Osseointegrated Prosthesis with Neural Control and Sensory Feedback

Nebojša Malešević

Abstract— **The state of the art research and development of the powered prosthetic devices controlled via neural interfaces are aiming at the problems that are preventing natural-like use of an artificial limb. Although in wide use, myoelectric prosthetic hands, interfaced via stumps and controlled using superficial EMG electrodes are known for their poor functionality, controllability and sensory feedback, mainly due to the use of surface electrodes. Furthermore, the interface with the user is established through the soft interface that deteriorate over time. In this paper we will discuss developing of a novel prosthetic hand with improved functionality, smart mechatronic devices for safe implantable technology, and improved paradigms for natural control (action) and sensory feedback (perception) of the prosthesis through the Osseointegrated implant.**

Index Terms—**Osseointegration, Prosthetic hand, Myoelectric Control, Sensory Feedback**

I. Introduction

This paper presents the concepts proposed within the EU H2020 project DeTOP (Dexterous Transradial Osseointegrated Prosthesis with neural control and sensory feedback). As the project started relatively recently, the majority of the paper will focus on the Project proposal, including state-of-the-art and the objectives of the DeTOP.

The DeTOP project targets people with reduced or absent hand sensorimotor capabilities, due to an amputation. It aims to develop and clinically implement robotic, sensing and long-term interfacing technologies for the next-generation transradial prosthesis. Core of the system will be a osseointegrated human-machine gateway, able to create bidirectional physiological links between a human and a state-of-art dexterous robotic prosthesis with artificial skin. Key objective of DeTOP is to translate, exploit and appraise already proven technology for transhumeral amputation to the most frequent case of transradial amputation. The overview of the project objectives is presented in Fig. **2**. In this paper, we will focus on the main components of the system: Implanted bone technology, Transradial prostheses, Decoding algorithms to control of artificial prostheses and Sensory feedback.

Research supported by the EU-funded DeTOP project (EIT-ICT-24-2015, GA #687905) and the Swedish Research Council (637-2013-444).

Nebojša Malešević is with the Dept. of Biomedical Engineering, Lund University, SE-221 00 Lund, Sweden (email: nebojsa.malesevic@bme.lth.se).

A. Implanted bone technology – bone-anchored prostheses

The conventional method to attach limb prostheses to the patient's stump is the use of a socket (Fig**.** 2). Sockets rely on mechanically compressing the stump to secure the limb prosthesis, and therefore loads are transferred through the soft tissue by direct contact on the skin. Compression is a constant aggression to skin and soft tissue, which results in a variety of problems ranging from inconvenient to disabling. As a result, socket suspension is regarded as a major source of problems for amputees [1-5].

The heavier the prosthesis, or the higher the loads developed during prosthetic use, the stronger will be the coupling required to keep the prosthesis in place. This translates into a higher compression and adhesion by the socket on the skin. For this reason, it is not surprising that the most active patients have an increased risk of dermatologic problems [3]. However, this situation is not exclusively reported by the most active prosthetic users, problems such as dermatitis and infected sores are also commonly reported by amputees due to this coupling mechanism [1-4, 6]. The hard frame of a socket, inherently limits the range of motion when close to the joints. Moreover, patients with short stumps cannot use a socket without locking or reducing the range of motion of the adjacent joint, which results in increase disability at the functional level, and potentially at the activity and participation levels as well. Overall, it is not surprising that the socket suspension has been found as a common denominator in problems affecting amputees' quality of life [2].

Due to the inherent problems of socket suspension, the idea of a direct coupling between the artificial limb and the residual bone has been explored since decades ago [7]. Aside to static bio-compatibility, the materials for such surgical approach must allow living tissue to tolerate the functional stresses generated by prosthetic use. The failure of initial attempts to consolidate this idea has been attributed to the poor mechanical integration between bone and implant. The introduction of titanium solved this problem and allowed the first successful skeletal attachment of limb prostheses in 1990 [8]. This was based on the principle of osseointegration which was discovered by P.I. Brånemark in Gothenburg, Sweden, in the 1950's [9]. Since then, research groups around the world have developed different bone-anchored systems [10].

