

Beyond pain scores: functional outcomes from 2 RCTs on DTM SCS for chronic back pain patients ineligible for spine surgery

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Introduction

- Treatment options for chronic back pain in patients ineligible for spine surgery are limited.
- Differential Target Multiplexed Spinal Cord Stimulation (DTM SCS)[†] has been shown to be an effective treatment for this patient population in 3 randomized controlled trials (RCTs)¹⁻³ which have consistently shown responder rates greater than 80%, along with significant and durable reductions in both back and leg pain scores¹⁻³.
- Although pain score reduction is a gold standard for assessing chronic pain clinical efficacy, functional outcomes are equally important assessments that can potentially provide a more holistic outlook on patient improvement.
- We assessed functional outcomes collected as part of 2 RCTs^{2,3} on DTM SCS for chronic back pain in patients ineligible for spine surgery, to evaluate the validity of these outcomes for assessment of clinical improvement.

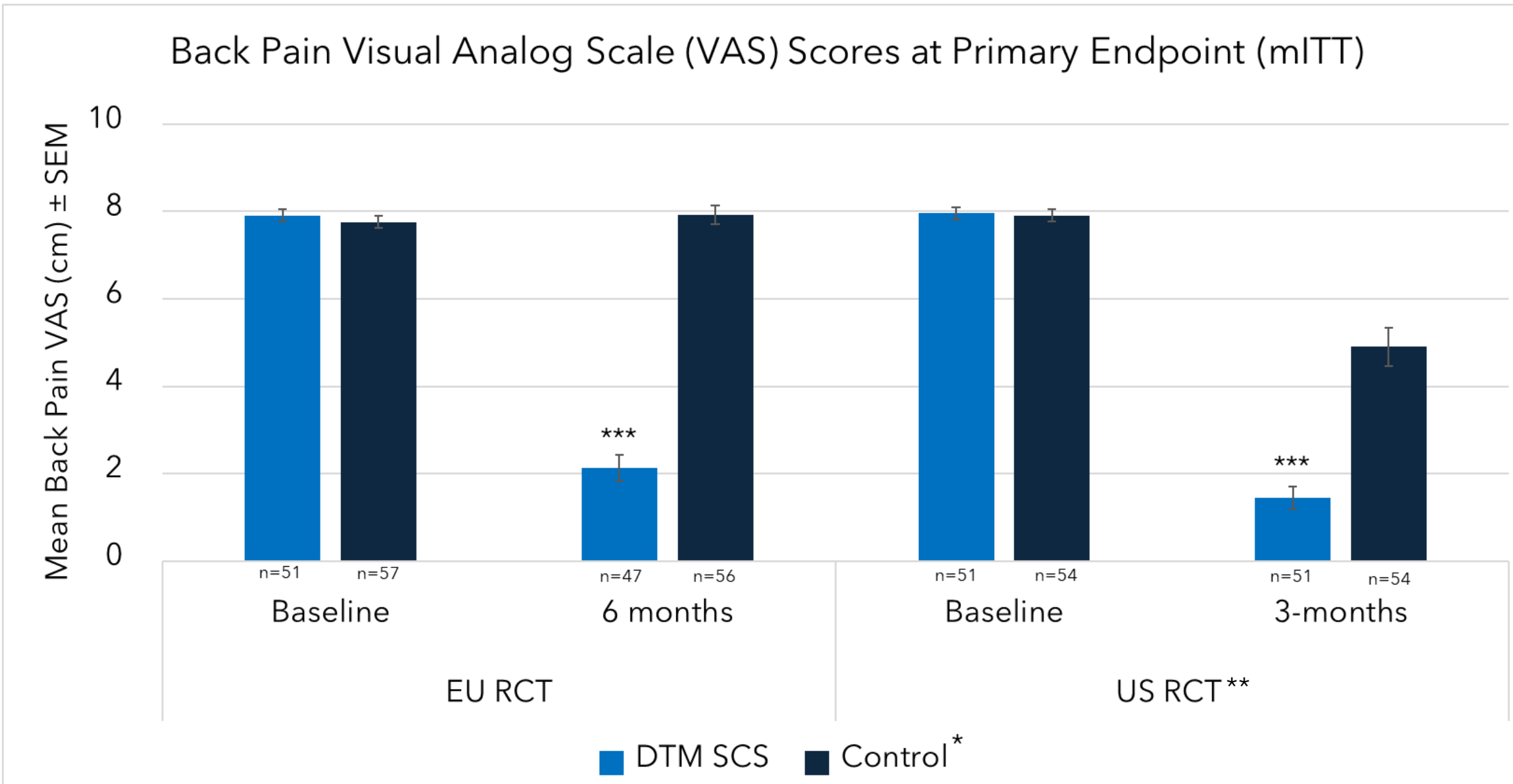
Materials & Methods

- Outcomes presented were collected from 2 post-market, multicenter RCTs comparing DTM SCS for patients with chronic back pain who are ineligible for spine surgery.
- One RCT conducted in the United States (US) compared DTM SCS versus conventional SCS through 12-months², and the other conducted in Europe (EU) compared DTM SCS versus conventional medical management through 24-months³.
- The primary endpoint was back pain responder rate (RR, $\geq 50\%$ relief) at either 3-² or 6-months³.
- Secondary endpoints included back and leg pain VAS, RRs, disability, health-related quality of life, therapy satisfaction, and Patient Global Impression of Change (PGIC).
- 112 subjects were randomized 1:1 at 12 EU sites and 121 subjects were randomized 1:1 at 20 US sites.

[†]Differential Target Multiplex™ SCS, and DTM™ SCS, are Medtronic trademarks.

