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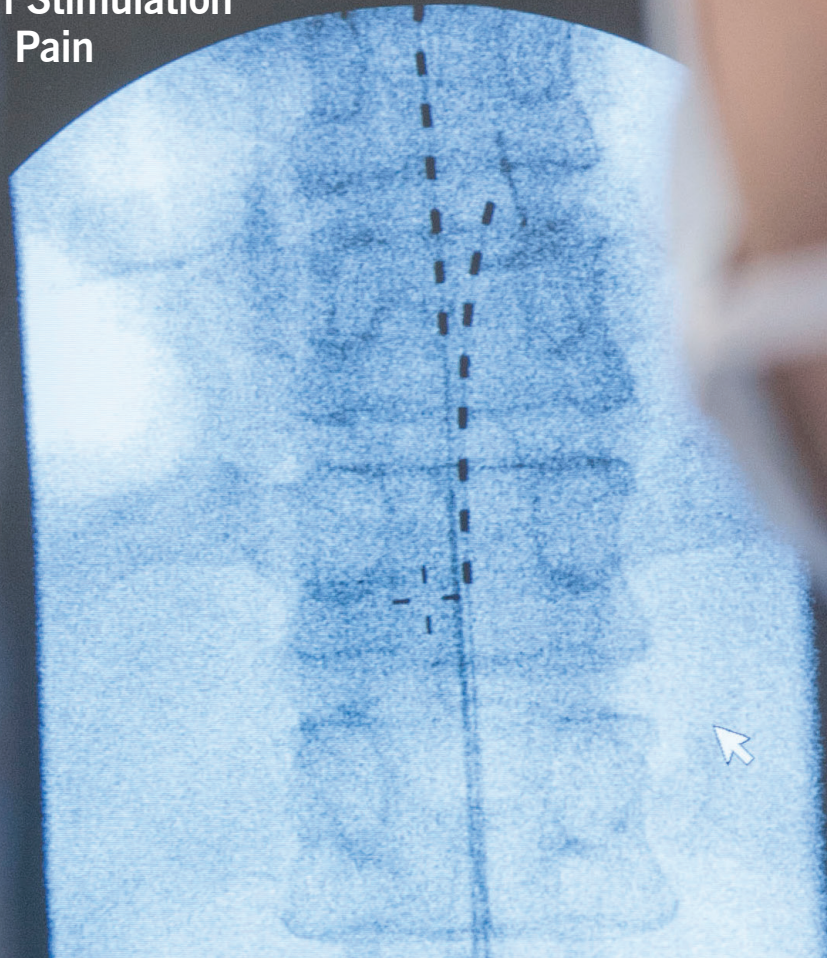
# Pain Consult

DEPARTMENT OF PAIN MANAGEMENT | 2015

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# Dear Colleagues,

First do no harm. This medical dictum has never been more applicable as the American health system goes through unprecedented changes, with hospitals required to deliver better patient outcomes and faster care at lower costs.

In all we do, Cleveland Clinic Pain Management staff are working with colleagues across the healthcare spectrum to transform care for the better and to move from volume-based to value-based care. It's an exciting time to be a pain practitioner as research has given us innovative new treatments, including medications and new devices and injections. We are also pursuing alternative therapies to help people live with and manage their pain.

With 100 million Americans affected by chronic pain and unprecedented growth in orthopaedic procedures, we are at the front lines of healthcare. Advances in treatment options are allowing us to target pain better, get patients home faster and deal with pain states more efficiently. This issue highlights the following:

- Our cover feature story puts a spotlight on our Chronic Abdominal Pain Clinic and the use of dorsal column stimulation (DCS). We take a closer look at one patient who tried multiple medications and nerve blocks to treat her chronic abdominal pain – all to no effect. When we performed DCS – a procedure more commonly used for other pain conditions – the patient was able to resume her life free from this pain.
- On p. 6, we look at research into the relationship between gender and differences in the experience of pain across a range of pain conditions. Statistics show that women visit physicians for pain management in a 2-to-1 ratio with men, and according to the National Institutes of Health (NIH), discoveries into how the different genders respond to treatment are leading to new directions in research on the relief of pain.
- Meanwhile, an important program at Cleveland Clinic is aimed at minimizing post-surgical pain for patients. On p. 8, learn about the Acute Pain Management Service (APMS), a multidisciplinary team dedicated to working with patients to proactively prepare for and curtail postoperative pain. The service provides a support network that is transforming the way many patients experience the surgical process.

In this issue, we also feature some exciting research studies underway at Cleveland Clinic and take a closer look at the anti-inflammatory diet as a pathway to pain reduction (p. 10-11). Finally, we highlight some of the myths about shingles in the infographic insert for you to share with your patients.

I hope you find this issue stimulating, and I urge you to contact me or my colleagues featured on these pages with your feedback and thoughts.



**Richard W. Rosenquist, MD**

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## Consult QD

A blog for healthcare professionals

To stay up on the latest research insights, innovations and treatment trends from Cleveland Clinic's Department of Pain Management, visit [consultqd.org/painmanagement](http://consultqd.org/painmanagement).

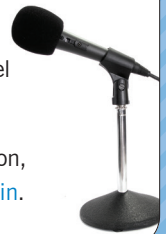


## Save the Date

*18th Annual Pain Management Symposium*

**March 5-9, 2016**  
Coronado Bay Hotel  
Coronado, CA

For more information, visit [ccfme.org/pain](http://ccfme.org/pain).



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## Procedure Spotlight:

# Dorsal Column Stimulation for Abdominal Pain



// FEATURING BRUCE VROOMAN, MD //



After exhausting other treatment options, including multiple medications and nerve blocks, Cleveland Clinic patient Claire A. (a pseudonym) underwent neurostimulation of the dorsal column to treat her chronic, intractable neuropathic visceral and truncal pain. In September 2014, Bruce Vrooman, MD, performed a one-week stimulator trial. Based on the success of that trial, he subsequently implanted a dorsal column stimulation system in November. (Read details of Claire A.'s story on p. 5.)

