

Feasibility of using an implanted neurosensing system to monitor center-of-pressure displacements for control of paraplegic posture

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Abstract

When paraplegic standing is restored with functional electrical stimulation (FES), the main challenges are to maintain balance and avoid fatigue. We evaluated the feasibility of monitoring postural sway with the implanted NeurostepTM system (Victhom Human Bionics) that sensed, amplified and processed the tibial nerve signals during manually imposed lateral sway in standing pigs. We monitored pressure changes under the pig's hind feet (F-Scan®, Tekscan) and compared to center-of-pressure (COP) displacements during human sway. In humans, pressure in loaded foot sole regions increased by $72 \pm 24\%$. In pigs, similar pressure changes were detected from the tibial nerve signal with 94% accuracy, and 84% of all pig sway events were detected from the tibial nerve signal. Our results suggest that sensory signals from the human foot soles may closely reflect COP displacement and if so, an implanted neurosensing system could provide feedback for closed-loop control of paraplegic posture.

1. INTRODUCTION

At the IFESS 2001 - FES User Forum, a high priority of participants with spinal cord injury was to be able to stand independently again [1]. Users said that standing with FES was 50-60% achieved, but balance remained a key problem.

In the intact human system, erect posture is regulated in part by sensory feedback from cutaneous receptors in the soles of the feet [2]. In this study we consider whether paraplegic standing could be stabilized with feedback from foot sole sensory receptors to the FES controller in order to monitor and appropriately respond to significant shifts in center of pressure (COP).

Electroneurographic (ENG) signals sensed with cuff electrodes from human nerves are used to detect heel strike events during gait [3,4]. In this study we used a pig model to investigate whether the foot sole pressure shifts that occur during human sway can also be detected from the ENG signals recorded with nerve cuffs.

2. METHODS

2.1 Pressure changes during human sway

We first studied the changes in pressure on the soles of human feet during intentional postural adjustments and investigated how this pressure distribution related to the innervation pattern of the human foot. We used the F-Scan® flexible shoe insole sensor system (Tekscan) to acquire data on relative loading of different areas of the feet during standing. F-Scan® sensors are 0.15mm thick, weigh 10g and include 960 SenselsTM that provide detailed moment-to-moment 'pictures' of pressure distribution.

We recorded F-Scan® movies from 6 healthy subjects (5 male, 1 female, ages 26–39 yr) who gave informed consent. Each subject wore comfortable footwear with heel height less than 2.5 cm and was asked to stand with arms down and eyes focused on a target on the wall. After standing quietly for 30 s the subjects were asked to slowly sway to their postural limit in eight different directions (forward, back, left, right and the 4 diagonals) and return each time to the resting position for quiet stance. Data were analyzed by exporting 2 sets of force files that were used to create a COP plot and a Force vs. Time plot for each of 6 foot sole regions that correspond to innervation fields of the foot sole by distal branches of the tibial nerve (Fig. 1).

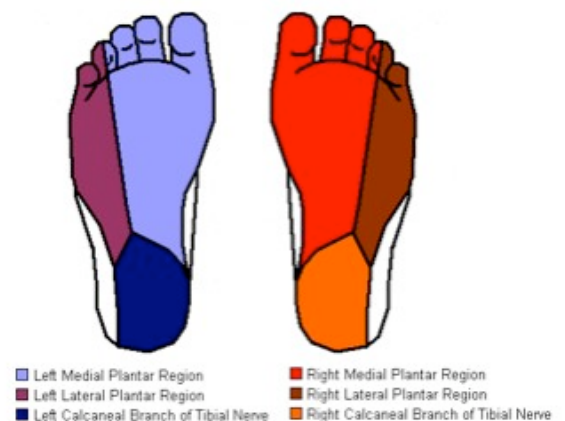


Fig. 1. Segmental distribution of cutaneous nerves of the sole of the foot into 6 regions (adapted from [5]).

After the COP file was created, it was possible to monitor the COP movement during sway. Time values were exported for the period of sway in each of the 8 directions when the COP moved from quiet standing to 75% of the directional “sway limit” described by Popovic *et al.* [6]. The pressure changes during postural sways were determined for the 6 foot sole areas.