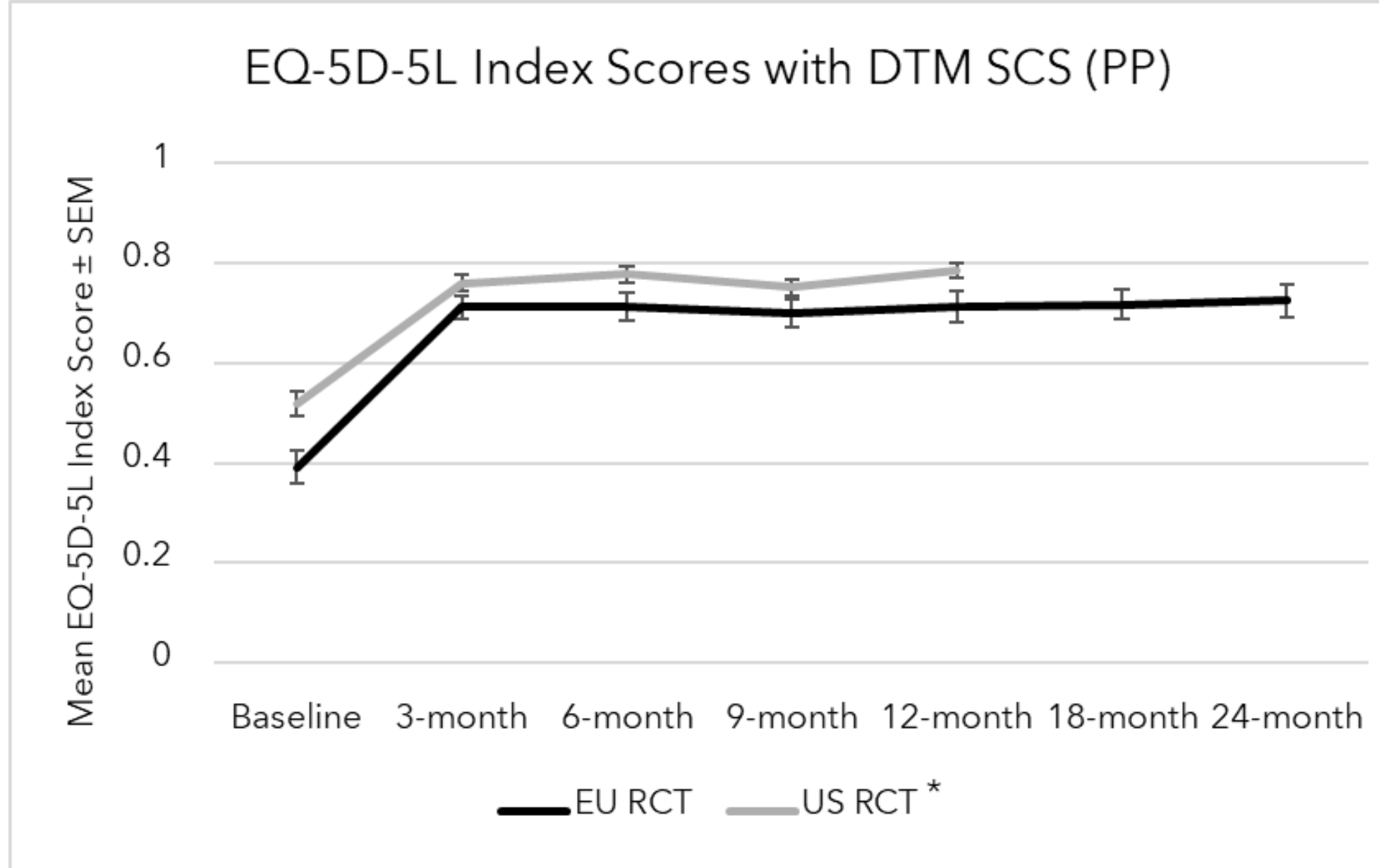
Results

Figure 1. Mean back pain VAS Scores at primary endpoint for both studies^{2,3}.



* Control arm in EU RCT is Conventional Medical Management (CMM); Control arm in US RCT is Conventional SCS (Conv-SCS)
**Imputation of Missing Data used for US RCT. Subjects with back pain records are as follows: 3-month (DTM n=46, Control n=44).
*** $p < 0.0001$

Figure 4. Mean EQ-5D-5L Index Scores with DTM SCS throughout study duration for both studies^{2,3}.



* Crossover subjects are included in the US RCT analysis at 9- and 12-month follow-ups.

PP Sample sizes are as follows for the EU RCT at each timepoint: Baseline n=45, 3-months n=45, 6-months n=45, 9-months n=42, 12-months n=43, 18-months n=42, 24-months n=40. Sample sizes are as follows for the US RCT at each timepoint: Baseline n= 44, 3-months n=44, 6-months n=40, 9-months n=54, 12-months n=53.

Figure 6. Mean change in daily dosage of analgesic opioid medication in the EU RCT³. Data presented as Morphine milligram equivalents, MME (percent change). Opioids analyzed were prescribed for the treatment of back and/or leg pain.

