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Through the Development of a Biomechatronic Knee Prosthesis for Transfemoral Amputees: Mechanical Design and Manufacture, Human Gait Characterization, Intelligent Control Strategies and Tests

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***Abstract*— This paper presents the development of a biomechatronic knee prosthesis for transfemoral amputees. This kind of prostheses are considered 'intelligent' because they are able to automatically adapt their response at the knee axis, as a natural knee does. This behavior is achieved by characterizing the amputee's gait through the signals captured with instrumentation of a prosthesis, which provides feedback about its current state along the gait cycle and therefore responds with the corresponding control action. In this case, unlike other commercially available intelligent knee prostheses, gait cycle characterization is based on accelerometers signals processed by an events detection algorithm. Two intelligent control strategies are presented: a bio-inspired approach, that consists of using a central pattern generator to generate a knee angle reference to be followed by the prosthesis during walking, and an adaptive scheme, that applies a control action proportional to the knee angle according to an auto-adaptive parameter dependant on gait speed. The mechanical design of the prosthesis is also presented, showing the knee joint mechanism and part of the manufacturing process. Results obtained from walking tests with both able body and amputees are shown, demonstrating the positive performance of the prosthesis in several aspects. Future works aimed at a finished product are also stated.**

I. INTRODUCTION

Extensive research in robotics and automation has been producing technologies that can be exploited in the development of systems designed to improve the quality of life to human beings, especially to help people with disabilities to perform tasks that would otherwise be impossible. A true example of this is encountered in the development of intelligent knee prostheses for transfemoral amputees. A knee prosthesis of this kind is a complex system comprised of a mechanical system, coupled with gait of the amputee patient through an electronics-based intelligent system, able to recognize lower-limb movements and then execute the control actions required to achieve a normal walking pattern. This paper presents an overview of the complete development of an intelligent magnetorheological knee prosthesis, successfully tested with an amputee patient.

The term 'intelligent' in lower-limb prostheses indicates the prothesis is able to change its response during walking. This concept arose once electronics was applied to the prosthetic field by Prof. Flowers and his collaborators at the MIT, during the 70's [1]. Since then, although several approaches have been carried out regarding control strategies applied to intelligent knee prostheses, only one has been fully developed into a commercial application which is the finite-state control [2], [3]. Even though acceptable performance of human gait is obtained with this strategy, we still consider that this architecture limits the adaptive capability of electronically-controlled knee prostheses because this applies control by stages, unlike biological control, which is continuous. Therefore, we were interested in exploring the ability to provide more natural biological control with this project. Two intelligent control strategies of this kind have been approached. First, a control via central pattern generator (CPG), which is motivated by the biological process that generates the coordinated movements of legs observed in animal locomotion. This has been used for controlling biped robots [4], [5], but not for controlling a human prosthesis in the way we have presented. Second, an adaptive proportional control (APC) based on a gait speed dependent algorithm for setting an auto-adaptive proportional gain in the controller was employed. Gait speed is estimated using only the accelerometry data of the prosthetic leg, whereas the control action is applied on the knee axis through the prosthesis actuator. Unlike commercial intelligent knee prostheses, that typically use load sensors to characterize the gait cycle, the development of a prosthesis that uses only accelerometers data for performing such task, as presented here, is a new idea that has shown promising results.

From the mechanical point of view, a prosthesis should satisfy certain requirements of strength to assure the integrity of the prosthesis and hence, of the user during walking. Also, a relevant issue at the mechanical design stage is the final aesthetical aspect of the prosthesis, as it may have an important influence on the final approval of the product by the user. For this purpose, commercial prostheses use an extra cover over the chassis. Here, the need for a cover has been resolved by designing a bio-inspired shape for the chassis. Another difference presented in this work is the use of new materials in the fabrication of the prosthesis, which differs from its commercial counterparts usually made of carbon fiber and aluminum. This prosthesis utilized mixes of polyethylene and polypropylene particularly to manufacture the chassis. These materials are easier to find in the domestic market and require a simpler manufacturing process.

