

Improved Pain Outcomes and Therapy Longevity After Salvage Using Novel SCS Systems: European Experience

Philippe Rigoard¹, Renaud Bougeard², Jose E. Llopis Calatayud³, Sylvie Raoul⁴, Georgios Matis⁵, Hayat Belaid⁶, Jan Vesper⁷, M. Angeles Canos-Verdecho⁸, Sarah Love-Jones⁹, Adam Williams⁹, Edward Goldberg¹⁰

1. Poitiers University Hospital, Spine-Neuromodulation-Handicap Unit, Poitiers, France 2. Clinique de la Sauvegarde, Lyon, France 3. Hospital Universitario de la Ribera, Valencia, Spain 4. CHU de Nantes-Hopital Laennec, Nantes, France 5. University Hospital Cologne, Cologne, Germany 6. Fondation Adolphe de Rothschild, Paris, France 7. Heinrich Heine University, Düsseldorf, Germany 8. University and Polytechnic Hospital La Fe, Valencia, Spain 9. Southmead Hospital, Bristol, UK 10. Boston Scientific Neuromodulation, Valencia, CA USA

BACKGROUND

Spinal Cord Stimulation (SCS) is an effective treatment option for chronic pain and its benefits are sustained long-term. However, some patients may become refractory over time and face loss of efficacy (LoE) over the course of their follow-up.^{1,2} Several factors may contribute towards loss of benefit such as neural plasticity, lead fibrosis or new areas of pain.³ Solutions range from reprogramming attempts, lead revision, and/or device explant.⁴ Besides LoE, some patients with previous generations of SCS devices may also face suboptimal battery longevity and/or recharging burden. Providing various waveforms and programming options can facilitate more customized delivery of neurostimulation to chronic pain patients. Patients who face suboptimal experiences with their previous SCS system may elect to undergo a “conversion” to a different SCS implantable pulse generator (IPG) capable of providing multiple neurostimulative modality and waveform options. The ability to connect a new IPG to existing leads with adapters may provide a simple solution for these patients, thus preventing the need for explantation. Here, we present real-world multicenter outcomes of previously-implanted SCS patients with optimized programming who were converted to a new SCS System equipped with multiple neurostimulative modality options using an adaptor to existing leads.

METHODS

Study Design	•Multicenter, Consecutive, Observational, Case-Series •ClinicalTrials.gov identifier NCT01550575 •All data collected by sites
SCS Device	SCS Systems (Boston Scientific) with below capabilities: •Paresthesia-based SCS with MICC (multiple independent current control) and 3D neural targeting algorithm •FAST (Fast-Acting Sub-Perception Therapy) •Dorsal horn modulation sub-perception therapy with Contour field shaping algorithm •Other sub-perception modalities (MicroBurst, High Rate) •Combination therapy
Adaptor	Precision M8 or S8 Adapter (Boston Scientific)
Cohort	73 patients diagnosed with chronic pain
Key Inclusion Criteria	Previous SCS system implant with optimized programming (non-Boston Scientific) and converted to a new SCS System (Boston Scientific)

