painaustralia

Spinal Cord Stimulator Implants

Consumer Experience Report

December 2023

Painaustralia is Australia's leading pain advocacy body working to improve the quality of life of the 3.4 million people living with pain, their families, to have their voice heard in health decision-making and to be true partners in co-design and the development of health policy that affects them in Australia.

We recognise that pain management is a complex and individualised process that requires a holistic and multidisciplinary approach. We do not favour or promote any specific treatment option over another, but rather support evidence informed discussion and the consumer's autonomy and voice in their pain journey.

This Report summarises the experience of 73 consumers of spinal cord stimulation implants. These stimulators are often a last resort treatment for chronic pain sufferers. The views of those surveyed were encouraging, although they were not a representative sample. It is important to appreciate there are diverse views regarding this form of treatment with other research raising doubts as to the sustained benefits of spinal cord stimulators and the risk of harm.[1,2]

Painaustralia makes four recommendations at the conclusion of this Report. There is a need for improved regulation to ensure there is consistent safe operation and quality assessment of the stimulator implants, formation of a registry of spinal stimulator recipients, and further independent research and clinical trials to evaluate spinal cord stimulator safety and effectiveness over time. Any treatment option needs to be considered in conjunction with the consumer's health professionals.

Acknowledgements

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INTRODUCTION

The 3.4 million Australians, or 1 in 5 people over 25, living with chronic pain suffer on multiple fronts in our community. Not only are most days of their life dominated by pain, unable to do the simplest of tasks and the many things they love including work and spending time with their families and friends, they are often mocked, belittled, and ignored when seeking help.

Pain is the poor cousin to all other chronic conditions as many clinicians still do not accept it is a chronic condition, while at the same time it is one of the most prevalent health conditions, causing 40% of early retirements. Only 1 in 100 people living with chronic pain are appropriately treated for their condition. The picture is bleak.

Pain does not discriminate and indeed it impacts people of all ages, more women than men, and leads to people:

- checking out of life,
- limiting their aspirations, and
- losing out both financially and in relationships.

Chronic pain is complex, and each person experiences it differently. In Australia, it carries a significant economic burden in lost productivity and health costs - estimated to be $74.47 billion in 2020 and, if nothing is done to address the issue, it will cost our society $215.6 billion by 2050 affecting 5.23 million people.[3]

As described by pain specialist pioneer and Painaustralia founder, Dr Michael Cousins, chronic pain is the silent epidemic with patients often suffering in silence. As he told his biographer:

"Society is silent: mostly, it's unaware of the enormous human and financial cost. Politicians are silent because the costs are overwhelming."

A huge gap exists between knowledge and practice. This gap is widening as knowledge increases exponentially, resulting in chronic pain to be regarded as the disease of the 21st century.[4]

There are also serious justice issues in how those with chronic pain are treated in this country with treatment options being reduced by government regulations causing greater distress, discrimination, and condemnation, demonstrating the imperative to greatly change the community conversation on pain.

Pain should be treated with the same level of funding and understanding that our society does with mental health and cancer, but we are decades behind and we need to develop many more treatment options for chronic pain.

The past five years of government reforms have impacted the treatment options for those living with chronic pain including:

- government restrictions to codeine in 2018,
- restrictions to opioids in 2020,
- a reduction in the number of MBS items for pain treatment, and
- recent efforts by the TGA to restrict the availability of paracetamol – a medicine that is used by hundreds of thousands of Australians to manage their pain.

Access to pain specialists can involve long waiting times; GPs don't always understand or have the time or training to manage chronic pain, and there is limited access to affordable multidisciplinary care involving physiotherapists, exercise psychologists and other allied health professionals to treat people with chronic pain, particularly for those who live in rural and regional areas.

Medication is often the default treatment, despite limited effectiveness, because it is accessible and affordable.

Suicide is also an issue for people who are at a loss to manage their chronic pain and access services. The rates of suicide for people with chronic pain is reported to be two to three times higher compared to the general population.[5]

We know that one in two people with chronic pain have considered suicide.

MORE CHRONIC PAIN TREATMENTS ARE NEEDED

Treatments for chronic pain are desperately needed in Australia – we need more options, funded research, and improvements to the multidisciplinary treatments that are available. There is no silver bullet - no perfect solution for pain.

Everybody needs to be considered as an individual, with tailored treatment that works best for them. If governments and the broader community do not invest in providing treatments for and addressing the issue of chronic pain, it will become an all-consuming cost to not only individuals but also to our society as a whole.

Increasingly, technology already is and will continue to play a vital role in how we treat chronic pain. Like all treatments, whether it be medication, a knee or hip replacement or a spinal cord stimulator implant there are risks and benefits and it is necessary to ensure that all treatment options are safe and have guidelines in place regarding their use.

Governments have a pivotal role in health technology. Their role is to keep the public safe, but we also know that consumers with chronic pain who have lost treatments over the past five years are keen to keep the treatments that do exist.

Painaustralia supports the availability of the current treatments for those with chronic pain. There is a need for increased funding for research and increased access to new evidence-based treatments whether they be implants, medications, multidisciplinary care, specialist care or allied health and primary care for this vulnerable cohort. We also support the need for quality controls and reasonable regulation of treatments to ensure they are safe for consumers to use.

We advocate for informative consumer education and awareness about the benefits and risks of all options.

Ultimately, once equipped with this information, it must be the consumer's choice to be able to make about their own health and well-being.

SPINAL CORD STIMULATORS

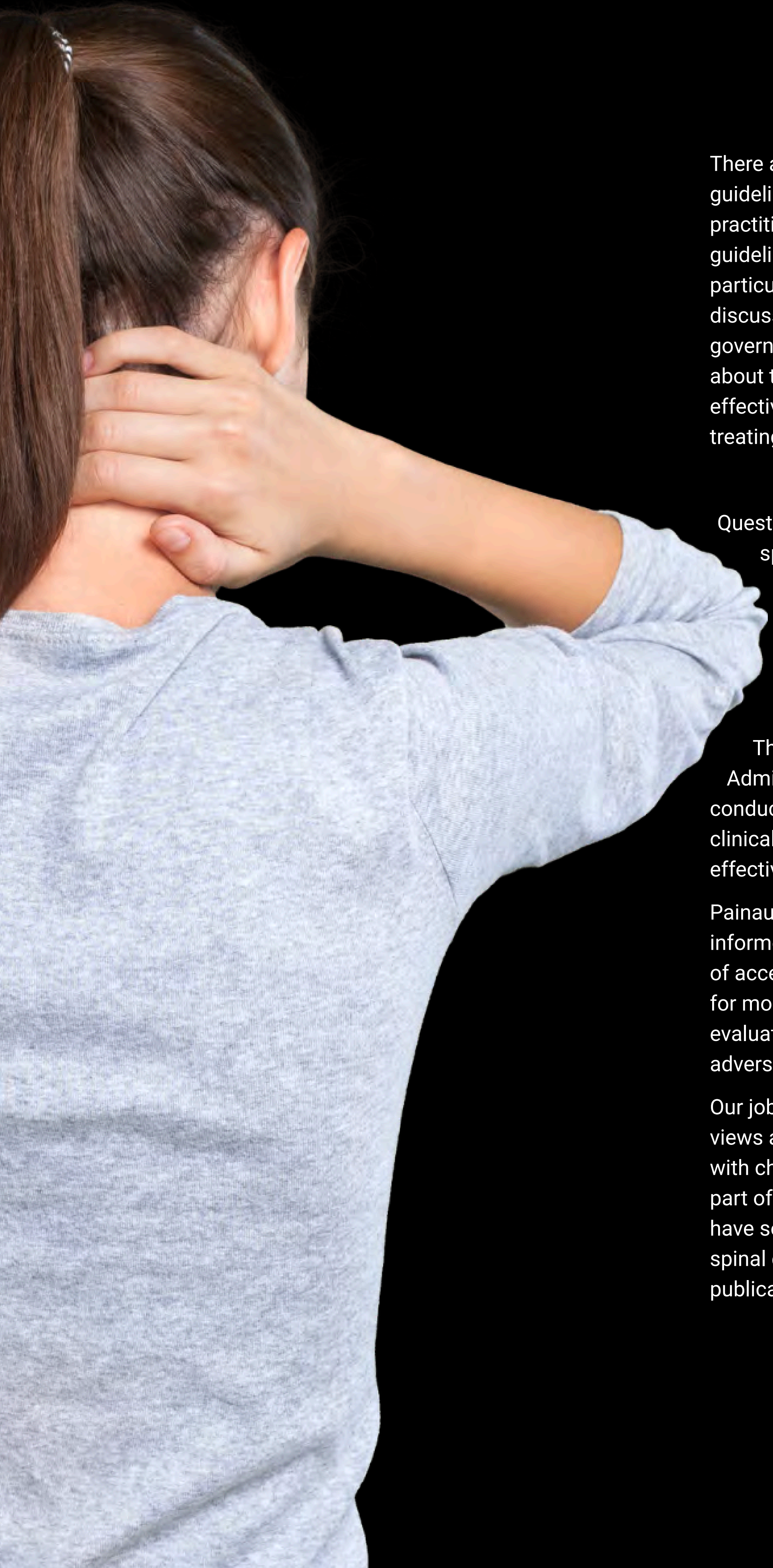
One of the last resort treatments for refractory neuropathic pain is spinal cord stimulation. More often than not consumers considering a spinal cord stimulator implant have previously tried all types of treatments from medication through to physiotherapy, psychology, and exercise.

The development of spinal cord stimulation for pain began in the 1960s in the US with the first spinal cord stimulator implant carried out in 1967.

In Australia, Dr Michael Cousins was one of the pioneers of spinal cord stimulation which was an integral part of his lifelong research in treating chronic pain. The first spinal cord stimulator was implanted in Australia at the Royal Perth Hospital in 1978. It wasn’t until the early 2000s that stimulators became more commonly used in Australia to treat chronic pain.

Spinal cord stimulators are implanted neuromodulation devices that send low levels of electricity directly into the spinal cord to relieve pain. They feature a flexible wire or lead that sits just outside the spinal cord that is connected to a small battery linked to a computer just like cardiac pacemakers.

In Australia, spinal cord stimulators (SCS) as a standardised treatment option for severe chronic pain, in particular back pain, is seen as contentious. The procedure can be performed by neurosurgeons or pain specialists.



