



# Comparative Efficacies of Transcutaneous Electrical Nerve Stimulation Protocols in Peripheral Neuropathy Subjects

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## Abstract

- Chronic neuropathic pain is a prevalent disorder and is difficult to treat.
- Calmare a therapeutic method of transcutaneous electrical nerve stimulation, has shown promise in treating neuropathic pain.
- The goal of our study is to compare analgesic effects of Calmare and traditional TENS side-by-side.

## Methods

Nine male and nine female subjects with peripheral neuropathies were randomly assigned to either the (1) Calmare therapy group or (2) the traditional TENS therapy group. Subjects rated their baseline pain using the Washington Neuropathic Pain Scale (NPS) and the Visual Analog Scale (VAS).

To make the study **double blind**, we ran outputs from both Calmare and TENS through a black box with only one output for every two inputs, and one set of knobs controlling both output amplitudes (see picture below). A research assistant wirelessly controlled a switch in the box to give each subject the proper treatment. An experienced therapist, blind to the switch, then placed up to four electrode pairs on the subject's skin proximal to the region of pain, but on the same dermatome.

To begin, the therapist ramped up the intensity as high as the subject could comfortably endure. Throughout the treatment the intensity was increased as subject tolerance increased, typically 1-3 times.

TENS was administered in normal mode with an asymmetrical biphasic square pulse at 43 Hz and a pulse width of 300 microseconds. Calmare stimulates at about 50 Hz with a variable waveform. At three second intervals, the device produces a different complex waveform by combining a sample of 16 sine waves of various frequencies. Treatment sessions lasted for 30 minutes, after which subjects again evaluated their pain using the NPS and VAS forms. During a follow-up visit the next day, patients again rated their pain.

TENS group subjects were invited to return for a crossover, non-blind treatment session of Calmare which was otherwise identical to their TENS treatment session.

