

Multiple RCTs show consistent outcomes for DTM SCS in the treatment of chronic back pain

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Introduction

- Chronic back pain is estimated to impact nearly 16 million adults in the United States each year¹ and is recognized to place significant burdens on healthcare system resources.
- Spinal cord stimulation (SCS) has been demonstrated as a safe and effective treatment for chronic back pain in both PSPS-T1 (surgery naïve) and PSPS-T2 (failed surgery) patients, with multiple randomized controlled trials (RCTs) supporting the use of Differential Target Multiplexed SCS (DTM SCS)²⁻⁴ in these patient populations.
- Three RCTs have been conducted comparing DTM SCS to conventional SCS (Conv-SCS) or conventional medical management (CMM) for the treatment of chronic back pain²⁻⁴.

Materials & Methods

Three RCTs comparing DTM SCS to treat chronic back pain were compared by primary outcome measures, primary endpoint duration, intervention, and demographics.

Two RCTs^{2,3} with 12-month follow-up were conducted in the United States, and 1 RCT⁴ with 24-month follow-up was conducted in Europe (Figure 1). The primary outcome measure across RCTs was back pain responder rate (≥50% pain relief) at either 3-^{2,3} or 6-month⁴ follow-up. Two RCTs^{3,4} were designed with a 2-way optional crossover at 6-months. All RCTs studied DTM SCS in subjects with chronic back and leg pain. One RCT compared DTM SCS to conventional SCS in subjects with either PSPS-T1 or PSPS-T2². Two RCTs included only subjects with PSPS-T1 and compared DTM SCS to conventional SCS³ and CMM⁴, respectively.

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

Results

Note: data shown are values reported in individual cited study manuscripts. Refer to the cited manuscripts for details on analysis methodology. Analysis sets may vary based on individual study methodology.

Figure 1. Study Design and Reported Primary Endpoint Outcome of 3 RCTs on DTM SCS for Chronic Back Pain

	Fishman et al. 2021 ²	White et al. 2024 ³	Kallewaard et al. 2024 ⁴
Study Logistics and Design			
Number of Centers	12	20	12
Geography	United States	United States	Europe (Netherlands, Spain, Belgium, Germany)
Design	RCT	RCT	RCT
Study Duration	12-months	12-months	24-months
Crossover	No	Yes, 2-way at 6-months	Yes, 2-way at 6-months
Population	PSPS-T1 and PSPS-T2	PSPS-T1	PSPS-T1
Enrolled Sample Size	134	126	115
Test Arm	DTM SCS	DTM SCS	DTM SCS
Control Arm	Conventional SCS	Conventional SCS	CMM
Primary Endpoint (months)	3-month follow-up	3-month follow-up	6-month follow-up
Primary Endpoint Definition	Back pain responder rate (≥50% pain relief)	Back pain responder rate (≥50% pain relief)	Back pain responder rate (≥50% pain relief)
Primary Endpoint Outcomes			
Primary Endpoint Analysis Set	ITT*	mITT**	mITT**
Primary Endpoint Sample Size (n)	Test n=47, Control n=55	Test n=46, Control n=44	Test n=47, Control n=56
Test Responder Rate, ≥50% pain relief, at Primary Endpoint (95% CI)	80.1% (70.6, 89.7) [†]	93.5% (81.6, 97.9) ^{††}	85.6% (75.7, 95.5) [†]
Control Responder Rate, ≥50% pain relief, at Primary Endpoint (95% CI)	51.2% (40.0, 62.4)	36.4% (23.6, 51.4)	3.6% (0.0, 8.4)
Statistical Significance of Test vs. Control at Primary Endpoint Timepoint	p = 0.0010	p < 0.0001	p < 0.0001

DTM SCS = Differential Target Multiplexed SCS, CMM = Conventional Medical Management

SEM = Standard Error of Mean

*Intent-to-Treat Analysis Set (ITT) included all randomized subjects.

**Modified Intent-to-Treat Analysis Set (mITT) included all successfully randomized subjects who completed the SCS trial phase.

[†]Calculated using multiple imputation.

^{††}Calculated using repeated measures.

