COMPUTER AIDED LOCOMOTION BY IMPLANTED ELECTRICAL STIMULATION THE C.A.L.I.E.S. PROJECT

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INTRODUCTION

Every year in France, a thousand new cases of spinal cord injuries (SCI) patients, mainly from traffic accidents, are suddenly and dramatically confronted with the loss of autonomy and locomotion. In Europe, at present, the population of paraplegic patients represents approximately 25000 persons.

Verticalisation is, clinically, very useful for paraplegic people: bladder and bowel functions are improved, mineralization of the bone is better, and the physiological aspect of this activity is non disproved. All solution for mobility restoration by stand-in and orthotic devices are purely passive and not easily portable.

Considering the fact that a nerve innervating a group of muscles remains intact below the lesion, the application of electrical field has been proposed in order to induce a motion. Physiologically, the external electric field vector needed for a muscle contraction corresponds to the action potential of the nerve, which is in fact, an inversion of the membraneous potential. Thus, it is possible to induce this inversion by supplying a negative charge to the tissue surrounding the selected nerve. This charge is delivered from an external generator via the cathode. One of main problems is in determination of appropriate location for the stimulation electrode and corresponding anode.

THE **CALIES** APPROACH OF THE PROBLEM

Electrical stimulation, up to now, has been principally carried out using transcutaneous technique, but also with implanted electrodes and/or systems.

The main research and development of CALIES project is given with its name, **Computer Aided Locomotion by Implanted Stimulation**. The project aims to develop very ambitious technique to restore the ambulation and acting as this, needs the cooperation of several teams in Europe in the fields involved. In addition, the control method used here for a gait is a closed-loop system optimizing gait sequences.

TECHNICAL REQUIREMENTS OF THE PROJECT

The system would allow the patient to stand up and maintain upright posture for a while, enabling him to catch high positioned different objects, to ambulate on flat and rough floor, and to climb stairs. Those functions are essential daily living activities and they improve the patient's autonomy at and out of his home.

The basic technical requirements are:

- *internal or external bio-sensors. In fact, to control the gait the system needs information concerning the position of the different segments in regard to the reference system. Thus, the sequence can be automatized with a general supervisor, the patient himself;*
- *implanted electrodes. Several types may be needed: epimysial, and neural or fascicular. The last one requires a good knowledge and understanding of the intraneural topography. The nerve trunk is constituted of axons innervating the muscle. A group of axons within the nerve is called a fascicle. The nerve is composed of several fascicles. It is important. in case of fascicular electrodes application, to determine the target muscle and corresponding fascicle;*
- *implanted control device. Safety and reliability are the key words for this determinant part of the project.*

CLINICAL PROGRAM

There are four basic issues within the program.

1.Patient selection

In this phase we consider SCI lesions between T_4 and T_{12}. In higher SCI lesions the upper trunk is not balanced and if the lesion reaches cervical level the upper limbs will be affected, involving other problems, such as prehension, maintenance of balance with arm support and similar. In incomplete SCI lesions a certain number of muscles may be preserved, and locomotion is functionally possible in certain cases. In addition, the motor function of the muscles below the lesion have to be completely synthesized. The elements for the synthesis of the cyclic motor activity could be obtained through neurophysiological studies (EMG, evoked potentials, etc.) and muscle biopsy (determining different types of muscle fibres). The training and type of activities determine the type of muscle fibres. Slow fibres are developed for postural activity and general movements: those fibres are characterized by an important resistance to fatigue, but a lower developed force in comparison with fast firing muscle fibres. Slow fibres act always, even for movements requiring high forces. The muscle biopsy may quantify the types of fibres within a examined muscle population. It is known that, restrengthening procedure with low frequency electrical stimulation induces a change of fast firing muscle fibres into the slow fibres. Some research results pointed out that specific muscle conditioning may preserve fast fibres. For the use of patterned electrical stimulation, for generation of a functional movement, both muscle fibres are important, because both, force and fatigue resistance are required. Anatomical studies, using MRI,

are important as well for this study, providing valid information on the morphometric characteristics of muscles.

