LOWER LIMB PROSTHESIS: FINAL PROTOTYPE RELEASE AND CONTROL SETTING METHODOLOGIES

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Abstract: The current research activity on prostheses project at the Robotics Laboratory (Mechanics Department, Politecnico di Milano) is carried on in cooperation with Centro Protesi INAIL and STMicroelectronics. The team is both innovative and interesting, owing to the fact that it not only involves a range of specialists but also gives rise to interdisciplinary aspects. They are absolutely essential in project dealing with such complex issues. This Mechanic-Leg project, called Hermes, is an original solution in the field of prosthesis. Main aim of this research is the prototyping of a new kind of mechanical lower limb with an electronic control. The device, resorting to innovatory mechanical and electronic solutions, allows the controller to modify the type of step, passing from a slow to a fast walk, in an easy and intuitive way, taking care of patient's requirements. The Hermes M-Leg cost is comparable to the actual commercial non electronic controlled artificial knees. The distinguishing features of Hermes M-Leg project are an higher awareness in innovative aspects related to medical/biological/engineering research. Then, a pervasive use of cutting-edge technology (electronics, IT, material-related technologies, etc.). The controller architecture is built upon a low memory processing features. The hard analysis and test activity help to model the algorithm for step control. The adaptive behaviour is mostly due to an effective experience in testing and software tuning in cooperation with patients and clinical staff.

1 INTRODUCTION

A *prosthetic system,* totally replacing a lost human body part (thereby ensuring the functionality of a specific physiological system), acts as a true spare part which the person is able to interact with. The prosthesis designer takes into particular account the man-device interface. This is done to satisfy the patient driven requirements and to project a suitable prosthesis. According to this statement, a innovative design concept emerges in evaluating the prosthesis system.
The prostheses technological evolution has begun in sixties. The availability of advanced technologies coming from the automotive and aerospace industry, allowed to develop more comfortable, resistant and light materials. The prosthesis weight limitation is indispensable to reduce the user tiredness and to allow a longer use during the day. In the 80s, new materials were introduced provided of similar mechanical resistance but lower density compared to previous ones. The miniaturization of components is actually fundamental in the design system; it allows to reduce the prosthesis overall weight. So that many global requirements have arisen from technology development to user comfort. First, an electronic controlled prosthesis must give stability to the patient, support his weight and make his/her movements easy. Therefore, it is very important to minimize energy supplied by the patient and to fit a natural limb behaviour. Finally, the device should be adaptive and self learning.
In this paper it will described a methodology in device optimization from several points of view. The final release prototype developed mixes up design, mechanics and software issues due to long experience in prosthesis field. An accurate analysis is carried on about all design process, and it will be presented as well as a short description of produced device.

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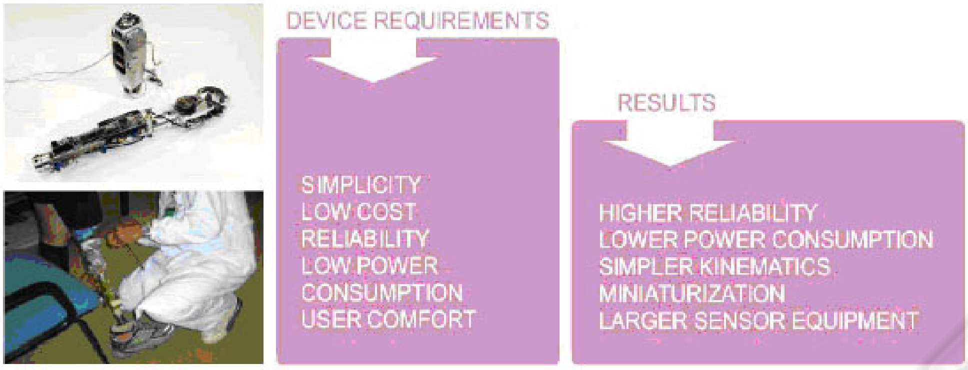

