

# Safety and Efficacy of Cervical 10 kHz Spinal Cord Stimulation (SCS) for the Management of Refractory Chronic Migraine\*: A Prospective Study

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## Introduction

- Significant unmet need: effective therapies for refractory Chronic Migraine (CM)
- Neurostimulation therapies (f.e. occipital nerve stimulation) showed disappointing therapeutic effects in large clinical trials<sup>1</sup>.
- Recent prospective study: HF-SCS shown promising efficacy in refractory CM and medication overuse subjects<sup>2</sup>.

### Study design & goal

- Single-center, open label, prospective, feasibility (of label) study
- Follow-up 12 months
- Safety, tolerability and efficacy of HF-SCS in refractory Chronic Migraine subjects

## Methods

\*Treatment of Chronic Migraine is investigational only and not on-label or indicated for use

- Age: ≥18 years old
- Chronic migraine with/without aura
- Refractory to ≥ 3 preventive treatments:
  - ✓ Topiramate & Botox (< 30% pain relief)

### Exclusion

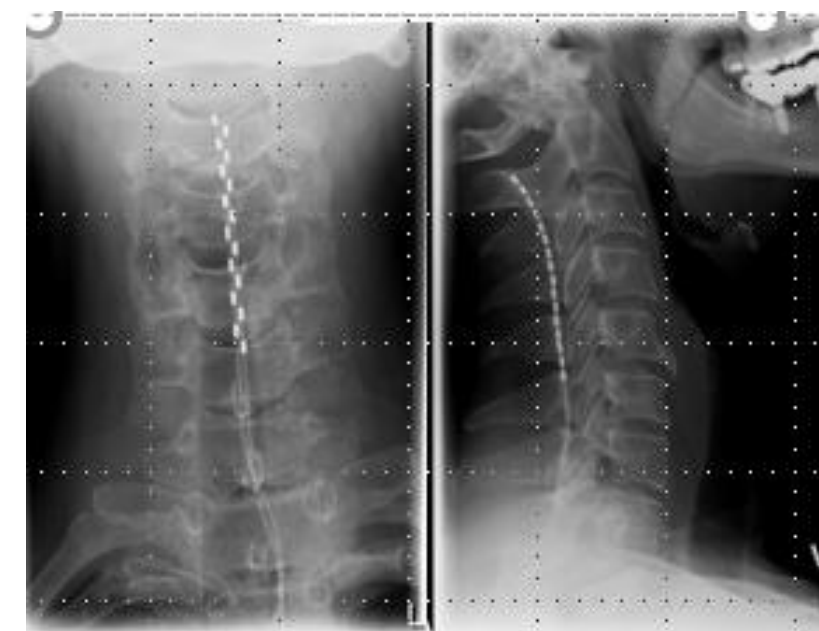
- Medication overuse headache
- Severe depression (PhQ-9>19)

### Implant Procedure

- Spinal Cord Stimulator (HF10) (Senza System, Nevro Corp, Redwood City, CA)
- Leads positioned at C2
- No stimulation trial

Responder = at least 30% reduction in headache days per month post-device activation

