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Design of an Innovative Integrated System for Upper Limb Prosthesis

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Abstract. Nowadays the prosthetic system can be configured as a multifactorial set that includes reciprocal relationships between the stump, the socket, the prosthesis and the tridigital/robotic hand. This system presents some critical issues that can be addressed by improving the integration between the parts and redesigning some components through innovative design-driven solutions. The paper describes the design of a sensorized liner for upper limb prostheses according to the User Centered Design methodology, focusing on the socket - which is conceived as an integrated system composed by Hypermat (the external rigid meta-structure) and the sensorized liner. The system was designed on the basis of the results that emerged in the focus group which involved amputee users, technologists and a heterogeneous set of design figures.

The project requirements on which the liner development and its integration with the Hypermat metastructure were based were defined. The paper describes the design of the sensorized liner taking into consideration the choice of materials, the application of myoelectric textile sensors and pressure sensors, the connector design for the connection between sensors and circuitry, the assembly and production methods.

Keywords: Sensorized liner · Smart textile · Upper limb prosthesis · Design for healthcare · EMG sensors · Pressure sensors

1 Introduction

People who underwent an upper limb amputation - due to occupational accidents, traumatological phenomena, diseases or musculoskeletal malformations need an adequate prosthesis that can restore autonomy and at the same time encourage work and social reintegration:

Upper limb prostheses can be classified as passive - those that don't have an actuator that activates the robotic hand - or on contrast active, those activated by body energy (kinematic) and/or extracorporeal energy (with myoelectric or electronic control).

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Upper limb prosthetic systems should be developed according to specific requirements in terms of electromechanical functions combined with aspects of aesthetics for acceptability and comfort. The main elements to consider in the design process are:

- the design of the system scalable on anthropometrics
- morphological and functional adaptation based onto anthropometry of the residual limb
- mechanical properties for supporting the motor of the hand and body integration
- usability and wearability for comfort and acceptance
- skin biocompatibility
- low weight
- aesthetic acceptability
- biosignals detection and processing for the actuation of electromechanical and/or robotic elements

Although the development of prostheses evolved a lot in recent decades, combining the manual skills of orthopedic technicians with technological know-how in terms of materials and sensors, some critical issues remains and must be analyzed and tackled while designing the prosthesis. From researches with users, the problems concern in particular the relationship between stump, socket and prosthesis are retrieved from literature and here below summarized:

- the perception in terms of stability of the stump-socket interface
- pressure points in specific areas that cause ulcers and skin irritation
- low breathability of the socket
- difficulties in the positioning of electromyographic electrodes
- the maintenance of necessary but comfortable friction forces
- the lack of customizable aesthetic and functional prosthetic cover

1.1 The Project

The aim of the Maps project is to improve the prostheses through the design of an integrated system based on innovative multifunctional materials and developed according to the User Centered Design (UCD) methodology.

A meta-structure has been designed, called Hypermat (Fig. 1), that is configurable according to the individual anatomical shapes needs of the user with a mapping of the distribution of the surface in relation to the functional areas of the prosthesis. The Hypermat was designed as an integrative solution between prosthesis and socket, which is conceived as a combination between the meta-structure that performs mechanical function and a sensorized textile liner for the detection of bio-signals (Fig. 2).

Innovative materials have been developed to integrate the ergonomic functional characteristics of Hypermat: phase shift materials (PCM) and graphene-based multilayers for better thermal behavior and piezoresistive materials inserted in the liner for the monitoring of pressure points.

This paper describes the methodology and development of the sensorized liner and its integration with Hypermat.

Fig. 1. The Hypermat meta-structure, designed by CNR ICMATE.

2 Materials and Methods

2.1 User Research

The improvement of the quality of life of the patient with amputation of the upper limb is the primary aim in the design of the liner and its respective integration with Hypermat.

The entire design process was based on the UCD method, in which the user is the central point of the design process. According to this methodology "The designer must understand the users, their cognitive behavior, attitudes and the characteristics of their work task" (Gulliksen and Goransson 2001), developing through an active and collaborative participation of the user in the different design phases.

Focus Group was chosen for the User analysis, and it carried out at the Centro Protesi INAIL in Vigorso di Budrio (Italy).

The focus group was attended by six patients with radial and trans-radial upper limb amputation with different types of prostheses, both active and passive, and the simultaneous presence of seven actors including technologists, bioengineers, designers and materials experts.