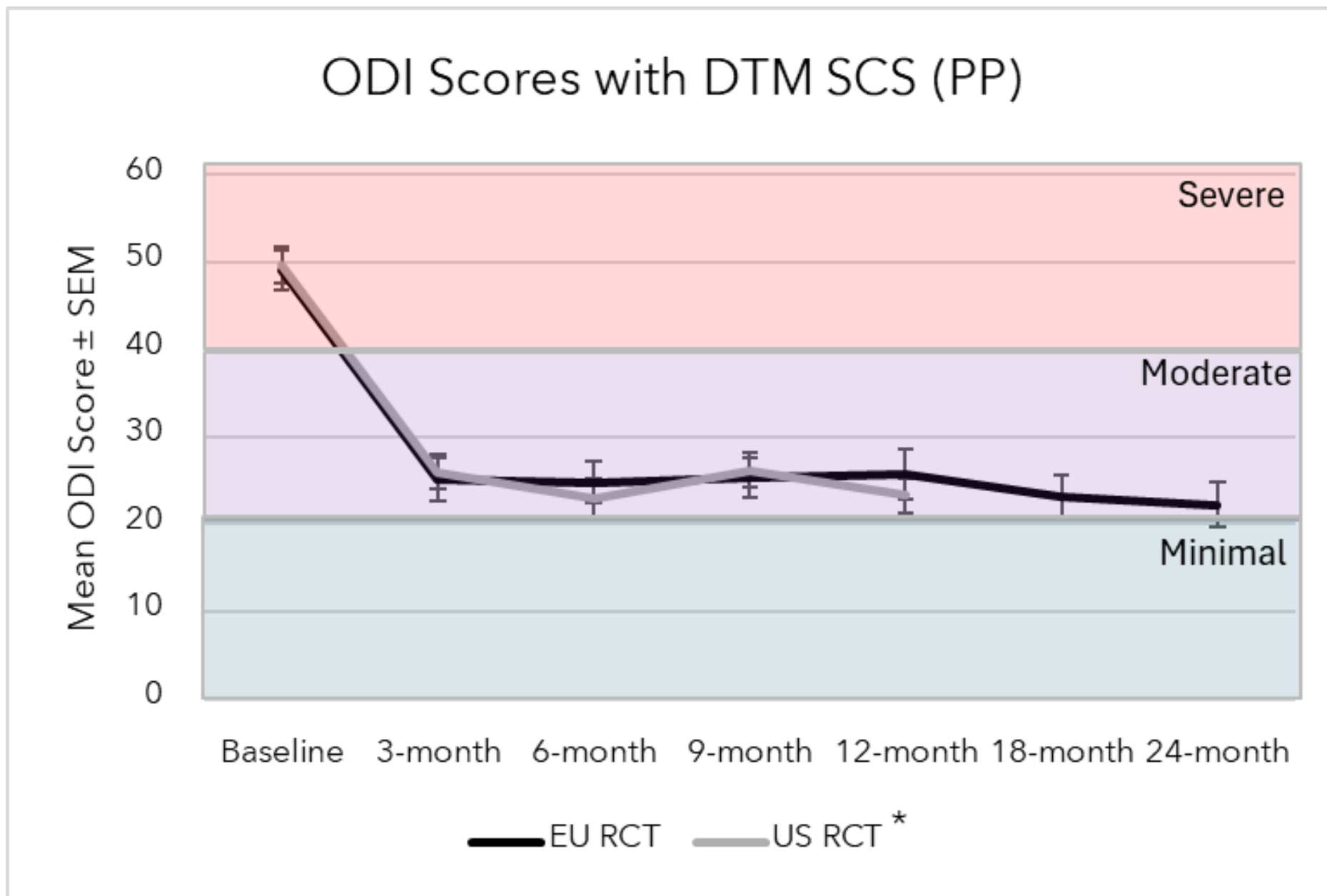
	DTM SCS ^a	CMM ^a	CMM to DTM SCS crossover ^b
3 months	-14.4 (-44.3%), N = 27	-1.9 (-5.2%), N = 34	-22.7 (-60.0%), N = 22
6 months	-13.3 (-40.8%), N = 27	+3.5 (+9.8%), N = 34	-22.8 (-60.3%), N = 21
12 months	-12.4 (-38.3%), N = 26	+6.6 (+25.0%), N = 4 ^c	-23.6 (-62.5%), N = 21
18 months	-19.5 (-60.0%), N = 25	+4.1 (+15.6%), N = 4	NA
24 months	-18.9 (-58.3%), N = 25	+4.1 (+15.6%), N = 4	NA

^a Baseline MME was 32.4 ± 29.0 for DTM SCS and 36.3 ± 39.0 for CMM.

^b Baseline MME was 37.8 ± 41.8 for subjects who crossed over at the 6-month study endpoint.

^c For subjects remaining after the 6-month crossover, the baseline MME was 26.5 ± 17.1.