2.2 Pig foot pressure and ENG recording

We used an ethics-approved pig model to assess the feasibility of using ENG signals arising from foot sole receptors to monitor movement of the COP during experimentally induced lateral shifts in posture. NeurocuffTM electrodes (Victhom Human Bionics) were implanted on the tibial nerves of 3 young adult pigs (2 of which were bilaterally implanted), distal to the major motor nerve branches (Fig. 2) such that the sources of ENG signal were largely cutaneous. Tibial nerve signals were monitored in real-time with a prototype version of NeurostepTM, a fully implanted, closed-loop, battery operated FES control system [4]. The ENG signals were rectified, integrated, sampled and telemetered out of the body by the NeurostepTM device and stored in a laptop computer. The F-Scan[®] system was used to simultaneously monitor pressure under both hind feet. Pressure data files were stored in the computer together with sampled ENG data files and were later merged.

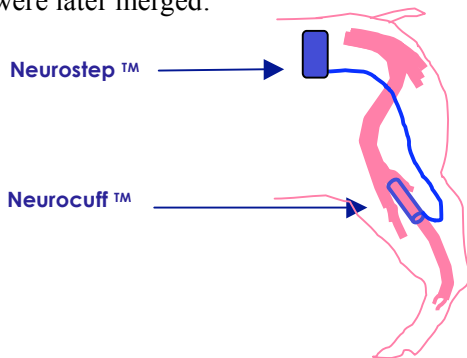


Fig. 2. Implanted device locations in pig hindlimb.

2.3 Data Analysis

We first analyzed the human data to establish the typical range of force and pressure changes measured in defined foot sole regions during self-paced sway events. Values were then converted into relative changes with respect to pressures during quiet stance. These values were compared to pressure changes observed in the pig data sets. The last phase of our analysis tested for changes in the ENG signal amplitude related to foot force or pressure changes seen during perturbations to the pig posture.

3. RESULTS

3.1 Force and pressure in human sway

Magnitudes of force changes during sway in 6 defined foot sole regions are seen in Fig. 3. Greatest weight shifts to one region occurred when sway was towards a corner of the postural space. For example, when the weight shifted towards back and left, the greatest load increase was on the left receptor region of the calcaneal branch of the tibial nerve (CT) with an increase of 260 ± 117 N. In contrast, when the weight was shifted forward and right, the weight supported by the left CT region declined by 184 ± 85 N.

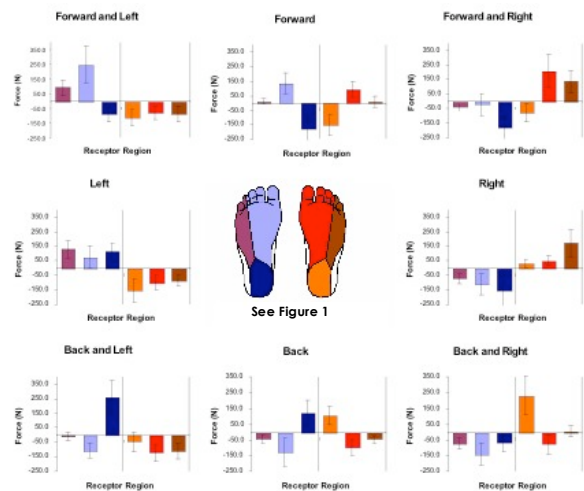


Fig. 3. Force changes during sway in 8 directions, measured in 6 foot sole regions (defined in Fig. 1).

Since force change data may not provide a clear indication of changes in receptor loading when areas of regions are unequal, it is better to use pressure as an indicator of receptor loading and to normalize pressures in order to compare the pressures measured in human and pig posture. Fig. 4 shows pressure changes for human sway.