Figure 1: general design requirements

2 DESIGN METHOD OF THE M-LEG SYSTEM

Accurate design of a lower limb prostheses requires analysis aimed at defining shapes, materials and way of utilization. Analysis issues are related to general requirements coming from both experience and commitment outlines. One of the goals of the research work is to design a prosthesis equipped with some trick for storing energy. It would also enable an amputee to perform almost the same type of (even complex) movements as those performed with a natural limb. Another objective of this project is the development of the mechanical structure strongly oriented to criteria of maximum reliability. So, through the design process, two criteria were identified: a functional and a structural criterion. When the design was in progress, however, a hard reduction in sizes was crucial. It aimed to reduce overall prosthesis weight and get the best compactness compared to requirements and constraints. The prosthesis must satisfy two different requirements relative to the de-ambulation. First is stability. This requiring the assessment of robust geometries in relation to steady loads. Second requirement is related to specific leg and foot trajectory, so it requires a variable geometry. Naturally in the M-Leg prosthesis both requirements are satisfied within the same system. A prosthetic device for a thigh amputee must allow general de-ambulation conditions. Each movement situation, i.e. walking, climbing stairs, sitting, running, shows different kinematical and dynamic characteristics. The prosthetic mechanism must be designed for flexible efficiency in all of them. In the prostheses design over the last few years two phenomena have come to light:

• The exponential development of electronics applied to prostheses;

• The increase of models differing widely from those currently available - from those equipped with only a spring to those with hydraulic circuits-.

These two elements are closely connected; in fact, both are linked to the fast progress in electronics, to the consequent cost reduction, to increased processing and storage performance of chips and, most of all, to the increasing convergence of mechanics and electronics. Listed requirements are all related to behavioural or mechatronic issues. They must be managed in an innovative way, encoding a methodology starting, for instance, from the design approach.

The knowledge in creation processes, analysis methods and design procedures allows a team to use not only the most suitable technology but also a methodological approach for complex problems solving. This process involves different stages each of which needs subsequently to be validated. Researchers and designers fundamental task lies in the ideas "materialization" through effective methods, pursuing fast and competitive product for market. Even in research field, effective tool must be developed in order to gain large yield in innovative applications. The decision to begin a new system in the high tech devices sector involves the undertaking of a process that is generally not only long and expensive in procedural terms but also in cognitive terms. The first step is the design phase. It includes an initial project plan involving:

• analysis of the available technologies as well as those required;
• selection of technological tools to be used;
• choice of materials and validation protocol;
• realization of prototypes;
• exploration of available clinical data, either inside the team skills or likely to be found in literature on similar products;
• assessment and reformulation of specifications;

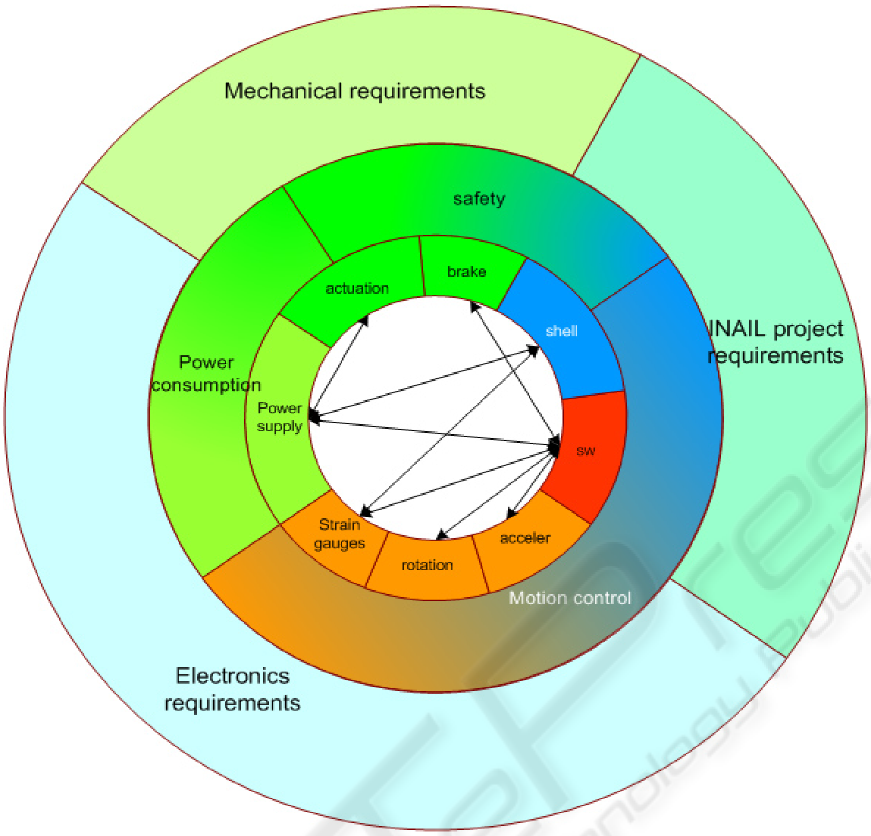

Figure 2: requirements and components

As a result, a structure of relationships among overall requirements leads towards project statements. This procedure may be codified and shared among the project team. Such procedure has been applied in last activity and final prototype production. In the next section it will be described the analysis methodologies transfer to project details and components.

