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ORIGINAL RESEARCH

H-Wave® Device Stimulation for Chronic Neck Pain: A Patient-Reported Outcome Measures (PROMs) Study

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ABSTRACT

***Introduction*:** Chronic neck pain (cNP) is one of the leading causes of disability worldwide, often being refractory to conventional forms of treatment. Various forms of electrical stimulation have been proposed to decrease pain and improve function. Patient-reported outcome measures (PROMs) for treatment of cNP have rarely been published.

***Methods*:** An independent retrospective statistical analysis of PROMs data for users of H-Wave® device stimulation (HWDS), prospectively collected by the device manufacturer over a 4-year period, was conducted. Final surveys for 34,192 pain management patients were filtered for pain chronicity limited to 3–24 months and device use of 22–365 days, resulting in 11,503 patients with "all diagnoses"; this number was further reduced to 1482 patients with cNP, sprain, or strain.

***Results*:** Neck pain was reduced by 3.13 points (0–10 pain scale), with significant (≥ 20%) relief in 86.6%. Function/activities of daily living (ADL) improved in 96.19%, while improved work performance was reported in 84.76%. Medication use decreased or stopped in 65.42% and sleep improved in 60.39%. Over 95% reported having expectations met or exceeded, service satisfaction, and confidence in device use, while no adverse events were reported. Subgroup analyses found positive benefit associations with longer duration of device use.

***Conclusion*:** Near-equivalent outcomes were self-reported by cNP HWDS patients as for (previously published) chronic low back pain (cLBP) patients. HWDS provided effective and safe cNP relief, improvements in function and ADL, along with additional benefits including decreased medication use, better sleep, and improved work performance.

Keywords: Chronic pain; Neck pain; Electrical stimulation; H-Wave®; H-Wave device stimulation; Patient-reported outcome measures; PROMs

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Key Summary Points
H-Wave® device stimulation (HWDS) for chronic neck pain is as safe and effective as previously reported for chronic low back pain.
Over 96% of patients self-reported improvement in function/activities of daily living.
Over 86% reported significant (≥ 20%) pain relief, averaging more than 3 points (0–10, visual analogue scale).
Other demonstrated benefits include decreased medication use, better sleep, and improved work performance.
Longer duration of HWDS use results in better outcomes.

INTRODUCTION

Neck and upper back pain are common musculoskeletal (MSK) disorder symptoms, resulting in functional decline which impacts an individuals' daily life, sleep, and work quality [1, 2]. Neck pain persisting for 3 months or longer, categorized as chronic (cNP), is the fourth leading cause of disability across the globe [1, 2]. Traditional treatment approaches for cNP involve use of pharmacological agents such as non-steroidal anti-inflammatory drugs, steroids, and opiates, while non-pharmacological treatments include temporary bracing, activity modification, physical therapy, chiropractic manipulation, laser therapy, and minimally invasive procedures such as radiofrequency ablation [1, 2]. Many of these conventional treatments either have notable side effects or provide only temporary relief, failing to specifically target the underlying pain generation etiology [3].

Over the past decade, there has been increased interest in applying different forms of electrical stimulation (ES) for neck pain including electrical muscle stimulation (EMS), interferential current (IFC) or therapy (IFT), galvanic current stimulation (GCT) or direct current (DC), percutaneous electrical nerve stimulation (PENS), neuromuscular electrical stimulation (NMES), and transcutaneous electrical nerve stimulation (TENS) [4]. A recent comparative review reported very low-quality evidence and/or limited effectiveness associated with most electrotherapies including EMS, IFC, IFT, GCT, DC, PENS, or NMES for the treatment of cNP [4]. A systematic review of seven randomized controlled trials (651 participants) reported very low-certainty evidence of any outcome differences between TENS, the most widely used form of ES, and sham TENS for reducing cNP [5]. Even for other body areas, most TENS studies have been at best only low-quality evidence, demonstrating short-term marginal pain improvement, with no beneficial effects on patient psychological parameters, physical function, or overall quality of life (QoL) [4, 6]. In contrast, recent studies utilizing H-Wave® device stimulation (HWDS), generally considered as low- to moderate-quality evidence, have consistently demonstrated significant decreases in reported pain and medication usage, as well as improvements in physical function and overall QoL [4, 6–10]. To date, there have been no publications specifically evaluating the efficacy of HWDS for cNP patients.

HWDS is a distinct form of transcutaneous ES, emitting a proprietary, biphasic exponentially decaying waveform [4, 6–10]. An H-Wave® device distributes 0–35 mA current and 0–35 V voltage at ×1000 load with an ultra-long pulse duration of 5000 µs [4, 6–10]. HWDS consists of two treatment components: 2 Hz low-frequency and 60 Hz high-frequency, with two dual modes permitting output of either two high- or two low- or a combination of high- and low-frequency therapies [4, 6–10]. The low-frequency component causes multiple physiological effects including: (1) stimulation of voluntary contraction of small, slow-twitch skeletal red muscle fibers, resulting in (2) non-fatiguing, low-tension contractions; (3) improved blood flow via nitric oxide-mediated vasodilation; (4) angiogenesis; and (5) augmented rhythmic lymphatic vessels drainage, through (6) stimulation of voluntary contraction of smooth muscle fibers, resulting in (7) elimination of fluid waste and proteins from inflammatory sites, leading to (8) restoration of tissue homeostasis [6, 7, 10]. In contrast, the high-frequency component induces significant

analgesic effects, persisting even after treatment termination, through additive suppressive effects on nerve action potentials via sodium channel pump deactivation [6, 7, 10].

