NANS 2021

ABSTRACT POSTERS

1

Wirelessly Powered, Battery-Free Cervical & Thoracic Spinal Cord Stimulation for the Treatment of Complex Regional Pain Syndrome

Wirelessly Powered, Battery-Free Cervical and Thoracic Spinal Cord Stimulation for the treatment of Complex Regional Pain Syndrome (CRPS)

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Background

Complex Regional Pain Syndrome (CRPS) is a chronic pain condition that most often affects one limb (arm, leg, hand or foot), usually after an injury, and is believed to be caused by damage to, or malfunction of, the peripheral and central nervous system. Herpes Zoster is well known clinically to be a precipitating factor in CRPS.

Case Report

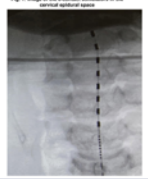
A 42-year-old female was referred to our clinic for management of her CRPS pain in the left upper extremity. She had a history of transverse myelitis, s/p multiple surgeries, including 2 intrathecal pumps and 2 SCS system (the pumps and generators eroded and were explanted because she is so thin). She suffered from herpes zoster, and she recalls waking up one morning with pain in the right arm and right leg. Her right arm became contracted. She complained of pain in the right leg from the knee down to the toes, the entire left leg, and entire right arm. She underwent ketamine infusions and stellate ganglion blocks. Other treatments included physical therapy and aquatic therapy. She denied acupuncture, chiropractor manipulation, or spinal surgery. She had previously tried gabapentin, duloxitine, and pregabulin and stated that she was allergic to all of these drugs.

Methods

Trial: The patient was implanted with two 8-electrode neurostimulators, at T9-T10 and at C2-C4 (Figure 1). Two 13G Tuohy needles were introduced percutaneously into the epidural space respectively at L2-L3 and T4-T5. Electrode arrays were inserted and positioned. The receivers were inserted and coupled to their respective electrode arrays. The trial stimulators were then secured to the skin with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

Permanent Implant: A small stab wound was made and the placement technique for the stimulators utilized in the trial was repeated utilizing two 8-contact, permanent stimulators. The steering styles were removed and receivers inserted into the inner lumen of the electrode arrays. A receiver pocket was created approximately 10 cm proximal to the first mark band, and the electrode arrays were tunneled beneath the skin to the receiver pocket. A knot was tied to permanently mate the receivers and electrode arrays. The distal portion of the stimulators were coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The patient wears the transmitter and antenna on her back. The devices were programmed with a frequency of 1499 Hz, pulse width of 30 µs, and 3.0 mA.

Fig. 1: Image of the 8-contact stimulators in the cervical epidural space



Results

The patient received a permanent system after a successful trial, and reported 80% pain relief two months after the permanent implant. The patient rates her satisfaction as 7/7; her quality of life has increased, and she now is able to sleep through the night. Her range of motion has dramatically improved and she is now able to move her fingers again.

Discussion

This case is unique in that we used a single stimulator brand that could provide different modalities (cervical, dorsal). In addition, the system is wireless, which allowed us to place stimulators in the epidural space without the implantation of a battery, by instead using an external antenna and generator.

Conclusions

Wirelessly powered spinal cord stimulation in the thoracic and cervical region was a successful option for this patient suffering of chronic pain as a result of CRPS. Minimally invasive, battery-free SCS is devoid of complications associated with the bulk of an implantable pulse generator.

Wireless System Components

The Freedom SCS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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2

Peripheral Nerve Stimulation for the Treatment of Lower Extremity Peripheral Neuropathy in a Diabetic Amputee

Peripheral Nerve Stimulation for the Treatment of Lower Extremity Peripheral Neuropathy in a Diabetic Amputee

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Background

A typical presentation for peripheral nerve entrapment is burning pain brought about by activity, with motor and/or sensory symptoms being regional. Symptoms do not always present with clear neurologic signs of motor weakness, sensory loss or change in reflexes; thus diagnosis is often delayed. The common peroneal, superficial peroneal and saphenous nerves are most commonly at risk for entrapment, with trauma being a primary cause.

Case Report

A 29-year-old female with type-1 diabetes mellitus (complicated by a non-healing right foot wound resulting in a right below knee amputation) presented to our clinic with left lower extremity neuropathic pain. She complained mostly of pain on the lateral and medial aspects of her left lower calf. Treatment with traditional medications (gabapentin, pregabulin) did not provide sufficient pain relief. A diagnostic injection at the distal peroneal and saphenous nerves at the left ankle relieved the majority of her pain for ~36hr. Subsequently, patient was considered a candidate for wireless peripheral nerve stimulation.

Methods

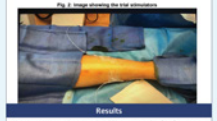
Trial: Fluoroscopy, ultrasound and palpation were used to plan the introducer entry point and route for two, 8-contact trial stimulators, targeting the left superficial peroneal and superficial saphenous nerves. A 13-gauge introducer and then an eight-contact electrode array was directed at the superior portion of the medial malleolus.

Placement was confirmed with fluoroscopy. A second 13-gauge introducer was used to insert the second eight-contact electrode array along the lateral aspect of the leg, and placement was confirmed with fluoroscopy to be at the anterior portion of the tibiofibular junction, with the electrode arrays viewed anterior to posterior (Figure 1). The steering stylets were removed and receivers were inserted into the inner lumen of the electrode arrays. After stimulation was confirmed, the trial stimulators were knotted after the second marker band and were then secured to the skin with a liquid adhesive and adhesive bandages and completely covered under a sterile bio-occlusive dressing (Figure 2).

Permanent implant: An incision was made at the previous entry site and the placement techniques for the stimulators utilized in the trial were repeated utilizing two four-contact, tined, permanent electrode arrays. The steering stylets were removed and the receivers were inserted into the electrode arrays. A receiver pocket was created and both stimulators were tunneled beneath the skin to the receiver pocket. A knot was tied to permanently mate the receivers and electrode arrays. The distal portion of the stimulators were coiled, sutured to themself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The devices were programmed with a frequency of 80 Hz, pulse width of 360 µs, and current of 3 mA.

Fig. 1: Image showing the 8-contact electrode arrays at the peroneal and saphenous nerve

Fig. 2: Image showing the trial stimulators



Results

The patient obtained 90% pain relief after a 4-day trial which remained consistent at 1 and 3 months after permanent implant (8/10 decreased to 1/10). The patient wears the antenna vertically on the mid leg on the medial and lateral side. Quality of life and functionality has dramatically improved.

Discussion

A battery-free system offers advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator, and flexibility as related to device placement and programming protocols. We feel this therapy is an excellent option for pain management in young patients with neuropathic pain.

Conclusions

Wirelessly powered, battery-free peripheral nerve stimulation was a successful option for this diabetic patient suffering of chronic contralateral left leg neuropathic pain as a result of change of gait due to right lower limb amputation.

Wireless System Components

The StimQ PNS System (Fig. 3) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 3: System components

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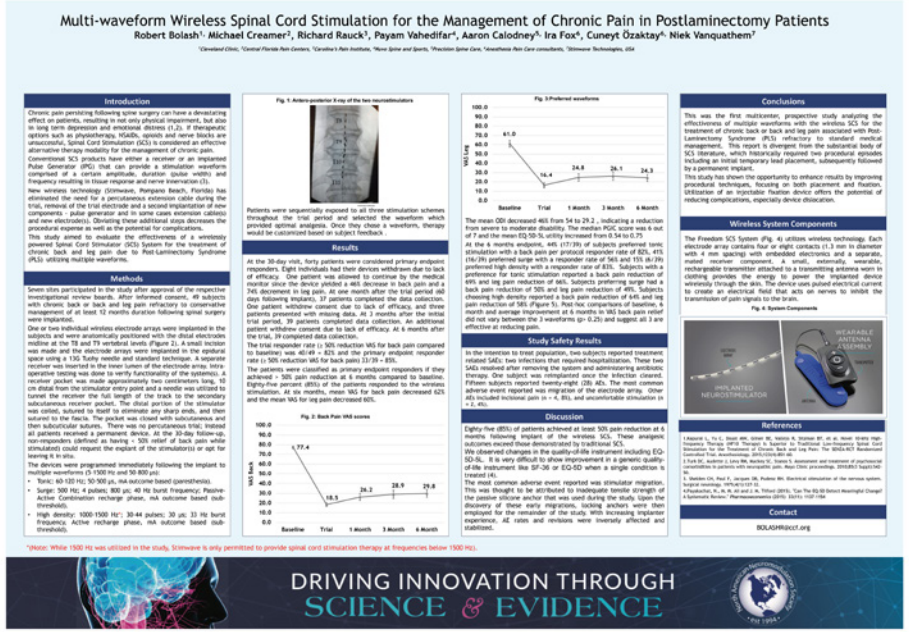
3

Multi-Waveform Wireless Spinal Cord Stimulation for the Management of Chronic Pain in Postlaminectomy Patients



FREEDOM FROM CHRONIC PAIN

stimwave TECHNOLOGIES

4

Wireless, Battery-Free Stimulation of IPS Nerve to Treat Chronic Bilateral Knee Pain from Osteogenesis Imperfecta

Wireless, Battery-Free Stimulation of IPS Nerve to Treat Chronic Bilateral Knee Pain from Osteogenesis Imperfecta

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Background

Osteogenesis Imperfecta (OI), also known as "brittle bone disease" is a group of genetic disorders that mainly affect the bones. It is caused by a defect in the gene that produces the protein collagen The term means "imperfect bone formation". People with this condition have bones that fracture easily, often from mild trauma or with no apparent cause and this often leads to chronic pain. There is no cure for OI and treatment is based on specific symptoms. These treatments include physical therapy, mobility aids, occupations therapy, medicine, surgery and pain management. Preventing further fractures is imperative in people with OI and as such they need to avoid activities that put them at risk for a fall or collision, or put too much stress on the bones.

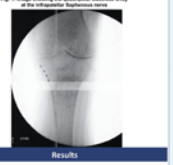
Case Report

A 72-year-old female with osteogenesis imperfecta presented with bilateral knee pain after multiple fractures including compression fractures in the spine, ankle and most recently left femur due to OI; she was wheelchair bound due to the pain. She used to rely heavily on her upper body (arms) to transfer to and from her wheelchair and required the assistance of a caregiver.

Methods

Trial: Fluoroscopy and palpation were used to plan the introducer entry point and route for a 4-contact trial stimulator targeting the right Infrapatellar Saphenous nerve. A 13-gauge introducer was used to enter the skin and the electrode array was inserted through the introducer and positioned along the planned route at the medial aspect of the proximal tibia just before the tibial plateau (Fig. 1). The steering stylet was removed, and the receiver inserted into the inner lumen of the electrode array. The trial stimulator was then secured with Mastisol and Steri Strips and a sterile Tegaderm. The procedure was repeated for the left leg.

Permanent Implant: A small incision was made and the placement technique for the permanent stimulators was repeated. The steering stylets were removed, and receivers inserted into the inner lumen of the electrode arrays. Receiver pockets were made approximately 10 cm from the first marker band on the electrode arrays and the neurostimulators tunneled to the pockets. A knot was tied to permanently mate the receivers and electrode arrays. The distal portion of the stimulators were coiled, sutured to themselves to eliminate any sharp ends, and then sutured to the fascia. The pockets were closed with subcutaneous and then subcuticular sutures.