3 ACTUAL RELEASE OF ARTIFICIAL LIMB PROSTHESIS. FROM DESIGN METHOD TO COMPONENT DESIGN

Long trained prototypes and maturity of skills in limb prosthesis development have drawn into final release of the artificial knee. This is due to a complete review of previous releases and to the fulfilling of special requirements in every detail. Conceptual scheme in figure 2 depicts the relationships between project requirements, functional features of the device and related hardware components. The scheme helps the team to manage the design effort. The design action is particularly devoted to clinical and safety aspects. Moreover, from a technical point of view, the motion control involves the largest part of hardware components. Many efforts are given in accomplishing an artificial device behaviour as natural as possible. Both these high level requirements are interconnected in the software features for control. For this reason, the control represents the final largest activity. Many tests and control concepts are developed on the basis of measurements and sensors acquisition. In section 4 it will be described the general architecture and the tests carried for that. Finally, another large efforts in developing the final release is due to sensor equipment. It has been enriched from the last release and many components have been re-engineered.

Both safety and motion regulation are due to a brake system. Figure 3 depicts the global requirements, most of which are related to a robust and reliable braking system. The requirements analysis in the

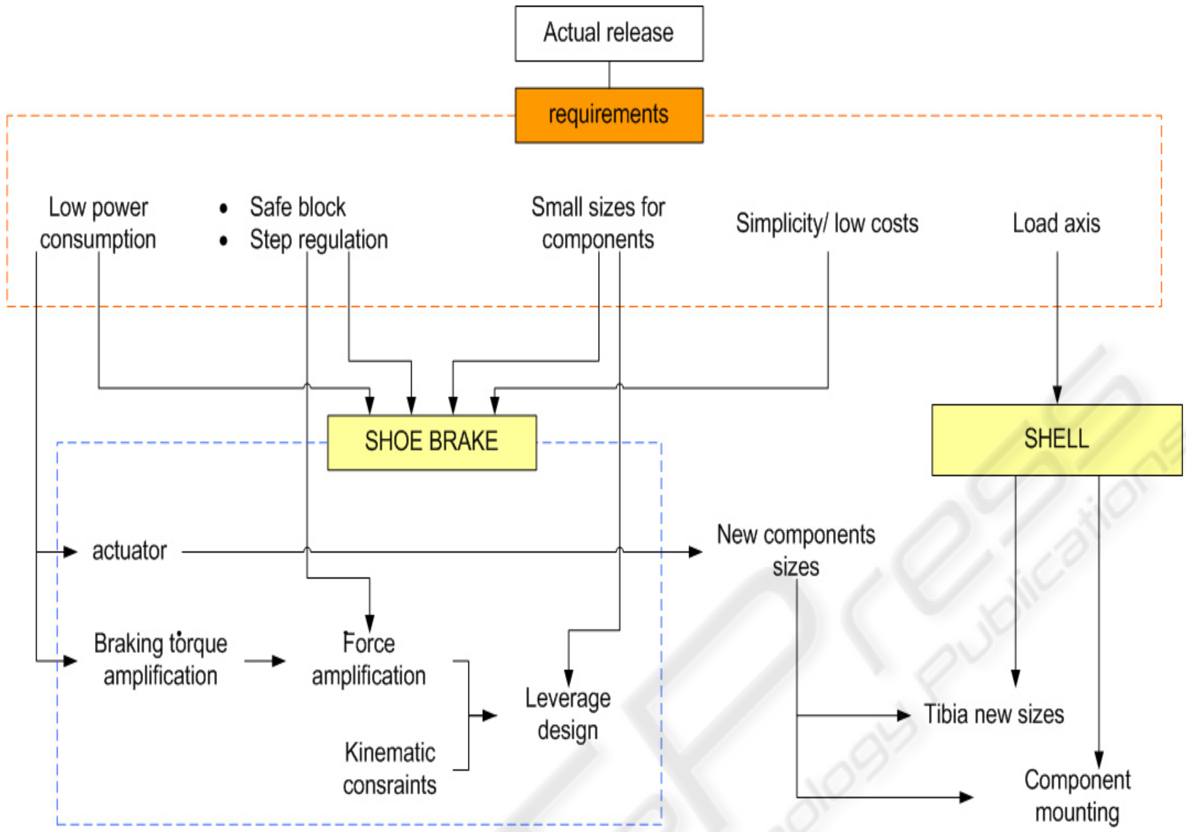

Figure 3: brake system requirements analysis

scheme makes the general requirements of figure 2 deeper. It shows the features of core components to develop or re-design. Design choices in the whole mechanical equipment are taken upon this analysis. The produced prototype works on combined active and resistive principles. The device is not designed to autonomously provide energy for walking. For this reason a constant force spring is used to accumulate energy, during hip backward flexion. This energy, coming from user stump, is given back to motion of the artificial limb by the spring itself. The step regulation, during both the walking and other conditions, is due to a shoe brake. It is mounted inside the artificial knee and guarantee reactive force and safety. It's clear why the brake system represents the largest design effort from a mechanical point of view. In analysis scheme, the choices about the braking technology, the auxiliary mechanisms and the mounting structure are taken on the basis of a well planned design process.
