

JUNE 29, 2016

Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation Shows Promise

New Orleans—Brian M. Ilfeld, MD, MS, has been involved in more than his fair share of regional anesthesia research, adding his name to more than 100 publications and receiving some \$4.5 million in grant support. Now, however, Dr. Ilfeld says he's involved in something as exciting as anything he's ever worked on.



(/aimages
/2016/AN0716_018a_1889_150.jpg)

Brian M. Ilfeld,
MD, MS

Dr. Ilfeld feels this strongly about the potential for ultrasound-guided percutaneous peripheral nerve stimulation, a technology that he says has the potential to forever change the way anesthesiologists treat acute postoperative pain. He discussed the results of a prospective feasibility study—and the potential for the technology's future—at the 2016 annual Regional Anesthesiology and Acute Pain Medicine meeting (abstract A1265).

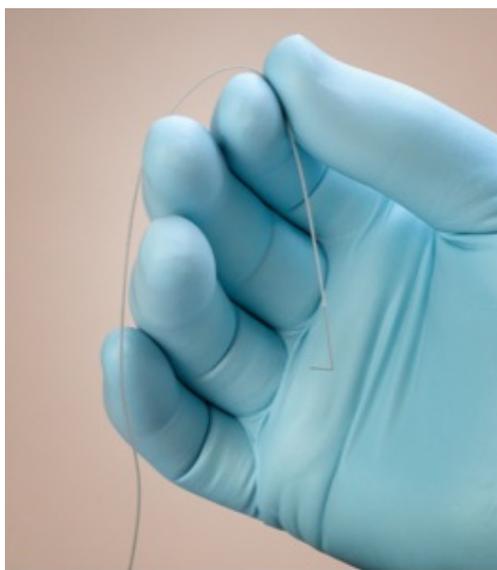
ADVERTISEMENT

Gradually, a Technique Emerges

“There were very early reports of using electricity applied cutaneously to provide analgesia following surgical procedures,”

said Dr. Ilfeld, professor of anesthesiology in residence at the University of California, San Diego. “It just never went very far, because you need to turn up the current so high to trigger the deeper target nerves that the skin’s sensory nerves fire, and it hurts so badly that you ended up inducing more pain than you are relieving.”

Other novel innovations used an implantable electrode placed around the peripheral nerve itself. While there has been some success with this approach, it has been historically extremely invasive, requiring surgery with general anesthesia to both implant and extract the electrode. “So it was a pretty big deal in the last few years when there were scattered reports of percutaneously inserted leads providing



(/images
/2016/AN0716_001a_1889_300.jpg)

Photo courtesy of SPR Therapeutics.

postoperative analgesia,” Dr. Ilfeld said. While early leads didn’t fare particularly well due to design flaws, innovations in lead manufacture and the advent of ultrasound guidance may have ushered in a new era for this technology.

To help determine the feasibility of the technology to provide analgesia for acute postoperative pain, Dr. Ilfeld and his colleagues studied it in five patients undergoing primary unilateral total knee arthroplasty. Patients were excluded if they:

- suffered any postoperative complications that would place them at increased risk—such as deep vein thrombosis;
- had an infection;
- had an implanted cardiac pacemaker/defibrillator or deep

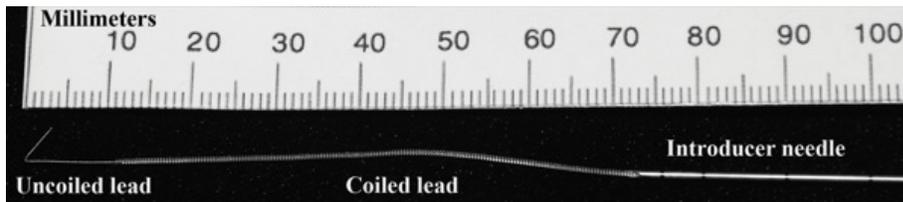
brain stimulator;

- had a bleeding disorder (or international normalized ratio ≥ 1.5 for those on warfarin); and
- had any confounding conditions, such as nerve damage or unrelated pain in the affected lower limb.

In each case, the needle electrode (SPR Therapeutics, Cleveland) was inserted to within 0.5 to 3.0 cm of the femoral and/or sciatic nerve trunks under ultrasound guidance, and then replaced with a coiled fine-wire lead using the same technique. Nerve stimulation was delivered with an external pulse generator at 15 to 200 μsec , 0.2 to 20.0 mA and 100 Hz to evoke comfortable sensations in the painful area. The researchers assessed pain (0-10 numerical rating scale) at rest, and range of motion with the stimulation off and on. The intervention was assessed between eight and 58 days after surgery; leads were removed after assessment.