Patient-reported outcomes (PROs) denote the status of patients' health condition, including physical, psychological, and well-being [11]. The National Quality Forum (NQF) defines PROs as any description of the condition of a patient's health status, behavior, or experience with treatment that arises straight from the patient, without interpretation of the patient's answer by a clinician or anyone else [12]. PROMs additionally define the actual instrument, metric, or tools utilized [12]. NQF defines PROMs as several tools (e.g., instruments, scales, or single-item measures) that allow administrators, researchers, and others to evaluate patient-reported health status for mental, physical, and social well-being [12]. Although not specifically applicable for this study, PRO-PM (performance measures) is another emerging concept for institutions, involving comparative PROMs for the measurement of clinical value, performance, and quality in healthcare [12]. PROMs and the principles of PRO-PM development are strongly supported by specialty organizations like the American Academy of Orthopaedic Surgeons, being gradually implemented by major health coverage providers including the Centers for Medicare and Medicaid Services for MSK conditions [12, 13].

We hypothesize that HWDS for cNP is safe and efficacious for reduction of pain, improvement in function and sleep quality, and decrease in medication usage. The purpose of this PROMs study is to specifically evaluate the efficacy and safety of HWDS in a large cohort of cNP patients.

METHODS

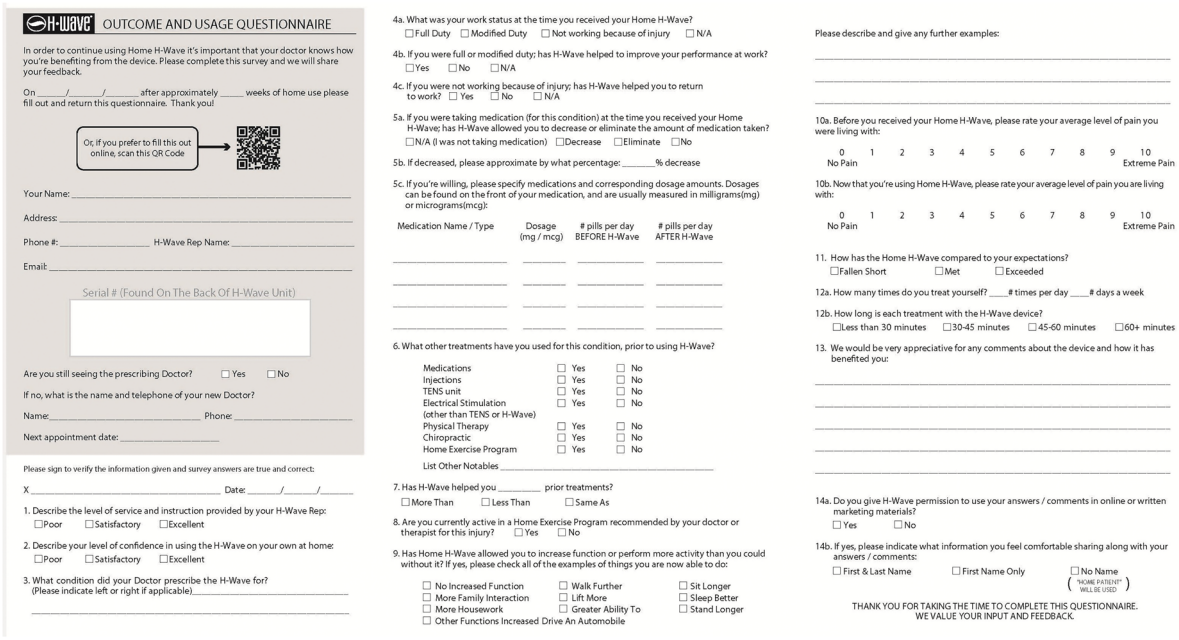
Data Source and Study Design

This is a retrospective analysis of survey data, consisting of several PROMs regularly collected by Electronic Waveform Lab, Inc. (Huntington Beach, CA, USA), of a cohort of 34,192 pain management patients who utilized HWDS for a myriad of conditions. The surveys were consecutively completed over 4 years from January 1, 2019 to December 31, 2022, where no protected health information was reviewed. To avoid duplication, only the latest patient surveys were included and analyzed. This study has been approved by the South Texas Orthopaedic Research Institute Institutional Review Board (number: STORI02272024-1, dated: 2/27/2024). Electronic Waveform Lab, Inc. gave permission for this data to be accessed. The data were de-identified. The participants provided their informed consent for the collected data to be analyzed for publication in a scholarly journal.

The primary focus of this analysis is on patients ≥ 18 years old, prescribed an H-Wave® device for non-specific cNP, reporting symptom chronicity from date of injury until HWDS initiation between 90 and 730 days, duration of HWDS treatment between 22 and 365 days, with diagnoses of neck pain, sprain, or strain (cervicalgia; sprain of joints and ligaments of neck; sprain of ligaments of cervical spine; strain of muscle, fascia and tendons at neck level). Excluded neck region diagnoses included cervical disc disorder, cervical disc degeneration, other specified dorsopathies, spondylosis, segmental and somatic dysfunction, and spondylosis with myelopathy or radiculopathy of the cervical region. Incomplete survey forms were excluded from individual measures analysis. All participants received formal instructions and training on how to properly use an H-Wave® device. Primary study outcome measures include the impact of HWDS on reported pain relief, medication usage reduction, and improvements in activities of daily living (ADL), and sleep. Secondary outcome measures include HWDS effects on work performance, patient satisfaction with service, and patient confidence in device use, as well as patient expectations and preference for HWDS compared to prior treatment.

