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## ORIGINAL ARTICLE

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# Transcutaneous Electrical Nerve Stimulation for Phantom Pain and Stump Pain in Adult Amputees

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Matthew R. Mulvey, PhD<sup>\*,†</sup>; Helen E. Radford, BSc<sup>†,‡</sup>; Helen J. Fawkner, PhD<sup>\*,†</sup>; Lynn Hirst, BSc<sup>‡</sup>; Vera Neumann, MD<sup>‡</sup>; Mark I. Johnson, PhD<sup>\*,†</sup>

*\*Faculty of Health and Social Sciences, Leeds Metropolitan University, Leeds, U.K.;*

*†Leeds Pallium Research Group; ‡Leeds Teaching Hospitals NHS Trust*

■ **Abstract:** Following amputation, 50% to 90% of individuals experience phantom and/or stump pain. Transcutaneous electrical nerve stimulation (TENS) may prove to be a useful adjunct analgesic intervention, although a recent systematic review was unable to judge effectiveness owing to lack of quality evidence. The aim of this pilot study was to gather data on the effect of TENS on phantom pain and stump pain at rest and on movement. Ten individuals with a transtibial amputation and persistent moderate-to-severe phantom and/or stump pain were recruited. Inclusion criteria was a baseline pain score of  $\geq 3$  using 0 to 10 numerical rating scale (NRS). TENS was applied for 60 minutes to generate a strong but comfortable TENS sensation at the site of stump pain or projected into the site of phantom pain. Outcomes at rest and on movement before and during TENS at 30 minutes and 60 minutes were changes in the intensities of pain, nonpainful phantom sensation, and prosthesis embodiment. Mean (SD) pain intensity scores were reduced by 1.8 (1.6) at rest ( $P < 0.05$ ) and 3.9 (1.9) on movement

( $P < 0.05$ ) after 60 minutes of TENS. For five participants, it was possible to project TENS sensation into the phantom limb by placing the electrodes over transected afferent nerves. Nonpainful phantom sensations and prosthesis embodiment remained unchanged. This study has demonstrated that TENS has potential for reducing phantom pain and stump pain at rest and on movement. Projecting TENS sensation into the phantom limb might facilitate perceptual embodiment of prosthetic limbs. The findings support the delivery of a feasibility trial. ■

**Key Words:** transcutaneous electric nerve stimulation, phantom limb pain, stump pain, analgesia, neuralgia, stump, prosthesis embodiment

## INTRODUCTION

Over 77% of pain specialists use transcutaneous electrical nerve stimulation (TENS) to manage chronic pain, and over half of chronic pain patients given TENS report that they find it beneficial and wish to continue using it.<sup>1</sup> TENS is recommended as a non-pharmacological treatment for phantom pain and stump pain,<sup>2-6</sup> yet a recent Cochrane review conducted by our team failed to find any randomised controlled trials. We concluded that there was insufficient evidence to judge TENS effectiveness in this setting.<sup>7</sup> Contralateral stimulation sites were used because of concerns that TENS may exacerbate pain in

Address correspondence and reprint requests to: Prof Mark I. Johnson, PhD, Faculty of Health and Social Sciences, Leeds Metropolitan University, Civic Quarter, Leeds LS1 3HE, U.K. E-mail: m.johnson@leedsmet.ac.uk.

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individuals with tactile allodynia associated with stump neuromas. In addition, there are concerns that TENS may cause skin irritation which may affect stump integrity. Published case series have failed to report pain intensity data, and this has prevented the calculation of adequate sample sizes needed for a subsequent clinical trial.<sup>8-10</sup> They also failed to provide adequate information on TENS protocols, safety and tolerability, and satisfaction including potential barriers to use.<sup>7</sup> Moreover, recent literature reviews have called for further investigations into efficacy and mechanisms of nonpharmacological interventions for phantom pain and stump pain, including TENS.<sup>11,12</sup>

It is known that stimulating sensory afferents above the stump can generate sensations of touch, joint movement, and position in the phantom limbs of amputees.<sup>13-17</sup> However, it is unclear whether it is possible to target phantom pains by projecting TENS paresthesia into the phantom limb, using electrodes placed over peripheral nerves in the residual limb. If one can, it is uncertain whether this would reduce or exacerbate phantom limb pain. Moreover, we have previously hypothesized that TENS could be used to facilitate perceptual embodiment of the prosthetic limb (the perceptual awareness of the prosthesis in relation to the body) into the body schema,<sup>18</sup> and initial experimental studies using able-bodied participants and a visuotactile illusion suggest that this is the case.<sup>19</sup> Nevertheless, no clinical data on the use of TENS to aid the perceptual embodiment of prosthetic limbs are available to date.