## Results



Picture 1: X-ray AP and Lateral view of the implanted lead of the SCS system

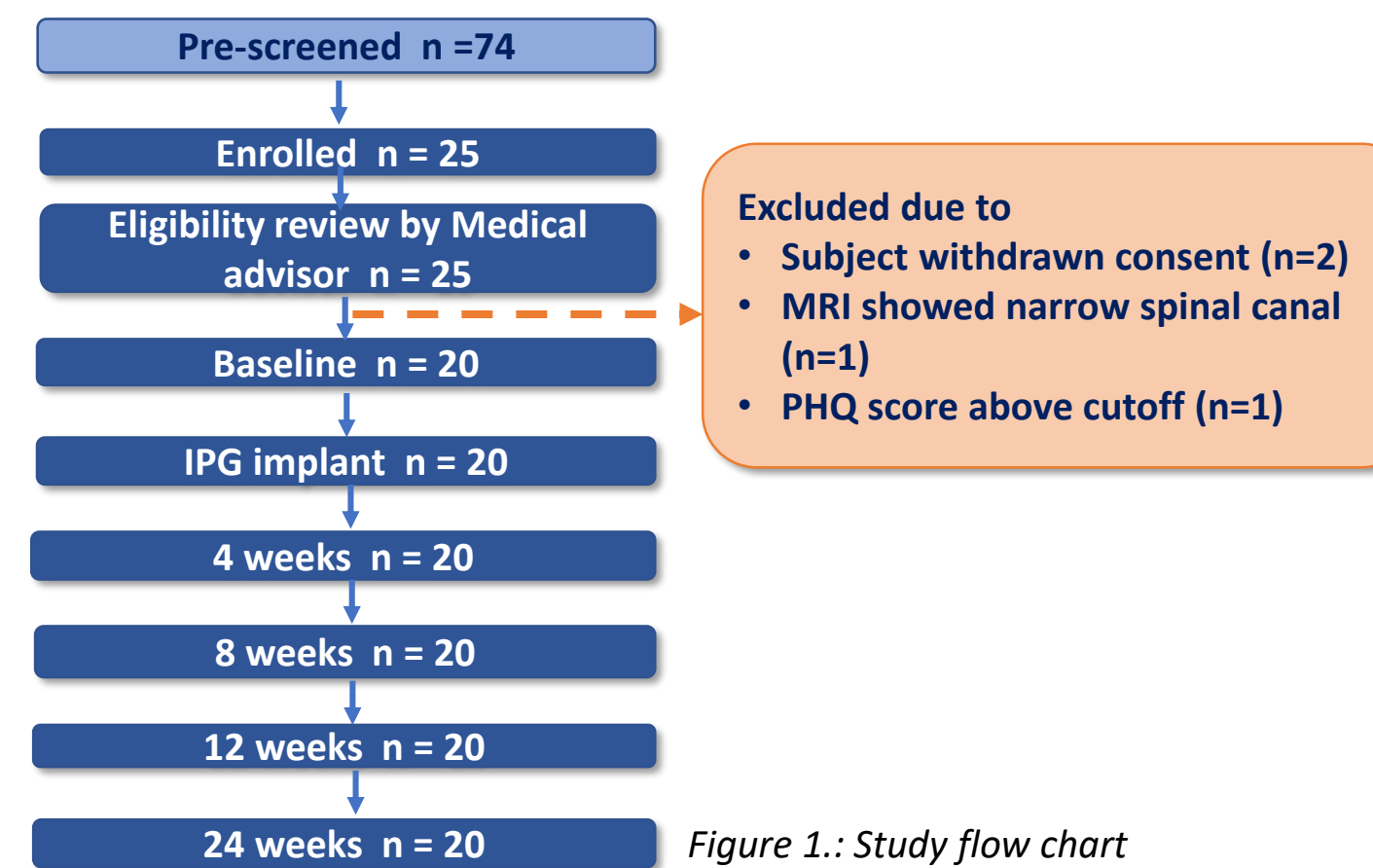
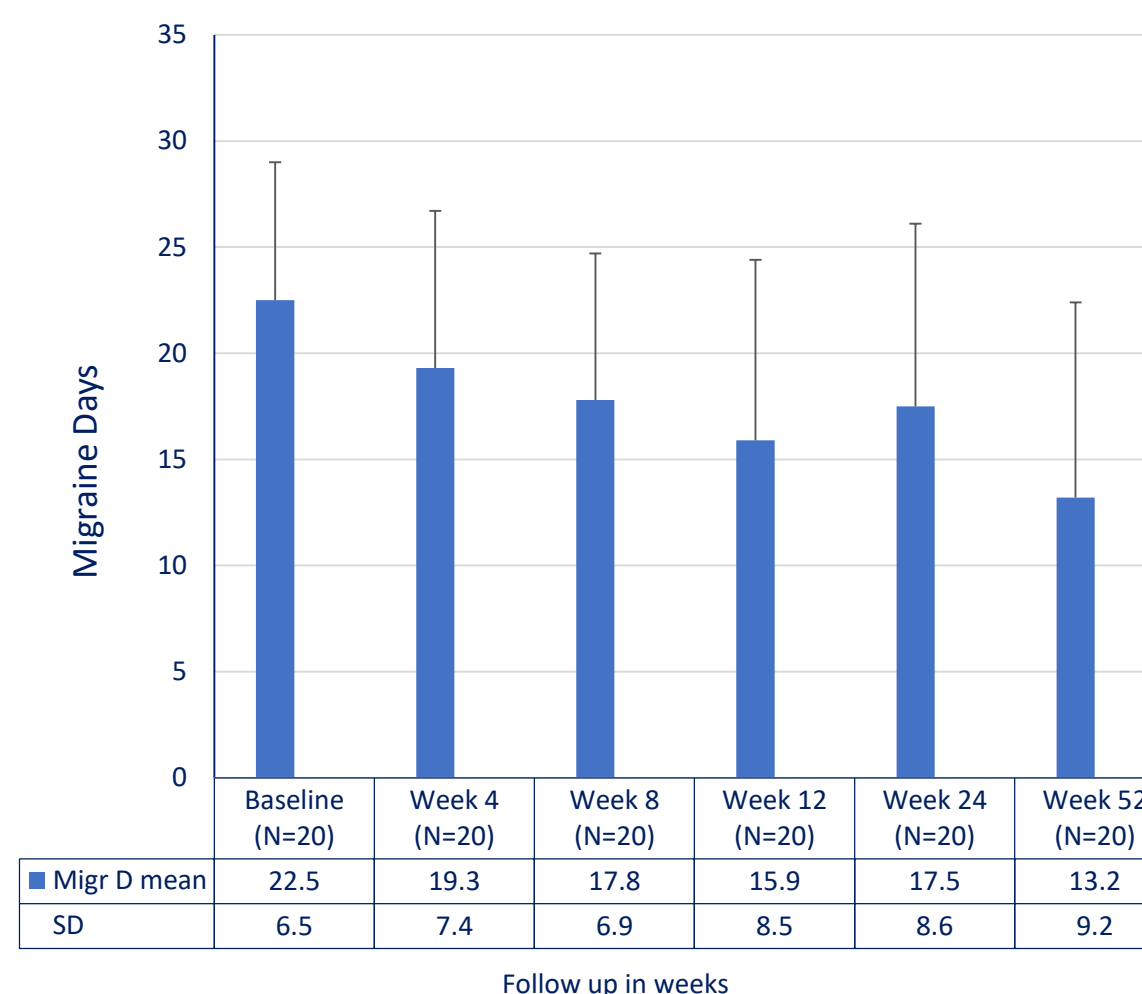
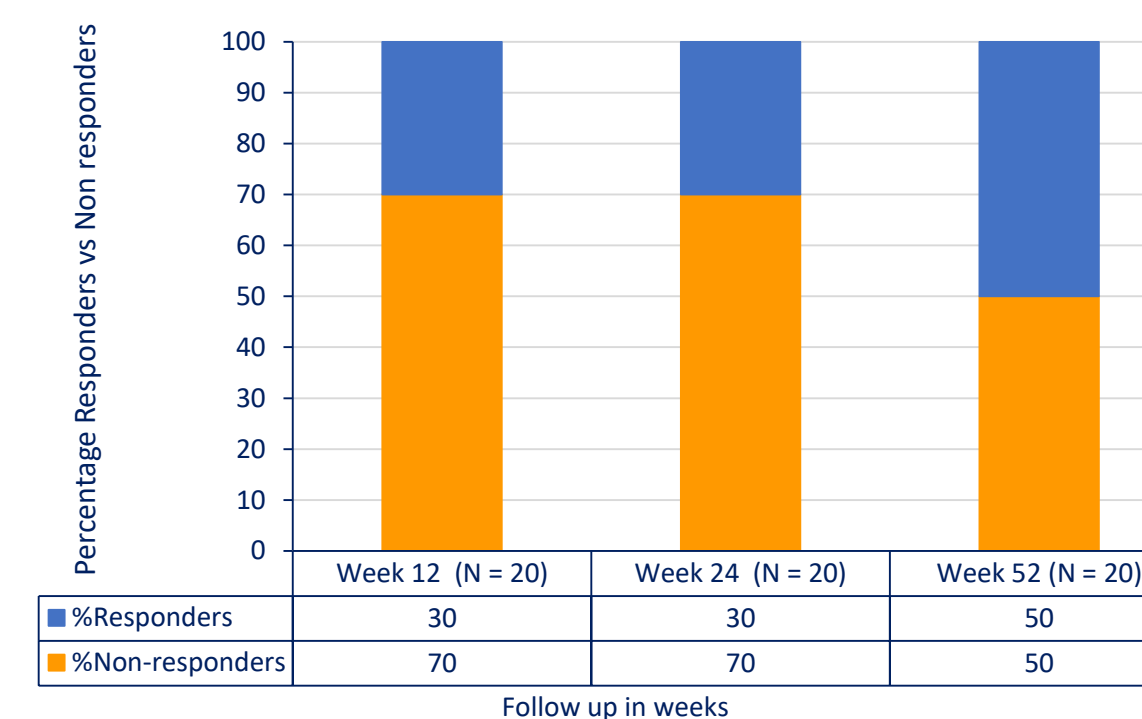
