intrathecal Pump Refill

Procedure: Intrathecal Drug Administration System Analysis Refill and Reprogramming (Physician Performed)

Pump Type: Medtronic Synchromed II
Volume: *** ml

Present Pump Solution: ***
Refill Pump Solution: ***

After confirming written and informed consent and discussing the risk, benefits and alternatives for the procedure, the patient had the correct site identified by the physician performing the procedure.

The Intrathecal Pump had been queried. The new pump solution content was checked against the medical records and prescription. The anticipated residual volume was noted. The Medtronic Pump Refill Kit was utilized.

The physician's hands were cleaned with an alcohol-containing solution. A hat and mask were worn throughout the procedure. Sterile gloves were worn. The patient was placed in the supine position. The skin overlying the intrathecal pump was prepped with chlorhexidine gluconate. A sterile drape was then applied. The pump outline was assessed and palpated. Landmarks were utilized to determine its orientation.

While employing sterile technique, a 22G Huber type needle was inserted into the pump reservoir via the central access port. The metal back plate was contacted. *** ml of fluid was easily aspirated from the pump. The aspirated volume was consistent with the anticipated volume. The refill solution syringe and provider filter were connected to the refill extension. The clamp was released.

The pump was then slowly filled with the refill solution. After the first 5 ml of new drug solution was injected into the pump, aspiration was performed which revealed 2 ml of clear solution consistent with the drug solution. Aspiration was repeated after the next 10 ml of drug solution was injected, which revealed 2 ml of clear solution consistent with the drug solution. The pump pocket area shape did not change.

The needle was removed intact and a bandaid was applied. Vital signs remained stable throughout the procedure.The pump was reprogrammed by the physician to reflect the new volume and any rate changes.

The patient was monitored, reassessed and discharged after an appropriate observatory period. No complications were noted. Signs and symptoms of granuloma formation were reviewed.

Intrathecal Pump Replacement

After discussing risk, benefits and alternatives with the patient in detail, informed consent was obtained with the patient verbalizing understanding. The specific risks of bleeding and infection were discussed, as were the risks of seroma and post-dural puncture headache. The correct operative sites was then marked by the physician.

The patient was brought to the operating room. Anesthesia care was initiated by the anesthesia team. Prophylactic antibiotics were administered by the anesthesia team, specifically Ancef 2 g IV. The patient was placed in the *** position. Ample padding was provided for pressure points as well as an axillary roll. The patient position was secured by taping the patient at the lower leg, upper leg and across the chest. Each of the secured points were padded with eggcrate. The patient was prepped from hips to chest and to the table to table with chlorhexidine gluconate. The patient was then draped. A down drape was placed from the waste to the feet. A sterile laparotomy drape was then placed, with the drape opening being expanded to expose the entire operative field. Ioban was then placed over the operative field. The fluoroscopy arm was then sterilely covered. A sterile drape was then clamped to the field drapes to provide a sterile cover for the lower aspect of the fluoroscopy arm.

A formal time-out was performed involving the physician, operating room RN, anesthesia team and the physician.

Next, the pump pocket was opened in the *** lower quadrant. Approximately 10 ml of 0.25% bupivacaine were used to anesthetize the incision site and underlying tissue. A #15 blade was used to make the initial incision. Dissection with electrocautery and blunt dissection using Metzenbaum scissors and key elevators was performed down to fascia. Hemostasis was

established. The existing pump was identified and removed from the pocket. This was discarded.

Next, the new Medtronic Synchromed II pump was prepared on the back table. The factory-instilled saline was removed via the refill port, and the patient's previously prescribed compounded drug, *** , was filled into the pump.

The pump was placed in the anterior pocket and was fixed to the fascia with 2-0 silk sutures going through the pump anchor loops. Two anchor sites on the pump were secured to the underlying fascia. Satisfactory lie of the catheter was noted posterior to the pump and good CSF flow was noted by aspirating via the catheter access port.

Hemostasis was established. Each wound was closed with an interrupted layer of 2-0 Vlock, followed by a layer of 3-0 Vlock. Dermabond was placed over the wounds.

