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Exec Chat: Abbott's Burton Talks About Abbott's Plans To Address Chronic Pain With SCS

by Reed Miller

Allen Burton, the medical director of Abbott's neuromodulation business and a leader in pain medicine, talked to *Medtech Insight* about the FDA's new labeling for Abbott's spinal cord stimulation devices that includes non-surgical back pain.

Abbott is bringing its spinal cord stimulation (SCS) technology to chronic back pain sufferers who currently have no clear treatment path.

In May, the US Food and Drug Administration approved a new indication for Abbott's spinal cord stimulation (SCS) devices that includes people with chronic back pain that cannot be treated with surgery. (Also see "*Minute Insight: FDA Approves Abbott's SCS For Non-Surgical Back Pain*" - Medtech Insight, 16 May, 2023.)

The new labeling covers all of Abbott's SCS devices sold in the US, including recharge-free Proclaim SCS devices and the rechargeable Eterna SCS platform. Proclaim and Eterna deliver BurstDR, the company's proprietary low-energy stimulation waveform.

Abbott's SCS devices will compete directly with *Nevro*'s Senza HFX devices, which earned FDA approval for the non-surgical back pain indication in January 2022. (Also see "*Nevro Attacks Pain And Competition With Individualized AI-Enabled Spinal Cord Stimulator*" - Medtech Insight, 6 Apr, 2023.)

The approval is based on the results of the 270-patient randomized *DISTINCT* trial, which is the largest randomized controlled trial of SCS in people with non-surgical back pain, according to Abbott.

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In the trial, more than 85% of the patients implanted with an Abbott SCS device reported a significant reduction in back pain compared to only 7.1% in the conservative medical management arm. Also, 91.4% of subjects treated with SCS therapy reported either significant pain relief or significantly improved function. The average improvement in pain scores was about 70%.

The FDA also recently expanded the magnetic resonance imaging labeling for Abbott's Eterna SCS, allowing a wider selection of MRI-compatible leads.

Medtech Insight talked to Allen Burton, the divisional vice president and chief medical officer of Abbott's neuromodulation business, to learn more about Abbott's specific approach to SCS and how it expects to bring the therapy to more people with chronic pain.

DR. ALLEN BURTON, CMO OF ABBOTT'S NEUROMODULATION BUSINESS *Abbott*

As an experienced pain medicine physician, Burton has published more than 50 peer-reviewed articles and co-authored textbooks on managing pain in cancer patients and assessing movement skills. Prior to joining Abbott in 2015, Burton was chairman of the department of pain medicine at the University of Texas MD Anderson Cancer Center for eleven years.

This interview has been edited for length and clarity.

Q ***Medtech Insight*: What makes Abbott's BurstDR technology different from its competitors?**

A Allen Burton: One differentiating characteristic is that the patient doesn't feel it operating. With most older types of neurostimulation, the patient felt a "buzzy," tingling feeling that sort of replaces the painful areas, which in some people is terrific and other people could be a little bit bothersome because they felt it operating.

With BurstDR, very few patients have any sensation that the device is operating other than the fact that they're getting relief and that they look at their controller and they see 'Oh, it's operating.' They don't really feel it because it's outside of what we call the 'sensory range' in terms of its electrical parameters. That, in itself, is very helpful.

Also, this is one of the first clinical studies in spinal cord stimulation (SCS) that used a group of interventional pain physicians – who are the most common adopters of spinal cord stimulation – as well as a similar sized group of spine surgeons.

So it brought a collaborative group of surgeons and interventional pain specialists together around this therapy and around this patient set. Part of our goal going down this pathway – getting the study done and getting the FDA approval – is to enlighten surgeons about something that they can do and participate in actively for this group of patients.

Besides the current realm of the conservative-care options, a lot of surgeons had told those patients, more or less that those were their only options. And then the patient comes back and said, 'Well, that didn't really work,' and then the surgeon said 'Well, go do it again. And go do it again and go try some more.'