There are no Australian standards or guidelines for this procedure, instead practitioners tend to rely on international guidelines. The past few years particularly has seen much debate and discussion among health stakeholders, government regulators and the media about the risks, benefits, and effectiveness of the procedure for treating chronic pain.

Questions have been raised about spinal cord stimulators by health insurance companies who have called for them not to be funded through Medicare[6] and there is research to suggest the benefits are not sustained.

The Therapeutic Goods Administration is currently also conducting a post-listing review on the clinical effectiveness and cost-effectiveness of SCS devices.

Painaustralia supports ongoing evidence informed discussions about the benefits of access this treatment with the need for more trials and regulation for routine evaluation of clinical outcomes and any adverse effects.

Our job at Painaustralia is to ensure the views and experiences of consumers with chronic pain are voiced and form part of the public debate. This is why we have sought consumers' feedback on spinal cord stimulator implants for the publication of this report.

SURVEY

This report provides an analysis of a survey conducted by Painaustralia to gauge the views of participants who have either had or investigated whether to have a spinal cord stimulator to address their chronic pain. In addition, the report features three individual stories from consumers who have had a spinal cord stimulator and the impact it has had on them and their pain conditions.

The survey was conducted over a three-week period in February and March 2023 with survey questions sent to 100 recipients.

A total of 73 people undertook the survey. Ten of these consumers were recruited by a Painaustralia social media call out.

Neurosurgeons and pain specialists provided the details of 100 people with their consent of which 63 responded to the survey. The responses of both groups of consumers were similar.

The questions for this consumer led survey were developed through consultation with consumers, members of Painaustralia's Consumer Advisory Council, health professionals, pain specialists, and neurosurgeons. The feedback from all of these groups was incorporated.

The survey included a mixture of nominal questions, open-ended questions, closed-ended questions, Likert scale questions, and rating scale questions.

Participant profile

The majority of respondents were women (44) with 29 men taking part in the survey. Participants were aged from 32 to 89 with the majority of those who received a spinal cord stimulator aged 48 to 66 years. Of those who responded to the survey 34 lived in urban areas, 20 in a regional area, and 18 said they lived in a rural area.

The majority of the respondents had back pain (24), followed by neuropathic pain (11), and a spinal injury (9). Of those who responded to the survey two people did not proceed with the procedure after initially investigating the spinal cord stimulator as a treatment option for their pain. Therefore, the survey predominantly reflects the views of users of the stimulators rather than those who undertook the trial but chose not to proceed with the implant; the process of recruitment of participants for this survey may also have resulted in more persons participating who had a positive outcome.

The respondents who had lived with chronic pain prior to implant ranged from 8 months to 40 years, with the majority of respondents (69) living with pain for longer than 2 years and an average of 11 years.

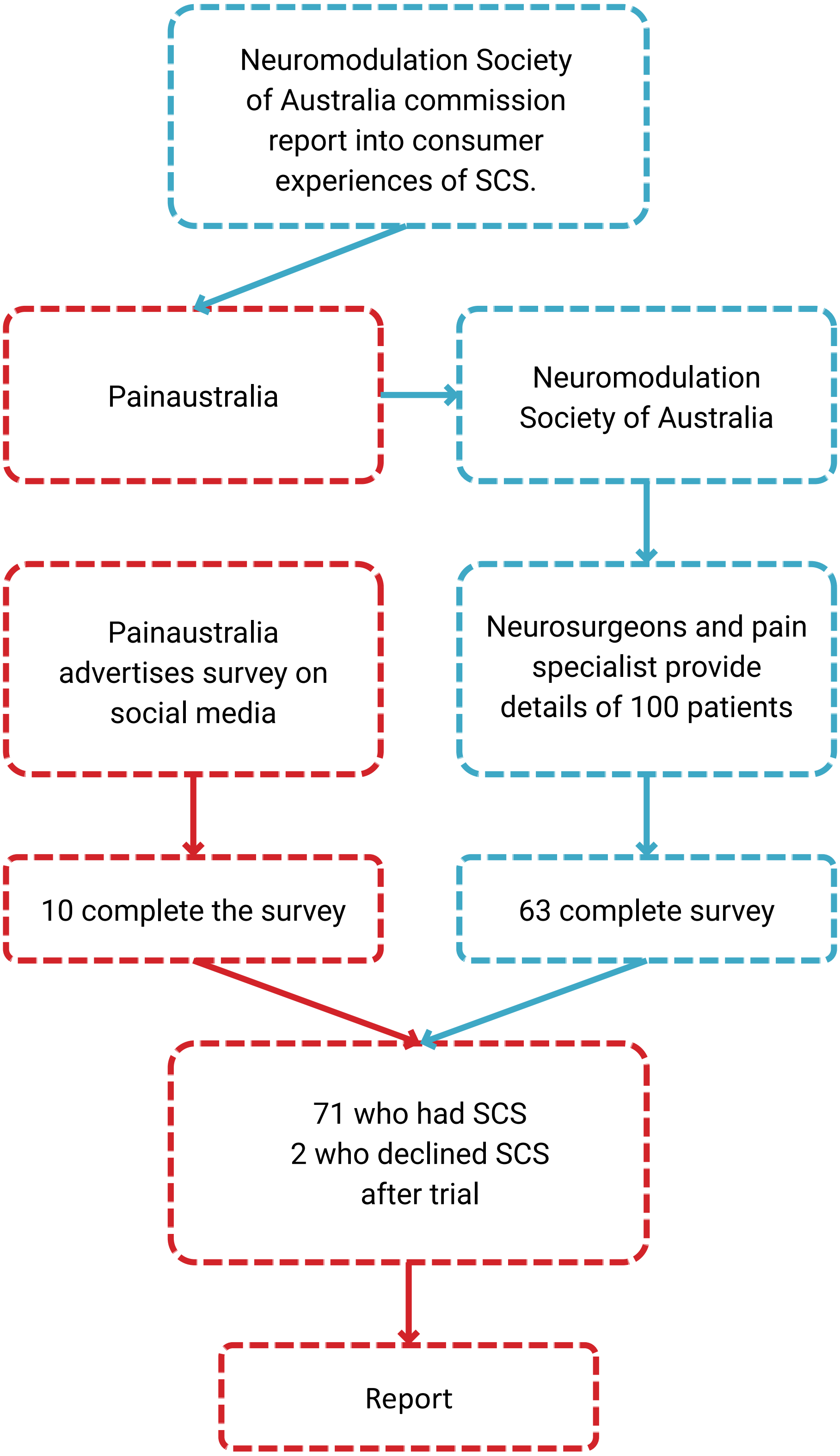
Of those who had the stimulator one person has since had it removed and said they had done so as they needed a replacement.

The length of time that the survey participants have had their spinal cord stimulator implanted ranged from less than three months to many years with one participant having had a stimulator for 25 years.

The majority of respondents have had their stimulator for 3 years and under, and there was a second smaller group who have had their stimulator for between 5 and 10 years.

The majority had their operation in a private hospital (45), 16 were part of a Workcover claim, seven were funded by the Department of Veteran Affairs (DVA), and two had their Implant inserted in a public hospital.

PROCESS

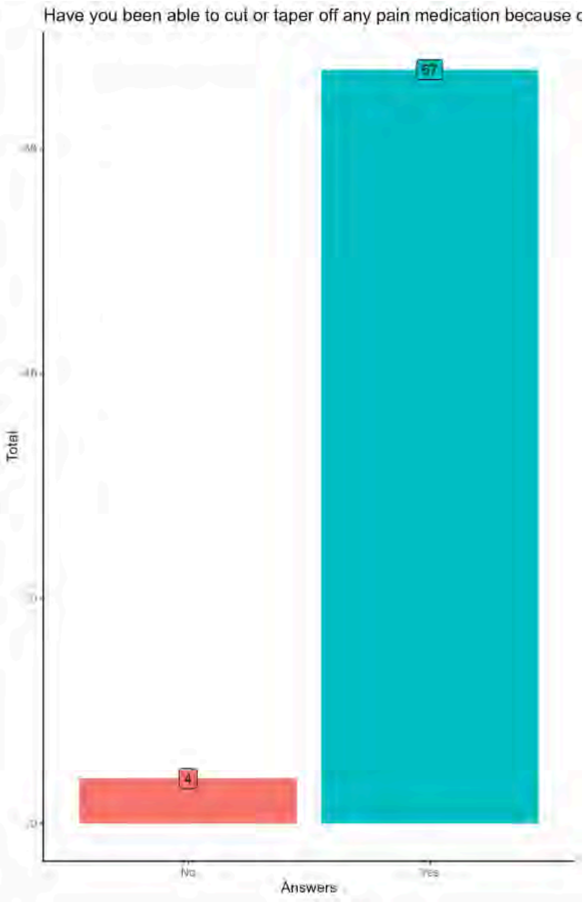

Neuromodulation Society of Australia commission report into consumer experiences of SCS.
Painaustralia
Neuromodulation Society of Australia
Painaustralia advertises survey on social media
Neurosurgeons and pain specialist provide details of 100 patients
10 complete the survey
63 complete survey
71 who had SCS
2 who declined SCS after trial
Report

FINDINGS

The survey found those who had chosen to have a spinal cord stimulator implant were enthusiastic about their experience saying that the treatment was an effective option that had allowed them to manage their pain.

The majority of the respondents said the spinal cord stimulator implant improved their quality of life, allowing them to return to a resemblance of a normal life.

Following implantation of a spinal cord stimulator many of the respondents, most who had their surgery done privately, were able to reduce their medication or stop it altogether and they were able to undertake more everyday activities with families and friends, allowing them to socialise, carry out housework and hobbies, return to work and be a better parent, friend, and partner.



> *I sleep better, my brain isn't muddled by huge doses of pain medication, my work became easier, I can do activities with my kids.*

BENEFITS

Respondents reported reducing their medication

Due to a lack of treatment options, services and costs, medicines are often the mainstay of treatment for people with chronic pain although this is not considered best practice, particularly amid concerns of opioid dependency.

One of the benefits of the spinal cord stimulator implant, reported by respondents, was the associated reduction of opioid medication to manage long term pain. 94% (67 out of 71 respondents) were able to taper their pain medication as a result of their SCS implant.