› *Dr. Bruce Vrooman is a pain management specialist and anesthesiologist in the Department of Pain Management.*

Dorsal column stimulation (DCS), also known as spinal cord stimulation (SCS), is a neuromodulation therapy that works by applying an electrical current to the spinal cord at the source of the pain. It is an accepted treatment for patients with chronic back or limb pain who have not responded to other treatments. As the nerve fibers are stimulated, patients experience a pleasant sensation rather than the pain that had previously plagued them. DCS systems have three primary components: stimulating electrodes, an

implantable pulse generator (IPG) and a generator remote control.

During the outpatient procedure, which takes approximately two hours, patients lie face down. They receive monitored anesthetic care, usually with fentanyl or propofol. The surgeon makes an incision in the skin superficial to the lumbar spine and over the iliac crest. Using a scalpel, a small pocket – about one centimeter deep – is created to hold the IPG, which can either be rechargeable or nonrechargeable.

Next, the surgeon places a needle into the epidural space above the posterior

elements of the spinal cord. This requires a small incision and some dissection with electrocautery. A small space is created under the subcutaneous fat and above the ligament so the needle can enter the epidural space. Then the surgeon advances two flexible silicone leads through the needle. The leads have anywhere from four to 16 contacts, depending on the extent of the painful region.

Once the leads are advanced into the epidural space, they are steered into the thoracic region for abdominal pain or the cervical region for neck and arm

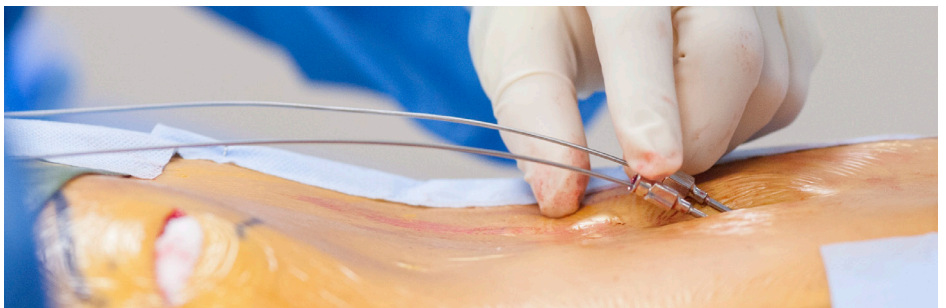
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pain. The leads are pulled down slowly while the patient is awake to report the results of the stimulation. Next, the needle is retracted and the leads are secured to ligaments in the back with a silicone anchor.

After the leads are secured, the surgeon uses a tunneling device to reach the pocket where the IPG is implanted. The leads are advanced through a straw to the IPG site, where they are connected and impedance is checked to ensure the leads are working. Then the surgeon irrigates the pocket with an antibiotic solution and secures the IPG in place with two silk sutures. A mix of deep dermal sutures, subcuticular sutures and surgical glue is used to close the incisions and epidermis before a small dressing is applied. Programming of the IPG occurs in the recovery area, and the patient is given the generator remote control to control the DCS system.

DCS is not for everyone: It's suited to chronic pain patients who have exhausted other treatment options and



have reasonable goals for relief and resumption of normal activities. It is an elective treatment option that can work in conjunction with medications and conservative therapies. DCS is a relatively new treatment for neuropathic abdominal pain. More commonly, the therapy is used to treat the following:

- Failed back surgery syndrome
- Radicular pain or radiculopathies from herniated disk
- Epidural fibrosis
- Arachnoiditis
- Type 1 complex regional pain syndrome (formerly known as reflex sympathetic dystrophy)

- Type 2 complex regional pain syndrome (formerly known as causalgia)

It's critical that patients rule out any organic cause for pain prior to undergoing DCS. At Cleveland Clinic, all candidates for the procedure must first meet with a pain psychologist, who runs a series of tests to evaluate the patient's expectations. Then the case is presented to an interdisciplinary committee to discuss the patient's background and confirm that other pain management options have been explored. But for those who fit the criteria, DCS can be a good option to manage chronic pain.

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## A PATIENT'S STORY ABOUT DEBILITATING ABDOMINAL PAIN

Claire A. (a pseudonym to protect privacy) is a 43-year-old female from out of state who was referred by Cleveland Clinic gastroenterologist Maged Rizk, MD, to Cleveland Clinic's multidisciplinary Chronic Abdominal Pain Clinic in the Department of Pain Management.

Claire A.'s extensive workup had ruled out cancer but had not revealed a clear, identifiable gastrointestinal cause for her pain. She partially attributed the pain to having had a hysterectomy five years earlier, though follow-up evaluations with her gynecologist did not identify any complications from this surgery.

Her pain was located in the left upper quadrant of her abdomen and radiated toward her umbilicus. The sharp, burning neuropathic pain ranged from seven to 10 out of 10 in intensity. Eating made her pain worse, and by avoiding eating, she had lost 30 pounds over a few months. She reported that she slept only three hours a night due to her discomfort.

She had tried multiple medications, including opioids and membrane-stabilizing medications, including gabapentin and pregabalin, though none helped her significantly and they contributed to her feeling sedated and confused. She continued to work, but only part time, due to her discomfort and the side effects of the medication.

Given her history, Claire A. was a good fit for the Chronic Abdominal Pain Clinic. Says Dr. Rizk, "We use a team approach to abdominal pain, making sure all healthcare providers are on the same page. We determine the etiology of the abdominal pain, ensure that nothing life threatening is identified and use sustainable means in our approach. After an extensive GI evaluation, the patient and I discussed the importance of using another approach to her pain."

"The first procedure we performed was a diagnostic celiac plexus nerve block under fluoroscopy, to help in diagnosing and at least temporarily treating a visceral neuropathic component of her pain," says her surgeon, Bruce Vrooman, MD, an anesthesiologist in Pain Management. "The patient had relief for two weeks after the first block and for one month after a repeated block. A third block provided relief again for one month, and she was able to tolerate food better and be more active at home and at work."

Claire A. said that she valued the pain relief provided by the celiac plexus nerve blocks, but did not wish to drive hours from out to state to Cleveland every month. "So we discussed a trial of a dorsal column stimulator, or 'spinal cord stimulator,' as a therapy to help treat her chronic, intractable visceral and truncal pain," says Dr. Vrooman.