Figure 2. Reported Back pain Visual Analog Scores (VAS) with DTM SCS at Baseline and 12-months

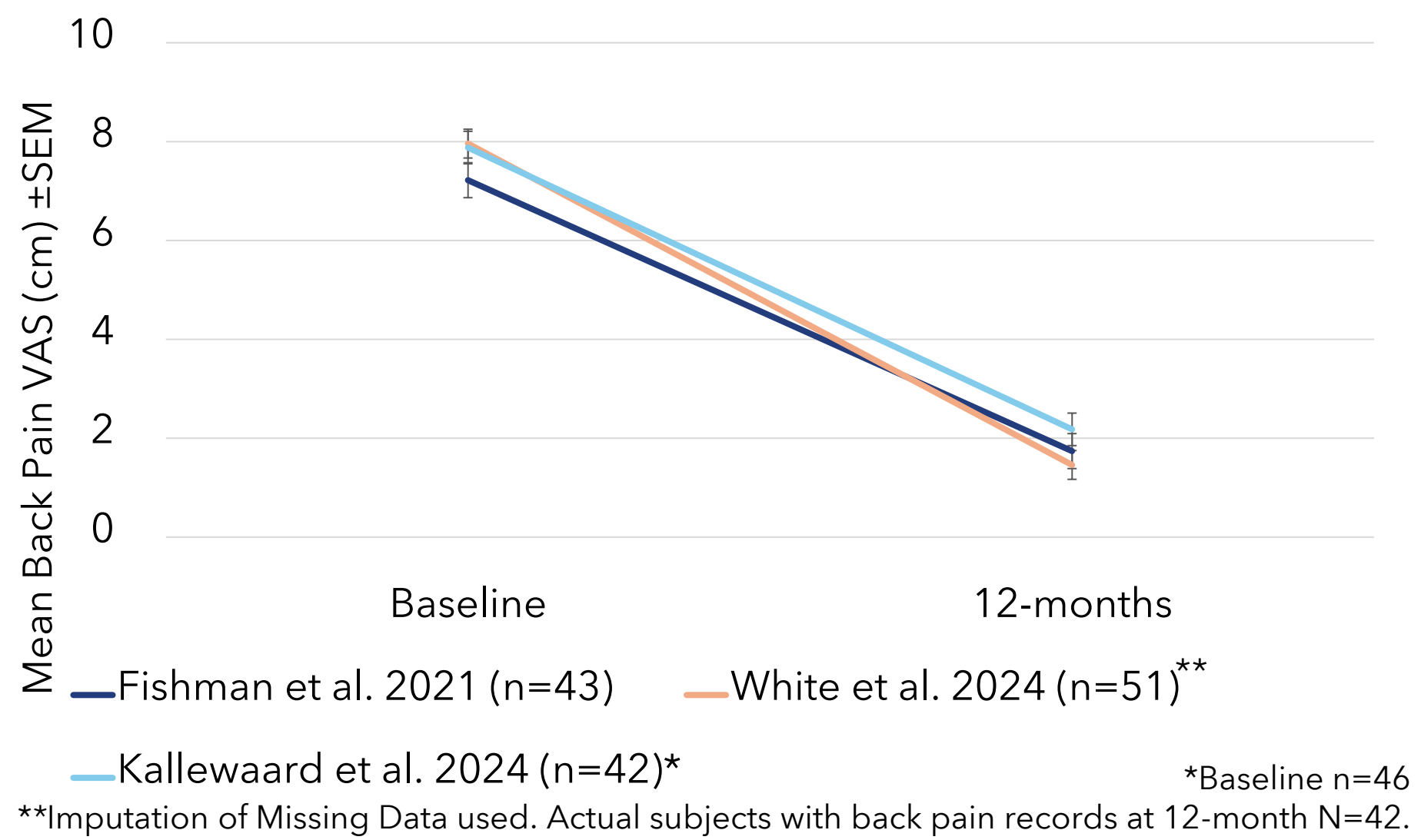


Figure 4. Reported Leg pain Visual Analog Scores (VAS) with DTM SCS at Baseline and 12-months

