Cutaneous Whole Nerve Recordings Used for Correction of Footdrop in Hemiplegic Man

Morten K. Haugland and Thomas Sinkjær, *Member, IEEE*

Abstract—**One hemiplegic patient with a dropfoot was chronically implanted with a cuff on the sural nerve, and recordings were made regularly during a period of two years. The results showed that the human sural nerve responded in a similar way to mechanical inputs applied on the skin, as the tibial nerve did in cats [11], indicating that previous experimental systems using natural sensory feedback for closed-loop FNS are possible to adapt to humans. During walking, the recorded nerve signal modulated strongly and gave a clearly detectable response at foot contact and a silent period when the foot was in the air through the swing phase of the walking cycle. A portable system was built that used the recorded signal to control a peroneal stimulator to correct for footdrop. There were two reasons for this: first, to show in a relatively simple system the possibility of solving the practical problems involved in recording nerve activity during stimulation and second, to remove the external heel switch used in existing systems for footdrop correction, thereby making it possible to use such systems without footwear and preparing it to be a totally implantable system. The method for removing artifacts, as developed in animal experiments, was adapted to provide usable nerve signals while stimulating the ankle dorsiflexor muscles.**

I. Introduction

In upper motor neuron diseases, functional neuromuscular stimulation (FNS) of paralyzed muscles can restore motor function. Many different systems have been developed around the world, but the complexity and lack of reliability of the systems seen from the user have in most cases limited the use of them, ie, [30], [32]. However, electrical stimulation of the peroneal nerve used for correction of the gait has proven to be a potentially useful means for the restoration of functional movement of multiple sclerosis and hemiplegic patients [31]. The stimulation is applied during the swing phase of the affected leg and prevents dropfoot so that the patient walks faster and more securely. The stimulator is often located distal to the knee on the lateral part of the tibia. The stimulator can be either external or partly implantable [22]. In both cases, the stimulator is triggered by an external heel-switch linked to the stimulator through a wire running from the switch under the heel up to the stimulator.

Several devices for stimulation of the common peroneal nerve have been developed (see [31], [32]). In many cases, external systems have been abandoned due to different problems such as daily positioning of the surface electrodes, failures within the external heel-switch, unwanted reactions of the skin, and possible unpleasant sensations [35]. Also, external systems are typically difficult to calibrate, require frequent recalibration, are sensitive to environmental factors (like moisture and temperature), and are bulky and unsightly and thus cosmetically undesirable. Some of these problems can be overcome by using partly or fully implantable stimulators [19]. In such systems, problems are still experienced a.o. with failures and the cosmetic appearance of the external heel-switch.

Sensing natural neural signals to control assistive devices was suggested a number of years ago [29]. For a review on myoelectric hands and legs, see Graupe and Kohn [8]. In man, it has been possible to record afferent signals using the microneurography technique developed by Vallbo and Hagbarth [34]. During restricted motor tasks the technique is able to provide a detailed picture of single afferent fibers in the peripheral nerves of human subjects [17], [36]. The drawbacks of this technique are that the population of units, which can be sampled, is relatively small and the recording electrode is easily dislodged if any significant movement of the surrounding tissue occurs. These limitations can be circumvented when using the whole nerve cuff electrodes [29]. Whole-nerve recordings with cuff electrodes provide information from the activity of many nerve fibers which represent various sensory modalities and arise from widespread skin areas. The longevity and the stability of the electrode are very good [6]. The whole nerve cuff gives a more global picture of neural activity than the microelectrode. On the other hand, nerve cuff signals feature considerable spatial and temporal averaging and are therefore far less sensitive to the specific location and detailed pattern of the skin input than signals recorded from single mechanoreceptors [15].

Nerve cuff electrodes implanted on cutaneous nerves of cats have proven to provide useful and reproducible information for feedback purposes in FNS systems [11]–[13]. It has also been shown that comparable recordings can be obtained from a human peripheral nerve instrumented with a cuff electrode [27]. Based on this experience, the present study was aimed at demonstrating that, in a practical FNS system, neural activity recorded with a cuff electrode can be useful as a feedback signal for control of a muscle stimulator.

We "replaced" the heel-switch by a single sural nerve cuff which monitored whether or not the affected foot was supporting weight. The use of the natural tactile information

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The authors are with the Center for Sensory-Motor Interaction, Department of Medical Informatics and Image Analysis, Aalborg University, Fredrik Bajers Vej 7D, DK-9220 Aalborg, Denmark.

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from the foot made it possible for the patient to walk without footwear and without wires running from heel to stimulator.

Parts of these experiments have been reported earlier [26].

II. Methods

A. The Nerve Cuff Recording Electrode

The cuff electrode was designed as described by [15], consisting of a length of silicone tubing (Dow Corning) with an inner diameter at least 30% larger than the diameter of the sural nerve. The insulating cuff served to resolve the small action currents generated by nerve fibers by constraining the current flow within a long, narrow, resistive path. On the inside of the cuff were three circumferential electrodes; one in the center and one in either end of the cuff. The electrodes were the deinsulated ends of Teflon coated multistrand stainless steel wires (Cooner Wire, AS634, with 40 strands), which were also used to connect to the external amplifier. The length of the cuff used in this study was 30 mm, (similar to cuffs used in previous cat studies [11]), and the inner diameter was 2.2 mm. Impedances (at 1 kHz) to an external ground electrode placed around the ankle were approximately 1 kΩ for the end electrodes and 1.5 kΩ for the center electrode.

B. Implantation Procedure

The electrode was implanted on the sural nerve of a 35-yr-old spastic hemiplegic male subject with a dropfoot. The patient had a slowly progressive disability which made his walking ability worse over time. A clinical examination had revealed that the patient had an Achilles tendon contracture and tremor around the ankle joint. During local anesthesia, he was instrumented with a tripolar whole nerve cuff electrode on the sural nerve, approximately 7 cm proximal and 3 cm posterior of the lateral malleolus of the right ankle joint (see Fig. 1). The three wires from the cuff electrode were externalized through the skin approximately 25 cm above the lateral malleolus, anchored subcutaneously in a 3 × 3 cm sheet of dacron mesh (Meadox®). The nerve cuff was placed so that the nerve was neither pulled nor torqued by the wires, and a loop was made on the wires near the cuff and another near the exit point for strain relief.

