

Patient Experience of Closed Loop Multi-Waveform Spinal Cord Stimulation

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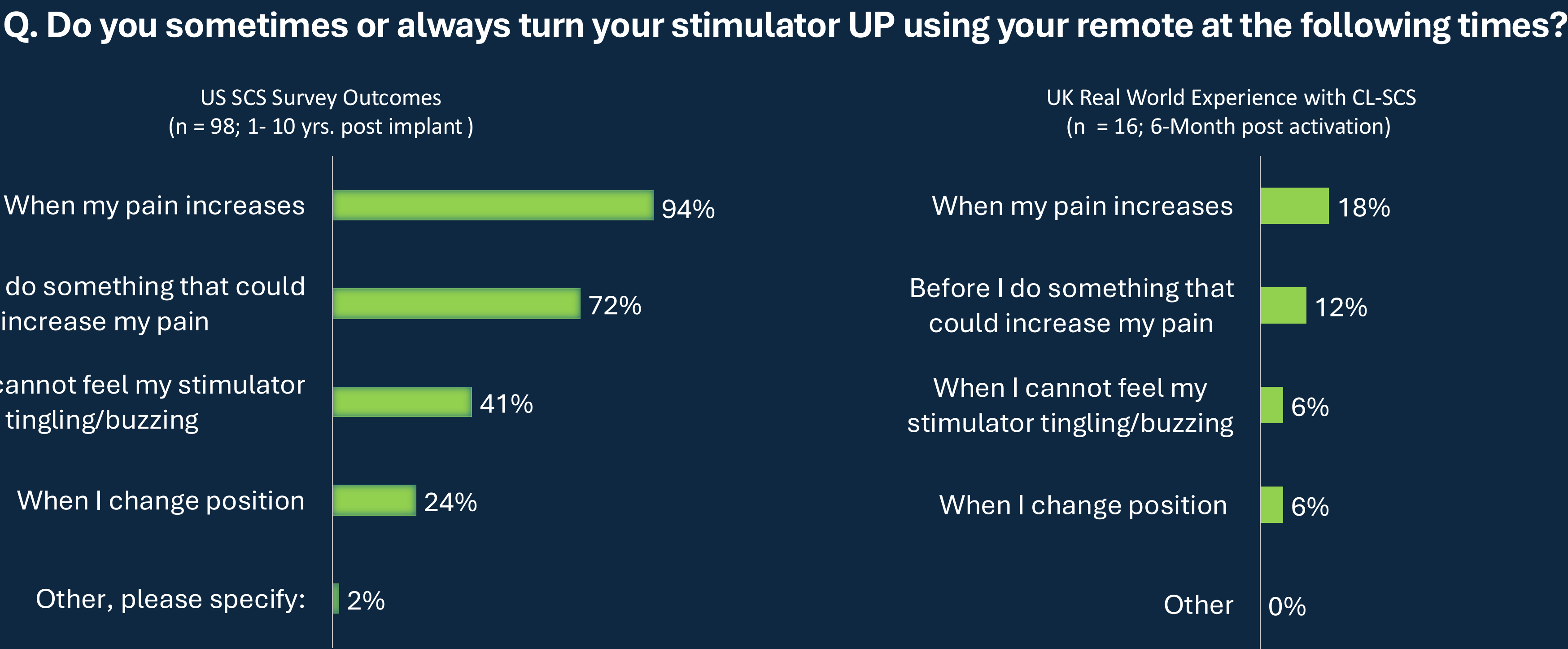