PATIENT CHARACTERISTICS

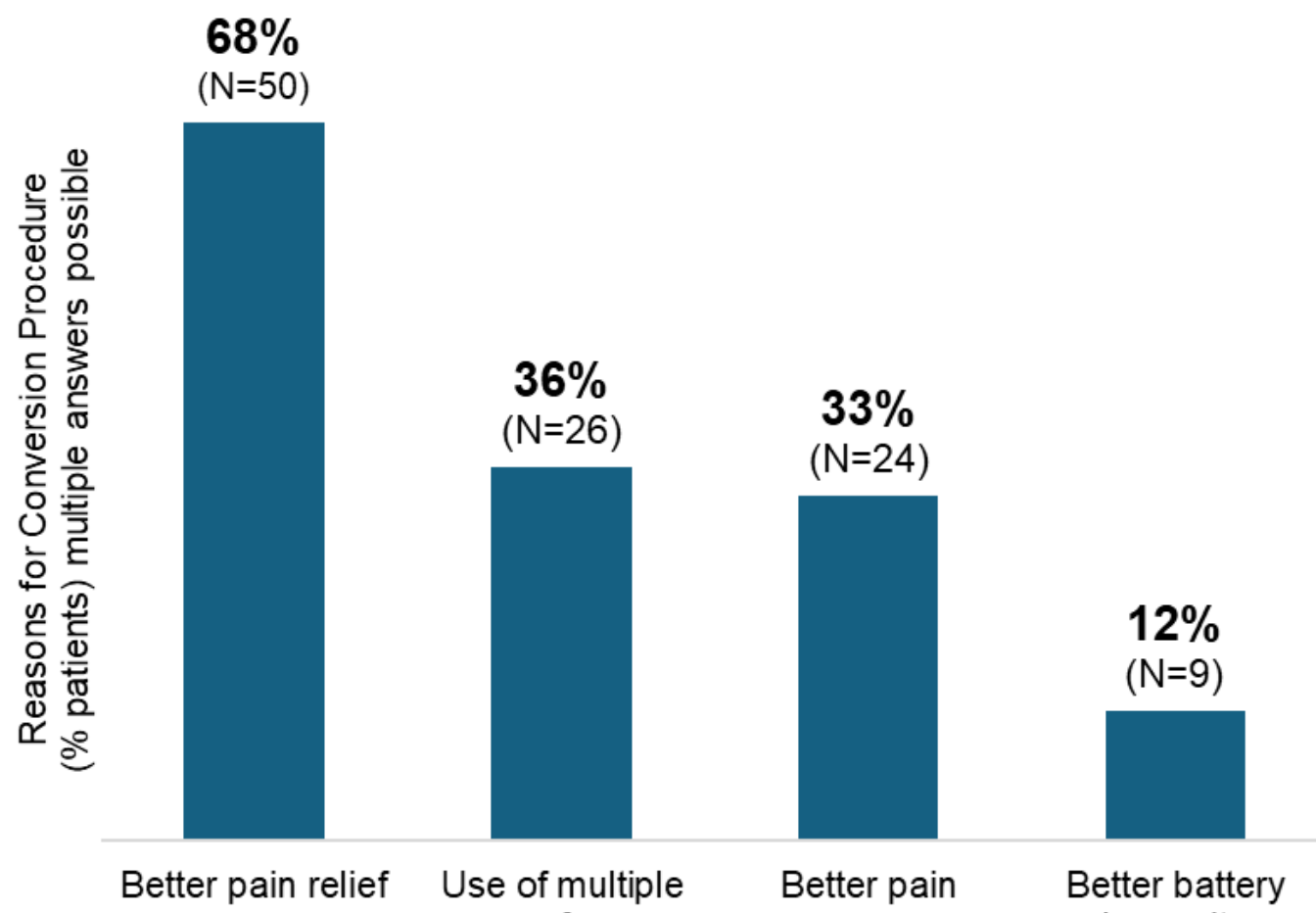
Baseline characteristics (n = 73)

Gender - Females (%)	53% (35/66)
Age [Mean (SD)]	54.3 (10.3) years n = 66
Most frequent pain locations prior to current system n (%) (multiple pain locations may be reported)	Low Back 35 (48%)
	Lower Limbs 33 (45%)
Pre-SCS Pain Scores [Mean (SD)]	7.8 (1.8) n = 57
Pre-Conversion Pain Scores [Mean (SD)]	6.7 (2.3) n = 70
Duration with previous system† [Mean (SD)]	6.1 (4.6) years n = 73
Duration with current system‡ [Mean (SD)]	2.0 (1.7) years n = 65
Number of patients undergoing conversion to improve clinical outcomes (i.e., “rescue” group)	66 patients (90%)
Number of patients undergoing conversion for other reasons (i.e., “sustain” group)	7 patients (10%)

†Previous System = non-Boston Scientific SCS System
‡Current System = Boston Scientific SCS System

Rationale for Conversion

68% of patients (50/73) chose to convert for better pain relief followed by the need to personalize therapy with multiple waveforms (36%) and/or to get coverage of new areas of pain (33%)