The subject gave his consent, and the study was approved by the local ethical committee.

C. Experiments

At the start of each experiment the impedances of the three electrodes to the external ground electrode were measured (at 1 kHz) to determine if the electrode was in working order. Then the innervation area of the sural nerve was investigated by touching the skin lightly at different places on the foot and ankle while monitoring the nerve response acoustically (in a loudspeaker). We defined the innervation area using a handheld pen with a narrow nib. The nib was slid along the skin from outside to within the innervation area. The border of the innervation area was defined at the location where we detected a response in the raw electroneurogram. The applied force of the pen did not give rise to any visually detectable skin stretching.

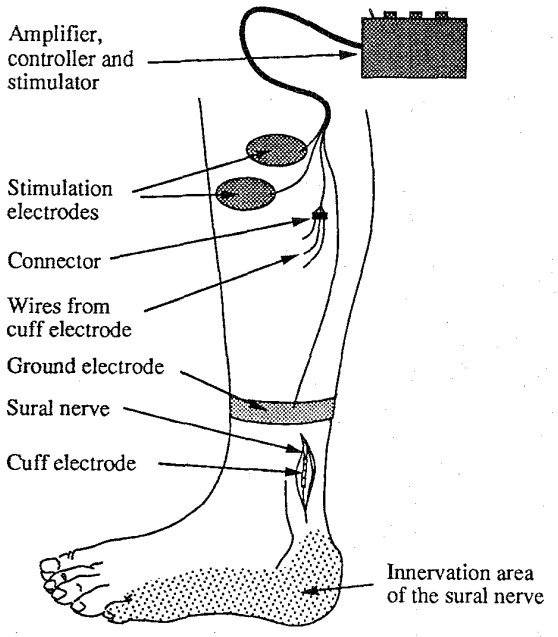

Fig. 1. Apparatus and electrode placement for portable footdrop orthosis.

Recordings were started one day after surgery (recording was attempted immediately after surgery, but the nerve was completely blocked by the local anesthetic). Recordings were then made every two days for two weeks, whereafter they were performed once every two to four weeks with interruptions due to holidays and other practical reasons.

Two sets of recordings were performed during walking on the floor with and without shoes. One was carried out to record sural ENG during walking without applying stimulation or any other type of assistance to the dropfoot. The other one was carried out to record sural ENG during walking while using a peroneal stimulator (KDC 2000A, produced by KDC Development, Århus, Denmark). The peroneal stimulator used surface electrodes placed above the tibialis anterior muscle (anode) and above the common peroneal nerve (cathode) just distal to the branching off of the superficial peroneal nerve (Fig. 1). In this position, it was possible to recruit a major fraction of the deep peroneal nerve which dorsiflexes the foot. For reference, a contact-sensor (Interlink Electronics, force sensitive resistor) was adhered under the foot at the heel; in later experiments another two sensors were placed under the lateral and medial footpads.

D. Signal Analysis

To characterize the nerve activity during walking, the amplified and filtered signal was sampled into a digital signal processor (DSP) with a sampling frequency of 20 kHz, where it was rectified and bin-integrated. The DSP was a TMS 320C25 placed on an add-on card in an IBM-AT compatible 80386 computer. When a whole bin was sampled, the DSP interrupted the PC (i.e., with a frequency of 100 Hz), which then saved

the integrated value as a single sample. The result of the rectification and bin-integration was a signal representing the overall activity in the nerve as it has earlier been described for cat experiments [11]. Other signals were sampled in the same manner, but without rectification. All raw signals were saved on tape for backup.

III. The Portable Footdrop Orthosis

Analysis of the nerve signal recorded during walking made it possible to extract information about the exact timing of foot contact. Initially, a computer was used to control the stimulator, with which we gained enough experience to build a portable unit containing an amplifier, a signal analysis/control circuit, and a peroneal stimulator. This unit will be described in the following sections.

A. Amplifier and Filter

Literature on amplifiers for the recording of physiological signals is abundant [1], [24], [29], [37]; one type commercially available and specially suited for cuff recordings is the QT-5B from Leaf Electronics. We chose to build our own, however, because to our knowledge none suitable are available for recording of nerve activity from a cuff electrode and at the same time small and energy efficient enough to be suitable for use in a portable device. The amplifier was based on an AMP-01 integrated instrumentation amplifier from PMI with a gain of about 100, 000 (100 dB) [9]. The amplifier was battery-supplied and optically isolated from the mains to increase common mode rejection (CMR) and to reduce the risk of electrocuting the subject. To reduce noise further, an external reference (ground) electrode was placed around the leg (Fig. 1) and connected to the first stage of the amplifier. Within the given bandwidth of the amplifier (800 Hz–3.6 kHz), it had a measured noise level of 0.4 μV_{RMS} with shorted input. With shorted inputs, a CMRR of 124 dB at 1 kHz was measured.

B. Bin-Integrator and Artifact Suppression

The method used for artifact suppression was described in detail in Haugland and Hoffer [13]. It is intimately related to the method for extraction of the envelope of the signal, and is, in essence, based on rectification followed by integration of the signal during noise-free periods (bin-integration). For the experiments performed on cats [12], the bin-integration was performed by a general purpose and commercially available unit (Bak Electronics), which was synchronized to the stimulator. For the purpose of making the device portable, a new circuit was constructed and dedicated to the task.

A block diagram of the entire circuit removing stimulation artifacts and producing the envelope of the nerve activity is shown in Fig. 2(a). Initially, the signal from the amplifier was high-pass filtered to remove remaining EMG and noise contamination of the nerve signal, which was still present even after passing the filter in the amplifier. This was done by a second-order Sallen–Key active high-pass filter with a cutoff frequency of 800 Hz. At this stage the nerve signal had passed a total of four orders of high-pass filtering. The signal was then rectified in an active rectifier (or absolute value circuit) and sent to the bin-integrator. The bin-integrator was controlled by the synchronization signal from the stimulator so that it would start integrating a fixed period of time after a stimulus occurred; and then just before a new stimulus started, the integration stopped and the result was stored in a sample-and-hold circuit and used for output. The signal at this output was termed "RBI-ENG" (Rectified and Bin Integrated ENG). The delay between the stimulation pulse and start of integration (the "blanking period") was controlled by the timer and could be set by an external potentiometer.