Furthermore, 59% (42 out of 71 respondents) said they had been able to entirely come off pain medication as a result of the stimulator.

> “*I am now totally off opioid medication down from 90mg of a combination of Endone and Oxycontin.*”

The Consumer Voice

Reduction of 80% (yes, 80%!) in **medication, improved cognition,** able to **enjoy life,** far less medication side effects.

I **sleep** better, my brain isn't muddled by huge doses of pain medication, my **work became easier, I can do activities with my kids.**

I could go to **work for 6 hours** without taking pain medication.

Decreased Pregabalin by half and the Palexia by one fifth. **No longer using the walking stick** daily. No longer needing the stair lift although I still walk up and down slowly and carefully. Am not resting on the bed as frequently as I used to.

Didn't have to use transdermal pain patches. Reduced the number of pain killers I needed to use. Returned to **exercise classes.** Started to participate in my previous life activities again. **Reduced sick leave** at work. Better **sleep** patterns. Reduced visits to doctors.

Improved quality of life and a return to everyday activities

> ***I was unable to work. Now I can work full time, exercise and live a full life. I am not restricted in any way. I've lost 15 kg and am the fittest I've ever been.***

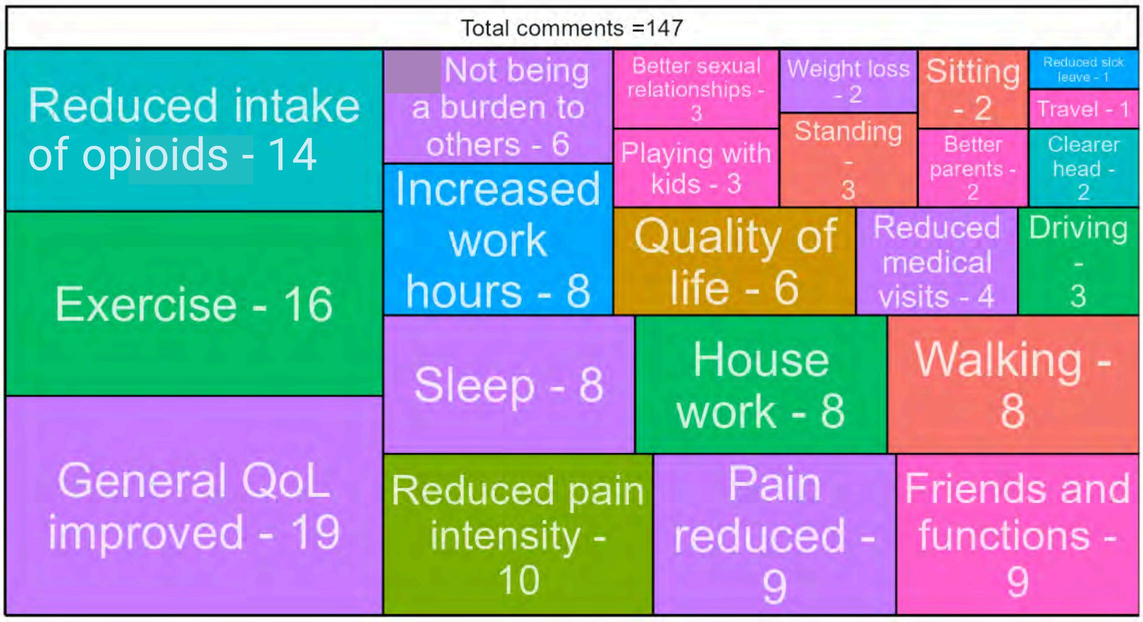
People living with chronic pain will often tell you that the simplest things are the hardest when living in constant pain. They lose relationships, they often cannot work, they can't socialise, and housework or hobbies such as gardening and exercise are sometimes literally impossible. They are often accused of having made up their pain, are told that "it's in their head" and report experiencing stigma and misunderstanding.

When asked whether their quality of life improved or deteriorated after their spinal cord stimulator implant surgery, 44 respondents said their quality of life strongly improved, 24 said it had improved, and three people reported no change. There were no reports of deterioration.

When detailing how their lives had improved with a spinal cord stimulator respondents said:

- their self-esteem and health improved,
- they were able to sleep more,
- they had less pain,
- they reduced their medication,
- they had clearer heads,
- they were able to travel,
- they were able to walk, exercise, garden and return to other hobbies,
- they could play with their children,
- they had reduced medical visits, and
- they were a better partner and friend.

How life has changed (improved).



The Consumer Voice

Absence of pain and sciatica meant I was now able to: **Exercise** more, **socialise** more, **lose weight,** resume activities, resume **hobbies,** go on **holidays**, do my own **housework,** drive a **car,** join **social** groups, **not go to doctors** very often, enjoy life more, improve my **sex life,** do some educational courses, **live like a normal human being.** People stopped calling me a drug seeker.

Sleep for more than 4 hours without waking up in pain. **Walk** for 60 minutes without stopping. Sit for 3 hours. Do hip flection exercises. **Drive** for an hour without stopping. **Gardening** (raised garden beds and pot plants) for a morning or an afternoon. **Cook** a meal for the family, then sit and **eat with my family,** then spend time in the lounge with everyone for a couple hours. Go out for dinner with my partner and **comfortably sit** and enjoy a meal together.

I had **less fatigue,** I could focus, I could hear and recall details, I could work, **I laughed, enjoyed myself,** it restored quality of life. I'm not 100% but I can see I'm pacing forward

Attend **concerts** and actually enjoy them. **Gardening.** Throwing the ball for the dogs. **Baking. Sex.** Even though I'm limited because of the joint, I can lift light things without severe jolts of pain. I did try to do most activities before hand but experienced pain and discomfort so 95% of the time avoided stuff

I was able to sit at a social gathering for more than 5 minutes. I was able to **play** on the ground and wrestle with my children. I was able to spend more than 5 minutes standing up at one time. **I could do work** around the house without feeling like I'd need to spend the next day in bed. I could, quite frankly **contribute to family life** instead of feeling like I was a burden on my family.

I returned to work as a Registered Nurse working in an Endoscopy Theatre with appropriate limitations to lifting, bending, stretching as per my pain specialist's recommendations (approximately 40hrs/fortnight) I can perform general household duties - **washing, cooking, cleaning** etc. I can care for my grandchildren taking into consideration my ability/restrictions regarding lifting and carrying. I am now able to **care for my horse and ride** him approximately 3 times a week in between my shifts at work. I carry out all of the above within my current physical capacity and adhere to limitations and guidelines provided by my pain specialist and spinal cord stimulator provider.

I pace myself appropriately as recommended by them. Without the two spinal cord stimulators I now have, I would not be able to live the life I now live or be a functioning and **contributing member of society.** I am so thankful and grateful to have received the opportunity of receiving spinal cord stimulator implants. **It has changed my life for the best.**

Reduced sick leave at work. **Better sleep** patterns. Reduced visits to doctors.

CONSUMER SPOTLIGHT

Amanda's story

At her lowest point of living with chronic pain, Amanda, a Canberra mother of two young girls told her partner he should leave her and walk away as she faced a life of living in aged care, being incontinent, in constant pain, unable to walk, and at times only able to crawl to the bathroom two metres from her bed.

It was 2018 and the 38-year-old gym instructor and personal trainer had a fall while instructing a gym class. Subsequent investigations including an Xray and an MRI showed she had a ruptured disc with multiple vertebral fractures.

A range of treatments including medications - Lyrica, Palexia, Endone, anti-inflammatories, cortisone nerve root injections and microdiscectomy surgery - had all failed to provide any relief. Her injury was getting worse rather than better.

She was unable to work, unable to do any activities with her children other than lie on an inflatable mattress or, on the days she could manage to walk, needed a walking stick to lean on.

It wasn't until Amanda was referred to the Royal North Shore Pain Management Unit for an eligibility assessment which she attended months after her accident, that she was informed that the pain management course would not assist her to manage the pain symptoms due to the damage to her spinal cord. It was at this point that one of the doctors suggested a spinal cord stimulator implant, suspecting that this might help her.

December 18th, 2018, the trial stimulator was implanted and, other than post-surgical discomfort, it was like "someone had pulled the plug out of the bottom of the bath, the pressure and pain just disappeared."

"I went from someone who outwardly appeared to have had a stroke, suffered from muscular dystrophy, cerebral palsy or arthritis in the spine to being able to stand up straight, walk unaided and without impairment for the first time in months."

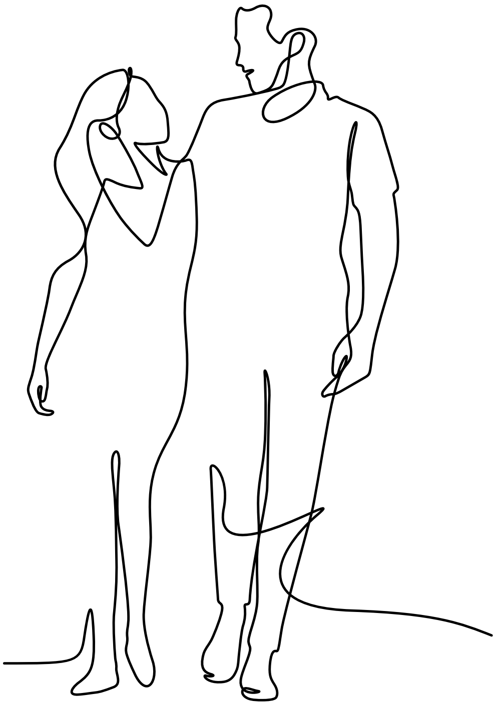
As this was a trial, Amanda had to then have the implant removed. "It was amazing, I cried when I was told they would have to take it out."

That day was 2 days prior to Christmas Eve and within 10 minutes she was "straight back into the pain and discomfort."

She received her permanent spinal cord stimulator on 4th February, 2019. Two days earlier she had given the eulogy at her grandfather's funeral in pain leaning on a walking stick. She said that before he passed away, he told her to be brave and "get it done".

Incredibly, three days after the implant she was able to travel (as a passenger!) the three-hour drive home to Canberra. In the months that followed she was able to complete several charity walks and even completed the 35 kilometre "Bloody Long Walk" in Canberra in four hours and 45 minutes, being the 41st person to cross the finish line.