The aim of this pilot study was to collect data on pain intensity at rest and on movement (primary outcome), perceptual embodiment of the prosthetic limb (at rest and on movement) and tolerability during a 1-hour in-clinic TENS intervention. In addition, data were gathered on recruitment rates from a local NHS Amputee Rehabilitation outpatient Clinic and a Pain Management outpatient clinic in West Yorkshire, U.K.

## METHODS

This was a single-center study of 10 transtibial amputee participants with phantom pain, stump pain, or both. This study received ethical approval from the National Research Ethics Service, Leeds (Central) Research Ethics Committee (REC reference: 08/H1313/66). Participants were identified from local NHS Amputee Rehabilitation and Pain Management Service databases (searched January to November 2009) and approached at their scheduled clinic review.

Participants interested in taking part received an information pack and were contacted via telephone approximately 1 to 4 days later to be formally invited to take part in the study.

Inclusion criteria were average pain of at least 3 of 10 on a numerical rating scale (NRS) during the last month and use of a prosthesis for at least 2 hours, 2 times a week. Exclusion criteria were contraindications to TENS (noncomprehension of instructions, allergic response to electrodes or conductive gel, dermatological lesions, epilepsy),<sup>20</sup> and changes to opioid analgesic medication within 3 days of study visit. Information regarding co-analgesics (such as anticonvulsants or antidepressants) was also collected but participants were not excluded if these had changed within 3 days prior to study visit, as they have minimal immediate effects on pain scores.

The study visit lasted approximately 2 hours and was facilitated by the Principal Investigator (MM). Following written consent, the condition of the skin around the stump was noted for lesions. Participants selected a painful movement that occurred regularly during daily activity, for example, standing up from sitting, standing from lying supine, walking, bending to pick up an object off the floor, or pulling on prosthetic limb socket liner. The optimal TENS electrode placement positions were identified using a process of trial and error which took no longer than 15 minutes. Two TENS electrodes (approximately 5 × 5 cm in size) were placed at various sites above the distal end of the stump in an attempt to project TENS paresthesia to the most painful site, which was either in the stump, phantom limb, or both. Once the optimal location of TENS sensation was established, the TENS device was switched off until the investigator was ready to begin the TENS intervention. Participants were instructed that they may need to adjust TENS amplitude to maintain a strong nonpainful TENS sensation during the 60 minutes intervention. TENS parameters were in line with International Association for the Study of Pain (IASP) recommendations.<sup>21</sup> Conventional TENS settings were chosen which were continuous pulse pattern, pulse duration of 80 μs, pulse frequency of 100 Hz, strong but comfortable intensity.

During the TENS intervention, a Pro-TENS device (Nidd Valley Medical, Knaresborough, U.K.) was switched on and the amplitude of current increased until strong nonpainful TENS sensations (electrical paresthesia) were at the site of pain. TENS was switched off after 60 minutes, and a second stump

observation was performed and any changes in skin condition noted. The following measures were taken at rest and on movement at baseline and at 30 and 60 minutes during the TENS intervention using an 11-point NRS: intensity of phantom pain and/or stump pain (0 = no pain, 10 = worst pain imaginable), intensity of nonpainful phantom limb sensation (0 = no sensations, 10 = strongest sensation imaginable), and intensity of prosthetic limb awareness (0 = no awareness, 10 = strongest awareness imaginable).

A telephone follow-up 48 hours after the study visit was used to gather information about adverse events and changes in concomitant medication. Intensity scores for pain phantom sensation and prosthesis embodiment relative to baseline were calculated for each participant, and a descriptive analysis was performed.