C. Heel-Strike Detector and Stimulator Control

To produce a control signal for the stimulator it was necessary to process the RBI-ENG further. As illustrated in Fig. 2(b), the first step was band-pass filtering to produce a smooth signal, reflecting changes in the nerve activity rather than the absolute activity. The high-pass filter was necessary to remove any dependency on slow changes in noise level and background activity which might change the dc-offset of the signal used for detection. Any changes occurring slower than the gait-cycle were not interesting in this context, and a first-order filter with a cutoff frequency of 1 Hz was chosen. Second, a low-pass filter was necessary to remove the effects of the high frequencies produced by the steplike transition from bin to bin in the bin-integrated signal. A first-order low-pass filter with a cutoff frequency of 20 Hz was found appropriate.

It was noticed that this filtered RBI-ENG often contained a sharp positive peak at heel contact followed by a sharp negative peak caused by the fast increase and decrease in the unfiltered RBI-ENG. To increase detection reliability, the filtered signal was rectified in an active rectifier so that both the positive peak and negative peak were used for detection.

After high-pass filtering and rectification, heel-strike was detected by simple threshold comparison, implemented as a comperator. The threshold voltage could be set by the user via an external potentiometer.

As will be described in the results, only the start of the stance phase (the moment of heel contact) could be detected reliably from the nerve signal, which was used to turn *off* the stimulator at the end of a swing phase. To start the stimulator at the beginning of a swing phase, a timer was started by the detected signal; when time was out, the stimulator was turned on. If the timer was set to the approximate time of the stance phase, it would turn on the stimulator at the correct time. The duration of the timing period could be set by the user via an external potentiometer and was adjustable between 0–2.7 s.

D. Stimulator

The stimulator was a commercially available peroneal stimulator (KDC 2000A) with a single channel for surface stimulation. It was originally designed for use with an external heel-switch mounted in a shoe, but the heel-switch was exchanged with a transistor controlled by the circuit described above. This stimulator had controls for stimulation amplitude, which were set by the user via an external potentiometer, and

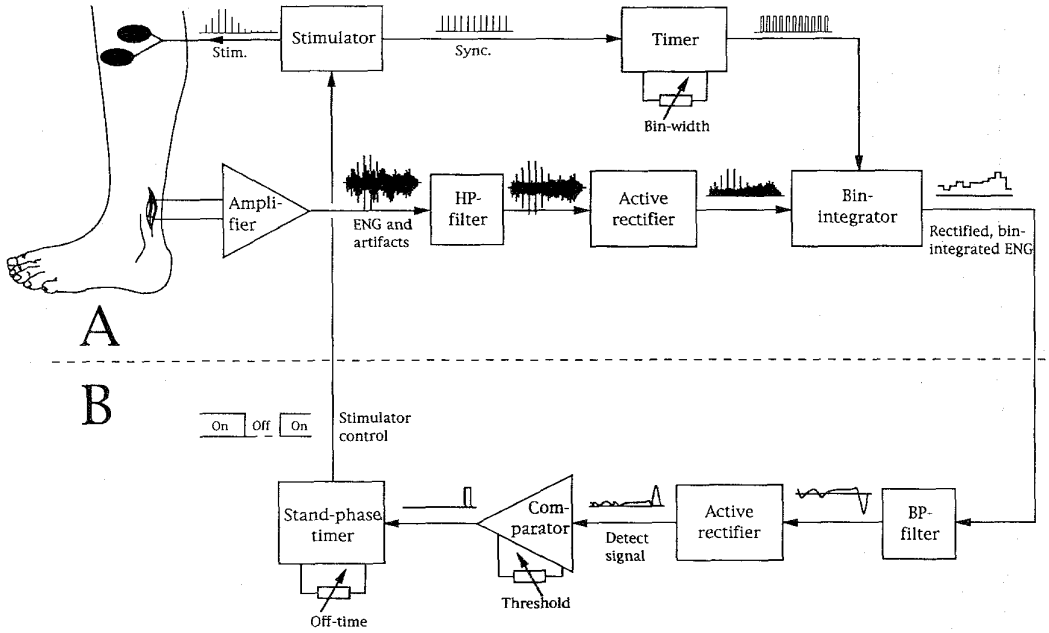

Fig. 2. Block diagram of portable unit for correction of footdrop. (a) Bin-integrator and artifact suppressor. (b) Heel-strike detector and stimulator controller. See text for description.

the stimulation frequency could be set by an internal trim-potentiometer. The frequency was set to 37 Hz for most of the recordings, but recently lowered to 30 Hz to obtain longer noise-free periods in the nerve signal. The stimulator had an automatic time-out function which turned it off after stimulating continuously for 3–4 s.

IV. Results

A. Innervation Area of the Sural Nerve

The innervation area of the sural nerve was found to be the lateral part of the foot including only a small or no part of the plantar surface (shaded area in Fig. 1). This is consistent with observations in four acute experiments [10]. In the chronic subject where the innervation area could be more precisely defined (less noisy environment during the experiment), the lateral border of innervation ran along the lateral part of the foot which just touched the floor while the patient was standing. The innervation area included the little toe and covered about one third of the dorsal/lateral surface of the foot extending up to 2–3 cm from the implant site of the electrode. This corresponds well with previous anatomical and physiological studies of the sural nerve (i.e., 2, 3, 4, 7). The sural nerve branches into several branches just below the lateral malleolus, and at the level of the implant it is already divided into several fascicles [5]. It was observed that the nerve of the chronic subject was rather flat, having a large diameter of about 2 mm. The cuff electrode was round, having an inner diameter of 2.2 mm and had therefore a very loose fit around the nerve.

A neurophysiological standard test of the nerve was performed 10 days before implantation and at day 469 after implantation, measuring conduction velocities with needle electrodes by stimulating the nerve at the lateral malleolus (distal to the cuff) and measuring the CAP at a point about 16 cm proximal to this. The max. compound conduction velocity was measured to 54.0 m/s before implantation and 52.6 m/s at day 469 after implantation, which were both well within the normal range.

The electrode impedances were steady on 1.0 kΩ from each of the end electrodes to ground and 1.6 kΩ from the center electrode to ground. This verified that the electrode leads were well functioning during the whole period of so far 36 mos.