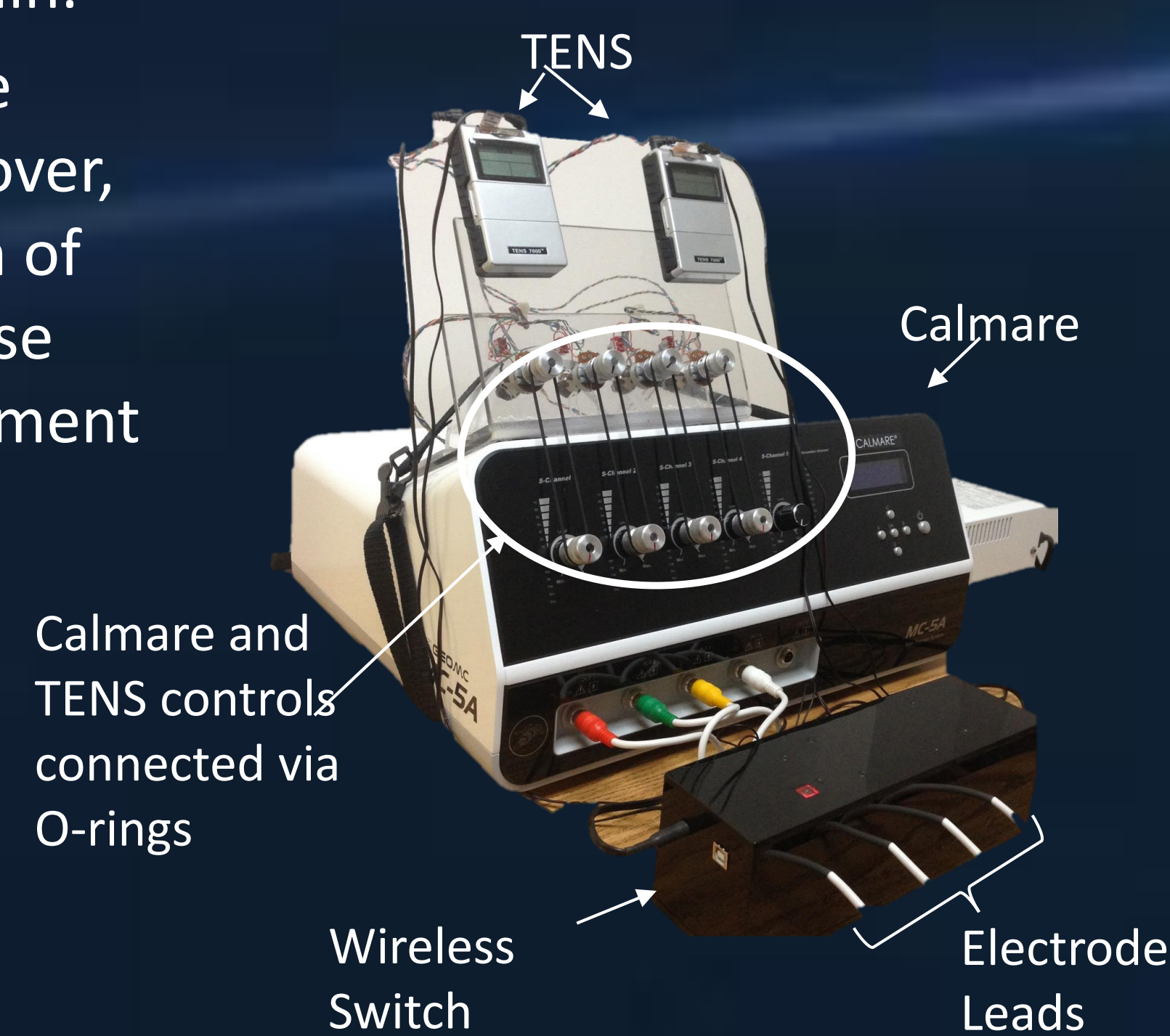
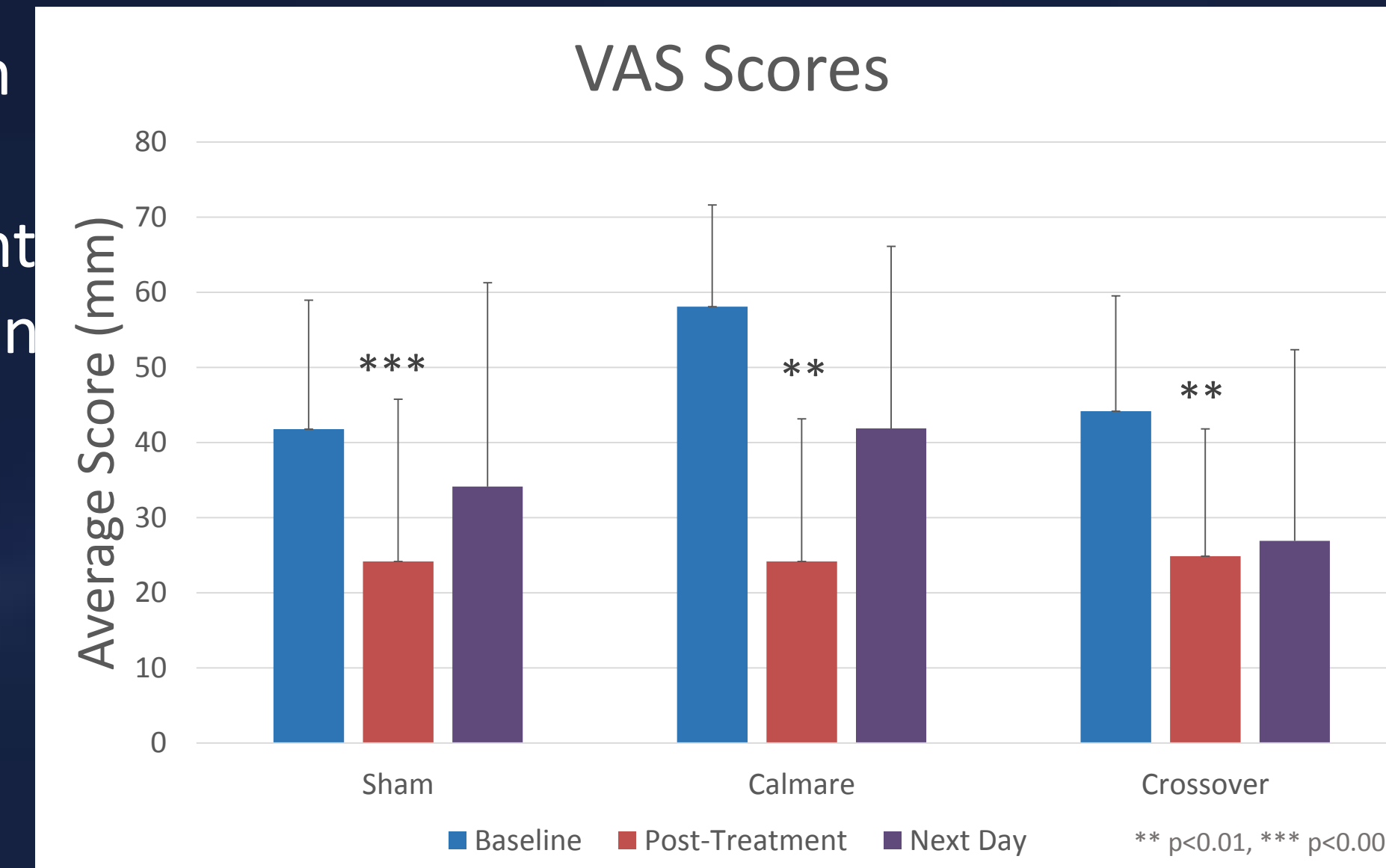