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II. OVERVIEW OF THE STATE OF THE ART

The predominant control strategy in intelligent knee prostheses is the finite-state control, indeed, it is the only control that has been applied to commercial knee prostheses, as for example the Rheo-knee, released by the company *Ossur* in 2001 [6]. Another application of this control is found in [7], where researchers have developed a monopropellant technology-based pneumatically powered knee prosthesis that uses a finite-state impedance control with sensors located only in the prosthetic leg. A similar control idea is presented in [8], a work on advances toward the development of an electrically powered active knee and ankle prosthesis able to generate human-scale power at the joints. Current trends in this area are focussed in new intelligent control strategies that differ from finite-state control, and in the passive-active actuator trade-off. A novel approach for the development of a semi-active knee prosthesis was recently presented in [9], where the design proposed combines the well-proved passive hydraulic actuator with an active component consisting of a pump driven by an electric motor. Both passive and active stages are combined in order to optimize kinematics of the amputees' walking. Regarding these research trends, this work presents two different intelligent control strategies applied to a passive prosthesis, both based on characterization of human gait from accelerometry. This paper is also accompanied by a video presenting the different stages covered during this project [10].

III. MECHANICAL DESIGN AND MANUFACTURE

An intelligent knee prosthesis is a biomechatronic device involving three main aspects: (1) the development of a structural component which performs as the knee joint mechanism and connects the socket with the rest of the leg; (2) the development of the instrumentation and control that modulates the response of the prosthesis actuator and therefore, the performance of the prosthesis during walking; and (3) the development of a prosthetic device that will enable a person to walk, thus considering the biological and psychological issues possibly implied. The physical component is fundamental, not only because it is the one which actually substitutes the amputated leg, but also because it defines the shape and finishing of the prosthesis, and some of its features determine the development of the instrumentation and control to be applied later.

A. *Specifications*

The prosthesis presents a monocentric design equipped with a commercial magnetorheological actuator. These actuators offer resistance to motion according to the current that passes through their electromagnetic circuit, therefore, being the torque applied on the knee joint during walking mostly resistive [11], it is expected this kind of actuator shows a good performance for this application [2], [6]. On the other hand, it was proposed to manufacture the chassis with materials found locally, such as domestic polymers, unlike commercial prostheses that are made of carbon fiber, titanium and special alloys of aluminum. It was also suggested a bio-inspired design for the chassis with regard to its external appearance. The idea was to combine its functional part with the aesthetic finishing of the prosthesis, all in one piece, allowing to eliminate the need of wearing a cosmetic cover on the prosthesis. Regarding the instrumentation of the prosthesis, all the sensors should be on the prosthetic leg. A goniometer would measure the knee angle and accelerometers would capture acceleration signals at certain points of interest.

B. *CAD Design*

The prosthesis was designed in ProENGINEER Wildfire 3.0. The mechanism consists of three main parts: the chassis, the knee joint and the actuator, but the first feature that catches the eye is the bio-inspired shape of the chassis, which makes the prosthesis look more realistic, as seen in Fig. 1(a). The chassis was designed according to dimensions of the first author's leg; measurements were made by cross-sectioning the leg virtually along the tibia, and then taken into the software to generate the external surface of the chassis. On the other hand, the interior of the chassis was defined basically to contain the actuator and the knee joint, as shown in Fig. 1(b), since the electronics was supposed to be placed outside the prosthesis in this first prototype. Also, Fig. 1(c) shows a longitudinal cross-section showing the main parts of the mechanism, as well as the axes that connect them, in three different knee angular positions: 0, 45 and 85°.

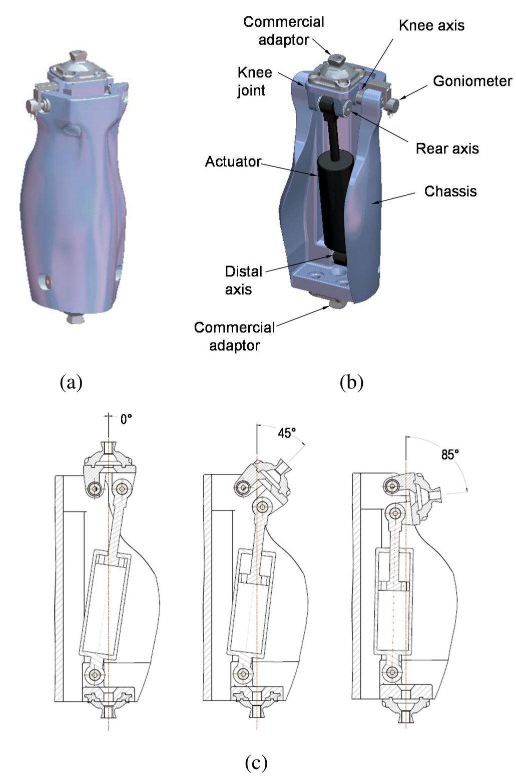


Fig. 1. Mechanical design of the prosthesis: (a) External appearance of bio-inspired chassis, (b) Rear view and components, (c) Longitudinal cross-section at different knee angles

