Pressure Ulcer Formation Prevention in Paraplegics using Computer and Sensory Substitution via the Tongue: First Steps in a Sustainability Study.

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Abstract

Since pressure ulcers remain a major health issue in individuals with spinal cord injuries, a new medical device is being developed. Based on the principle of sensory substitution, it aims at compensating the sensory deprivation in the buttock area by the tactile sensory modality in the tongue area. This paper concisely describes the last home-made medical device and reports the first methodological steps of a sustainability study: an open pilot prospective clinical study in 10 healthy seated subjects with 92% success in 100 performed tests; a current open randomized prospective controlled clinical trial with the methodology used.

Keywords: Medical Device, Evaluation Studies, Sensory Substitution, Paraplegia, Deprivation

Introduction

The prevalence of pressure ulcers ranges from 23% to 39% in adults with spinal cord injuries and remains high in this population. Pressure ulcers are recognized as the main cause of rehospitalization for adults with paraplegia. Their treatment is always long difficult and expensive. This pathology appears thus to be a major health issue for this population.

The concept of sensory substitution has its origins in the works of P. Bach-y-Rita for blind people. To demonstrate his statement "we do not SEE with the eyes but with the brain" - the visual image does not go beyond the retina, but is turned into patterns of pulses along nerves and is carried to the brain - a human-machine interface, the Tongue Display Unit (TDU), was developed. It consists in an array of electrodes put in contact with the tongue surface. Visual information is then transmitted from the digitalized signal of a TV camera to this array of electrical stimulator which transmits information to the brain. Evidential results were obtained, as, for instance, the capacity of executing complex "eye-hand" coordination tasks.

Our research aims at particularizing works of P. Bach-Y-Rita for blind people to paraplegics by compensating the sensory deprivation in the buttock area through the tactile sensory modality in the tongue area. This compensation would indeed enable paraplegics to feel again "information" arising from the buttock area, from which they could adopt suitable movement in order to prevent the formation of pressure ulcer in this area.

Materials and Method

A new medical device has been developed to compensate for sensory loss in paraplegics in the buttock area. It consists of three components: a ***pressure mapping system***, the **T**ongue **D**isplay **U**nit (***TDU***), and a ***laptop***.

The ***pressure mapping system***, built by the Vista Medical® Company, connected with the laptop, enables the real-time acquisition of the pressure applied on the seat/skin interface. The **TDU**, initially developed by P. Bach-y-Rita and colleagues, has been improved and miniaturized by the Coronis-Systems® Company to put the whole human-machine interface into an orthodontic retainer with real-time reliable wireless transmission from the laptop to the TDU. The ***laptop***, which enables communication between the pressure mapping system and the home made TDU, has been programmed to send electro-stimulations to the tongue. According to the detection of pressure maximum applied at the seat/skin interface during one minute, the best direction of chest movement that the paraplegic has to adopt to correct this detected pressure maximum (and thus to prevent the tissue suffering) is then sent.

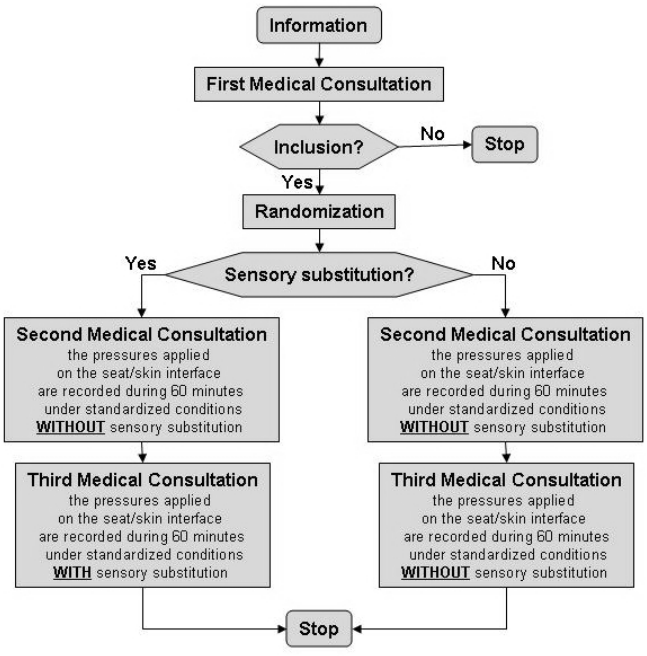
Two first steps have been performed to study the potential sustainability of this new approach to prevent the formation of pressure ulcers in paraplegics. The first one is a pilot open prospective clinical study in 10 healthy subjects. In this study, each subject has to move his chest according to an electro-stimulated direction. The detection of an adapted resulting movement is established by the adequacy between the electro-stimulatory information and the recorded pressure changes induced by the chest movement. The second one, performed in paraplegics, is a randomized double-blind prospective controlled biomedical study. The primary outcome is to evaluate the possibility of improving, in a determinist way, the spatio-temporal distribution of the pressure applied at the seat/skin interface in order to avoid tissue suffering. The secondary outcomes are related to the quantitative and qualitative evalua-