In September 2014, Dr. Vrooman and the surgical team performed a one-week stimulator trial with two flexible leads advanced to the T5 level in the epidural space. The leads were connected to an external generator during the trial when the patient experienced greater than 90 percent pain relief and had improved performing activities of daily living. The stimulator produced a comfortable sensation over previously painful areas. "Based on her successful trial, we subsequently performed an implantation of a stimulator system comprising two leads and a rechargeable generator," says Dr. Vrooman. "She was given a remote control device to help in programming her stimulator."

The patient reported much improvement at her postoperative visit as well as three months later, when she came in for a follow-up and reported almost full resolution of her abdominal pain. Claire A. said her greatest satisfaction came in knowing she could eat without pain. She decreased her opioid use to nil and also discontinued other pain medications. Soon the patient returned to work full time and was able to exercise and perform activities that once caused her pain.

At the Chronic Abdominal Pain Clinic, each patient's pain story is unique. The multidisciplinary team of gastroenterologists, surgeons, psychologists and pain medicine physicians helps in identifying a cause of the pain and also in treating pain. "Successful treatment through counseling, medication adjustment, or performing procedures when indicated can be rewarding to a patient, a patient's family, and the physician alike when a patient feels better, regains control of basic functions and goes on to lead an active life," says Dr. Vrooman.

# Women and Pain: New Research Delves into Differences in the Pain Experience for Women Compared with Men



// RICHARD W. ROSENQUIST, MD, BETH MINZTER, MD,  
AND JILL MUSHKAT CONOMY, PHD //

For the past two decades, research on gender and pain has been a topic of significant scientific and clinical interest. Recent research has expanded into how the overall pain experience for women differs from that of men. As described here, we start with the knowledge that many conditions and pain syndromes are more likely to occur in women, including headache, irritable bowel syndrome (IBS), chronic regional pain syndrome (CRPS), trigeminal neuralgia, fibromyalgia, multiple sclerosis and osteoarthritis.

Historically, medical research has been conducted predominantly with male participants. Some posit that the closer look at gender and pain began in 1997 when the National Institutes of Health (NIH) issued a request for applications titled “Sex and Gender-Related Differences in Pain and Analgesic Responses.” This request generated great interest from the scientific community and sparked numerous research programs.

The implications of gender differences are important for patient care. Multiple factors play a role in how an individual experiences pain, including genetics, social status, exercise and information processing in the brain. Hormonal variation, puberty, reproductive status and menstrual cycle also affect pain threshold and perception. Let’s take a closer look at four common pain conditions and the experience women have with them.

## MUSCULOSKELETAL PAIN

The NIH cites many studies that have looked into the prevalence of musculoskeletal pain in men and women. In one

study that spanned 17 countries on six continents with more than 85,000 participants, it was shown that the prevalence of chronic pain is higher among females than males. Other studies from Europe and Australia also indicated that chronic musculoskeletal pain is more common in females than males. Under review were

several specific types of musculoskeletal pain, including back pain, whole body pain, fibromyalgia and osteoarthritis. As women age, they experience more compression fractures, vertebral changes such as kyphosis and scoliosis, loss of bone mass, and osteoarthritis than do men. Any one of these conditions puts them

## PREGNANCY PAIN AND OPIOIDS

Pain during pregnancy is another area of concern for female patients. Pregnancy pain can be caused by multiple factors, including weight gain (commonly), ligamentous relaxation due to hormones, a change in posture and pelvic floor dysfunction. According to the Centers for Disease Control and Prevention (CDC), nearly one-third of women of reproductive age had an opioid prescription filled each year between 2008 and 2012. The NIH reports, “Regular exposure to such substances during pregnancy has maternal and fetal implications.” They go on to say that managing narcotic dependence should be based on the individual patient and “may include discontinuation of narcotics with careful observation, limitation of prescription dispensing, or substitution therapy with methadone or buprenorphine.”

“We have seen that some patients taking opioids on a chronic basis may feel worse overall because of the side effects, which can include constipation, sedation and depression,” says Beth Minzter, MD, a staff physician in Cleveland Clinic’s Department of Pain Management. “Some patients even experience worsened pain when treated with chronic opioids, an effect known as opioid-induced hyperalgesia. This alone may be a strong argument for avoiding regular prescription use of opioids for the majority of patients, including parturients.”

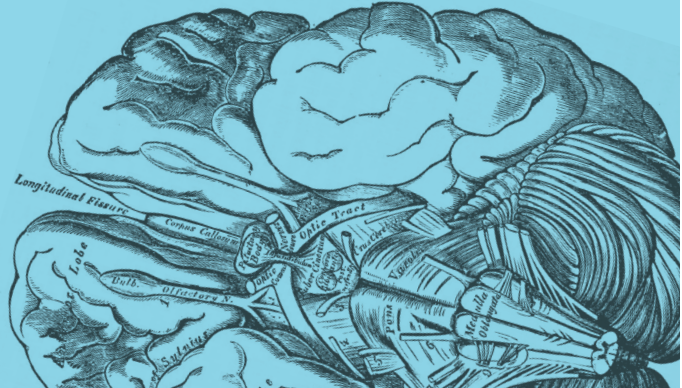
## EVALUATION BY A PAIN PSYCHOLOGIST

Specialists may refer patients for a psychological evaluation and treatment if they are concerned about issues contributing to a patient's pain. Cleveland Clinic pain psychologist Jill Mushkat Conomy, PhD, points out the following, specific to women and pain:

“For women, issues of family stress, weight gain and sexuality can be front and center when it comes to the onset of pain. When meeting with patients, I share a long list of biological, psychological and social issues to consider to get the conversation started.”

Issues include everything from experiencing physical trauma to having feelings of depression. Once the areas of concern

are pinpointed, Dr. Mushkat Conomy often uses cognitive behavioral therapy (CBT) to help patients rethink their pain and find different ways to manage and live with it.



at a higher risk of breaking a bone during a fall, which can add to their pain.

### ABDOMINAL PAIN

According to a number of epidemiological studies recently reported on by the NIH, there is a higher prevalence of abdominal pain in women. In fact, several country-based studies of abdominal pain generally support increased prevalence among females. More specifically, the NIH reports that there is approximately a 3-to-1 female-to-male ratio in the diagnosis of IBS in the United States. This chronic syndrome is characterized by recurring symptoms of abdominal pain and problems with bowel habits.