Results

The devices were programmed with a frequency of 1499 Hz and a pulse width of 30 µs. This patient had excellent relief during the trial and reported approximately 100% pain relief. Both neurostimulators were placed permanently and patient reported 100% overall improvement 6 months later, and describes her improvement in pain, quality of life and functionality as a "dramatic improvement". She is now able to independently transfer without lower limb pain and without excessive use of her upper body. Her limiting factor currently is instability and no longer pain.

Discussion

A wireless peripheral nerve stimulation system offers advantages in difficult to treat subjects, such as significant pain relief, devoid of complications and cosmetic concerns associated with the bulk of an implantable pulse generator with extensive wiring.

Conclusions

Wirelessly powered, peripheral nerve stimulation was a successful option for this patient suffering of debilitating bilateral knee pain as a result of trauma due to osteogenesis imperfecta. This battery-free system is able to offers advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator.

Wireless System Components

The SttimQ PN5 System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

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5

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation at the Suprascapular Nerve for the Treatment of Chronic Shoulder Pain

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation at the Suprascapular Nerve for the Treatment of Chronic Shoulder Pain

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Background

Shoulder pain can find its origin in many sources, including rotator cuff, brachial plexus, and the cervical spine among others (1). Suprascapular neuropathy is a cause of shoulder pain; injury to the nerve is intrinsically related to the anatomy and course of the suprascapular nerve. Suprascapular neuropathy can be diagnosed through physical examination and electrodiagnostics, after exclusion of other possible causes. Symptoms can include shoulder weakness, with atrophy in severe cases, and aching or burning pain at the entire shoulder girdle (2). Management of suprascapular nerve pain is challenging. Treatment options include pharmacological treatments such as acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), anti-seizure medications and antidepressants. Non-pharmacological treatments include physical and occupational therapy. When these therapies fail, interventional procedures including surgical decompression, steroid injections and neuroablation may be considered (3). Pain control may be unsatisfactory despite all of the above modalities.

When the pain remains resistant to medications and interventions, peripheral nerve stimulation (PNS) might provide an alternative. PNS involves electrical stimulation of a specific nerve that supplies a distinct area of the body. Electrode arrays can be placed under open dissection or percutaneously. However, conventional battery-based systems that use implanted power generators (IPG) are not usually suitable for PNS due to the bulk and wiring of these systems, which are placed inside the patient's body; because the IPG requires enough tissue to create a large pocket, they often need to be tunneled long distances. Complications related to the IPG include: dislocation, erosion, and infection. Additional issues may arise from the implantable battery with displacement and pocket pain as common events (4, 5). The novel, wireless StimQ PNS system (Stimwave Technologies Incorporated) is designed to mitigate some of these types of complications and challenges.

Case Report

A 62-year-old female with a past surgical history of right shoulder arthroplasty presented with joint pain in both shoulders. Multiple shoulder injections, including subacromial bursa injections and suprascapular nerve blocks were unsuccessful in delivering long term relief.

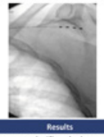
Methods

Surgical description for the trial implant: A 13 gauge introducer needle was percutaneously inserted 4 inches medial to the scapula and was advanced laterally under fluoroscopic guidance until the tip of the introducer was just inferior to the suprascapular notch on the right side. The needle stylet was removed, and a 4 contact, trial stimulator was placed through the introducer with the tip ending at the suprascapular nerve branches inferior to the suprascapular notch. The steering stylet was removed, and the receiver inserted into the inner lumen of the electrode array. The trial stimulator was then secured with *Mastisol* and Steri Strips and completely covered under a sterile Tegaderm.

During the trial, her average pain came down to a 0/10 from 7.5/10. Given the excellent results of the trial, the patient agreed to move forward with the permanent implant.

Surgical description for the permanent implant: The trial stimulator was explanted and replaced by a permanent system similar to the trial procedure. The suprascapular notch was visualized by fluoroscopy, and an introducer entry and route were planned and marked on the skin. A small skin stab wound was made and the introducer was placed subcutaneously along the planned route from medial to lateral, directed toward the shoulder joint. The electrode array was inserted and advanced near the right suprascapular notch (Fig. 1). After confirming location, the introducer was removed, then the steering stylet was removed from the device, and the receiver was inserted into the inner lumen of the electrode array. A receiver pocket was created, approximately 10 cm from the first marker band on the electrode array and the neurostimulator tunneled to the pocket. A knot was tied to permanently mate the receiver and electrode array. The distal portion of the stimulator was coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The patient wears the transmitter and antenna between the scapula and the spine. The external RF transmitter was programmed with a frequency of 1499 Hz, pulse width of 30 µs, and 6.0 mA.

Fig. 1: Image showing the four-contact neurostimulator at the suprascapular nerve branches inferior to the suprascapular notch



Results

The patient reports significantly decreased pain (100%) at 1-month post-implant and is better able to perform activities of daily living. She is less dependent on her opioids and is excited to wean them, whereas this was a topic she was not amenable to prior to the implantation.

Discussion

The suprascapular nerve can be injured or irritated in several ways. *Mechanical* stress, compression, or injury from surgical procedures or trauma can cause serious damage and lasting pain (6, 7). Suprascapular neuropathy may lead to weakness in muscles supplied by the nerve including the supraspinatus and infraspinatus muscles. In addition, patients may complain of weakness in the shoulder during movement, which may, or may not, be appreciated on clinical exam (8, 9).

Diagnosis overall can be challenging as there are several other conditions that can paint a similar clinical picture including rotator cuff injury, cervical radicular pain, brachial plexopathy, bursitis and myofascial pain. A thorough history and exam are essential in finding the true source of the symptoms. Diagnostic injections of the suprascapular nerve are an important diagnostic tool.

Placing an IPG in certain areas of the body can be challenging due to the lack of subcutaneous tissue, which makes the IPG placement risky and likely to cause significant discomfort to the patient

Conclusions

Wireless peripheral nerve stimulation at the suprascapular nerve was a successful option for this patient suffering of chronic pain in the right shoulder. This battery-free system is able to offers advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each stimulator contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

References

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6

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation of the Posterior Tibial Nerve for Painful Diabetic Neuropathy & Chronic Regional Pain Syndrome (CRPS)

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation of the Posterior Tibial Nerve for Painful Diabetic Neuropathy and Chronic Regional Pain Syndrome (CRPS)

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Background

The tibial nerve is a larger terminal branch of the sciatic nerve passing through the popliteal fossa to the arch of the soleus with root values of L4, L5, S1, S2 and S3. Peripheral nerve injury secondary to trauma to feet and ankles is an uncommon problem, which may lead to severe pain and serious disability. As there is no uniform definition or diagnosis to describe nerve pain as results of trauma, such conditions may be described as complex regional pain syndrome (CRPS).

Case Report

A 78-year-old male had pre-existing painful diabetic neuropathy and had a left above the knee amputation. Patient's left leg prosthetic failed while walking in 2017 and caused him to fall, resulting in tri-malleolar ankle fracture. Patient underwent surgery to stabilize the right ankle, but he continued to suffer from a large amount of pain secondary to a sustained posterior tibial nerve injury and required large amount of opioid medications. He was diagnosed with CRPS type 2 and was offered peripheral nerve stimulation as a possible alternative to opioids for the treatment of pain.

Methods

Trial: Fluoroscopy, ultrasound and palpation were used to plan the introducer entry point and route for a 4-contact trial stimulator, targeting the right posterior tibial nerve. The electrode array was inserted through the introducer and placed caudal to cephalad with the contacts aiming cephalad. Contacts were placed midline with the posterior aspect of the fibula, approximately 13 cm superior of the insertion site (ankle). Placement was confirmed with fluoroscopy (Figure 1). The steering stylet was removed and receiver inserted into the inner lumen of the electrode array. The trial stimulator was then secured to the skin with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

Permanent Implant: A small stab wound was made and the placement technique for the stimulator utilized in the trial was repeated for the posterior tibial nerve utilizing a quadripolar, tined, permanent stimulators. The steering stylet was removed and receiver inserted into the electrode array. A receiver pocket was created, and the electrode array was tunneled beneath the skin to the receiver pocket. A knot was tied to permanently mate the receiver and electrode array. The distal portion of the stimulator was coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The devices were programmed with a frequency of 1499 Hz, pulse width of 30 µs, and current of 3.5 mA.

Fig. 1: Image showing the quadripolar electrode arrays at the right posterior tibial nerve

Results

The patient wears the antenna and transmitter around the ankle. The patient received a permanent system after a successful trial (pain decreased from 9/10 to 1/10) and later reported 78% pain relief (2/10) 6 months after the permanent implant. Quality of life has dramatically improved, medication reduced by at least 50% and satisfaction was rated at 6/7.

Discussion

A battery-free system offers advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator, and flexibility as related to device placement and programming protocols.

Conclusions

Wirelessly powered peripheral nerve stimulation was a successful option for this patient suffering of excruciating pain in foot and ankle as a result of trauma related CRPS.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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7

Wirelessly Powered SCS & PNS for Treatment of Multiple Pain Sites After MVA

Wirelessly Powered SCS and PNS for Treatment of Multiple Pain Sites After MVA

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Background

Motor vehicle accidents (MVA) can trigger chronic widespread pain development. Whether such widespread pain develops via the evolution of pain from regional to widespread or via the early development of widespread pain with non-recovery is currently unknown.

Wireless nanotechnology (Stimwave Technologies, Pompano Beach, FL) is a recent advancement in neuromodulation. This wireless neurostimulator system only requires placement of electrodes with embedded micro-processor and does not require implant of an IPG or extensions. There is an external generator with antenna, which needs to be worn over one layer of clothing, to power the stimulator. This system is able to mitigate complications associated with implantable batteries and its extensions.

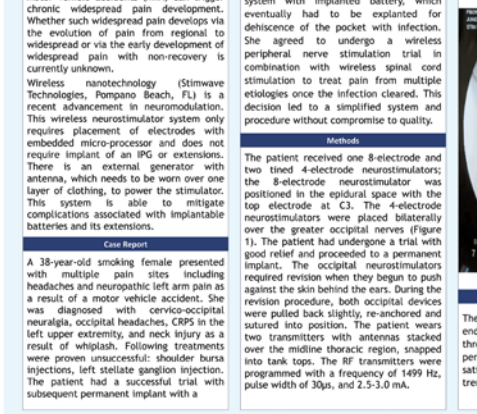
Case Report

A 38-year-old smoking female presented with multiple pain sites including headaches and neuropathic left arm pain as a result of a motor vehicle accident. She was diagnosed with cervico-occipital neuralgia, occipital headaches, CRPS in the left upper extremity, and neck injury as a result of whiplash. Following treatments were proven unsuccessful: shoulder bursa injections, left stellate ganglion injection. The patient had a successful trial with subsequent permanent implant with a Conventional spinal cord stimulation system with implanted battery, which eventually had to be explanted for dehiscence of the pocket with infection. She agreed to undergo a wireless peripheral nerve stimulation trial in combination with wireless spinal cord stimulation to treat pain from multiple etiologies once the infection cleared. This decision led to a simplified system and procedure without compromise to quality.

Methods

The patient received one 8-electrode and two tined 4-electrode neurostimulators; the 8-electrode neurostimulator was positioned in the epidural space with the top electrode at C3. The 4-electrode neurostimulators were placed bilaterally over the greater occipital nerves (Figure 1). The patient had undergone a trial with good relief and proceeded to a permanent implant. The occipital neurostimulators required revision when they begun to push against the skin behind the ears. During the revision procedure, both occipital devices were pulled back slightly, re-anchored and sutured into position. The patient wears two transmitters with antennas stacked over the midline thoracic region, snapped into tank tops. The RF transmitters were programmed with a frequency of 1499 Hz, pulse width of 30μs, and 2.5-3.0 mA.