Data Collection

All participants were asked to answer a predefined set of questions (Fig. 1) related to their HWDS experiences, including effects on function and/or ADL, work performance, pain relief, medication use, work status, prior treatment,


H-Wave OUTCOME AND USAGE QUESTIONNAIRE

In order to continue using Home H-Wave it's important that your doctor knows how you're benefiting from the device. Please complete this survey and we will share your feedback.

On _____/_____/_____ after approximately _____ weeks of home use please fill out and return this questionnaire. Thank you!

Or, if you prefer to fill this out online, scan this QR Code

Your Name: _____

Address: _____

Phone #: _____ H-Wave Rep Name: _____

Email: _____

Serial # (Found On The Back Of H-Wave Unit)

Are you still seeing the prescribing Doctor? ☐ Yes ☐ No

If no, what is the name and telephone of your new Doctor?

Name: _____ Phone: _____

Next appointment date: _____

Please sign to verify the information given and survey answers are true and correct:

X _____ Date: _____/_____/_____

1. Describe the level of service and instruction provided by your H-Wave Rep:
☐Poor ☐Satisfactory ☐Excellent

2. Describe your level of confidence in using the H-Wave on your own at home:
☐Poor ☐Satisfactory ☐Excellent

3. What condition did your Doctor prescribe the H-Wave for?
(Please indicate left or right if applicable)_____

_____

4a. What was your work status at the time you received your Home H-Wave?
☐Full Duty ☐Modified Duty ☐Not working because of injury ☐N/A

4b. If you were full or modified duty; has H-Wave helped to improve your performance at work?
☐Yes ☐No ☐N/A

4c. If you were not working because of injury; has H-Wave helped you to return to work? ☐Yes ☐No ☐N/A

5a. If you were taking medication (for this condition) at the time you received your Home H-Wave; has H-Wave allowed you to decrease or eliminate the amount of medication taken?
☐N/A (I was not taking medication) ☐Decrease ☐Eliminate ☐No

5b. If decreased, please approximate by what percentage: _____% decrease

5c. If you're willing, please specify medications and corresponding dosage amounts. Dosages can be found on the front of your medication, and are usually measured in milligrams(mg) or micrograms(mcg):

Medication Name / Type	Dosage (mg / mcg)	# pills per day BEFORE H-Wave	# pills per day AFTER H-Wave

6. What other treatments have you used for this condition, prior to using H-Wave?

Medications	☐ Yes	☐ No
Injections	☐ Yes	☐ No
TENS unit	☐ Yes	☐ No
Electrical Stimulation (other than TENS or H-Wave)	☐ Yes	☐ No
Physical Therapy	☐ Yes	☐ No
Chiropractic	☐ Yes	☐ No
Home Exercise Program	☐ Yes	☐ No

List Other Notables _____

7. Has H-Wave helped you _____ prior treatments?
☐More Than ☐Less Than ☐Same As

8. Are you currently active in a Home Exercise Program recommended by your doctor or therapist for this injury? ☐Yes ☐No

9. Has Home H-Wave allowed you to increase function or perform more activity than you could without it? If yes, please check all of the examples of things you are now able to do:

☐ No Increased Function ☐ Walk Further ☐ Sit Longer
☐ More Family Interaction ☐ Lift More ☐ Sleep Better
☐ More Housework ☐ Greater Ability To ☐ Stand Longer
☐ Other Functions Increased Drive An Automobile

Please describe and give any further examples:

_____

_____

_____

10a. Before you received your Home H-Wave, please rate your average level of pain you were living with:

0 1 2 3 4 5 6 7 8 9 10
No Pain Extreme Pain

10b. Now that you're using Home H-Wave, please rate your average level of pain you are living with:

0 1 2 3 4 5 6 7 8 9 10
No Pain Extreme Pain

11. How has the Home H-Wave compared to your expectations?
☐Fallen Short ☐Met ☐Exceeded

12a. How many times do you treat yourself? ____# times per day ____# days a week

12b. How long is each treatment with the H-Wave device?
☐Less than 30 minutes ☐30-45 minutes ☐45-60 minutes ☐60+ minutes

13. We would be very appreciative for any comments about the device and how it has benefited you:

_____

_____

_____

_____

_____

14a. Do you give H-Wave permission to use your answers / comments in online or written marketing materials?
☐Yes ☐No

14b. If yes, please indicate what information you feel comfortable sharing along with your answers / comments:
☐First & Last Name ☐First Name Only ☐No Name ("HOME PATIENT" WILL BE USED)

THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE.
WE VALUE YOUR INPUT AND FEEDBACK.

Fig. 1 H-Wave® outcome and usage questionnaire

satisfaction on service, confidence with device use, expectations, and sleep improvement. Patient characteristics, including age when injured, gender, duration of pain chronicity, and duration of HWDS usage, were also recorded and entered in the database. The survey completed by each study patient was proprietary for HWDS, containing key components of validated PROMs, including Visual Analogue Scale (VAS, 1–10) for pain and Oswestry Disability Index (ODI) for function. Of the 34,192 surveys, some patients had completed multiple surveys (between 2 and 7). For uniformity and to avoid duplication, only a single final survey completed was included for the purpose of this study. Any duplicate or missing data survey responses were also omitted before conducting the analyses.