### HEADACHE

Headache is one of the most common pain conditions. After reviewing more than 60 studies, the NIH concluded that the prevalence of headaches and migraines is higher for women than men. In the NIH American Migraine Study II, which included more than 29,000 adults, it was estimated that the one-year prevalence of migraine in the U.S. is 18 percent in women and 7 percent in men.

According to the Women's Health Office of the U.S. Department of Health and Human Services, migraines are most common in women between the ages of 20 and 45, and women more than men report more painful and longer-lasting headaches with more associated symptoms, including nausea and vomiting.

### PELVIC PAIN

For women suffering from chronic pelvic pain, absent a physical injury, childbirth or identifiable procedural cause, there is a significant potential for a history of intimate partner violence. According to the Centers for Disease Control and Prevention, three in 10 women in the U.S. have experienced intimate partner violence, physical violence or rape versus one in 10 men. Data suggest that this can contribute to pain conditions. “There are different considerations when treating a 27-year-old man for pelvic pain versus treating a 27-year-old woman with pelvic pain,” says Richard W. Rosenquist, MD, Chairman of Cleveland Clinic's Department of Pain Management. “It is crucial to listen to the responses to questions to determine the underlying cause so you

can pursue the right treatment plan. We must take into account that abuse can sometimes be a factor in pain onset and longevity.” For some patients, an appointment with a pain psychologist is critical in evaluating underlying causes and developing a successful treatment plan.

Looking at the research on these subsets of patients is instructive to our practice. We must take into account these data and look to further research to find new and better ways to approach pain treatment for female patients. Another issue noted in current research is the possibility of gender bias in the delivery of pain treatment. According to the NIH, there is concern that women are at greater risk for undertreatment of pain, although the use of prescription and nonprescription analgesics is higher among women than men.

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# Cutting-Edge Program Targets Postoperative Pain

Program aims to minimize pain following surgery



// FEATURING KAMAL MAHESHWARI, MD, AND LORAN MOUNIR SOLIMAN, MD //

Housed within Cleveland Clinic's Department of Pain Management, the Acute Pain Management Service (APMS) uses state-of-the-art, evidence-based pathways proven to reduce postoperative pain, involving combinations of nerve block, epidural, intravenous and multimodal analgesic drug therapies.

The APMS is one of the few in the country providing this service via a dedicated multidisciplinary team that works 24/7.

The program is also unique in proactively identifying patients who are more likely to experience pain after surgery and intervening in advance. What's more, the APMS team pioneered the practice of sending patients home with indwelling catheters, allowing for minimal use of sedating oral medications and reducing hospital length of stay.

Pain management programs are most often run by surgeons or anesthesiologists, or by the nursing staff. At Cleveland Clinic, the team involves surgeons, anesthesiologists, pharmacy, nurses, nurse managers, nurse practitioners and physical therapists, comprising about 30 individuals in all.

"We all collaborate to deliver the same message to the patient," says APMS founder and director Loran Mounir Soliman, MD, who joined Cleveland Clinic's anesthesiology department in 2006 and began building the APMS the following year. Dr. Soliman is also director of the acute pain/regional anesthesia fellowship.

The elaborate infrastructure sets Cleveland Clinic's acute pain management program apart from others, says anesthesiologist Kamal Maheshwari, MD, who joined APMS in 2009. "This is a huge service with unparalleled infrastructure and focus on keeping patients safe and comfortable."

## PREVENTING PAIN

Ineffective treatment of postoperative pain can lead to many negative outcomes, including deep vein thrombosis, pulmonary embolism, myocardial infarction, poor wound healing and insomnia. Those complications raise costs, prolong hospital stays and prompt readmissions. One study found that pain was the most common reason for readmission following same-day surgeries in the U.S., accounting for about 38 percent of the total.

At Cleveland Clinic, where about 45,000 surgeries are performed annually, that percentage is far lower. This is in large part because of the APMS, which serves between a fifth and a quarter of patients undergoing surgery at the institution.

Patients referred to the APMS fall into several categories:

- 1) Those undergoing the specific procedures known to cause moderate-to-severe pain, such as total knee and shoulder replacement, are automatically referred by the surgeons in advance.
- 2) Patients who have had prior problems with pain control or who have been on long-term treatment for chronic pain.
- 3) If the surgeon unexpectedly has to extend the incision or if other unanticipated problems occur during surgery that might increase postsurgical pain, APMS is consulted.
- 4) When excessive postoperative pain wasn't anticipated and the surgical team is unable to control the patient's pain.

Patients in the first two categories meet with APMS prior to their procedures. "Our program is unique in trying to identify patients who might have issues with pain control, so we have a chance to discuss options and what to expect after surgery. We educate patients to set realistic expectations for how to cope with pain in the first few days. We do that for patients upfront," Dr. Soliman says.



## SURGERY-SPECIFIC PAIN MANAGEMENT

The APMS team has developed several pain management pathways, including those following upper abdominal procedures, total knee and shoulder replacements, and spine surgeries. More pathways are being developed, and the current ones are revised on an ongoing basis.

These pathways involve step-wise patient evaluations and use of surgery-specific pain control modalities. For example, extremity surgery usually involves nerve blocks, while surgery in the abdomen or thorax typically will require epidural infusion.

Post-head and neck surgery patients receive multimodal analgesia, combining two or three drugs from different classes and aiming for the fewest side effects from each one.

According to Dr. Maheshwari, “Joint replacements and especially total knee replacements result in significant pain, but we make patients comfortable by using specific nerve blocks. The same goes for ankle and shoulder surgery. Patients used to stay in the hospital three to four days just for pain control. Now they go home the same day if they want, or maybe the next day.”

## TAKE-HOME PAIN RELIEF

Orthopaedic surgery patients are able to leave the hospital so soon because they take their pain meds home with them, via indwelling peripheral nerve catheters and a disposable pump containing the anesthetic. Nurses call the patients every day for a week to make sure things are going as planned.

“We have the ability to follow up with patients while they are at home and troubleshoot any issues. That’s how we reduce length of stay. Patients are

*“We have the ability to follow up with patients while they are at home and troubleshoot any issues. That’s how we reduce length of stay.”*

– Kamal Maheshwari, MD

staying with their families more, which helps in their recovery,” Dr. Maheshwari says.