Fig. 1: Image of the stimulators bilateral over the occipital nerves and in the epidural space



Results

The patient reported 80% pain relief at the end of the trial, which was consistent throughout the 3 months since the permanent implant. She rates her satisfaction as 7/7 and self-reports "a tremendous benefit".

Discussion

There have been recent advances with nanotechnology and wireless approaches to SCS and PNS. A wireless device reduces the the invasiveness of the surgery. A wireless device is smaller which, potentially reduces the complications from surgery while improving pain relief, comfort and cosmesis. Wireless technology allows for a customized approach in placement and waveforms.

Conclusions

Wireless peripheral nerve and spinal cord stimulation was a successful option for this patient suffering of excruciating pain as a result of MVA. This wireless system is able to offers advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator.

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8

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation of the Femoral Nerve for Chronic Hip Pain

Wirelessly, Powered, Battery-Free Peripheral Nerve Stimulation of the Femoral Nerve for Chronic Hip Pain

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[1]Interdisciplinary Pain Management Clinic (IPMC), [2]Stimwave Technologies

Background

The femoral nerve is one of the largest nerves in the legs and is located near the groin, controlling the muscles that help straighten legs and move the hips. It also provides sensation to the lower extremity and the front of the thigh. When the femoral nerve is damaged, it can cause chronic pain in hips and groin and can affect the ability to ambulate.

Chronic hip pain can be resistant to conservative medical management treatment, including physical therapy, medications and injections. Peripheral nerve (PNS) has been used effectively to treat pain of peripheral nerve origin. It can be difficult to determine whether hip pain originates from nerves within the joint itself, or neuropathy in surrounding nerve tissue. A series of nerve blocks can be administered to identify the origin of the pain. They can assist in determining the most appropriate placement for a peripheral nerve stimulator for treating pain in the hip joint region.

Case Report

A 41-year-old male presented with constant, dull right hip and groin pain presumably due to a superior labral tear. However, a labral tear repair procedure was unsuccessful in providing pain relief. His pain level did not improve despite several courses of physical therapy and medication management.

Next, he received several right intra-articular corticosteroid injections which provided only a few days of significant relief. He then received multiple right intra-articular hip platelet-rich plasma (PRP) injections, which provided greater than 50% pain relief; however these injections would only last about 3-4 months.

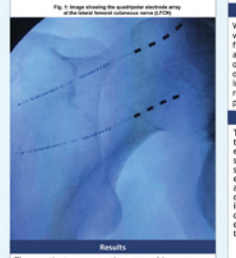
A diagnostic fluoroscopic guided nerve block of the femoral articular branches was performed, which provided greater than 75% pain relief for several days.

Methods

Trial: Ultrasound, palpation and fluoroscopy were used to plan the introducer entry point and route for two, 8-contact trial stimulators, targeting the femoral articular branches. The trial stimulators were inserted through the introducer to the femoral head neck junction overlying the articular branches. Fluoroscopy was used to confirm placement. The steering stylets were removed, and the receivers inserted into the inner lumen of the electrode array. The trial stimulators were then secured with Mastisol and Steri Strips and completely covered under a sterile Tegaderm. The patient completed a several-day trial and reported 90% pain relief.

Permanent Implant: The path of the femoral nerve in the groin was visualized, and a introducer entry point and pathway were planned using ultrasound, palpation and fluoroscopy. After local anesthetic infiltration, an incision was made and a PNS introducer was passed through the subcutaneous tissue and advanced in an inferior-lateral to superior-medial approach under ultrasound guidance, via an approach parallel and superficial to the femoral head-neck junction. A 4-electrode array was advanced through the introducer and placed next to the femoral articular branches. The same technique was used to place the second electrode array parallel and slightly inferior to the first (Figure 1). The steering stylets were removed, and receivers coupled to the electrode arrays. A receiver pocket was created distal to the insertion locations and both stimulators were tunneled to the pocket and sutured to deep fascia with the tails of the stimulators coiled within the receiver pocket.

Fig. 1: Image showing the quadripolar electrode array at the lateral femoral cutaneous nerve (LFCN)



Results

The patient wears the wearable antenna assembly on his right lateral thigh. A stimulation scheme with a pulse rate of 1499 Hz and pulse width of 30 µs at 2.0 mA was tested and found effective. The patient reported consistent pain reduction (75% pain relief) over 12 months after permanent implant. No complications were reported, and he was able to return to full duty at his job as a warehouse worker.

Discussion

Chronic musculoskeletal pain is often thought to be to be purely nociceptive in nature, but there can often be a neuropathic component to the pain. Nerve blocks can be a good diagnostic tools in determining whether there is a significant neuropathic component to an individual's pain.

Conclusions

Wirelessly powered, peripheral nerve stimulation was a successful option for this patient suffering from debilitating hip and groin pain secondary to a superior labral tear. This battery-free system offers advantages of significant pain relief devoid of complications associated with the bulk of an implantable pulse generator and flexibility as related to device placement and programming protocols.

Wireless System Components

The StimQ System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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9

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation for the Treatment of Abdominal Pain from Post-Partum & Hysterectomy Complications

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation for the Treatment of Abdominal Pain from Post-Partum & Hysterectomy Complications

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Background

Iliohypogastric and ilioinguinal neuralgia are under recognized causes of abdominal and pelvic pain that can present after abdominal or hernia surgery and result in disabling pain. Long-term complications are rare, but can include nerve damage. Management of chronic pelvic pain can be challenging and requires a multi-disciplinary approach. There are several treatment options for chronic post-surgical pelvic pain including: pain medications, nerve block, nerve ablation and peripheral nerve stimulation. Conventional spinal cord stimulation systems have inherent issues when targeting peripheral nerves such as cosmetic concerns and complications due to extensive tunneling. Novel wireless peripheral nerve stimulation systems devoid of wires and implantable batteries might provide a solution.

Case Report

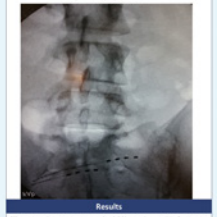
A 43-year-old female presented with pain in the lower abdomen and pelvis, which began after a Caesarean section and partial hysterectomy. She was diagnosed with chronic pain due to iliohypogastric and ilioinguinal neuralgia and CRPS. Previous treatment included peripheral nerve blocks, TENS, NSAIDS, physical therapy, and chronic opioid therapy prior to peripheral nerve stimulation.

Methods

Surgical description for the trial implant: The paths of the ilioinguinal and iliohypogastric nerves in the abdomen were visualized, and introducer entry points and pathways were planned using US, palpation, and fluoroscopy. After local anesthetic infiltration, a flexible introducer designed for PNS was advanced subcutaneously and the 8-electrode array was inserted and advanced to the ilioinguinal and iliohypogastric nerves approximately 2 cm superior to low transverse surgical scar, with the tail of the stimulator running across the lower abdomen toward the right hip. The second electrode array (also 8 contacts) was placed parallel to the first using the same technique. The steering stylets were removed, and the receivers inserted into the inner lumen of the electrode arrays. The trial stimulators were then secured with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

Surgical description for the permanent implant: The trial stimulators were explanted, two small stab wounds were made and 4-contact permanent systems were positioned with placement technique similar to the trial procedure (Fig. 1). After confirming location, the introducers and then the steering stylets were removed from the device, and the receivers were inserted into the inner lumen of the electrode arrays. A receiver pocket was created, approximately 10 cm from the first marker band and the neurostimulator tunneled to the pocket. A knot was tied to permanently mate the receivers and electrode arrays. The distal portion of the stimulators were coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The two electrode arrays were programmed at a frequency of 1499 Hz and pulse width of 30 µs. The patient was recommended to wear the antenna horizontally between the right hip and umbilicus either snapped into a long camisole, or in a Stashband® wearable.

Fig. 1: Image showing the four-contact neurostimulators at the ilioinguinal and hypogastric nerve



Results

The patient reported 80% pain relief (pain decreased from 10/10 to 2/10) at the end of a trial period, which remained consistent up to 6 months after permanent implant. Some days she reports no pain at all. She is now leading a normal life with more activity, was able to return to work and is no longer bed-ridden by pain.

Discussion

The preliminary results of this case are equivalent to those reported in previous studies, thus validating the efficacy of the PNS System. Conventional SCS devices with IPGs are responsible for a large percentage of adverse events. The use of wireless stimulation with no IPG eliminates complications related to the IPG implant.

Conclusions

Wirelessly powered peripheral nerve stimulation has proven to be a successful treatment option for this patient suffering from debilitating abdominal and pelvic pain due to iliohypogastric and ilioinguinal neuralgia and CRPS. This case supports a viable option for significant pain relief, devoid of complications associated with the bulk of the battery from an implantable pulse generator while offering more flexibility as related to device placement and programming protocols.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each stimulator contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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10

Wirelessly Powered, Battery-Free, Peripheral Nerve Stimulation of the Femoral Nerve & Superior Gluteal Nerve for Treatment of Chronic Hip & Groin Pain

Wirelessly Powered, Battery-Free, Peripheral Nerve Stimulation of the Femoral nerve and Superior Gluteal Nerve for the Treatment of Chronic Hip and Groin Pain

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Background

The femoral nerve is one of the largest nerves in the body. It begins in the pelvis and branches into several smaller nerves. Damage to the femoral and gluteal nerve due to injury or surgical procedure can cause chronic pain, numbness, weakness, or paralysis to the legs and pain in hips and groin.

Chronic hip pain can present with non-specific symptoms that may be confused with pain of various origins, whether intra-articular or extra-articular. In addition, neuropathy of nerves innervating the hip region can cause radiating pain in an extended region of the trunk, buttocks, and upper leg, which can further complicate an accurate diagnosis (1,2).

Chronic hip pain can be resistant to conservative medical management treatment, including physical therapy, medications and injections. Peripheral nerve (PNS) and peripheral field nerve stimulation (PFNS) have been used effectively to treat pain of peripheral nerve origin. It can be difficult to determine whether hip pain originates from nerves within the joint itself, or neuropathy in surrounding nerve tissue. A series of nerve blocks can be administered to identify the origin of the pain. They can assist in determining the most appropriate placement for a peripheral nerve stimulator for treating pain in the hip joint region.

Case Report

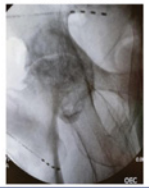
A 66-year-old male presented with excruciating chronic pain in the right hip, upper gluteus, and groin radiating into the posterior thigh, and was diagnosed with femoral neuropathy of the right lower extremity and lumbar radiculopathy. Subject was treated with peripheral nerve blocks, RF ablation, NSAIDS, and chronic opioid therapy. The patient opted for wireless peripheral nerve stimulation due to its minimally invasive and reversible nature instead of having a total hip replacement.

