

Domiciliary Non-invasive Peripheral Neurostimulation for Chronic Pain: Patient reported outcomes from more than 10407 patients

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BACKGROUND

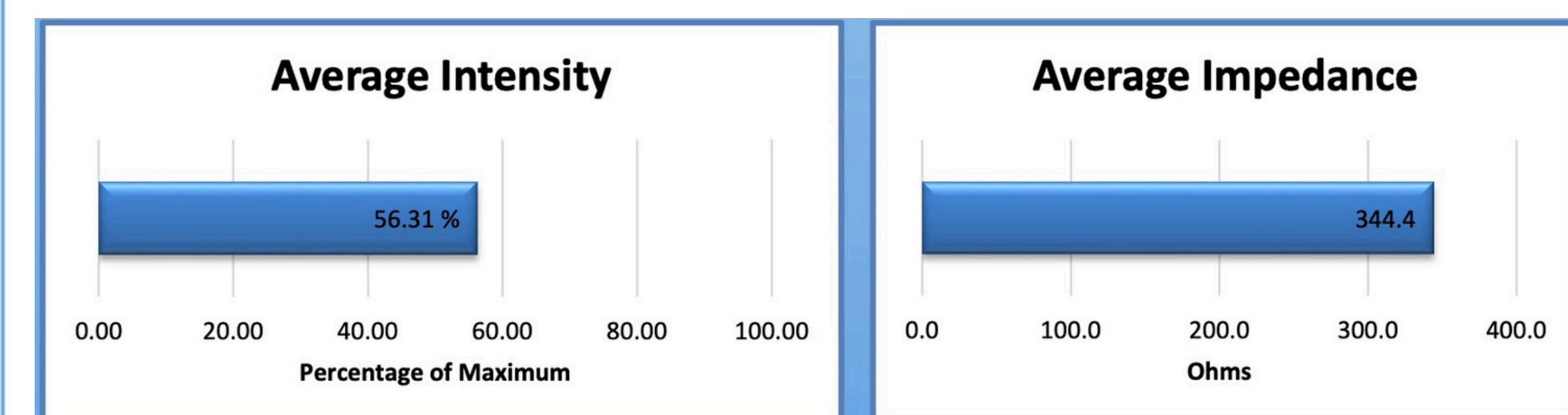
Chronic pain imposes a substantial burden on healthcare systems, with pharmacologic and interventional therapies often limited by side effects and diminishing efficacy. Neuromodulation, including spinal cord and dorsal root ganglion stimulation, can be effective but remains costly and inaccessible to many. Emerging studies have questioned SCS cost-effectiveness for low back pain and sciatica, underscoring the need for careful patient selection. Here we report 10,407 patient-reported outcomes from an external neurostimulation device across diverse pain conditions.

MATERIALS AND METHODS

IRB was deemed unnecessary given that outcomes were self-reported by participants, with informed consent and data anonymization for analysis. Data were collected from 10,407 patients using questionnaires and feedback forms retrieved from Trustpilot, Google reviews, and the Digital Health Platform App as voluntary patient-reported outcomes. Participants used an external stimulator at home to target chronic pain conditions, with stimulation delivered via two high-frequency sinusoidal signals (3858 Hz and 3980 Hz) between two surface electrodes placed over one or more pain sites, under a patented neurostimulator (BioWave, Norwalk, CT, USA).