“Every day of hospital stay adds cost and complications. The hospital is safe, but there’s always the chance of hospital-acquired infection and other complications. Also, if patients are consuming less opioid medication because of the nerve blocks, the recovery is much faster,” he notes.

## THE DATA SPELL SUCCESS

Data collected pre- and post-APMS validate the program’s success. On discharge from the post-anesthesia care unit (PACU) following total knee replacements, for example, patients reported significantly reduced pain on the Visual Analog Scale, 2 versus 4 points ( $P < 0.005$ ). Opioid use in the PACU was also reduced, at 2.9 compared with 14.6 morphine equivalents in milligrams ( $P < 0.007$ ).

Patients were discharged from the PACU in an average of 4.1 hours compared with 6.4 hours postsurgery ( $P < 0.001$ ) and had shorter average length of overall hospital stay, 2.1 versus 4.5 days ( $P < 0.001$ ).

Importantly, total knee replacement patients who received APMS care had better function at six months after the procedure, with Knee Scoring System scores of 59.4 versus 46.9, a significant difference at  $P < 0.05$ .

## TEAMWORK

None of this would be possible without extensive staff collaboration. Development of each pain management pathway involves several initial meetings to make sure all team members understand their roles and the application of the pathway; then there are meetings to revise any problem areas. For example, the nurses need to be clear on what they will be teaching the patient regarding their pain, and physical therapy has to know what approaches to use.

Meetings to develop pathways are usually held monthly for the first six months, then less frequently. “Along the course, you do change your original plan. There is constant updating of the pathways,” Dr. Soliman says.

Indeed, says Dr. Maheshwari, “It’s a dynamic practice. We adapt to patient needs, and to the data. The goal always is better patient outcomes.”

Here’s Dr. Soliman’s advice to other institutions interested in creating a similar program: “You have to have agreement among all the stakeholders who care for the patient and commitment that they will comply with the plan. You can’t say you’re running late so you’ll skip it. You’ve made a commitment to the patient.”

*Dr. Maheshwari can be reached at maheshk@ccf.org or 216.445.4311; Dr. Soliman can be reached at mounirl@ccf.org or 216.445.4868.*

# A Closer Look at Three Promising Research Projects by Cleveland Clinic Investigators

## 1 – MANDIBULAR NERVE BLOCK FOR TMJ PAIN

A collaborative multidisciplinary team at Cleveland Clinic is achieving encouraging success in relieving temporomandibular joint (TMJ) pain for an increasing number of patients, using a unique mandibular nerve block technique.

**Jianguo Cheng, MD, PhD**, of the Anesthesiology Institute, and **Joseph Krajekian, MD, DMD**, of the Head & Neck Institute, devised this approach to help reduce the number of patients who need to have a joint replacement by Dr. Krajekian.

“Most patients with TMJ pain do not have a major structural problem, but they are in debilitating pain,” says Dr. Cheng. “We are focusing on helping this population.”

**He describes the procedure as having two steps:**

1. Perform a nerve block to determine whether the pain can be reduced significantly.

2. In patients with persistent pain, use radiofrequency ablation to denature the nerve.

“To our surprise, most people do not need the second step, although some need to have the nerve block repeated in six to nine months,” says Dr. Cheng. “If the block is only effective for about two weeks, then those patients need to move on to radiofrequency ablation.”

He and his colleagues presented their findings at the American Academy of Pain Medicine recently and hope to announce a large cohort of outcomes data in one to two years. He says it is exciting to see what a big difference this procedure makes in people’s lives.

“They are free from debilitating pain in their jaw, and from the headaches it causes,” he says. “Many of them gain their life back after only one block.”

## 2 – DRG FOR LOWER EXTREMITY PAIN

Anesthesiology Institute researchers were involved with the testing of a dorsal root ganglion (DRG) stimulator designed to relieve lower extremity pain that is now pending approval by the U.S. Food and Drug Administration.

The stimulator technology (created by Spinal Modulation and now owned by St. Jude Medical) was tested in a 17-site study. **Samuel Samuel, MD**, of Cleveland Clinic’s Anesthesiology Institute, was the principal site investigator in Cleveland.

“The device mimics a pacemaker, but what’s new about it is that it targets the pain-generating structure in the spine – the dorsal ganglion,” he says. “It can target pain from the waist down very specifically. For example, we can treat just the left foot, or the left foot and the right groin, or the right knee and the left foot, which is difficult to cover with conventional spinal cord stimulation therapy.”

He says this would be useful in chronic pain after surgeries for hernias or knee replacement, for example, or for patients with complex regional pain syndrome or failed back surgery syndrome with predominant leg pain (among other uses).

Dr. Samuel and his colleagues implanted a standard spinal cord stimulator, technology that has been in use for 25 years, into a group of patients, and then implanted the DRG stimulator in one patient – one of only 72 people in the country to receive it. That patient is doing very well and is happy with her results, after suffering with pain in one foot for years, he says.

“The results are very encouraging,” Dr. Samuel says. “Several papers on it were presented in June at the International Neuromodulation Society meeting in Montreal. The hope is for FDA approval potentially by the end of 2015.”

### 3 – STUDY USES STEM CELLS TO RESTORE DEGENERATIVE DISKS

Last winter, **Nagy Mekhail, MD, PhD**, of Cleveland Clinic's Department of Pain Management, began enrolling patients for a double-blind, randomized, controlled study to ascertain whether stem cells can alleviate pain arising from degenerative intervertebral disks. Dr. Mekhail serves as principal investigator at Cleveland Clinic, one of 13 sites in the U.S. and Australia participating in the research.

"When intervertebral disks develop fissures, nerve endings can grow into these cracks and cause pain," says Robert Bolash, MD, a collaborator on the project. Options for patients with diskogenic pain have been relatively limited, including spinal fusion surgery and artificial disk replacement. Other treatments include intradiskal electrothermal annuloplasty (IDET), where nerve endings are cauterized, and biacuplasty, a method that uses water-cooled radiofrequency to treat injured disks.

"For the last 70-plus years, pain management physicians have sought to destroy nerves that send pain signals," says Dr. Mekhail. "With this research, we hope to change the paradigm by regenerating the lumbar disks to treat nonradicular low back pain."