Methods

Trial: Fluoroscopy, ultrasound and palpation were used to plan the introducer entry point and route for two, 4-contact trial stimulators, one targeting the right femoral nerve and the second to target the right superior gluteal nerve. A 13 Gauge PNS introducer needle was passed through the subcutaneous tissues toward the femoral nerve. The needle was advanced subcutaneously in the fascial plane. The electrode array was inserted through the needle and advanced to the femoral nerve. The electrode placement was confirmed again with fluoroscopy and ultrasound. A second 13 G introducer was used to enter the skin just superior and posterior to the greater trochanter and placed inferiorly towards the knee. The second trial electrode array was inserted through the introducer and placement was confirmed with fluoroscopy to be at the superior gluteal nerve. The steering stylets were removed and receivers inserted into the inner lumen of the electrode arrays. The trial stimulators were then secured to the skin with Mastisol and Steri Strips and completely covered under a sterile Tegaderm. The patient completed a trial and reported 50% pain relief.

Permanent Implant: an incision was made and the placement techniques for the stimulators utilized in the trial were repeated for the femoral and Superior Gluteal nerves (Figure 1) utilizing two quadripolar, tined, permanent stimulators. The steering stylets were removed and receivers inserted into the electrode arrays. A receiver pocket was created on the outer hip where the devices overlapped, and both electrode arrays were tunneled beneath the skin to the receiver pocket. A knot was tied to permanently mate the receivers and electrode arrays. The distal portion of the stimulators were coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures.The devices were programmed with a frequency of 1499 Hz, pulse width of 30 µs, and current of 0.7-0.9 mA.

Fig. 1: Image showing the quadripolar electrode array at the femoral and gluteal nerve



Results

The Patient wears the antenna horizontally on the outer right hip either snapped into boxer briefs or in a Stashband. The patient obtained further relief (VAS of 3/10 and 70% relief) at 6 months after permanent implant. He reports drastically improved sleep and has reduced his opioid intake by 50%. The patient feels that he will not need to pursue a hip replacement any time in the near future with the relief he is experiencing!

Discussion

The anatomical course of both nerves, in close proximity to the hip, can make diagnosis of pain in the region challenging. Nerve blocks are generally good diagnostic tools in determining whether neuropathy is a factor. Pain in the hip joint region has varying origins, which can be related to the joint itself, muscles and tendons around the joint and/or neuropathy of nerves in close relation to the joint. While nerve blocks did not provide lasting relief, they were successfully utilized to diagnose the cause of the pain.

Conclusions

Wirelessly powered, battery-free, peripheral nerve stimulation was a successful option for this patient suffering from debilitating pain due to femoral neuropathy and lumbar radiculopathy. This case supports a viable option for significant pain relief, devoid of complications associated with the bulk from the battery of a traditional implantable pulse generator while offering more flexibility as related to device placement and programming protocols.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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11

Wireless, Battery-Free Sural Nerve Stimulation for the Treatment of Chronic Foot Pain in Athletic Patient

Wireless, Battery-Free Sural Nerve Stimulation for the Treatment of Chronic Foot Pain in Athletic Patient

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Background

The sural nerve, a sensory nerve, descends down the postero-lateral aspect of the calf; it innervates the skin over the distal one third of the lateral shin and the outside of the foot towards the fifth toe. It can be damaged by trauma, which may present as long-term neuropathic pain, which may hinder athletic activity.

Case Report

A 46-year-old male athlete fractured his left foot in an MVA. He reported pain along the outside of his foot, from 5th toe to heel and was not able to put any weight on the foot, which prevented him from enjoying sports. Alternative therapies such as ultrasound-guided injections and medication proved unsuccessful in the long term. After reporting a dramatic reduction in pain after a sural nerve injection, we decided to try peripheral nerve stimulation.

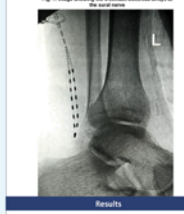
Methods

Trial: Fluoroscopy, ultrasound and palpation were used to plan the introducer entry points and route for two 8-contact trial stimulators, targeting the left sural nerves. The electrode arrays were inserted through the introducers and placed subcutaneously along the planned route, directed toward the heel.

Placement at the sural nerve was confirmed with fluoroscopy (Figure 1). The steering stylets were removed and receivers inserted into the inner lumen of the electrode arrays. The trial stimulators were then secured to the skin with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

Permanent Implant: A small stab wound was made at the anterior aspect of the left calf and the placement technique for the stimulators utilized in the trial was repeated for the sural nerve utilizing two 8-contact, permanent stimulators. The steering styles were removed and receivers inserted into the inner lumen of the electrode arrays. A receiver pocket was created approximately 10 cm proximal to the first mark band, and the electrode arrays were tunneled beneath the skin to the receiver pocket. A knot was tied to permanently mate the receivers and electrode arrays. The distal portion of the stimulators were coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The devices were programmed with a frequency of 1499 Hz, pulse width of 30 µs, and current of 6.0 mA. The patient wears the transmitter and antenna in a neoprene sleeve on his calf.

Fig. 1: Image showing the 8-contact electrode arrays at the sural nerve



Results

The patient received a permanent system after a successful trial (60% pain reduction) and later reported 78% pain relief (9/10 to 2/10) 12 months after the permanent implant, which has remained consistent up to 3 years post-implant. The patient rates his satisfaction as 6/7, quality of life increased 60%, and he is now able to sleep through the night. He has since returned to sports.

Discussion

A wireless peripheral nerve stimulation system offers advantages such as significant pain relief, devoid of complications and cosmetic concerns associated with the bulk of an implantable pulse generator with extensive wiring.

Conclusions

Wirelessly powered peripheral nerve stimulation at the sural nerve was a successful option for this patient suffering of chronic pain in his left foot. This battery-free system is able to offers advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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12

Wirelessly Powered, Battery-Free, Peripheral Nerve Stimulation of the Genicular Nerves for Treatment of Bilateral Osteoarthritic Knee Pain

Wirelessly Powered, Battery-Free, Peripheral Nerve Stimulation of the Genicular Nerves for the Treatment of Bilateral Osteoarthritic Knee Pain

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Background

Chronic knee pain after total knee arthroplasty occurs in approximately 20% of patients. They often experience debilitating pain with diminished quality of life. When conservative measures such as physical therapy, local nerve block injections, neuroablation, medications and pain management fail to provide resolution, patients are left with very few options. Osteoarthritis is the most common form of arthritis in the knee. It is a degenerative "wear-and-tear" type of arthritis that occurs most often in people 50 years of age and older. In osteoarthritis, the cartilage in the knee joint gradually wears away, often resulting in chronic pain.

We report one patient who successfully responded to the use of wireless peripheral nerve stimulation at the genicular nerve to treat her chronic knee pain.

Case Report

A 71-year-old female presented with constant dull/aching/sharp pain in bilateral left >right knees. The pain worsened with standing, walking and exercising. The pain was relieved with rest, relaxation and pain medication. The patient was diagnosed with bilateral primary osteoarthritis. Intra-articular injections were successful in relieving her knee pain, but the effects were temporary. The patient was offered a chance to trial a wireless peripheral nerve stimulator system for the treatment of her left knee.

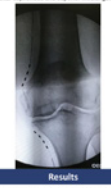
Case Report

Trial: Ultrasound, palpation and fluoroscopy were used to plan the introducer entry point and route for two trial stimulators.

The first introducer was placed subcutaneously along the planned route. The 4-electrode array was inserted and placed at the left infrapatellar saphenous (IPS) nerve, distal to the medial tibial plateau. After confirming location, the steering stylet was removed from the device and the receiver inserted into the inner lumen of the electrode array. A similar technique was used to position the second 4-electrode array at the left superior medial genicular nerve, proximal to the medial femoral condyle (Fig. 1). The steering stylet was removed, and the receiver inserted into the inner lumen of the electrode array. The trial stimulators were then secured with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

Permanent Implant: The trial stimulators were explanted. An incision was made and a permanent system was positioned with a technique similar to the trial procedure. After confirming location, the introducer was removed, then the steering stylet was removed from the device, and the receiver was inserted into the inner lumen of the electrode array. A receiver pocket was created, approximately 10 cm from the first marker band on the electrode array and the neurostimulator tunneled to the pocket. A knot was tied to permanently mate the receiver and electrode array. The distal portion of the stimulator was coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The patient wears the transmitter and antenna as part of a knee wrap. The external RF transmitters were programmed with a frequency of 1499 Hz, pulse width of 30 µs, and 3.0 mA.

Fig. 1: Image showing the quadripolar electrode arrays at the left infrapatellar saphenous and superior medial genicular nerve



Results

This patient had very good relief while using both the IPS and the superior medial genicular stimulators interchangeably and reported approximately 60% pain relief during the trial. Both neurostimulators were placed permanently and 10 days later, patient reported 100% overall improvement, which continued at the 6 months post-implant visit. The patient has requested to be treated with the same approach for her right knee.

Discussion

The lack of subcutaneous tissue makes it very difficult to treat chronic knee pain with PNS using conventional IPG-dependent systems and can lead to multiple complications such as erosion, infection and pocket pain. The StimQ PNS system is designed to mitigate these types of issues and facilitate PNS in areas where anatomical obstructions can be overcome.

Conclusions

Wirelessly powered, peripheral nerve stimulation was a successful option for this patient suffering of debilitating knee pain as a result of osteoarthritis. This battery-free system is able to offers advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: Device Components

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13

Wirelessly Powered, Battery-Free PNS at the Peroneal Nerve for the Treatment of Tumor Nerve Pain

Wirelessly Powered, Battery-Free PNS at the Peroneal Nerve for the Treatment of Tumor Nerve Pain

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Background

Peripheral nerve tumors (such as Schwannomas) are growths in or near peripheral nerves. These tumors can occur anywhere in the body, and though most of them are not malignant, they can lead to pain, nerve damage and loss of function in the affected area.

The common peroneal nerve is a branch of the sciatic nerve beginning just cephalad to the popliteal fossa, then splitting into additional branches at the fibular head and continuing through the outer calf (1). It can be vulnerable to damage from trauma as portions along its pathway are fairly superficial. It is also one of the most commonly involved nerves in complex regional pain syndrome (CRPS) of the foot and ankle region (2).

Case Report

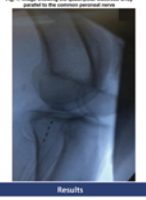
A 60-year-old male was diagnosed with a Schwannoma of the right lateral calf. An MRI revealed a "11x11x12mm well circumscribed T2 hyperintense enhancing lesion in the fibular longus muscle in the extensor compartment". An excision of this intramuscular mass was performed but the patient reporting persistent stabbing, dull pain in the right lateral calf. A right common peroneal nerve block with stimulation guidance provided short-term relief, and the patient was subsequently offered a PNS trial with a battery-free peripheral nerve stimulator (Stimwave Technologies, Pompano Beach, FL).

Methods

Trial: Fluoroscopy and palpation were used to plan the introducer entry point and route for a 4-contact trial stimulator targeting the right peroneal nerve. A 13-gauge (G) introducer was used to enter the skin and was positioned subcutaneously progressing from the mid outer calf to the posterior aspect of the fibular head. The electrode array was inserted through the introducer and placed parallel to the common peroneal nerve. The steering stylet was removed and receiver inserted into the inner lumen of the electrode array. The trial stimulator was then secured to the skin with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

Permanent Implant: A small incision was made and the placement technique for the permanent stimulator was repeated. The steering stylet was removed and a receiver inserted into the inner lumen of the electrode array, approximately 10 cm from the first marker band on the electrode array and the neurostimulator tunneled to the pocket. A knot was tied to permanently mate the receiver and electrode array. The distal portion of the stimulator was coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The device was programmed with a frequency of 1499 Hz and a pulse width of 30 µs.

