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Retrospective Evaluation

Use of Observational Mechanical Gateway Connector in Spinal Cord Stimulation Trials

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Background: Spinal cord stimulation (SCS) is an established treatment option for chronic pain. Prior to permanent implantation, temporary trials are performed to evaluate the SCS treatment. Currently there are multiple manufacturers with varying fundamental differences in delivery and resultant paresthesias. However, trials are typically limited to one manufacturer for the patient to evaluate.

Objective: To evaluate the role of the Observational Mechanical Gateway (OMG) Connector for patients undergoing SCS trials.

Study Design: Retrospective cohort design study. Patients undergoing SCS trials were offered at the end of the 7 day trial to experience stimulation using the OMG Connector.

Setting: Academic university-based pain management center.

Method: Participants were trialed using the OMG Connector at the end of the 7 day spinal cord stimulation trial. Data based on participants' preference were collected.

Results: The average pain score at baseline was 7.3 on a 10-point scale overall, with improvement during the SCS trial to 2.9 overall; 3.5 in Medtronic (MT); and 2.4 in St. Jude (SJ) SCS trials (P = 0.04). The average pain score with OMG was 2.6 overall; 2.8 in MT; and 2.4 in SJ (P = 0.28). In terms of overall coverage of pain distribution, paresthesia and overall satisfaction, the ***P*** values were 0.24, 0.21 and 0.33 respectively. Overall, 12 of 16 participants underwent permanent implantation. One of the 4 failed trials was successfully retrialed with the OMG Connector.

Limitations: Small sample of participants and the duration of the OMG Connector trial.

Conclusions: The OMG Connector offers patients another opportunity to better access the available treatment options during the SCS trial period.

Key words: Spinal cord stimulation, OMG Connector, paresthesia, neurostimulation, constant current, constant voltage, chronic pain, dorsal column

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Spinal Cord Stimulation (SCS) is an established treatment option for chronic intractable pain (1-10). Prior to any permanent implantation, a temporary trial is performed. Due to an SCS trial's reversibility, minimal invasiveness, low complication rate, and effectiveness, a trial allows the patient and physician to assess the individual response and potential benefit. Indications for SCS include failed back surgery syndrome, complex regional pain syndrome, peripheral neuropathy, peripheral vascular disease, and recently,

certain types of visceral pain (2,4-9,11-28). Use of SCS has steadily increased with improved efficacy due to advancements in technology, electrode placement, and patient selection (2,4-6,10,11,13).

By delivering electrical pulses to the spinal neural tissue, paresthesia is generated and the overlapping with the region of pain is believed to be the mechanism by which SCS provides pain relief (13-15,29-31). Currently, SCS devices deliver electrical pulses by either constant voltage or constant current. The constant voltage devices supply a fixed voltage by varying the amount of current depending on changes in the impedance, whereas constant current devices supply a fixed current by adjusting the amount of voltage depending on impedance. The first commercially available SCS devices were voltage controlled with newer devices being current controlled; both have been shown to provide effective paresthesia for successful pain relief (18-23). However, the fundamental differences in delivery and resultant paresthesia sensations, along with different manufacturers and technological features, have yielded anecdotal reports about varied success in pain relief and patient satisfaction.

During the SCS trial period, patients are able to assess the stimulation as well as be evaluated for their willingness and compliance with the SCS treatment. The reasons for failure to proceed to a permanent implantation are numerous. They include, but are not limited to: lack of pain relief, lack of concordant paresthesia, dissatisfaction with the paresthesia sensation and extraneous paresthesia (24). Currently 3 different device manufacturers (Boston Scientific, Valencia, CA; Medtronic, Minneapolis, MN; St. Jude, Plano, TX) are available for patients to select from for their SCS trial. With the primary goal of providing patients the most complete trial period for assessment of the trialed SCS system, the limitation of trialing with only one SCS device at a time exists. Also, with the inherent costs and relatively invasive nature of the medical devices, multiple SCS trials with each manufacturers' system are not a viable option for practitioners.

The Observational Mechanical Gateway (OMG) Connector made by Boston Scientific, is an external accessory that enables connection to a Medtronic (MT) or a St. Jude (SJ) trial system. The OMG (Fig. 1) provides the patient the opportunity to assess the Boston Scientific SCS device for differences, if any, between the MT and ST device systems. This allows the patient to compare and experience another system without the need for another SCS trial.

Fig. 1. *Observational Mechanical Gateway (OMG) Connector (Boston Scientific, Valencia CA)*

Methods

Participants

The study was approved by the West Virginia University Institutional Review Boards for Protection of Human Research Subjects (IRB).

The participants were referred to a university-based pain management center for evaluation and treatment of chronic pain. The participants were treated during a 3 month interval in 2009.

Procedure

The participants were all evaluated and the treatment option of SCS was offered. All 3 manufacturers' information was provided to all participants for review. They were all screened and cleared by Pain Psychology and Psychiatry Services in the Department of Behavioral Health prior to proceeding to the SCS trial. Data was collected on 16 total participants who chose to undergo SCS trial with MT (8 participants) or SJ (8 participants). All participants underwent a 7 day SCS trial with an additional same day trial with the OMG connector prior to lead removal.

Data Collection

A staff physician collected the data at the end of the 7 day SCS trial period prior to the lead removal. Participants were asked about their baseline pain level (Visual Analog Scale 0-10), pain level during the SCS trial period, and with the OMG connector. They were also asked if the OMG provided "same," "better," or "worse" coverage of their pain distribution, paresthesia, and overall satisfaction. Their decision on proceeding to a permanent implantation was also recorded.