C. Manufacturing Process

The chassis was manufactured with prosthetics and orthotics materials and technology found in a local specialized workshop. The chassis resulted a multilayer material composed of two layers of co-polymer (a mix of polyethylene and polypropylene typically used to laminate prostheses and orthoses), which defined its interior and exterior surfaces, filled with a layer of medium-density polyurethane between both. Finally, the chassis was laminated with fiberglass in resin to seal the exterior and provide further strength through a very thin but rigid layer. The metallic pieces were manufactured with conventional metal-working machines found locally. The overall weight of the prosthesis was 2,059.1g, which is slightly heavier than similar commercial devices, which range between 1,400 and 1,700g approximately.

IV. HUMAN GAIT CHARACTERIZATION

The first step toward the design of an intelligent control strategy for this prosthesis was the study of the phenomenon to be controlled: bipedal locomotion. Basically, the idea of characterizing human walking is to determine the current instant along the gait cycle in order to control the prosthesis response accordingly. Previous work has been done on this matter using an analytical approach, as the study presented in [12], which aimed to optimize an above-knee prosthesis based on the kinematics of gait cycle. Considering the fact that a single type of sensor (accelerometers) was desired, subsequent characterization of the gait cycle had to be performed from the signals captured with these specific sensors. For this purpose, we preferred an experimental statistical approach instead of the analytical one. A series of trials were carried out to acquire acceleration data during walking of a healthy person first [13], as shown in Fig. 2 (a), and then, with an amputee patient wearing the prosthesis equipped with the same instrumentation, as seen in Fig. 2 (b). Four accelerations were taken into account: two at the knee joint, and two at the ankle joint. The Y axis of the biaxial accelerometers coincided with the tibia major axis, as shown in Fig. 2. Thus, we counted with the following data: $\{a_{k_x},\ a_{k_y},\ a_{a_x},\ a_{a_y}\}$, where a_k represents the knee accelerations and a_a, the ankle ones.

Since the knee angle was already characterized for normal walking on level floor [14], it was captured simultaneously with the acceleration data, as shown in Fig. 3, in order to have a reference to compare with. This procedure allowed designing an algorithm dedicated to detection of events along the gait cycle from the accelerometers data [13]. Then, seven events were detected: four corresponding to the stance phase, and three to the swing phase, including the two most important ones of heel-strike and toe-off. This accelerometry-based events detection algorithm (AEDA) used accelerations and jerks of the lower-limb in the sagittal plane and, by applying thresholds to the signals, was able to identify features considered as gait events, such as the initial contact of the heel, marked by the predominant negative overshoot of a_{a_x}, observed in Fig. 3. By then, the sampling frequency was 50Hz and the AEDA was based on hand-tuned thresholds set off-line. Also, this had been proved only with a healthy person walking at a self-selected speed and automation of the thresholds setting was still required. In additon, the system needed testing with different patients and at variable gait speeds.

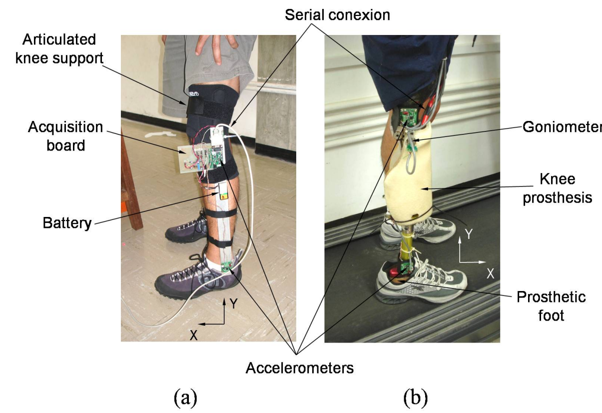


Fig. 2. Location of the accelerometers when performing gait cycle characterization: (a) Sound leg, (b) Knee prosthesis