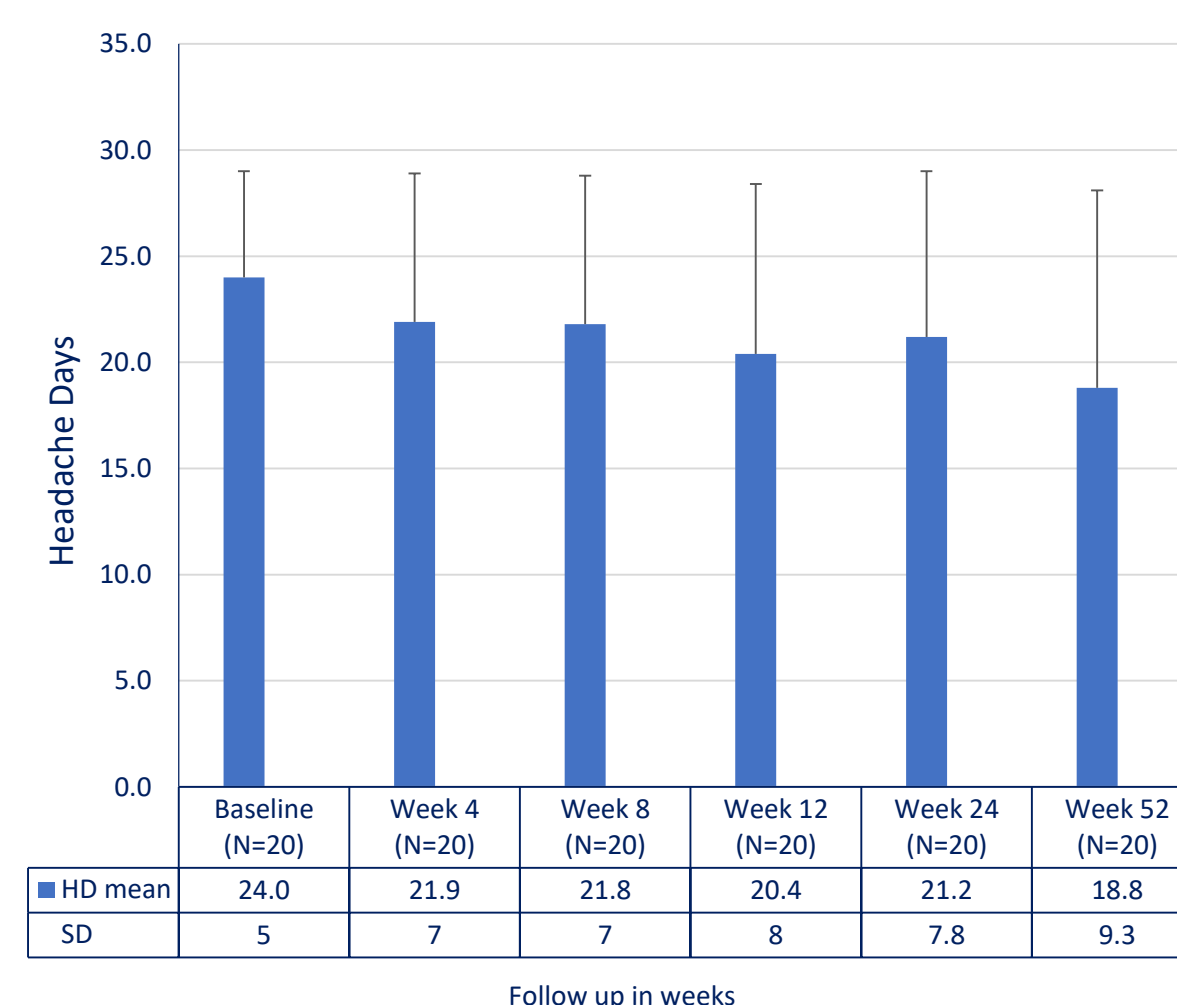
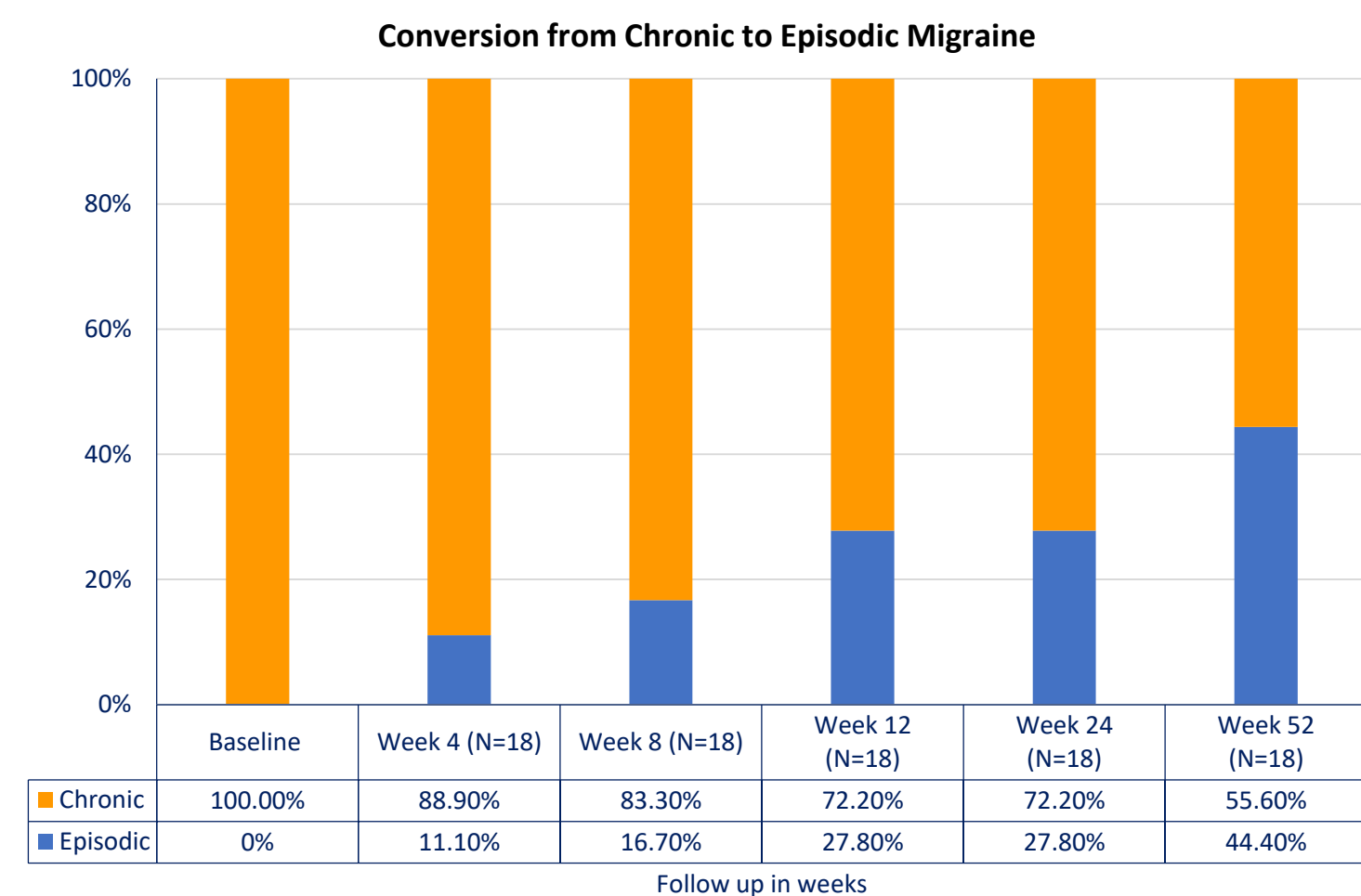