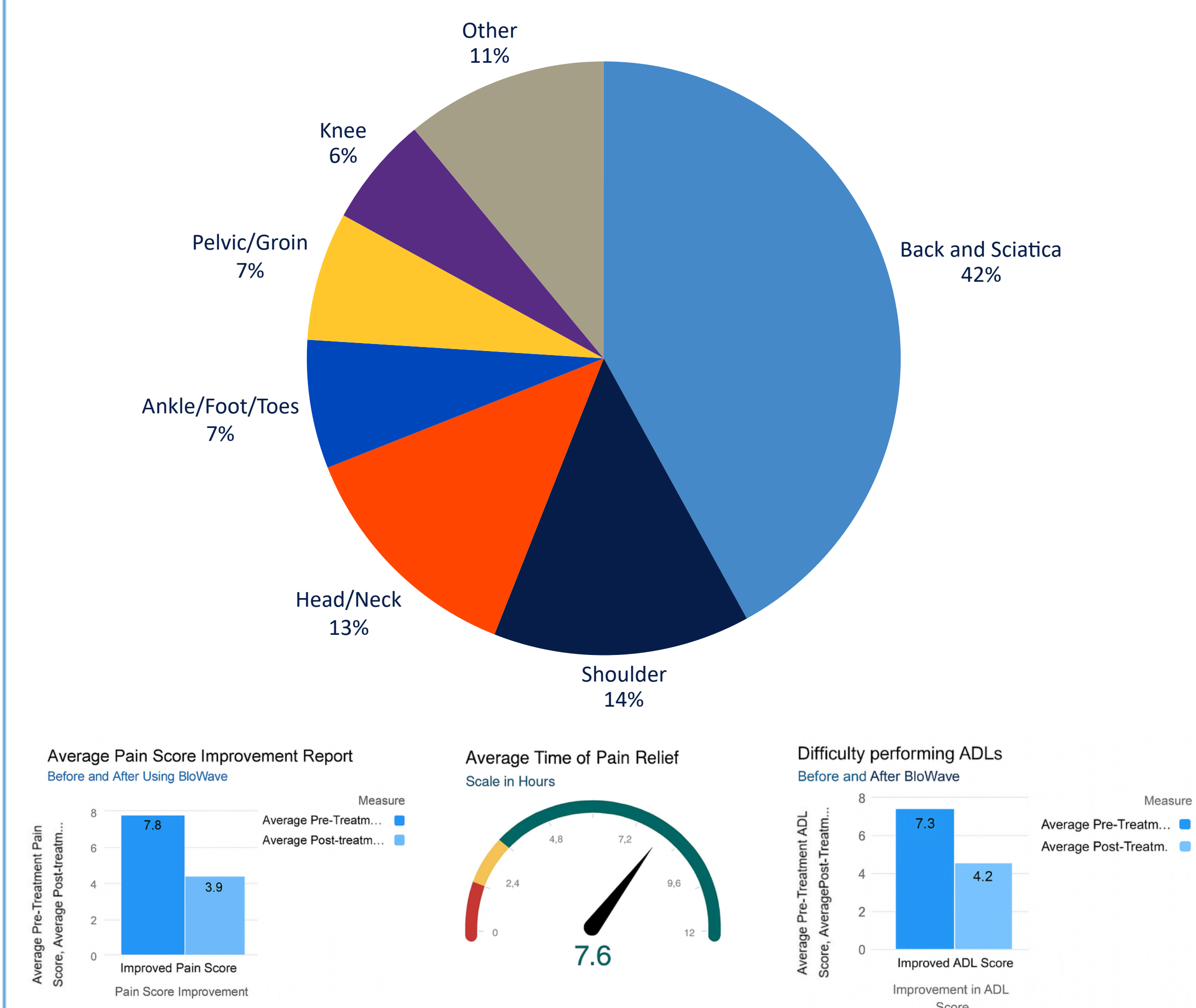
Patients reported improvements across multiple domains after two or more weeks of treatment, including pain intensity and duration of relief, activities of daily living, analgesic consumption, quality of life, mood, sleep, functional outcomes, and overall satisfaction. Data reflect real-world, self-reported experiences across diverse pain conditions, highlighting perceived benefits and areas for further studies and validation in controlled settings. Qualitative reporting of analgesic benefit and impact on daily activities were also collected.