So this is meant to raise awareness to the surgical community that even in those patients where they can't necessarily correct the problem structurally in the patient's spine, there is an evidence-based treatment that they can apply.

The patients have a trial period with SCS, which is a really important attribute of this therapy. The patient can – and in fact, must, by most insurance companies' rules – have a trial run of the of the technique for about a week to assess the effectiveness of it. And then, based on that, they get the device implanted.

The results were really good. In our study, we looked at pain relief and functionality, as well as psychological measures, and then patient satisfaction and overall consumption of health care, including medications.

Across the board. It's a home run.

You know, older studies focused mostly on pain and only a little bit on function and

some satisfaction issues. But DISTINCT had some robust measures around the functionality of the patients.

Now we are starting to quantify some of the economics. These devices are interventional and they're expensive, but ongoing chronic pain for 12 years, with rounds of physical therapy and injections and medications, as well as the persistent debilitating pain, all has a cost. So we're teasing out a lot of that data.

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Q **My understanding is that non-surgical back pain has been treated with SCS in the past, but that the payers have been reluctant to reimburse for it. Will this new labeling with this clinical data help change that?**

A We always want to raise the bar of evidence for our therapies. Historically, most patients getting stimulators have had previous back surgery and ongoing pain. That's probably the biggest group of people who've ever gotten stimulators.

And then there were patients who got SCS treatment who weren't candidates for back surgery, but it wasn't widely adopted and it was never really studied specifically. It was part of bigger studies in that there are always a few patients in SCS studies who weren't candidates for back surgery, but it was never before identified as a as a target group.

Then over the last five to 10 years, payers increasingly got more and more restrictive, and said, 'No, we're not approving SCS for that patient because there's no evidence for that.' We'd say, 'Well, we do it for people who've had back surgery,' and they

would say, 'Yeah, but that's a different population.'

Payers put more scrutiny on procedures like neurostimulators, and so we have had to raise our bar and do more studies and really show them this does work for this indication.

Part of our study design was done in collaboration with dialogue back and forth with insurance companies and some of their medical directors. We took a lot of input from them to ask what they wanted to see. What would be a large enough study? What would be the meaningful characteristics of the patients? How long should they be followed? What should the outcomes assess in terms of quality of life, functionality, medication consumption and pain relief?

We think we designed an impactful study that will answer relevant questions for the insurance companies to make a good decision. We're about to publish our first paper showing our primary endpoint results in the study – in the near future – that will be a cornerstone of what we take to the big insurance companies.

And we'll try to change their policy. This is a covered indication for patients with Medicare, but in the US that there's a lot of patients with commercial insurance who would struggle to get coverage for this indication.

Q **Was there any particular reason to fear that SCS would not work for non-surgical back pain after it had worked for surgery patients?**

A It's a very good question. I think the challenge is that there are a lot of causes for back pain, so people with persistent severe back pain need an evaluation to tease apart correctable issues that can be treated with physical therapy, or sometimes a combination of therapy and injections.

And there are some problems that can be addressed, and have really good outcomes,

with surgery. And the surgery is increasingly performed as an outpatient or minimally invasive procedure. There's reason to be optimistic for this.

But the payers needed a modern data set, reflecting what is done today. All these patients in our trial had MRI scans, they were all evaluated by spine surgeons to make sure they weren't candidates for some of these relatively simple minimally invasive, corrective approaches or more conservative therapies.

But then there are patients that continue to have pain despite of all that conservative care. So the ones we're really targeting are the are the ones who continue to have persistent problems following those initial rounds of therapy. The payers particularly wanted a modern-era study done to ensure that contemporary types of state-of-the-art therapy – active physical therapy, chiropractic therapy, etc. – that are available were incorporated.

And these are top-notch spine centers across the country. It's a really impactful study.

The investigators were most interested in the pain outcomes and the surgical investigators were most interested in the functional outcomes. About 85% of those patients had at least 50% or greater back pain reduction. So that, in itself, was really remarkable, considering that those patients had over a decade of severe pain.