Participants were asked to describe the activities they carry out in their daily routine, considering awakening, personal hygiene activities, meals, work and study, sports and leisure, with the aim of understanding and evaluating how they use the prosthesis in these activities.

The results of the Focus Group highlighted a series of user's needs which can be summarized here:

- Excessive system's weight
- Problems related to the stump/socket interface in terms of perception of stability
- Difficulty in dressing/undressing clothes, in particular as regards friction between the prosthesis and clothes (t-shirt, shirt)
- Difficulty in cleaning and hygienisation of parts
- Skin irritation due to poor breathability and local points pressure
- Overheating of the electronic parts during the summer with consequent malfunctioning
- High cost for replacing EMG sensors in case of failure
- Difficulty in wearing the prosthesis

2.2 Requirements Definition

Based on the results emerging from the focus group, the project team has defined the following design requirements for the development of an innovative prosthesis socket integrated with the Hypermat; it should be:

- Integrable with pressure sensors for the monitoring of pressure points
- Morphologically fitted to the volumetric daily variations of the stump
- Increase the wearability in dressing/undressing clothes and of the prosthesis itself
- Washable
- Economically sustainable in terms of replacement for breakdown or malfunctioning
- Reproducible for easy substitution
- Integrable with the electronic components of the robotic hand
- Aesthetically fine and customizable

2.3 Project Developments

Refers to the design requirements, a sensorized liner intended as an interface between the meta-structure and the stump was designed (Fig. 2). The liner - developed in fourway stretch fabric - supports myoelectric sensors and two pressure sensors. These sensors embedded in the liner are made in conductive fabric based on silver yarn to detect the myoelectric signal, and in sintered TPU loaded with graphene to detect the pressures.

The myoelectric ones are made by laser cutting the silver-based 3D fabric and embedding them within the liner through thermo-adhesivation process, meanwhile the pressure ones are fabricated through an innovative sintering process developed by CNR IPCB.

The realization of the sensorized fabric liner allows to produce the system with lower costs than the production method currently in use, since the sensors can be reproduced at the INAIL Centro Protesi's production department. In addition to the EMG sensors, two pressure sensors are embedded on the liner, which are placed in two specific points that are identified like the most stressed area in terms of daily volumetric variation of the stump.

In addition, the textile sensorized liner can be washed to allow a better hygienisation of the system.

The myoelectric sensors, made in 3D fabric, were tested through 50 manual washes, reporting a negligible loss of conductivity. The pressure sensors are instead embedded in the liner through a double thermo-adhesive protective film that makes them waterproof.

In the lower part of the liner - near the apical area of the stump - there is a connector that carries the EMG and pressure signals to the electronic unit for the movement of the robotic hand.

The liner required the implementation of specific materials and technologies in the development process. EuroJersey's Sensitive Bold fabric was implemented for the textile support, which answer the requirements of elasticity, breathability, mechanical strength and biocompatibility.

From the production point of view, it was decided to develop the liner through a manufacturing process that involves the use of laser cutting, additive and thermoadhesive printing technologies.

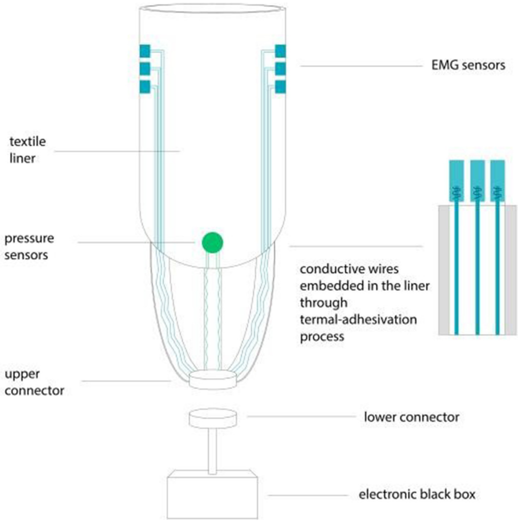

Fig. 2. Drawing of the liner and its components.

The choice was based on the design decision to use the same tools and production processes both in the prototyping phase and in anticipation of the subsequent production phase, starting from two-dimensional mathematical models easily scalable according to the different anthropometries of the patients. This solution involved the implementation of a thermo-adhesive system based on double-sided elastic glue to allow stable bonding and waterproofing of the parts.