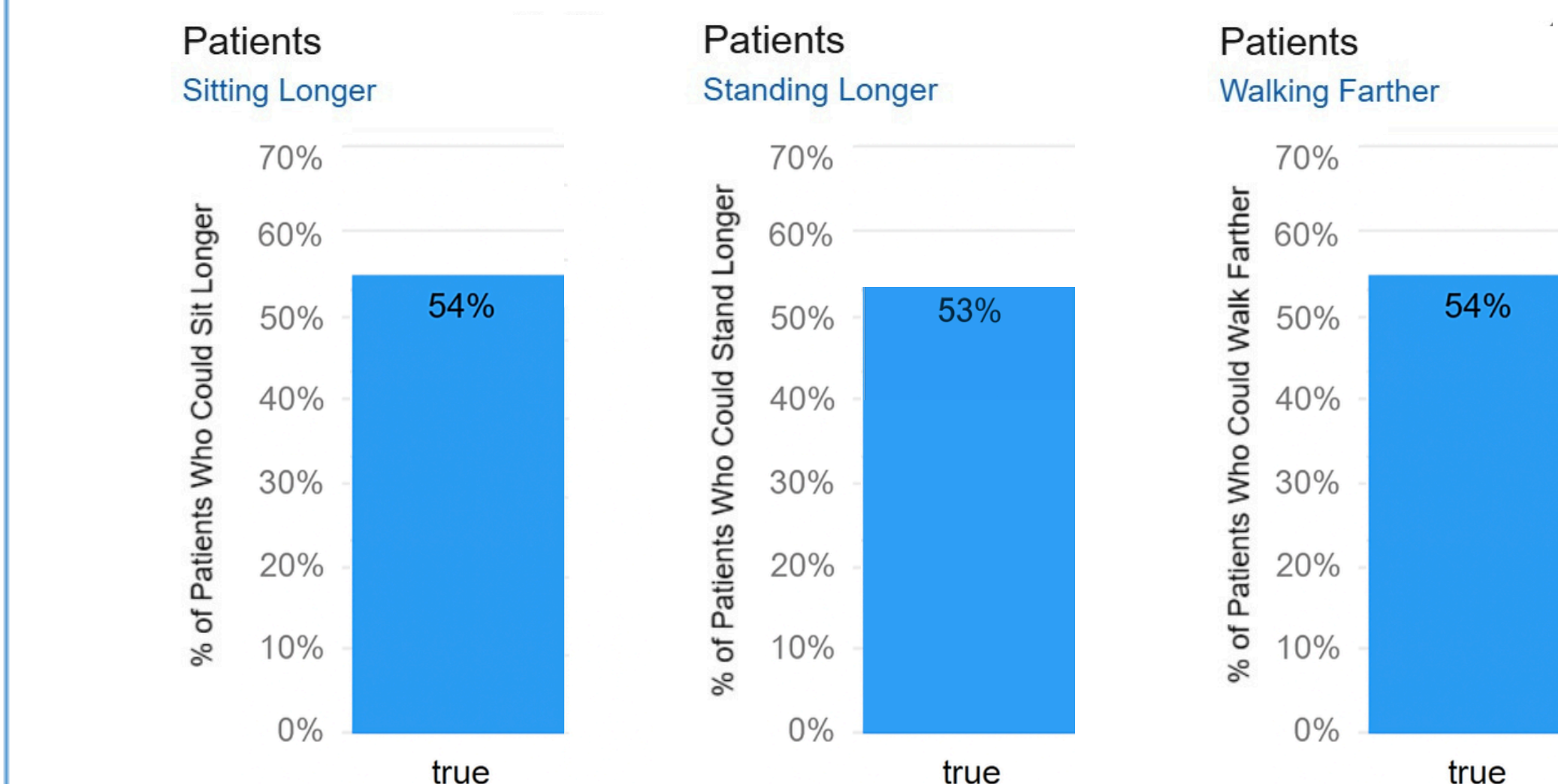
RESULTS

Treatments by Body Location

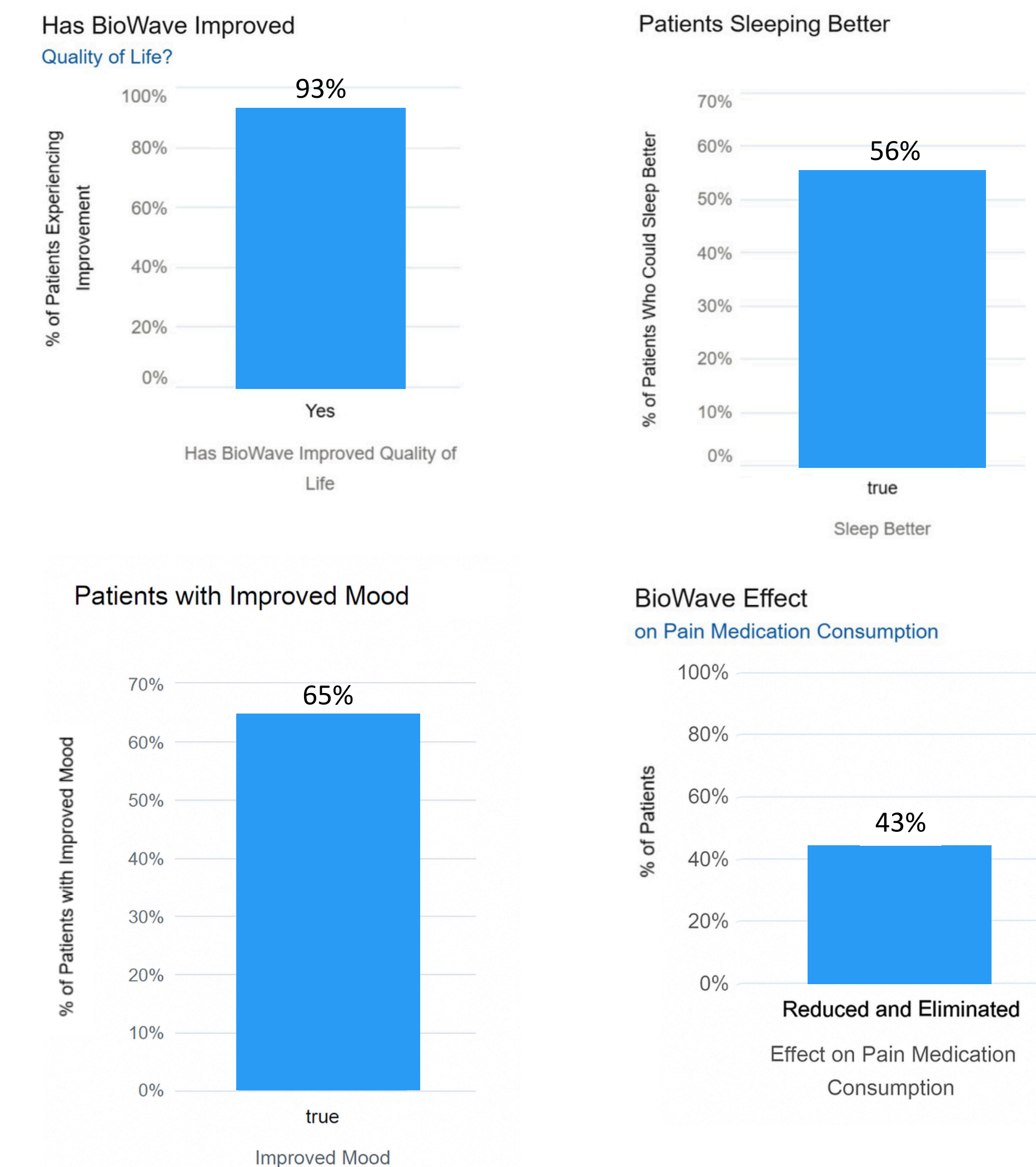
Data from 10,407 patients was analyzed based on self-reported outcomes. A total of 5,492 treatments were recorded by location. The largest cohort comprised patients with back pain and sciatica (42%), followed by those with shoulder pain (14%), headache/neck pain (13%), ankle/foot/toe pain (7%), pelvic/groin pain (7%), and knee pain (6%). Most patients experienced musculoskeletal pain, neuropathic pain, or both.



The average pain score on the VAS improved significantly from 7.8 to 3.9, with pain relief lasting an average of 7.6 hours. Difficulty in performing activities of daily living decreased from 7.3 to 4.2. There were notable improvements in sitting longer (54%), standing longer (53%), and walking farther (54%).

