Improved Versatility and Frequency Pairing Capabilities with 10 kHz Spinal Cord Stimulation for the Treatment of Chronic Pain

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Introduction

Chronic intractable pain presents a treatment challenge for interventional pain physicians. Previous studies have demonstrated the efficacy of high frequency spinal cord stimulation at 10 kHz (10 kHz SCS) in providing durable pain relief, along with high long-term responder rates in both a randomised controlled trial and real-world study setting.1,2 Despite these advances, a small number of patients may remain refractory to long-term pain relief, requiring a more versatile therapeutic approach to optimize their success (Fig 1 and 2.). The objective of this retrospective audit is to investigate how increased versatility and paired waveforms can improve outcomes in a select challenging population.

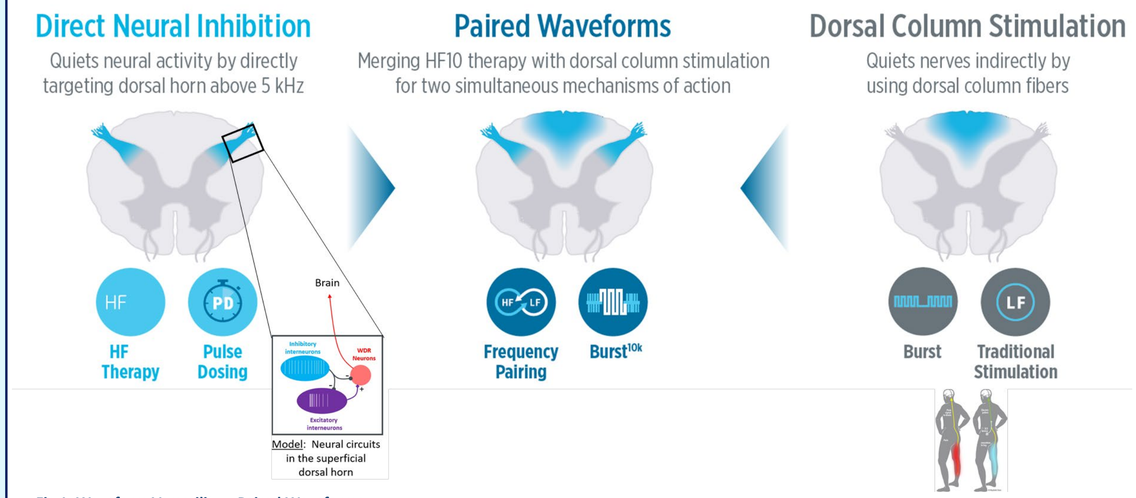


Fig 1. Waveform Versatility – Paired Waveforms

There are two distinct mechanisms of action in spinal cord stimulation Direct Neural Inhibition and Dorsal Column Stimulation. Direct Neural Inhibition, directly targets pain causing neurons in the dorsal horn. Pre-clinical and clinical research shows this mechanism only becomes effective at frequencies above 5 kHz. The second mechanism is Dorsal Column Stimulation, which is based on mapping paresthesia to the pain location. Therapies that rely on this approach include traditional stimulation therapies between 40-60 Hz, burst waveforms or therapies at 1 kHz. With waveform versatility we can pair these unique mechanisms. Having access to both mechanisms, independently or paired allows the versatility needed to achieve the best possible clinical outcomes.

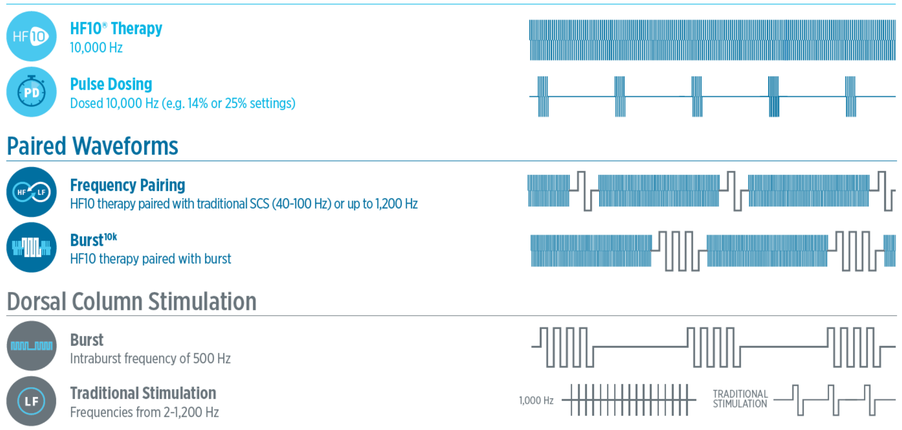


Fig 2. Waveforms Across Multiple Mechanisms

The various waveforms. The top graphic demonstrates constant delivery of 10,000 Hz, whilst pulse dosing delivers the same therapy in packets. Pulse Dosing can reduce charge requirements significantly while maintaining efficacy.