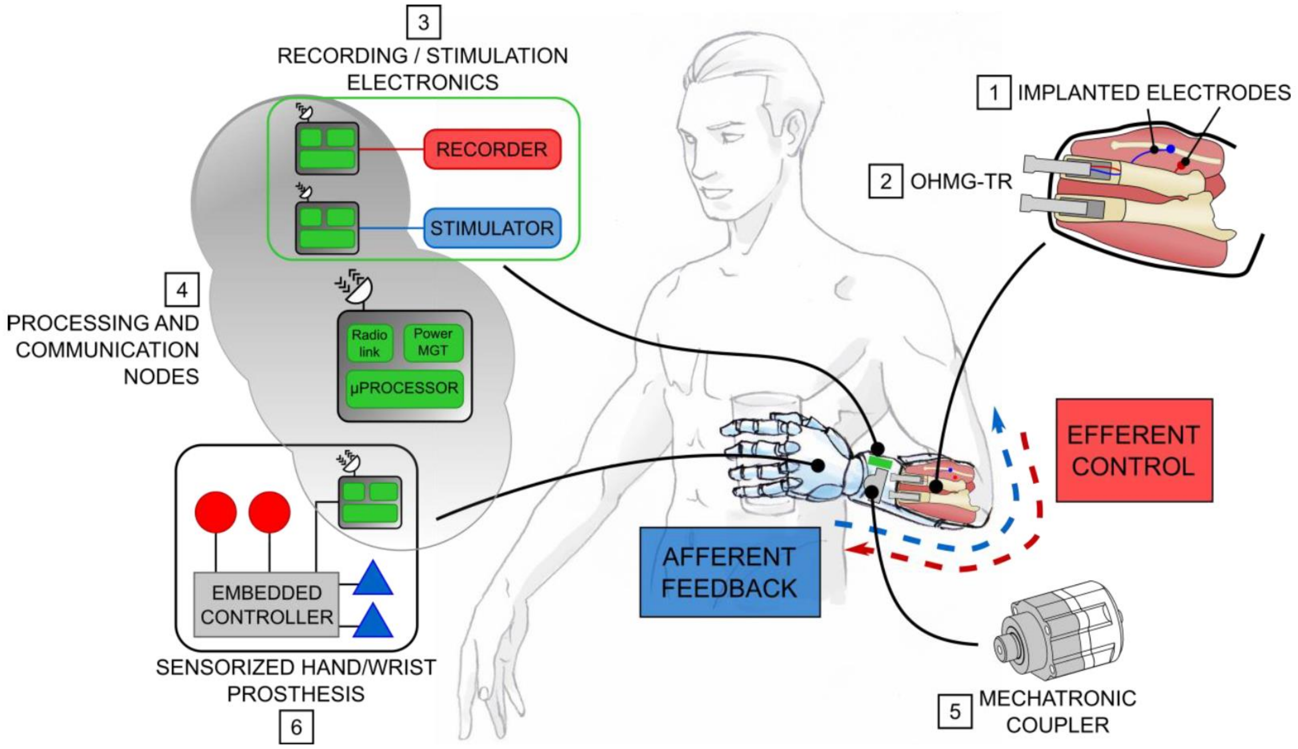

Fig. 1 Main components of the Osseointegrated Prosthesis with Neural Control and Sensory Feedback: 1) Implanted electrodes for acquisition of intramuscular electromyography (iEMG) and afferent stimulation, 2) The Osseointegrated Human-Machine Gateway for trans-humeral amputees (OHMG-TR), 3) Embedded electronics for recording/stimulation, 4) Processing and communication nodes, 5) Mechatronic coupled for interfacing implanted components with the electronics and prosthetic hand and 6) Prosthetic hand

Researchers at Gothenburg University, Sahlgrenska University Hospital, and Chalmers University of Technology have pioneered the use of osseointegration in a variety of applications since its discovery [8]; from dental implants [11] to bone conducting devices to restore hearing impairment [12, 13].

Based on the experience gathered with the first bone-anchored prostheses, R. Brånemark and colleagues established the Osseointegrated Prosthesis for the Rehabilitation of Amputees (OPRA) treatment protocol in 1999 [14], which has shown to provide stable and long-term fixation through radiostereometric analysis [15]. The Centre of Orthopaedic Osseointegration at the Department of Orthopaedics, Sahlgrenska University Hospital was established the same year to further develop the novel treatment concept (Fig. 12). By the end of 2013, the Centre of Orthopaedic Osseointegration at Sahlgrenska University Hospital treated approximately 200 patients with osseointegrated limb prostheses (OPRA Implant System8, Fig. 12), of which the majority has been transfemoral amputations, but also transtibial, transhumeral, transradial and thumb amputations have been treated. Additionally, this treatment has been expanded to clinics around the world and it is currently provided in Australia, Belgium, Chile, Denmark, England, France, Netherlands, Portugal, and Spain.