## RESULTS

Fifty-four individuals were invited to take part over an 8-month period. Ten of these individuals agreed to participate (6 women; age range, 22 to 72 years; mean age, 54; SD, 13.8) and all completed the study (Table 1). In the month prior to the study, all 10 participants experienced phantom limb pain, 9 experienced phantom limb sensations, 9 experienced stump pain, and 2 had tactile allodynia on the stump.

Transcutaneous electrical nerve stimulation was tolerated well by all participants. Participants reported no difficulty in using the TENS device or titrating TENS amplitude to produce a strong nonpainful tingling sensation. No adverse events were reported during the 60-minute TENS session or at 48-hour telephone follow-up. Post-TENS stump examination revealed slight reddening of the skin under the electrodes in two participants but this resolved within 5 minutes in both cases. There were no other reports of skin irritation as a result of having electrodes in situ.

### Optimal Electrode Placement

For all participants, it was possible to apply TENS electrodes to the residual limb and project TENS sensation to the most painful site, which was either in the stump ( $n = 5$ ) or in the phantom limb ( $n = 5$ ). This was achieved by applying electrodes below the knee onto the stump for 9 participants. One participant had pain which extended above the knee so electrodes were placed above the knee at the leading edge of the pain. For two participants who reported tactile allodynia,

the electrodes were placed on nonpainful skin either side of the affected area and TENS sensation was projected into the area of pain and allodynia. This method of applying TENS did not exacerbate their pain.

In 3 participants with phantom pain, it was possible to elicit an evoked phantom sensation by palpating the stump. By placing TENS electrodes at these sites, it was possible to project TENS sensation directly into the phantom limb which participants reported to be beneficial. It was not possible to elicit a referred phantom sensation in the remaining 2 participants with phantom limb pain, although it was still possible to project TENS sensation directly into the phantom limb through a process of trial and error.

All participants were able to wear their prosthesis and sit, stand, and walk with TENS electrodes in situ during stimulation. During the 60-minute TENS intervention, all participants remained seated, except when undertaking the painful movement task.

### Outcome Measurements at Rest and on Movement

The mean baseline NRS for pain intensity at rest was below 3 of 10 for 4 participants (Table 2) despite these participants reporting an average pain of at least 3 of 10 on NRS during the last month. For one participant, resting pain intensity was zero at baseline and remained at zero during TENS (Table 2). Resting pain intensity decreased for the remaining 9 participants at 30 minutes of TENS and continued to decrease for 8 of these participants at 60 minutes of TENS (Figure 1A). Mean baseline NRS for pain intensity on movement was 3 or above for all participants (Table 2). Pain intensity on movement decreased from baseline for 9 participants at 30 minutes of TENS and for all participants at 60 minutes (Figure 1B).

The mean (SD) change relative to baseline at 60 minutes of  $-1.8$  (1.6) at rest and  $-3.9$  (1.9) on movement was statistically significant ( $P < 0.05$ , Wilcoxon signed-rank test). These inferential analyses should not be used to establish the magnitude of treatment effects as the study was designed to allow estimation of parameters for a feasibility study and was not appropriately powered to establish intervention effectiveness. There was a marginal increase in mean nonpainful phantom sensations after TENS at rest and on movement; however, these changes did not reach significance. Scores for the intensity of prosthetic limb awareness were maximal for all participants at baseline and at 30 minutes and 60 minutes of TENS.