tions by paraplegics of the tongue calibration step which is required because of the personal spatial anisotropy of the tongue sensibility, and of the potential acceptability by paraplegics of this new medical device in everyday life.

Results

With 92% success in 100 performed tests, the first study in healthy subjects demonstrates three main points: first, the healthy subjects have a strong perception of the electro-stimulated information on the tongue; second, this information is both meaningful and correctly interpreted; and third, the action resulting from the interpreted information is adapted, with changes in pressure, to the electro-stimulatory information.

The second study is currently performed according to the French biomedical research law. This clinical study takes place in the Grenoble Clinical Investigation Centre (GCIC) in collaboration with the Grenoble Technological Innovation Centre (GTIC). Two arms (with and without electro-stimulation) have been planed in the clinical trial (cf. figure 1) to evaluate the potential impact of the electro-stimulation on the spatio-temporal distribution of the pressure. The statistical unit is the difference, by subject, of the results adapted with changes in pressure. The statistical analysis will compare means (medians) between the two groups. The statistical tests will be performed after verifying the conditions of use. The



secondary outcomes will be principally analyzed in a descriptive way.

Figure 1 – An open randomized prospective controlled biomedical research

Discussion

To our knowledge, there has been no study to date that uses sensory substitution via the tongue in order to prevent the formation of pressure ulcers in paraplegics.

One of the main difficulties of using sensory substitution reported by P. Bach-y-Rita was the development of a practicable user-friendly human-machine interface. As this device has to be wholly accepted by paraplegics, we built a new cosmetically acceptable interface into an orthodontic retainer, with FM transmission of the signals from the laptop connected to the pressure mapping system to the tongue device unit for relay to the brain.

The first study shows that communication from the organ of sensory substitution "towards" the region of sensory loss is achieved (pressure motion adapted to the electro-stimulatory information). The reverse communication from the buttock area to the tongue is currently evaluated in the randomized prospective controlled clinical trial. If this reverse communication is confirmed, it would then enable the simulation of the whole conscious or subconscious loop defined in the healthy subject by ***perception*** of a stimulus coming from the buttock area (alert), ***analysis*** of this signal and ***action*** adapted to the signal in order to correct the cause of this alert.

Further research has to be performed to determine the type of information that will be applied through tongue electro-stimulation as well as the electro-stimulation scheme. For instance, in the first case, should low-level information (pressure) be used with the subject having to interpret this "raw" information? Or should high-level information be used, such as an optimal direction of movement computed in an automated way from pressure maps?

The sustainability evaluation of new medical innovative devices is always difficult because of the complexity of the different components that have to be taken into account. Our studies are made easier by the Grenoble Technological Innovation Centre, a French structure which is playing a real interface part between the three essential actors of the innovation: the University, the Hospital and the Companies.

To determine the real sustainability of this new medical device, future evaluations would have to be as exhaustive as possible, from a clinical relevance point of view to a public health point of view, as, for instance, by taking into account the economic point of view (cost-effectiveness analysis).

Conclusion

Because pressure ulcers are still a major health issue for individuals with spinal cord injuries, a new health strategy to address this problem is developed. This paper reports the principles of a new approach using computer and sensory substitution via the tongue and the first steps performed in a sustainability study.