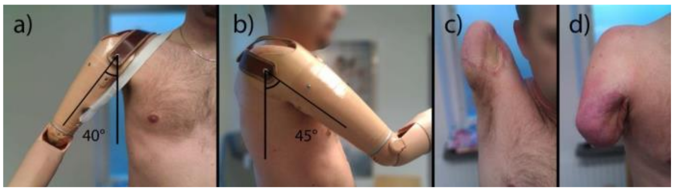

Fig. 2 Example of a transhumeral amputee fitted with a socket prosthesis which limits shoulder abduction (a) and flexion (b) to less than 45°, despite that the patient is still capable of full range of motion (c). The distal part of the stump consists of approximately 40 mm of soft tissue which cannot be used to transfer load to the prosthe-sis, thus a harness is necessary to provide enough suspension (prosthetic fittings vary depending on the stump anatomy). Additionally, skin irritation can be observed at the stump due to the socket compression (d). Pictures by Stewe Jönsson adapted with permission.

There are inherent advantages of bone-anchored over socket suspension. The first and most obvious is the elimination of the socket itself, and thus the soft tissue compression, skin obstruction, limitation in the range of motion, and locking of adjacent joints. An additional advantage is the ease of donning and doffing (Fig. 3), which has been found as an important consideration for patients [16]. Moreover, it has been found that OPRA patients use more sophisticated prosthesis, arguably because they can take better advantage of such devices when not afflicted by socket related problems [17].

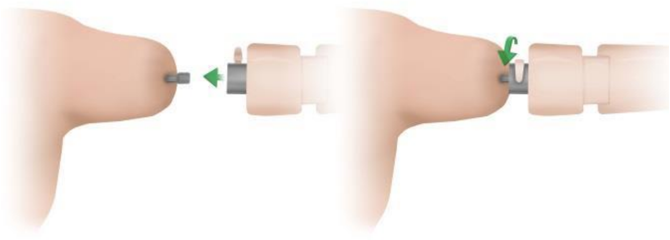

Fig. 3 Donning and doffing of a bone-anchored transhumeral prosthesis using a clamp mechanism.

B. *Transradial prostheses – artificial hands*

Upper limb prostheses are divided into cosmetic, body powered, and myoelectric hands, where the latter are the most technologically advanced. A traditional myoelectric hand is based on a pincher, covered by a cosmetic glove, in which a rigid movement is activated by the EMG signal picked-up from the residual antagonist muscles, processed by a surface interface [18]. The thumb is in fixed opposition with regard to index and middle fingers. Non-articulated fingers are all simultaneously actuated by a single motor. Because the resulting grip has just a few contact points, it is intrinsically unstable. These hands are able to exert 100 N between thumb and fingers; they are relatively light and very robust. Myoelectric hands have been commercially available since the early 70s, manufactured by a few companies: Ottobock (Austria), RSL Steeper (UK), Motion Control and LTD (USA).

In July 2007 a Scotland based company, Touch Bionics, has launched a novel multi-articulated prosthesis: the i-LIMB hand. This is the first-to-market prosthesis with five individually powered digits and a thumb abduction/adduction passive movement. Although the hand is capable of different grasping patterns, it still uses a traditional two-input EMG system to simultaneously open and close all fingers. Over and above, no sensory feedback is delivered to the individual. Surveys on using traditional artificial hands reveal that 30–50% of upper-extremity amputees do not use their prosthetic hand regularly [19]. The main factors are the low functionality, poor cosmetic appearance, and low controllability [20]. Traditional prosthetic hands are not functional in power grips (useful in 35% of activities of daily living, [21]): for these grips—characterized by high stability due to multiple contact points between the hand around the objects—the rigid non-articulated fingers of the prosthesis do not allow an adequate wrapping of the hand on the object. The second problem is related to the aesthetic appearance of the prosthesis both statically and dynamically: the hand doesn't seem natural either while moving or once stopped. The controllability problem is basically caused by the lack of natural or intuitive control interfaces and because of the lack of sensibility: no haptic feedback related to what the prosthesis is actually sensing is delivered to the person. According to hand surgeons, a stump with good sensibility is often more functional than an insensitive prosthesis.