Intrathecal Pump Implant

After discussing risk, benefits and alternatives with the patient in detail, informed consent was obtained with the patient verbalizing understanding. The specific risks of bleeding and infection were discussed, as were the risks of seroma and post-dural puncture headache. The correct operative sites was then marked by the physician.

The patient was brought to the operating room. Anesthesia care was initiated by the anesthesia team. Prophylactic antibiotics were administered by the anesthesia team, specifically Ancef 2 g IV. The patient was placed in the left lateral decubitus position. Ample padding was provided for pressure points as well as an axillary roll. The patient position was secured by taping the patient at the lower leg, upper leg and across the chest. Each of the secured points were padded with eggcrate. The patient was prepped from hips to chest and to the table to table with Duraprep. The patient was then draped. A down drape was placed from the waste to the feet. A sterile laparotomy drape was then placed, with the drape opening being expanded to expose the entire operative field. Ioban was then placed over the operative field. The fluoroscopy arm was then sterilely covered. A sterile drape was then clamped to the field drapes to provide a sterile cover for the lower aspect of the fluoroscopy arm.

A formal time-out was performed involving the physician, operating room RN, anesthesia team and the physician.

Fluoroscopy was utilized to delineate the anatomy and location of the lumbar and thoracic spine. Incision lines were delineated with a sterile marker, and all landmarks were delineated. 15 ml of 0.25% bupivacaine with epinephrine were used to anesthetize the anticipated incision lines. A #15-blade was used to create an incision lateral to the spinous processes. Dissection with electrocautery, blunt dissection with Metzenbaum scissions and key elevators were used to expose the field down to fascia to prepare a satisfactory insertion site for the introducer needle. The exposed site was maintained using Weitlaner retractors.

Next, a 15G, 3.5-inch modified Tuohy needle was advanced from the inferomedial aspect of the right L3 pedicle toward the midline. Real-time fluoroscopy was utilized to advance the needle in the proper direction. The needle was directed in a right paramedian approach until it penetrated ligamentum flavum at the L2-L3 interlaminar space. The bevel tip was oriented parallel to the longitudinal fibers of the dura as the dura was penetrated. The needle bevel was then redirected in a cephalad direction after penetration of the dura. The stylet of the Tuohy needle was

removed and free-flowing CSF was obtained. Confirmation of the spinal needle placement was confirmed by both AP and lateral fluoroscopic views.

A styletted Medtronic Ascenda spinal infusion catheter was advanced in a cephalad direction within the intrathecal space via live continuous fluoroscopy, until the tip reached the T7-T8 interspace. The Tuohy needle was then retracted approximately 2 cm to remove the needle portion from the intrathecal space to reduce CSF loss. 2-0 silk suture was then used to place a pursestring suture around the needle insertion site. The needle was removed with live fluoroscopic visualization of the catheter tip. The stylet was carefully removed from the catheter using live fluoroscopic guidance to confirm the location of the catheter tip. CSF flow was noted from the catheter after removal of the stylet. Intrathecal placement was confirmed with myelogram with approximately 1 mL of Isovue 180.

The catheter was anchored to the fascia using the Medtronic anchoring system. The anchor was advanced over the catheter, then inserted through the fascia, over the catheter. 2-0 silk sutures were next anchored to the fascia, then to the anchor device. After completion of the anchoring, CSF was aspirated from the catheter confirming flow through the catheter. The wound was irrigated with bacitracin-containing solution. The pocket was then packed with gauze.

Next, the pump pocket was made created in the right lower quadrant. Approximately 10 ml of 0.25% bupivacaine were used to anesthetize the incision site and underlying tissue. A #15 blade was used to make the initial incision. Dissection with electrocautery and blunt dissection using Metzenbaum scissors and key elevators was performed down to fascia. Hemostasis was established. The pocket was fashioned in the abdominal wall, superficial to the rectus fascia. The pocket incision was placed in the superior aspect of the pocket, with pocket and pump being placed caudad to the incision. The pump was temporarily placed in the pocket for sizing.

Next, the Medtronic Synchromed II pump was prepared on the back table. The factory-instilled saline was removed via the refill port, and the patient's previously prescribed compounded drug *** was filled into the pump.