The mechanical system is designed to be functional to control action. The control itself, however, is submitted to the same general requirements of figure 1. In particular low power consumption, simplicity and low costs are the main features to achieve in software development. The electronic control must be reliable and effective using a limited amount of memory and processing performances. The design challenge is related to optimization of control action by hardware available. For this reason the device is equipped with several sensors which supply information to recognize artificial limb dynamic. Finally, the design aspects are very important to compactness of the device. It must be stand alone, reliable and safe. The design contribution proves itself in hardware components definition, the structure and shape of the device in order to let the user feel comfortable. The user must be supported and facilitate during all motion situations, allowing flexibility of movements and stability.
As a result a very compact device is developed and tested. In order to fulfil many requirements, the electro-mechanical brake is used as regulation system. Moreover, it's mounted in a way that let the housing of rotating mechanical parts. Functional kinematical components are all mounted around the

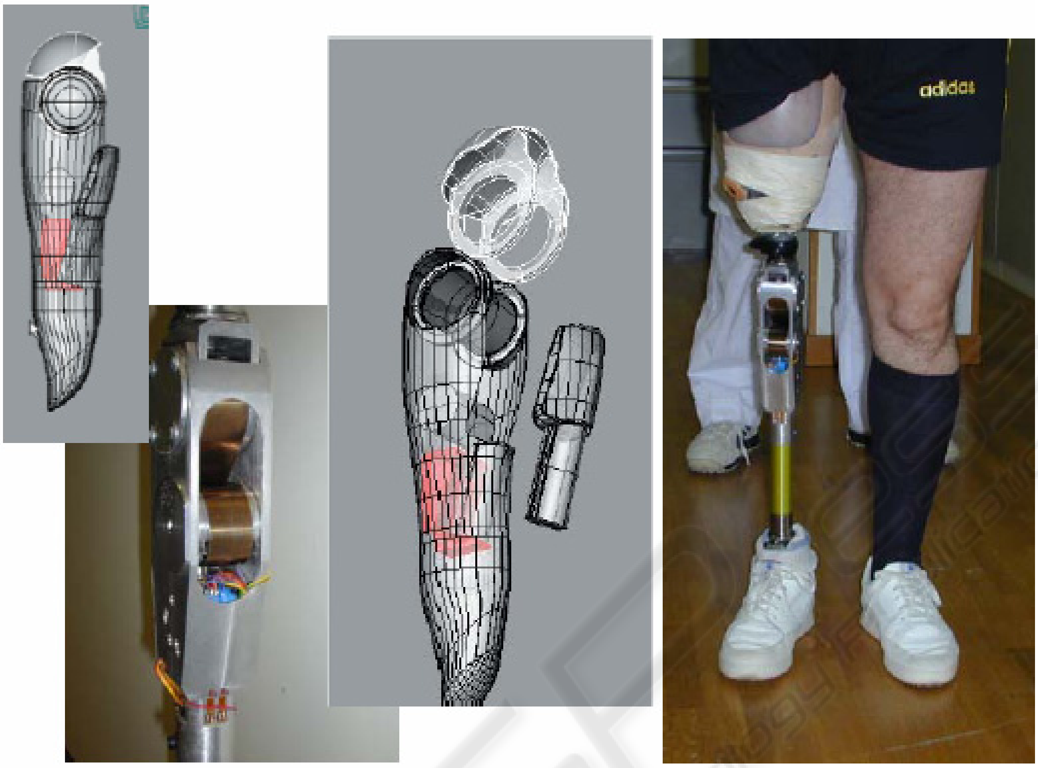

Figure 4: final release. Design, compactness and test.

knee knuckle, even the elastic part in knee joint. M-Leg is a semi-passive prosthesis because of partial potential energy accumulation. The particular shape of the spring makes it very easy to control. The overall compactness is evident from the electronic equipment above anything else. The micro-controller by STMicroelectronics allows data acquisition, signal conditioning and output generation; it is a very miniaturized equipment and provides the correct execution control algorithm. It must be pointed out that, under many aspects, the innovatory criteria applied along all the phases of the development are original in solutions, ever used before in none of the existing prosthesis.