Research Prosthesis. In the last decade robotic knowledge has been applied to improve some of the basic components of prosthetic hands such as the overall dexterity, the sensing ability of the device and the low-level controller. One of the most challenging tasks in this field is certainly that of developing a dexterous intrinsic prosthetic hand, i.e. a hand that contains in its structure all its functional components (actuators, sensors, control electronics, etc.), that can be used for patients after distal transradial amputation. Researchers at the University of Southampton [21] have developed a new ultra-light limb (400g) that mimics movements in real hands with 6 sets of motors and gears so that each of the five fingers can move independently and the thumb can change its opposition plane. In 1995 the MARCUS [22] three fingered sensorized prosthesis controlled by a hierarchical controller [23] based on the SAMS scheme [24] was presented. The MANUS project [25] proposes a prosthesis having ten joints of which three are independently driven, and in addition to these, bendable joints have been included in the fourth and fifth fingers. From a sensory point of view, force and position sensors are distributed in the hand, which is controlled by means of a hierarchical control architecture. Research at the Forschungszentrum Karlsruhe [26] has concentrated on the development of a prosthetic hand with a high number of grasping patterns with a low weight and good cosmetic appearance. The SmartHand prosthesis [27], developed by SSSA is an innovative transradial hand because of its tight design including actuators, control system and an extensive sensory system with 40 sensors. Due to its universal interface the SmartHand is ready to be connected to basically all types of interfaces. The SmartHand was exploited by Prensilia s.r.l., a SME spun out from SSSA, that developed a motorized robust robotic hand, named Azzurra IH2, already in use by 20 Research Institutes worldwide.

Many other examples may be listed: the TBM hand [28], the RTR II hand [29], the Soft hand [20], the KNU hand [30]. Even if all the cited prototypes differ in mechanisms, sensory equipment, performances and objectives, they all share the requirements of being low power, low weight, still allowing a number of prehension patterns useful in activities of daily living (ADLs). Such constraints have been met by the use of different underactuated mechanisms (fundamental for reducing the number of actuators, thus the weight and dimensions) and clutching systems (to save power once the grasp is stable): i.e. the two basic mechanical components in a prosthetic hand. Other significant research even if related to extrinsic hands to be used as neuroscientific prosthetic hand platforms include the Cyberhand [31, 32], the Yokoi hand [33], and the Vanderbilt University prototypes [34, 35]. In August 2008, researchers and companies supported by DARPA Revolutionizing Prosthetics Program (RPP) 2009 presented preliminary results at the Myoelectric Controls/Powered Prosthetics Symposium (MEC) held in Fredericton, NB, Canada. In particular: the RPP intrinsic hand [36], a prototype from the Rehabilitation Institute of Chicago [37], and the Ottobock Michelangelo hand [38], were presented. Later, in May 2010 new prototypes or products from manufacturers were firstly exhibited at the ISPO (Intl. Society on Prosthetics and Orthotics) world congress held in Leipzig, Germany: in particular the Ottobock Michelangelo hand, the RSL Steeper Bebionic hand, and the second release of i-Limb, namely Pulse, from Touch Bionics. All of these, present the same limitations of previous prostheses. Despite the important effort on the development of prosthetic hands, the new dexterous devices are not yet used in clinical trials because of the lack of adequate interfaces with the user.

C. Decoding algorithms to control of artificial prostheses

The challenges towards real neuro-controlled prostheses are in two areas: robotics and neuroscience. The problems researchers are facing are (i) how to develop a dexterous mechatronic hand with actuation and sensory features comparable to the human hand, and (ii) how to control this dexterity.

There are several ways to tap into the neural information for hand prosthesis control, ranging in hierarchical location (cortex, peripheral nerves, and nerve ending at muscles) and invasiveness (direct electrodes in tissue: intra-fascicular, needles, cuffs, or surface electrodes for electromyography, EMG or electroencephalography, EEG) [39-47].

