Attività per Assegno di Ricerca DIMSAI nell'ambito del progetto MyLEG

Le attività che verranno svolte dall'assegnista avverranno nell'ambito del progetto di ricerca H2020 MyLEG. In particolare esse riguarderanno attività di:

1. Progettazione della nuova protesi per arti inferiori e si intersecheranno con quanto previsto nel
    a. WP2 relativo a "*Requirements, benchmarks, and ethical issues*" al fine di acquisire le informazione utile per una progettazione integrata della protesi medesima
    b. WP3 relativa a "*Mechatronic design and realization of the MyLeg transfemoral prosthesis*" al fine di contribuire alla progettazione della protesi in cooperazione con il gruppo di ricerca di Groningen
2. Studio, sviluppo e validazione sperimentale dei materiali compositi per la realizzazione della nuova protesi, attività che verrà sviluppata nell'ambito del WP4 avente come oggetto "*Development of novel composite materials*"
3. Disseminazione e valorizzazione dei risultati ottenuti durante il percorso di ricerca in coerenza con quanto previsto nel WP7 avente come oggetto "*Dissemination and promotion of exploitation*"

Nel seguito vengono riportate le parti essenziali relative ai WP del progetto MyLEG nelle quali il dottorando sarà coinvolto e, nell'ambito delle quali egli potrà sviluppare le proprie attività di studio e ricerca.

WP2 Requirements, benchmarks, and ethical issues

" ***Task 2.1: Amputee' requirements*** *(**RUMC**, All)* ***[M1-M3]***

This task analyses the amputees' reports and past evaluation experiences of OSSUR, of the rehabilitation center RRD, and of both the hospitals RUMC and UNDA. In a second iteration, more specific amputees requirements will be discussed directly with the amputees, which are part of the Advisory Board. The envisaged activities of daily living and the amputee's need will have to undergo a feasibility assessment by the MyLeg partners that will be concerned with their implementation. Therefore, a sketch modular elementary behaviors that can be composed in an inter- and intra-system manner to give rise to the required system capabilities will be specified already at this stage. The resulting functional primitives will then be elaborated further in a task below when the benchmark-driven requirements will be identified in detail. In order to get a direct insight into the work, a workshop with amputees will be organized in M3 to get a first-hand impression of the their need. The outcome of the workshop will be discussed directly with the amputees in order to deduce shortcomings in technical support of the current prostheses. Those deficits will then be directly inputs to technical platform specifications for Task 2.3.

Task 2.2: Benchmark specification and related performance measures *(**OSSUR**, All)* ***[M1-M6]***

Using the inputs of the Task 2.1, the benchmarks of the MyLeg prosthetic system will be detailed so to derive the capabilities of the MyLeg system and, therefore, its requirements. The benchmarks will be defined on the activities of daily living with an incremental level of complexity so that the MyLeg system capabilities will be sequentially added:

- *Normal walking: in this benchmark, the passive dynamics of the MyLeg prosthesis will be evaluated. Performance measurements will relate to the kinematic data that will be collected during the functional test* *performed and to the metabolic energy consumption data that will be collected during the tests performed with amputees (wearing their own sockets or with osseointegration). Performance measurements will relate to the power flow in the prosthesis and to the metabolic energy consumption of the amputees.*

- *From normal to slow and fast walking: in this benchmark, the MyLeg prosthesis will be evaluated together with its variable stiffness springs/actuator, developed with novel materials. Performance measurements will relate to the adaptability of the prosthesis to different walking velocities.*
- *Intuitive control: in this benchmark, the bidirectional control will be evaluated with transfemoral amputees. Performance measurements will relate to the capability of the MyLeg system to respond to the user demands.*
- *The complete MyLeg system in activities of daily living: in this benchmark, the overall system will be evaluated according to the amputees' needs as envisaged in Task 2.1.*

The benchmarks will be assessed by all the MyLeg partners in terms of feasibility with respect to their activities foreseen in the project.