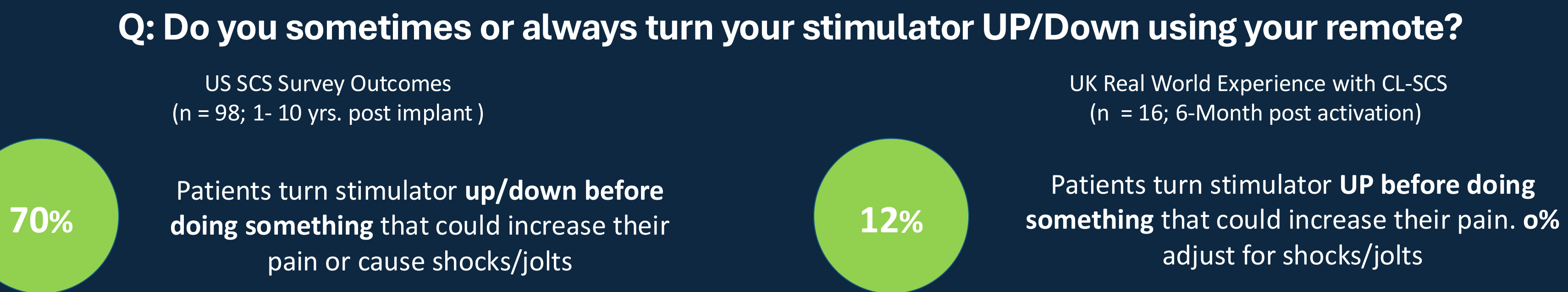
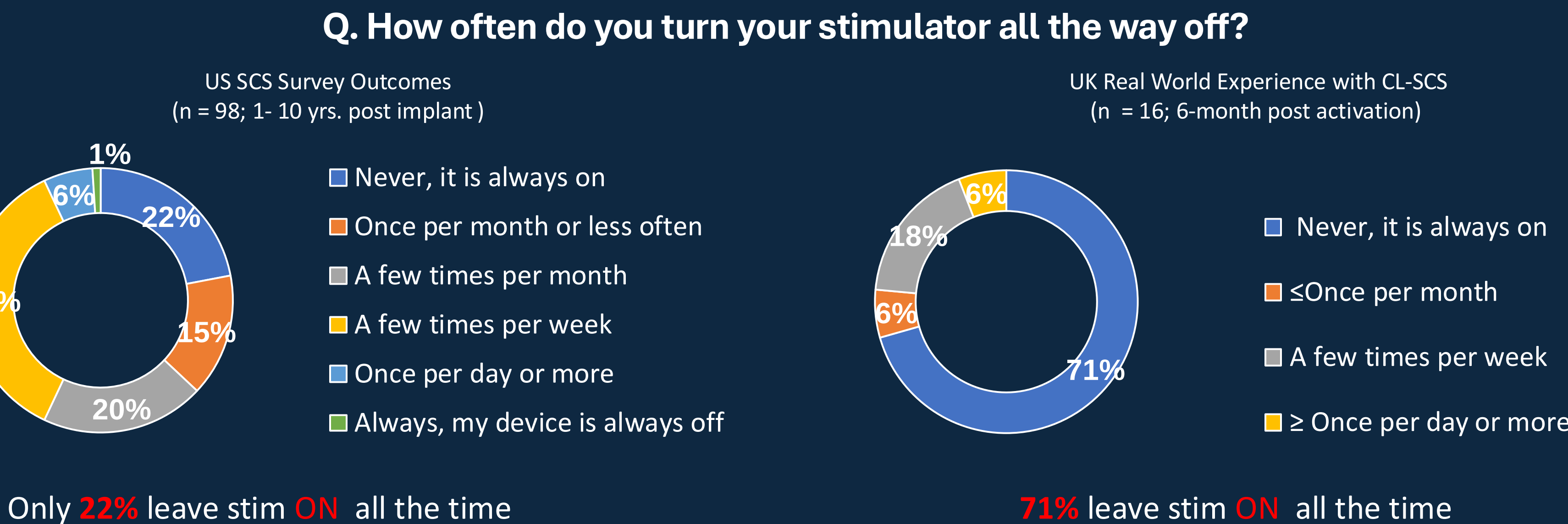
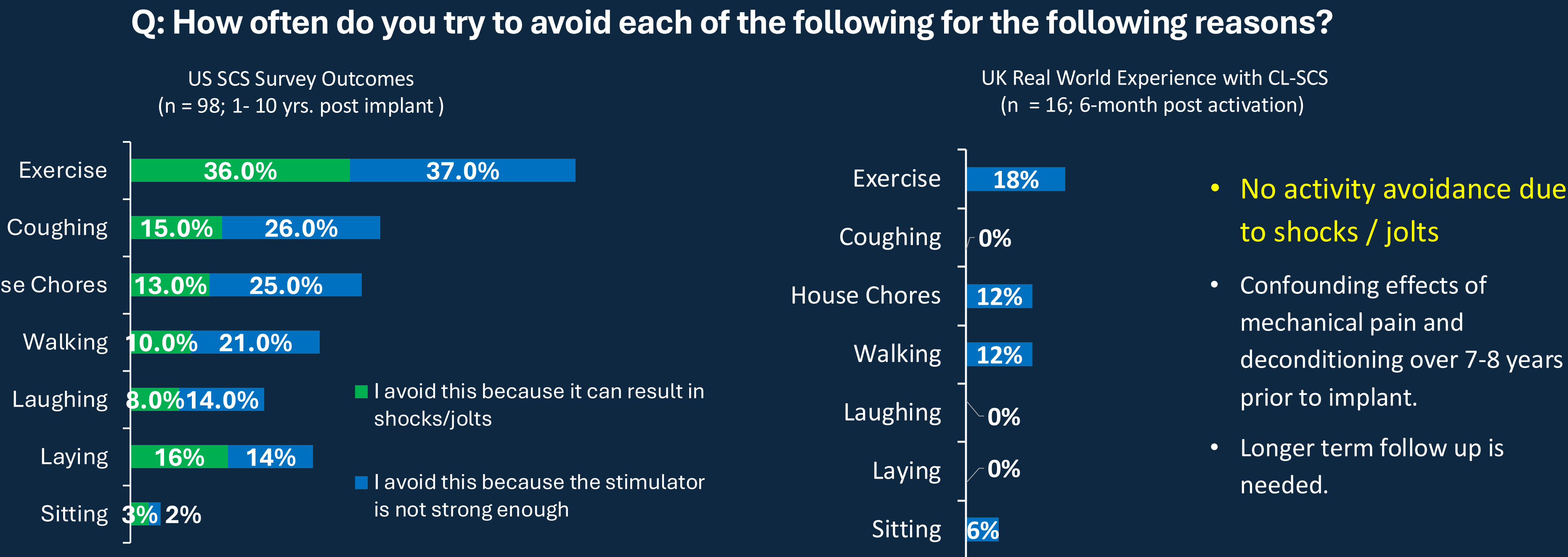
Introduction