It was two years later in 2022 that the damaged disc at L4/5 resulted in severe exacerbation of pain in April, September and then again in October causing constant pain despite the spinal cord stimulator and further surgeries. When investigated, Amanda's neuromodulators "found that I had a broken lead - the pain was progressively getting worse," she said.



"I had the stimulator removed and within days I was incontinent again, I had no function left, the left foot drop had returned, and I could only crawl to the bathroom. I was destroyed mentally." She pleaded with her surgeon to install a new implant as soon as possible.

A second device was implanted on 6th February 2023 and within four days her incontinence disappeared, and she was able to begin weaning off her medication. Her stimulator is constantly on, and if it is turned off it takes just 30 seconds for her pain to reappear.

Amanda is now able to work again and is in the final stages of becoming a pain psychologist. “I live with chronic pain/CRPS so I can empathise and help people in pain just by understanding what they’re going through.”

She continues to participate in charity walks and physically challenges herself every month but the best part of having a spinal cord stimulator implant is the positive impact on her interactions with her family.

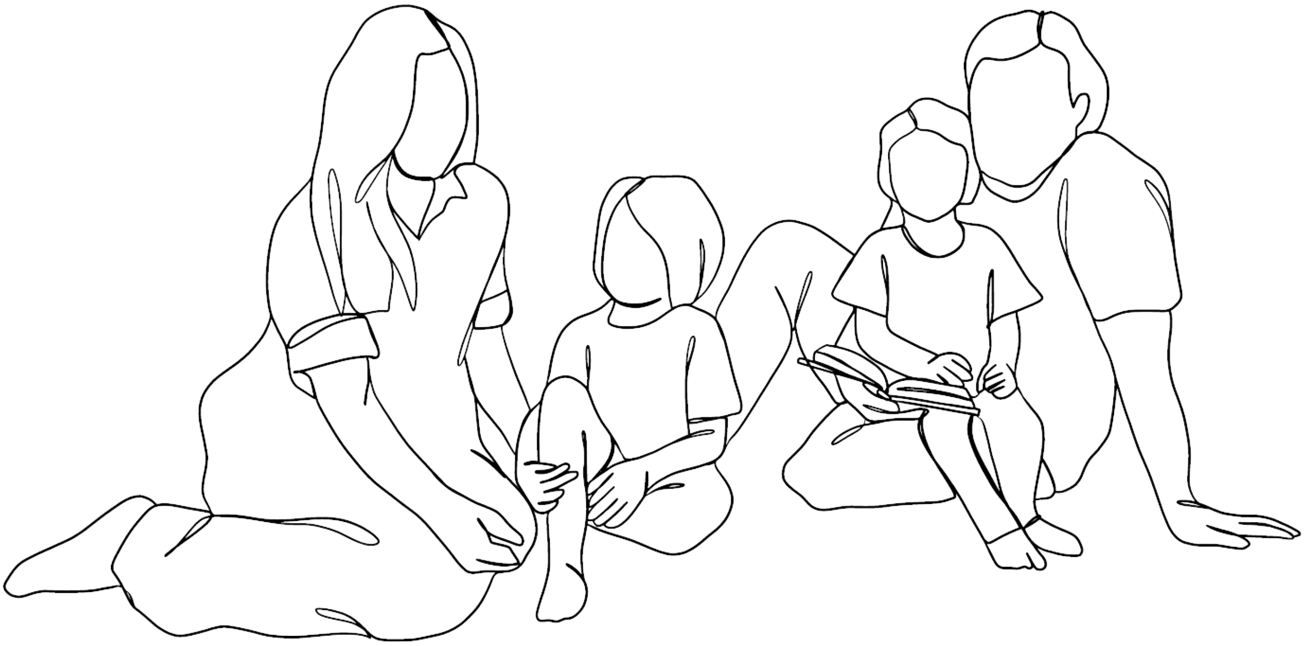
“The best thing is that I can muck around with my kids now. I can go on bike rides and hikes and camping.”

> ***The best thing is that I can muck around with my kids now. I can go on bike rides and hikes and camping.***

She credits the spinal cord stimulator with returning her to a life of activity and, importantly, without pain.

“To think that some people still view spinal cord stimulators as hocus pocus mumbo jumbo makes me angry – they have no idea what chronic pain can do and very little understanding of its impact. I actually had one person tell me it wasn’t real and was all in my head. If you have chronic pain, there is no reprieve. It is in every movement, it is in every moment, it is in every thought, it is unrelenting all day every day - even ‘resting’ hurts.”

And Amanda’s partner didn’t leave, instead when she told him he should walk away he asked her to marry him. At the time she thought she might have to walk down the aisle with a walking stick but a year later and with a spinal cord stimulator implant she proudly walked down the aisle without any aide and no pain.



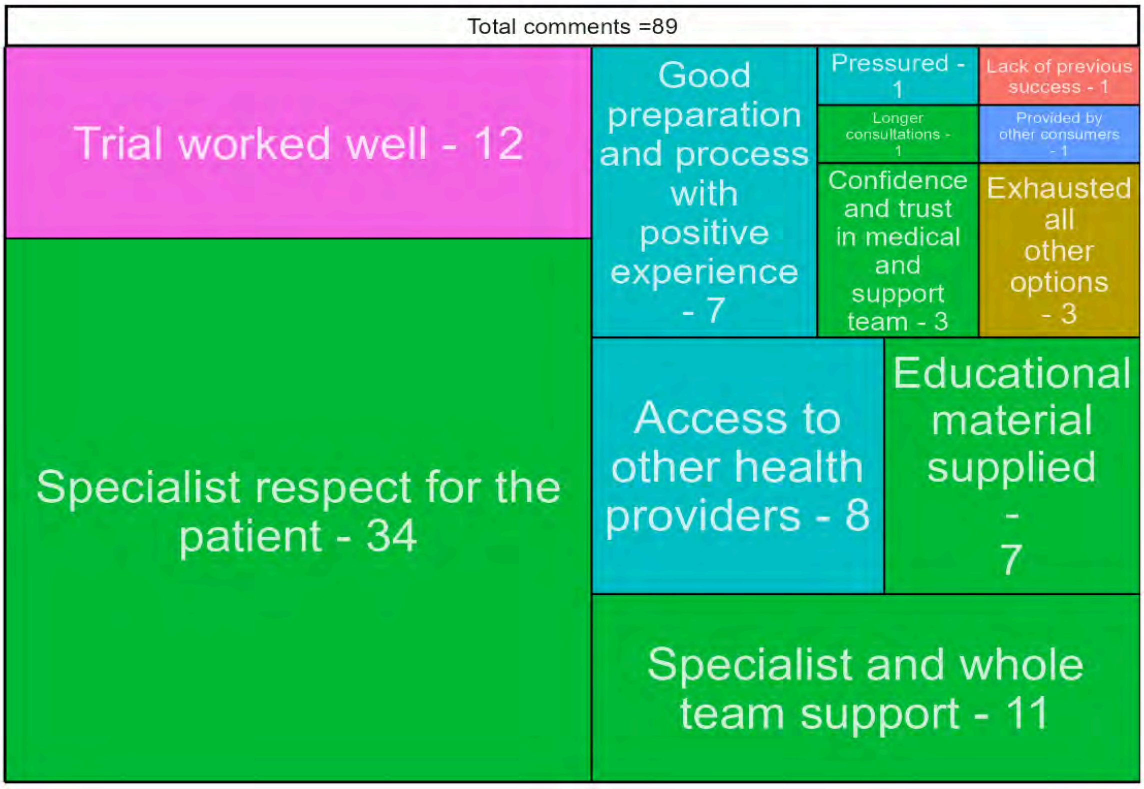
WHAT WORKED

Consumers reported a range of different aspects of what went well before and after their surgery. Patients told us a positive and satisfying experience was dependent on a number of factors including:

- having a trial,
- being supported before and after the surgery from the pain specialist and surgeon including being respected,
- being provided with a high level of support from the whole health team including follow up visits and being able to phone the nurse or technical staff about any issues,
- access to other health professionals including psychologists, and
- the provision of clear and understandable information.

> ***The procedure was thoroughly explained to me and I got to actually meet some people who had a stimulator already and hearing from them was helpful.***

Things that were done well in the lead up to surgery.



The Consumer Voice

Making sure I was physically & emotionally ready for whatever outcome could happen. I had rehab to strengthen my body in preparation for starting to move again when my pain reduced.

The surgical procedure (what and how) was **well explained.** Prior to the trial intervention and the surgery, I was referred to a psychologist to assess **I was in a "good space"** and understood the surgery procedure, risks.

I had appointments every few days at first to check the wounds and calibrate the stimulator. They then progressed to every week, then monthly, then 3 months and then I have my next appointment in 6 months. I have always had **the option to call and speak to the nurse** or the tech people when needed. All of my questions were answered, and I felt like each appointment was very **thorough** and **I wasn't rushed** at all.

Ongoing appointments with my specialist to touch base and assess my progress ie regarding my **pain scores,** any difficulties experienced or queries I may have. Provided ongoing **contact and appointments** with my spinal cord stimulator provider to provide **assistance with programming and troubleshooting.**

Education, psychological assessment and 2-week trial period, **information on restrictions** after SCS surgery.

My specialist **explained** me my treatment plans including **all other possible treatments** (medication plans/pain management sessions with allied health team/ other invasive treatments) and set up the SCS at the last (Explained me not only once but repeatedly as well as **positive and negative affects** with SCS mechanics to solve any queries). Therefore, when the benefits of all other treatment did not last long, I smoothly reached to the conclusion of the SCS. Also, it was very **beneficial** to make the decision of having permanent SCS **that I had the chance of having a trial** of SCS.

The information given out was thorough and **written in a way I could understand.** The contact between myself and the doctor was **consistent**, and **all my questions were answered.**

Weekly visits while in recovery. Access to phone **counselling** in between visits. Constant **contact and support** from the technical staff for the first year.

THE DOWNSIDES

As with any surgery there are risks along with benefits – 68 respondents said before going ahead with their surgery they were informed about the risks of a spinal cord stimulator.