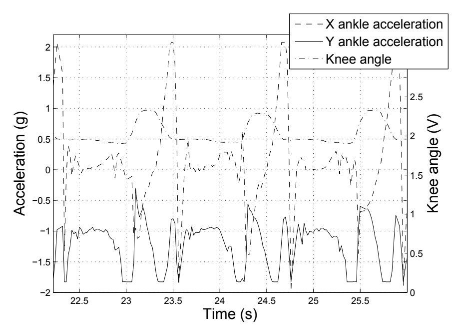
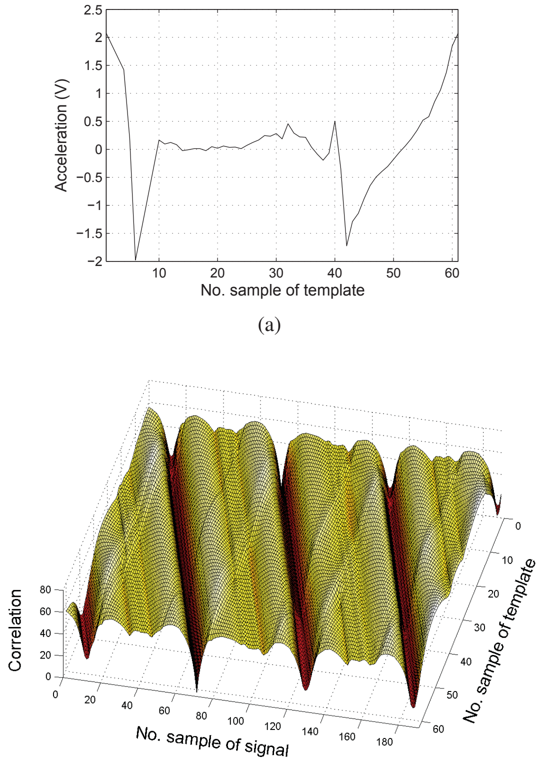


Fig. 3. Ankle accelerations and knee angle of sound leg

A. Correlation-Based Gait Cycle Tracker

One of the alternatives studied to overcome the aforementioned situation was a correlation-based gait cycle tracker. A waveform corresponding to a single gait cycle may be extracted as shown in Fig. 4(a). Using this waveform as a template, it is possible to identify the gait cycle phase. By running the correlation between the template and the actual acceleration signal, an overall surface is obtained as shown in Fig. 4(b). In this figure, the local minimum along the template axis represents the instant at which the template completely overlaps with the actual signal, therefore indicating the current phase of the gait cycle. In other words, the correlation result allows tracking the progress of the gait cycle continuously, until reaching the next one. As seen, this approach proved good results on data captured from the healthy person walking at constant speed, however, this technique was abandoned because it showed serious limitations dealing with differences between the actual signal and the template, as those coming from gait speed changes, for instance.



(a)

(b)

Fig. 4. Correlation-based gait cycle tracker: (a) Gait cycle waveform, (b) Correlation surface

B. Statistics-Based Technique for Automation of Gait Events Detector

Once the prosthesis was built, similar waveforms of the accelerometers signals were obtained when testing it with the amputee patient. A solution to automatically adapt the thresholds initially set by hand-tuning emerged through the use of statistics. The original AEDA was modified to work directly with the signals captured by the accelerometers on the prosthesis, applying their recent statistics to set the corresponding thresholds automatically. The block diagram of the algorithm is shown in Fig. 5. The signal conditioning block (SCB) filters out high frequency electrical noise and its outputs enter into the threshold levels setting block (TLSB) and the signal spikes isolation block (SSIB). The TLSB sets the threshold levels based on recent statistics of the corresponding signal. Then, the SSIB applies the corresponding thresholds to every signal in order to isolate the overshot spikes from which gait events are detected. Finally, the local minima (on valleys) or maxima (on peaks) of the signals are determined via differentiation, which are directly the events detected by the algorithm as output of the local minima/maxima calculation block (LMMCB). The three acceleration signals used by the automated version of the AEDA are shown in Fig. 6, as well as the events detected in real-time as LMMCB outputs.