4 CONTROL STATEMENTS METHODOLOGY

The control target lies in device adaptation to different dynamic conditions of user motion. The device must follow the behaviour of a natural leg and give a good mechanical response to user needs in equilibrium and mobility. It must do this in real time mode. Information coming from sensors input is very important to outline the current situation. The update of signal reading and output elaboration allow the artificial knee to supply the right action. The input channels are knee joint rotation, stress on lower leg structure and upper segment acceleration. The signals are provided by common strain gauges for compression and bending, and micromachined sensors for inertial parameters. The knee rotational speed is calculated by the rotation angle derivative. A calibration session has been done before using such signal. The kinematics of knee joint is single-centre, i.e. it has only one centre of rotation, and an external reference is used to check the linearity of sensor response. This procedure is required because the potentiometer is not mounted directly on rotation axes, but its connected to displaced integral shaft.
The software design comes after the acquisition session of the whole sensor equipment. This is necessary to find out the recursive patterns in step evolution and, in parallel, in signal records. The pattern recognition phase is especially done for walking conditions. This is the case of major content in regulation statements. The walking shows periodicity of profile during the step cycle. But it’s marked by a large variability. This is added to noise and variability of input signals. As a result it

happens to be very useful to have several sensor available for step condition clustering. It's only by all signals comparison that the walking behaviour can be recognized. The preliminary phase for control algorithm design is to recognize periodical pattern at a reference conditions and to use the brake action without any regulation. (The fundamental feature of an electronic controlled device is the real time adaptation to different conditions).

The walking pattern recognition is the result of an accurate analysis on the acquisition of final release device. The analysis is based upon the long trained experience in step recognition during the many years limb prosthesis development. That experience proves to be very useful now that the input signals for control are related to final device and very reliable.

In this section the preliminary study of control logic is discussed. First the signal acquisition from sensor is described. The records are used to define the signal recurrent patterns. Pattern are the basis on which a real time recognition and regulation algorithm is able to work. Then a number of states are defined in order to cluster the recorded patterns. This phase is very important because it is the modelling approach for software architecture. The states definition allows to set the transitions between states and the pattern related to transitions. Then the control unit is turned on, but only for simple constant impulse. This working mode is used during explorative tests in order to map the relationship between step velocity, sensors information and braking effect.

The motion analysis starts from walking. The framework for signal interpretation is the natural walking. the topics is well known and several studies have been done in Biomechanics in last decades. Many techniques let experts to measure biometric parameters, such as rotations, angles, segment position and so on. Literature data are very important in finding out related pattern in records from an artificial device. Such data set the *walking cycle* or *step* as the complete motion of both lower limbs between two following resting upon ground by the same foot. The step can be split into two main phases: the stance phase, when a foot is touching the ground and the body weight is diversely leaning on that foot, and the swing phase, when the same foot is lifted from the ground and flies straightforward. The stance starts from the heel rest. Then the foot sole rolls as long as the toe leaves the ground. In that moment the swing starts till the next heel ground touch.

The whole cycle is made up of 60% of stance and 40% of swing. The symmetry and periodicity of walking may induce to give the same duration to both the phases, but for a small amount of cycle both the feet are resting on the ground. This is counted in stance. There are two short interval of simultaneous foot resting within the cycle, each counting the 10%. Both stance and swing phases can be divided into sub-phases. This is due to better understanding the step dynamic and recognizing it in signals records.

The stance phase is formed by five sequences.

1. initial contact: this is very critical in the step dynamic. The safety of standing on the artificial limb depends on this moment for the largest part. The firmness of the artificial limb must be comparable to natural one, both for safety and for self confidence in motion.
2. first double touch (10% of walking cycle): the body weight is pushed forward lifting the rear foot heel and lowering the front foot toe. In this phase the weight is passing from a leg to the other and it can be easily detected by the stress on the device structure.
3. half touch (20%): from the lifting of the rear foot toe to the lifting of the front foot heel. During this phase the rear foot passes the front one. The weight rests on a single limb.
4. final touch (20%): starts from the resting foot heel lifting and goes up to the finish of the other limb swing phase. This is a very complex and slight movement to detect. The touching limb shows a flexion and a waving pattern affected by large variability.
5. second double touch (10%): inverted compared to the first.

