

A Comparison of Pain Relief from Spinal Cord Stimulation between Patients with and without Failed Back Surgery Syndrome

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Introduction

Spinal cord stimulation is often used to treat patients with residual back or leg pain after lumbar spine surgery. This is often referred to failed back surgery syndrome (FBSS). Few large-scale studies have been published to document the efficacy of SCS to treat back and leg pain for patients without a history of back surgery. The purpose of this study is to evaluate the outcomes in patients with back and leg pain and compare patients with previous back surgery and patients without previous back surgery.

Materials and Methods

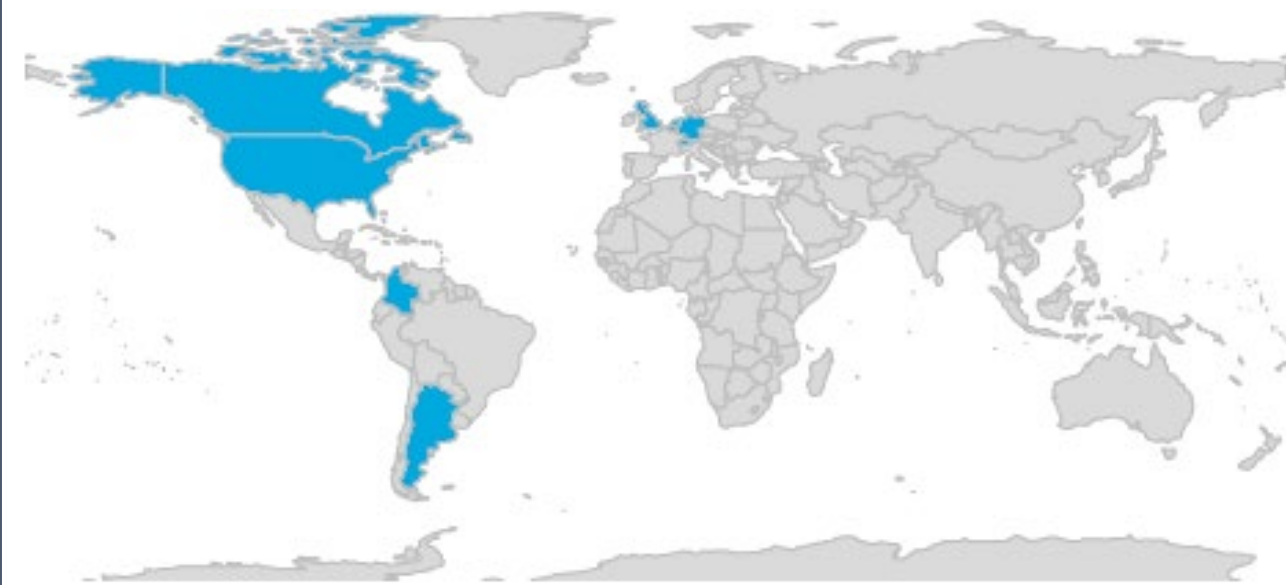


Figure 1: Countries with Spinal Cord Stimulation Patients in Registry (highlighted)

A retrospective analysis was performed using the Medtronic Product Surveillance Registry data (cutoff date: April 30, 2021). Of the 6,012 patients in the SCS arm of the registry, 4,022 met the treatment indications of interest and had data regarding history of back surgery. Treatment indications for those without previous back surgery were Degenerative Disc Disease, Radicular Pain Syndrome, or Combination Back and Leg Pain.

Patient reported outcome scores were compared between patients with and without previous back surgery. EQ5D index, EQ5D VAS, ODI, back pain, and leg pain scores were evaluated between the groups at baseline, 6, and 12 months. The number of patients with paired observations at both baseline and 6/12 months ranges from 137 to 267 in patients with previous back surgery, and from 40 to 86 in patients without previous back surgery.