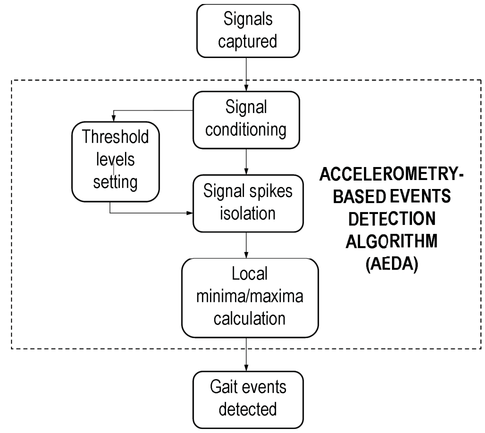


Fig. 5. Block diagram of the algorithm

V. INTELLIGENT CONTROL STRATEGIES

A. Control with Reference Knee Angle via Central Pattern Generator

Today there are several bio-inspired applications in robotics regarding locomotion of legged robots [5], [15]. In such sense, we asked the question, "What if a reference of knee angle is generated to be followed by the prosthesis?". The answer was found in central pattern generators (CPGs), which have been broadly used in the last decade to generate and coordinate motion of legs in walking robots, for executing all gait modes physically possible [16], [17]. Of course, there is a difference because the prosthesis is not a robotic device, designed to behave according to the programmer's orders but to the patient's will. However, technically, it is a matter of coupling the reference generated by the CPG with the prosthesis during walking, almost exactly what controllers do to enable robots to walk [18]. With this purpose in mind, a particular CPG was developed based on Amplitude-Controlled Phase Oscillators (ACPOs) [19]. Actually, the CPG consists of one ACPO and a knee angle generator (KAG); the ACPO tracks the gait cycle phase running on the prosthesis and the KAG generates the knee angle reference to be followed in order to mimic a natural gait. The knee angle reference generated by the CPG is coupled with gait through the events detected by the AEDA, which update the ACPO phase. First, this was tested on a healthy person with both sound legs walking on level terrain, then, by the first author wearing the prosthesis on a treadmill by means of a special custom-made socket, and finally, by a transfemoral amputee walking with the prosthesis on the treadmill as well. In all cases, the coupling of the CPG-generated reference with gait was demonstrated, even during gait speed changes [20].

Fig. 7 shows the results with the prosthesis coupled with gait through the event corresponding to toe-off (see Fig. 7(a)), and being worn by an amputee patient walking at a self-selected speed as seen in Fig. 8(b) (after adapting the prosthesis length as in Fig. 8(a)). Two drawbacks were found regarding the prosthesis performance using the CPG

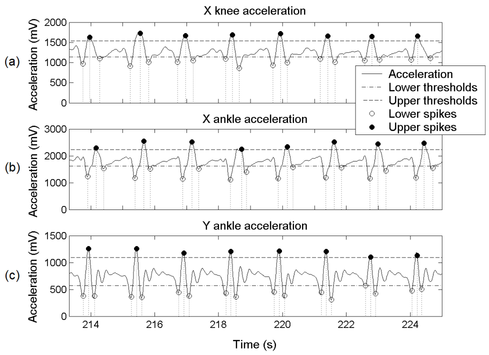


Fig. 6. Captured signals and events detected by the AEDA

approach. The first drawback was that the actuator takes the prosthesis to extension once the foot is off the floor. Thus, no further flexion is possible during swing and therefore, the natural maximum knee angle of 60° is impossible with this prosthesis as observed from Fig. 7(c). Nonetheless, the patient remarked that the prosthesis must return to extension as fast as possible during swing, so it is completely straight before next heel contact. Tests with more individuals are required to determine the real impact of this limitation on the prosthesis performance. The second drawback was that the amplitude of the knee angle is directly proportional to gait speed. However, given the first drawback, it was never approached though it is solvable by simply modulating the amplitude of the knee angle reference with gait speed.