B. Sural Nerve Responses to Mechanical Stimulation of the Skin

An example of the signals recorded from the cuff, when a steplike perpendicular force was applied on the lateral part of the foot, is shown in Fig. 3(a). In this case the force was applied with a linear motor. Noise from the amplifier and the electrode caused the rectified, integrated nerve signal to have a dc level corresponding to about 0.7 μV when no force was applied on the skin. When the force was applied, the nerve responded with a brief peak of activity to about 1.8 μV returning to a level only somewhat above the level before onset of the force. When the force was removed, another brief peak of activity appeared. These findings were in close resemblance to what has previously been seen in recordings from the tibial nerve in the cat when applying a force on the central footpad [11], although the human sural nerve seemed to have a smaller tonic response to a constant force.

The rectified and integrated nerve signal modulated in this case between 0.7–1.8 μV, which took place when very rapid change in force was experienced. Generally, the modulation

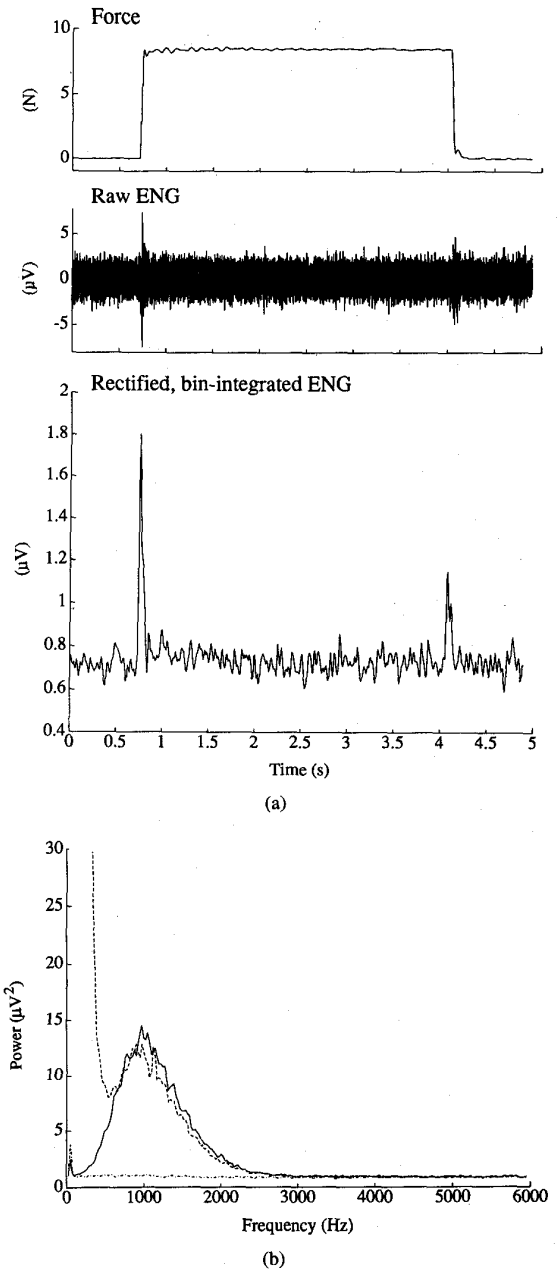

Fig. 3. (a) Raw signals while a steplike force was applied perpendicularly on the skin. Top: Perpendicular (solid) and lateral (dashed) skin contact force applied on the lateral part of the foot. Middle: Raw ENG. Bottom: Rectified and bin-integrated (RBI) ENG. (b) Amplitude spectrum of a recorded nerve signal. Solid: Skin was manually stimulated by the experimenter by stroking a hand across the lateral part of the foot. Dash–dotted: The skin was not touched. Dashed: Neural activity combined with muscle activity pickup. The skin was stroked with a hand while the subject strongly activated the calf muscles by pushing down against the hand of the experimenter. In the latter case, the spectrum had a peak at about 90 Hz with an amplitude of 700 μV^2.

was less than 1 μV (i.e., from resting activity to peak value), which was somewhat smaller than the signals previously obtained from cat tibial nerve.

The frequency contents of the neural signal corresponded to what has previously been seen in the cat tibial nerve instrumented with a cuff of the same length (3 cm), but had a slightly lower peak frequency. Fig. 3(b) shows a 512 point FFT (Fast Fourier Transform) averaged over 1 second of directly sampled ENG (F_s = 25 kHz, bandpass = 80 Hz–10 kHz). The solid trace depictures the ENG spectrum when the skin was mechanically stimulated by sliding a hand across the skin while the subject remained passive. The dashed trace shows similar nerve activity, but with the patient making a strong plantar-flexion against the hand of the experimenter. This resulted in a strong pickup of myoelectric activity in the signal recorded from the nerve cuff, which is shown as a large peak in the frequency spectrum below 500 Hz. Because of the large amplitude of this peak and the overlap with the neural activity, a high-pass filter with cutoff frequency at 800 Hz was used in all the following experiments, as described in Methods, in order to be able to compare neural activity during both passive and active situations. The dash-dotted trace shows the spectrum when no stimulus was applied and the subject was passive, in which case no apparent neural activity was present. This indicated that no or only very few units had a tonic resting activity.

C. Sural Nerve Activity During Hemiplegic Walking

We recorded data from the nerve while the subject walked on a flat floor (indoor) without any correction of the footdrop. It should be noted that the hemiplegia of the patient resulted in a slower and more insecure gait than normal. Data recorded from three steps with and without footwear are shown in Fig. 4. During a step, the ENG modulated between 0.6–1.2 μV with a distinct peak at heel-contact (Fig. 4(a)). In the swing phase, when the foot was in the air, the neural activity decreased to the background noise level of 0.6 μV. For reference, an external sensor was placed under the heel of the implanted foot producing a signal that increased with increasing force. It was not linear and it was most sensitive at low force levels.