Statistical Analysis

The data analysis involved the preliminary univariate, distributional analyses, correlation/association analyses, contingency table analyses, and the application of multiple logistic and linear regression techniques on all patient covariates collected to evaluate the efficacy of HWDS treatment. The stepwise model selection technique was used to obtain a parsimonious and statistically significant model (at 5% level of significance). The statistical programming language, R, along with SAS JMP, were used for the data preprocessing and analysis. When performing the linear regressions with the stepwise model selection techniques, model diagnostics and assessments were also conducted to check the normality assumption of the residuals.

RESULTS

Cohort and Exclusion

Of 34,192 survey respondents, 1482 patients met the inclusion and exclusion criteria and were included in this cNP study (Fig. 2).

The distribution for gender was uniform, with 42.85% males and 57.15% females. The average age (± standard deviation) when injured and when treated with HWDS were 45.96 ± 12.63 and 46.74 ± 12.67 years, respectively. The average duration of pain chronicity and H-Wave® device usage was 285.94 ± 173.93

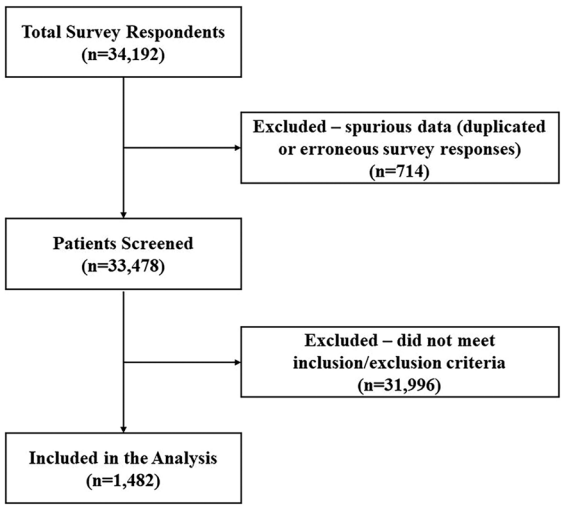


Fig. 2 Inclusion/exclusion flow diagram

Table 1 Characteristics of H-Wave® device stimulation (HWDS) intervention cohort

Characteristics	Proportion/ mean ± standard deviation
Gender	
Male	635 (42.85%)
Female	847 (57.15%)
Age when injured	45.96 ± 12.63 years
Age when treated with HWDS	46.74 ± 12.67 years
Duration of pain chronicity	285.94 ± 173.93 days
Duration of HWDS usage	97.67 ± 64.05 days

and 97.67 ± 64.05 days, respectively. These data are summarized in Table 1.

Device Usage

Of 1482 patients, 1440 reported using the device almost twice daily (1.84 ± 0.04) and 1438 reported using it for almost 5.5 days/week (5.40 ± 1.72). Of 1465 patients, over half (54.68%) used the device for sessions lasting 30–45 min.

Insurance Mix

This cNP study cohort involved workers' compensation (n = 784, 52.90%), personal injury (n = 499, 33.67%), auto-injury (n = 198, 13.36%), and Tricare (n = 1, 0.07%) claimants.

Concomitant Home Exercise Program

Of 1431 patients, two-thirds (n = 960, 67.09%) reported active involvement in a home exercise program, while the rest (n = 471, 32.91%) did not.

Safety

No adverse or severe adverse events associated with HWDS use were reported by any study participant throughout the duration of the study.

Primary Outcome Measures

Pain Reduction

The pre-treatment VAS score reported for 1472 patients was 7.47 ± 1.88 [95% confidence interval (CI): 7.37, 7.56), whereas the post-treatment score reported for 1467 was 4.33 ± 2.17 (95% CI: 4.22, 4.44). The difference between the pre-treatment and post-treatment scores reported for 1465 patients was 3.13 ± 1.88 (95% CI: 3.03, 3.23). A difference of 3 or more points in VAS score was found to be statistically significant (p = 0.004) (Fig. 3; Table 2). Approximately 50% (n = 424) of HWDS patients reported their pre-treatment VAS score to be 8 or higher, which dropped to 5 or less post-treatment.

Applying 20% pain reduction as a liberal estimate for minimal clinically important difference (MCID), of 1482 patients, 1283 (86.6%) reported pain relief of at least 20% compared to their baseline (p < 0.0001) (Fig. 4).

Function/ADL Improvement

Of 1418 patients (after exclusion of 64 missing survey data), 1364 (96.19%) reported statistically

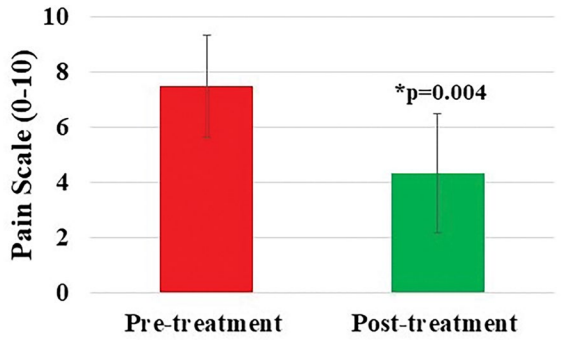


Fig. 3 Pain reduction post-treatment with H-Wave® device stimulation. A difference of 3 or more points was statistically significant ($p = 0.004$)

significant improvement ($p < 0.0001$) in function/ADL after treatment with HWDS (Fig. 5; Table 2).

