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Original Research Article

Spinal Cord Stimulation Provides Pain Relief with Improved Psychosocial Function: Results from EMP^{3}OWER

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Abstract

Objective. The EMP^{3}OWER^{TM} study evaluated spinal cord stimulation (SCS) safety and efficacy and the associated changes in psychosocial and functional outcomes.

Methods. Upon informed consent and IRB approval, 620 eligible subjects were enrolled prior to SCS trial evaluation and were assessed at baseline, 3, 6 and 12 months post-implant. Patient-reported pain relief (PRP), numerical rating scale (NRS), satisfaction, quality of life (QOL), and pain disability index (PDI) were assessed at all follow-up visits while the pain catastrophizing scale (PCS), short form-36 (SF-36), short form-McGill pain questionnaire version 2 (SF-MPQ-2), and the state-trait anxiety inventory (STAI) were assessed at the 6- and 12-month follow-up visits. Device and/or procedure-related adverse events were also recorded and reported. Subjects reporting a PRP $\geq$ 50% were considered responders. Repeated measures analysis of variance (RMANOVA) examined the changes across time for all continuous measures.

Results. A total of 401 (71%) subjects received a permanent implant. Mean (±SD) patient-reported pain relief was 59.3% (±26.2), 59.2% (±28.9), and 58.2% (±32.0) at 3, 6, and 12 months, respectively. A majority of enrolled subjects were responders at 3 (75.5%), 6 (74.7%), and 12 months (69.7%). RMANOVA revealed a statistically significant change for NRS, PCS, PDI, SF-36, SF-MPQ-2, and STAI scores. At 3 months, the majority of subjects (85.7%) were either very satisfied or satisfied with their device, with similar results at 6 and 12 months. At 3 months, the majority of subjects (73.3%) reported greatly improved or improved QOL with similar results at 6 and 12 months.

Conclusions. Spinal cord stimulation provided pain relief and significant improvement of patient psychological and functional outcome measures.

Key Words. Spinal Cord Stimulation; Chronic Pain; Functional Outcomes; Psychosocial Outcomes