Task 2.3: Overall MyLeg prosthetic system requirements** (**OSSUR**, All) **[M1-M6]

The detailed specifications for the MyLeg system form the final outcome of this work package and are conceived as an important input to the other work-packages. These specifications will concern the prosthesis, the variable stiffness springs, the high-level control, the power management and the sensors on the one hand, but also intuitiveness, perception, usability, dependability as far as required at that stage of the project. All partners will be strongly involved in the definitions of their concern.

Task 2.4: Ethical issues** (**RUMC**, All) **[M1-M48]

The MyLeg experimental activities will be conducted in The Netherlands (UT, RRD, and RUMC). All experiments will be conducted in accordance to Helsinki principles, and after the approval of the local Ethics Committee. A research protocol will be prepared for the foreseen validation of the MyLeg prosthetic system in the benchmarks defined in Task 2.2."

WP3: Mechatronic design and realization of the MyLeg transfemoral prosthesis

"Task 3.1: Mechatronic design/realization of the first prototype of the MyLeg transfemoral prosthesis** (**UT**, UNIBO) **[M1-M22]

The first prototype of the MyLeg transfemoral prosthesis will be a fully passive device, and will be designed and realized to accommodate (some of) the amputee's needs during nominal tasks (i.e., normal walking). More specifically, the first prototype will be energy efficient and lightweight. The design/realization of the first prototype will rely upon the deep understanding of the human motion and upon the definition of simple but competent models, by means of which the working principle of the prosthesis will be derived. The use of the port-Hamiltonian framework will be instrumental for the design of the mechanical structure, as it allows observing the energy flows between the different parts of the system. The prosthesis will rely on passive energy storage elements, realized with novel composite materials as developed in Task 4.1, which will realize an energetic coupling between the knee and the ankle joints. Thanks to this coupling, the energy storage elements will passively realize a powered movement (corresponding to the concentric contraction of the human muscles). This Task 3.1 is in-line with the OBJECTIVE 1 of the MyLeg project (see Section 1.1).

Task 3.2: Mechatronic design/realization of the second prototype of the MyLeg transfemoral prosthesis** (**UT**, UNIBO) **[M31-M30]

The second prototype of the MyLeg transfemoral prosthesis will be an active device, and will be designed and realized to accommodate (some of) the amputee's needs during not-nominal tasks (i.e., change of speed, stair ascending/descending, walking uphill or downhill, stopping/starting walking, sitting/standing). The second prototype will build upon the first prototype and it will be also intuitive, adaptable, and robust. The second prototype will include actuators and variable stiffness springs, realized with novel composite materials as developed in Task 4.2. In Task 3.2, the low-level control of the second prototype of the MyLeg transfemoral prosthesis will be designed in order to both control the actuators for not-nominal tasks and tune the intrinsic dynamic behaviour of the device according to the change of speed or to unexpected unevenness of the terrain (e.g., by allowing resistive moments when necessary, corresponding to the eccentric contractions of the human muscles). Intuitiveness will be achieved by using the results of Tasks 5.1 and 5.2 on the use of surface EMG signals and their integration on the low-level control of the transfemoral prosthesis's actuators. This Task 3.2 is in-line with the OBJECTIVE 2 of the MyLeg project (see Section 1.1).

Task 3.4: Mechatronic design/realization of the third prototype of the MyLeg transfemoral prosthesis** (**UT**, UNIBO, RRD)* ***[M28-M42]

The third prototype of the MyLeg transfemoral prosthesis will be build upon the second prototype. The third prototype will be dependable, it will enhance stability and energy efficiency, and it will reduce the cognitive effort of the transfemoral amputees. Sensors, made of composite piezoelectric materials as developed in Task 4.3, will be added on the sole of the prosthetic foot so to detect contact/no-contact, to measure the state of both the prosthesis and the environment, and to realize energy harvesters. This third prototype will include the high-level control, as developed in Task 5.3, which will endow the system of perception capabilities. This Task 3.3 is in-line with the OBJECTIVE 3 of the MyLeg project (see Section 1.1)."