As Dr. Ilfeld revealed, patients reported average pain relief of 93%. Indeed, each patient reported clinically significant reductions in pain ($\geq 50\%$) almost immediately. "My experience is that you turn on the stimulator and the relief is instantaneous," he told *Anesthesiology News*. "And a little smile comes on their face because they almost can't believe it. And that makes a smile come on my face because I almost can't believe it." With the stimulation off, three patients had pain levels of at least 4; no patient had pain of at least 4 once the stimulation had been turned on. Four of five patients reported complete (100%) pain relief.

Also, all patients were able to flex and extend their operative knee without assistance while receiving stimulation. Furthermore, clinically significant reductions in pain during movement ($\geq 30\%$) were observed in four of the patients under stimulation. Finally, the average reduction in pain during movement with stimulation was clinically significant.



(/aimages/2016/AN0716_018b_1889_600.jpg)

Photo courtesy of Brian Ilfeld, MD.

Hurdles Remain

Although he may be encouraged, Dr. Ilfeld still recognized that there are unanswered questions and potential drawbacks to the technology, not the least of which is the time required to place the leads under ultrasound guidance. "Right now it's taking between 20 and 30 minutes to put in each lead," he noted. "Also, it's not like a perineural catheter, where the patient could theoretically be anesthetized. Here you need an alert patient so they can tell you what they feel. So you need to sedate patients much less."

The other concerning issue is the fracturing of leads inside patients, which has occurred in 4% of patients in subsequent trials to date. "The retained lead is so small that it probably poses few risks," Dr. Ilfeld said. "The main question is around MRIs. If you have to go back and surgically remove 4% of these leads, that's going to be a problem. But if that's the case, then the company will probably just go back to the drawing board and make a new lead." Cost also has yet to be determined, and could pose a stumbling block.

"The last question that needs to be answered is, 'How much analgesia does it actually provide?'" Dr. Ilfeld asked. "So far, the answer has been 'a lot.' What's more, that analgesia comes with no motor block, no sensory block and no proprioception block."

The technology poses other benefits over current therapeutic methods, particularly continuous peripheral nerve blocks, including a much lower infection rate. "You also don't have a big bag of fluid that runs out every three or four days or a big, heavy

pump,” he added.

While percutaneous peripheral nerve stimulation has a significant effect on the chronic pain arena, Dr. Ilfeld also saw its potential in acute pain. “It could completely revolutionize treatment in acute pain,” he said, “because if you can use it in knee arthroplasty—which is one of the most painful procedures we do in patients—it could be used in other parts of the body for other surgical procedures.”

The Upside Is Large

With results such as these, it’s not difficult to forecast the treatment maintaining its effectiveness for several weeks after hospital discharge, and potentially even accelerating recovery, thereby reducing costs and improving long-term outcomes. “It could literally change everything we’ve been doing in anesthesia for 100 years,” Dr. Ilfeld added. “I have to say it’s one of the most exciting things I’ve worked on—ever.”

Marc A. Huntoon, MD, chief of pain medicine at Vanderbilt University Medical Center, in Nashville, Tenn., and editor-in-chief of *Regional Anesthesia and Pain Medicine*, also was excited about the technology’s prospects, but noted that research is still in its infancy. “I don’t know the exact numbers, but over the next 10 to 15 years, the number of total joint arthroplasties being performed in the U.S. is projected to double,” Dr. Huntoon said. “That means there’s tremendous potential for a technology such as this to make an impact. Of course, this is a very introductory study, so we can’t go ahead and make pie-in-the-sky predictions. But if further pilot data or a large introductory study all proved positive, then we could start to think that this technology might be ready for prime time.”

Dr. Huntoon believes that percutaneous peripheral nerve stimulation may not be the only technology to have such an effect on acute postoperative pain. “I’m a firm believer that perioperative pain control is going to include several techniques that have heretofore been considered chronic pain techniques,”

he added. “Another one that I think is interesting is radiofrequency ablation, which can be performed well before the surgery. And the advantage of that is that it doesn’t delay surgery. What’s more, peripheral nerve blocks themselves sometimes have unwanted side effects, such as quadriceps weakness, which we commonly see when we perform femoral nerve blocks. So the fact that we’re not going to see that may enable faster rehabilitation as well.”

—*Michael Vlessides*

Dr. Ilfeld noted that the study was funded by SPR Therapeutics and supported in part by the National Institute on Aging.