SCS programming

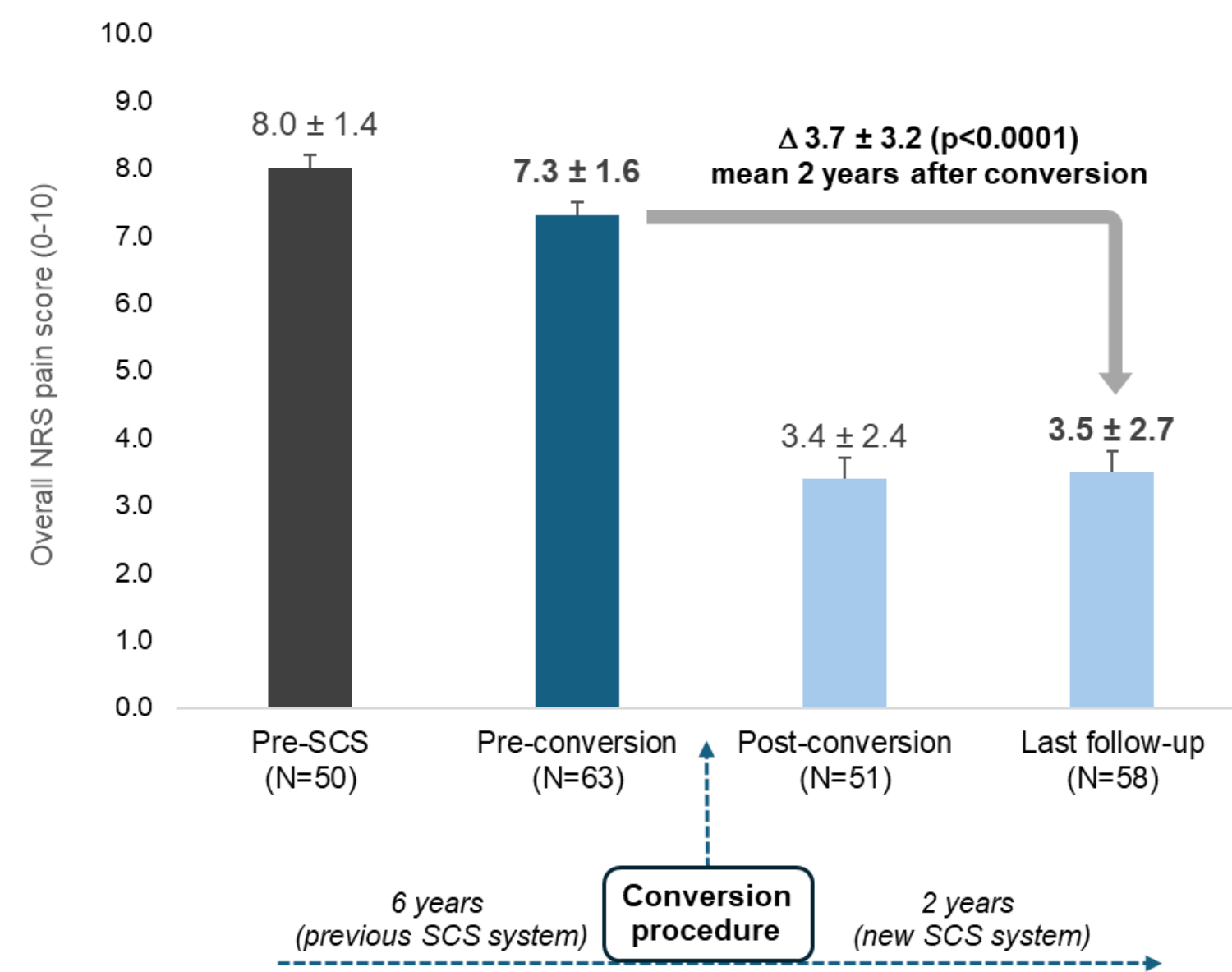
After conversion, different waveforms and field shapes were utilized by patients at last follow-up (2.0 years), including various sub-perception modalities, standard rate and combination therapy.

Post-Conversion SCS programming at last follow-up	
Standard rate	N=28
Sub-perception	N=32