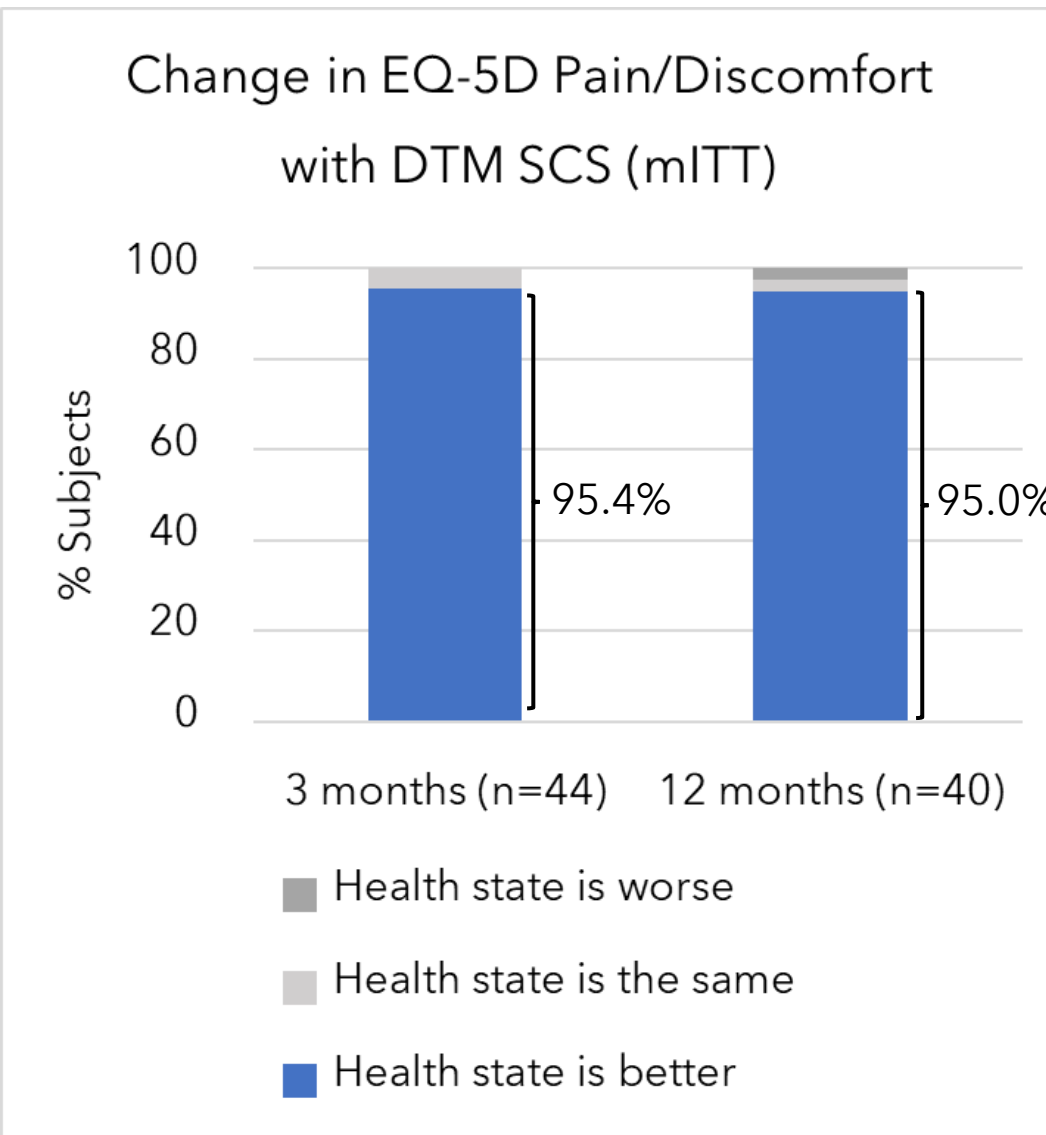
Figure 2. Mean Oswestry Disability Index (ODI) Scores with DTM SCS throughout study duration for both studies^{2,3}.



* Crossover subjects are included in the US RCT analysis at 9- and 12-month follow-ups.

PP Sample sizes are as follows for the EU RCT at each timepoint: Baseline n=45, 3-months n=45, 6-months n=45, 9-months n=42, 12-months n=43, 18-months n=42, 24-months n=40. Sample sizes are as follows for the US RCT at each timepoint: Baseline n= 44, 3-months n= 44, 6-months n= 40, 9-months n= 54, 12-months n= 53.