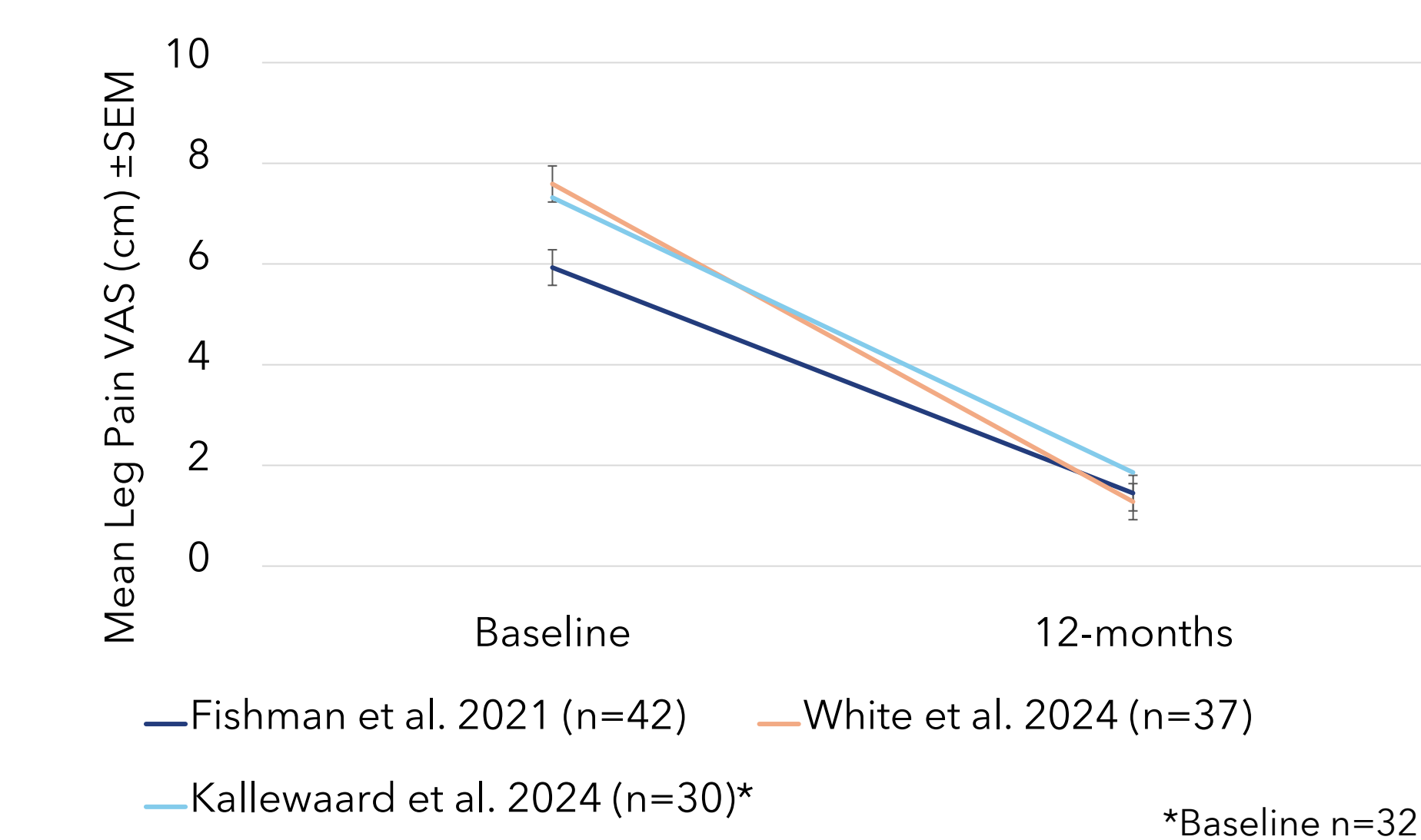


Figure 5. Reported Therapy Satisfaction with DTM SCS at 12-months

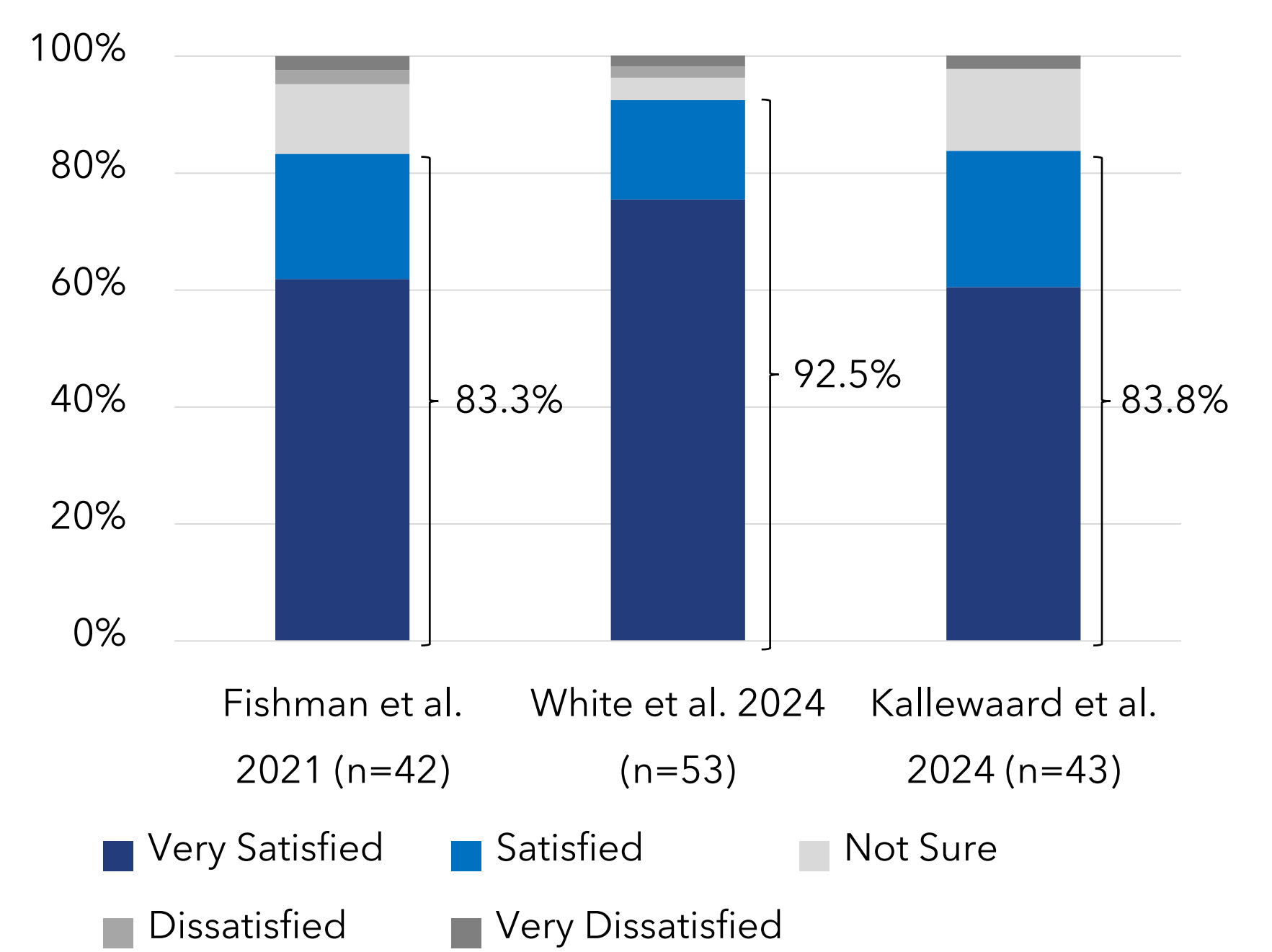


Figure 3. Reported Back pain VAS Reduction with DTM SCS at 12-months

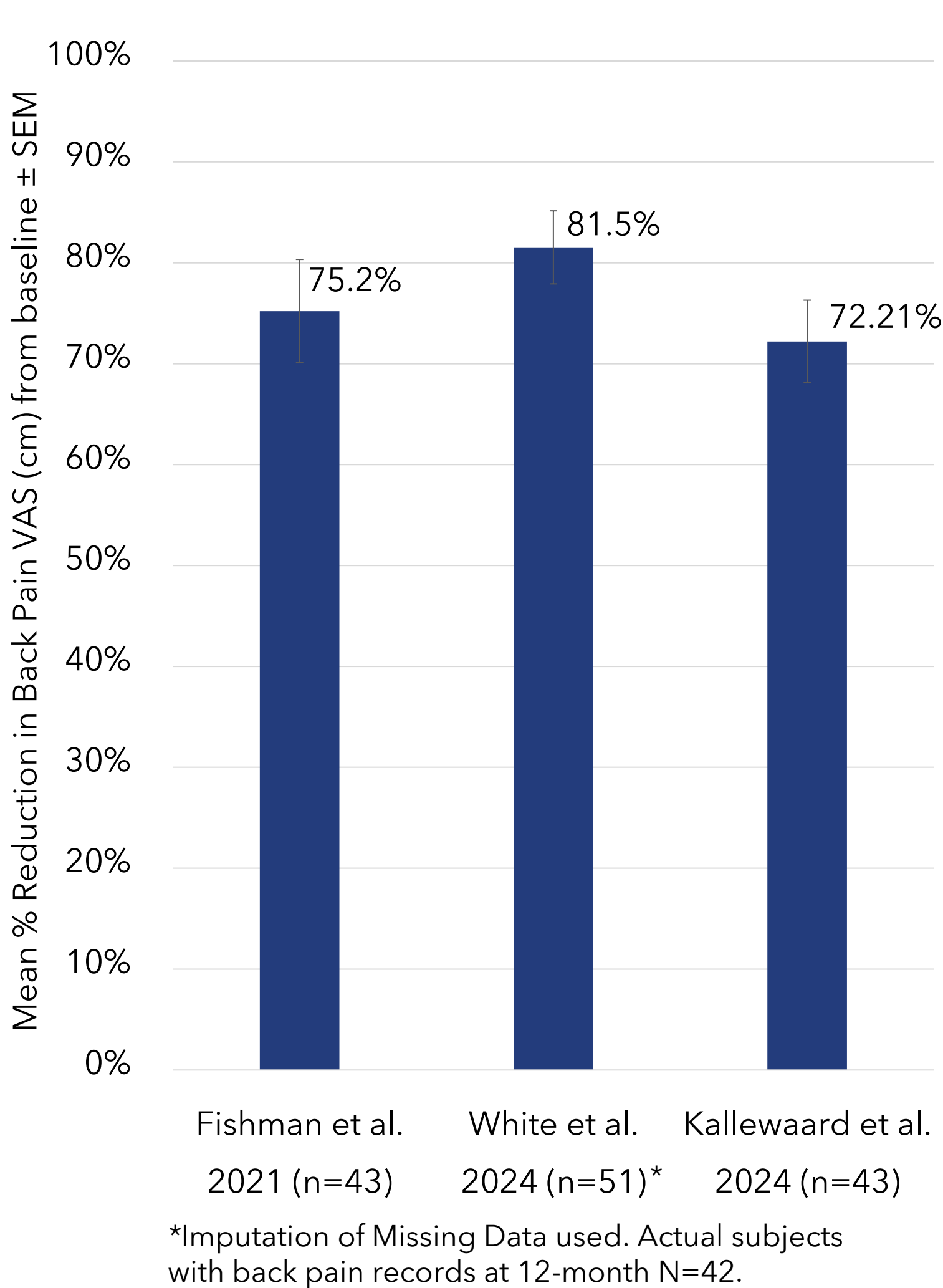
