Burst Stimulation Provided Effective Pain Relief And Reduced Pain Catastrophizing With Less Paresthesia: Interim Analysis Of A Large, Post Market Study

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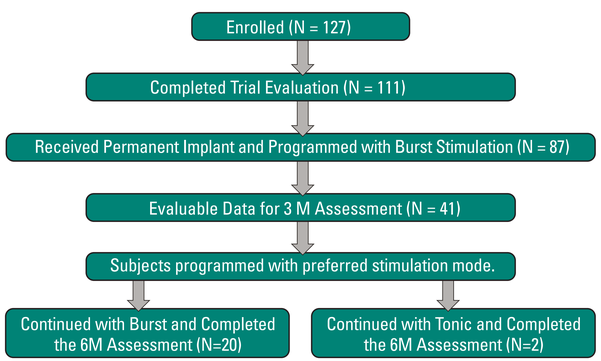
Objectives

Burst stimulation earned CE-mark for use in Europe. A Post Market Clinical Follow-up was initiated to confirm efficacy and safety of the therapy. Here we report the results of the interim analysis of the multicenter, prospective, observational study.

Methods

Subjects with chronic, intractable pain were enrolled across 21 European and Australian sites. Following successful trial evaluation, subjects used Burst stimulation (Prodigy™ SCS device, St Jude Medical) for 3 months, after which subjects could continue with either tonic or Burst therapy based on their preference. Assessments occurred at 3, 6, and 12 months using the visual analog scale (VAS), pain catastrophizing scale (PCS) and paresthesia body maps. Interim analysis included available data for 3 and 6 months.

Subjects



Results

- Subjects using Burst reported a significant reduction in pain through 6 months.
- Pain relief was accompanied by reductions in catastrophizing and improved in QoL.
- 79% of subjects reported less paresthesia with Burst than during the tonic trial. 58% of subjects reported no paresthesia with Burst.
- 63% and 55% of subjects achieved ≥50% pain relief at 3 and 6 months, respectively.

SUBJECT DEMOGRAPHICS	
Age (years) Mean ± SD (n)	55 ± 14 (127)
Female n/N (%)	71/127 (55.9%)
Weight (kg) Mean ± SD (n)	81.1 ± 17.7 (127)
Height (cm) Mean ± SD (n)	170.1 ± 9.3 (127)
Primary Diagnosis, n/N (%)	
CRPS I *	1/127 (0.8%)
Radiculopathy	13/127 (10.2%)
FBSS	99/127 (78.0%)
Other**	14/127 (11.0%)
Work Status, n/N (%)	
Full-time	17/127 (13.4%)
Part-time	18/127 (14.2%)
Not Working	92/127 (72.4%)
Time Since the Onset of Pain (years)	
Mean ± SD (n)	9.5 ± 9.2 (127)

* *CRPS I is an exclusion criterion. Subject was enrolled and withdrawn on the same day without participating in study procedures.*

** *Other include: 4 neuropathic pain, 1 low back pain, 1 neuropathy, 1 central neuropathy, 1 back and legs neuropathic pain, 1 ischialgia/neuropathic pain, 1 lumbal stenosis, 1 neurogenic stump pain, 1 failed neck surgery syndrome, 1 chronic pain due to spinal canal stenosis, 1 neuralgia.*

FUNCTIONAL PROFILE AT ENROLLMENT	
Impact of Pain on Life, n/N (%)	
Moderate	21/127 (16.5%)
Major	106/127 (83.5%)
Baseline Pain Catastrophizing	
Mean ± SD (n)	31 ± 12 (123)
Baseline EQ-5D	
Mean ± SD (n)	46 ± 22 (125)

Results

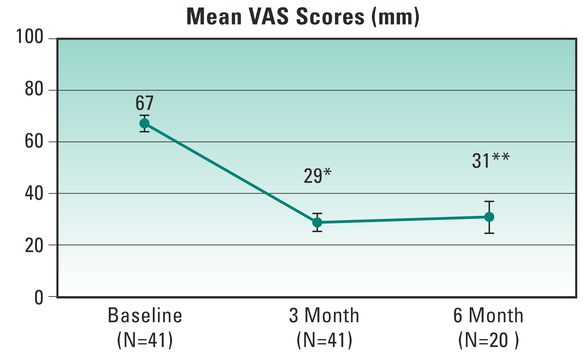


Figure 1. Mean VAS using Burst stimulation was significantly reduced from baseline. * Indicates a statistically significant reduction, p<0.001. ** Represents the mean of the 20 subjects who continued using Burst after the first 3 months. Statistical comparisons were not performed for the 6 month visit because few subjects had reached that visit at the time of this analysis. Error bars represent standard error of the mean.

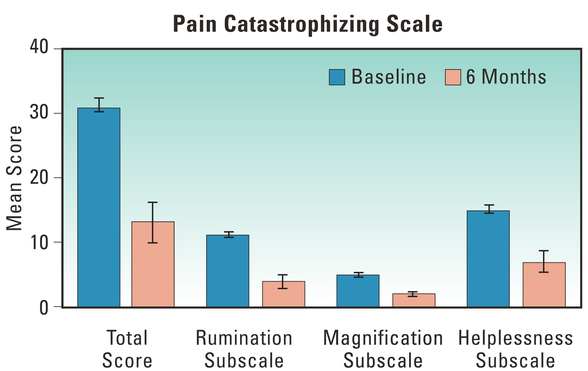


Figure 2. After 6 months of using Burst stimulation, a numerical decrease was observed for the mean scores on the PCS. Statistical comparisons were not performed for the 6 month visit because few subjects had reached that visit at the time of this analysis. Error bars represent standard error of the mean.

Results

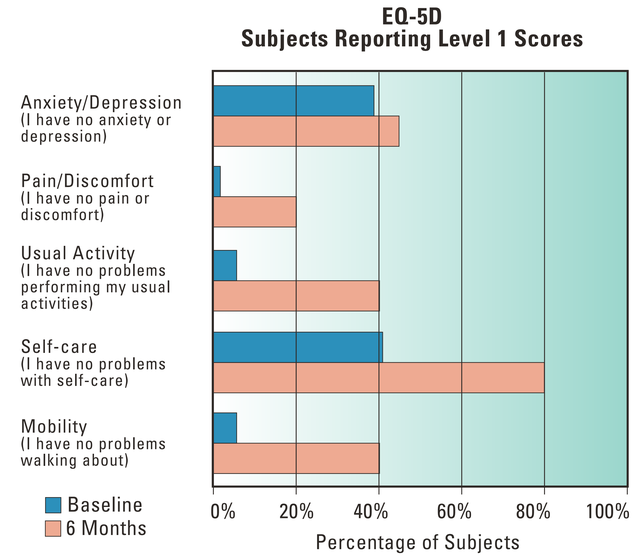


Figure 3. In almost all domains, a marked increased in the proportion of subjects reporting level 1 function on the EQ-5D was apparent after 6 months of Burst stimulation.

Conclusions

Interim results indicated Burst stimulation provided pain relief for most subjects and less paresthesia than during the tonic trial. When offered a choice after 3 months, a majority chose Burst stimulation and reported a clinically meaningful reduction in pain catastrophizing by 6 months. Results from the full cohort will be reported after all patients complete the 12 month visit.

Disclosures

This study was sponsored by St Jude Medical. Dr. Kretzschmar has served as a consultant for St. Jude Medical and Johnson & Johnson Codman Neuro Sciences.

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