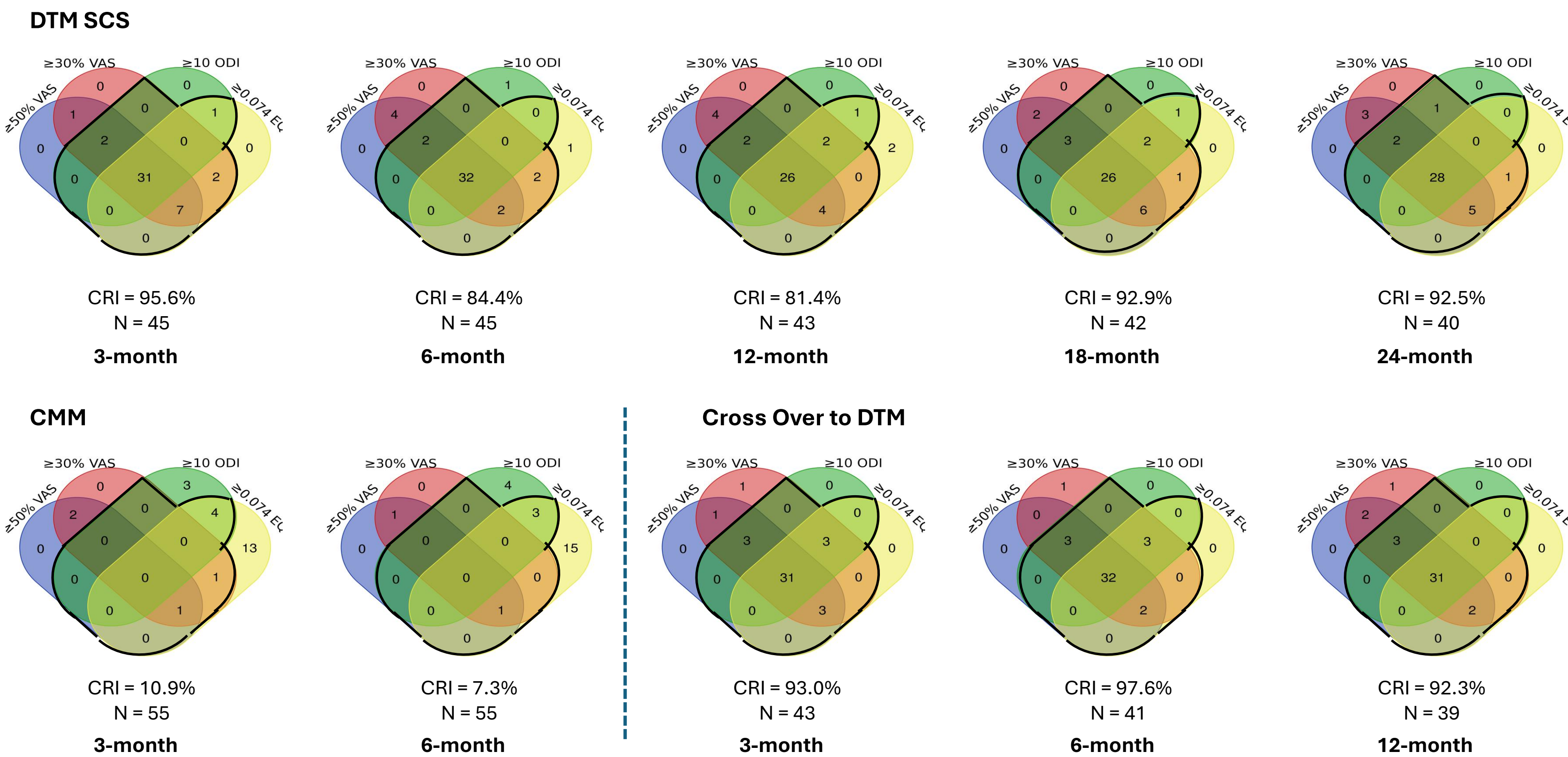
Figure 5. EQ-5D Pain/Discomfort Category with DTM SCS at 3- and 12-months in the US RCT*.



> 92% subjects reported being satisfied or very satisfied with DTM SCS in both studies at study end^{2,3}.

>82% of subjects reported feeling much improved or very much improved with DTM SCS in both studies at study end^{2,3}.

Figure 7. Composite Responder Index (CRI) through study duration in the EU RCT³. Venn diagrams showing the distribution of responders to at least two Patient Reported Outcomes Measures (PROMs; denoted by outlined area) used to calculate a CRI for subjects randomized to DTM SCS, CMM (up to 6 months) and those who crossed over to DTM SCS treatment. Per protocol populations were used for analysis. The higher the CRI, the more patients are responders to at least 2 PROMs. The CRI ranged from 81% to 96% for patients randomized to DTM SCS. In comparison, CRI was less than 11% for those treated with CMM before the crossover timepoint. The CRI for subjects who crossed over increased to range between 92% and 98%.



Discussion

Findings from these RCTs comparing DTM SCS for the treatment of chronic back pain in patients ineligible for spine surgery demonstrate consistent improvements in both back pain VAS as well as functional outcomes including disability and quality of life. These results suggest that functional outcomes may be a good indicator of therapy success in this patient population.

References

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