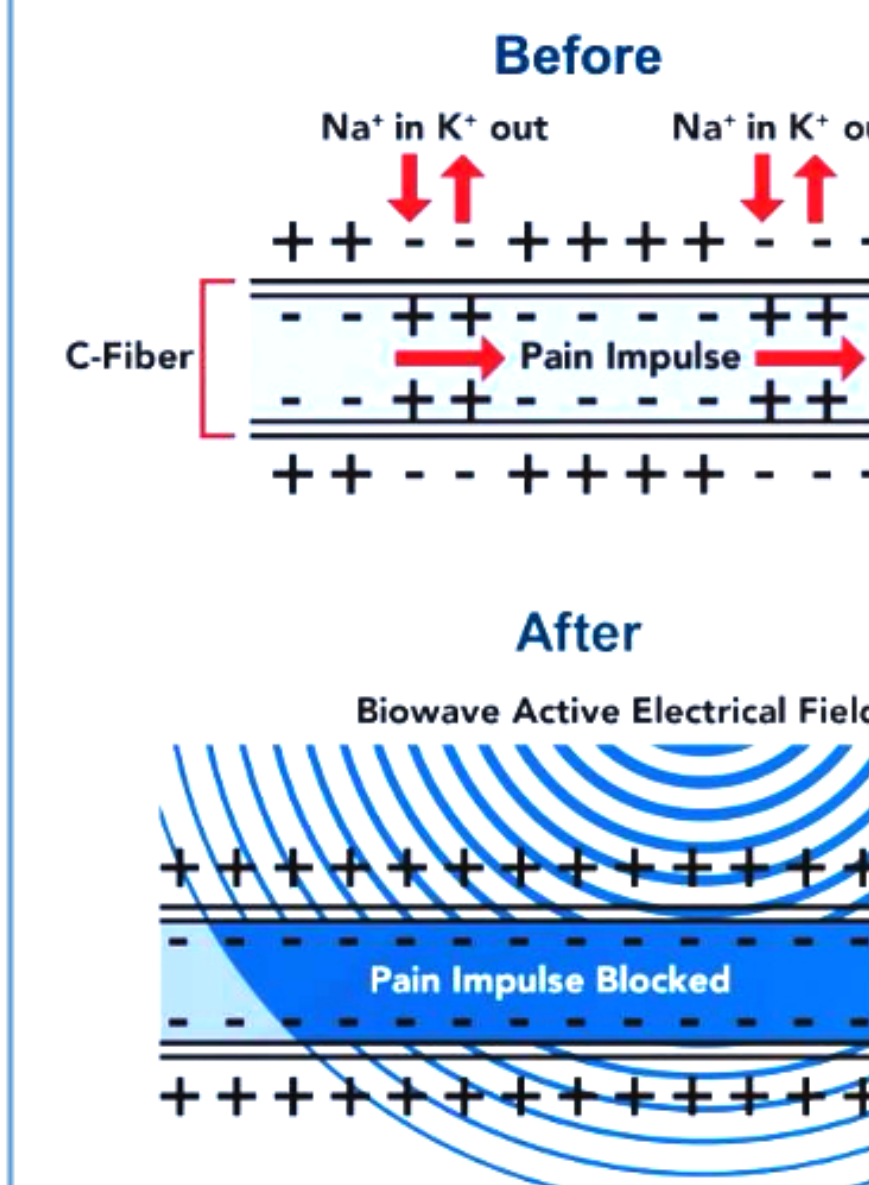


Quality of life improved in 93% of patients, with 56% reporting better sleep and 65% noting improved mood. Additionally, 43% reduced or eliminated analgesic medications.



An overwhelming 97% of patients expressed willingness to continue neurostimulation treatment with the patented device. Among 2,917 online reviews, the average satisfaction score was 4.9 out of 5, indicating exceptionally high patient satisfaction.

Mechanisms of Action



Active electrical field forms at the surface of nerves in a 3" diameter hemisphere beneath both electrodes and is effective at blocking both nociceptive and neuropathic pain.

Hyperpolarization of C Fibers

- Active electrical field inhibits sodium-potassium ion exchange across the membrane of C-fibers preventing action potential propagation

Hypoesthesia is induced on A-delta Fibers

- Hypoesthesia is induced 5 min into the treatment
- Light numbness last for up to 30 minutes following a 30 minute treatment

OTHER BENEFITS

- Blood flow is accelerated through volume of tissue** in hemisphere where active electrical field is present
- Muscle tissue is held in tension** during treatment. As a result, the treatment feels like a deep smooth pressure sensation and is much more comfortable than other forms of electrical stim (IFC, NMES, TENS), so patient compliance is excellent.
- Long carry over effect following treatment** is from more efficient production of endogenous opiates – endorphins, enkephalins, serotonin

DISCUSSION

Neuromodulation for chronic pain management has a history spanning more than five decades, with a primary emphasis on implantable devices designed to deliver spinal cord (dorsal column) stimulation and dorsal root ganglion stimulation. Systematic reviews, including Cochrane analyses, have raised questions regarding the long-term efficacy and cost-effectiveness of these implantable technologies. More recently, interest has grown in implantable peripheral nerve stimulation, targeting not only axial back pain but also various regional targets in the limbs, head and neck, and torso. Several approaches employ needle electrodes placed in proximity to peripheral nerves or in subcutaneous tissue to deliver targeted peripheral nerve stimulation or peripheral field stimulation. Implantable neuromodulation represents a high-cost therapeutic modality, currently available to only a minority of patients with moderate to severe chronic pain. Non-invasive stimulation technologies have advanced, including the use of high-frequency signals that improve tissue penetration and engage broader neural pathways beyond what conventional transcutaneous electric nerve stimulation (TENS) devices can achieve.

We advocate the use of non-invasive peripheral neurostimulation for chronic pain management as a first-line option in domiciliary settings, prior to consideration of ablative procedures, invasive neurostimulation, implantable devices, or long-term opioid therapy.

Adoption of this approach could facilitate broader stakeholder involvement in patient selection for implantable technologies, potentially enhancing clinical outcomes and achieving costsavings.

CONCLUSIONS

Non-invasive peripheral neurostimulation may offer efficacious, sustainable, and cost-effective management of diverse chronic pain conditions. Delivered at home or in primary care, this modality can expand access to neurostimulation and serve as an effective screening tool to assess suitability for implantable devices in conditions such as low back pain, sciatica, arthralgia, and pelvic pain. Further controlled studies are warranted to define patient selection criteria and long-term outcomes.

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