Frequency Pairing combines 10kHz with traditional SCS – either low frequency or 1000 Hz or combined with a burst waveform.
With the paired waveforms, the two mechanisms of action work simultaneously.

Method

Early Clinical Experience with Waveform Pairing

- Retrospective audit, 493 patients across 4 Australian sites.
- Selected patients not achieving adequate pain relief and exhausted current therapy options
- Hypothesized as may needing additional waveforms or mechanisms of action to optimize pain relief
- Provided Frequency Pairing or Burst[10k] at physician discretion
- n=26 consecutive patients (Table 1)

Table 1. Demographics

n=26 consecutive patients	
Ave duration of IPG (mean ± SD)	592.6 ± 79.9 days (approx. 1.6 years)
Follow Up (mean ± SD)	(72.9 ± 12.6 days)
Indication	• Predominant Back - 31.8% • Back = Leg - 31.8% • Other - 27.3% • Predominant Leg - 9.1%
Waveform Pairing	• Frequency Pairing – 20/26 • Burst[10K] – 6/26

Conclusions

Promising results using **waveform pairing** combining LF or Burst with **10,000 Hz** in difficult to treat patients

Clinically meaningful improvements

- MCID in pain relief improved from 30% to 76% at approx. two and a half months
- Responder rates improved from 17% to 60% at approx. two and a half months
- Improved sleep and function
- Reduction in pain medications

Further real world data around waveform pairing will be collected and shared in the future

Here we demonstrate that increased versatility and paired waveforms may help improve therapeutic outcomes in difficult populations

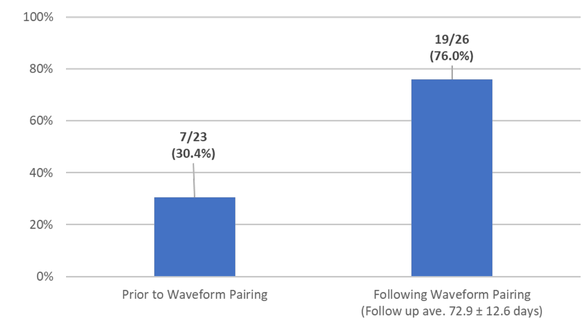
References

1. Taylor et al. Spine (Phila Pa 1976), 2005, Vol. Jan 1;30(1):152-160
2. Kapural et al. Neurosurgery, 2016, Vol. 79(5): 667-677
3. Dworkin et al. J Pain. 2008;9:105–121

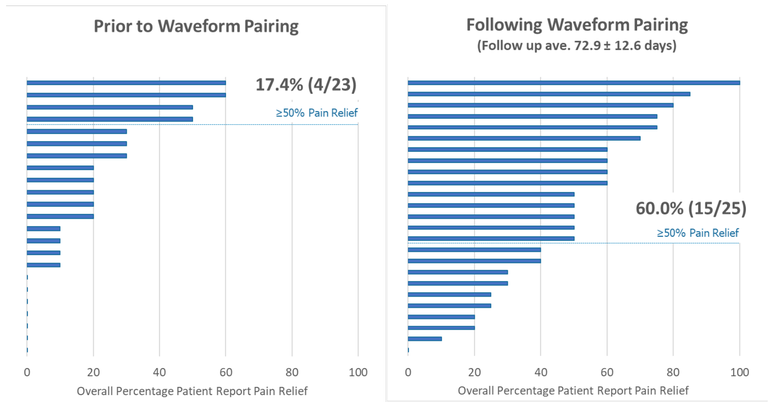
Results

Minimum Clinical Important Difference: Pain Relief

Proportion of patients reporting a minimum clinical important difference (30%)[3] in pain intensity from baseline



Waveform Pairing – Responder Rate



Waveform Pairing – Quality of Life Outcomes

Quality of Life Outcomes	
Improved SLEEP since last follow up* Data available for n=18	Yes: 10/18 (55.5%) No: 8/18 (44.4%)
Improved FUNCTION since last follow up* Data available for n=19	Yes: 14/19 (73.7%) No: 5/19 (26.3%)
Change in PAIN MEDICATION since last follow up* Data available for n=21	Decreased: 8/21 (38.1%) No change: 11/21 (52.4%) Increased: 2/21 (9.5%)

*Last Follow Up: (72.9 ± 12.6 days)