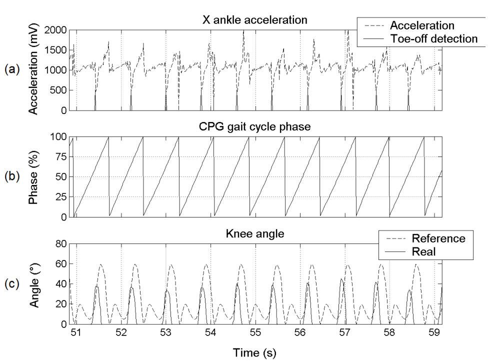


Fig. 7. Test results of control with reference knee angle via CPG

B. Adaptive Proportional Control with Non-Characterized Gait Cycle

Considering the limitation of the prosthesis having a passive actuator, and on the other hand, taking into account the patient's requirement, an APC strategy was developed consisting of a control action proportional to the knee angle measured at the joint axis. This action is applied only during extension, allowing the knee to flex freely during terminal stance and pre-swing, and later to extend quickly and smoothly during the swing phase, guaranteeing complete extension before next heel strike. The proportional gain Kp is adapted according to the user's gait speed. If it increases, the Kp is reduced in order to allow the knee to extend rapidly and vice versa, if gait speed is decreased, then the Kp is augmented in order to slow knee extension. The gait speed is estimated through the events detected by the AEDA. No other characterization of the gait cycle is required. In order to cope with possible false detections, two different measures were taken: a median filter applied to the different gait period estimations obtained from each pair of equivalent events, and the other measure was to take into account that a singular event (heel contact, for example) cannot occur two or more consecutive times in one gait cycle. For this, it was developed a logical filter to remove consecutive repeated detections.

More in detail, from Fig. 9(a), the gait speed is estimated through the period computed from the events detected by the AEDA. It must be pointed out that there is a delay between gait speed and the proportional gain Kp. For example, when the gait speed decreases, as in 45.7s (see Fig. 9(a)), the Kp increases after two gait cycles (see Fig. 9(b)). Then, for a gait speed increase, as in 57s, the Kp decreases after one gait cycle, as observed at 58s. Those delays are not symmetrical in time duration. Such asymmetry occurs because the estimation of walking speed is obtained each time an event is detected, thus at a low gait speed, the update rate is lower than at a higher gait speed. In Fig. 9(c), both control signals are shown: a step signal corresponding to the stance phase, and the proportional signal that follows the knee angle, but applies only during extension in the swing phase. The control signal corresponding to the stance phase was included, to avoid the knee buckling during load response after heel contact. Finally, Fig. 9(d) shows the knee angle achieved with the APC strategy and the prosthesis worn by a transfemoral amputee.

(a) (b)

Fig. 8. Transfemoral amputee wearing the prosthesis: (a) Adjustment of the length, (b) Walking on the treadmill

C. Comparative Discussion

The first approach with the CPG to generate the knee angle reference to be followed by the prosthesis during walking was proved feasible, however given the passive condition of the actuator, it did not make sense to utilize this technique with this prosthesis because there were segments of the reference trajectory along gait cycle that would be impossible to reproduce [20]. Nevertheless, this approach looks very promising for active lower-limb prostheses. The second approach with the APC resulted in a simple and effective means for controlling the prosthesis designed in this project. This removed the need for characterizing the gait cycle and also allowed for dealing with the change of knee angle amplitude as a function of gait speed because the control action is directly coupled to the knee angle measured on the prosthesis. This APC control strategy was the method finally applied, and demonstrated to be appropriate for this prosthesis.

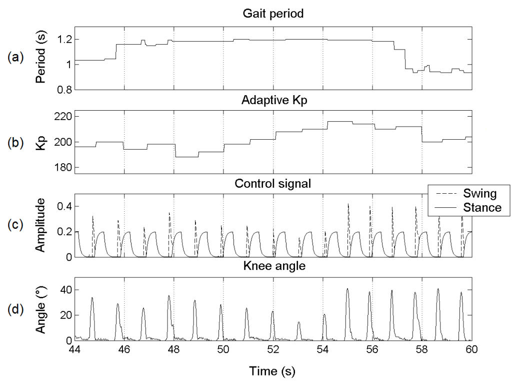


Fig. 9. Test results of APC with non-characterized gait cycle

VI. CONCLUSION AND FUTURE WORKS

The main objective of developing an intelligent knee prosthesis for transfemoral amputees was accomplished in this project. Gait cycle characterization was performed through a specially-designed accelerometry-based events detection algorithm, the AEDA. Two intelligent control strategies were developed: CPG and APC approaches, concluding that an adaptive scheme (APC) is particularly appropriate according to the prosthesis performance. Regarding the mechanical design, a bio-inspired shape for the prosthesis was presented and manufactured using polymeric materials, as polyethylene and polypropylene, combined in a novel multilayer manufacturing process. The prothesis was tested with an amputee patient, whose feedback in the psychological aspect was taken into account throughout the design and evaluation process. There are several aspects of the design that need further attention before having a finished product, which is our final goal. First, the prosthesis needs to be tested with additional amputees. Secondly, all the electronics, including the batteries, must be embedded into the prosthesis, so patients can wear it freely, in open areas and for long periods. Finally, a new chassis shall be developed through an optimization process, to reduce weight.

VII. ACKNOWLEDGMENTS

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