Medical Device Offers Pain Management Alternative to Opioids

by Ryan Bushey - Digital Editor - @R_Bushey
The opioid epidemic in the U.S. has reached a critical juncture.

A new research report from the QuintilesIMS Institute, titled *The United States for Non-Dependence*, highlights how widespread this issue has become in the country, especially due to surgeries.

The analysis notes that overprescribing has led to 3.3 billion unused postsurgical opioids every year, with patients receiving an average of 85 pills each following surgery.

Nearly 3 million people who had surgery in 2016 became persistent opioid users, continuing to take these medications three to six months after their procedure.

There is no easy solution for combatting this issue, but one medical device company is working to tackle it.

Cleveland, Ohio-based SPR Therapeutics developed a wearable device known as the SPRINT Peripheral Nerve System (PNS) system, which is an FDA cleared stimulation system that preferentially activates target nerve fibers to deliver pain relief. The device does not require surgery, anesthesia or a permanent implant, and is the only percutaneous PNS system on the market currently. It is designed help patients overcome pain without the side effects and risks of opiates or more invasive surgical procedures.

**Fulfilling a need**

The idea of using electrical stimulation to treat pain has been around for decades, said Maria Bennet, the founder and CEO of SPR Therapeutics, in an interview with *R&D Magazine*.

However, while the current crop of electrical stimulation devices are known to be effective in the treatment of pain, they have been relegated to a treatment of last resort.

“That’s largely because of their cost, invasiveness, and the need for surgery, since they are fully implantable devices,” said Bennett.

Less invasive devices—which are placed on the surface of the skin and deliver the necessary treatment through electrodes— produce lower-end electrical stimulation. They are not as effective because turning up the therapeutic level can become painful for the patient, explained Bennett.

Essentially, Bennett saw that there was a gap in the middle of the treatment continuum for a device that was less expensive, less invasive and could be introduced earlier in the pain continuum.

**How it works**

The center of the SPRINT system is a wearable stimulator connected to wire inserted through the skin.

The thread-like wire built into SPRINT is percutaneously placed through the skin via a needle introducer, where it resides in proximity to
the targeted nerve that is causing the pain.

During the clinical testing process, engineers working on SPRINT had to ensure the wire maintained flexibility and didn’t introduce foreign contaminants.

“Imagine the shape of a traditional telephone cord. It’s coiled to allow for more flexibility,” said Bennett.

This specific wire becomes coiled inside the body, stabilizing it so it doesn’t move in and out of the skin. This allows the skin interface to seal around those coils, ultimately preventing infection.

Next, the wire is connected to an external simulator. The patient is then able to go home with it, and use the device for 60 days when it gets promptly removed.

“The uniqueness of our device— unlike the implantable devices that have to be on all the time for the life of the patient to treat a chronic pain condition—is that our device demonstrated through clinical studies it can have significant pain relief over a short period of time, as well as have a sustained carry-over effect upon its removal,” said Bennet.

**Maintaining relief**

Usually, there are several levels of therapy physicians prescribe for different levels of chronic pain.

The first option typically involves a mix of physical therapy or some anti-inflammatories, which may mask the pain as long as the patient remains compliant. Another avenue could be some form of steroid injection or a technology called radiotherapy ablation; however these treatments need to be administered every few months and have no sustained carry-over effect.

Chronic pain patients or individuals recovering from postsurgical could also receive an opioid regimen, but that comes with its own issues associated with the treatment path.

The added benefit of the SPRINT system is that it bypasses all these challenges by emitting a non-narcotic alternative that doesn’t involve invasive surgery or risk tissue destruction.

**Further advancement**

Last year, the firm received clearance from the U.S. Food and Drug Administration (FDA) for SPRINT to treat chronic and acute pain, especially the post-operative and post-traumatic pain variety.

The firm recently raised $25 million in a Series C financing to support commercialization and growth.

Next, they plan to support two large clinical trials to test SPRINT’s efficacy with lower back pain and postsurgical pain following knee replacements.

These two areas have significant unmet needs, according to Bennett.

“A majority of patients following a knee replacement continue to have pain at least 30 days following their surgery,” she said. “They’re given prescription of opioids and potentially go through some physical therapy, but there’s nothing that really gets them over that hump of being at home or trying to get back to work so maybe SPRINT could bridge that.”

There are similar reasons to explore the low back pain market, as there is no defined device that can be introduced prior to surgery.

Bennett is excited about what the future holds for the medical device industry overall.

“I’ve been in the industry for over 20 years now and … [it’s impressive]… to see the innovations and ideas coming out of academia and industry get translated into the standard of care and treatment of choice in a cost-effective manner that reduces side effects and makes a real difference in people’s lives,” she said.