The study will enroll 100 patients with single-level diskogenic back pain. Researchers will inject stem cells into the injured disk and allow them to differentiate into the tissue. They will follow patients for one year, measuring pain relief in several ways:

- The patient's reported pain score
- A decrease or elimination in pain medication
- A reduced need for surgery or injections
- Improvement in the patient's daily function

Patients also will undergo MRIs to see if the treated disks have regained height, which is lost during fracture.

"This line of research truly represents something cutting-edge," says Dr. Bolash. "It has the potential to be a very exciting treatment, which could be offered to patients who haven't gotten relief with traditional methods."

## Talk Diet with Patients



// FEATURING WILLIAM WELCHES, DO, PHD //

Research shows that diet should be an integral part of a pain management program — especially as patients age. A vegan or Mediterranean diet — or healthier eating inspired by these diets — can control insulin and cholesterol levels and reduce inflammation, which is the pain culprit.

Inflammation is the body's immune response to "purify" and remove toxins, and over time it can trigger chronic diseases. A fair amount of research indicates that diet can correct fibromyalgia and chronic pain symptoms. Patients who have followed rigorous vegan or Mediterranean diets have seen complete turnarounds in their pain symptoms.

**These are three diet basics we should encourage all of our patients to consider:**

#### 1. EAT THE RAINBOW

Consume eight to nine servings of vegetables each day — a couple of those servings can be fruit.

#### 2. RESTRICT DAIRY AND GRAINS

Eat dairy products in limited quantities. When choosing grains, stay away from simple carbohydrates with refined sugar. Opt for whole grains, including barley, buckwheat, oats, quinoa, brown rice, rye, spelt and wheat.

#### 3. AVOID RED MEAT

Eat red meat the way we eat turkey right now — twice a year. Have it on very special occasions, very infrequently. Instead, include fish as the "meat" or eat vegetarian main dishes. Chicken is neutral — not harmful but not beneficial in the anti-inflammatory sense.

*Dr. Welches can be reached at [welchew@ccf.org](mailto:welchew@ccf.org) or 216.295.1010.*



# Pain Management Trials Now Enrolling Patients

Cleveland Clinic's Department of Pain Management is enrolling patients in a range of ongoing clinical studies, including those outlined below. To explore referring a patient, see the contact listing for each study. For more trial listings, visit [clevelandclinic.org/paintrials](http://clevelandclinic.org/paintrials).

## SELECTED CLINICAL TRIALS IN THE DEPARTMENT OF PAIN MANAGEMENT

Study name	Site PI and contact	Description/objective	Patient population/key inclusion criteria	Sponsor
<b>WHISPER:</b> A Randomized Controlled Study to Evaluate the Effectiveness of the Precision Spinal Cord Stimulator System at Sub-Perception Amplitude	<b>PI:</b> Nagy Mekhail, MD, PhD <b>Contact:</b> Holly Amirault (Study Coordinator) 216.445.0466 Tariq Niazi, MD, 216.445.8270	Randomized, controlled trial to evaluate the Boston Scientific Precision SCS System. Programmed with commercially approved settings but without providing tingling sensations in subjects who have chronic low back and/or limb pain.	Patient 22 years or older already implanted with Precision SCS System for at least 6 months prior to informed consent.  Interested in SCS-induced pain relief without paresthesia.  Willing to comply with protocol requirements.	Boston Scientific
<b>Thermal-Cool:</b> A Randomized Controlled Trial Comparing Thermal and Cooled Radiofrequency Ablation Techniques of Thoracic Facets' Medial Branches to Manage Thoracic Pain	<b>PI:</b> Nagy Mekhail, MD, PhD (National PI) <b>Contact:</b> Tariq Niazi, MD, 216.445.8270	Randomized, double-blind trial comparing standard thermal radiofrequency ablation (RFA) with cooled RFA for chronic thoracic back pain. Primary outcome measure is VAS pain score at 6 months.	Patients 18 years or older with chronic thoracic spine-mediated back pain at least 3 months in duration and not responsive to oral medication and physical therapy	Cleveland Clinic (with Kimberly-Clark Corp. as collaborator)
<b>Diclofenac:</b> Treatment of Knee Pain with Topical Diclofenac Cream 8% or Diclofenac Gel 1%	<b>PI:</b> Daniel Leizman, MD (National PI) <b>Contact:</b> Tariq Niazi, MD, 216.445.8270	Randomized, double-blind trial to evaluate whether diclofenac 8% cream is more efficacious than diclofenac 1% gel without an increase in systemic toxicity	Patients 18 years or older with acute or chronic knee pain or with postoperative knee pain lasting more than 2 months	FPR Specialty Pharmacy
<b>Lumbar RFA:</b> Effect of the Temperature Used in Thermal Radiofrequency Ablation on Outcomes of Lumbar Facet Medial Branch Denervation Procedures: A Randomized Double-Blind Trial	<b>PI:</b> Nagy Mekhail, MD, PhD <b>Contact:</b> Tariq Niazi, MD, 216.445.8270 Holly Amirault 216.445.0466	Randomized, double-blind study in patients undergoing thermal radiofrequency ablation of 3 or 4 lumbar facet medial branches on one side only. Will assess effect of the temperature used (80°C vs. 90°C) in terms of pain relief and potential complications over 1-year follow-up.	Patients 18 years or older with predominantly axial low back pain at least 3 months in duration with no radicular pain below the knee. Enrollees will have chronic back pain attributed to lumbar facet joint arthropathy based on clinical evaluation, with no previous back surgery at the planned treatment levels.	Cleveland Clinic Department of Pain Management
<b>Mesoblast Study:</b> A Prospective, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of a Single Injection of Rexlemestrocel-L Alone or Combined with Hyaluronic Acid (HA) in Subjects with Chronic Diskogenic Lumbar Back Pain Through 12 Months	<b>PI:</b> Nagy Mekhail, MD, PhD <b>Contact:</b> Tariq Niazi, MD, 216.445.8270 Holly Amirault 216.445.0466	Treatment of chronic diskogenic lumbar back pain (more than 6 month's duration) associated with moderate degenerative disk disease (DDD) not adequately controlled by conservative measures	Male and female subjects, at least 18 years of age, inclusive, and skeletally mature, in the opinion of the investigator.  Have documented diagnosis of moderate DDD from L1 to S1, with one symptomatic disk, in the opinion of the investigator.  Baseline of at least 40 mm and less than 90 mm of 100 mm on low back pain VAS (average pain over 24 hours).	Mesoblast, Ltd.
<b>Hydromorphone Study:</b> Safety and Efficacy Study of Hydromorphone HCl by Intrathecal Administration Using a Programmable Implantable Pump	<b>PI:</b> Nagy Mekhail, MD, PhD <b>Contact:</b> Tariq Niazi, MD, 216.445.8270	Controlled, two-arm, parallel-group, randomized withdrawal study to determine the safety and efficacy of hydromorphone HCl by intrathecal administration using a programmable implantable pump	Patients 18 to 75 years with a clinical diagnosis of chronic pain for at least 6 months who are presently on intrathecal pain medication and have (or are eligible for) SynchroMed® II pump implantation	CNS Therapeutics