Using EMG signals recorded by epimysial electrodes and connected through the OHMG-gateway is the most realistic and appropriate near term solution for transradial amputees (who represent the most frequent cases of amputation). Sophisticated interfaces connecting to peripheral nerves using extraneural or intraneural techniques for motor control exist and have been used by several research groups [42, 48]. This type of research, albeit representing breakthroughs in the field, has revealed several limiting factors both in terms of technology and clinical implementation. Today's PNS electrodes such as tf-LIFE [48] have low capacity charge density, so their effective recording capability is unknown. For example, a signal from a peripheral nerve is typically in the regions of uV while an EMG signal is in the region of mV making the EMG signal easier to record. Furthermore, nerve signals are typically masked by the EMG-signals of the surrounding muscle [49] making them a more unreliable source for control.

Other approaches include a promising procedure recently introduced, the Targeted Muscle Reinnervation (TMR) [50], or implantable EMG sensors [36]. However, for individuals with a hand amputation at a transradial level, a TMR procedure can be considered unnecessary as most of the forearm sensorimotor is system still intact therefore the deployment of TMR is debatable. Implantable electrodes are an interesting option which has advantages similar to those of epimysial electrodes and have recently shown promising results in the first in-human implantation [51]. However, a potential downside with this approach is the low resolution (8 bits) and the high power consumption, making it difficult to use in a battery-powered system such as a prosthetic hand.

Non-invasive EMG recorded at the surface of the arm is commonly used in clinical practice and in research when trying to find ways of improving controllability of a prosthesis [52]. One of the first attempts at improving controllability was through the use of pattern recognition techniques almost 50 years ago [53]. To this day, the use of pattern recognition along with surface EMG has yielded interesting academic results [45, 54]. Yet, most of these results are far from everyday use due real-life adverse effects caused by the weight and inertia of the prosthesis [55] and electrode shift in respect to the muscles when e.g. the arm is rotated or the prosthesis is donned/doffed [56].

Despite several decades of academic research in this field, commercial prosthetic devices are still controlled exclusively with approaches proposed 60 years ago. Naturally controllable prostheses are not yet available due to the lack of intuitive and reliable interfaces offering a large bandwidth channel for efferent control and afferent perception. The ideal controller for myoelectric prostheses supports intuitive control of multiple DoFs simultaneously and proportionally, is robust to factors of variability, use of a small number of electrodes, requires minimal or even absence of training, provides intuitive closed-loop information, and at a limited computational cost [57].

Recent and ongoing work by members of the DeTOP consortium has contributed to the progress in this field [32, 55, 58-61].

D. Sensory feedback in prosthetics

Nowadays, none of the prostheses used in clinical practice have purposely designed closed-loop controllers. Control is achieved by the individual, by means of visual feedback and incidental stimulation (audition, socket pressure, harness, etc.) but not often through design intention. Somatic receptors in the upper limb are divided in cutaneous and subcutaneous mechanoreceptors, muscle and skeletal mechanoreceptors, nociceptors and thermal receptors. This complex sensory system encodes and transmits, to the CNS, information about four major modalities: touch, proprioception, pain and temperature. After amputation, that is after the loss of receptors and interruption of the physiological channels, there are two potential ways to elicit sensory feedback: invasively, by interfacing directly to physiologically relevant neural structures in the peripheral nervous system or the CNS or noninvasively, by providing feedback to intact sensory systems (e.g., tactile stimuli on the residual limb, chest, etc.) [62]. DeTOP will address this issue by stimulating the peripheral nerves through cuff electrodes.

This area has recently gained a lot of interest due to the publication of few studies. Tactile sensations elicited by neural stimulation through chronically implanted electrodes in amputees were reported in 2014, "natural" sensations were reported by two patients during long-term follow-up [63], and our group reported similar results in one patient [60]. Such findings have also been reported for short-term intraneural electrodes [64]. These findings are at odds with previous results for neurologically intact volunteers, and more fundamental research is necessary to fully explore and understand relationship between peripheral stimulus patterns and the elicited sensations, in both the healthy and in patients [65, 66]. In addition to this currently there is no information on the long-term effect of neurostimulation to produce sensory perception in activities of the daily living, not even for a single location. In other words, no patient has been fitted with a prosthesis that allow a single percept of appropriate sensory feedback, and being free to use unrestrictedly outside a research lab (ADL). It should be noted that the patient implanted on Jan 2013 with the OHMG, did not have a portable neurostimulator in its prosthesis.