Table 1. Participant Demographics and Pain Intensity Scores

Age/Sex	Amputation Side, Etiology	Time Since Amputation	Preamp Pain and Duration	Current Medication	Electrode Positions*	Location of Pain	Rest Pain Pre-TENS	Rest Pain @30 Minutes	Rest Pain @60 Minutes	Selected Movement	Movement Pain Pre-TENS	Movement Pain @30 Minutes	Movement Pain @60 Minutes
60 F	Left, vascular	7 year, 10 months	Yes, < 1 week	Gabapentin	Above stump anterior and posterior	Phantom	3	0	0	Reach—weight bearing on stump	4	2	0
59 M	Left, trauma	3 year, 7 months	Yes, < 5 years	Paracetamol, tramadol, gabapentin	Above knee posterior and anterior	Stump	4	0	0	Walking	3	1	0
22 F	Right, trauma	3 year, 3 months	No, N/A	Paracetamol, ibuprofen (RLP); gabapentin, amitriptyline (PLP)	Above stump anterior	Stump	0	0	0	Walking	6	7	4
58 F	Right, vascular	1 year, 3 months	Yes, < 6 months	Pre-gabalin, fentanyl patch	Above stump posterior	Phantom	1	0	0	Walking	8	0	0
55 F	Right, vascular	7 year, 7 months	Yes, > 5 years	Gabapentin, MST	Above stump anterior and posterior	Phantom	4	3	2	Walking	5	3	3
47 F	Left, trauma	3 months	Yes, > 5 years	Paracetamol (RLP), gabapentin (PLP)	On stump anterior	Phantom	7	4	3	Walking	8	6	5
? M	Right, vascular	1 year, 1 months	Yes, < 6 months	Gabapentin	Above stump anterior	Stump with tactile allodynia	3	0	0	Putting on sock liner	7	2	1
52 M	Left, BKN re-amputation	21 year, 2 months	Yes, > 5 years	Cocodamol, ibuprofen, paracetamol	On stump anterior	Stump with tactile allodynia	3	2	3	Walking	5	3	3
61 F	Right, trauma	18 year	Yes, > 5 years	Cocodamol	Above stump posterior	Stump	1	0	0	Walking	5	2	1
72 M <sup>†</sup>	Left, trauma	3 year, 3 months	Yes, < 6 months	None	Above stump anterior	Phantom	0	0	0	Walking	6	3	1

TENS, transcutaneous electrical nerve stimulation; Preamp, preamputation; RLP, residual limb pain; PLP, phantom limb pain; BKN, below knee.

\*Below knee unless otherwise stated.

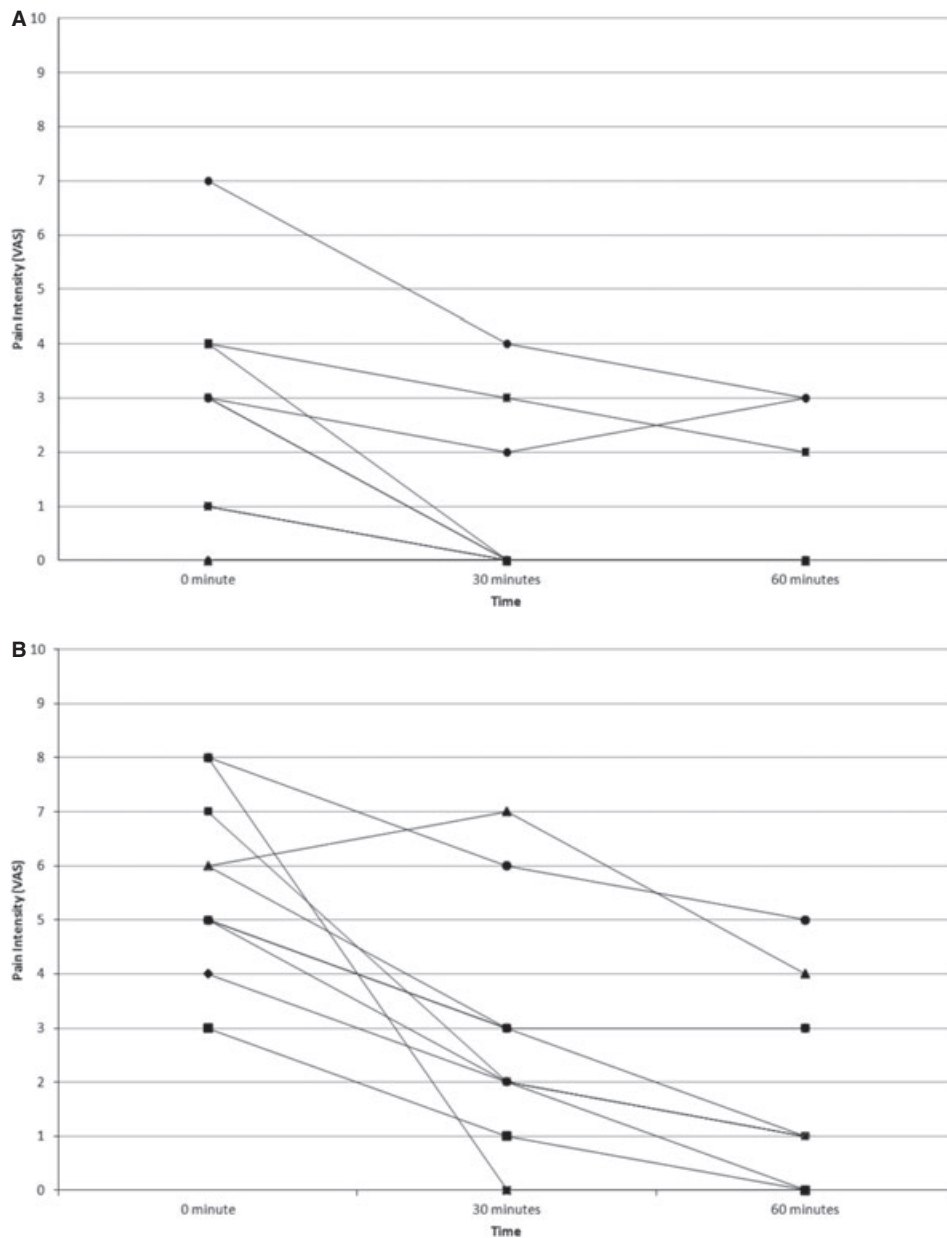
†All participants reported both stump and phantom pain over the previous month except <sup>†</sup> who had stump pain without phantom pain.