The EMG sensors have been made of conductive fabric based on silver yarn, laser cut and applied to the textile structure through thermo-adhesive. The myoelectric signal is carried by the sensors to the terminal base of the liner by conductive filaments that are inserted inside metal probes. These probes, three for each of the two EMG sensors, are mechanically inserted and welded inside a male connector, made of polymeric material, on which a connection plate is inserted. The male connector is inserted in the female connector through a system of magnets which allows to stabilize the contact between the parts (Fig. 3).

Fig. 3. The male-female connector to carry the signals to the electronic device

The connector plate has been designed to house 6 connections for the electromyographic signals and 4 connections for the signals deriving from the two pressure sensors. These one have embedded in the liner trough by thermo-adhesive and also they have a connective structure based on metallic wires and probes the same one used for EMG sensors. The sensorized liner was completed with the electronic board which allows to detect the signals from the pressure and EMG sensors. The electronic system was equipped with two OY Motion Gravity digital boards for acquisition, processing and transmission of EMG signals, a custom made board for the acquisition of pressure sensors' signals and 500 mA battery (Fig. 4).

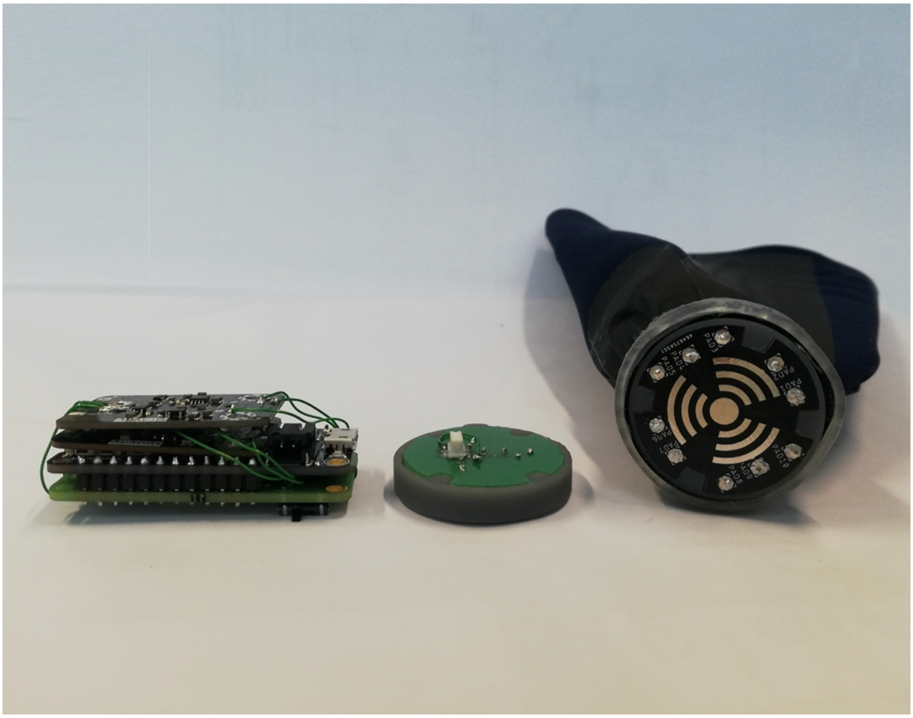

Fig. 4. The final prototype, ready for the testing.

3 Conclusions and Future Developments

The development of a sensorized upper limb liner integrated with Hypermat allows the replacement of the reservoir currently used in orthopedic prosthetic departments with a scalable solution based on patient anthropometrics and economically sustainable. The proposed solution also allows the monitoring of point pressures on the stump on two different skin areas of the stump and improves the hygienisation of the socket system thanks to the breathability and washability of the fabric. The next steps will focus on the improvement of different system components such as: the development of semi-finished composites made with single-sided adhesive and metal fibers arranged sinusoid to ensure more stable and flexible connections between the sensors and the connector and the realization ad hoc of metal probes inside the connector itself. Positive preliminary comfort test was done with users. No group comparison because of unicity of the prosthesis. In a subsequent phase, extensive of usability tests are planned with a panel of users of the INAIL Prosthesis Center for the quantitative assessments of the prototype.

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