Results

Compared to baseline, both patient groups had statistically significant increases in EQ5D index scores at 6 and 12 months and EQ5D VAS scores at 6 months; they also had statistically significant reductions in ODI, leg pain, and back pain scores at 6 and 12 months. At 12 months, the back pain mean score of patients without previous back surgery was significantly lower than patients with previous back surgery (P value=0.05); the EQ5D index mean score of patients without previous back surgery was significantly higher than patients with previous back surgery (P value=0.03).

Patient Reported Outcome	Baseline	6 - months	12 - months
Back pain scores	0.12	0.22	0.05
Leg pain scores	0.39	0.64	0.36
EQ5D Index scores	0.24	0.70	0.03
EQ5D VAS scores	0.82	0.97	0.81
ODI scores	0.07	0.10	0.11

Figure 2: P values between Prior Surgery and No Prior Surgery Groups

Change in pain from baseline to 6 months/12 months were calculated as 6-month/12-month score minus Baseline score, where a negative change represents an improvement.

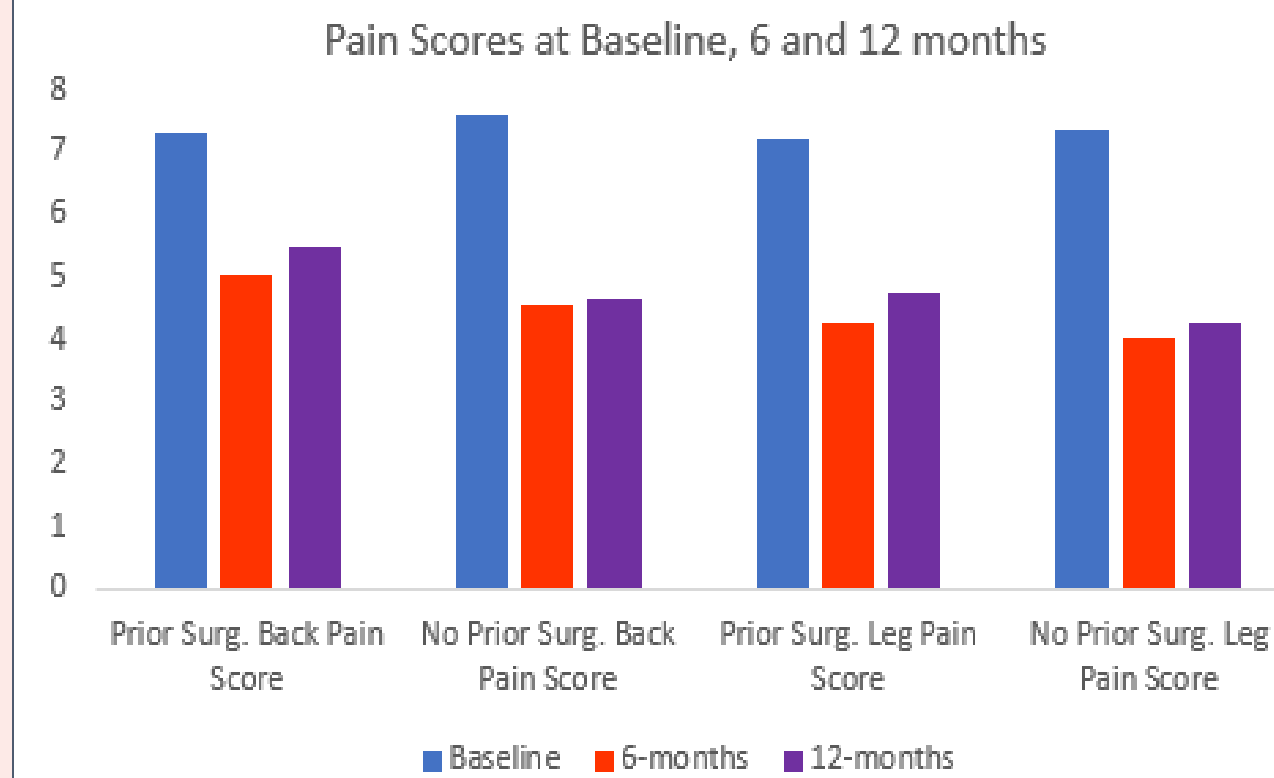


Figure 3: Pain Scores between Prior Surgery and No Prior Surgery Groups

Change in EQ5D VAS score from baseline to 6 months/12 months were calculated as 6-month/12-month score minus Baseline score, where a positive change indicates an improvement. Change in ODI score from baseline to 6 months /12 months were calculated as 6-month score /12-month score minus Baseline score, where a negative change indicates an improvement.