VAS = visual analog scale

# Department of Pain Management Staff

Our specialists are available at multiple locations across Northeast Ohio.



## Richard W. Rosenquist, MD

Department Chair

216.442.5728 | rosenqr@ccf.org

Cleveland Clinic main campus

**Specialties:** Postsurgical pain syndromes, neuropathic pain, neck pain, low back pain, pain in athletes



## Emad Daoud, MD, PhD

Department Vice Chair, West Region

216.476.7331 | daoude@ccf.org

Lutheran Hospital, Westlake Medical Campus Building A

**Specialties:** Back and neck pain, CRPS, neuropathic pain, interventional and neuro-modulational pain management, cancer pain



## Teresa Dews, MD

Department Vice Chair, East Region

440.312.7246 | dewst@ccf.org

Hillcrest Medical Office Building I, Chagrin Falls Family Health Center

**Specialties:** Back and neck pain, leg and arm pain, injection therapy, radiofrequency ablation



## Joseph Abdelmalak, MD

216.444.3030 | abdelmj@ccf.org

Cleveland Clinic main campus, Fairview Hospital

**Specialties:** Chronic back/neck pain, pelvic pain, musculoskeletal/joint pain, cancer pain



## Benjamin Abraham, MD

216.587.8830 | abrahamb@ccf.org

Marymount Hospital, Elyria Family Health and Surgery Center

**Specialties:** Cancer pain, abdominal pain, angina, arachnoiditis, back pain in athletes



## Philippe Berenger, MD

440.695.4000 | berengp@ccf.org

Lorain Family Health and Surgery Center, Richard E. Jacobs Health Center

**Specialties:** Abdominal pain, back pain in athletes, cancer pain, spine pain, spinal cord stimulation, work-related injuries



## Robert Bolash, MD

216.444.3134 | bolashr@ccf.org

Cleveland Clinic main campus

**Specialties:** Back pain, neck pain, degenerative joint disease, cancer pain, pain management



## Jianguo Cheng, MD, PhD

216.445.9572 | chengj@ccf.org

Cleveland Clinic main campus

**Specialties:** Spine pain, nerve pain, joint pain, abdominal pain, neck and back pain



## Shrif Costandi, MD

440.695.4000 | costans2@ccf.org

Richard E. Jacobs Health Center, Cleveland Clinic main campus

**Specialties:** Cancer pain, chronic low back pain, neuropathic pain, neuromodulation, targeted drug delivery



## George E. Girgis, DO

216.476.7331 | girgisg@ccf.org

Fairview Hospital, Lorain Family Health and Surgery Center

**Specialties:** Cancer pain, cancer fatigue, neuromodulation of pain (spinal cord stimulation), degenerative joint disease and pain



## Kenneth Grimm, DO

440.878.2500 | grimmk@ccf.org

Strongsville Family Health and Surgery Center, Lakewood Hospital

**Specialties:** Interventional pain management, back pain, neck pain, arachnoiditis, neuropathic pain, myofascial pain



## Riad Laham, MD

440.312.7246 | laham2@ccf.org

Hillcrest Medical Office Building I, Hillcrest Hospital

**Specialties:** Back pain, chronic neuropathic pain, myofascial pain syndrome, neck pain, spine pain, cancer pain

**Garrett LaSalle, MD**

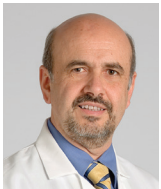
216.295.1010 | lasallg@ccf.org  
South Pointe Hospital, Cleveland Clinic  
main campus

**Specialties:** Back pain, neck pain,  
postsurgical pain, arthritis pain, CRPS,  
nerve-related pain

**Daniel Leizman, MD**

216.444.6323 | leizmad@ccf.org  
Cleveland Clinic main campus,  
Hillcrest Medical Office Building I

**Specialties:** Spine care, musculoskeletal  
injuries, degenerative joint disease,  
sports medicine, impairment and disability  
evaluation

**Nagy Mekhail, MD, PhD**

216.445.8329 | mekhain@ccf.org  
Cleveland Clinic main campus

**Specialties:** Cancer pain, chronic  
neuropathic pain, headaches, pelvic pain,  
spine pain/spinal stenosis

**Beth Minzter, MD**

216.444.9756 | minzteb@ccf.org  
Cleveland Clinic main campus

**Specialties:** Chronic back pain, back  
pain in athletes, neuropathic pain,  
musculoskeletal pain, cancer pain

**Fady Nageeb, MD**

216.692.8813 | nageebf@ccf.org  
Euclid Hospital, Willoughby Hills Family  
Health Center

**Specialties:** Back pain, chronic  
neuropathic pain, myofascial pain syndrome,  
neck pain, spine pain, cancer pain

**Ellen Rosenquist, MD**

330.888.4000 | rosenqe@ccf.org  
Twinsburg Family Health and Surgery Center

**Specialties:** back and neck pain, pediatric  
pain, CRPS, neuropathic pain, spinal cord  
stimulation, phantom limb pain,  
acupuncture

**Pasha Saeed, MD**

216.692.8813 | saeedp@ccf.org  
Euclid Hospital, Willoughby Hills Family  
Health Center

**Specialties:** Cancer pain, CRPS, joint pain,  
vertebral compression fractures

**Samuel Samuel, MD**

216.444.8621 | samuels@ccf.org  
Marymount Hospital; Broadview Heights;  
Cleveland Clinic main campus

