Geko™ system to predict peripheral nerve stimulation: reality or fantasy? A prospective pilot study

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Abstract

Peripheral nerve stimulation (PNS) is an established therapy for chronic pain refractory to conventional treatments. Wearable devices such as the geko™ system, originally developed to enhance lower limb circulation, may have potential as non-invasive screening tools to predict PNS candidacy.

The present prospective, uncontrolled pilot study aimed to evaluate the feasibility of using the geko™ device for predicting responsiveness to implanted PNS in patients with refractory chronic pain.

Twenty patients with refractory chronic pain were treated with low-frequency common peroneal nerve stimulation (1 Hz, 6 hours/day) for 10 consecutive days using the geko™ device. Outcomes included Numeric Rating Scale (NRS) pain scores, quality of life (QoL), oxygen saturation index (SpO_2), and patient satisfaction. The primary endpoint was defined as the proportion of patients achieving a reduction of ≥50% in NRS scores. Statistical significance was evaluated using paired t-tests ($p<0.05$).

Treatment led to significant improvements in pain, SpO_2, and QoL. Half of the patients achieved the primary endpoint, and no serious adverse events were reported. The satisfaction rate among completed cases was 100%.

The geko™ device shows promise as a non-invasive screening tool for PNS candidacy. These results should be interpreted cautiously, given the small sample size, lack of a control group, and exploratory design. Larger, controlled trials are warranted.

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Introduction

Chronic pain, particularly neuropathic pain, affects an estimated 20% of the European adult population, with neuropathic pain comprising 7-10% of these cases. It imposes a heavy burden on quality of life, functional ability, and socioeconomic costs.[1,2]

Conventional therapies, including pharmacological treatments (*e.g.*, NSAIDs, opioids, antidepressants), physical rehabilitation, and nerve blocks, often provide insufficient relief. Consequently, advanced therapeutic modalities, such as peripheral nerve stimulation (PNS), have gained traction due to their ability to modulate pain pathways, improve functional outcomes, and reduce reliance on systemic medications.

PNS involves the application of electrical impulses to specific peripheral nerves to alleviate pain and improve circulation. Traditional systems have required surgical implantation of leads and pulse generators, limiting their use to carefully selected candidates due to invasiveness and cost. However, recent innovations, such as low-frequency nerve stimulation (LFNS) delivered through wearable devices like the geko™ system, offer a minimally invasive alternative.[3,4] These technologies have demonstrated benefits in enhancing local blood flow, reducing edema, and modulating nociceptive signaling, particularly in the context of wound healing and neurovascular dysfunction.[5]

The geko™ device is designed to stimulate the common peroneal nerve transcutaneously, promoting microcirculation and triggering involuntary muscle contractions. Given its ease of use, portability, and minimal interference with daily activities, it is being explored as a tool not only for therapy but also for predicting responsiveness to implanted neurostimulation.[6]

This pilot study aims to assess the feasibility of using the geko™ device to predict patient response to PNS, while acknowledging its exploratory nature and methodological limitations.

Materials and Methods

This was a prospective, uncontrolled pilot study conducted at Rovereto Hospital, Italy. Ethics approval was obtained from the

Table 1. Bar chart comparing pre- and post-treatment values for NRS, QoL, and SpO_2. Notable improvements are observed in all domains following the use of the geko™ device.

Outcome	Baseline (mean±SD)	Day 10 (mean±SD)	p-value
NRS pain score	7.4±1.2	4.1±1.5	0.002
QoL (0-100)	48.5±12.3	65.4±10.7	0.03
SpO_2 (%)	94.2±2.1	96.8±1.7	0.01

SD, standard deviation; NRS, Numeric Rating Scale; QoL, quality of life; SpO_2, oxygen saturation index.

institutional review board, and all participants provided written informed consent.

Inclusion criteria were: age ≥18 years; diagnosis of refractory chronic pain for >6 months; and inadequate relief from ≥2 prior conventional treatments.

Exclusion criteria were: pregnancy; presence of a cardiac pacemaker; active skin infection at the intended electrode placement site; and severe cognitive impairment.

Twenty patients underwent common peroneal nerve stimulation (geko™ device, 1 Hz) for 6 hours/day over 10 consecutive days. Numeric Rating Scale (NRS) pain scores, quality of life (QoL, 0-100 scale), oxygen saturation index (SpO_2), and satisfaction (4-point Likert scale) were recorded at baseline and day 10. The primary endpoint was defined as a ≥50% reduction in NRS pain scores.

Statistical analysis was performed using paired *t*-tests for normally distributed data and the Wilcoxon signed-rank test for non-normally distributed data. A p-value of <0.05 was considered statistically significant.

Results

The mean age of the participants was 57.4±11.2 years, with 12 females and 8 males. The average duration of pain was 4.8±2.1 years. Etiologies varied, including neuropathic pain following surgery (n=8), peripheral neuropathy (n=6), complex regional pain syndrome (n=4), and post-traumatic nerve injury (n=2).

At baseline, the mean NRS score was 7.4±1.2, which decreased to 4.1±1.5 by day 10 (p=0.002). QoL scores improved from 48.5±12.3 at baseline to 65.4±10.7 (p=0.03). SpO_2 also increased from 94.2%±2.1 to 96.8%±1.7 (p=0.01) (Table 1).

Half of the patients (10 out of 20) achieved the primary endpoint. Two patients discontinued treatment early due to local discomfort, while no serious adverse events were reported.

Discussion

This pilot study suggests that the geko™ device, when applied to the common peroneal nerve, may offer early insight into potential responsiveness to PNS. Improvements in pain, oxygenation, and QoL were observed, and the device was well tolerated. However, the absence of a control group limits causal inferences. The placebo effect in chronic pain studies can be substantial, and future work should incorporate sham-controlled designs. Furthermore, the small sample size and short follow-up preclude definitive conclusions. Despite these limitations, our findings support further investigation into wearable neurostimulation as a step toward more personalized neuromodulation strategies.

Conclusions

Stimulation of the peroneal nerve using LFNS with the geko™ device may represent a comfortable and practical method to preliminarily assess potential responsiveness to PNS. The observed improvements in oxygenation and pain relief suggest a possible role in identifying suitable candidates for neurostimulation.

Importantly, this study explores a novel application of the geko™ device, not solely as a therapeutic modality, but as an accessible, non-invasive tool to support clinical decision-making in PNS implantation. The wearable nature of the device, combined with its capacity to mimic some mechanisms of implanted stimulation, offers clinicians a pragmatic way to gather early patient response data. However, these findings should be interpreted within the limitations of this small, uncontrolled pilot study. Validation in larger, randomized controlled cohorts is required before considering integration into standard patient selection protocols.

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