Figure 1.: Study flow chart

Variable	N	Mean	SD	Median	Range
Female	17 (85.0%)				
Age (years)	20	42.9	10.5	46	24 to 59
Height (cm)	20	166.4	7.3	165	156 to 186
Weight (kg)	20	77.7	14.9	75	56 to 112
Body Mass Index (kg/m <sup>2</sup> )	20	28	4.9	26	22 to 40
Duration of Migraine (years)	19	19.2	13.2	17	3 to 46
Duration of Chronic Migraine (years)	20	10.1	9.8	6	1 to 35
Number of Botox Treatments	20	3.4	1.8	3	2 to 8
Duration of Botox Treatment (months)	20	8.1	5	6	3 to 24



## Results (contd.)



### Anticipated Device related Adverse Effects :

- 5 subjects reported mild to moderate IPG pain
- 1 subject experienced slight lead movement
- No explants

## Conclusions

- HF-SCS may offer a safe & effective therapeutic option for refractory Chronic Migraine
- Efficacy similar as for Occipital Nerve Stimulation (ONS), however subjects treated with HF-SCS significantly more refractory
- Lack of implant-related additional surgery suggests that HF-SCS may offer a safer profile than ONS

## Disclosure

This study was sponsored by Nevro.

## References

1. Dodick DW et al, Cephalalgia, 2015
2. Arcioni et al. European Journal of Pain, 2016