And then the patients were monitored on the *Oswestry Disability Index*. And on that scale, the patients were moderate to severely disabled because of their back pain at time the entered the study. And by the primary endpoint at six months, those patients showed almost two categories of improvement in functionality.

That scale is meaningful to these spine surgeons, and they were blown away that the patients who had had 10 years of disability – becoming less and less able to walk upstairs or walk more than five or 10 feet – were now able to see substantial increases in their activity to the point where they improved down to a really a mild level of

disability on this scale. It's almost a 30-point improvement on this scale.

Part of the study was to show the FDA that this is safe and effective for this patient population and part was to show the payers why they should consider covering this for patients as a reasonable and, ultimately, impactful and cost-effective approach to managing chronic refractory back pain. I think it was a little bit to convince the surgeons that neurostimulation in 2023, using this Abbott device, and this therapy is a good option for these patients.

Some of these patients had 10 years of debilitating back pain and after they were treated in the trial, they started to get better within a week and were substantially better by six months. There's almost been a loss of hope with some of the doctors when a patient has had pain for 10 years, but there are multiple opportunities from this study to raise awareness about SCS as a treatment option, in addition to the pragmatic aspects of getting coverage for it.

"Until the release of this study, and until we get more insurance coverage for this indication, a lot of those people today are stuck with back pain and don't have a clear treatment path." – Allen Burton

Q **Do you know how durable the therapy will be? How long will you follow the patients?**

A We are planning to follow these patients out for 24 months. There's a crossover period after the primary endpoint at six months. Almost 90% of the patients randomized to conservative-therapy crossed over to get the stimulator and then all these patients will be followed out for two years in the study.

And then from there, they'll be back in routine follow-up with their physicians. And

we have other prospective datasets, and an ongoing registry study that will follow patients out to five years. And we know from other data in neurostimulation that there can be a little fall-off of this therapy over time.

We think there are a couple reasons for that. One is that, particularly with some of the older types of neurostimulation, the nervous system developed a little tolerance to ongoing stimulation so the pain relief wore off a little bit over time. We think that explained maybe a loss of a couple percent per year of effectiveness over a long period of time.

And then the other complicating factor is that people get new medical problems and new issues and as they age. If somebody goes from 70 to 80 or 75 to 85 or 90, they may get more degenerative spine disease, or their spine becomes more scoliotic or they may develop a new disc herniation. Or even at 40 or 50, the patient may develop further pain or a different problem. Sometimes the stimulator can cover those issues and continue to be effective and sometimes the patient needs other ongoing evaluation and treatment.

Those are ongoing issues for us to address in long-term care of patients with chronic degenerative spinal issues and other chronic pain issues. But our stimulators continue to improve, both in their short-term and long-term effectiveness. We think we're doing better on both fronts. Our current BurstDR stimulation has less tolerance associated with it than older modes of stimulation.

We also know that an important aspect of our new device is MRI compatibility. If a patient is down the road a few years and develops a new kind of recurrent back pain issue, they have better access to MRI to look at it to see if there's another disc herniated or there's something else structurally that needs to be corrected.

That is not prohibited by having a stimulator, so I think we're getting better at both the short-term care of these patients and also for long-term care, which is really important.

Q **Is there anything else you want to highlight or mention?**

A There are around 16 million Americans with persistent, chronic back pain, and many of them are not candidates for corrective surgery. Not everybody with back pain needs a stimulator, but we think there's a significant number of patients today who don't have good treatment options.

Until the release of this study, and until we get more insurance coverage for this indication, a lot of those people today are stuck with back pain and don't have a clear treatment path.

We are excited to be a part of defining an effective, safe path that they can prioritize and get pain relief. We're excited about these outcomes and we're really excited to bring that out more broadly to the general public, both in pain clinics, but also in spine surgery clinics around the country.