RESULTS AT 2-YEARS FOLLOW-UP

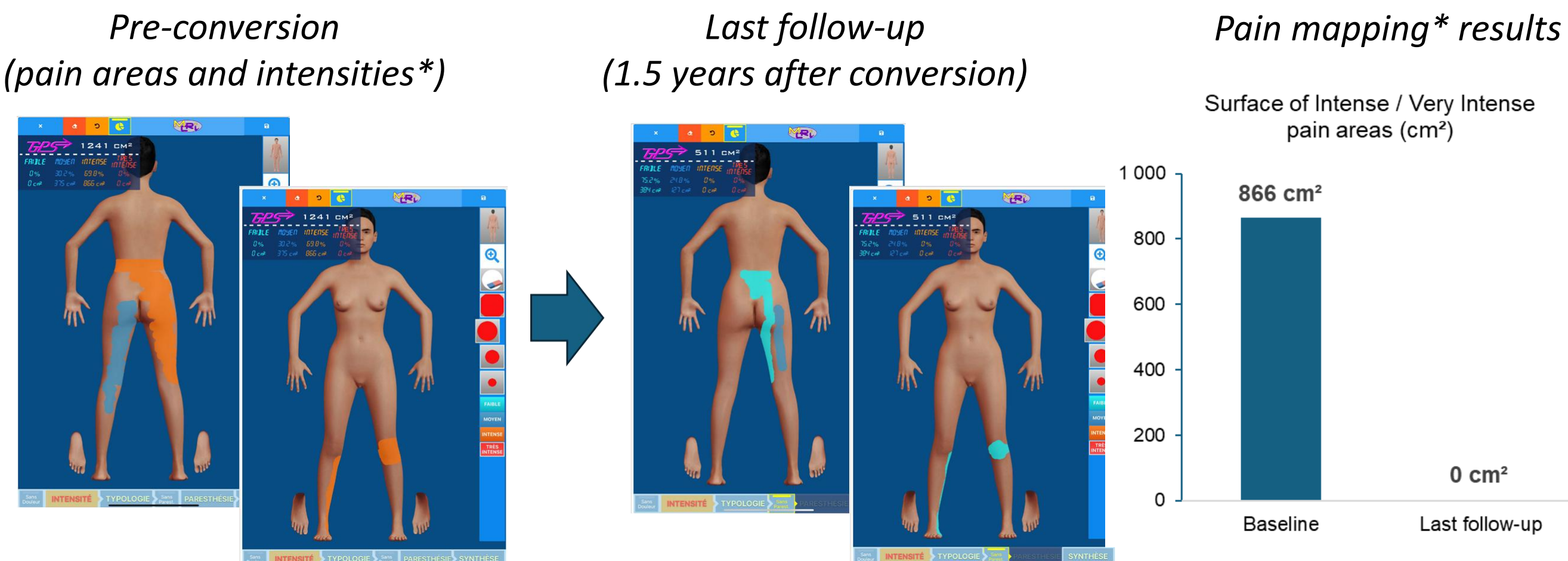
Rescue group (N=66)

- **2 years after conversion to a new SCS device, the overall pain improved by 3.7-point compared to pre-conversion status.**
- **Total time with SCS was 8.0 years on average.**



Responder Rates	Post-conversion	Last follow-up (mean 2.0±1.7 years after conversion procedure)
≥ 50% pain relief	76% (38/50)	66% (37/56)
≥ 70% pain relief	46% (23/50)	39% (22/56)

Rescue case example (SCS + PNFS, Persistent Spinal Pain Syndrome type 2)



Sustain group (N=7)

- Total time with SCS was 8.7 years on average (7.3 years with prior system, 1.4 years with new system).
- Overall pain was 1.5±1.2 prior to conversion and was sustained at 2.6±3.1 at the last follow-up (1.4 years after the conversion procedure).
- Responder rate (≥50% pain relief) post-conversion was 100% (6/6) and 71% at last follow-up (5/7).

CONCLUSIONS

Results from this multicenter, observational case-series suggest that patients who lose efficacy over time (previous system mean implant time: 6.0 years) may benefit from conversion to a new IPG capable of engaging different mechanisms using an adaptor connected to existing leads.

Significant and sustained improvement in overall pain was observed in patients converted to a new SCS device (current system mean implant time: 2.0 years) capable of providing multiple device programming options including anatomically-guided paresthesia-based stimulation, combination therapy, and novel sub-perception modalities.

In patients for whom conversion was performed to “rescue” sub-optimal outcomes with the previous system, a responder rate of 76% and 66%, was noted at post-conversion procedure and last follow-up (2.1 years after conversion), respectively.

These findings provide evidence that novel programming capabilities can help restore efficacy of SCS, and that a simple procedure may sustain therapy at long-term (8 years on average in our report) and prevent explantations due to loss of efficacy.

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* WAVE-UP EXPLORER