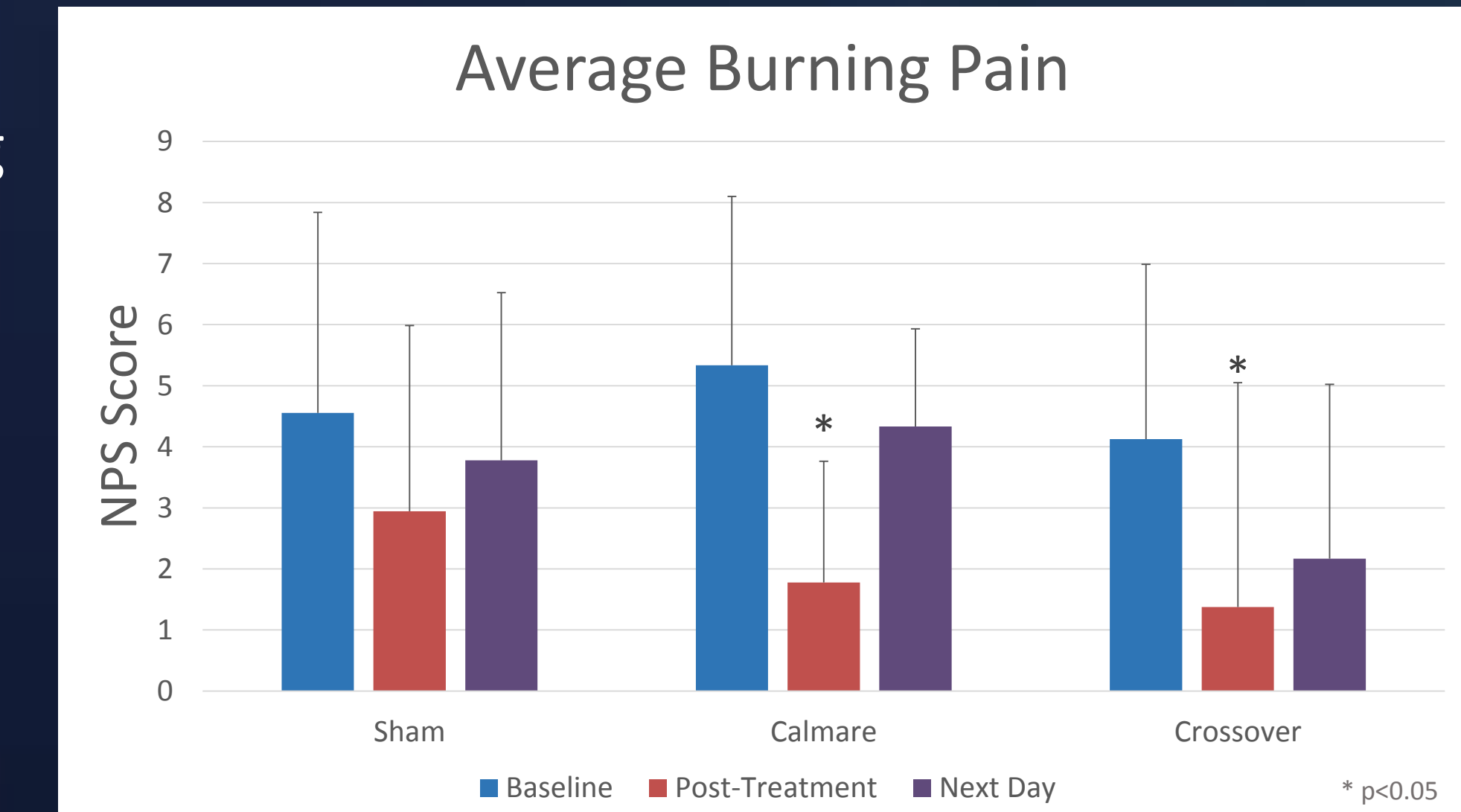