- Spinal cord stimulation (SCS) is a cost-effective therapy providing clinically significant pain relief from chronic neuropathic pain.
- A double-blind independent survey done in the US investigated patient experiences as they performed activities of daily living. Regardless of sub- or supra-perception therapy, 58% patients reported experiencing overstimulation and 46% reported under stimulation. Most of the participants (85%) reported avoiding one or more activities of daily living and 70% reported turning therapy down/up proactively to avoid these side effects, resulting in a significant burden of device management.^{1,2,3,4}.
- Variation in the dose delivered arises as the relative distance between a spinal cord stimulator electrode in the epidural space and the spinal cord changes with everyday changes in body position.
- Closed loop stimulation using ECAPs can ensure optimal dose delivery and avoiding over or under stimulation.
- In this prospective case series, we assessed patient reported outcome measures in terms pain relief and patient satisfaction with ECAP sensing spinal cord stimulator system capable of multiple waveforms; Differential Target Multiplexed (DTM™, High Dose, Low Dose as well as all other types of programming /cycling which gives the broadest options for the patients.

Methods

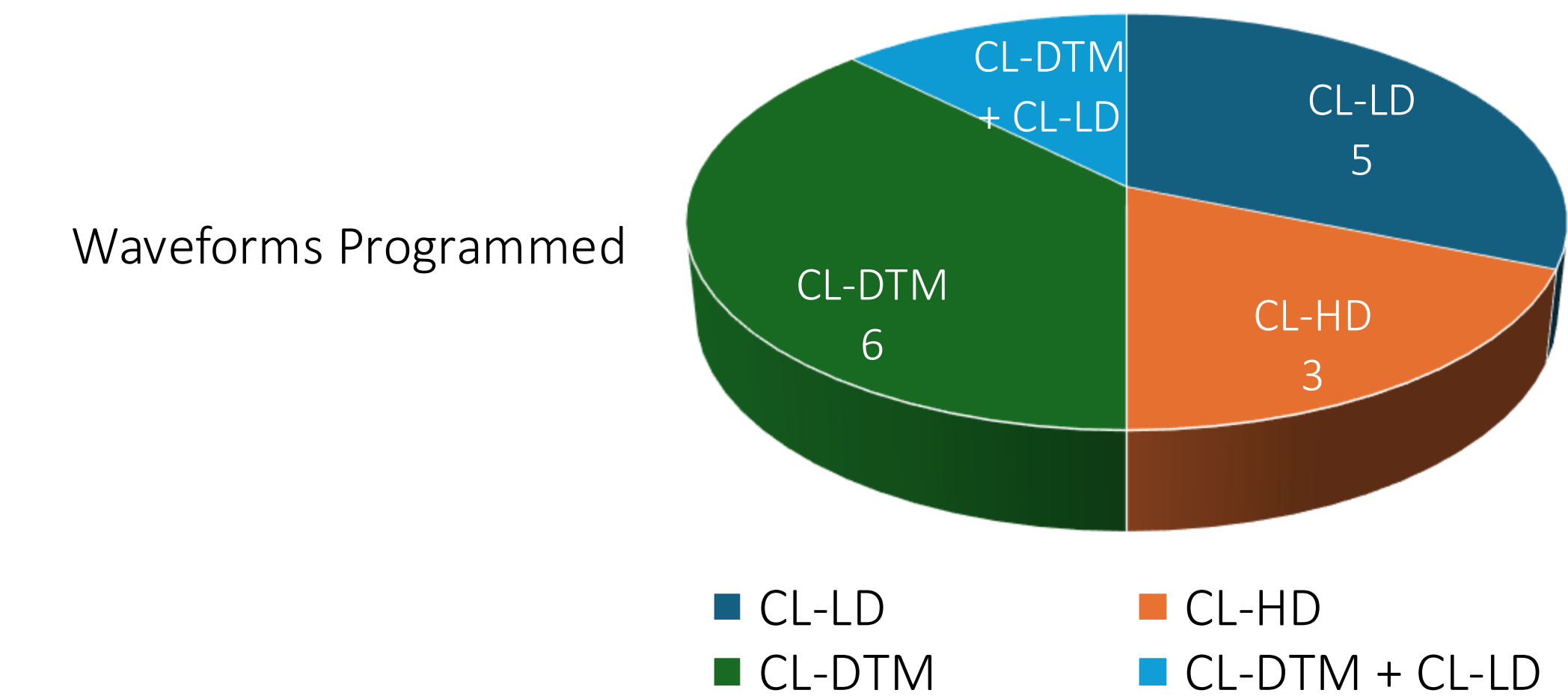
- 16 patients with NICE approved indications⁵ for SCS were implanted with Inceptiv™ stimulator capable of closed-loop stimulation across multiple waveforms.
- After implantation, patients were programmed with the most suitable program for their pain distribution.
- Patients independently completed outcome measures for comfort of stimulation and patient satisfaction at baseline and 6 months.