Fig. 1: Image showing the quadripolar electrode array parallel to the common peroneal nerve



Results

The patient responded to the trial with 60% relief, then he underwent implantation of a permanent peripheral nerve stimulator. At 1 month follow up, he was doing remarkably well, reporting 2/10 pain with improved functionality which remained consistent with pain "well managed " at 3 month post-permanent implant, all while being weaned off opioids.

Discussion

A wireless stimulator provides technical advantages compared to the conventional methods of tunneling leads to IPGs. This experience hints at advantages such as significant pain relief devoid of complications associated with the bulk of an implantable pulse generator, and flexibility as related to device placement and programming protocols.

Conclusions

Wirelessly powered peripheral nerve stimulation was a successful option for this patient suffering of debilitating leg pain due to a tumor.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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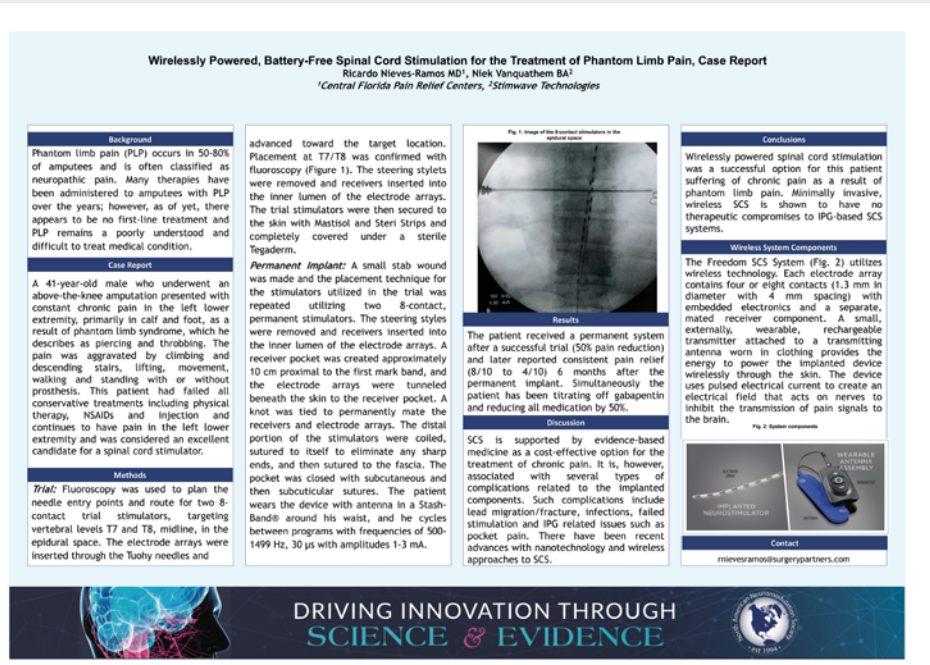
14

Wirelessly Powered, Battery-Free Spinal Cord Stimulation for the Treament of Phantom Limb Pain, Case Report



Wirelessly Powered, Battery-Free Spinal Cord Stimulation for the Treatment of Phantom Limb Pain, Case Report

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Background

Phantom limb pain (PLP) occurs in 50-80% of amputees and is often classified as neuropathic pain. Many therapies have been administered to amputees with PLP over the years; however, as of yet, there appears to be no first-line treatment and PLP remains a poorly understood and difficult to treat medical condition.

Case Report

A 41-year-old male who underwent an above-the-knee amputation presented with constant chronic pain in the left lower extremity, primarily in calf and foot, as a result of phantom limb syndrome, which he describes as piercing and throbbing. The pain was aggravated by climbing and descending stairs, lifting, movement, walking and standing with or without prosthesis. This patient had failed all conservative treatments including physical therapy, NSAIDs and injection and continues to have pain in the left lower extremity and was considered an excellent candidate for a spinal cord stimulator.

Methods

Trial: Fluoroscopy was used to plan the needle entry points and route for two 8-contact trial stimulators, targeting vertebral levels T7 and T8, midline, in the epidural space. The electrode arrays were inserted through the Tuohy needles and advanced toward the target location. Placement at T7/T8 was confirmed with fluoroscopy (Figure 1). The steering stylets were removed and receivers inserted into the inner lumen of the electrode arrays. The trial stimulators were then secured to the skin with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

Permanent Implant: A small stab wound was made and the placement technique for the stimulators utilized in the trial was repeated utilizing two 8-contact, permanent stimulators. The steering styles were removed and receivers inserted into the inner lumen of the electrode arrays. A receiver pocket was created approximately 10 cm proximal to the first mark band, and the electrode arrays were tunneled beneath the skin to the receiver pocket. A knot was tied to permanently mate the receivers and electrode arrays. The distal portion of the stimulators were coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The patient wears the device with antenna in a Stash-Band® around his waist, and he cycles between programs with frequencies of 500-1499 Hz, 30 µs with amplitudes 1-3 mA.

Fig. 1: Image of the 8-contact stimulators in the epidural space

Results

The patient received a permanent system after a successful trial (50% pain reduction) and later reported consistent pain relief (8/10 to 4/10) 6 months after the permanent implant. Simultaneously the patient has been titrating off gabapentin and reducing all medication by 50%.

Discussion

SCS is supported by evidence-based medicine as a cost-effective option for the treatment of chronic pain. It is, however, associated with several types of complications related to the implanted components. Such complications include lead migration/fracture, infections, failed stimulation and IPG related issues such as pocket pain. There have been recent advances with nanotechnology and wireless approaches to SCS.

Conclusions

Wirelessly powered spinal cord stimulation was a successful option for this patient suffering of chronic pain as a result of phantom limb pain. Minimally invasive, wireless SCS is shown to have no therapeutic compromises to IPG-based SCS systems.

Wireless System Components

The Freedom SCS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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15

Wireless Stimulation of Superior Cluneal Nerve for Chronic Low Back Pain, a Case Series

Wireless Stimulation of Superior Cluneal Nerve for Chronic Low Back Pain, a Case Series (n=13)

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Background

Chronic low back pain (CLBP) is a widespread issue with profound effects on an individual's level of activity and quality of life. CLBP may originate from a variety of spinal structures but its etiology is non-specific in the majority of patients. The superior cluneal nerves (SCN) are an under-recognized cause of CLBP. SCN are cutaneous nerves of the buttocks. These nerves are responsible for providing sensory innervation to the skin. Historically, there have been limited treatment options for nerve pain experienced in this area of the body. Currently, peripheral nerve stimulation (PNS) is highly regarded as a vigorous modality for the treatment of cluneal peripheral nerve pain. Technological advancements allow for less invasive placement procedures and improvement in cosmesis, making implantation less morbid and more accessible.

Case Report

We report 13 subjects (6 females, 7 males), with a mean age of 73 years old, who presented with CLBP described as "burning" (six subjects had pain radiating into the buttocks and hips) impacting their functionality and ambulation. Subjects were diagnosed with either mono-neuropathy of the SCN, cluneal neuritis, scoliosis, sacroiliitis, superior cluneal neuralgia and/or post-laminectomy syndrome. Previous conservative treatments included physical therapy, injections, ablations, opiates, intrathecal pump and SCS trials that were all unsuccessful.

Methods

Trial: Fluoroscopy, ultrasound and palpation were used to plan the introducer entry point and route for a 8-electrode trial stimulator targeting the superior cluneal nerve (Figure 1). A 13-gauge introducer was used to enter the skin approximately 6 cm medial to the posterior superior iliac spine (PSIS). The electrode array was inserted through the introducer and advanced towards the superior cluneal nerve along the iliac crest. The steering stylet was removed and receiver inserted into the inner lumen of the electrode array. The trial stimulator was then secured to the skin with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

Permanent Implant: A small incision was made and the placement technique for the 4-contact permanent stimulator was repeated. The steering stylet was removed and a receiver inserted into the inner lumen of the electrode array. A receiver pocket was made approximately 10 cm from the first marker band on the electrode array and the neurostimulator tunneled to the pocket. A knot was tied to permanently mate the receiver and electrode array. The distal portion of the stimulator was coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The devices for all patients were programmed with a frequency of 1499 Hz, pulse width of 30 µs and current as preferred by patients.

Fig. 1: Image showing placement at superior cluneal nerve

Results

All subjects were successfully treated with wirelessly powered PNS and reported high satisfaction, with increased levels of activity, improved sleep, and medication reductions. Mean pain scores reduced from 8.3 at baseline to 1.2 at the end of the trial, 1.3 at 3 months (n=8) and 1.9 at 6 months (n=8) post-implant. Quality of life and functionality was improved drastically, medication was reduced, and mean satisfaction was rated at 7/7. No complications were reported.

Discussion

A wireless stimulator provides technical advantages compared to the conventional methods of tunneling leads to IPGs and implanted batteries. Wireless peripheral nerve stimulation is an effective option for chronic pain of peripheral nerve origin including the superior cluneal nerves.

Conclusions

Wirelessly powered, battery-free PNS was a successful option for patients suffering of debilitating low back pain as a result of mononeuropathy of the superior cluneal nerves and cluneal neuritis following laminectomy. Wireless neurostimulation allows PNS in difficult to access sites with limited options for a traditional IPG placement.

Wireless System Components

The Freedom PNS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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16

Patient with CRPS Type 2 of Distal Radial Nerve Chose Peripheral Nerve Stimulation (PNS) Over Spinal Cord Stimulation (SCS)

Patient with CRPS Type 2 of Distal Radial Nerve Chose Peripheral Nerve Stimulation (PNS) Over Spinal Cord Stimulation (SCS)

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Background

Degloving or avulsion is a type of severe injury that happens when the top layers of the skin and tissue are ripped from the underlying muscle, connective tissue, or bone. It can affect any body part. Degloving injuries are often life-threatening as they involve large amounts of blood loss and tissue death. When the skin and tissue is ripped away, exposing muscle, bone, or connective tissue, it's known as open degloving. Treatment options include: reattaching the skin, skin grafts, reattachment and amputation. All of these options usually require multiple surgeries. Due to the initial trauma and repeated surgeries, chronic pain after the fact remains highly likely.

Case Report

A 65-year-old male presented with severe chronic pain in the distal radial nerve of the forearm, wrist and hand. Trauma of the distal radial nerve was a result of a work related degloving injury. The patient had subsequent reattachment of the forearm and 11 additional surgeries on the forearm prior to being referred to pain management. The patient was offered a trial with both cervical spinal cord stimulation and peripheral nerve stimulation of the radial nerve to assess whether on treatment would provide superior relief to the other.

Methods

Trial: The patient underwent a trial with cervical spinal cord stimulation (covering C4, C5, C6) and peripheral nerve stimulation over the distal radial nerve using two Stimwave 8-contact Freedom stimulators. He tested both systems independently during the trial period with subthreshold stimulation settings at a frequency of 1 kHz, pulse width of 30 µs with amplitudes 1-3 mA.

Permanent Implant: A ¼ inch incision facilitated the introduction of two 10-inch coude needles proximally to distally into the subcutaneous tissues over the radial nerve in the left forearm. An 8-contact electrode array was advanced through each needle and placed directly over his maximal complaint of pain corresponding to his left radial nerve (Fig.1). A receiver pocket was created approximately 10 cm proximal to the first marker band, and the electrode array were tunneled beneath the skin to the receiver pocket. A knot was tied to permanently mate each receiver and electrode array. The distal portion of the stimulators were coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The patient wears the transmitter with antenna on his forearm. Stimulation settings were set at a frequency of 1 kHz, pulse width of 30 µs with amplitudes 4.8 mA.