Medication Usage Decrease

Of 1128 patients (after exclusion of 354 missing survey data), 738 (65.42%) reported statistically significant ($p < 0.0001$) decrease or elimination of pain medications usage. Specifically, 621 patients (55.05%) decreased and 117 (10.37%) completely stopped use of pain medications (Fig. 6; Table 2).

Sleep Improvement

Of 1482 patients, 895 (60.39%) reported statistically significant ($p < 0.0001$) improvement in their sleep quality (Fig. 7; Table 2).

Secondary Outcome Measures

Work Status and Performance

Of 1308 patients (after exclusion of 174 missing survey data), almost half (649, 49.62%) were not working when starting HWDS treatment, while 323 (24.69%) were doing modified work and 336 (25.69%) were fully working. Of the 649 patients who were not working, 390 specifically reported their injury to be the reason. Of these 390 off-work patients, 164 (42.05%) reported that HWDS had helped them return to work.

Of the 597 patients (after exclusion of 62 missing survey data) on full or modified duty, 506 (84.76%) reported statistically significant ($p < 0.0001$) improvement in their work performance after treatment with HWDS (Fig. 8; Table 2). Further subgroup analysis demonstrated that HWDS is more likely to improve work performance in individuals whose pain level was reduced by at least 20% following treatment with HWDS (odds ratio = 5.918; 95% CI 3.108, 11.112).

Prior Treatment and Preference for HWDS

Of 1482 patients, almost all (1464, 98.78%) reported use of other treatment modalities prior to starting HWDS ($p < 0.0001$). Of 1419 patients (after exclusion of 63 missing survey data), 915 (64.48%) reported that HWDS helped them significantly ($p < 0.0001$) more than prior treatments, whereas 475 (33.47%) reported similar efficacy and only 29 (2.04%) reported less effectiveness (Table 2).

Patient Expectations

Of 1418 patients (after exclusion of 64 missing survey data), 1359 (95.84%) reported that HWDS use exceeded or met their expectations. Specifically, 503 patients (35.47%) reported exceeded and 856 (60.37%) reported met expectations, being statistically significant ($p < 0.0001$) compared to those whose expectations were not met (Fig. 9; Table 2).

Patient Satisfaction with Service

Of 1432 patients (after exclusion of 50 missing survey data), 1427 (99.65%) reported that service provided by H-Wave® team was excellent or satisfactory. Specifically, 1228 patients (85.75%) reported excellent and 199 (13.90%) reported satisfactory service, being statistically significant ($p < 0.0001$) compared to those who reported poor service (Fig. 10; Table 2).

Patient Confidence in Device Use

Of 1432 patients (after exclusion of 50 missing survey data), 1420 (99.16%) reported

Table 2 Analysis of primary and secondary outcome measures

Outcome measures		Parameter	Value	*p* value (description)
Primary outcome measures	Pain	Pre-treatment score	1472 patients (7.47 ± 1.88)	0.004* (difference)
		Post-treatment score	1467 patients (4.33 ± 2.17)	
		Difference	1465 patients (3.13 ± 1.88)	
	Function/ADL	Yes	1364 patients (96.19%)	< 0.0001*
		No	54 patients (3.81%)	
	Medication usage	Eliminated	117 patients (10.37%)	< 0.0001* (decreased + eliminated vs. no effect)
		Decreased	621 patients (55.05%)	
		No effect	390 patients (34.57%)	
	Sleep improvement	Yes	895 patients (60.39%)	< 0.0001*
		No	587 patients (39.61%)	
Secondary outcome measures	Work performance	Yes	506 patients (84.76%)	< 0.0001*
		No	91 patients (15.24%)	
	Preference for HWDS compared to prior treatment	More	915 patients (64.48%)	< 0.0001* (HWDS vs. prior treatments)
		Same	475 patients (33.47%)	
		Less	29 patients (2.04%)	
	Patient expectation	Exceeded	503 patients (35.47%)	< 0.0001* (exceeded or met vs. fallen short)
		Met	856 patients (60.37%)	
		Fallen short	59 patients (4.16%)	
	Patient satisfaction on service	Excellent	1228 patients (85.75%)	< 0.0001* (excellent or satisfactory vs. poor)
		Satisfactory	199 patients (13.90%)	
		Poor	5 patients (0.35%)	
	Patient confidence on device use	Excellent	1097 patients (76.60%)	< 0.0001* (excellent or satisfactory vs. poor)
		Satisfactory	323 patients (22.56%)	
		Poor	12 patients (0.84%)	

*Demonstrates statistical significance

their confidence in device usage to be excellent or satisfactory. Specifically, 1097 patients (76.60%) reported excellent and 323 (22.56%) reported satisfactory confidence in device use, being statistically significant ($p < 0.0001$)