Figure 1. Subject VAS pain ratings before and after treatment. Each treatment significantly reduced mean VAS scores. Inter-group comparisons show that reductions of pain were not significantly different among groups. (+SD)



## Results

Figure 2. The Calmare therapy reduced burning pain significantly in both the original Calmare and crossover Calmare groups. TENS did not significantly reduce burning pain. Pain recovery is seen in all groups. (+SD)



The plots below show differences between treatment groups in the NPS questions yielding the largest reduction after treatment. The type of pain with the greatest drop is designated for each subject by the color of the line, as indicated by the key below.

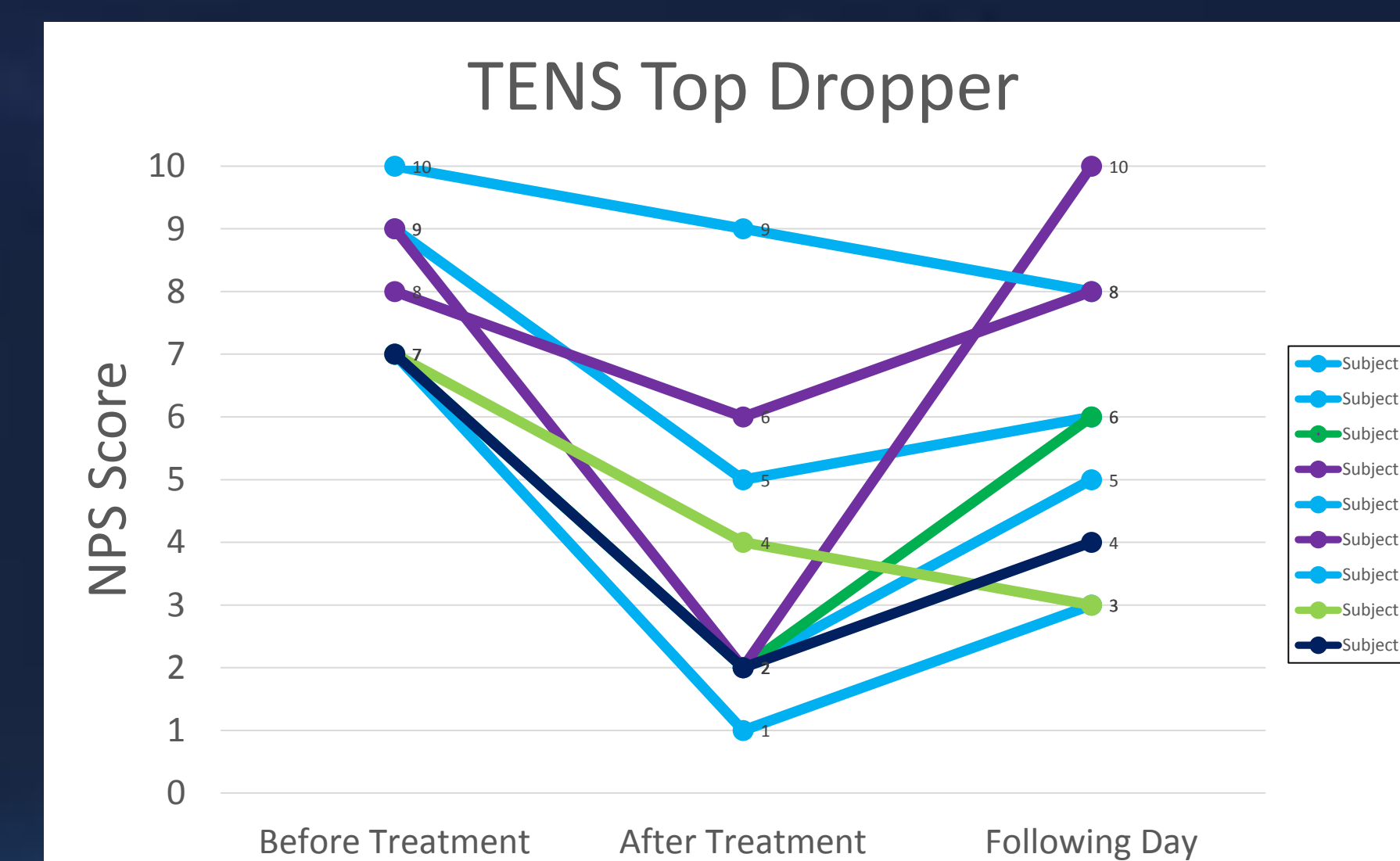


Figure 3. TENS produced the largest reductions in sensitive (light blue) and superficial (purple) pain.