**Table 2. Summary Data for Sample—Mean (SD)**

	Baseline	30 Minutes	Change at 30 Minutes*	60 Minutes	Change at 60 Minutes*
<b>Intensity of pain</b>					
Rest	2.6 (2.2)	0.9 (1.5)	-1.7 (1.4)**	0.8 (1.3)	-1.8 (1.6)**
On movement	5.7 (1.6)	2 (2.1)	-2.8 (2.3)**	1.8 (1.8)	-3.9 (1.9)**
<b>Intensity phantom sensation</b>					
Rest	7.8 (3.5)	9.3 (1.4)	1.5 (2.4)	9.7 (0.9)	1.9 (3.1)
On movement	8.0 (3.4)	9.7 (0.9)	1.7 (2.9)	9.7 (0.9)	1.7 (2.9)
<b>Intensity prosthesis awareness</b>					
Rest	10 (0.0)	10 (0.0)	0.0	10 (0.0)	0.0
On movement	10 (0.0)	10 (0.0)	0.0	10 (0.0)	0.0

\*A negative difference implies pain reduction at 1 hour.

\*\*Significant reduction in pain intensity rating ( $P < 0.05$ ) using Wilcoxon signed-rank analysis.



**Figure 1.** Individual response trajectories to transcutaneous electrical nerve stimulation (A) resting pain, (B) movement pain. VAS, visual analog scale.

Unsolicited comments made by participants reflected the benefit of TENS:

*“TENS took my pain away in my phantom limb and my stump... It didn't just dull the pain, as I had expected it would, it actually took the pain away!”* (Participant 1). The five participants for whom TENS paresthesia was projected into their phantom limb reported that the sensation of TENS felt as it was arising from their prosthetic limb. One participant commented *“it feels like the tingling is coming from my prosthetic leg”*.

## DISCUSSION

This study demonstrates that TENS is acceptable and well tolerated when placed on the amputation stump in lower limb (transtibial) amputee patients. TENS reduced pain at rest and on movement when TENS sensation was projected into the main site of pain which was either the phantom limb or stump. In some but not all participants, it was possible to identify optimal electrode positions by mechanically palpating the stump region to elicit a referred phantom sensation. In addition, some participants reported that they experienced TENS sensation arising from their prosthetic limb itself. Attributing TENS sensations to a prosthetic limb may help improve proprioceptive awareness of the prosthesis and facilitate perceptual embodiment.<sup>18</sup>

The primary purpose of this study was to provide pilot data on treatment outcomes and tolerability, as well as recruitment strategies, to inform the design of future investigations. The findings of this study are limited by the small number of participants involved, which was in part due to recruitment difficulties. Furthermore, the lack of a control group prevents comparisons of effectiveness being made. The short duration of treatment per participant limits the extent to which the results can inform the outcome of long-term treatment use with TENS for amputee patients.