The catheter at this time was tunneled underneath the flank to reach the pump pocket, this was done utilizing a catheter tunneling device. The catheter was attached to the pump using the Medtronic sutureless connector and a pressure test was performed to confirm patency and lack of leaks. A rubber shod clamp was placed over the catheter, and an access needle was inserted into the pump. Preservative free normal saline was attempted to be injected through the catheter access port into the catheter, and no leaks were noted. The rubber shod was then removed, and saline was injected into the catheter, and CSF was aspirated through the catheter indicating the patency of the system.

The pump was placed in the anterior pocket and was fixed to the fascia with 2-0 silk sutures going through the pump anchor loops. Two anchor sites on the pump were secured to the underlying fascia. Satisfactory lie of the catheter was noted posterior to the pump and good CSF flow was noted by aspirating via the catheter access port.

Hemostasis was established. Each wound was closed with an interrupted layer of 2-0 Vlock, followed by a layer of 3-0 Vlock. Dermabond was placed over the wounds.
An abdominal binder was placed and the patient was transferred to the recovery room on a stretcher.

Kyphoplasty and Osteocool

Plan for Kyphoplasty

The patient has an *** compression fracture at ***.
Imaging was last performed ***, *** and demonstrates ongoing bone marrow edema.
The patient is symptomatic with severe limitation in mobility and activities of daily living due to a greater than 3-week history of significant axial pain.
The pain is worsened with activity and is related to movement, leading to a reluctance to move.
Patient has risk factors for vertebral body compression fractures including ***.
***A referral to the osteoporosis clinic has been placed.
The patient has failed nonsurgical management in the form of bed rest, oral analgesics including ***, and bracing.
The patient continues to have a VAS greater than 5/10 despite conservative treatment.
Their Roland Morris Disability Questionnaire is ***.

Due to the patient's persistent, severe debility and severe pain secondary to the compression fracture, we have discussed a kyphoplasty at ***.
There is no evidence of osteomyelitis, discitis or active infection.
There no relative contraindications present.

We have opted for a minimally invasive modality given the failure of conservative management.
The patient understands the elective nature of this procedure.
The patient is aware of the risk associate with the surgery which include cement embolization, trocar excursion outside of the vertebral body into vascular structures or the spinal canal.
Patient understands that the alternative to this treatment is continued conservative management.
Given the patient's declining daily function, we will pursue kyphoplasty at the affected levels.
We will do this with a general anesthesia.

Kyphoplasty

After confirming written and informed consent and discussing the risk, benefits and alternatives for the procedure, the patient had the correct site marked by the physician performing the procedure. The specific risks of bleeding, infection, vascular puncture, nerve injury and cement embolization were discussed. The patient was taken to the operating room.

General anesthesia was initiated by the anesthesia team.

A hat and mask were worn, and the hands were cleaned with an alcohol-containing solution. Sterile gloves were then worn.

The patient was then placed in the prone position. The skin overlying the thoracolumbar spine was then prepped with Duraprep. Sterile towels were placed to frame the operative field. A sterile down drape was placed over the lower extremities. A laparotomy drape was placed with the opening over the operative site. Ioban was placed over the opening. A time out was then performed involving the physician, registered nurse, radiology technician.

Fluoroscopy was then used to identify the anatomy of the thoracolumbar spine. 2 c-arms were used, to image the lateral view and AP view simultaneously. After obtaining a satisfactory image, the right *** pedicle was identified. A skin incision was made approximately 1 cm lateral to the 3 o'clock position on the pedicle, using a #15 blade. The working cannula with a diamond

stylette was used to contact the 3 o'clock position on the right pedicle. The cannula was seated in the pedicle, and advanced with the mallet using intermittent fluoroscopy. Frequent use of lateral and AP images were used to confirm proper advancement of the working cannula. Once the working cannula was seated through the posterior wall of the vertebral body, the *** was used to create a tract from the working cannula to the anterior aspect of the vertebral body. Frequent imaging was used to confirm proper advancement of the drill. After an adequate path was created, the balloon was placed to reduce the fracture. *** psi was obtained, with a total balloon volume of *** ml.