Results Comparing Fixed-Amplitude Survey Outcomes and CL-SCS Real World Experience



Main Results

- The average baseline pain score of 8.0 ±1.2 dropped to 2.6 ±2 numerical rating scale at 6 months.
- None of the 16 patients, reported shocks or jolts during activities of daily living.
- None needed to reduce the stimulation due to unwanted tingling or buzzing.
- None of the patients turned off their stimulator for any kind of activity.
- Two patients temporarily turned off the stimulator to test if it still provided pain relief or not.
- Most Patients rarely interacted with their controller: 8 patients reported never adjusting their stimulator, 2 patients adjusted a few times per month, and 5 reported adjusting a few times a week.
- Overall, the burden of the therapy is significantly reduced.



Conclusions

- This is the first 'real-world' prospective case series of Inceptiv™ ECAP-controlled CL-SCS system.
- It shows clinically significant pain relief across low rate and high-rate programs without any therapy related side effects or limitations on activities of daily living due to overstimulation.

References

- Schultz DM, Webster L, Kosek P, Dar U, Tan Y, Sun M. Sensor-driven position-adaptive spinal cord stimulation for chronic pain. Pain Physician. 2012 Jan-Feb;15(1):1-12.
- Buyten JP. The performance and safety of an implantable spinal cord stimulation system in patients with chronic pain: a 5-year study. Neuromodulation. 2003 Apr;6(2):79-87.
- Medtronic Pain Therapies, Information for Prescribers. M006349C007 Rev A 2022-02-28
- US SCS Patient Market Research Conducted in June/July 2023 by StrataMark LLC, an independent 3rd party market research agency (N=100, double-blinded, 20-minute online survey)
- <https://www.nice.org.uk/guidance/ta159>