WP4: Development of novel composite materials

"Task 4.1: Elastic elements with composite materials** (**UNIBO**, UT)* ***[M1-M22]

This task focuses on the design of the elastic elements for the first prototype of the MyLeg prosthesis, which will be realized in composite materials to achieve an overall lightweight structure. The design of these elastic elements will be a preparatory work for the design of the variable stiffness elastic element, focus of the Task 4.2, for the second MyLeg prototype.

The elastic elements will be made of Fiber Reinforced Epoxy (FR-Epoxy) laminate, they will be passive and they will be designed to support the maximum loads on the prosthesis. More specifically, thanks to these elastic elements, the first prototype will be an energy-recycling mechanism in which the energy stored in the knee joint will be transferred to the ankle joint so to achieve ankle push-off.

The accomplishment of the Task 4.1 will enable the accomplishment of OBJECTIVE 1 of the MyLeg project (see Section 1.1).

Task 4.2: Variable stiffness elastic elements with composite materials** (**UNIBO**, UT)* ***[M13-M34]

This task focuses on the design and realization of the variable stiffness elastic elements for the second prototype of the MyLeg prosthesis. The variable stiffness elastic elements will be made of electro-active composite laminates, characterized by a tunable stiffness. This task will be organized in the following steps:

- *Production of the active layer – The active layer will be made of ceramic piezoelectric submicro-fibers that will be produced by sol-gel electrospinning process. The stabilized sol system, which contains all the ceramic precursors such as titanium, zirconium, and lead, will be processed by a dedicated electrospinning equipment in order to avoid any ageing phenomena, and to establish a secure and cost-effective manufacturing process. The electrospun membrane will be heat-treated in order to obtain the final and stable piezoelectric ceramic material. The piezoelectric ceramic material will undergo a Scanning Electron Microscopy (SEM) morphological analysis and an X-Ray Diffraction (XRD) analysis. After these preliminary characterizations, the piezoelectric ceramic material will be coated by electrospun conductive nanofibrous mats to obtain an electro-active layered material, which will be flexible and porous. The electro-active layered material will be characterized by determining the stress-strain curve under different levels of electrostatic stimuli. The stress-strain-voltage characteristic will be used to design the variable stiffness elastic elements.*
- *Production and characterization of the variable stiffness elastic elements – The variable stiffness elastic elements will be made of the active layer (produced in the previous step) interleaved with fibrous reinforced layers (glass and carbon fibers reinforced materials will be used). An autoclave-curing process will be applied to consolidate the material. Several prototypes of electro-active (variable stiffness) elastic elements will be realized and characterized. In particular a single, a double and a triple active layers composite laminates will be realized. Stress-strain axial and bending tests will be done under different voltage values in order to evaluate the stress stiffening effect of the active material. Fatigue and creep tests will also performed in order to determine the durability of the electro-active elastic element. The manufacturing process and the material itself will be both undergo to Life-Cycle-Analysis and Life-Cycle-Cost.*

The accomplishment of the Task 4.2 will enable the accomplishment of OBJECTIVE 2 of the MyLeg project (see Section 1.1).

Task 4.3: Sensors and energy harvesters with composite materials** (**UNIBO**, UT) **[M25-M42]

This task focuses on the design and realization of the sensors and energy harvesters that will be placed on the sole of the third prototype of the MyLeg transfemoral prosthesis.

The sensors will be realized by means of electrospun piezoelectric polymer materials and, more specifically, the PVdF-based copolymer PVdF-TrFe. The design of the sensors is organized in the following steps:

- *The PVdF-TrFe copolymer will be processed through electrospinning techniques. Nanofibers membrane with different thickness will be prepared and electro/mechanically characterized in order to determine the most appropriate material configuration that will be able to satisfy the requirements derived in WP2. The preliminary laboratory characterization will be: (SEM) to evaluate the nanofibers morphological quality, XRD to determine presence of the piezoelectric phase and to determine the electrical permittivity and conductivity of the electrospun membranes.*
- *After this preliminary characterization, the electrospun membrane exhibiting the best characteristics will be covered by conductive nanofibers in order to obtain a complete electro-responsive nanofibrous system, which can be easily integrated into different types of matrices.*
- *The complete electro-responsive nanofibrous system will be embedded into different matrices in coherence with the requirements defined in WP2. The embedded electro-responsive nanofibrous system will be characterized in terms of: i) maximum voltage intensity when the sensor system is subject to both mechanical bending and impulsive loads (loads will be varied in terms of intensity and of frequency); ii) signal reliability (quality and repeatability of the output signal during repeated tests and under different environmental conditions, such as in presence of humidity and other liquids which can be present during the sensor real life, according to the environmental conditions defined in WP2); iii) sensor durability (accelerated life tests will be done considering as critical parameters the maximum load, the frequency of loading, the temperature and the presence of external liquids having different grade of PH); iv) recycling strategy (when the sensing material will end its function it must be considered a specific recycling strategy depending on its residual*

characteristics and the type of the used matrices). Life-Cycle-Analysis and Life-Cycle-Cost will be done on both the manufacturing process and the material produced.

The energy harvesters will be realized by means of electrospun piezoelectric polymer materials and, more specifically, the PVdF-based copolymer PVdF-TrFe. The electrospinning process will generate a porous and flexible nanofibrous active membranes. In order to achieve a power response of the piezoelectric material as high as possible, a high electric conductive nanofibers will be produced and integrated into the active material. In particular, layer-by-layer electrospinning process will be adopted in order to maximize the power extraction from each piezoelectric nanofiber of the membrane. The active membrane, including the conductive nanofibers, will be embedded into flexible matrices (e.g., polyurethane) to protect them and to incorporate them into the sole of the third prototype of the MyLeg prosthesis. The membrane will be characterized by determining their electric response when subjected to mechanical loads: pressure-power, low-velocity-impact-power and bending-power will be determined. Repeatability and durability tests will be done on manufactured materials under different environmental conditions to optimize the material.

The accomplishment of the Task 4.3 will enable the accomplishment of OBJECTIVE 3 of the MyLeg project (see Section 1.1).”

WP7: Dissemination and promotion of exploitation

*“**Task 7.1: Public Visibility** (**UT**, All) **[M1-48]***

Within the framework of this task all the activities that aim to increase the public visibility of the MyLeg project will be scheduled, organized and accomplished. The activities within this contain the dissemination material of the scientific results as well as non-strictly scientific actions and aim to raise awareness, inform, promote the project results and pave the way for further opportunities. More specifically, the following two subtasks will constitute this task:

<u>*Dissemination Profile and Material*</u>*: The aim of this task is to produce a project coordinated image and dissemination materials, which will be distributed to specific target groups and the general public. The goal is to increase awareness across the world and the community about what robotics can achieve and how MyLeg contributes scientifically and towards advanced prosthetic systems. These goals will be achieved through*

- *Publications in top-notch scientific conferences and journals*
- *Participation in healthcare conferences and workshops, robotics forums and exhibitions*
- *Preparation of general-public dissemination materials in printed and digital form*

As well as the organization of:

- *Public demonstration events to show the MyLeg prosthetic capabilities in operation*
- *Press conferences in the association with some of the main events of the project (kick-off meeting, experimental validation periods, final dissemination workshop)*

<u>*Online material*</u>*: The aim of this task is to create and manage a website for public dissemination of results as well as establish other methods of communication. It will consist of:*

- *Project introduction section, where the partners, their profile, the main objectives as well as a technical analysis of the concepts to be addressed by the project will be presented.*
- *A web-management tool for quick online management of internal partner information.*

- *Project update section, where the project current status, main achievements and results will be reported in the form of a timeline slideshow accompanied with links to further dissemination material (publications, videos, articles or presentations in the media).*
- *Material developed for the summer school and for the final dissemination workshop (see Task 7.2)*
- *Public calendar, so that anyone can track the progress and the main events of the project.*
- *An open source section, where all the software code developed from the academic partners during the project will be published and fully documented based on the highest standards of the open-source community.*

Understanding that the use of internet has changed over the last few years through the introduction of social media, special attention will be paid to use this channel of public dissemination. In that sense a) a YouTube video channel will be maintained and b) Facebook/Twitter accounts will be linked automatically with the website updates.