Before taking the decision to have a spinal cord stimulator in addition to the trial many consumers told us they:

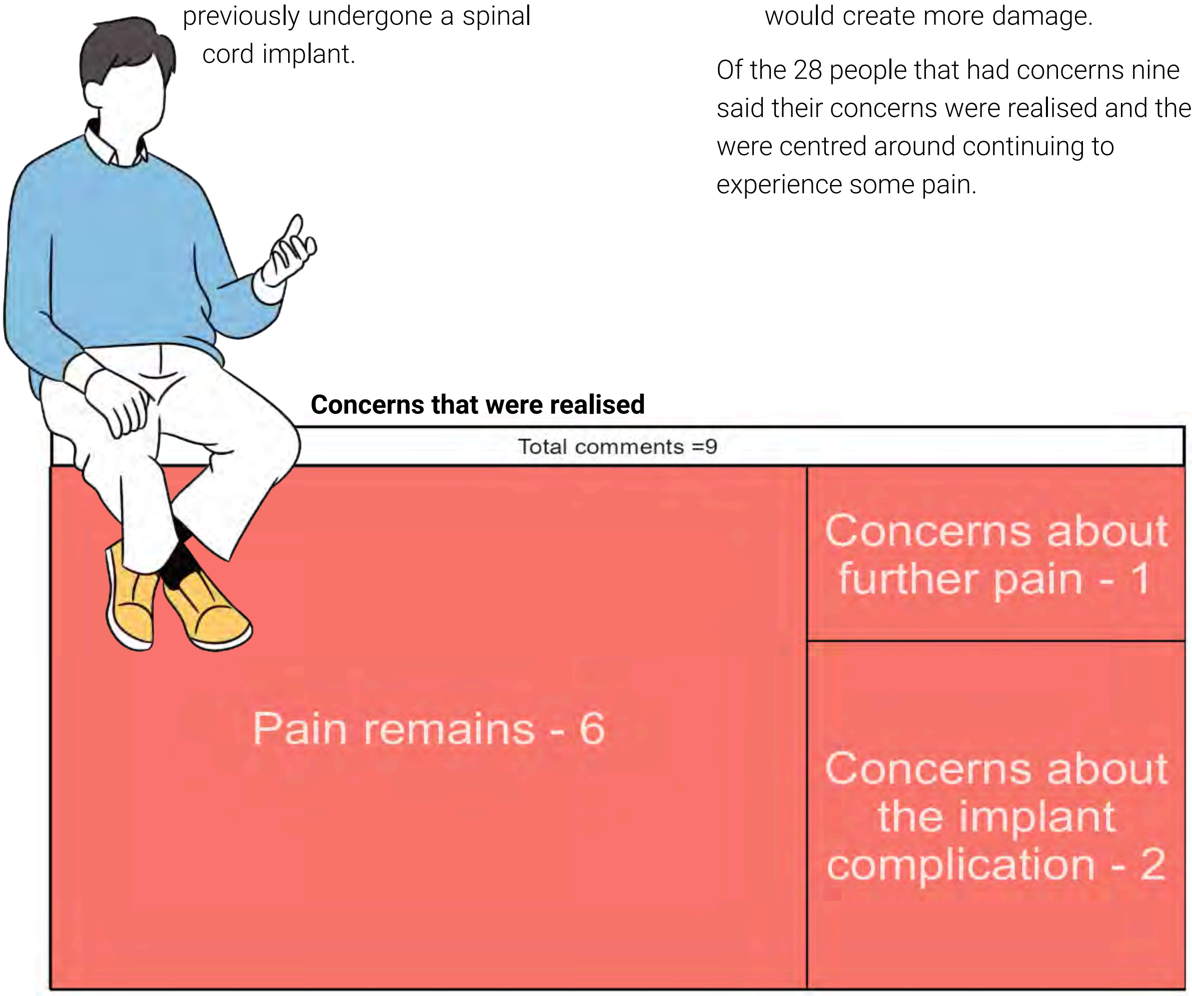
- undertook their own research,
- received information handouts and educational material from their specialists,
- consulted their GPs,
- consulted other health professionals, and
- spoke to other patients who had previously undergone a spinal cord implant.

61% (43 respondents out of 71) respondents said they did not have any concerns about getting a spinal cord stimulator implant before their surgery while 39% (28 respondents out of 71) said they did.

The reported concerns included:

- whether it would be effective in managing their pain,
- whether there would be post op complications,
- concerns about their ability to work in the future,
- concerns about having a foreign object in their body, and
- worry about whether the implant would create more damage.

Of the 28 people that had concerns nine said their concerns were realised and they were centred around continuing to experience some pain.



Concerns that were realised

The Consumer Voice

Still having waves of pain but not as severe when walking.

Results **not as good as I hoped** but **definitely an improvement.**

I was still getting **episodes of pain,** but they were a lot less.

The surgery (ie. Implant) **has not removed the pain but has helped to lessen the frequency** of the real bad periodic "stabbing" pain.

Only the **post op pain was a concern,** it wasn't excruciating however, the **pain was a challenge at the battery site** and lead placement site for approx. 2-3 weeks.

CONSUMER SPOTLIGHT

Daniel’s story

Something as simple as tripping over on a one-inch step on uneven ground and rolling an ankle while working as a security guard led Daniel Deakin to experiencing more than six years of intense pain, an inability to work and his life being changed in an instant.

The Victorian father of four was working one night when he tripped on uneven ground hurting and spraining his ankle. What initially seemed like a small incident led to intense nerve pain that grew stronger and stronger and years of failing treatments and scepticism from various doctors left him seriously wanting to have his leg amputated.

Daniel was 36 at the time that he tripped and sprained his ankle. The resulting pain which got worse and worse left him in a wheelchair, being unable to work, unable to stand or walk, or undertake any activities with his young family.

“My life was the bedroom, the bathroom, and my garage where I sat in my rocking chair. I was depressed and had put on weight, no-one wanted to be with me as I was not a nice person as I was constantly in pain,” he said.

He went to various doctors for help but instead he experienced disbelief and scepticism leaving him disillusioned and distressed.

“Doctors would touch my leg and think I was faking it and looking at me as if I was insane,” he said.

Having previously rode motorbikes, bulls and horses Daniel had experienced many falls and broken bones including ribs and a collarbone.

“I have had 77 broken bones over my lifetime, but I have never experienced pain like it,” he said.

“I nearly lost my marriage and my house, I went to doctors, had cortisone injections, was on medication and had ketamine injections for more than three and a half years.”

Eventually he was diagnosed with Complex Regional Pain Syndrome (CRPS) and turned to a pain specialist in Melbourne to help. “I was begging to have my leg cut off”.

As a last resort he had a spinal cord stimulator inserted as part of a trial and had even prepared himself that it may not work. “When I woke up, I opened my eyes and thought my dreams have come true”.

For the first time he was able to put his feet on the ground, stand and walk without excruciating pain. “I had my feet back.”

After his trial he had the spinal cord stimulator permanently put in and surprised his friends when they turned up to see him afterwards by being able to not only walk but able to run as well. It has now been a year since he had the stimulator implant.

While he isn't completely free of pain and goes through "pain spikes" he can control the pain by adjusting the levels of the electric pulses from his stimulator.

Before the stimulator, even having a shower was distressing as the water on his foot was so painful and he couldn't wear any footwear.

"Now I can wear full military footwear again."

He is also finally back at work. Daniel says the stimulator has saved his life and wants to see it available for people like himself who are in the worst of pain.

"My children are now happier as they see their dad working, not stressing about life and whether there is enough money coming in. I describe it as the jewel in the box," he said.

"There are hardly any options out there for people like me, CRPS does not leave you alone, it is 24 hours a day, it is a silent killer," he said.

> ***My children are now happier as they see their dad working, not stressing about life and whether there is enough money coming in. I describe it as the jewel in the box,***

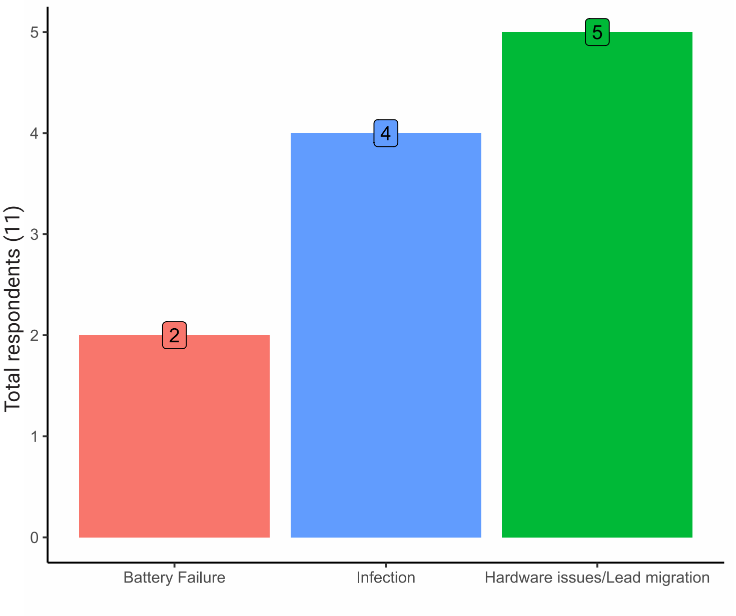
> ***My life was the bedroom, the bathroom and my garage where I sat in my rocking chair.***

Complications and side effects

The hardware

The survey results indicate that the majority of respondents (56 in total) experienced no complications following their surgeries. Conversely, 15 participants did encounter post-surgical complications. Hardware- related complications were identified five times, predominantly involving lead migration. Infections were reported by four respondents, while two instances of battery failure were also noted. Other post- operative side effects, including constipation, headaches, fractures, neurological changes, and spinal fluid leakage, were reported in nine instances.