II. Novelty of the DeTOP project approach

A. Implanted bone technology – bone-anchored prostheses

Overall, we aim to produce clinically viable technology which will be actually used to treat patients along the project, as opposed to be exclusively research experimentation with no direct benefit to the patients. No other approach today can offer a clinically ready solution. Our osseointegrated interface will be the first long-term stable bidirectional interface used to control trans-radial prostheses in activities of the daily living, and we have previously demonstrated our capabilities to achieve such goal at the transhumeral level (Fig. 4, Fig. 5).

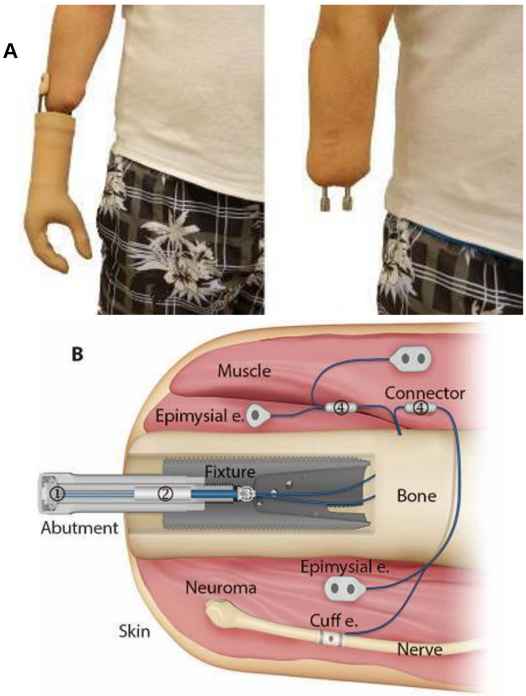

Fig. 4 A) Transradial amputee treated with the OPRA Implant System, B) The Osseointegrated Human-Machine Gateway (OHMG) for trans-humeral amputees; a long-term and bidirectional communication interface between neuromuscular electrodes and the artificial limb. Animation illustrating the concept at *http://youtu.be/w8hlziytLkM*

While other technological developments are focused on wireless communication interfaces, between implanted components and externals systems, our approach provide a wired alternative that reduces complexity and eliminates recognized problems of wireless devices such as lower rate, power consumption, overheating, coupling and orientation.

Without an osseointegrated implant for prosthesis fixation, suspension (rather than fixation) via suction sockets is the only alternative solution. Sockets rely on mechanically compressing the stump to secure the limb prosthesis, and therefore loads are transferred through soft tissue by direct contact on the skin. Such compression is a constant aggression to skin and soft tissue, which results in a variety of problems ranging from inconvenient to disabling. As a result, socket suspension is regarded as a major source of problems for amputees [1-5]. Moreover, in the case of trans-radial amputees, the socket locks the capabilities of wrist rotation, despite that often these patients can naturally produce pro/supination with appropriate proprioception.

Fig. 5 Transhumeral patient treated with the OHMG performing daily and professional activities. This patient has operated his prosthesis daily using the implanted neurosmucular electrodes for over 2 years (https://youtu.be/Z3uE4bRSkMc).

Owing to the aforementioned problems known to wireless communication and socket attachment, we consider our approach a novel technologically superior solution.

B. Transradial prostheses – artificial hands

The hand will be based on the MyHAND prototype (Fig. 6) developed by the Scuola Superiore Sant'anna (SSSA) within the homonymous national project (first prototype ready in 2015). It is a five fingered robotic hand, with 4 degrees of freedom, actuated by 3 motors. The transmission scheme, based on a Geneva wheel. The hand is able to perform a broad range of movements which include: lateral grasps, cylindrical grasps, thumb-index grasps, adduced finger grasps (grasp between fingers, laterally), pointing index up (press buttons) and pointing index down (keyboard). MyHAND is probably one of the lightest robotic hands ever developed (skeleton <300 g), significantly lighter than state-of-art commercial prostheses (in the order of 5-600 g).

Fig. 6 MyHAND prototype.