This was repeated on the left. After obtaining a satisfactory image, the left *** pedicle was identified. A skin incision was made approximately 1 cm lateral to the 9 o'clock position on the pedicle, using a #15 blade. The working cannula with a diamond stylette was used to contact the 9 o'clock position on the left pedicle. The cannula was seated in the pedicle, and advanced with the mallet using intermittent fluoroscopy. Frequent use of lateral and AP images were used to confirm proper advancement of the working cannula. Once the working cannula was seated through the posterior wall of the vertebral body, the *** was used to create a tract from the working cannula to the anterior aspect of the vertebral body. Frequent imaging was used to confirm proper advancement of the drill. After an adequate path was created, the balloon was placed to reduce the fracture. *** psi was obtained., with a total balloon volume of *** ml.

The balloons were deflated and removed. Cement was placed using frequent fluoroscopic guidance. *** ml of cement was placed through the right cannula; *** ml of cement was placed through the left cannula. No evidence of vascular uptake was noted. The cement cannula was removed, no evidence of cement tracking to the working cannula was noted. The cannula was removed. Dermabond was used to close the incision.

Kyphoplasty with Osteocool

After confirming written and informed consent and discussing the risk, benefits and alternatives for the procedure, the patient had the correct site marked by the physician performing the procedure. The specific risks of bleeding, infection, vascular puncture, nerve injury and cement embolization were discussed. The patient was taken to the operating room.

General anesthesia was initiated by the anesthesia team.

A hat and mask were worn, and the hands were cleaned with an alcohol-containing solution. Sterile gloves were then worn.

The patient was then placed in the prone position. The skin overlying the thoracolumbar spine was then prepped with Duraprep. Sterile towels were placed to frame the operative field. A sterile down drape was placed over the lower extremities. A laparotomy drape was placed with the opening over the operative site. Ioban was placed over the opening. A time out was then performed involving the physician, registered nurse, radiation technologist and anesthesia team.

Fluoroscopy was then used to identify the anatomy of the thoracolumbar spine. 2 c-arms were used, to image the lateral view and AP view simultaneously. After obtaining a satisfactory image, the right *** pedicle was identified. A skin incision was made approximately 1 cm lateral to the 3 o'clock position on the pedicle, using a #15 blade. The working cannula with a diamond stylette was used to contact the 3 o'clock position on the right pedicle. The cannula was seated in the pedicle, and advanced with the mallet using intermittent fluoroscopy. Frequent use of lateral and AP images were used to confirm proper advancement of the working cannula. Once the working cannula was seated through the posterior wall of the vertebral body, the *** was

used to create a tract from the working cannula to the anterior aspect of the vertebral body. Frequent imaging was used to confirm proper advancement of the drill.

This was repeated on the left. After obtaining a satisfactory image, the left *** pedicle was identified. A skin incision was made approximately 1 cm lateral to the 9 o'clock position on the pedicle, using a #15 blade. The working cannula with a diamond stylette was used to contact the 9 o'clock position on the left pedicle. The cannula was seated in the pedicle, and advanced with the mallet using intermittent fluoroscopy. Frequent use of lateral and AP images were used to confirm proper advancement of the working cannula. Once the working cannula was seated through the posterior wall of the vertebral body, the *** was used to create a tract from the working cannula to the anterior aspect of the vertebral body. Frequent imaging was used to confirm proper advancement of the drill.

The radiofrequency probes were then inserted. Radiofrequency ablation of the tumor was carried out for *** minutes at 60 degrees.

Fluoroscopy was then used to identify the anatomy of the thoracolumbar spine. 2 c-arms were used, to image the lateral view and AP view simultaneously. After obtaining a satisfactory image, the right *** pedicle was identified. A skin incision was made approximately 1 cm lateral to the 3 o'clock position on the pedicle, using a #15 blade. The working cannula with a diamond stylette was used to contact the 3 o'clock position on the right pedicle. The cannula was seated in the pedicle, and advanced with the mallet using intermittent fluoroscopy. Frequent use of lateral and AP images were used to confirm proper advancement of the working cannula. Once the working cannula was seated through the posterior wall of the vertebral body, the *** was used to create a tract from the working cannula to the anterior aspect of the vertebral body. Frequent imaging was used to confirm proper advancement of the drill.