Complications



Type of implant

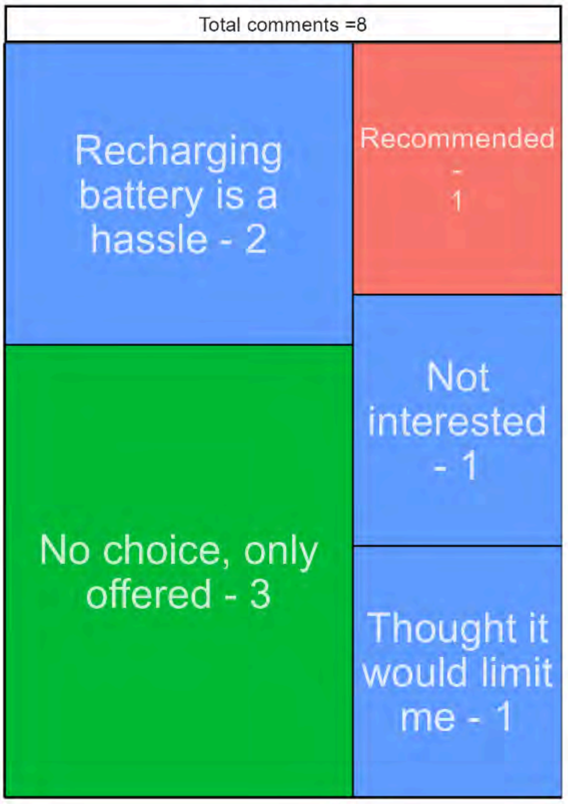
The majority of respondents (62) chose to have a stimulator with a rechargeable battery. The reasons for doing so included:

- they were recommended,
- better compliance,
- trial and error, and
- being informed that it was the better option.

Those who chose not to have a rechargeable battery said their main reasons for doing so were:

- thinking that recharging the battery would be a hassle,
- that it might limit their activities especially when it came to travel, and
- the cost of batteries in the future particularly if it needed to be replaced years after the operation.

Reasons for not having a rechargeable battery



The Consumer Voice

My first two SCS were rechargeable and I found **recharging everyday a big hassle** and mentally challenging. They were replaced with non-rechargeable batteries after 6 years.

I didn't want to have to engage mentally with my pain on a daily basis, **I wanted to be able to function daily** without having to be cognisant of my pain and I felt that needing to recharge my battery would mean engaging on a daily basis.

I was made aware that I would need my batteries replaced, I have private health cover so was not paying a lot of attention to how much the batteries will cost to replace. **I am concerned that the cost of the battery could become unaffordable** if they are not covered on Medicare into the future.

CONSUMER SPOTLIGHT

Kat’s story

Five years ago, at the age of 29, Kat, who was in the air force at the time, had just moved to a new city and was living by the beach. Instead of being able to enjoy her life as a young woman in her 20s she was forced to spend most of her time in bed, hating life and not wanting to leave the house - all because of her chronic pelvic pain.

It took a couple of years for Kat and her medical team to diagnose and treat her condition, endometriosis and adenomyosis. She underwent multiple laparoscopies which led to a full hysterectomy in 2022, however the entire time she had an underlying pain that would just not go away and felt different to the pelvic pain.

“This pain, mostly through the left side was still there, and then when it was at its worst, it would sweep across to my right hip and then it would essentially go down my left leg and then I would be a bit disabled. I could no longer run and when walking I had a really wide gait. It felt as though I had a balloon in my hip that I couldn’t get my leg around,” she said.

Her pain also limited what she could wear as everything was tight and uncomfortable. In addition, she was on medication and her diet and social life were all affected.

Kat was referred onto a pain specialist in Adelaide by her gynaecologist, which was funded through the Australian Defence Force, and she was diagnosed with sodium channelopathy – a condition where the sodium channel in her nerves sends the signal that something is wrong but in reality, there isn’t.

“My nerves treat it as if it is Chinese whispers and my body is not stopping that pain message, so it spreads down my leg and because that message was going on for so long it was becoming debilitating and ingrained.”

Kat tried medication but, in the end, stopped it. “I would rather have a physical disability than a mental disability, it completely zonked my mind, and I was not going to accept that,” she said.

With the suggestion of her specialist, Kat decided to try a spinal cord implant. She had a trial in 2019 which helped tremendously with the pain. However, when it ended, and they turned the stimulator off she actually passed out from the intensity of the pain as it returned. Kat proceeded with the permanent implant.

“However initially the four wires in my back did not quite fit with how my body would move so I had them repositioned a few months later,” she said.

“The device has been in since then and it is really effective – it has really changed my life and I am even back to running.

> “***The device has been in since then and it is really effective – it has really changed my life and I am even back to running.***”

"It is so responsive; as soon as I have forgotten to charge my device the pain on my left side starts to come in and sweep across, and my body starts trying to get around that balloon in my hip again. I charge it and I am completely free of pain again."

"Now I am in the Invictus Pathway Program and am out building a business and I socialise again. I went to a networking event, and I was able to walk from my home the 2.5kms to the event just because I could."

"The stimulator helped me get back into life and I was really worried for a while there that I would be a potato-mind on a cocktail of medication and that would be me for the rest of my life. It has given me back everything."

Kat has since been medically discharged from the air-force and still has a physical limitation with the implant as she does not have a full range of 360-degree movement "that's my biggest limitation."

She said she can feel the wires but is used to it and after the surgery had to de-sensitise the scar tissue and wear clothes that didn't aggravate the scarring.

Kat believes using and developing technology is the best way to solve health problems rather than relying on medication, particularly in the digital age.

She wants to see more research into spinal cord stimulators so that people who need them can access and afford them. She was fortunate that the Defence Force paid for hers. But she does urge anyone considering a spinal cord stimulator to explore all their options.

"You need to do that investigation yourself and with the right doctors and the right treating team of different specialists and see whether the device is the right outcome for you," she said.

THOSE THAT DID NOT GO AHEAD

Of the 73 respondents, two people reported that after the trial they did not go ahead with the procedure. It was unfortunate that the survey was not able to reach more persons who decided not to proceed with the implant after their trial. The reasons these two persons gave for not proceeding included:

- not being convinced of the technology,
- safety concerns,
- the cost, and
- poor information and service.

The Consumer Voice

I was **not given any information** about the procedure except "It's simple, five minute procedure". When I asked for information, I was told the spinal cord stim manufacturer would get in touch. They didn't. **I was not offered choice - pros and cons about different options,** and to cap it all off, they told me I needed to pay **$4000 in cash, upfront,** which is my pain doctor's 'fee'. That's above and beyond the scheduled fee, just for him. **For 'maintenance'.**

I had a trial, my pain levels in my legs were improved but the **pain levels in my back remained the same.** My surgeon said unless it was 100% improvement it wasn't worth the full implant. On a personal level **I'm not 100% sure on the technology,** and the model I was offered was a no MRI model - interestingly if I had had that surgery, **I wouldn't have been able to have the MRI** I had last year that diagnosed my hip dysplasia and bone on bone requiring a hip replacement, so **I'm very glad I didn't go down that path.**

WHAT NEEDS TO IMPROVE

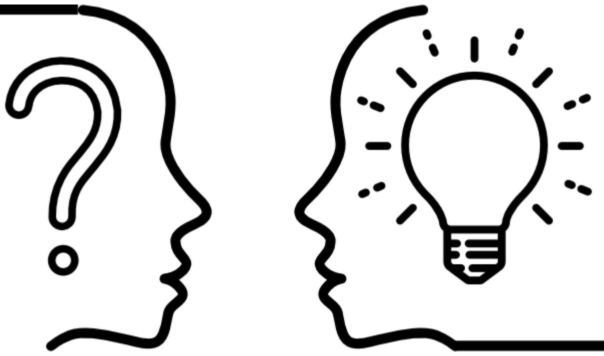
While consumers were overall positive about the process, they did identify several ways to improve the system to make it easier and better for patients. A recurring theme was the importance of communication not only with pain specialists but with the whole health team. Good communication led to a feeling of respect for consumers, resulting in a higher level of trust in their surgeons and also in the whole process. Patients also wanted to be well prepared with as much information about the procedure detailing information about the risks, the benefits and about how much the pain would decrease.

> ***The ability to talk to another patient that has a SCS. I was asked to talk with a patient that was considering a SCS. He turned into a friend, and we have been in hospital a number a times together.***

Suggested improvements include:

- the need for better communication with health professionals particularly from the surgeon undertaking the procedure,
- greater awareness and clear and plain English education material about pain, surgical pain, and the device in general including that it is not always a complete fix for all of the pain,
- more support from health professionals including more visits with allied health, surgeons, nursing staff and pain specialists, and
- the ability to be able to speak to other patients that had undergone the procedure.

Respondents were also extremely supportive of the need for greater transparency and information about spinal cord stimulators. **60 respondents said they would find a neurostimulator device registry to be helpful and 32 supported an annual report being published and available for patients about the number of neurostimulators that are implanted each year in Australia.**



The Consumer Voice

Explain that **the trial is not going to feel like the full implant.** As in the trial you have pain killers and numbing around the site. When the real implant is done, and all the medication is finally out of your system then you get to feel if it works or not. **More follow ups after surgery.**

Getting **to chat with other patients** with stimulators.

More **information on benefits/ risks,** would have liked **patient reviews** (maybe support groups etc).

More info on **surgical pain and side effects** of pain meds.

More education needed prior to surgery.

WOULD YOU DO IT AGAIN?