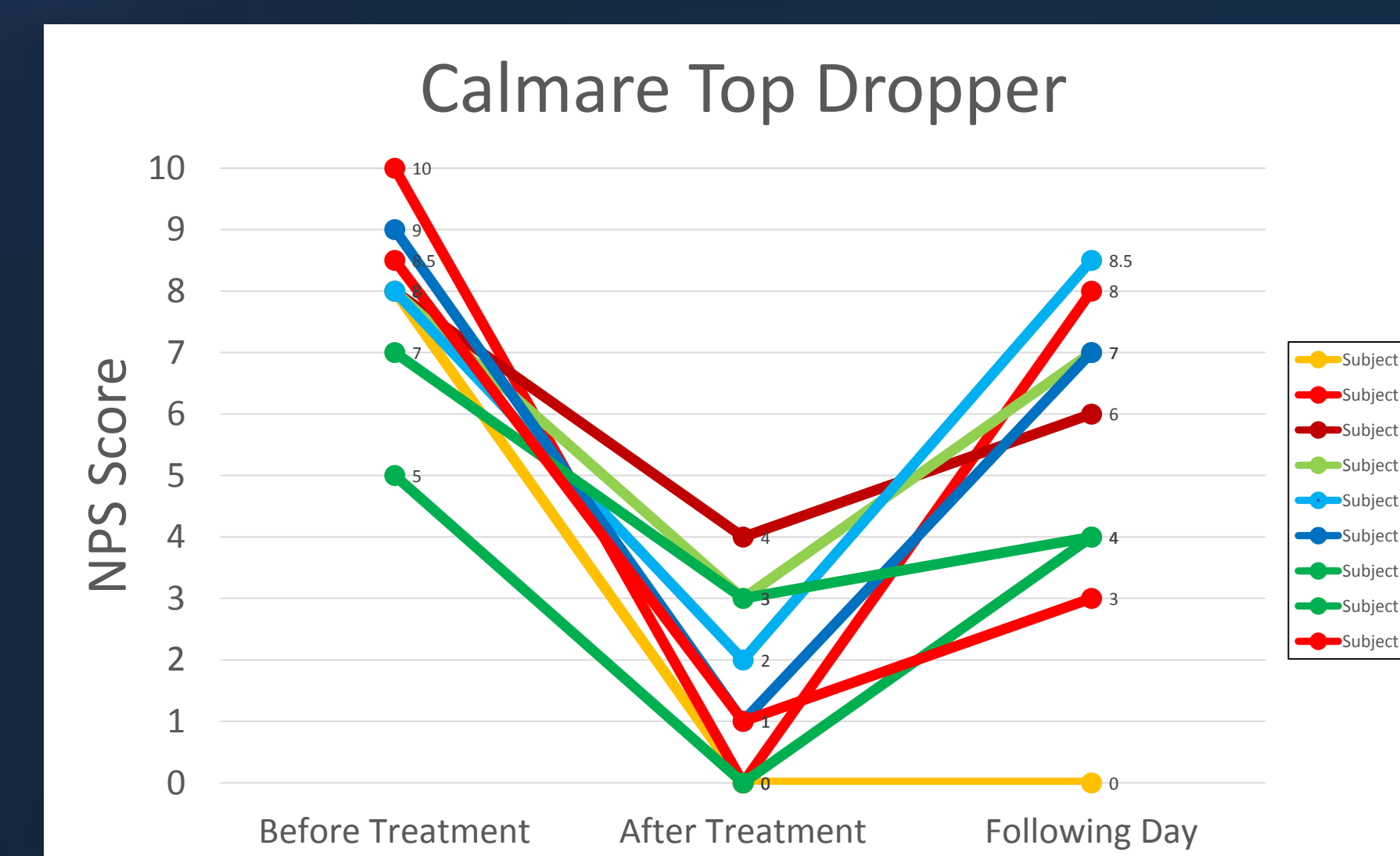


Figure 4. Calmare produced the largest reductions in sharp (red) and cold (dark green) pain. Complete elimination of hot pain (yellow) is also noteworthy.