This was repeated on the left. After obtaining a satisfactory image, the left *** pedicle was identified. A skin incision was made approximately 1 cm lateral to the 9 o'clock position on the pedicle, using a #15 blade. The working cannula with a diamond stylette was used to contact the 9 o'clock position on the left pedicle. The cannula was seated in the pedicle, and advanced with the mallet using intermittent fluoroscopy. Frequent use of lateral and AP images were used to confirm proper advancement of the working cannula. Once the working cannula was seated through the posterior wall of the vertebral body, the *** was used to create a tract from the working cannula to the anterior aspect of the vertebral body. Frequent imaging was used to confirm proper advancement of the drill.

The radiofrequency probes were then inserted. Radiofrequency ablation of the tumor was carried out for *** minutes at 60 degrees.

The probes were removed. Balloons were placed to reduce the fractures. *** psi for a volume of *** ml was obtained on the right at ***. *** psi for a volume of *** ml was obtained on the left at ***. ** psi for a volume of *** ml was obtained on the right at ***. ** psi for a volume of *** ml was obtained on the leftt at ***. The balloons were deflated and removed. Cement was placed using frequent fluoroscopic guidance. *** ml of cement was placed through the right cannula of ***; *** ml of cement was placed through the left cannula of ***. *** ml of cement was placed through the right cannula of ***; *** ml of cement was placed through the left cannula of ***. No evidence of vascular uptake was noted. The cement cannula was removed, no evidence of cement tracking to the working cannula was noted. The cannula was removed. Dermabond was used to close the incision.

Spinal Cord Stimulator Procedures

Plan for Spinal Cord Stimulator Trial

The patient has severe, intractable pain related to ***.
The patient has failed or had unsatisfactory functional improvement with ***from the neuropathic agent class, ***from the antidepressant class, ***for the muscle relaxant class, ***from the opioid class.
As it relates to interventional techniques, the patient failed to see benefit with ***.
The patient has been evaluated by a multidisciplinary team, including psychology.
The patient demonstrated *** improvement during the trial. ***

We will pursue a permanent spinal cord stimulator implantation.
We discussed the risk, benefits, alternatives. We discussed my very specific concerns of device infection, epidural hematoma and lead migration.
The patient is aware this is an elective procedure.
We will use *** for anesthesia.
I have prescribed Hibiclens to use the night before surgery, and the morning of surgery.
We obtained a MRSA swab today. If positive, we will prescribe mupirocin for the week prior to surgery and use vancomycin intraoperatively.
We will obtain a CBC and urinalysis the week of surgery. The patient is aware that if any infectious concerns are found, we will postpone the surgery.

Spinal Cord Stimulator Trial

Procedure: Fluoroscopically Guided Placement of Temporary Spinal Cord Stimulator Leads

Pre-op Diagnosis: 1. Chronic Pain Syndrome
2. ***

Post-op Diagnosis: Same

Anesthesia: Local anesthesia and IV moderate conscious sedation

Complications: None

After confirming written and informed consent and discussing the risk, benefits and alternatives for the procedure, the patient had the correct site marked by the physician performing the procedure. The specific risks of bleeding and infection were discussed. Intravenous access was obtained. Prophylactic antibiotics, specifically *** g, was given over 30 minutes prior to the start of the procedure. The patient was taken to the fluoroscopy suite. Standard ASA monitors including pulse oximetry were established, in addition to visual and verbal monitoring. The patient was then placed in the prone position. The skin overlying the lumbo-sacral spine was then prepped with chlorhexidine gluconate and a sterile drape was placed. A hat and mask were worn, and the hands were first cleaned with a chlorhexidine surgical scrub, then with an alcohol-containing solution. A sterile gown and sterile gloves were then worn. A time out was then performed involving the physician, radiology technician and the patient.