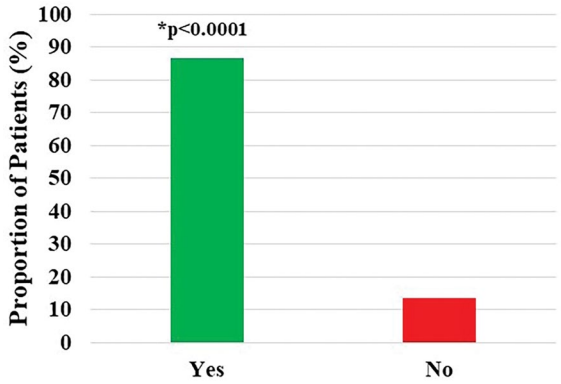


Fig. 4 Pain relief of at least 20% post-treatment with H-Wave® device stimulation, which was statistically significant ($p < 0.0001$)

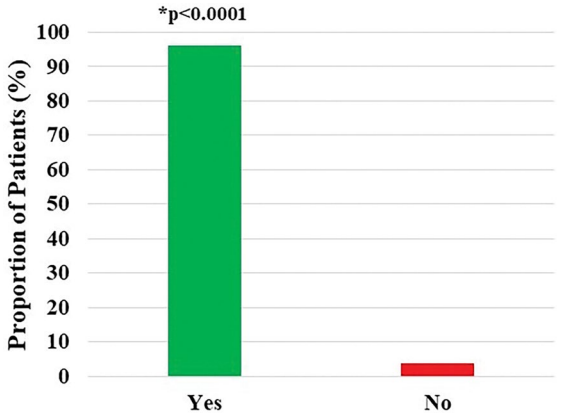


Fig. 5 Improvement in function/ADL post-treatment with H-Wave® device stimulation, which was statistically significant ($p < 0.0001$)

compared to those who reported poor confidence (Fig. 11; Table 2).

Outcomes Based on Treatment Length Periods

Survey patients were further stratified into three subgroups based on number of days they used HWDS, with a "trial period" ranging from 22 to 35 days (3–5 weeks), an "early treatment period" from 36 to 98 days (5–14 weeks), and a "late treatment period" from 99 to 365 days (14–52 weeks). Sample size in the trial period, early treatment period, and late treatment

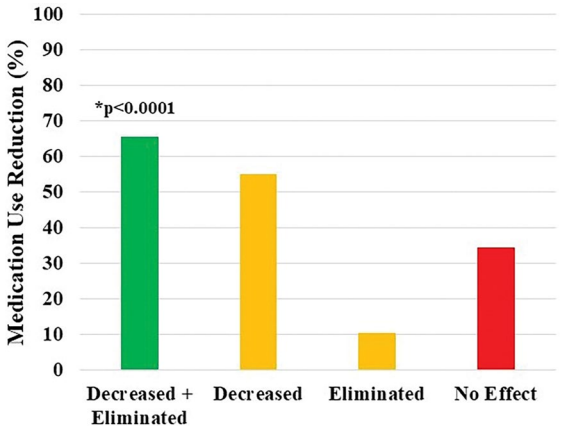


Fig. 6 Decrease or elimination in use of pain medications post-treatment with H-Wave® device stimulation. Decreased + eliminated versus no effect was statistically significant ($p < 0.0001$)

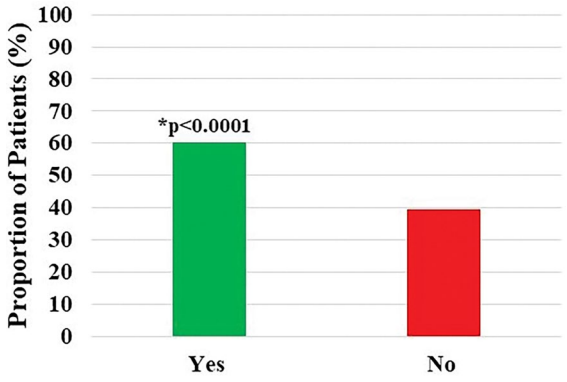


Fig. 7 Improvement in quality of sleep post-treatment with H-Wave® device stimulation, which was statistically significant ($p < 0.0001$)

period included 373 (25.46%), 333 (22.73%), and 759 (51.81%) patients, respectively.

Subgroup comparison analysis results were generally consistent without any major deviation, although using the device for longer periods resulted in better outcomes of pain relief, medication elimination, sleep improvement, and work performance (Table 3).

These observations were confirmed with statistical significance by supplementary multiple regression analyses, where duration of device usage, participation in a home exercise program, and full or modified work are all vital positive

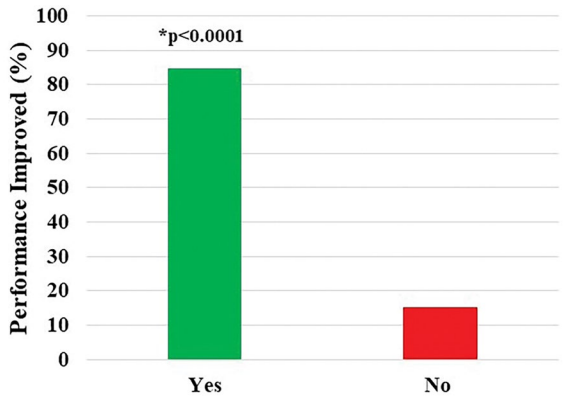


Fig. 8 Improvement in work performance in patients on full or modified duty post-treatment with H-Wave® device stimulation, which was statistically significant ($p < 0.0001$)