Although this study did not include a control group and was not powered for a test of difference, it was noteworthy that the mean reduction in movement pain intensity (relative to baseline) after 60 minutes of TENS was  $-3.9$  (1.9) NRS points, which is almost double the criteria for clinically meaningful change in pain of two NRS points as described by the IMM-PACT guidelines.<sup>22</sup> The reduction in pain at rest was just below clinically meaningful at  $-1.8$  (1.6). Taking into consideration the limitations of this pilot trial, these data merit further exploration to establish

magnitude of effect against a placebo TENS control, such as that described by Rakel et al.<sup>23</sup> The low baseline pain scores at rest may have masked potential reductions in resting pain during TENS (ie, a floor effect) as 7 participants were pain free after 60 minutes of TENS. The use of a pain relief scale, which standardizes participants' baseline scores (ie, zero pain relief), may prove more useful in monitoring TENS effects when baseline pain intensity scores at rest are low.

Transcutaneous electrical nerve stimulation did not exacerbate pain or irritate the skin at the stump in the 10 participants. Two participants with tactile allodynia who reported sharp stabbing and shooting stump pain in response to light touch tolerated the application of TENS electrodes to nonallodynic skin proximal to the pain and also tolerated TENS sensations projected within the allodynic area. This observation is interesting because allodynia is generated in part by activation of low threshold mechanoreceptive peripheral afferents ( $A\beta$ ) whose input is amplified via sensitisation in the central nervous system, resulting in pain.<sup>24</sup> Paradoxically, TENS did not exacerbate pain in these cases despite activating low threshold mechanoreceptive peripheral afferents ( $A\beta$ ). Human studies and animal models have demonstrated that peripheral TENS decreases ongoing central sensitisation by inhibiting the activity of nociceptive responsive second order neurons which may account for the reduction in symptoms of mechanical hyperalgesia and allodynia seen here.<sup>25-28</sup>

This study demonstrated that it was possible to project TENS sensation into a phantom limb by placing the electrodes over the stump. Optimal placement was on areas that elicited referred phantom sensations when mechanically stimulated. Although TENS reduced phantom pain relative to baseline, it did not change in the intensity of nonpainful phantom sensation scores although this may have been due in part to high baseline intensity scores (ie, ceiling effect).

Prosthesis limb awareness scores were maximal for all participants at baseline, suggesting that they had perceptually embodied their prosthetic limb, which is not unexpected as they were all established prosthetic limb users. Nevertheless, the study found that five participants reported experiencing paresthetic sensations arising from their prosthetic limb itself when TENS was projected into their phantom limb. The synthesis of visual inputs from their prosthesis and the proprioceptive experience of their phantom limb is likely to be driving this enigmatic experience of misattribution of

TENS sensations to the prosthesis. We have previously published this hypothesis.<sup>18</sup>

Underlying mechanisms are likely to involve the intermodal correlation of touch, visual, and proprioceptive sensory information in the somatosensory areas of the cortex, which are modulated by pre-existing body representations.<sup>29–32</sup> Integrating sensory function into a prosthesis and experiencing the prosthesis as a corporeal structure (ie, a natural extension of one's own body) have been shown to be key elements of successful prosthetic rehabilitation.<sup>33,34</sup> Incorporating sensory function into prosthetic limbs involves highly invasive and costly surgical procedures.<sup>16,17,35–37</sup> TENS may prove to be an inexpensive, noninvasive self-administered technique to aid the perceptual embodiment of a new prosthetic limb. The findings support the delivery of a feasibility trial.

## CONCLUSION

This study found that participants tolerated TENS delivered to a painful phantom and/or stump and that TENS may reduce pain both on movement and at rest. The study also found that TENS sensation can be projected into a phantom limb and that the TENS sensation feels as if it arises from a prosthetic limb. This may prove a useful aid for perceptual embodiment of an artificial limb. A feasibility study that includes a placebo/sham TENS control as described by Rakel et al.<sup>23</sup> is recommended to establish the potential for undertaking a full randomised controlled trial.

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