In addition, evaluation of automatic medullary phenomena is essential. When a muscle is deprived of voluntary control it appears some reflexes, that are inhibited, normally by the brain influence. The muscles could become sensitive to a stretch (spasms), generating a non-volitional and uncontrolled contraction. The skin or internal organs could generate spasms which are automatic movements, and which create disturbances difficult to control. A certain kind of lesion presents those complications and needs to be excluded from this project. Extreme spasticity is regarded as an contraindication for CALIES.

Finally, tests to quantify the muscle performance with electrical stimulation have to be performed. A force transducer is used for the measurements of the muscle force in different leg positions. The study of a muscle performance and joint torque in different positions of the joint should be recorded before strengthening procedure. Recruitment curve, representing the force developed as a function of stimulation parameters (pulse width and/or amplitude) for each muscles have to be recorded.

2.Pre-operative training

Two issues are included in this phase:

- *strengthening of the muscle with electrical stimulation applied with surface electrodes. The achieved performance will be compared with initial measurements and performance of normal individual;*
- *walking machine tests. Patients will be trained to maintain upright posture and to walk using a new version of motorized external skeleton system. Externally controlled and powered six degree of freedom walking system will be used to produce unbalanced gait, resembling to the one generated by electrical stimulation. Under-elbow crutches will be integrated in the system. This model will be used to develop some control laws useful to control muscular actuators and necessary feed-back loops.*

3.Surgical procedure

One of the goals of this project is to respect the body integrity. In order to achieve such a goal we are currently studying the possibility to use endoscopic approach for the implantation of the electrodes and electronic devices of the CALAIS package. Such a technic seems possible and needs to design specific implementation. Endoscopy is more and more employed for abdominal surgery. As the nerves implied in the actuation of the target muscles are in the abdominal cavity, and as the electronic implanted part has to be fixed within the cavity, it seems rather possible to use it. It allows us to implant the electrode and the electronic via small holes in the skin of the abdomen. We are working on intraneural topography to optimize the location of the electrodes. Tests are performed on cadavers to verify such a possibility. This emphasizes the technology transfer needed in this European project. Obviously, the use of this technique implies the formation of multidisciplinary surgery teams, justifying the creation of a European Clinical Network.

4.Post-operative training

After the implantation, the patient needs to be stimulated with specific pattern in order to preserve his muscles at the same functional state as prior to the implantation.

This training includes training while laying or sitting, verticalisation with the system, gait training with specifically generated patterns. The pattern will be adapted to meet personal requirements and needs of each patient. Climbing pavements and stairs will be done in a letter phase.

All specific adaptation should be done during the training protocol. The patient will be taught to command with the system.

ORGANIZATION OF THE RESEARCH AND DEVELOPMENT

Regarding the CALIES organization, 4 countries are officially members of the program: France, Italy, The Netherlands and Ireland.

The specific coordination of the project is assured by Professor P. Rabishong. The industrial cooperation is assured by BERTIN Company.

Another structure, in the frame of the CALIES project, will be created during the first months of 1990. This structure called C.E.C.N. (Calies European Clinical Network). It is composed of three committees which group one expert per country in three fields, even in the country which does not participate in the CALIES. One committee for rehabilitation, coordinated by Professor G.Zilvold (Enschede, The Netherlands), the second committee for the surgery coordinated by Professor Samii (Hanover, Germany), and the third one for technical procedure coordinated by Professor A.Pedotti (Milano, Italy).

The goal of the CECN is to provide information in different countries of the European Community, and to coordinate the formation of pilot centres in the field of implanted electrical stimulation system.

INSTEAD OF CONCLUSION

At this stage of the R & D, we would like to point out some other perspectives of the CALIES project. The CALIES concept could be expanded to some other application of rehabilitation. This approach can be transferred to other types of injuries resulting with different motor deficiencies such as:

- *hemiplegia, where only one side is affected,*
- *control of prehension in cervical SCI lesions,*
- *bladder control in SCI patients and the like.*

It is clear that the expansion of the program requires some other expertise and extension of the project to some other rehabilitation and research centres.

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