The swing phase is formed by three sequences:

1. swing start (10%): starts from the lifting of foot toe. The limb gets a backward acceleration.
2. half swing (15%): the knee flexion reaches the maximum extension. The sub-phase ends at the touching heel lifting. It's hard to recognize because of the large variability of simultaneous values of data related to maximum extension and heel lifting.
3. end of swing (15%): starts from the touching heel lifting till the flying heel touching. The limb decelerates in order to prepare the following ground touch.

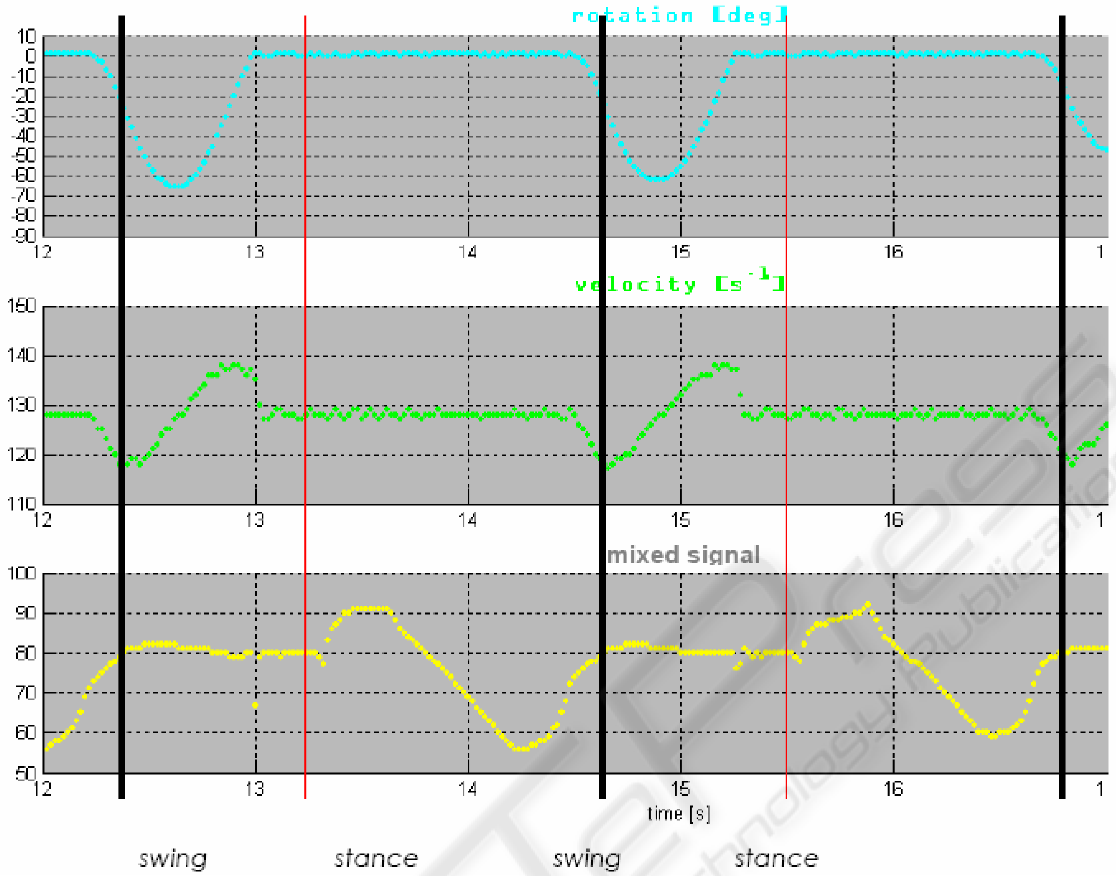

Figure 5: acquired signals from sensors equipment

The sensors signal records are analyzed in comparison with the natural walking cycle definition. This is useful for modelling the step behaviour and building the software architecture. In real time control is not so important to recognize and define the whole set of sub-phases.

But there are some critical transitions that must be detected and complied. In particular, it's necessary to react to the swing end before the ground contact, the flexion extension of flying limb and the whole weight resting upon only one limb for stability. The signal used to detect the limb behaviour are the rotation angle, its derivative, a mixed signal coming from an arrangement of compression and bending signals. These signals are given by a double Wheatstone bridge.

First, such signal are acquired in a test session with the brake system turned off. The black lines in figure 5 mark the limits of each walking cycle. The red ones mark the stance and swing phases. The rotation angle is reported in indirect degrees size. This is due to the potentiometer return shaft. The relationship between the knee rotation and the potentiometer shaft angle has an amplifying factor due to the different diameters of return mechanism. The calibration set up guarantee the linear ratio between knee rotation and potentiometer angle. The mixed signal size is reported in percentage of weight. The signal gets the contribution of two types of stress signal, so the size is not directly related to an absolute value. The signal used for first analysis are collected from a standard step succession. The user is invited to walk as naturally as usual trying to keep the speed constant. The resulting signals are averaged among several walking acquisition on the basis of a predetermined reference point. The output pattern are very regular and predictable of standard pattern.