Fig. 1: Image of the 8-contact stimulator over the radial nerve.

Results

He received 60% reduction in pain when using the cervical SCS lead but reported 100% pain relief when using only the lead placed over the distal radial nerve. Following the trial, the patient decided to proceed with only the peripheral nerve stimulator system over the distal radial nerve in the forearm. At his 6 months follow up visit, he continued to report 100% pain relief along with improvement in his range of motion and a 50% reduction in opioid use.

Discussion

Wireless neurostimulation systems posses an inherent flexibility as related to placement location and programming possibilities. Both spinal cord and peripheral nerve stimulation are possible and effective options. Wireless systems are devoid of complications associated with implantable batteries and wiring.

Conclusions

A patient with chronic regional pain syndrome type 2 after multiple surgeries caused by a degloving injury may realize more pain relief with a peripheral nerve stimulator over a spinal cord stimulator.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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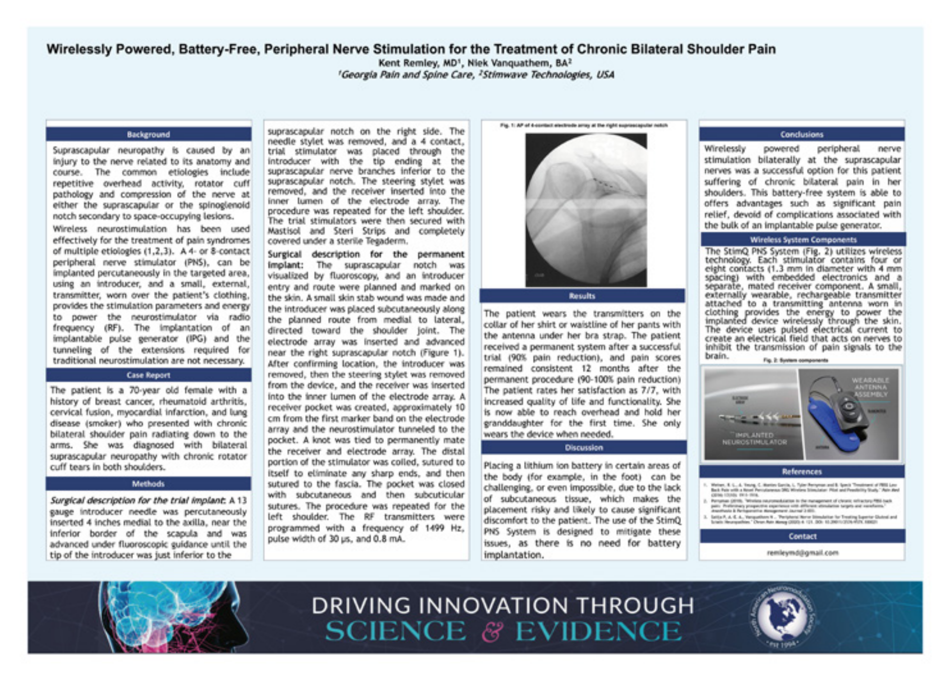
17

Wirelessly Powered, Battery-Free, Peripheral Nerve Stimulation for the Treatment of Chronic Bilateral Shoulder Pain



Wirelessly Powered, Battery-Free, Peripheral Nerve Stimulation for the Treatment of Chronic Bilateral Shoulder Pain

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Background

Suprascapular neuropathy is caused by an injury to the nerve related to its anatomy and course. The common etiologies include repetitive overhead activity, rotator cuff pathology and compression of the nerve at either the suprascapular or the spinoglenoid notch secondary to space-occupying lesions.

Wireless neurostimulation has been used effectively for the treatment of pain syndromes of multiple etiologies (1,2,3). A 4- or 8-contact peripheral nerve stimulator (PNS), can be implanted percutaneously in the targeted area, using an introducer, and a small, external, transmitter, worn over the patient's clothing, provides the stimulation parameters and energy to power the neurostimulator via radio frequency (RF). The implantation of an implantable pulse generator (IPG) and the tunneling of the extensions required for traditional neurostimulation are not necessary.

Case Report

The patient is a 70-year old female with a history of breast cancer, rheumatoid arthritis, cervical fusion, myocardial infarction, and lung disease (smoker) who presented with chronic bilateral shoulder pain radiating down to the arms. She was diagnosed with bilateral suprascapular neuropathy with chronic rotator cuff tears in both shoulders.

Methods

Surgical description for the trial implant: A 13 gauge introducer needle was percutaneously inserted 4 inches medial to the axilla, near the inferior border of the scapula and was advanced under fluoroscopic guidance until the tip of the introducer was just inferior to the suprascapular notch on the right side. The needle stylet was removed, and a 4 contact, trial stimulator was placed through the introducer with the tip ending at the suprascapular nerve branches inferior to the suprascapular notch. The steering stylet was removed, and the receiver inserted into the inner lumen of the electrode array. The procedure was repeated for the left shoulder. The trial stimulators were then secured with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

Surgical description for the permanent implant: The suprascapular notch was visualized by fluoroscopy, and an introducer entry and route were planned and marked on the skin. A small skin stab wound was made and the introducer was placed subcutaneously along the planned route from medial to lateral, directed toward the shoulder joint. The electrode array was inserted and advanced near the right suprascapular notch (Figure 1). After confirming location, the introducer was removed, then the steering stylet was removed from the device, and the receiver was inserted into the inner lumen of the electrode array. A receiver pocket was created, approximately 10 cm from the first marker band on the electrode array and the neurostimulator tunneled to the pocket. A knot was tied to permanently mate the receiver and electrode array. The distal portion of the stimulator was coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The procedure was repeated for the left shoulder. The RF transmitters were programmed with a frequency of 1499 Hz, pulse width of 30 µs, and 0.8 mA.

Fig. 1: AP of 4-contact electrode array at the right suprascapular notch

Results

The patient wears the transmitters on the collar of her shirt or waistline of her pants with the antenna under her bra strap. The patient received a permanent system after a successful trial (90% pain reduction), and pain scores remained consistent 12 months after the permanent procedure (90-100% pain reduction) The patient rates her satisfaction as 7/7, with increased quality of life and functionality. She is now able to reach overhead and hold her granddaughter for the first time. She only wears the device when needed.

Discussion

Placing a lithium ion battery in certain areas of the body (for example, in the foot) can be challenging, or even impossible, due to the lack of subcutaneous tissue, which makes the placement risky and likely to cause significant discomfort to the patient. The use of the StimQ PNS System is designed to mitigate these issues, as there is no need for battery implantation.

Conclusions

Wirelessly powered peripheral nerve stimulation bilaterally at the suprascapular nerves was a successful option for this patient suffering of chronic bilateral pain in her shoulders. This battery-free system is able to offers advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each stimulator contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

References

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18

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation for Treatment of Chronic Ilioinguinal Neuralgia Status Post-Inguinal Hernia Repair

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation for the Treatment of Chronic Ilioinguinal Neuralgia Status Post-Inguinal Hernia Repair

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Background

An inguinal hernia occurs if there is an abnormal opening or defect through which organs or tissue protrude. There are 2 kinds of inguinal hernias: indirect hernias and direct hernias (which are fairly common in older adult males but can occur in females as well). Inguinal hernia repair is a very common surgery. However, like all surgeries, it has certain risks including infection, bleeding, and pain that is not relieved by medication. Complications can occur resulting in chronic pain from scar tissue inducing neuritis or iatrogenic nerve injury. Ilioinguinal/iliohypogastric neuralgias are an under recognized cause of abdominal pain that can present after hernia surgery and may result in disabling inguinal pain in the incidence of chronic inguinal pain after hernia repair regardless of surgical technique ranges from 2-7%.

Case Report

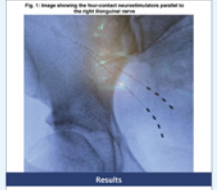
A 43 year-old female presented with severe pain in the right lower abdominal quadrant and inguinal region, which began after a laparoscopic inguinal herniorrhaphy. She was diagnosed with chronic pain due to ilioinguinal neuralgia and unspecified mononeuropathy of the right lower limb. Previous unsuccessful treatments included re-exploration surgeries, abdominal trigger point injections, NSAIDS, membrane stabilizers, topical Lidocaine, physical therapy, and topical CBD prior to a successful ultrasound guided diagnostic block at the right ilioinguinal nerve followed by a trial with peripheral nerve stimulation.

Methods

Surgical description for the trial implant: A 13 gauge introducer needle was percutaneously inserted at the right lateral abdominal wall, 2 cm caudad and medial to the anterior superior iliac spine (ASIS) and advanced subcutaneously using in-plane ultrasound guidance. The needle stylet was removed, and a 4-contact, trial stimulator was placed through the introducer and positioned parallel to the right ilioinguinal nerve, medial to the right ASIS. The steering stylet was removed, and the receiver inserted into the inner lumen of the electrode array. A second stimulator was placed parallel to the first using the same technique. The trial stimulators were then secured with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

Surgical description for the permanent implant: The trial stimulator was explanted, an incision made and two permanent systems were positioned with placement technique similar to the trial procedure. After confirming location, the introducers were removed, then the steering stylets, and the receivers were inserted into the inner lumen of the electrode arrays. A receiver pocket was created, approximately 10 cm from the first marker band on the electrode array and the neurostimulators tunneled to the pocket. A knot was tied to permanently mate the receivers and electrode arrays. The distal portion of the stimulators were coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The two electrode arrays were programmed at a frequency of 1499 Hz and pulse width of 30 µs.

Fig. 1: Image showing the four-contact neurostimulators parallel to the right ilioinguinal nerve



Results

The patient wears the antenna horizontally between the right hip and umbilicus snapped into a Stashband® wearable. The patient reported 50% pain relief (pain decreased from 8/10 to 4/10) at the end of a trial period, which improved to 100% (0/10) with the permanent device at 1 month post-implant and remained consistent up to 6 months. She is now able to sleep again, clean her house, and exercise; she is no longer taking any oral medications for pain, has improved functionality and reports a drastic improvement in quality of life.

Discussion

Wireless stimulator provides technical advantages compared to the conventional methods of tunneling leads to IPGs. This case confirms an effective option for peripheral nerve pain treatment that can provide relief to an under-treated patient population.

Conclusions

Wirelessly powered peripheral nerve stimulation has proven to be a successful treatment option for this patient suffering from debilitating abdominal pain due to ilioinguinal neuralgia. This case supports a viable option for significant pain relief, devoid of complications associated with the bulk of the battery from an implantable pulse generator.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each stimulator contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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19

Wireless Peripheral Nerve Stimulation Bilateral Sural Nerves for Chronic Pain in Lower Extremities

Wireless Peripheral Nerve Stimulation Bilateral Sural Nerves for Chronic Pain in Lower Extremities

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Background

The sural cutaneous nerve consists of the fusion of the medial sural cutaneous nerve, which is a terminal branch of the tibial nerve, and the lateral sural cutaneous nerve from the peroneal nerve. These two branches are connected by the sural communicating branch and form the sural nerve. The nerve courses subcutaneously from the mid posterior popliteal fossa to just posterior to the lateral malleolus. It supplies sensation to the skin of the lateral foot, calf, and lower ankle. The sural nerve descends down the postero-lateral aspect of the calf its primary role is to innervate the skin over the distal one third of the lateral shin and outside of the foot towards the fith toe. It can be damaged by trauma and may present as long-term neuropathic pain.

