A Robust, Economic and Ergonomic Sensor Device for Gate Phase Detection for an Implanted FES System

D'Attanasio Honiger S., Micallef J.P., Peruchon E., Guiraud D., Rabischong P.
Clinique PROPARA, Université de Médecine, Montpellier, France

Abstract

This article presents a device based on three capacitive sensors and integrated in an implanted FES system for paraplegics. The prototype is able to detect the four gate phases with a successful rate of 100% during experiments, allowing the control of stimulation sequence timing. Its main advantages are: simplicity of fabrication and use, high mechanical robustness, reliability of output signals, customizability, extremely low cost and invisible mounting. The main requirements followed during the sensor design have been the patient acceptance and the device usability. These characteristics are of paramount importance in the design of all components integrated in a human-centered system, i.e. systems where the user has an active central role. The development of efficient and ergonomic sensors represent in fact one of the most critical aspect of these systems and it is essential in order to envisage the use of FES system in daily life.

Introduction/Background

Functional electrical stimulation (FES) is a technique which consists in stimulating muscles artificially, in order to restore motor functions in certain handicapped people. Our research concerns the stimulation of leg muscles by means of appropriate current patterns in paraplegics, persons who have lost the control and the mobility of lower limbs. As a general concept, FES systems are human-centered systems, that means that the human being is an essential component. The successful integration of such "component" may pose certain problems, mainly related to the interaction between the user and the system. Consequently, system ergonomy, in terms of simplicity, easy of use, and overall aesthetic, plays a key role in determining the acceptance of the patient and, therefore, the real usability of the system. The difficulty of satisfying these criteria, as well as the technical ones and the overall cost, has confined to research and clinical environments the application of the majority of FES systems, whose use in daily life is not yet a reality.

In this framework, the development of suitable sensors represents one of the key issues to take into account in the design of a FES system. Sensors, in fact, are needed to provided feedback information in order to control the system, compensate for disturbances, and interact with the user. Due to the human-centered characteristic of a FES system, these sensors have to satisfy not only the general technical requirements, such as accuracy, repeatability, sensitivity, robustness and efficient acquisition electronics, but also the requirements imposed by the human component of the system. The patient will to use and "wear" sensor devices mainly depends on the easy of use, on the limited device size and cabling, and on an affordable cost.

In order to explore feasible solutions in terms of sensor design, a compromise between performance and ergonomy must be done and minimal sensor configurations have to be considered. Sensible improvements in FES system control can be in fact achieved by means of simple sensors, which can also be easily accepted by patients. It is following this philosophy, and focusing mainly on patient's needs, that the research presented in this article has been carried out. A simple sensor configuration for gait phase detection to be integrated in an implanted FES system for paraplegics is proposed. It consists of three capacitive sensors integrated in an insole and allows the control of sequence pattern timing. The main advantages of the device rely in the simplicity of fabrication and use, high mechanical robustness and reliability of electrical output signals, extremely low cost and invisible mounting and positioning.

Methods

The sensor device has been designed to be integrated in the implanted FES system described in [1]. The system comprises 16 implanted electrodes (8 for each leg) connected to an implanted stimulator. An external antenna connected to a portable programmer transmits power and stimulation sequences to the stimulator. The stimulation sequence corresponding to a single step is triggered by the patient, by pressing a button on each of the two helping sticks. The main problem of the system is the low flexibility given by the open loop configuration: intensity and timing must be manually programmed and tuned, by means of visual feedback either by the experienced patient or by the assisting medical personnel. In this context, the integration of a sensor device for feedback control has not the aim of achieving an automatic step execution. Too many are in fact the external and internal disturbances (such as trunk motion and muscle fatigue respectively) which are not completely and easily measurable. Our goal is instead to assist the patient in performing the task, by alleviating him/her from tedious and repetitive small sequence tuning actions. It is for this reason that gait phase detection has been chosen as a useful parameter to synchronize sequence timing and step execution.