**Specialties:** Back pain, neck pain,  
postsurgical pain, arthritis pain, CRPS,  
nerve-related pain

**Hong Shen, MD**

216.363.2391 | shenh@ccf.org  
Lutheran Hospital, Westlake Medical  
Campus Building A

**Specialties:** Arthritis, back pain, bursitis,  
cancer pain, chronic myofascial pain

**Paul Shin, MD**

330.721.5700 | shinp2@ccf.org  
Medina Medical Office Building,  
Wooster Family Health Center

**Specialties:** Interventional pain manage-  
ment, diskogenic back pain, herniated disks,  
postlaminectomy syndrome, implantation  
of spinal cord stimulator

**Michael Stanton-Hicks, MD**

216.445.9559 | stantom@ccf.org  
Cleveland Clinic main campus

**Specialties:** Back pain, chronic back pain,  
CRPS, chronic neuropathic pain, myofascial  
pain syndrome

**Bruce Vrooman, MD**

216.445.9641 | vroomab@ccf.org  
Cleveland Clinic main campus

**Specialties:** Abdominal pain, back pain,  
CRPS, spinal cord stimulation, peripheral  
nerve stimulation, head and neck pain

**William Welches, DO, PhD**

216.295.1010 | welchew@ccf.org  
South Pointe Hospital, Euclid Hospital

**Specialties:** Osteopathic manipulation  
therapy, acupuncture, anti-inflammatory diet,  
cranial sacral therapy, headache, back pain

**New Staff****Jijun Xu, MD, PhD**

216.444.4080 | xuj3@ccf.org  
Cleveland Clinic main campus

**Specialties:** Neuropathic pain, CRPS, chron-  
ic back and neck pain, musculoskeletal pain,  
abdominal and pelvic pain, headache/facial  
pain, cancer pain

# The Department of Pain Management

## WHO WE ARE

**25** Physicians with board certification in pain medicine

**92** Employees

**5.2** Research staff (physicians + PhD researchers)

## WHO WE TREAT – AND HOW

(2014 NUMBERS)

 **73,781** Patient visits  
53,785 Outpatient visits | 19,996 Inpatient visits

 **57** International patients

 **42,718** Procedures

 **11,584** Imaging studies sent to Cleveland Clinic Imaging Institute

## OUR OTHER MISSIONS

 **21** Active research projects

 **\$802,500** External funding for research

 **31** Residents for the year

 **10** Fellows for the year

 **255** Attendees at our 17th Annual Pain Management Symposium, February 2015

## OTHER KEY ACCOMPLISHMENTS OF 2014-2015

- Reduced department cost structure by \$1.35 million
- Main campus facility renovations
- Full-time Inpatient Midlevel provider in collaboration with Digestive Disease Institute for Chronic Abdominal Pain Patients
- Established and implemented the Abdominal Pain Care Path
- Increased collaborations with other Cleveland Clinic Institutes: Digestive Disease, Emergency Services, Neurological and Nursing





## RESOURCES FOR PHYSICIANS

### 24/7 Referrals

Referring Physician Hotline

**855.REFER.123 (855.733.3712)**

Hospital Transfers

**800.553.5056**

On the Web at [clevelandclinic.org/refer123](http://clevelandclinic.org/refer123)

Stay connected with us on...



**Consult QD**

### About Cleveland Clinic

Cleveland Clinic is an integrated healthcare delivery system with local, national and international reach. At Cleveland Clinic, more than 3,200 physicians and researchers represent 120 medical specialties and sub-specialties. We are a nonprofit, academic medical center with a main campus, eight regional hospitals, more than 90 northern Ohio outpatient locations (including 18 full-service family health centers), Cleveland Clinic Florida, Cleveland Clinic Lou Ruvo Center for Brain Health in Las Vegas, Cleveland Clinic Canada, Sheikh Khalifa Medical City and Cleveland Clinic Abu Dhabi.

In 2015, Cleveland Clinic was ranked one of America's top 5 hospitals in *U.S. News & World Report's* "Best Hospitals" survey. The survey ranks Cleveland Clinic among the nation's top 10 hospitals in 13 specialty areas, and the top in heart care (for the 21st straight year).



### Physician Directory

View our staff online at [clevelandclinic.org/staff](http://clevelandclinic.org/staff).

### Same-Day Appointments

To help your patients get the care they need, right away, have them call our same-day appointment line, **216.444.CARE (2273)** or **800.223.CARE (2273)**.

### Track Your Patients' Care Online

Establish a secure online DrConnect account for real-time information about your patients' treatment at [clevelandclinic.org/drconnect](http://clevelandclinic.org/drconnect).

### Critical Care Transport Worldwide

To arrange for a critical care transfer, call **216.448.7000** or **866.547.1467**. Learn more at [clevelandclinic.org/criticalcaretransport](http://clevelandclinic.org/criticalcaretransport).

### Outcomes Data

View Outcomes books at [clevelandclinic.org/outcomes](http://clevelandclinic.org/outcomes).

### Clinical Trials

We offer thousands of clinical trials for qualifying patients. For pain-related trials, visit [clevelandclinic.org/paintrials](http://clevelandclinic.org/paintrials).

### Consult QD Blog for Healthcare Professionals

Discover the latest research insights, innovations, treatment trends and more at [consultqd.org](http://consultqd.org).

### CME Opportunities: Live and Online

Visit [cfcme.org](http://cfcme.org) for convenient learning opportunities from the Cleveland Clinic Center for Continuing Education.

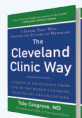
### Executive Education

Learn about our Executive Visitors' Program and two-week Samson Global Leadership Academy immersion program at [clevelandclinic.org/executiveeducation](http://clevelandclinic.org/executiveeducation).



### Physician Referral App: Download Today!

Contacting us is easier than ever. With our free Physician Referral App, you can view all our specialists, transfer a patient and get in touch immediately with one click of your iPhone®, iPad®, or Android™ phone or tablet. Download today at the App Store or Google Play.



### *The Cleveland Clinic Way*

By Toby Cosgrove, MD  
CEO and President, Cleveland Clinic

Great things happen when a medical center puts patients first. Visit [clevelandclinic.org/ClevelandClinicWay](http://clevelandclinic.org/ClevelandClinicWay) for details or to order a copy.