

28.3

Last Follow Up

(N=21)

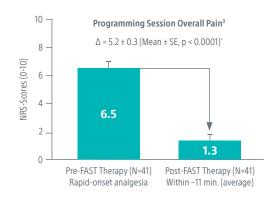


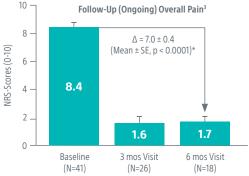
FAST-Acting Sub-perception Therapy (FAST™) Clinical Summary

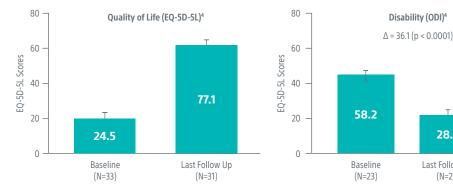
FAST Therapy is backed by Published Real-World Data¹, Preclinical Data² and Computational Modeling³

Published Real World Data Demonstrate Profound Paresthesia-Free Pain Relief in Minutes with FAST Therapy¹











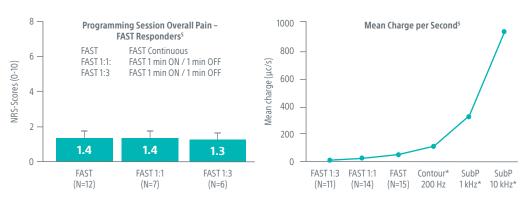
- Overall pain was reduced by a mean 5.2 ± 0.3 points versus pre-FAST Therapy activation within 11.2 ± 1.9 minutes (N = 34).
- Overall pain was reduced by a mean 7.0 ± 0.4 points (N = 41, p < 0.0001) at 6 month follow-up.

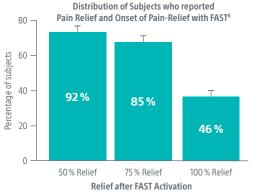
At last follow-up (mean = 412 ± 338 days)

- Improved functional outcomes and quality of life reported with use of FAST
- Improvement in disability: A 36.1-point mean reduction in ODI. Improvement in one disability level (e.g. from severe to moderate disability)

➤ FAST provides clinically meaningful pain relief while preserving device longevity and improving battery consumption management⁵

New Prospective Data Confirms FAST Immediate Pain Relief and Demonstrates High FAST Responder Rate⁶





Pain Relief (FAST Responders)	Mean Time (min) analgesia onset
50 % Pain Relief (12 of 12)	2.3 min
75 % Pain Relief (11 of 12)	4.8 min
100 % Pain Relief (6 of 12)	3.5 min
Maximum Pain Relief (12 of 12)	4.9 min

- All FAST stimulation options show >50% responder rate.
- FAST responders achieve profound pain relief (NRS <2) with the use of all FAST stimulation options.
- FAST stimulation energy consumption is 95% lower compared to conventional Sub-perception SCS.

- FAST responders achieved maximum paresthesia-free pain relief within 4.9 ± 1.5 minutes.
- FAST Achieved a 92% Responder Rate and an 85% Profound Responder Rate (>75% Relief) within minutes.

- * Difference calculated based on pre- and post follow-up with data per patient.
- † Time interval data were only available for 34 out of the 41 total patients assessed during the FAST Therapy programming session.
- ‡48 subjects diagnosed with chronic pain and report to prefer FAST stimulation at last follow-up.
- 1. Metzger et al. A novel fast-acting sub-perception spinal cord stimulation therapy enables rapid onset of analgesia. in patients with chronic pain, Expert Review of Medical Devices 2021.
- 2. Gilbert J, Titus ND, Zhang TC, Esteller R. Grill WM. Mechanisms of Low Frequency Sub-Perception Spinal Cord Stimulation. INS 2022.
- 3. FAST MOA computational modeling by Dr. Warren Grill's lab at Duke University. Gilbert et al. Computational modeling predicts dorsal columns are involved in fast-acting sub-perception spinal cord stimulation (SCS). SFN 2021
- 4. Bayerl, S et al. Clinical outcomes using a new Fast-Acting Sub-perception Therapy (FAST) for chronic pain. A Multicenter European Observational Study. INS 2022.
- 5. North J. Enhanced Efficiency and Spinal Cord Stimulation Outcomes Using Fast-Acting Sub-Perception Therapy (FAST) for Chronic Pain. INS 2022.
- 6. Anitescu et al. Prospective, Multicenter Evaluation of Novel Fast-Acting Sub-Perception-Based Spinal Cord Stimulation for Chronic Pain: FAST Study. INS 2022

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