Case Report

A 55-year-old male presented with bilateral sural neuralgia due to chronic compression. His pain originates at the mid-calf bilaterally and extends distally in a sural distribution to his feet. Conservative therapies including physical therapy, NSAIDS, and previous SCS trial were unsuccessful in treating his pain. Ultimately, it was decided to trial peripheral nerve stimulation.

Methods

Trial: Fluoroscopy, ultrasound and palpation were used to plan the introducer entry points. An 8-contact electrode arrays was inserted through the introducers and placed subcutaneously at the right sural nerve. The steering stylet was removed and receiver inserted into the inner lumen of the electrode arrays. The trial stimulator was then secured to the skin with Mastisol and Steri Strips and completely covered under a sterile Tegaderm. The same technique was used for the left leg.

Permanent Implant: A small stab wound was made at the anterior aspect of the right calf and the placement technique for the permanent 4-contact stimulators was repeated (Fig. 1). The steering style was removed and receiver inserted into the inner lumen of the electrode array. A receiver pocket was created approximately 10 cm proximal to the first marker band, and the electrode arrays were tunneled beneath the skin to the receiver pocket. A knot was tied to permanently mate the receiver and electrode array. The distal portion of the stimulator was coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The technique was repeated for the left leg. The transmitters were programmed with a frequency of 1499 Hz, pulse width of 30 µs, and 8.0 mA.

Fig. 1: Image showing the quadripolar electrode array at the sural nerve

Results

The patient wears the transmitters and antennae on his calves. The patient received a permanent system after a successful trial (100% pain reduction), and pain scores remained consistent 6 months after the permanent procedure (100% pain reduction) The patient rates his satisfaction as 7/7, with increased quality of life and functionality.

Discussion

A wireless peripheral nerve stimulation system offers advantages such as significant pain relief, devoid of complications and cosmetic concerns associated with the bulk of an implantable pulse generator with extensive wiring.

Conclusions

Wirelessly powered peripheral nerve stimulation bilaterally at the sural nerves was a successful option for this patient suffering of chronic pain in his calves. This battery-free system is able to offers advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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20

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation of the Iliohypogastric & Ilioinguinal Nerves for Treatment of Groin & Testicular Pain

Wirelessly Powered, Battery-Free Peripheral Nerve Stimulation of the Iliohypogastric and Ilioinguinal Nerves for the Treatment of Groin and Testicular Pain, After Failed Temporary PENS

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Background

An inguinal hernia occurs if a small part of the intestine drops into the scrotum with the testes. There are 2 kinds of inguinal hernias: indirect hernias (usually seen in young males) and direct hernias (which are fairly common in older adult males). Inguinal hernia repair is a very common surgery. However, like all surgeries, it has certain risks including infection, bleeding, nerve damage, and chronic groin pain that is not relieved by medication. Management of chronic groin pain can be challenging and requires a multi-disciplinary approach. There are several treatment options for chronic pain after inguinal hernia repair including pain medications, nerve blocks, nerve ablation and peripheral nerve stimulation. Conventional spinal cord stimulation systems have inherent issues when targeting peripheral nerves including cosmetic concerns and complications due to extensive tunneling. However, novel wireless peripheral nerve stimulation systems devoid of implantable batteries might provide a solution.

Case Report

A 38-year-old male presented with left groin and testicular pain following a left inguinal hernia repair with mesh. He underwent a successful diagnostic ultrasound-guided ilioinguinal/iliohypogastric local anesthetic injection, which provided 100% relief for approximately 10 days. Upon return of his pain, he underwent percutaneous peripheral nerve stimulation with a temporary, helically-coiled device. He experienced approximately 80% pain relief for the duration of the therapy. After the planned removal of the device, he experienced an acute return of his pain. He then opted to undergo pulsed radiofrequency denervation of the involved nerves. This procedure was poorly tolerated and provided minimal relief. He resumed neuropathic pain medications, which were increased until limited by side effects. Operative intervention was considered to be of little benefit. He was then offered a PNS trial with a battery-free peripheral nerve stimulator (Stimwave Technologies, Pompano Beach, FL).

Methods

Surgical description of the trial implant: A 13-gauge introducer was percutaneously inserted at the left lateral abdominal wall, 5 cm cephalad to the anterior superior iliac spine (ASIS) perpendicular to the inguinal ligament and advanced subcutaneously using in-plane ultrasound guidance (Fig.1). The needle stylet was removed, and a 4-contact, trial stimulator was placed through the introducer and positioned within the internal oblique muscle, 0.5 cm superficial to the left ilioinguinal and iliohypogastric nerve as they travel between the internal oblique and transversus abdominus muscles, medial to the left ASIS (Fig. 2). The steering stylet was removed, and the receiver inserted into the inner lumen of the electrode array. The trial stimulator was then secured with liquid adhesive and adhesive strips and completely covered under a sterile bio-occlusive dressing. During the trial, his average pain came down to a 1.5/10 from 8/10. Given the excellent results of the trial, the patient agreed to move forward with the permanent implant.

Surgical description of the permanent implant: The trial stimulator was explanted, and a permanent system using a 4-contact tined electrode array was positioned under US with placement technique similar to the trial procedure. After confirming location, the introducer and steering stylet was removed from the device, and the receiver was inserted into the inner lumen of the electrode array. A receiver pocket was created, approximately 10 cm from the first marker band on the electrode array and the neurostimulator tunneled to the pocket. A knot was tied to permanently mate the receiver and electrode array. The distal portion of the stimulator was coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The patient wears the transmitter and antenna over his anterolateral abdomen . The external RF transmitters were programmed with a frequency of 1499 Hz, pulse width of 30 µs, and 6.0 mA.

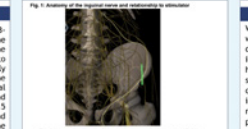

Fig. 2: Image showing the four-contact neurostimulator superficial to the left ilioinguinal and hypogastric nerve

Results

At the 3-month follow up, he was doing remarkably well, reporting 0/10 pain, improved functional capacity and consistently restful sleep without pharmacologic assistance. When his pain suddenly returned, the patient opted for revision of the device. This successfully restored the pain relief. He is now 6 months status post-revision and reports his pain to be manageable at only about 1/10.

Discussion

Wireless stimulator provides technical advantages compared to the conventional methods of tunneling leads to IPGs. This case confirms an effective option for peripheral nerve pain treatment that can provide relief to an under-treated patient population.

Conclusions

Wirelessly powered peripheral nerve stimulation was a successful option for this patient suffering of debilitating testicular and groin pain due to iliohypogastric and ilioinguinal neuralgia after hernia repair. This experience hints at advantages such as significant pain relief, devoid of complications associated with the bulk of an implantable pulse generator, and flexibility as related to device placement and programming protocols.

Wireless System Components

The Stim Q System (Fig. 2) utilizes wireless technology. Each stimulator contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 3: System components

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21

Peroneal Nerve Wireless Peripheral Nerve Stimulation to Treat Lower Extremity Complex Regional Pain Syndrome

Peroneal Nerve Wireless Peripheral Nerve Stimulation to Treat Lower Extremity Complex Regional Pain Syndrome

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Background

The common peroneal nerve is a branch of the sciatic nerve beginning just cephalad to the popliteal fossa, then splitting into additional branches at the fibular head and continuing through the outer calf (1). It can be vulnerable to damage from trauma as portions along its pathway are fairly superficial. It is also one of the most commonly involved nerves in complex regional pain syndrome (CRPS) of the foot and ankle region (2). Symptoms of CRPS include "burning" and "aching" pain as well as a variety of stimulus-evoked pain sensations, including hyperalgesia and allodynia (with mechanical, cold, and sometimes heat sensitivity)(3).

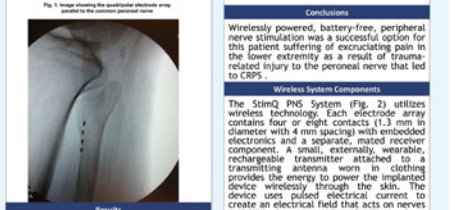
Case Report

A 50-year-old male presented with pain along the left lateral calf and dorsal aspect of the foot subsequent to trauma to his leg 20 years prior that injured the superficial peroneal nerve. Spinal cord stimulation (SCS) was previously tried, but did not provide pain relief to the affected area. Other failed therapies include NSAIDS, opiates and physical therapy. Prior to his peripheral nerve stimulator trial, the patient was only able to ambulate for 15 minutes.

Methods

Trial: Fluoroscopy and palpation were used to plan the introducer entry point and route for a 4-contact trial stimulator targeting the left peroneal nerve. A 13-gauge (G) introducer was used to enter the skin and was positioned subcutaneously progressing from the mid outer calf to the posterior aspect of the fibular head. The first electrode array was inserted through the introducer and placed parallel to the common peroneal nerve. The contacts were confirmed to be over the fibular head. The steering stylet was removed and receiver inserted into the inner lumen of the electrode array. The trial stimulator was then secured to the skin with Mastisol and Steri Strips and completely covered under a sterile Tegaderm. The patient completed a trial and reported 50% pain relief.

Permanent Implant: The trial stimulator was removed, an incision made and the placement technique for the permanent stimulator was repeated. The steering stylet was removed and a receiver inserted into the inner lumen of the electrode array. approximately 10 cm from the first marker band on the electrode array and the neurostimulator tunneled to the pocket. A knot was tied to permanently mate the receiver and electrode array. The distal portion of the stimulator was coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. The pocket was closed with subcutaneous and then subcuticular sutures. The device was programmed with a frequency of 1499 Hz, pulse width of 30 µs, and current of1.2 mA. The Patient wears a sleeve with pocket to hold antenna vertically on the outer calf



Results

The patient received a permanent system after a successful trial (with VAS lowering to 3/10 from 7/10) and later reported 70% pain relief (VAS lowered to 2/10 from 7/10) 6 months after the permanent implant. He is now able the stand and walk for several hours, has increased sensation in his foot and is less likely to stumble or catch his toes as he walks.

Discussion

A wireless stimulator provides technical advantages compared to the conventional methods of tunneling leads to IPGs and implanted batteries. Wireless peripheral nerve stimulation is an effective option for chronic pain of peripheral nerve origin including the peroneal nerve.

Conclusions

Wirelessly powered, battery-free, peripheral nerve stimulation was a successful option for this patient suffering of excruciating pain in the lower extremity as a result of trauma-related injury to the peroneal nerve that led to CRPS .

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each electrode array contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally, wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

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22

Wirelessly Powered, Battery-Free, Quadripolar Brachial Plexus PNS to Treat CRPS: A Case Series

Wirelessly Powered, Battery-Free, Quadripolar Brachial Plexus PNS to Treat CRPS: A Case Series (n=8)

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Background

The brachial plexus is the ventral rami of C5 to T1. The plexus runs through the anterior neck, beneath the clavicle, to the axilla and down the arm to the hand. Brachial plexus neuropathy occurs after damage in the neck or upper anterior shoulder while the nerves are still closely bundled together, causing pain, decreased sensation, and decreased range of motion in the shoulder, arm, with limited range of motion of the shoulder, arm, and hand.

Physiotherapy and non-steroidal anti-inflammatory drugs (NSAIDs) are the first treatments of choice for chronic pain patients. The next step in the treatment ladder is opioids, but these can result in dependence, addiction, abuse, overdose, opioid-induced hyperalgesia, constipation, respiratory or immune dysfunction, hormone imbalance, and death (1). Nerve blocks are effective, but only short term, and have no predicting value when considering other irreversible therapies such as radio-frequency ablations (2).

