Chronic Pain and Spinal Cord Stimulation (SCS) Frequently Asked Questions

1) What is chronic pain?

Chronic pain is defined as continuous, long-term pain that has lasted for more than six months, or that prolongs after the time that healing would have been thought to have occurred.[1] Chronic pain can also occur when no obvious cause for it can be found; this is thought to be due to changes in the body's nervous system.[2]

2) How many types of chronic pain exist?

Chronic pain is divided into two classifications: nociceptive and neuropathic.[3] All people will experience nociceptive pain at some point and it includes such things like cutting yourself, a burn, or an injury. Conversely, neuropathic pain is caused by a problem with nerve pathways, which means the way that the nerve sends pain messages to the brain is affected.[4]

- Neuropathic pain is often described as numbness, tingling, or like an electric shock.[3]
- It is a debilitating condition and although the exact prevalence is unknown, some European based studies have estimated it at anything from seven to 37 per cent.[4]
- It is often under-diagnosed and under-treated.[4]

3) What causes chronic pain?

Causes can be various. Chronic pain may follow an illness or an injury that appears to have healed or may develop for no apparent reason. Chronic pain can occur anywhere in the body. Common types of chronic pain include back pain, headaches, arthritis, cancer pain and neuropathic pain. In Europe, the back is the most commonly reported location for chronic pain.[5]

4) How many people suffer from chronic pain in Europe?

Chronic pain is thought to be one of the most common conditions for which people seek medical attention.[3] Results from the Pain in Europe Survey indicate that pain affects one in five adults in Europe.[5] This number (or prevalence) equates to 95 million of the adult population (15-64 years) who suffer from this debilitating condition,[6] a number greater than those suffering with diabetes (60 million).[7]

- Chronic pain reduces the quality of life more than almost any other condition.[8]
- A third of chronic pain patients are in constant pain.[9]
- One report suggests that over a fifth of chronic pain patients suffer with such pain for 20 years or more.[5]

5) How does chronic pain affect patients?

Chronic pain has a serious impact on quality of life[10] including impaired physical and social functioning and reduced energy and vitality.[11] Activities of daily living become increasingly difficult, particularly when the pain is severe. Many people are unable to continue working because of their pain. In fact, one in five people living with pain have lost their job as a result of chronic pain[9] and 16 per cent are forced to change their job responsibilities.[9]

Being in pain for a long time can have a devastating impact. Most chronic pain patients will be prone to depression and drug dependency[3] which results in a further burden to the healthcare system. The risk of suicide in chronic pain patients is at least doubled.[12]

6) What are the treatment options?

Pain therapy generally begins with conservative treatment options such as physical therapy and over-the-counter pain medications. If those options are not effective, prescription medications (painkillers) are tried, as well as invasive surgeries such as back surgery. However despite these approaches sometimes patients continue to remain in chronic pain.

There is an urgent need for alternative treatment approaches in chronic neuropathic pain management to allow people living with chronic pain the chance of achieving a better quality of life. More than 50 per cent of chronic pain sufferers wait at least two years before their pain is adequately managed.[13]

7) What is spinal cord stimulation?

Spinal cord stimulation (SCS) is a minimally invasive option for patients with chronic pain that have not been relieved by conventional medical management or other treatment approaches. SCS was first used in 1967 and is a *reversible method* of managing chronic pain that has been given to over 350,000[16] patients worldwide.

8) How does spinal cord stimulation work?
The technique involves implanting a battery-powered small device often called an implantable pulse generator (IPG) under the skin usually in the abdomen, upper buttocks or below the collarbone. The IPG is connected to a lead(s) that stimulates the nerve fibres in the spinal cord. This action creates a tingling sensation called paraesthesia that masks the pain signals to the brain. It can be used to treat patients with more than one pain area including patients with back or neuropathic pain.[14]

9) Is SCS safe?
Yes. SCS has been proven safe and effective and has been in use for decades[15]. Over 350,000[16] people worldwide have benefited from SCS therapy. The Precision™ Plus SCS system was approved in 2004 by the U.S. Food and Drug Administration (FDA) and received European approval in 2005. Now more than 60,000 patients have been treated using the Precision Plus SCS system.

10) What are the realistic expectations for pain control?
People using SCS therapy may feel less pain. People differ in the amount of pain relief that they receive with SCS therapy. When the trial is successful, some people enjoy complete pain relief, while others experience a significant reduction in pain sensations.

11) What is the clinical evidence behind SCS therapy?
Two randomised controlled trials have compared the effectiveness of SCS versus other pain management treatments such as conventional medical management and repeat back surgery. A study published in 2005[17] tested the authors' hypothesis that SCS is more likely than repeat back surgery to result in a successful outcome by standard measures of pain relief and treatment outcome. They observed that SCS is significantly more successful than repeated operation, by multiple outcome measures, in selected patients with failed back surgery syndrome (FBSS).