The hand currently embeds position and torque (motor current) sensors. During DeTOP the MyHAND prototype will be further developed in order to allow unconstrained use at home, and will be fitted with state of art touch sensors developed by SSSA in order to promote natural sensory feedback via the OHMG-TR (Fig. 7). In fact a comprehensive sensory system including proprioceptive and exteroceptive sensors, is a must for next-generation thought-controlled prostheses as it should: (i) be used to implement low-level control of hand action (e.g. insure proper force closure, avoid object slippage, manipulate objects within fingertips), and even more importantly (ii) be used for measuring interactions with the environment and proprioception for delivering enriched sensory feedback to the patient through afferent nerve stimulation. Recent studies have preliminarily shown the possibility to deliver force and position afferent information directly to the PNS, by means of an implanted neural interface [41, 48], and it has been concluded from numerous neurophysiological studies that humans rely on detecting discrete mechanical events that occur when grasping, lifting and replacing an object, i.e., during a prototypical manipulation task [67]. Based on these findings the consortium will investigate a sensory system ready-for-interfacing. Moreover, proprioceptive (joint angle) and touch sensors will be distributed on the palmar surfaces of the hand. Such sensory system will allow easy integration with the afferent coding algorithms. SSSA has a long experience in assessing robotic hands with patients; previous versions of MyHAND, namely SmarthHand (by SSSA) and Azzurra IH2 have been assessed with 15+ amputees employing different bi-directional non-invasive and invasive interfaces.

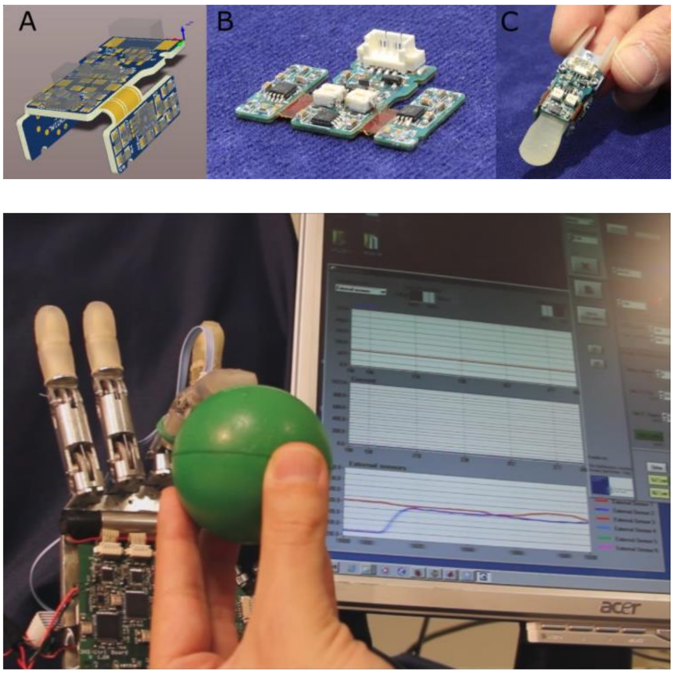

Fig. 7 The new PCB for the biaxial fingertip force sensor. A) Rigid-flexible PCB board CAD project; B) Rigid-flexible PCB board prototype; C) PCB assembled with the load cell and on the mechanical interface for the IH2 Hand.

The wrist developed together with the hand will endow 2 controllable degrees of freedom and/or systems that will allow reducing or cancelling compensatory movements. In the case of long stump, the rotation of the hand/wrist will be implemented using natural/anatomical rotation movements. It is recalled that this is not possible with conventional sockets, which lock any natural forearm rotation. Flexion/extension of the robotic hand will be implemented exploiting the concept of a mechatronic wrist with automatic compliance switching, preliminary demonstrated by SSSA [68]. In the case of short-stump a robotic wrist enabling rotation as well as flexion/extension and will restore full mobility – it should be noted that this solution is not currently commercially available. Video available on:

http://www.youris.com/Health/Disabled/The_Magic_Touch.kl

C. *Decoding algorithms to control of artificial prostheses*

DeTOP will advance the state-of-the-art in terms of controllability of hand prostheses by leveraging the OHMG-TR gateway which allows the collection of epimysial EMG signals (Fig. 8). EMG collected at the level of the Epimysium when compared to EMG recognized at the surface of the skin, allows for a more selective recording of superficial and deep muscle groups alike. Novel decoding algorithms will be developed in order to maximize the benefit of the OHMG-TR gateway for different levels of transradial amputation. To enable the development of these algorithms before the actual implantation, a iEMG database of fine-wire EMG recordings