Task 7.2: Dissemination of scientific results and training** (**UT**, All) **[M7-48]

The main focus here is related with the scientific publications in conferences and journals in the robotic, (bio-)mechatronic, rehabilitation, and medical fields. A final dissemination workshop will be organized in one of the aforementioned conferences with the aim to attract all scientists working in similar fields.

Special attention will be paid on organizing training activities and particularly:

- *A workshop to meet the amputees to evaluate their needs in activities of daily living will be organized on M3 of the project. This workshop aims at deriving the MyLeg system requirements.*
- *A summer school on topics relative to the project results will be organized on M42 of the project. The summer school will target PhD students and postgraduate and it will represent the main training event of MyLeg.*
- *A final dissemination workshop on M48 that will aim at presenting final results and scientific contributions achieved within the project as well as live experimental demonstrations. The workshop will equally focus on academic institutions and industrial end-users.*

Task 7.3: Open data management** (**UT**, All) **[M6-48]

MyLeg will participate in the Open Research Data. A Data Management Plan (DMP) will be developed describing the data management life cycle for all data sets that will be collected. More details the DMP will specify what data the project will generate, whether and how it will be exploited or made accessible for verification and re-use, and how it will be curated and preserved. A deliverable containing the DMP will be produced on M6.

Task 7.4: Strategic market-based dissemination** (**OSSUR**, All) **[M37-48]

This task builds focuses on the dissemination activities required to spread the technical results of the project to a wide subset of the potential end-users and stakeholders that are active in the area of prostheses, rehabilitation/assistive robotics, and more (i.e., the areas of the MyLeg subsystems). The technical results will be combined with market analysis. To aid successful dissemination, key public authorities and private enterprises relevant to the field will be invited to attend the MyLeg public demonstration events. Additionally, the direct channels of OSSUR will be utilized to raise interest to end-users to increase the visibility of the project results in the industrial/commercial robotic and industrial sector. Among other ways, the Consortium will focus on participating in technological exhibitions. A special role will be played by the Advisory Board

Task 7.5: Harmonization and standardization** (**UT**, All) **[M1-48]

This task involves efforts on harmonizing and integrating MyLeg with other relevant research projects that took place or are currently taking place within the European research area as well as all the main international research efforts. This will be achieved via collaborative organization of workshops, participation in common *events, round-table meetings to exchange ideas and directions as well as through the role of the MyLeg Advisory Board and by releasing open software contributions. An extensive list of relevant projects will be available at the MyLeg website.*

Task 7.6: Exploitation, management of knowledge *(**UT**, All)* ***[M25-48]***

The objective of this task is to ensure the further exploitation of the project outcome. This will be achieved via the identification and assessment of the knowledge and technological contributions generated in the different WPs. This analysis will be related with studies on the potential market success in short- and mid-term in order to conduct focused actions that will raise awareness and attract interest. The Consortium will focus on both exploiting the results on the specific area of transfemoral prosthesis as well as on the individual technologies and subsystems that can have an impact in the wider area of robotic/industrial applications. The goal is to increase the role of European enterprises in the worldwide robotics market while also forming collaboration with international enterprises.

Task 7.7: Technology assessments and business development *(**UT**, All)* ***[M37-48]***

This task aims at identifying the suitable safety regulatory guidelines for the correct development of the device. The goal is to perform risk analysis on the device developed within the project, taking into account user safety and system effectiveness. Then, to cover the final step that separates a product from a market, the project will consider solutions for the industrialization, commercialization and distribution of the product, in particular considering the possibility of spinning-off the labs, either by founding new companies or by merging with existing industrial entities."