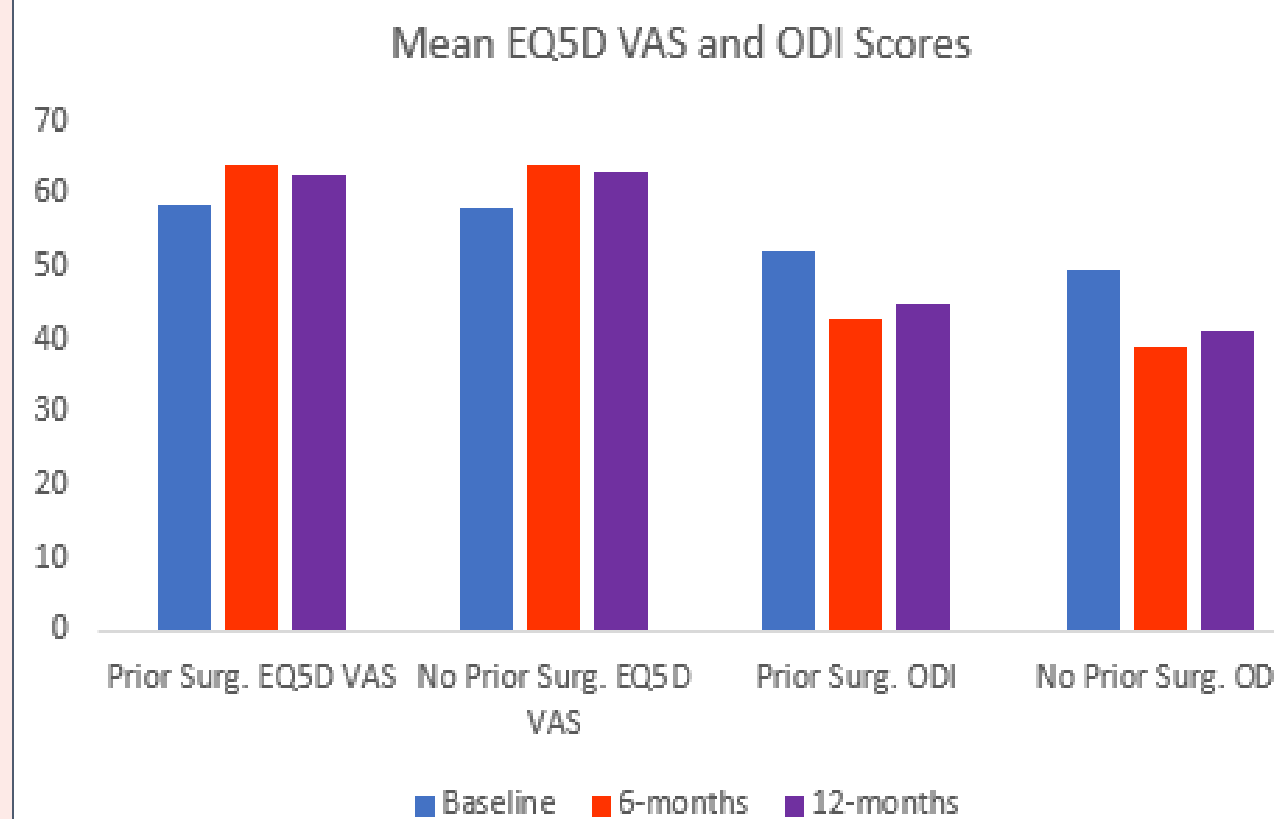
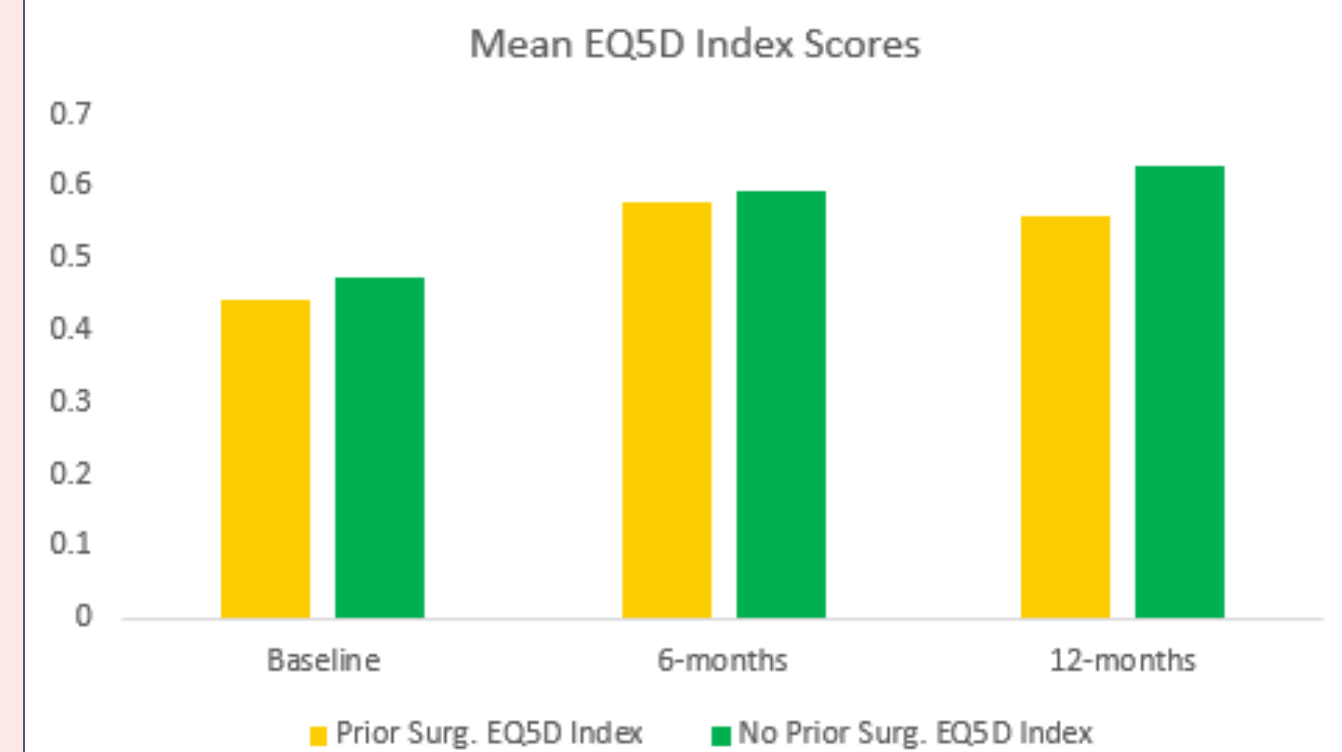


Figure 4: EQ5D VAS and ODI between Prior Surgery and No Prior Surgery Groups

Change in EQ5D index score from baseline to 6 months/12 months were calculated as 6-month/12-month score minus Baseline score, where a positive change indicates an improvement.

Figure 5: EQ5D Index scores between Prior Surgery and No Prior Surgery Groups



Conclusion

1. SCS appears to be an effective treatment to **reduce neuraxial pain, increase function and increase quality of life** for patients who have back and leg pain with FBSS as well as patients who have not undergone corrective back surgery.
2. Patients who have such pain, but **no previous back surgery, may benefit from spinal cord stimulation** before undergoing much more invasive corrective spine surgery to treat pain.