The activity in the nerve modulated with the step-cycle. In the swing-phase, the activity was low having an amplitude comparable to the resting activity when the subject was sitting still with the foot in the air. Exactly when the foot touched the ground, the nerve responded with a sharp peak of activity as when a force was suddenly applied on the skin (Fig. 3(a)). This peak was followed by a series of small, distinct bursts in the stance phase of the step that coincided with fluctuations in the heel-contact. We attributed the bursts to a slight tremor in the foot, and the resulting variations in force on the skin made the receptors fire in phase with the tremor. There was generally not much change in the nerve activity when the heel was lifted from the floor at the end of the stance phase. The level remained high, until the whole foot was in the air, showing no clear feature indicating heel-lift. This was attributed to two things: the innervation area of the sural nerve covers the whole length of the foot, not just the heel; and when the angle of the ankle joint was changed (as it was during the whole stance phase until the foot was in the air), the mechanoreceptors on the side of the foot responded strongly. Because of the lack of ability to lift the foot, the toes would often slide on the floor during the initial part of the swing phase, which gave not only a mechanical input to the skin under the foot, but

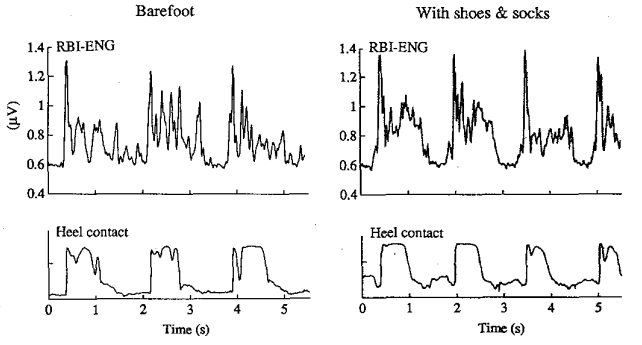

Fig. 4. Data from walking without stimulation. With (left panel) and without (right panel) shoes and socks (recorded on day 45 after implant). Top signal is the rectified and bin-integrated sural nerve activity (RBI-ENG), and the bottom signal is from the heel-sensor. This signal was high during heel contact and low during heel off.

also made the ankle angle change until the toes were lifted clear off the floor–both of which lead to an increased level of mechanoreceptor activity.

Slight differences between nerve responses during gait with shoes and without shoes were observed. The nerve activity recorded while the subject wore shoes and socks usually increased during the stance phase compared to when the subject walked barefooted. Since only a very small part of the skin innervated by the sural nerve was in contact with the floor during walking without footwear, the nerve signal was mainly generated by stretching of the skin caused by changing joint angle and deformations of the skin of the sole. When footwear was used, stronger inputs to the lateral part of the foot were produced by the shoe sliding across the skin, due to the weight put on the sole and the change in ankle angle in the stance phase, which again caused a stronger nerve response. Generally, this resulted in a more clear transition between stance and swing.

D. Removal of Stimulation Artifact

When the ankle dorsiflexor muscles were stimulated applying the portable footdrop orthosis, large artifacts contaminated the recorded nerve signal, as did the electric response from the muscles to each stimulation pulse. In Fig. 5(a) typical records from the cuff electrode during walking with the peroneal stimulator are shown. When the stimulator was turned off, it slowly decreased the stimulation current rather than turning it off abruptly. This resulted in the varying sizes of M-waves (response to each stimulus pulse) in the superimposed traces of Fig. 5(a). Compared to similar recordings from the cat experiments described previously [13], the stimulation artifacts and EMG pickup were comparable in amplitude, but since the nerve signal was generally smaller in the human recordings, the signal to noise ratio was lower. Also, the muscle responses to stimulation (M-waves) came later and were longer in the human case. However, filtering with a sharp high-pass filter (4th order, or 24 dB/octave) at 800 Hz removed the pickup of EMG [Fig. 5(b)], and long periods of "noise-free" ENG could be recorded between the stimulation artifacts. The stimulation artifacts contained strong high-frequency components

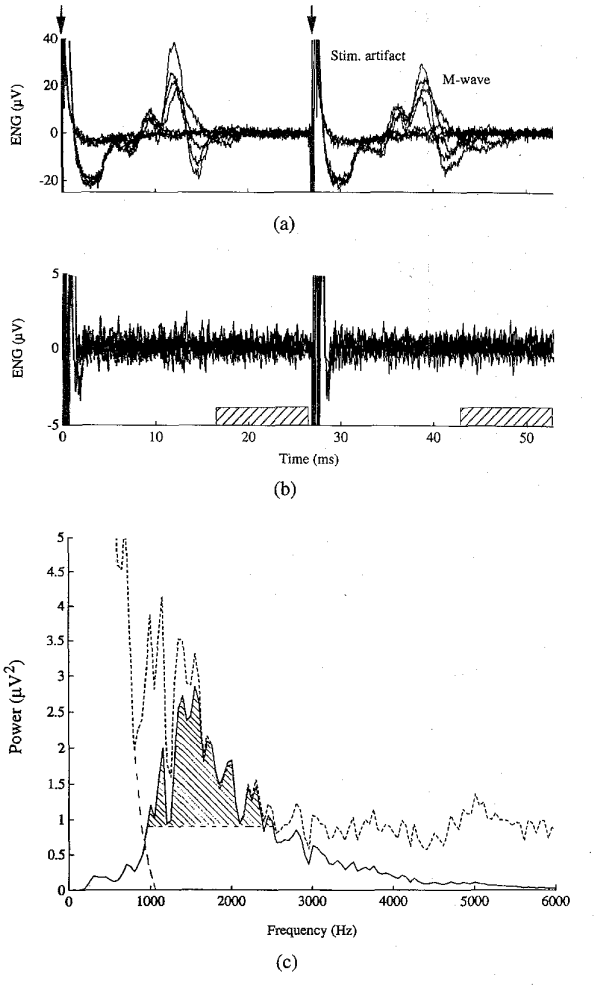

Fig. 5. Recorded signal from the sural nerve cuff during stimulation of the ankle dorsiflexors during walking. Eight traces are superimposed, each having a different stimulation amplitude showing the changes in amplitude of the picked-up muscle response (M-wave). In (a) the filters were open corresponding to a frequency range of 80 Hz–10 kHz. In (b) the signal was filtered with a 4th-order bandpass filter between 800 Hz–3.6 kHz, and it can be noticed that the muscle responses were removed. Stimulation artifacts saturated in both the negative and positive direction in all cases (c). Average power spectra of the traces shown in A (dashed trace) and B (solid trace). Only data *between* stimulations were used, i.e., the stimulation artifacts were not included. Each trace is an average of the spectra from 21 interpulse intervals. Dashed trace peaks in 100 Hz with an amplitude of 5000 μV^2. Hatched area corresponds to the neural component, and the shaded area is an estimate of the remaining EMG contamination after filtering.

and were only slightly damped by the filter. Notice that in the cat experiments there were only 10 ms between stimulation artifacts to retrieve nerve information; in the human there were about 27 ms (at 37 Hz stimulation frequency).