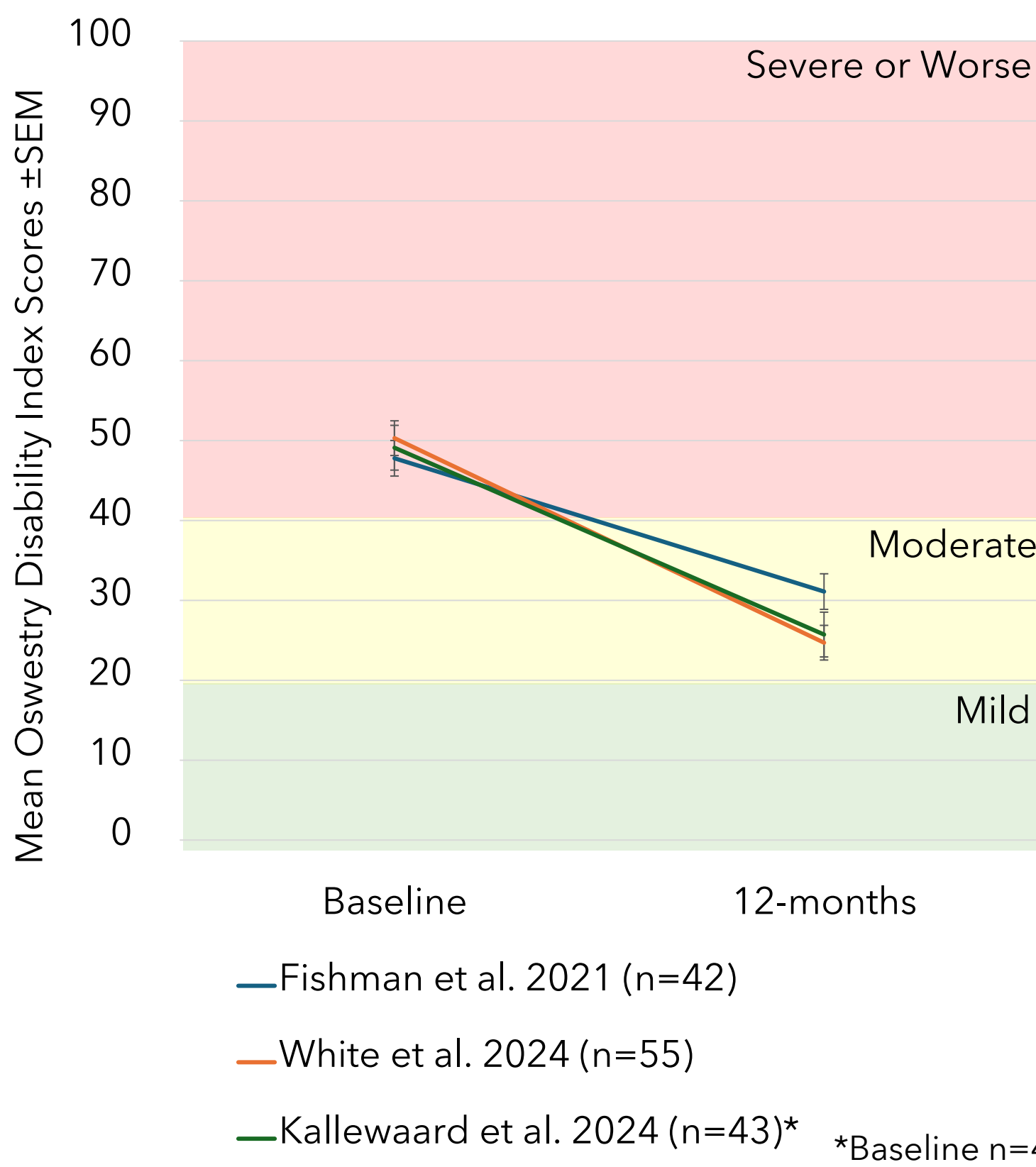


Figure 6. Reported Oswestry Disability Index (ODI) Scores with DTM SCS at Baseline and 12-months



Discussion

Three RCTs have all shown DTM SCS as a durable, effective treatment option for chronic back pain in patients with PSPS-T1 and PSPS-T2 with superior results to Conv-SCS and CMM. In all 3 RCTs²⁻⁴, DTM SCS provided consistently and statistically superior back pain relief to control at the primary endpoint, with responder rates greater than 80%. Additionally, DTM SCS resulted in consistent reductions in back and leg pain from baseline to 12-months, clinically meaningful improvements in disability⁵, and a high degree of therapy satisfaction. This represents one of the strongest bodies of evidence for any SCS waveform in this patient population.

References

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