Peripheral nerve stimulation (PNS), though considered a more invasive therapy modality, has been demonstrated to be an effective alternative for the management of neuropathic peripheral chronic pain (3) since the early 1960's (4) but a variety of difficulties have limited the widespread use of PNS, including cosmetic concerns and complications. New wireless neuromodulation technology does not include IPGs but instead consists of a four- or eight-contact electrode array with embedded electronics, a separate mated miniature receiver, and a small, externally wearable re-chargeable transmitter. Thus, the potential complications related to the implant of an IPG, which can be up to 40% (5,6), are avoided.

Case Report

Eight subjects (4 females, 4 males), mean age of 65 years, presented with shoulder pain radiating to the upper arm; six patients experienced pain radiating down into the hand. Subjects were diagnosed with brachial plexus neuritis and CRPS. Treatment options including physical therapy, analgesic injections, cryoneuroablation, NSAIDS, opiates and, in a few instances, cervical SCS, were unsuccessful.

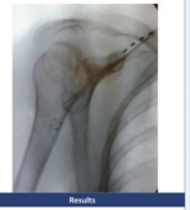
Methods

Surgical description for the trial implant: A small incision needle entry point was made at the anterolateral shoulder and the 13 gauge introducer was percutaneously advanced lateral to medial to cross over the midportion of the clavicle. An 8-contact, trial stimulator was placed through the introducer toward the target location. The steering stylet was removed, and the receiver inserted into the inner lumen of the electrode array. The trial stimulator was then secured with Mastisol and Steri Strips and completely covered under a sterile Tegaderm.

All subjects reported great pain reductions during the trial, with mean pain scores reducing from 8.1/10 to 1.5/10. Given the excellent results of the trial, the patients agreed to move forward with the permanent implant.

Surgical description for the permanent implant: Patients were positioned supine and the area overlying the brachial plexus was identified under fluoroscopy and in some cases , ultrasound. A small incision needle entry point was made at the anterolateral shoulder and the introducer was advanced lateral to medial to cross over the midportion of the clavicle (Fig 1). A tined 4-contact electrode array was threaded through the introducer, the needle and steering stylet removed, and the receiver inserted into the inner lumen of the electrode array. The neurostimulator was anchored in the incision. A receiver pocket was made in the upper arm, and the device was tunneled from the insertion site to the receiver pocket. A knot was made at the end of the neurostimulator to prevent dislodgment of the receiver. The tail of the system was secured into a looped coil with 2-0 silk sutures and then secured to the fascia in the receiver pocket using 2-0 silk sutures. The pocket was closed with subcutaneous and then subcuticular sutures. Subjects wore the transmitter and antenna over the upper arm and received stimulation at 1499Hz and 30μs with amplitudes customized to subject needs.

Fig. 1: Image showing the four-contact neurostimulator at the brachial plexus



Results

All subjects were successfully treated and reported increased levels of activity and improved sleep. Mean pain scores reduced from 8.1/10 at baseline to 1.5/10 at the end of trial (n=8), 1/10 at 3 months (n=7) and 1.8/10 at 12 months (n=5) post-implant. The medication intake was assessed at baseline and at the last follow-up undergone by the patient. One patient had never used medications for pain relief, six patients reduced the overall intake of medication, and four out of seven patients could stop the use of opioids. No complications were reported.

Discussion

With new wireless stimulation technologies, cosmetic concerns and complication rates are reduced, since percutaneous placement of a wireless stimulation device adjacent to affected peripheral nerve(s) is a minimally invasive and a reversible method of pain control in patients with neuropathic pain refractory to conventional medical management. This enables a more adequate study of the parameters and effects of PNS.

Conclusions

Wirelessly powered, battery-free peripheral nerve simulation was a successful option for patients suffering of debilitating shoulder and arm pain due to brachial neuritis and CRPS, allowing PNS in difficult-to-access sites with limited options for a traditional IPG.

Wireless System Components

The StimQ PNS System (Fig. 2) utilizes wireless technology. Each stimulator contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

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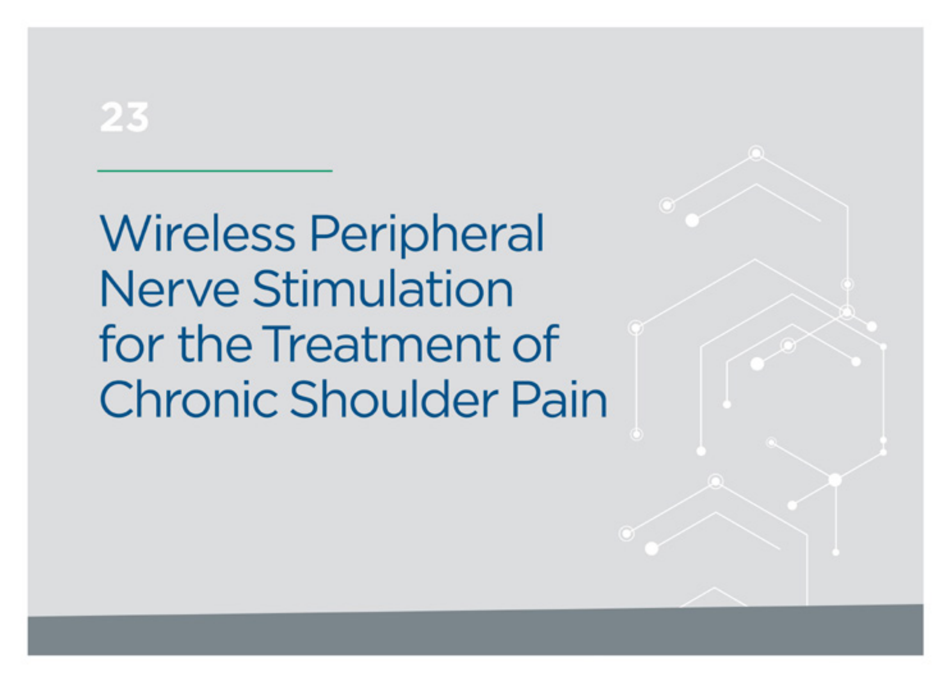
DRIVING INNOVATION THROUGH SCIENCE & EVIDENCE

FREEDOM FROM CHRONIC PAIN

stimwave TECHNOLOGIES



Wireless Peripheral Nerve Stimulation for the Treatment of Chronic Shoulder Pain

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Background

Shoulder pain has an estimated population prevalence of 4% to 26%. About 1% of adults aged over 45 years in the UK consult their GP with shoulder pain every year. The most common source of shoulder pain is the rotator cuff, accounting for over two-thirds of cases (1). Other sources of shoulder pain are avascular necrosis, brachial plexus injury, broken arm or collarbone, bursitis, cervical radiculopathy, dislocated shoulder, frozen shoulder, impingement, osteoarthritis, polymyalgia rheumatica, rheumatoid arthritis, rotator cuff injury, separated shoulder, septic arthritis, sprains, tendinitis or tendon rupture and torn cartilage, among others.

Wireless neurostimulation has been used effectively for the treatment of pain syndromes of multiple etiologies (2,3,4). A 4- or 8-contact peripheral nerve stimulator (PNS), can be implanted percutaneously in the targeted area, using an introducer, and a small, external, transmitter, worn over the patient's clothing, provides the stimulation parameters and energy to power the neurostimulator via radio frequency (RF). The implantation of an implantable pulse generator (IPG) and the tunneling of the extensions required for traditional neurostimulation are not necessary.

Case Report

A 65-year old male presented with sharp, localized pain on abduction of the left shoulder since 2015. A CT guided arthrogram (5/2017) revealed a full thickness tear of the supraspinatus muscle, degenerative tearing of the inferior and superior labrum, degenerative hypertrophy of the acromioclavicular (AC) joint and mild to moderate glenohumeral (GH) joint degenerative arthritis. Several treatment options were attempted but these never provided long lasting pain relief. A left suprascapular diagnostic nerve block proved 100% pain relief for about 6 hours. A left suprascapular peripheral nerve stimulator trial was offered to the patient.

Methods

Trial Procedure: A suprascapular 8-contact peripheral nerve stimulator was trialed (Figure 1), and the pain went from a VAS rate of 3-7/10 to 100% relief post-implant. The patient was satisfied with the results and opted for a permanent implant.

Permanent Implant: A 4-contact electrode array with tines was laid on the prepped skin and the distal electrode at the tip of the device was placed at the proximal anatomical (osseous) location where the suprascapular nerve was identified by fluoroscopy. Using a skin marker, a 1cm sagital line was marked over the needle entry location proximally. The skin and deeper tissues were anesthetized using a mixture of 1% lidocaine with epinephrine and 0.5% bupivacaine. Using a #11 blade, an incision was made with a scalpel to allow insertion of the introducer, which was passed through the subcutaneous tissues toward the desired nerve target. The introducer was placed at a shallow angle and advanced using a "tenting" approach to stay within the subcutaneous layer and to prevent diving into the muscular fascia. The electrode array was inserted through the introducer and advanced towards the target nerve under fluoroscopic guidance. At this point, the skin was infiltrated with local anesthetic and a 1 inch incision was made to create a receiver pocket, about 10 cm medial to the electrode array entry site incision. The needle was passed subcutaneously from the receiver pocket to the electrode array entry site. The proximal end of the electrode array was threaded through the distal tip of the needle to the subcutaneous receiver pocket. After withdrawal of the needle, the receiver was inserted into the inner lumen of the electrode array and intraoperative testing was completed with an external transmitter. Good paresthesia coverage of the painful areas was obtained. A knot was tied in the electrode array containing the receiver and the remaining end of the neurostimulator was coiled, sutured to itself to eliminate any sharp ends, secured to the fascia with fixation suture and the pocket closed using 4-0 *Monocryl*.

Fig. 1: AP of trial device placement

Results

Six months post-implant, the patient answered the EQ-5D-5L quality of Life questionnaire and reported excellent mobility of the shoulder, no problems with self-care or usual activities, no pain or discomfort and no anxiety or depression. He scaled his health as related to the shoulder as 95 % (100% best, 0% worst). He also reported a patient global impression of change as a 7/7. The Oswestry Disability Index (ODI) 6 weeks post-surgery was 4% (0% = no disability, 100% = bed ridden).

18 months post-implant, the patient still had close to 100% pain relief and was able to decrease his medication intake from morphine sulfate extended release 15 mg from 3 times a day to 2 times a day and morphine immediate release 30 mg from 4 times a day to 3 times a day.

Discussion

The anatomical conditions of the area are such that the implant of a conventional system's lead with an IPG would have been very difficult. In general, peripheral nerve stimulation is difficult with conventional devices which require not only an IPG but also extensions to the site where the IPG is implanted. With the wireless system, these drawbacks are avoided and the implant of a single lead with the corresponding antenna, both smaller than conventional systems, enable neurostimulation in areas where conventional systems cannot be used (5,6).

Conclusions

Wireless peripheral nerve simulation was a successful option for this patient suffering of debilitating left shoulder pain due to a left rotator cuff tear of the supraspinatus muscle.

Wireless System Components

The StimQ System (Fig. 2) utilizes wireless technology. Each stimulator contains four or eight contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a separate, mated receiver component. A small, externally wearable, rechargeable transmitter attached to a transmitting antenna worn in clothing provides the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Fig. 2: System components

IMPLANTED NEUROSTIMULATOR

WEARABLE ANTENNA ASSEMBLY

References

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