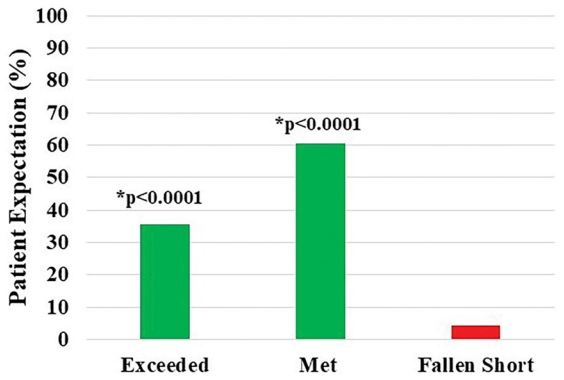


Fig. 9 Level of patient expectations, where the proportion reporting H-Wave® device stimulation either exceeded or met expectations was statistically significant ($p < 0.0001$)

variables to consider when evaluating the efficacy of HWDS. Negative variables to consider include longer pain chronicity and older patient age when injured. Specific statistically significant inferences of interest include the following:

- Longer device usage results in more pain relief ($p < 0.0001$).
- Pain reduction is better for those working than not working ($p = 0.0046$).
- A higher pain level prior to the treatment is related to more significant pain relief ($p < 0.0001$).
- Longer pain chronicity leads to less pain reduction ($p < 0.0001$).

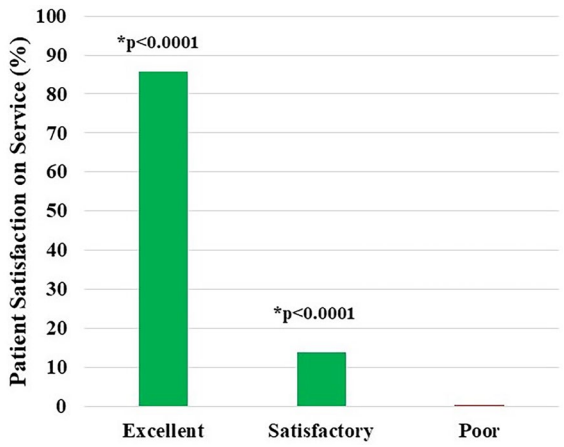


Fig. 10 Level of patient satisfaction with service, where the proportion reporting H-Wave® device stimulation instruction to be excellent or satisfactory was statistically significant ($p < 0.0001$)

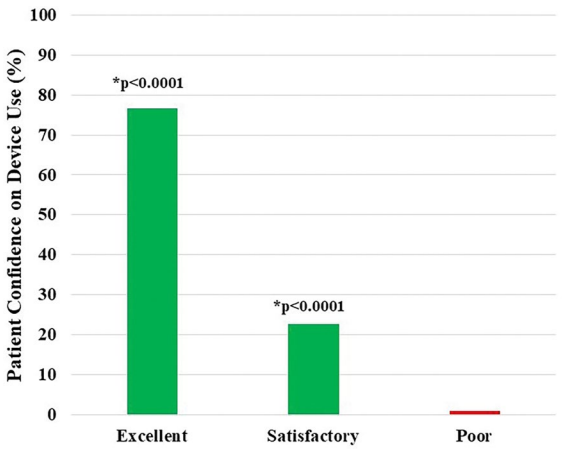


Fig. 11 Level of patient confidence in device use, where the proportion reporting H-Wave® device stimulation use on their own being excellent or satisfactory was statistically significant ($p < 0.0001$)

DISCUSSION

The value of PROMs studies has been highlighted here and in a previously published HWDS study on treatment of non-specific chronic low back pain (cLBP), which noted the advantages of relative objectivity and reduction of biases derived from outcomes data collected directly from patients without coercion or

Table 3 Effect of treatment duration on outcome measures

Outcome measures	Parameter	Trial period	Early treatment period	Late treatment period
Pain relief (pre-/post-treatment score difference)	Average ± SD	2.65 ± 1.76	2.82 ± 1.75	3.50 ± 1.92
	95% interval	(2.47, 2.83)	(2.64, 3.01)	(3.36, 3.64)
	Sample size	373	333	759
Medication usage (%)	Eliminated	3.87	8.37	14.34
	Decreased	58.10	50.99	55.31
	No effect	38.03	40.64	30.35
Sleep improvement (%)	Yes	54.23	53.41	66.49
	No	45.77	46.59	33.51
Work performance (%)	Yes	83.11	80.14	87.66
	No	16.89	19.86	12.34

manipulation [10]. PROMs analyses have been steadily gaining favor among clinical investigators, and, when performed in good faith, add moderate-quality research value to the current peer-reviewed literature.

With the recent publication of similar PROMs data, derived from the same core dataset, albeit for cLBP, some comparisons can now be considered [10]. The cLBP study included 2711 patients with chronic low back pain, sprain, or strain, compared to similar diagnoses for 1482 cNP patients.

The authors questioned if any outcomes would be much different if the single variable of pain chronicity were extended to 3 years, rather than the 2 years being reported for both cNP and cLBP. All cNP outcomes turned out to be essentially equivalent, with the expected exceptions that 3-year pain chronicity increased from 286 to 351 days and the number of surveyed patients increased to 1,657. Positive primary and secondary outcomes for cNP and cLBP were also notably quite similar, with only several minor differences. Females dominated the cNP cohort (57%) but were outnumbered by males (53%) for cLBP. Workers' compensation claimants were 53% for cNP and 64% for cLBP, with 56% of cLBP patients not working, compared to 50% for cNP.

