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Appendix

What BWC Wants You to Know About Spinal Cord Stimulators

Ohio Bureau of Workers' Compensation wants you to have the highest quality of care. That can only occur if you know how a spinal cord stimulator may affect your health and recovery.

BWC is providing the following instructional form to aid in the process. Your physician will discuss this information with you before the surgery so you can make the best-informed decision. In preparation, please study this form and discuss the information with your healthcare team. Afterwards, you and your physician of record or your operating surgeon will need to sign the form.

THIS IS NOT A SURGICAL CONSENT FORM.

Studies have shown the following post-operative outcomes:

Of those patients that undergo a trial of a spinal cord stimulator, between 63% to 78% decide to have a stimulator permanently implanted.

EFFECTIVENESS

Studies show 23% – 58.5% of patients undergoing a spinal cord stimulator implant reduced or eliminated opioid usage (Mayank). However, according to the 25th edition of the Official Disability Guidelines, as many as 40% of patients may experience a permanent unit **NOT** providing pain relief even after a successful trial.

Patients with greater number of preoperative opioid prescriptions prior to spinal cord stimulator implantation may not attain the same benefit from the intervention as patients with less opioid use. Patients with lower dose opioid use pre-operatively were more likely to stop opioid use.

Elimination of opioid dependence after spinal cord stimulator implantation has been found to be highly dependent on preimplant dose, with patients on lower doses of opioids being most likely to wean completely.

In a study evaluating the use of spinal cord stimulators in a workers' compensation population in 2010, there was no difference found in outcomes (≥ 50% improvements in pain, function, and opioid use) among a group receiving implants, a group with usual care, and a group receiving specialty care in a pain clinic at 12 months and 24 months.

Spinal cord stimulator implantation has been characterized by reports of decline in efficacy over time (the unit may lose its effectiveness). Loss of therapeutic effect is a common reason for therapy discontinuation.

COMPLICATIONS

An overall complication rate of 30% to 40% has been reported. Mechanical complications include lead fracture or disconnections (5% to 9%), lead migration (in up to 27%), and generator failure (1.7%). Biological complications include allergic reaction, pain at implant site, implantable pulse generator seroma, epidural fibrosis, epidural hematoma, dural puncture, and neurological injury (rare). Infection is report in 2.5% to 12%.

NEED FOR REVISION

Revision rates are generally reported to be 19% to 37%. A leading cause of revision is hardware failure which accounts for 24-50% of revisions.

REMOVAL

The rate of explantation (removal of the unit) is high, generally within 2 to 5 years. A 15-year follow-up study at Harvard found an explantation rate of 30%. In a similar study conducted over 17 years at the Allegheny General Hospital in Pittsburgh, PA, the explant rate was similar (27.7%). The causes for explantation included inadequate pain control, biological complications, and hardware complications.

Chronic pain patients receiving high doses of opioids prior to implant had an increased incidence of spinal cord stimulator removal.

Mounting evidence has suggested that increased body mass index (BMI), smoking, substance abuse, and untreated depression and anxiety tend to correlate with less favorable outcomes.

By signing this form, the injured worker attests that they have discussed the information presented here with their physician of record and/or surgeon, they understand this information, and they wish to proceed with the spinal cord stimulator trial / implantation. We also understand that this information does NOT take place of, and is separate and distinct from, any surgical form that we will complete prior to surgery.

_____

Injured Worker
Date: _ / _/_