Statistical Analysis

Due to the relatively small number of participants, the average responses were calculated and compared. T test and Chi square analysis were used for determination of significance; < 0.5 was considered significant.

Table 1A. *Medtronic*

Age	Sex	Diagnosis	Pain Location
44	Female	Meralgia paresthetica	Right lower extremity
51	Female	Complex regional pain syndrome	Right upper extremity
60	Male	Post laminectomy syndrome	Back/ bilateral lower extremity
54	Female	Post laminectomy syndrome	Back/ left lower extremity
70	Male	Peripheral vascular disease	Bilateral lower extremity
44	Male	Post laminectomy syndrome	Back/ left lower extremity
41	Female	Post laminectomy syndrome	Back
60	Male	Cervical stenosis/ Raynaud disease	Neck/ bilateral upper extremity

Table 1B: *Medtronic*

Pain Score at Baseline (0-10)	Pain Score with SCS Trial	Pain Score with OMG/ SCS Trial	Coverage of Pain Distribution	Paresthesia	Overall Satisfaction	Proceed to Permanent Implant
5	3	3	Same	Same	Same	No *
7	4	4	Better (Hand)	Better	Better	Yes
9	3	2	Better (Back)	Better	Better	Yes
6	4	3	Same	Better	Same	Yes
6	5	3	Same	Better	Better	No **
9	2	2	Same	Same	Same	Yes
8	5	3	Better (Less abd) ???	Better	Better	No ***
6	2	2	Same	Better	Same	Yes

*Lack of satisfaction with SCS and OMG paresthesia
**Due to changes in medical condition, was not a candidate for retrialing
***Lack of low back coverage, led to successful retrial

Table 2A: *St. Jude*

Age	Sex	Diagnosis	Pain Location
57	Male	Post laminectomy syndrome	Back/ right lower extremity
45	Male	Diabetic peripheral neuropathy	Bilateral lower extremity
66	Male	Post laminectomy syndrome	Back/ bilateral lower extremity
70	Male	Intercostal neuralgia	Bilateral ribs
41	Male	Post laminectomy syndrome	Back/ left lower extremity
62	Female	Spinal stenosis	Back/ bilateral lower extremity
82	Male	Post laminectomy syndrome	Back/ bilateral lower extremity
58	Female	Post laminectomy syndrome	Neck/ left upper extremity

Table 2B: *St. Jude*

Pain Score at Baseline (0-10)	Pain Score with SCS Trial	Pain Score with OMG/ SCS Trial	Coverage of Pain Distribution	Paresthesia	Overall Satisfaction	Proceed to Permanent Implant
7	2	2	Same	Same	Same	Yes
6	4	4	Same	Better	Same	No *
8	3	5	Same	Worse	Worse	Yes
8	4	3	Same	Same	Same	Yes
9	2	1	Same	Better	Better	Yes
9	1	2	Same	Same	Same	Yes
6	1	0	Better (back)	Better	Better	Yes
8	2	2	Same	Same	Same	Yes

*Lacked satisfactory coverage of feet with SCS and OMG

Results

The average pain score at baseline was 7.3 overall; 7 for MT and 7.6 for SJ. The pain score during the SCS trial was 2.9 overall; 3.5 in MT and 2.4 in SJ SCS trials. The *P* value was 0.04. The average pain score with OMG was 2.6 overall; 2.8 for MT and 2.4 for SJ. The *P* value was 0.28. In terms of overall coverage of pain distribution, paresthesia and overall satisfaction, the *P* values were 0.24, 0.21, and 0.33 respectively.

Discussion

In this preliminary study, we evaluated the possible role of the OMG connector in SCS trial patients using other manufacturers' systems. With the availability of multiple systems with differing fundamental technology, and the limited opportunity to truly assess all the options available, the OMG connector provides a unique option for patients undergoing SCS trials.

Overall, regardless of the system used, the initial SCS trial resulted in pain score improvement with 75% (12 of 16) proceeding to a permanent implantation. The pain score reduction was more significant in the SJ trials when compared to the MT system, with more proceeding to permanent implantation. With the limited data on the existence of participant preference for constant voltage versus constant current SCS, it is unclear of the role, if any, that the type of pulse generation had on the results (25,26).

With the trial of the OMG connector, there was an improvement of the overall pain score in MT trial participants. The improved score resembled the overall pain score of SJ participants, 2.8 of 10 versus 2.4 of 10. No difference in the overall pain score was noted in the 8 SJ participants. In addition, no significant results were noted in pain distribution coverage, paresthesia or overall satisfaction. However, the OMG connector system did change the trial outcome in 2 of the 3 failed MT trials, with one resulting in a retrial and permanent implantation (the other participant who noted improved overall satisfaction experienced significant changes in his medical condition and was no longer a candidate for permanent implantation). Additionally, the OMG was reported to provide better paresthesia and overall satisfaction in at least half the MT SCS trial patients.

Since the goal of SCS is to provide pain relief and satisfaction, the OMG connector offered the partici-

pants another opportunity to better access the available treatment options during the SCS trial period. Though only one participant benefited from the OMG connector, resulting in a successful retrial and implantation, the option provided by the OMG connector suggests further evaluation should be done to assess its clinical value during the SCS trial period.

Limitations

Without randomization, limited sample size, and lack of true crossover periods with initial and OMG connector SCS trials, the study does not provide significant statistical evidence. The OMG connector was only used at the end of the trial period with limited duration. In addition, company representatives were used to provide SCS adjustments, adding the possibility of varying skill level as well as differing interpersonal skills.

Conclusion

The OMG connector offers patients another opportunity to better access the available treatment options during the SCS trial period.

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