Methods: Two prospective, multi-center clinical trials were initiated in Australia and the USA to confirm performance of this novel SCS system in patients with chronic, intractable pain. Study subjects (n=36 combined) were followed for up to 1-year post-implant. Data were captured regarding daily duration of use, comfort and ease-of-use with the external wearable and adhesive clips. Studies were approved by independent Ethics Committees and conducted in compliance with local regulations.

Introduction: In the 1980’s early spinal cord stimulation (SCS) systems used large external components that were held in place using rudimentary skin adhesives. In the past 40 years, SCS and adhesive technologies have improved considerably. We evaluated a novel SCS system that includes a micro-Implantable Pulse Generator (mIPG) and external wearable components (Nalu Medical, Inc., Carlsbad, CA). The wearable external component uses a hydrocolloid adhesive, which has been used for decades with stoma patients. The comfort, useability, and compliance with this novel, externally-powered SCS therapy is described here.

Results: To date, data are available on over 400,000 total combined wear hours. Subjects have worn the external components for an average of 18 months following activation (range: 1.4 to 32 months). A majority of subjects reported comfortably wearing the device >23 hours per day. 100% (33/33) of patients rated the external wearables as comfortable. 97% (32/33) rated the SCS system as easy to use at 3-months (no data was available for 3 subjects).

Conclusion: Subjects reported the external wearables to be comfortable and easy to use. Designing a neurostimulation device with the battery on the outside allows for a marked reduction in implant volume to ~1.5 cc, which is advantageous to the patients and surgeon. Overall, study subjects demonstrated a robust decrease in leg and low back pain using the Nalu neurostimulation system. These findings should be confirmed in further studies.

References