In another study published in 2008, [18] SCS and conventional medical management were compared with conventional medical management alone in patients with FBSS. The study concludes that at 24 months of SCS treatment, selected FBSS patients report sustained pain relief, clinically important improvements in functional capacity and health-related quality of life, and satisfaction with treatment.

12) What is the Precision Spectra™ SCS rechargeable system?
The Precision Spectra SCS System by Boston Scientific is the world's first rechargeable spinal cord stimulator with 32 contact points and 32 dedicated power sources, designed to provide more pain relief to a wide range of patients who suffer from chronic pain.

As with other SCS devices, the Precision Spectra SCS IPG is implanted under the skin. The device delivers electrical impulses to specific locations along the spinal cord to reduce the pain signals.

The Precision Spectra SCS System may provide substantial benefits for patients with chronic pain, especially for those where conventional therapies have failed. The Precision Spectra device offers patients a 32 contact system which is designed to provide more coverage of pain areas and offers the possibility of managing patients' unique pain patterns and supporting those with multiple pain areas.

The Precision Spectra system includes a cordless charger, cordless remote and 16 available program settings aimed at improving ease of use and patient satisfaction.

In addition, the Illumina 3D™ software used to program the Precision Spectra System is the first and only software to take into account the complex 3-dimensional environment in which the leads exist. The algorithm incorporates 3-dimensional lead location and creates a customized stimulation field designed to improve pain targeting.

13) How does the Precision Spectra™ SCS system work for patients?
The Precision Spectra SCS System may consist of up to four 8-contact or two 16-contact leads (or a combination of both) implanted along the spinal cord, and an IPG placed under the skin, usually in the abdomen, upper buttocks or below the collarbone.

The system works by sending impulses, via the 32 contacts, to specific locations along the spinal cord to reduce the pain signals. These impulses then travel to the brain where they are perceived as a smooth, tingling sensation called paraesthesia, and the feeling of pain may be reduced.
With the Precision Spectra SCS System, patients control the stimulation intensity and location via the cordless remote control which can store up to 16 different pain management programs. This allows adjustments for different pain problems or postures throughout the day.

The easy-to-use cordless remote allows patients to conveniently and discretely adjust pain control exactly when they need it, now made even easier with 360 degree telemetry. The convenience of a rechargeable, lightweight and cordless system provides the freedom of on-the-go charging to fit in with a patient's lifestyle.

Patients typically have the opportunity to trial the Precision Spectra SCS System before having the surgical implant. Using a temporary, non-implanted (external) system for

about one week, the patient has the opportunity to determine whether the Precision Spectra SCS system fits their pain needs and lifestyle.

14) How long does the Precision Spectra Rechargeable SCS battery last?
The Precision Spectra Battery is designed to last at least 5 years and provides up to 12 years of service. In contrast, patients using a conventional non-rechargeable battery can expect it to last between 2.5 to 4.5 years[19] following which it may need to be replaced.

Rechargeable SCS systems may have more capabilities compared than non-rechargeable battery-powered systems with respect to clinical benefits. These clinical benefits include extending therapeutic longevity by avoiding frequent replacement surgeries and complications that may arise from repeated surgeries.
Only the Precision Spectra SCS System uses a powerful rechargeable implanted battery with Zero Volt™ technology.

15) What is Zero Volt™ technology?
Zero Volt is a battery technology. If for any reason a patient should forget to recharge their battery and it fully discharges, it does not matter how many times this occurs it will remain possible to recharge it without causing any battery damage. Avoiding damage to the battery means that it will not need to be replaced via another surgical intervention.

16) How does the patient recharge the battery?
The charging system comes with a base station and a cordless charger. The base station is used to recharge the charger. Once the charger is fully charged, the patient can then recharge their implanted battery. To do this the patient takes the charger and places it over the implant site. The patient can then either use an adhesive patch or the charging belt provided to keep it in place. Once the patient's battery is fully charged the charger will emit a distinct double beep for up to a minute to let the patient know that charging is completed.[20]

17) How convenient is it for patients to recharge their battery?
Recharging the battery is convenient and simple. The system provides the freedom of on-the-go charging to fit in with a patient's lifestyle. The charger is light-weight, portable and cordless.

18) What is the impact of rechargeable SCS devices on healthcare systems? Due to the longer-term cost savings, and benefits of reduced replacement surgeries, and therefore complications, the rechargeable Precision Spectra SCS System enables the efficient use of healthcare resources. The costs of a rechargeable SCS system compared to a non-rechargeable system can be offset 4.1 years after implantation[1]

In 2008 the UK'S National Institute for Health and Clinical Excellence (NICE) concluded that SCS is more effective than conventional medical management for the treatment of failed back surgery syndrome and complex regional pain syndrome and would therefore be a cost-effective use of NHS resources[21]

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