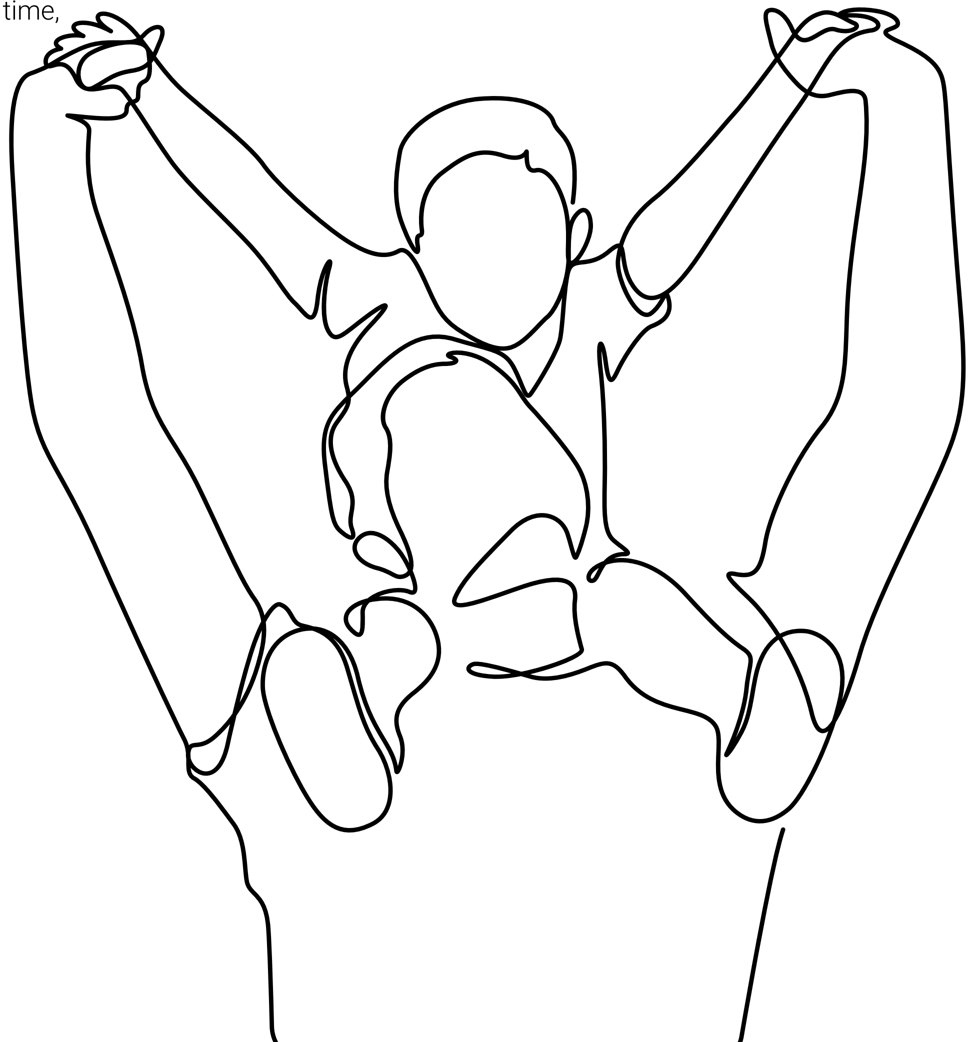
What consumers would do differently

When asked what they would do differently if they had to go through the process again a majority of respondents (69 percent) said there would be no change to how they would proceed. One person said they would avoid it.

Other things respondents said they would do differently include:

- they should have done it sooner,
- would have a longer trial period,
- change the location of the device to another side of their body,
- go to a different hospital,
- have more recovery time, and
- learn more about the technology.

> *I would have a longer trial period.*



The Consumer Voice

What I would do differently is **increase recovery time,** seek **allied health** services, and do a bit **more research** and be informed, if anything more research into the mechanics of the device.

Pay more attention to the trial and **comparison** of the **two different models.**

I would plan for more **recovery time** and go to a **physio** to aid my physical recovery from the surgeries, I had many surgeries and an open back surgery to reinstate the fractured wires so it was quite significant.

Pick **a better hospital** to go through recovering in and **speak** about the **complexity** of my **pain experience** more clearly.

Maybe **try earlier,** 28 years of increasing pain is difficult.

I would **take the recovery process a little slower.** The simulator works so well, you think that you can do anything. You need to remember that you usually may have an underlying injury that can flare up if you don't take the recovery slowly.

I'd get the **battery pack** installed on the **right side.** It gets bit annoying on the left sometimes.

Would have looked into **the pros and cons** of **leads vs a paddle** and discussed with specialists.

I wouldn't change a thing.

PEER TO PEER ADVICE

However, some respondents said they would encourage patients to:

- make sure they do their research,
- thoroughly inform themselves of the benefits and risks, and
- talk to other patients who had undergone the procedure.

> ***I would advise them to go ahead after they had been informed and educated as I so expertly was by my pain specialist. It has totally changed my life for the better and I am so very blessed and grateful to have been able to have this incredible technology available to me. I would not be able to live my life in the manner in which I am today without this amazing technology.***

The Consumer Voice

Definitely do it, but **be patient it takes time to fully work** with readjustment of settings, programs to give the relief needed.

Go ahead and have the implant. **Best thing I have ever had done.** I would absolutely recommend.

It is definitely worth trying. **It gave me my life back.**

Give it a go, do the trial then **make an educated decision.**

Do your own research as well as looking at the information given from your Dr and SCS rep. Do the trial and workout if this is going to be right for your condition and life circumstances. Be aware they are **not a cure for your condition.** They are a very good **pain management tool** used in conjunction with other allied health services.

To learn all there is. Find a specialist with experience in implanting stims. It worked very well for me, **it's a tough process but I believe it's worth it.** The trial is key and then of course making sure the leads are in the exact place when implanted.

Definitely go with it as it can **change your life.**

Look fully into it. Ensure you **understand all costs medically, surgically and machinery ones.** Ensure you realise **it is not a silver bullet.** The pain doesn't magically vanish after a period of time but becomes more manageable with you as the controller of how it works. **Ensure you have realistic expectations** of the what the benefits maybe but also know you are responsible for its upkeep, ie the charging. It is not difficult to make time to charge it up but YOU are the one who must do it. Be positive of the benefits. That is **look at it half full, not half empty.** It can't remove the pain but any not drug therapy that helps you, grab it with both arms and run with it.

I would advise them to research pain specialists and not believe everything you read on Facebook Community pages. **I would advise them to take plenty of recovery time off work** if they're still working - 4-6 weeks at least. I would advise them to have a very positive mind set and to do everything the specialist tells you to do pre and post op.

IF SCS WERE NOT AVAILABLE AS A TREATMENT OPTION

When asked to comment if in the future spinal cord stimulator treatment would not be available in Australia respondents were very clear in their views saying they would be disappointed and devastated.

Other responses included:

- patients going overseas for the procedure,
- being unable to work as their quality of life would be reduced, and
- ending up on opioids to manage their pain.

> *I believe spinal cord stimulators are a very important tool that can be used very effectively to treat chronic pain. If they fail, they can be removed, whereas other surgery (eg. spinal fusions) are a lot more difficult to treat if they don't have the desired outcome. A stimulator has improved my life physically and also psychologically (no more depression). The benefits far outweigh the cost.*

The Consumer Voice

Australia spends millions of dollars a year on methadone clinics, to treat opioid addiction. There is evidence that it doesn't work, people are just addicted to a different drug. Yet it still continues to be the "treatment" of choice for opioid addiction. **Spinal Stimulators work for many, many people. SS's change lives and give people back their lives.** If it works for some of us, why take the option away? That would be cruel.

If this therapy was no longer an option in Australia, then you would be condemning a lot of people to a pain filled existence. **All alternative therapies have a place in health,** and this is one of the better ones.

I would travel to another country to get the procedure done. **To take away this therapy would be absolutely devastating.** I can't imagine having to go back to living in pain all the time. It was bad enough having the trial stimulator removed knowing I would have to wait in pain until I could get the approval for the permanent implant.

Many people who may receive benefits from SCS will be **forced to use less effective methods** or higher medication levels and associated side effects etc.

Something is better than nothing. People with chronic pain **need all the support, help and interventions available** to try.

I would be unable to work or have an active life. I would be living with severe depression and chronic pain. There would be many people that would be affected in the same way. **You can't put a price on having the chance of taking away a person's chronic pain.**

There are so many people living in pain that do not need to be. **This therapy will/can/has saved lives.** I heard about it from a fellow Digger in New Zealand. He and his wife had got to the stage that suicide was what they going to do next. I was nearly there myself. This procedure should be available to everyone with chronic pain.

It would be a big mistake and disappointment, as it was my last resort and **the only thing that has helped and improved my life since my injury.** And I believe that it would help a lot of other people with no other options.

I would seek it out elsewhere. **It would be criminal to remove this therapy from Australia.** It would cost the country in medication, hospital doctors and specialist fees.

It would be **devasting** for people like myself.

I would be shattered. If I had to have mine removed or couldn't get my battery replaced I would be devastated. **I couldn't go back to my life before this procedure.**

CONCLUSION

The consumers sampled in this study were overwhelmingly positive about their experience of their spinal cord stimulator. They strongly agreed that this treatment should remain available to others. At the same time, the consumers want to be better supported and provided with more education and awareness to help them make their own choices to manage their chronic pain.

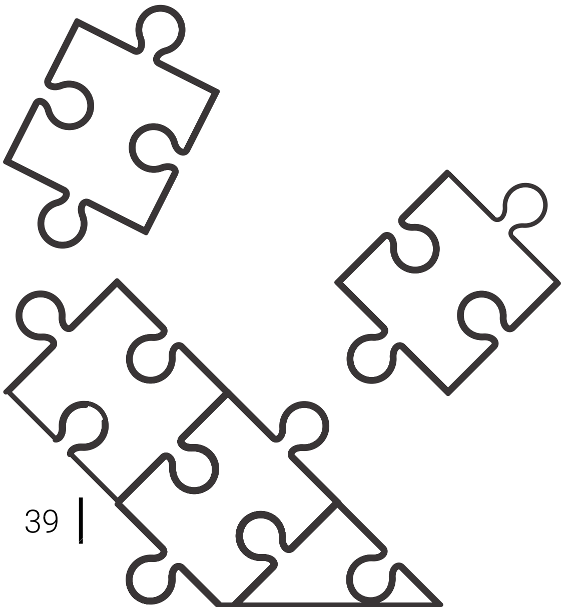
Spinal cord stimulators as a technology and implantable medical device are evolving and as illustrated by the respondents in our survey can provide many people in chronic pain with an option to manage their pain and live the fulfilling lives they deserve to.

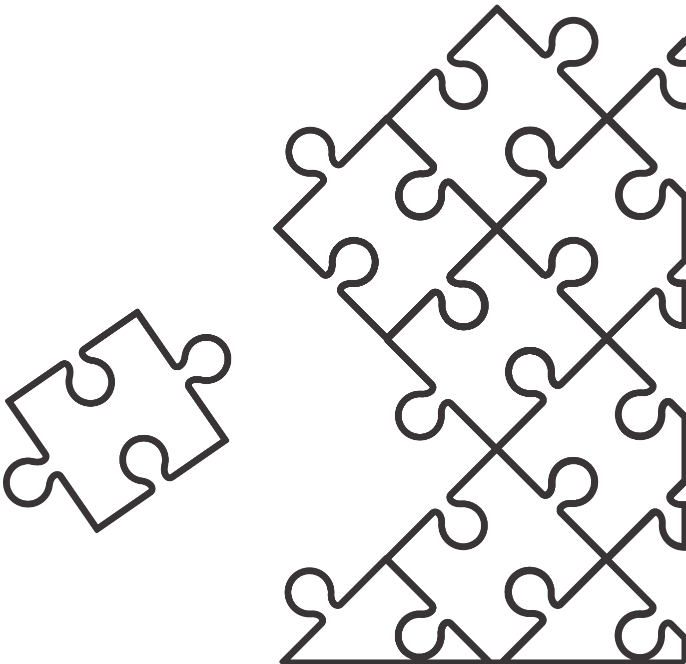
The survey shows that for some people, spinal cord stimulators provide marked benefits improving their lives for the better. While others report improved benefits and some did report hardware complications.