The state of the art proposes many works, using different measuring principles and methods. Three force sensors are used in [2] and [3] alone, or combined with goniometers at joints in [4], or with an inclinometer in [5]. These solutions are mainly based on FSR (force sensing resistors) technology, whose mechanical robustness represents the main drawback. Moreover, the cost of the device has to take into account the FSR sensors, often coupled with resistive or inertial sensors, and the control electronics. Other solutions are available, measuring foot pressure and force and thus gate phases, but they are even more complex, expensive and fragile to use ([6, 7, 8] or the commercial F-scan and EMED insoles). In conclusion, an optimal solution satisfying at the same time the criteria of robustness, low cost, efficiency and ergonomy does not really exist.

The solution proposed in this article consists in an insole integrating three capacitive sensors. The main drawback of insoles is the continuous and strong mechanical solicitation (whole body weight) that the insole must withstand. Moreover, the working environment, the internal part of a shoe, is humid and at a relatively high temperature (40°). Capacitive sensors have no temperature and time drift, if compared to resistive, such as FSR, or inertial sensors, such as accelerometers and gyroscopes, and provide highly stable and reproducible output signals. The main drawback is the critical robustness of this technology. To combine the "aesthetics" of insole configuration (invisible) and the advantages of capacitive measurement, in a low cost and robust design, the sensors have been developed using highly robust materials. The dielectric has been fabricated using a rubber foil, and the capacitive plates have been fabricated using a flexible metal foil. The electronic circuit for signal detection is made up of three NE555 IC and few resistors and capacitors, resulting in a compact circuitry of 1,5cmx1,5cmx0,5cm size, which can be easily further miniaturized and integrated in the shoe. Sensors can be cut according to patient foot size. The insole prototype is showed in Fig. 1.

Results

The sensor device has been tested on healthy subjects. It has been worn eight hours per day during a week, for two weeks. At the end of these test sessions, the sensor device didn't show any decrease in

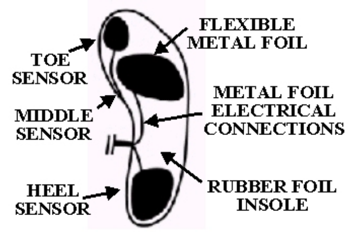

Fig. 1: The insole integrating three capacitive sensors.

performance or mechanical problems. Signal acquisition has been performed at 60Hz. Sensor output was compared with the simultaneous acquisition of a trimmer based knee goniometer. If we consider the trimmer response as in real time, sensor signals showed to be synchronized with the goniometer, with a negligible delay (in the order of 1 sampling period). Delay due to the capacitor time constant are also negligible, due to the low sensor capacitance value in the order of 100pF. Four logic expression are used to detect the four gate phases, heel strike, stance, heel off, swing:

Heel strike: (heel on) AND (middle off) AND (toe off);
Stance: (heel on) AND [(middle on) OR (toe off)];
Heel off: (heel off) AND [(middle on) OR (toe on)];
Swing: (heel off) AND (middle off) AND (toe off).

Fig. 2 shows the gait phases detected using the above described logical expressions. The rate of successful recognition was between 99 and 100% during the tests. Sensors signals are processed only when the step is triggered by the patient. Therefore there is no danger in mixing up a weight shifting during standing with a walking pattern. Sensors are considered as switches (on/off detectors). Rubber natural hysteresis has therefore a negligible influence on measurements, simplifying the electronics. The analogic output is compared to a threshold, a fraction of the maximum stroke, which determines the delay in phase detection and thus the device sensitivity. A compromise between the threshold value and the force must be done, in order to avoid an undesired sensor triggering and an erroneous phase detection. A fast reset procedure takes into account sensor pre-loads once the device is worn, and set automatically the threshold. Fig. 3 shows the relationship between sensor output signals and force for the middle sensor. Sensor saturation takes place at 4Kg (3Kg for the toe sensor), a value which minimizes the detection of undesired contacts, due to forces exerted by the foot on sensor surface caused by a tight shoe or a thick sock. The extent of the sensor area allows the phase detection even if the contact between foot and insole is not regular, due to a particular contact surface or foot plant. The vertical scattering of experimental data in Fig. 3 is due to a varying sensor sensitivity respect to different areas within the same sensor. This can be improved by improving the technique used to fix the metal foil to the rubber dielectric. Tests were in fact made by manually (thus non uniformly) spreading of a glue layer between foils.