The filtered signal was integrated within a window (bin) which started a fixed period after each stimulation and ended just before a new pulse was elicited (indicated by the bars in Fig. 5). The exact window length was adjusted from trial to trial by the experimenter, but was usually set to be within the last 10 ms of the interpulse interval, where the pickup of EMG was considerably small. This indicated that in spite of the heavy filtering, which was supposed to remove EMG contamination of the nerve signal, there was still some

left. There were probably several reasons for the apparent residual EMG pickup. One is that the EMG and ENG spectra overlapped slightly so that a small component of EMG could not be removed by filtering (Fig. 3(b)). Another is that the filter was not sharp enough to remove the very large EMG-component, as can be seen in Fig. 5(c), where the spectrum of the recorded signal in between stimuli is shown. Dashed trace shows the "unfiltered" signal (bandwidth = 80 Hz–10 kHz) and the solid trace shows the spectrum after filtering (bandwidth = 800 Hz–3.6 kHz). Filtering removed the main part of EMG contamination (below 800 Hz) and amplifier noise (above 3.6 kHz). If the neural component corresponded to the *hatched* area above the noise in Fig. 5(c), and the remaining EMG pickup corresponded to the *shaded* area, the EMG contamination was shown to be a significant fraction of the signal compared to the neural activity. The spectra are averages of 21 interpulse intervals chosen randomly in the step cycle, some with stimulation and some without, and some with neural activity and others without. At the moment of heel-strike, the M-wave was at its maximum, which might cause an even greater EMG contamination than shown in Fig. 5(c). Presumably, since the ENG was also higher during this period, the averaged spectra may give a wrong impression of the amplitude of both EMG and ENG components just at the moment of heel-strike, but it appears that the nerve activity was generally a lot lower during electrical stimulation than during manual stimulation (Fig. 3(b)). Also, the EMG pickup was much stronger when electrically stimulated (a peak of 5000 μV^2, see Fig. 5(c)) compared to when naturally evoked (a peak of 700 μV^2, see Fig. 3(b)).

E. Detection of Heel Contact During Walking

Data recorded from three steps while the subject walked with the portable footdrop orthosis system in function, either with or without footwear are shown in Fig. 6. During a step, the RBI-ENG modulated between 0.6–1.3 μV with a distinct peak at heel-contact (Fig. 6(a)), this was also shown when the subject walked without any stimulation (Fig. 4). This signal was bandpass filtered and rectified as described above and the result is shown in Fig. 6(b). This signal was then compared to a threshold value (horizontal line in Fig. 6(b)) and used for control of the stimulator, which was turned on during the periods indicated by the hatched bars in Fig. 6(c). In both cases (with and without shoes), heel-contact was detected properly and the stimulator turned on during the swing phase and off during the stance phase. Notice that since the subject walked slightly slower in the example *with* footwear, the periods where the stimulator was on were longer than in the other example; whereas the periods where it was off had a fixed duration, as set by the timer.

One obvious effect of the stimulation was that the steps became more secure as the foot was lifted clearer off the floor. This can also be seen from the heel sensor signal in Fig. 6(c), which shows a more stable and well defined stance phase than without stimulation (Barefoot walking, Fig. 4).

It was still possible to extract foot-contact information from the nerve signal and use it for stimulation control as the

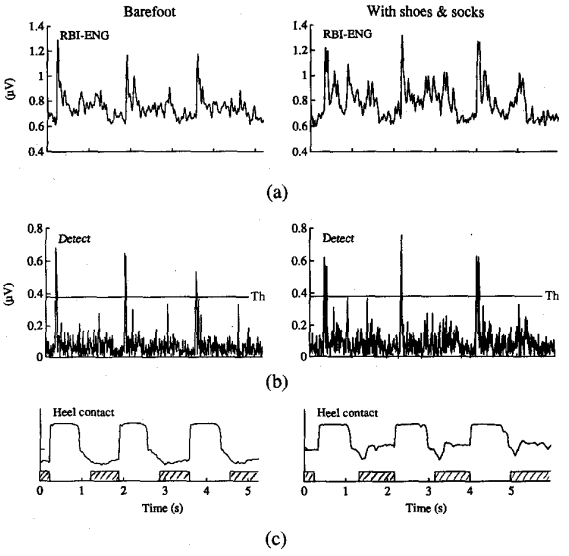

Fig. 6. Data from walking with stimulation of the ankle dorsiflexors, without and with shoes and socks (day 59). From top to bottom are shown (a) rectified and bin-integrated sural nerve activity (RBI-ENG), (b) high pass filtered and rectified RBI-ENG (Detect). (c) heel-sensor signal and trigger-pulse to stimulator. The heel-sensor is low during heel-off and high during heel-contact. The trigger-pulse to the stimulator (hatched bars in (c)) was decided on the basis of the threshold of 0.38 μV in (b) shown with a horizontal line labeled "Th."

disability of our patient grew progressively worse over time. In Fig. 7 an example of this is shown for 60 seconds of continuous walking in the hallways of our laboratories on day 521 after implant. The detect signal (Fig. 7(b)) showed a clear spike every time the foot landed on the floor.

It was evident from the data recorded during gait with the stimulator (Figs. 6(a) and 7(a)) that the above described artifact removal scheme functioned very well. No noticeable increase was shown in the level of the RBI-ENG when the stimulator was turned on, as would be expected if the signal was contaminated by artifacts and remaining EMG pickup. However, a problem had arisen when all the electronics were mounted in the same housing (a 15 × 8 × 5 cm^3 plastic box), because the high-voltage circuit of the stimulator gave a strong burst of high-frequency interference in the nerve signal when stimulation was turned on. This resulted in a very high value of one or two bins of the rectified and integrated nerve signal at the start of each swing phase. To remove this effect, a timer was introduced making the system ignore any "nerve activity" the first 200 ms after turn on of the stimulator. In the data shown in Fig. 7, the spikes are removed to clarify the figure.