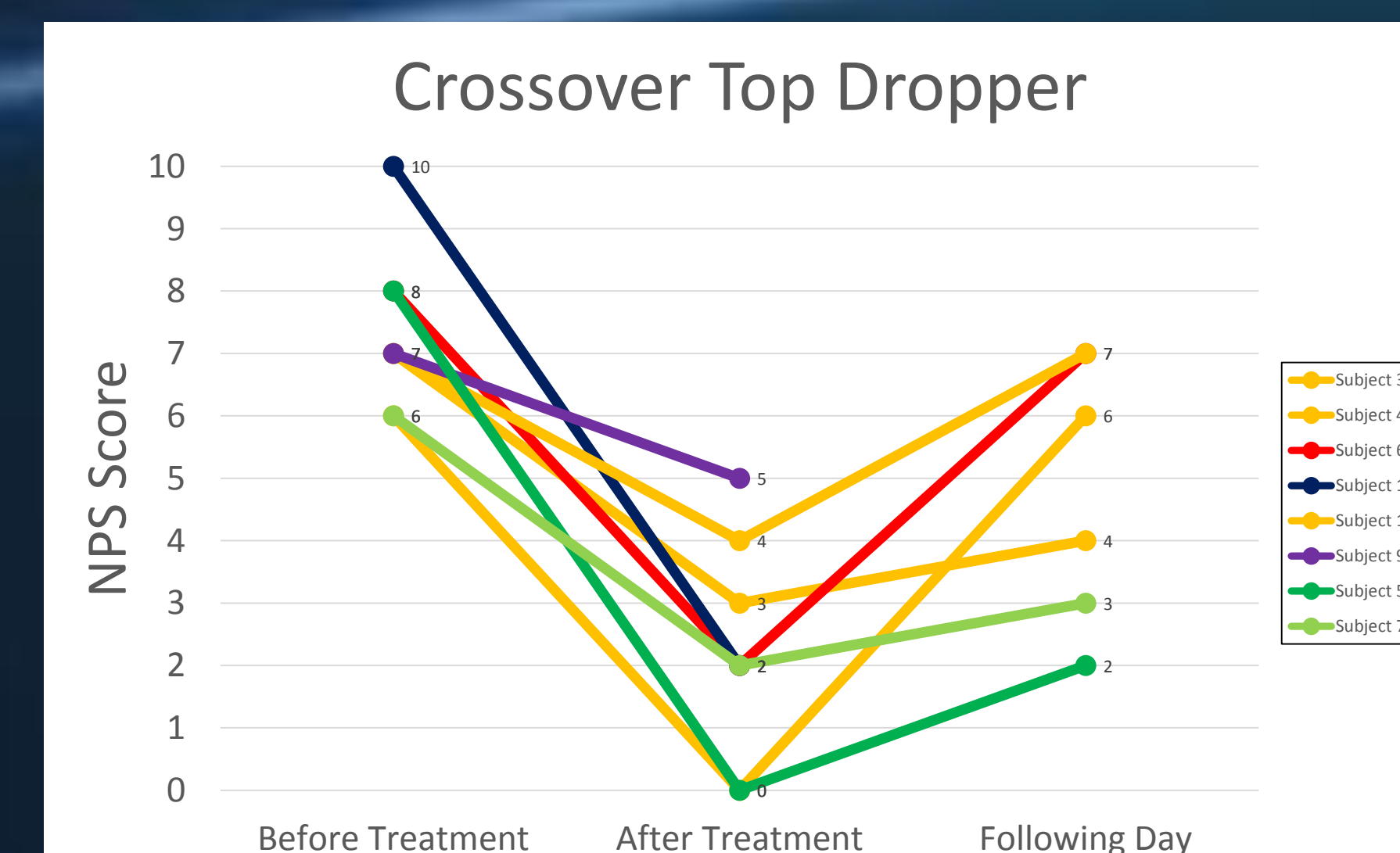


Figure 5. The Calmare crossover group experienced the largest reductions in hot pain (yellow). Note the difference in color scheme between the TENS and crossover groups.

## Discussion

In this study we compared the analgesic effects of one 30 minute treatment of TENS and Calmare on nine male and nine female subjects with peripheral neuropathies. There was no difference in the decrease of mean VAS scores between Calmare and TENS groups. However, differences in the reduction of specific pain modalities (e.g. burning, sharp, intense pain) suggests that the two devices may reduce pain by different mechanisms. However, due to the limited scope of this one-day study, future studies should examine the possibility of more distinct differences between Calmare and TENS over a longer treatment periods.

## Conclusions

- Calmare and TENS have a similar total analgesic effect after one treatment.
- However, treatment-specific changes in some pain modalities indicate that there may be differences.
- Future studies should examine long-term differences between these treatments.