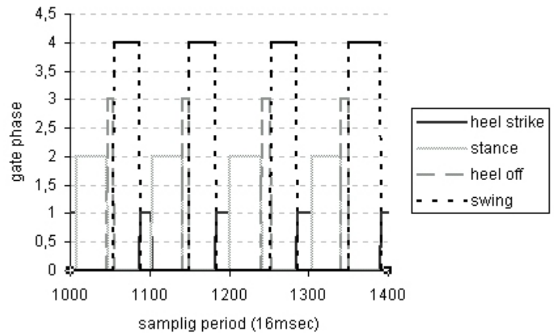

Fig. 2: Gate phase detection with experimental data.

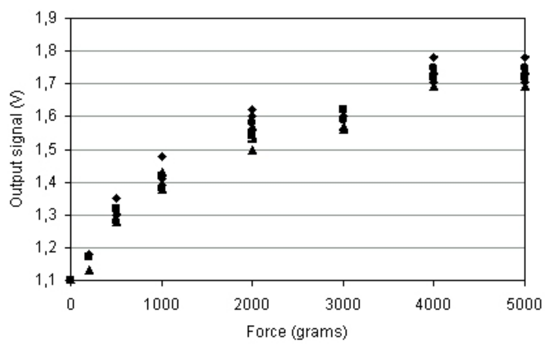

Fig 3: Relationship between output signal and force for the middle sensor.

Discussion/Conclusions

In this paper, a sensor device based on three capacitive sensors has been presented. The sensor is integrated in the shoe of the paraplegic user and the output signal is used as feedback information to control the timing of stimulation sequences in an implanted FES system. In particular, the heel off phase, caused by voluntary patient weight unbalance, triggers joint flexion; during the swing phase, the stance phase of the other foot is checked to control the correct stimulation (extension) of hip and knee joints; heel strike phase determines the end of ankle joint flexion and the start of hip and knee joint extension (back to stable standing posture). Experimental results showed that the device is able to detect the four gait phases, heel strike, stance, heel off and swing with a successful rate of almost 100% and with a controllable time delay. The most important advantages of the sensor are: simplicity of fabrication and use, size customizability, high mechanical robustness, reliability of electrical output signals, extremely low cost and invisible mounting and positioning. These characteristics are of fundamental importance for envisaging the daily use of the system, which requires an ergonomic, robust and aesthetic design. Further tests on paraplegic subjects are planned to improve the control technique. New materials are under study to improve sensor performances and device assembling.

References

[1] Guiraud D., et al., “Description of a sixteen-channel FES implantable system”, in Proc. of IFESS2000, June, Aalborg, Denmark, 2000.

[2] Lawrence T.L., Schmidt R.N., “Wireless in-shoe force system”, 19th IEEE Int. Conf. of the Eng. In Medicine and Biology, Chicago USA, 1997.

[3] Skelly M.M., Chizeck H.J., “Real time gait event detection during FES paraplegic walking”, 19th IEEE Int. Conf. of the Eng. In Medicine and Biology, Chicago USA, 1997.

[4] Kostov A., et al., “Machine learning in control of functional electrical stimulation systems for locomotion”, IEEE Trans. Biomed. Eng., 42, 541-551, 1995.

[5] Pappas I.P., Keller T., Popovic M.R., “A novel gait phase detection system”, Automed99, 2. Workshop “Automatisierungstechnische Verfahren der Medizin”, Darmstadt, Feb., 1999.

[6] Abu-Faraj Z.O., et al., “A Holter-type, micro-processor-based, rehabilitation instrument for acquisition and storage of plantar pressure data”, J Rehab. Res. Dev., 34(2), 187-94, 1997.

[7] Zhu H., et al., “An umbilical data-acquisition system for measuring pressures between foot and shoe”, IEEE Trans. Biomed. Eng., 37(9), 908-11, 1990.

[8] Péruchon E., Jullian J.M., Rabishong P., “Wearable unrestraining footprint analysis system. Applications to human gait study”, Med. Biol. Eng. Comp., 27, 557-65, 1989.

Acknowledgments: The authors would like to thank the PROPARA center in Montpellier, France, for their support during the project. The research was funded in the framework of the MobiNet Project of the European Union.