An antero-posterior fluoroscopic view of the lumbar spine was obtained to identify and mark the midline position of the lumbar spine. Next, the *** pedicle of the *** vertebral body was identified to be used as the skin entry site for the introducer needle. The skin overlying this pedicle and the anticipated trajectory of the introducer needle was anesthetized with approximately 10 ml of 1% lidocaine. Next, a 14 G 4 inch modified Tuohy needle was

advanced using a paramedian approach, directed towards the midline of the *** interspace using an approximate 45 degree angle. Loss of resistance with normal saline was utilized to verify penetration of the ligamentum flavum. A contralateral oblique fluoroscopic view was obtained to confirm the location of the tip of the Tuohy needle in the epidural space. Aspiration was negative for heme or CSF. The patient did not complain of pain or paresthesias during the needle placement. The stylette was then removed from the Tuohy needle, and under direct and live visualization with fluoroscopy the stimulating lead was advanced in the epidural space.

Next, this procedure was repeated in order to place a second temporary spinal cord stimulator lead. The *** pedicle of the *** vertebral body was identified to be used as the skin entry site for the introducer needle. The skin overlying this pedicle and the anticipated trajectory of the introducer needle was anesthetized with approximately 10 ml of 1% lidocaine. Next, a 14 G 4 inch modified Tuohy needle was advanced using a paramedian approach, directed towards the midline of the *** interspace using an approximate 45 degree angle. Loss of resistance with normal saline was utilized to verify penetration of the ligamentum flavum. A lateral fluoroscopic view was obtained to confirm the location of the tip of the Tuohy needle in the epidural space. Aspiration was negative for heme or CSF. The patient did not complain of pain or paresthesias during the needle placement. The stylette was then removed from the Tuohy needle, and under direct and live visualization with fluoroscopy the stimulating lead was advanced in the epidural space. Both leads were advanced in the epidural space. A lateral fluoroscopic image was taken to confirm that the leads were located in the posterior epidural space.

Using live, direct fluoroscopic guidance, the first Tuohy needle was removed leaving the stimulating lead in place. This was repeated for the second Tuohy needle using live fluoroscopic guidance. The stimulation leads were then anchored to the patient with Dermabond being placed over the puncture site, and benzoin was used to secure a Stayfix dressing to the skin.

Finally, the temporary connector was attached. The patient tolerated the procedure without difficulty and was transported to the recovery area. No complications during the procedure or recovery period were noted.

The spinal cord stimulator device representative instructed the patient on the use of the stimulator during the trial, and again explained precautions such as avoiding getting the area wet and motion limitations. The patient was reminded to notify the clinic immediately if there were any complications such as signs of infection at the needle entry site, fever, chills or increasing back or neck pain.

The patient understood the instructions and was scheduled to return for a follow up appointment to assess the efficacy of the trial. After meeting discharge criteria, the patient was discharged home with a driver.

Trial Summary:
Device Manufacturer: Medtronic
Lead Type: Vectris 8 Contact
Final Superior Location: Left Lead Top of ***, Right Lead Top of ***

Plan for Spinal Cord Stimulator Implant

The patient has severe, intractable pain related to ***.
The patient has failed or had unsatisfactory functional improvement with ***from the neuropathic agent class, ***from the antidepressant class, ***for the muscle relaxant class, ***from the opioid class.
As it relates to interventional techniques, the patient failed to see benefit with ***.
The patient has been evaluated by a multidisciplinary team, including psychology.
The patient demonstrated *** improvement during the trial. ***

We will pursue a permanent spinal cord stimulator implantation.
We discussed the risk, benefits, alternatives. We discussed my very specific concerns of device infection, epidural hematoma and lead migration.
The patient is aware this is an elective procedure.
We will use *** for anesthesia.
I have prescribed Hibiclens to use the night before surgery, and the morning of surgery.
We obtained a MRSA swab today. If positive, we will prescribe mupirocin for the week prior to surgery and use vancomycin intraoperatively.
We will obtain a CBC and urinalysis the week of surgery. The patient is aware that if any infectious concerns are found, we will postpone the surgery.

Spinal Cord Stimulator Implant

After discussing risk, benefits and alternatives with the patient in detail, informed consent was obtained with the patient verbalizing understanding. The correct operative site was then marked by the physician. The specific risks of bleeding and infection were discussed, as was the risk of seroma.