As with all evolving health technologies, the systems for regulation must drive improvement, increased safety, functional outcomes and patient satisfaction.

Spinal cord stimulation is an option for many consumers who have provided testimony in our survey to the life altering benefits it has achieved for them. However regulation and further research is required to ensure consumers are protected and can continue to access this as a treatment option.

While not without their risks, just like so many other treatment therapies, spinal cord stimulator implants should be regulated, further research should be conducted into the long-term benefit and harms, and consumers should be provided with transparency about their efficacy.





RECOMMENDATIONS

1

Recommendation

Australian specific guidelines and standards for clinical practice to ensure the consistent safe operation, implementation, and ongoing quality assessment of spinal cord stimulator implants.

2

Recommendation

A national data registry should be established to provide consumers the necessary information about the different technology and models available, their relevant safety record and their effectiveness. The registry should include information about adverse effects.

3

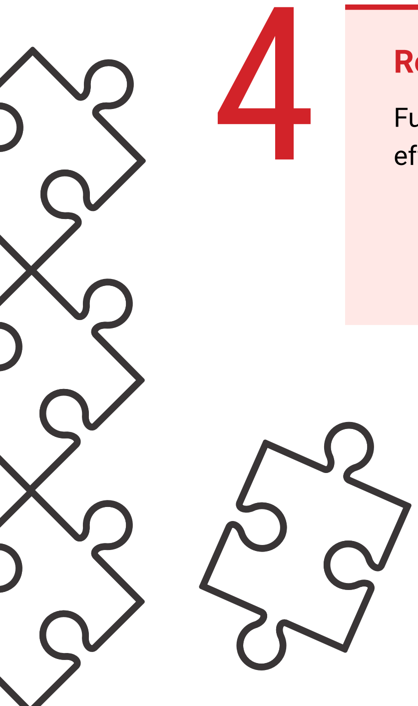
Recommendation

An annual report to be published by the MTAA and publicly available to consumers based on the registry data and containing information about the number of spinal cord stimulators implanted in Australia each year.

4

Recommendation

Further research and clinical trials to measure and evaluate the effectiveness of spinal cord stimulators over time.



Walk, sleep better. Shower without help, drive my car for longer, go to events and feel good to **be involved in community again.** It changed my life.

Completely changed my life. I only have pain if I overdo it but being able to move and exercise without pain, I've lost over 40kg, can go hiking long distances, returned to dancing after 25 years. **Living a life I once thought was impossible.**

I no longer feel like I wish my arm was amputated in the car accident. I just have aches instead of those plus intense neurological pain. **I can actually enjoy life,** use my arm more, be social.

Interact with friends, drive without severe pain, read more complex books, **holidays became much more possible and we have taken more.**

THE CONSUMER

It took 11 years before I was aware of this option and even then it was accidental (I was sent to the specialist regarding another treatment that turned out to be right for my condition). **It would be good if this sort of device was more widely known about** in the GP community.

I am able to garden for longer. I love driving which I can do for longer and longer periods. **I feel like I'm a better dad** as I have been camping and fishing with my youngest son. My son had to set up camp but it was great.

It's the only thing that has **given me my life back.** I know its not going to completely cover the pain but it was the only hope for me after all those years of pain and no answers.

Find an experienced pain specialist to provide thorough information. Meet with your technician prior to **answer all questions.** Ask what further monetary outlays there may be if battery or device fails.

See a pain specialist who specializes in this technology. **Have realistic expectations about the relief that you will achieve** (i.e. don't expect 100% pain free). My goal was to reduce or eliminate opioid usage. Definitely trial the device before proceeding and be honest about how the trial went.

Do my shoelaces up. Walking much further distance. Improved my lifestyle.

It is not a 100% pain reduction solution. Manage your expectations. It can be difficult to live with. Do the trial. **Don't be scared of the trial device conditions.** Be honest with the reps about how you feel and keep a diary of your settings and pain. It will take time to dial in the programs. **Be patient. Keep doing your physio/mental health work.**

Do the trial, if you can feel the difference please don't hesitate and just get it done. **Was the BEST decision I have ever made** and it has made such a positive impact on my life, my mental health and my relationships with family and friends. I'm nicer to be around now. My stimulator **targets my right arm,** I'm looking into using the spare ports to target my leg that was also injured. It is that good. I can easily change the level to increase the sensations and it is super effective when I've overextended my limits.

I would be devastated if it was no longer available. I'm 57 and felt that I couldn't go on with my pain for much longer. I have had nerve pain and CRPS since 2012, and severe back pain since 2003. It was so debilitating, that **I didn't think there was any other option, than to be in pain.** This therapy is non addictive. This therapy can be a life changing experience, if the surgeon is responsible and honest. **I can't imagine life without my SCS**.

VOICE

I was very sceptical at first but very surprised that **it actually worked.**

I was able in time to almost ween myself from opiates or suedo-opiates, stopped anti-inflammatories, no physiotherapy. As an aside, my bilateral chronic bursitis almost vanished and has stayed that way in the interim. I know the machine was not supposed to effect this condition but **I will take what I feel are all positives from it.** At 70 I am still able to have reasonable control of my pain levels, though I still get a some not so good days**. I can still function as a husband, father and grandfather** as needed but I know my limitations of activity. My intake of prescription tablets has lessened for this condition and I feel I am in a reasonable place to control my life. **I have never expected a "silver bullet"** with the neuro but I did hope it would help me, and it has to a very noticeable degree. I recommend friends and family at least look into possibly getting one... I had a battery replacement about 2 years ago and it provided me with more settings to utilise, which I do.

Return to the dark ages of back pain management. Depriving those who need it of the chance to be pain free and reclaim their lives. **Depriving doctors of the chance to offer their patients the best possible treatment for their back pain**, one they can be confident of truly helping their patients.

Yes, don't have the illusion that SCS therapy don't work. Yes, **they don't always work for everyone for some reason or another. But they are the bees knees for a lot of people** who rely on them and are very aware that they are not a cure for their pain conditions.

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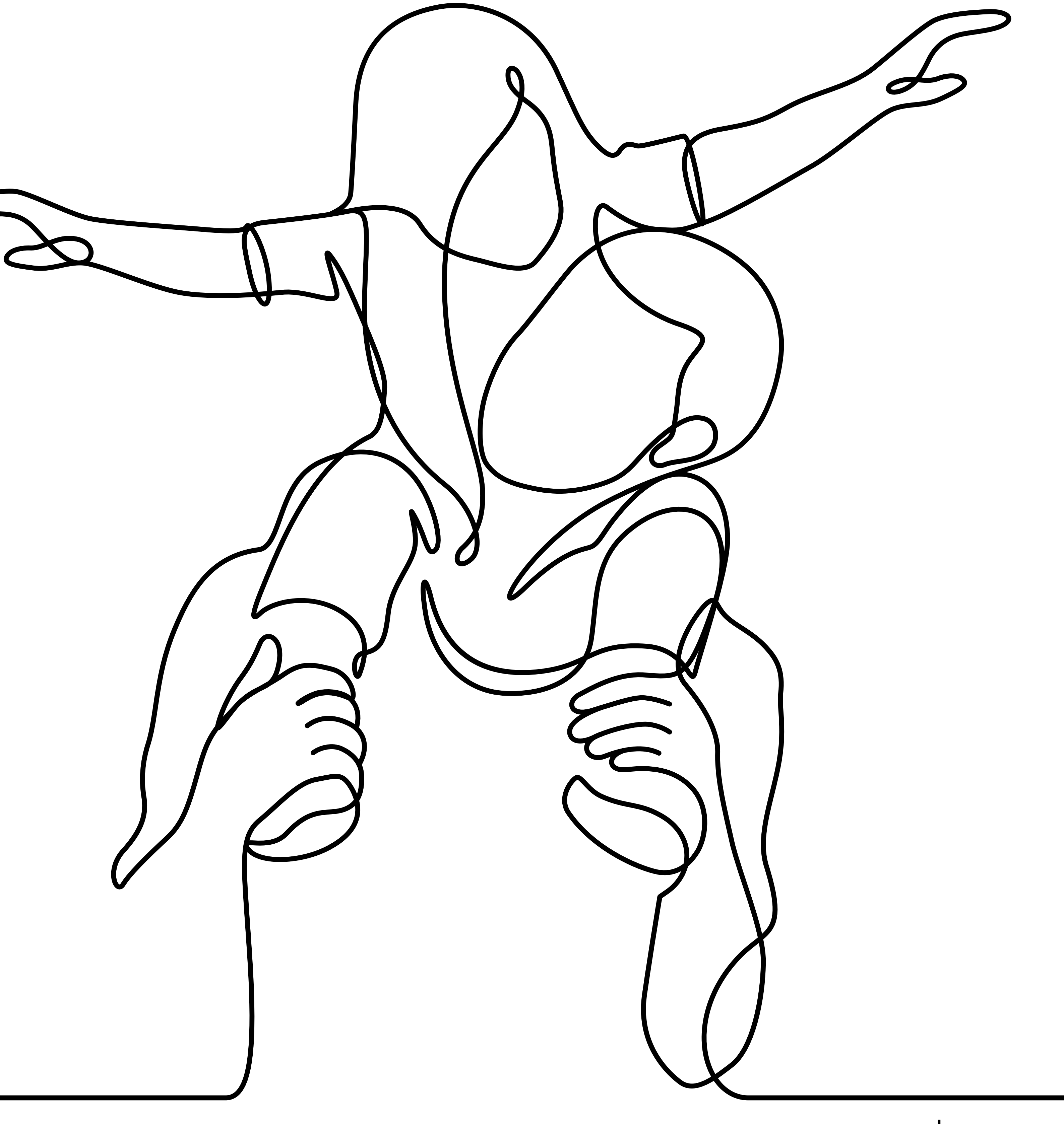

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