The three contact-sensors adhered under the foot (see Methods) showed how the dropfoot contacted the floor (Fig. 7(c)). Because of the nonlinear behavior of the sensors to the applied force, the amplitude of the sensor signals is not useful. However, the relative timing of the three signals can be used to show how the foot landed on and was lifted from the floor. When the stimulator functioned correctly, the heel touched the floor before or simultaneously with the front part of the foot, whereas without stimulation the toes landed first. Further, with stimulation, the toes were lifted clear off the floor during

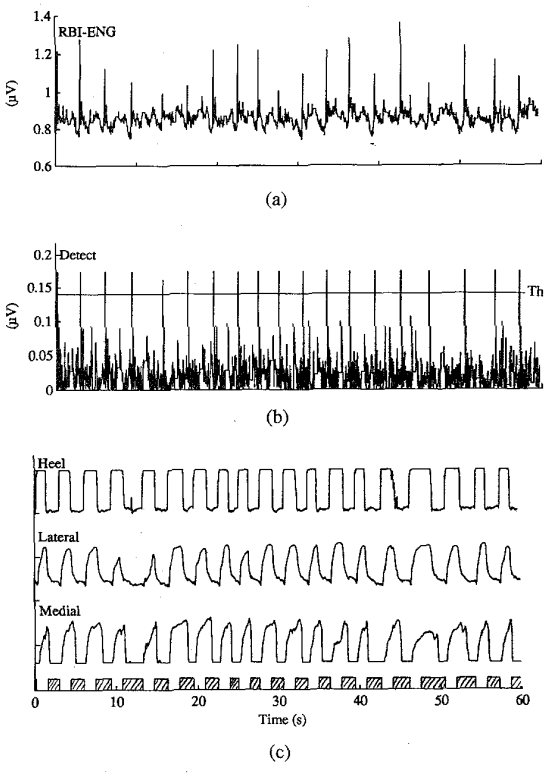

Fig. 7. Long sequence of data from walking barefooted with stimulation of the ankle dorsiflexors (day 521). From top to bottom are shown (a) rectified and bin-integrated sural nerve activity (RBI-ENG), (b) high pass filtered and rectified RBI-ENG (Detect). The threshold used for detection of heel-contact is shown with the horizontal line labeled "Th." and (c) contact-sensor signals and stimulator control (bars).

the swing phase, compared to sliding/dragging across the floor when no stimulation was applied. The stimulator usually produced a strong eversion because of difficulties in placing the surface stimulation electrodes precisely enough to get pure dorsiflexion (excessive eversion is also a common finding of implanted single-channel systems [19]). This turned up in the contact signals by the medial part of the foot touching the floor earlier and leaving the floor later than the lateral part.

The gait patterns of our subject have changed in the period from just after implantation till present time. This allowed us in a sense to evaluate the system on "two subjects" with different levels of disability. The conclusion from this is that it was possible to make the system work even if the subject did not walk very well, but also that it was much easier to make it work reliably when the subject had a fast and secure gait. We often saw that when one or two secure steps had been taken, the subject would increase the speed, which again would make it easier for the system to detect heel contact. The opposite situation also arose. For example, if the system failed, the next step would be insecure, which made it more difficult for the system to detect the time of heel contact which could result in a new detection error, and so forth.

V. Discussion

This is the first human study demonstrating a functional use of cutaneous mechanoreceptors recorded by an implantable whole nerve cuff recording electrode. Using the distinct peak in the neural signal at heel contact and a timer set to the approximate duration of the stance phase, we were able to control a dropfoot stimulator during walking.

The natural sensory nerve activity recorded from the chronically implanted electrode was comparable to activity recorded in previous cat studies [11], [14]. This is of great importance for the development of FNS systems using natural sensory information as a source of feedback signals, since previous studies with a cat model of such a system have given encouraging results.

At the time of this writing the electrode is still implanted (without any discomfort to the patient) and provides a source of stable neural information, which can be used for further studies of skin receptor activity, as well as for developing methods for improved control of functional electrical stimulation using natural sensory feedback.

A. Whole Nerve Cuff Recordings in Man

The whole nerve cuff recordings presented in this study behaved as could be expected from the large body of data from single sensory units obtained in other studies. Single-unit recordings from humans have been found to be very important for precision grip in persons with normal sensory-motor function [17], [18], encouraging further attempts to use natural neural feedback in FNS systems.

There was, however, a considerable difference in amplitude of the signals recorded from the cat tibial nerve and the signals from the human sural nerve. The difference was attributed to two things: Firstly, the inner diameter of the cuff was larger in the human (chronic) experiment compared to the nerve diameter than it was in the previous cat experiments. Second, the receptor density in the skin of the human foot is smaller than it is in the central footpad of the cat. About 300 myelinated fibers innervate the central footpad of the cat [16] which has a surface area of about 2 cm^2 corresponding to about 150 tactile units per square centimeter. The sural nerve contains between 1500–4000 myelinated fibers with diameters larger than 7 μm [2], and the surface area of the innervated skin is roughly 100 cm^2. If it is assumed that all these fibers are tactile afferents, then there are about 15–40 units per square centimeter in the human skin innervated by the sural nerve, which is a factor of 4–10 less than in the central footpad of the cat. Buchtal [3] estimated there are 10–20 mechanoreceptive units per square centimeter in the distal cutaneous branch of the human sural nerve.

The chronically implanted cuff electrode was found to function infallibly during the whole period of implant, which is still in progress at the time of this writing. The impedances of the three electrodes in the cuff have been steady on 1 kΩ, 1.6 kΩ, and 1 kΩ since a few days after implantation. Our greatest concern has been the skin reaction where the three wires come out, but there have been practically no problems with this. The wires and the small connector soldered on them were tied down by a piece of adhesive film (Tegaderm^{TM}) without covering the wounds, and this was changed every 3–4 days either by us or by an assistant to the subject.

B. Sural Nerve Signal Responses During Hemiplegic Walking

During walking the nerve activity modulated in phase with the step cycle having a higher level of activity during the stance phase than during the swing phase. Since the innervation area of the nerve included only a small fraction of skin under the foot, much of the nerve activity during walking was attributed to stretching of the skin, caused by changes in ankle angle and forces pulling the skin from underneath the foot. Because of the sensitivity of most glabrous skin mechanoreceptors to fast changes in force, the nerve responded strongly to even slight tremors in the muscles acting on the ankle joint. Although it was concluded that the nerve and electrode had remained stable during the whole period of implant, a noticeable difference in nerve activity during the gait was noticed. The modulation during a step cycle was lower, especially when walking without footwear. This was attributed to the developing disability of our subject causing a changed gait pattern with a slower and more cautious gait combined with a stiffer ankle joint, resulting in less mechanical input to the receptors (which were especially sensitive to rapid movements).