The rotation signal shows the typical pattern, no hyperextension is supposed to be detected and the knee flexion happens to be short compared to step cycle. This is due to the reduction of swing percentage in prosthesis users. The flying phase of the artificial limb is faster than the natural one.

One of the objective in device control is to allow the user walk as much naturally as possible. This means to arrange the symmetry of walking cycle between both the limbs. The zero axes crossing in velocity,

related to changing versus of rotation belongs to a narrow distribution, and the average value of maximum knee angle recorded is 45°.It's smaller than natural value because of the shorter duration of knee flexion. The lower leg has not enough time to accelerate and reach larger values. The region of rotation related to maximum extension is one of the most interesting in regulation of rotation range. The reason lies in complete absence of direct control by the user. The user has non chance to control the artificial limb backward flexion. This is over the impulsive energy give to the hip at the start of swing phase.
The mixed signal is very useful to evaluate the swing-stance transition and the stance sub-phases. The mean non-scaled value is related to absence of weight. It corresponds to swing phase when the rotation is active and for a while after the complete knee extension just before touching the ground. After the heel touches the ground an increase in signal due to compression stress is gathered. The peak is short and not marked because of the step velocity. The body weight, in fact, is thrown straightforward passing the vertical axis of the device. In this way the torque due to bending changes sign and decreasing the value below the mean. The absolute value is larger the compression phase one because of the longer leverage for torque and the duration of rolling on the foot sole. In the final release the two contribution are separately evaluated.

From this first analysis two main output are available: the states definition and the transition average values. These issues are fundamental in setting the architecture model for control software and in software requirements statements. These features are related to transitions, so the braking action coming from control regulation must fulfil the needs of the user shown through the signal record.
From the detected pattern it can be assumed:

1. a brake action is required between swing and stance in order to guarantee the safety and stability in touching the ground. The brake must be on as long as the weight is passed across the vertical axis.
2. the velocity at the end of swing phase drops very quickly. This is due to initial acceleration in forward rotation due to spring elastic force and the mechanical block at the complete extension, 0°. This provokes a stroke to the device transmitted to the socket and, finally, to the hip and the backbone of the user. The return rotation must be decelerated before the end of its range.
3. other requirements could be revealed by a finer analysis of device behaviour with the brake turned on. An important feed back is given by the user, pointing some features he may be consider useful or comfortable.

These requirements come from pattern first analysis and must be added to general ones dealing with

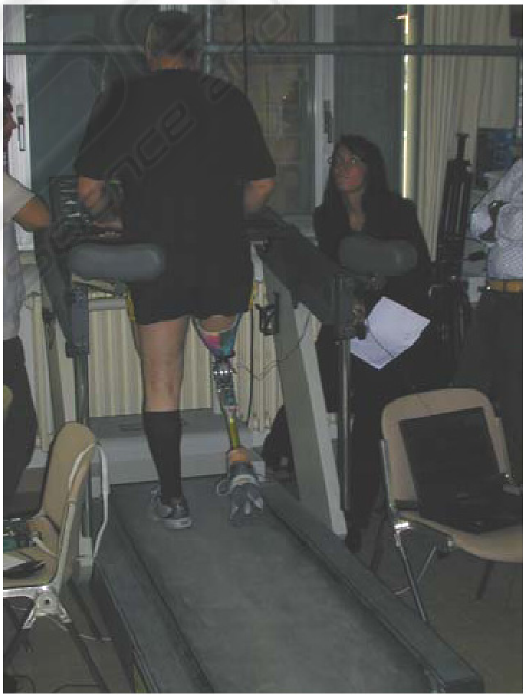

Figure 6: acquisition tests at constant velocity.