The patient was brought to the operating room. Anesthesia care was initiated by the anesthesia team. Prophylactic antibiotics were administered, specifically Ancef 2 g IV, prior to incision. The patient was placed in the prone position. Ample padding was provided for pressure points. The patient was prepped across the thoraco-lumbar spine and associated paraspinous region with Duraprep. The patient was then draped. Blue towels were used to frame the operative field. A sterile laparotomy drape was then placed, with the drape opening being expanded to expose the entire operative field. Ioban was then placed over the operative field. The fluoroscopy arm was then sterilely covered. A sterile drape was then clamped to the field drapes to provide a sterile cover for the lower aspect of the fluoroscopy arm.

A formal time-out was performed involving the radiation technologist, operating room RN, anesthesia team and the physician.

An antero-posterior fluoroscopic view of the lumbar spine was obtained to identify and mark the midline position of the lumbar spine. Next, the left pedicle of the *** vertebral body was identified to be used as the fascial entry site for the introducer needle. Incision lines were delineated with a sterile marker, and all landmarks were delineated. The skin overlying this pedicle and the anticipated trajectory of the introducer needle, and the incision line was anesthetized with approximately 10 ml of 0.5% bupivacaine. A #15-blade was used to create an incision lateral to the spinous processes. Dissection with electrocautery, blunt dissection and Metzenbaum scissions were used to expose the field down to fascia to prepare a satisfactory insertion site for the introducer needle. The exposed site was maintained using Weitlaner retractors.

Next, a 14 G 4 inch modified Tuohy needle was advanced using a paramedian approach, directed towards the midline of the *** interspace using an approximate 45 degree angle. Loss of resistance with normal saline was utilized to verify penetration of the ligamentum flavum. A lateral fluoroscopic view was obtained to confirm the location of the tip of the Tuohy needle in the epidural space. Aspiration was negative for heme or CSF. The stylette was then removed from the Tuohy needle, and under direct and live visualization with fluoroscopy the stimulating lead was advanced in the epidural space.

Next, this procedure was repeated in order to place a second spinal cord stimulator lead. The left pedicle of the *** vertebral body was identified to be used as the skin entry site for the introducer needle. Next, a 14 G 4 inch modified Tuohy needle was advanced using a paramedian approach, directed towards the midline of the *** interspace using an approximate 45 degree angle. Loss of resistance with normal saline was utilized to verify penetration of the ligamentum flavum. A lateral fluoroscopic view was obtained to confirm the location of the tip of the Tuohy needle in the epidural space. Aspiration was negative for heme or CSF. The stylette was then removed from the Tuohy needle, and under direct and live visualization with fluoroscopy the stimulating lead was advanced in the epidural space. Both leads were then advanced to the thoracic spine. A lateral fluoroscopic view was obtained confirming location of the leads in the posterior epidural space.

Next, the first lead was anchored into place using the supplied manufacturer's anchoring device. A 2-0 silk suture was secured to the anchor. The anchor was advanced over the first lead, and the anchor was inserted through the fascia. The suture was secured to the anchor, and then the anchor was secured to the fascia. Fluoroscopy was then utilized to provide final confirmation of the location of the stimulating lead. This was then repeated for the second lead. Fluoroscopy was then utilized to provide final confirmation of the location of the stimulating lead.

Next, a pocket was created over the *** buttock. The expected incision line was demarcated with a sterile marker. The skin overlying this incision and the anticipated shape of the generator pocket was anesthetized with approximately 10 ml of 0.5% bupivacaine. A #15-blade was used to create an incision. Dissection with electrocautery, blunt dissection, and Metzenbaum scissions were used to expose the field down to fascia to prepare a satisfactory insertion site for the generator. The exposed site was maintained using Weitlaner retractors.

The leads at this time was tunneled underneath the flank to reach the generator pocket, this was done utilizing a lead tunneling device. The leads were then secured to the generator. Proper contact between the leads and the generator was confirmed by the device rep. The pockets were irrigated with saline. Vancomycin powder was placed in the pockets. The generator was placed in the pocket.

Hemostasis was established and the wounds were closed with 1 layer of 2-0 Vicryl. 3-0 Monocryl was used to close the external layer. Dermabond was placed over the incisions. The patient was then transported to the recovery room.