C. A Portable System for Footdrop Correction Applying Natural Sensory Feedback

A portable system for footdrop correction was developed, which included a custom made amplifier for the nerve signals, a custom made control unit that transformed the recorded signal into a stimulator control signal, and, finally, a commercially available peroneal stimulator. The unit was contained in a plastic box which could be worn by the user in a belt around the waist. It was tested under different circumstances in and outside our laboratories.

The system functioned well under different circumstances, i.e., while using different shoes or walking barefoot, and while walking on different surfaces, i.e., concrete and grass. Also, because of the progressing disability of our subject, we tested the system for different levels of disability. The system worked best during a fast and secure gait, but the system works, although with a high rate of failures, even at the slow and insecure gait, which our subject can perform at present. Subjectively, our subject stated that it was a new and comfortable feeling to walk properly without shoes and to be able to feel the floor under the whole foot instead of just under the front part of the foot. This had not been possible with the regular footdrop stimulator and the external heel-switch which he usually used.

Although the results presented in this work have shown that it is possible to make a footdrop orthosis, which uses neural information instead of a heel switch, a number of improvements are necessary to make the system functional for everyday use.

First, it is necessary to solve the problem of the wires going through the skin. This can be done by a telemetric link, but since the signals are too small for direct transmission, it is necessary to implant the neural amplifier. Such an amplifier is at present not available and will have to be developed.

Second, it would significantly improve the signal-to-noise ratio of the bin-integrated signal if the period of integration between stimulation pulses (bin-width) could be increased. The 4th-order high-pass filter in the present version is apparently not enough to remove all pickup of EMG from the stimulated muscles. Possibly a better filter can reduce the residual EMG enough to allow the integration window to cover the whole period from disappearance of stimulation artifact until the next stimulus. A simple way to increase the bin-length would be to decrease the stimulation frequency, as we have done in the latest experiments. We now use a stimulation frequency of 30 Hz (instead of 37 Hz as we did in the start), but even lower rates (20 Hz) have been used for footdrop correction [19].

Thirdly, it is necessary to make the control unit and stimulator smaller and less power-consuming. At present, the control unit is implemented using standard analog components and the size can be reduced by using surface mounted devices (SMD), as we have already done with the amplifier. Further analysis of the nerve signal may result in a simpler scheme for detection of heel-strike and possibly also detection of heel-lift. This may reduce the complexity of the control unit, which again will reduce size and power consumption. However, a digital implementation of the control unit based on a digital signal processor is preferable, since such a system would provide more flexibility and computing power than an analog circuit can offer. Such devices have been developed for control of e.g. cochlear implants and multichannel FNS systems [20], [23] and can be made small and power-efficient enough to be suitable for the purpose. Furthermore, there seem to be no fundamental problems in trying to implement a digital version on a custom-designed chip (ASIC), which would include both the amplifier for the neural signals, the control unit, and the stimulator.

It should be noted, however, that although the results as presented show that the system worked as intended, it often had problems. The margin between success and failure was generally small, since it took just one misdetection to make the subject stumble or at least make the stimulator get out of phase with the step-cycle, which could require 2–3 steps as compensation. This was partly due to the high sensitivity of the nerve signal to small, fast inputs to the skin (i.e., if the foot happened to slide lightly across the floor during swing), which could result in erroneous detections of "heel contact." Also, the fixed timing of the stance phase was a problem, as it did not automatically adjust to the speed of the gait.

In the present study the sural nerve was used, but because of the dorsal/lateral position of the innervation area, the signals were not directly related to weight-bearing on the foot but rather to stretches of the skin due to changes in ankle angle and transferred forces from the sole. For this reason, the sural nerve may not be the most suitable nerve for a cuff implant to be used in a footdrop orthosis. It was chosen mainly because of the easy surgical procedure and the relatively low "cost" if the nerve should be damaged by the electrode. The tibial nerve close to the ankle joint *could* be a better choice for a new implant, since it innervates the sole of the foot. It should be noted that even at this distal part it contains a large amount of muscle afferents and efferents belonging to the intrinsic

muscles in the foot, which may contaminate the cutaneous information (but it may also add a useful component to the signal because of stretching of muscle spindles). Very recently we implanted a nerve cuff electrode on the calcaneal nerve (which is a pure sensory nerve that branches from the tibial nerve just proximal of the heel) of a multiple sclerosis patient. The nerve signal contained clear information about the changes in the force applied perpendicularly to the skin within the area of the heel. Preliminary results also indicate that a dynamic measure of heel "on" contact and heel "off" contact during walking may be obtainable [33].

D. Applications of Natural Sensors in Rehabilitation

In spite of the number of suggested improvements of the electrode, choice of nerve, the amplifier and control unit in the portable device, our study has shown that it is possible to get functional use of natural sensory feedback, as recorded from a cutaneous nerve with a nerve cuff electrode, while stimulating nearby muscles electrically with surface electrodes. These findings, in combination with a simple and reliable neurosurgical procedure and the consistency in the recordings, make this technique a feasible option for feedback regulation of implanted FNS systems, and may thus prove to be suitable to restore hand function [21], [25], gait, and stance in motor impaired subjects.

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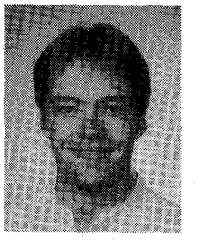

Morten K. Haugland was born in Holstebro, Denmark, on June 1, 1964. He received the M.Sc.E.E. degree in July 1989 and the Ph.D. degree in biomedical engineering in 1994 from Aalborg University, Denmark.

From 1989 to 1990 he worked as a Research Assistant in Dr. J. A. Hoffer's Laboratory at the University of Calgary, Canada. He is currently employed as Assistant Professor in the Department of Biomedical Engineering at Aalborg University, Denmark.

Thomas Sinkjær (M'84), for a photograph and biography, see this issue, p. 306.