emergency management, safe standing upon the device with the whole or partial body weight, different motion situations. In particular sitting down and climbing stairs are test routine run in order to achieve typical data. The methodology is the same about different shaped patterns.
The control model is thought to be implemented through a Finite State Machine (FSM). It's a traditional tool to describe formal requirements and relationships between defined states. It's not the control algorithm structure but the ideal framework of transition management. Such tool is quite powerful in setting states and transitions, is fit for limited amount of memory of processor and can be managed by several people inside the multidisciplinary team. A first prototype of FSM is implemented to turn on the brake system in detected and required points. The initial rules are based only on pattern analysis. This feature allows the tester to run some experiments for mapping the dynamic relationship between braking and step conditions.
Test regulation in control logic is assigned to fixed velocity/braking position ratio. It's obviously a simplification because this ratio changes during the walking. But for in lab test on leg simulator this is very useful. It helps to check the right brake activation due to sensor record and software regulation. The dynamic step regulation must adapt the braking action to the velocity and rotation angle. The dynamics of brake achieve effective resistive torque as a function of velocity, angle and time delay in impulse transmission. The larger the velocity, the larger must be the angle of activation or, in other words, the advance in getting the speed reduction. This set of relationships must be fitted among an empirical data setting and collection. The experiments take the first step towards the adaptive control required to electronic controlled prosthesis. They are carried by a specific tool of calibration and tuning described below. It's used to change regulation parameters both for initial test and for customization of stand alone final release. For such reasons a Calibration and customization tool has been developed.
Initial setting must be run before using the device. The controller sets internal parameters on the basis of user features. The main quantity to measure is the user weight. As usual procedure, the user stands on the device for a while. The device records a large amount of values of stress on its structure. The duration of record may last from six to twenty seconds. This allows the user to feel free to stand in natural way. In such way the weight distribution on both legs, the natural one and the artificial one, has the chance to vary in a wide range of usual conditions.
The setting tool has been developed for fine tuning the recorded parameters. The operator can set thresholds or constants related to step regulation. The fine tuning of thresholds is not so usual because of the initial auto-setting procedure. It's very useful to change comparison values inside control software. This is done to check particular features of device behaviour. For instance, several tests were run for

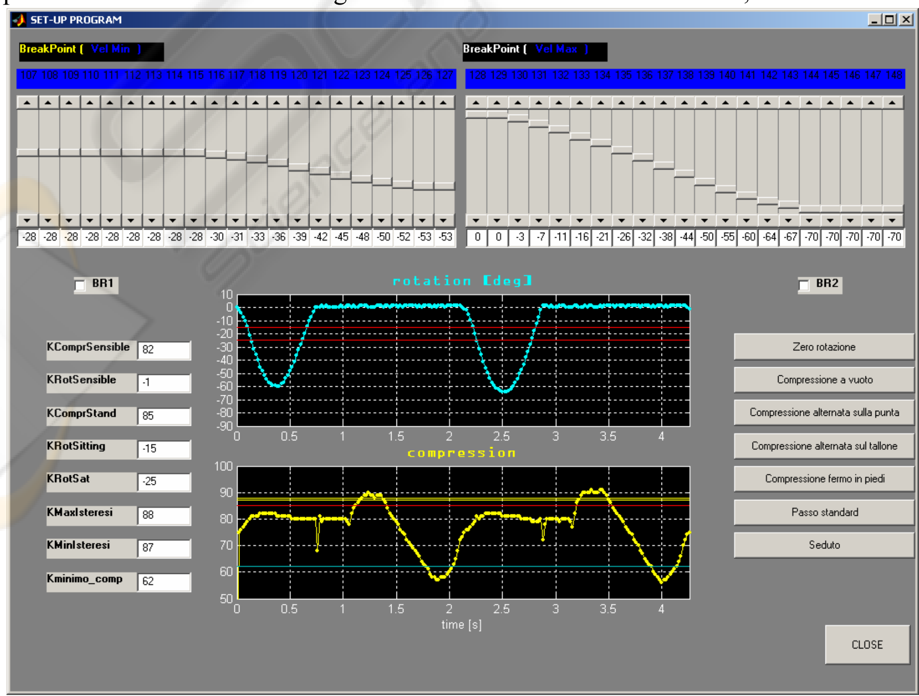

Figure 7: tuning, setting and customization tool.

understanding the right shape of velocity table curve during the software development. The user was forced to experience the same brake activation response for the whole walk. In that way the step time and step percentage profile were forced to be tightly constant. The user was so forced to walk at fixed velocity. The user was helped in do this by walking on a *tapis roulant* so that he could slightly feel the unnatural step regulation. The amount of tests was collected varying walking velocity and brake activation position.

5 CONCLUSIONS

A final prosthesis prototype is the result of a long design process. Experience and skills are supported now by coded methodologies and analysis tool. This process starts from a design approach leading towards details optimization. It's important to underline the methodology contribution to several re-engineering stages. By means of final release a large development in direct signal acquisition and testing became possible. The proposed methodology for step analysis was done with the constant help and experience supply of patients and INAIL staff. The presented methodology is basic for the further FSM development with self-learning and adaptive features.

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