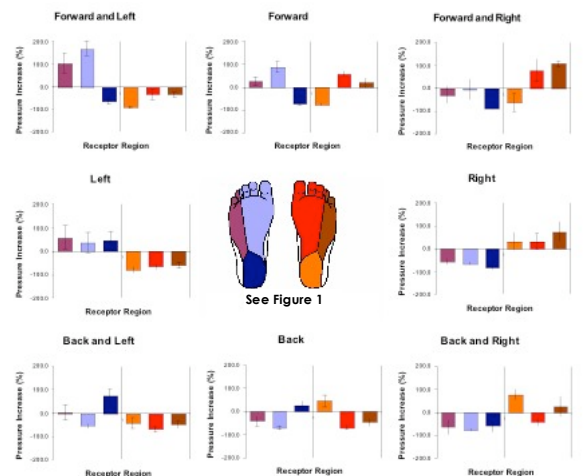


Fig. 4. Pressure changes during sway in 8 directions, measured in 6 foot sole regions (defined in Fig. 1).

3.2 Pressure and ENG during pig sway

Figure 5 shows examples of the quality of pig tibial ENG signals and some non-linear ENG signal properties in relation to changes in foot sole force when the pig posture was perturbed.

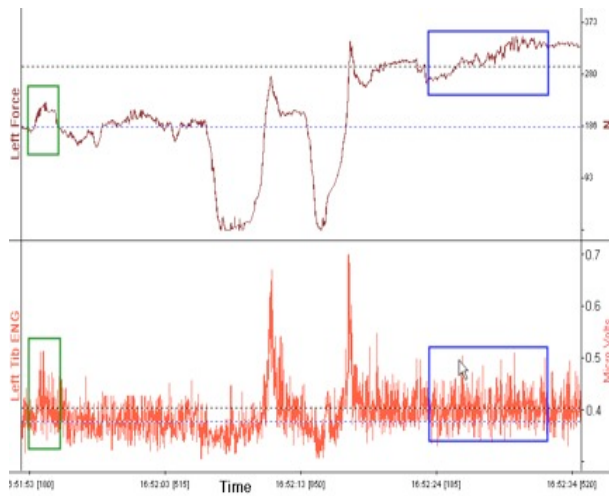


Fig. 5. Force (top) and ENG (bottom) during sway.

Consistent with the findings of Haugland *et al.* [7], the largest ENG signals occurred with large and fast force changes that started at very low force levels. The signal changes within boxes in Fig. 5 indicate the importance of the rate of pressure increase. The force change in the left-hand box was only 40 N (16% increase) and the rate of force increase was 62 N/s (24.6 %/s), yet the result was a large measurable increase in neural activity. In comparison, the force change in the right-hand boxes had a magnitude of 76 N (30% increase) but only at a rate of 12.7 N/s (5.1 %/s), and for these conditions, little or no increase in ENG signal occurred.

In spite of these non-linearities, the detection of sway events based on the ENG signal was quite robust because the changes in foot sole pressure were usually very significant. We defined a sway event as a rise in foot sole pressure $\geq 15\%$ above quiet standing pressure. We observed a total of 93 such events of which 78 (84%) were correctly detected based on the ENG signal and 15 events (16%) were missed. The average pressure increase for detected events was $58 \pm 30\%$, whereas the average rate of pressure increase was $121 \pm 89\%$. A total of 23 false event detections also occurred. It is of interest that when the pressure changes in pig sway events were of comparable amplitude to human pressure changes, pig sway detection accuracy based on the tibial ENG signal reached 94%.

4. DISCUSSION AND CONCLUSIONS

This study provides evidence that displacement of the COP during postural sway may be reliably detected from foot sole afferent ENG signals by an implanted neurosensing system and these ENG signals may provide appropriate feedback for control of paraplegic standing with FES. As the body center-of-pressure shifts, relative pressures on the soles of the feet change and there are associated changes in afferent discharge from different foot sole regions [2,8]. Given the significant changes in pressure we saw in the six separately innervated human foot sole regions, it seems plausible that an implanted neurosensing system for closed-loop control of postural sway could essentially operate on the basis of threshold detection, taking into account both amplitude and rate of change of ENG signals. A multi-channel nerve cuff recording system may be ideally suited for monitoring such changes in activity in the tibial nerve branches that supply the human foot.

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Acknowledgements

We thank Neurostream Technologies and Victhom Human Bionics for providing prototype NeurostepTM devices, pressure sensing equipment and technical support, M. Bush, E. Calderon, G. Jenne and W. Ng for valuable assistance with animal training and data collection, and the Simon Fraser University Animal Care Facility for excellent veterinary support.