The reporting of similar positive benefits for neck and low back patients is not surprising, given a previous analysis of "All diagnoses" data, for a sizable cohort of 11,503 HWDS patients, using the same 2-year exclusion variables, where all primary and secondary outcomes were nearly equivalent to those for cLBP [10]. It was therefore hypothesized that HWDS would prove to be similarly effective for other body areas and conditions, something now confirmed, at least for cNP.

The patient mix for this 2019–2022 cohort is somewhat unusual for clinical studies, since most research for medical procedures and devices specifically exclude legal claimants and workers' compensation patients, because they are widely considered to be more difficult to treat and study outcomes are generally worse. Many studies have indicated that workers' compensation status is a negative risk factor for outcomes after spine injuries and spine surgery [14]. As such, these encouraging outcomes in a cohort consisting primarily of "claimants", a particularly important concept for vehicular neck injuries, are compelling. These outcomes are consistent and better than previously reported H-Wave® positive outcomes in "end-stage" workers' compensation claimants with mean pain chronicity approaching 8 years [9].

HWDS for cNP resulted in pain reduction of over 3 (3.13) on a scale of 10, compared to TENS reports of less than 1 on a scale of 10 (0.884), which is generally regarded as clinically significant [10]. Over 86% of cNP patients reported significant (≥ 20%) pain relief. While the selection of 20% or more being considered significant may seem arbitrary, given that TENS results in about 10% VAS improvement, this higher conservative standard represents an order of magnitude greater pain relief. The value of MCID for PROMs, while touted to numerically express both extent of improvement and the value that patients place on it, has been strongly questioned due to wide-ranging thresholds obtained with different methodologies, resulting in large heterogeneity in reporting standards [15]. Attempts at MCID determinations for VAS have varied widely, although regarding acute post-operative pain relief as an example, analgesic interventions resulting in a change of 1.0/10.0 VAS signify MCID, even though VAS improvement of 3.3 represents what patients would consider to be acceptable pain control following surgery [16].

Improvements in function and ADL in over 96% of this cNP cohort is entirely consistent with previous HWDS studies, as is work performance improvement in almost 85% of those working [7–10]. Over 65% either decreased or stopped the use of pain medications, while sleep improvement was reported in over 60%. HWDS cNP patient satisfaction is quite high, in the upper 90th percentile, as reported for meeting expectations, service satisfaction, and device confidence.

In spite of the large cohort size and high turnout rate, this study is not without limitations. These include retrospective data analysis, narrow patient selection (claimants), lack of a control group, and some risk of selection bias. Additionally, using a partially unvalidated proprietary survey instrument and lack of longitudinal individual patient assessments over time, could possibly be improved in future studies.

CONCLUSIONS

PROMs data, consecutively collected from cNP HWDS users over a 4-year period, have been demonstrated to be notably just as positive as those from cLBP patients [10], as well as being similar to previous HWDS study outcomes [7–9]. Significant pain relief of 20% or more was reported in over 86% of cNP patients, with greater than 3-point reduction in pain on a scale of 0–10. Function and ADLs increased in over 96%, while work performance improved in almost 85% of working survey participants. Pain medication use decreased or stopped in two out of three, while sleep improved in over 60% of HWDS patients (Fig. 12). Almost all of those surveyed reported confidence in device use (99.16%) and service satisfaction (99.65%), as well as having expectations met or exceeded (95.84%).

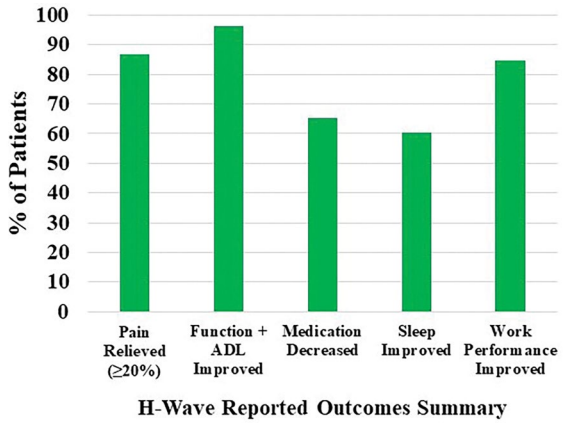


Fig. 12 Summary of H-Wave® device stimulation reported outcomes in chronic neck pain patients

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Author Contributions. Ashim Gupta and Stephen M. Norwood conceptualized the study.

Statistical analysis was performed by David Han. The first draft of the manuscript was written by Ashim Gupta and Stephen M. Norwood. Ashim Gupta, David Han and Stephen M. Norwood commented on the previous versions of the manuscript. Ashim Gupta supervised and administered the project. All authors read and approved the final manuscript.

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Declarations

Conflict of Interest. Ashim Gupta and Stephen M. Norwood are consultants for Electronic Waveform Lab, Inc. David Han has nothing to disclose.

Ethical Approval. This study was approved by the South Texas Orthopaedic Research Institute Institutional Review Board (number: STORI02272024-1, dated: 2/27/2024). Electronic Waveform Lab, Inc. gave permission for this data to be accessed. The data was de-identified. The participants provided their informed consent for the collected data to be analyzed for publication in a scholarly journal.

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