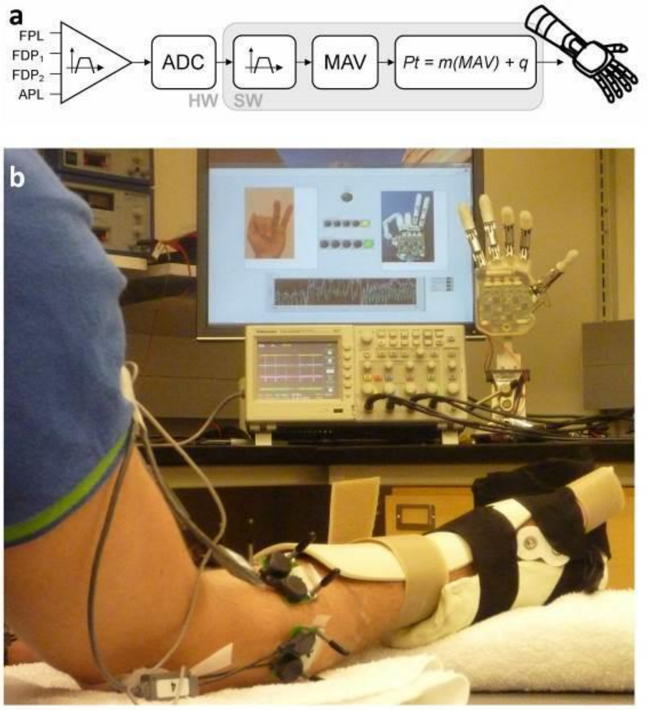

Fig. 8 Normally limbed subject -wearing an orthopedic splint on the experimental hand - in front of a computer screen and controlling a robotic hand using intramuscular EMGs from physiologically appropriate muscles. From *Cipriani et al., 2014.*

will be created that closely resembles the signals expected from the implanted epimysial EMG electrodes. For development and evaluation of these algorithms Matlab and eg. BioPatRec [69] will be utilized before they are finally integrated in the embedded controller. There is no clinically available embedded system employing the type of algorithms that will be developed in DeTOP.

A novel approach to the control of hand function that has been developed and successfully tested with amputees by consortium members will be further developed and adapted for the use with epimysial EMG signals. Furthermore, this control will be extended to accommodate modalities to seamlessly control the wrist and hand function. For this, a fully EMG driven as well as an alternative semiautomatic control modality for the wrist will be investigated. The semiautomatic control will be achieved through intelligent fusion of sensory information encoding the hands position in space with the voluntary control input decoded from EMG.

Methods for providing simultaneous and proportional control of individual DoFs of the hand prosthesis will be developed, tested and evaluated off-line utilizing the data from the iEMG database. Primarily, direct control using a one-to-one and proportional mapping between controlling muscle and a specific degree of freedom of the hand-wrist prosthesis will be used. However, depending on the pathology of the amputation, the residual muscles might not be sufficient to directly control all DoFs of the prosthesis. For such cases other approaches using pattern recognition along with supplementary techniques allowing for proportional control will evaluated to assure good controllability for the given pathology of the amputation. Several candidate algorithms will be tested e.g. using parallel LDA classifiers [51] with modifications to allow for proportional control e.g. velocity ramp [70] or multiple parallel Support Vector Regressors [54].

Further a clinical tool to determine the implant sites of epimysial electrodes will be developed. Currently visual inspection of high density surface EMG (HD-SEMG) is used as guidance to determine where the epimysial electrodes will positioned. In order to implement a well-defined process to determine the optimal placement sites for the electrodes, a procedure applying channel or feature selection algorithms to the HD-SEMG recordings and using the target control algorithm as the actual evaluator will be developed.

D. Neural sensory feedback

The fact that OHMG-TR provides a wired electrical interface is a considerable advantage with respect of classical fully implanted devices that rely on inductive link or batteries for power supply and radiofrequency transmission for data. The classical approach thus induces many hard constraints such as implantable antennas design but however low power ratios, limited bandwidth transmission for data and when RF is used, needs for encryption of data. In contrast, wired links allow for high data rate and efficient power transfer.

The overall goal is to advance implanted stimulator control to a level that aim to towards true sensory mimicry, including higher-order sensory aspects such as pleasantness or preference for tactile stimuli (Fig. 9).

Fig. 9 The transhumeral amputee treated with the OHMG undergoing afferent stimulation of mechanoreceptors through microneurography.

In DeTOP we will investigate through microneurographic recording, human tactile receptor response to complex tactile stimuli, during active tactile exploration (Fig. 10). This knowledge will be used to identify patterns of neural stimulation that can reliably elicit sensations of varying intensity and character by using a combination of basic research on tactile physiology in volunteers, and directly applying these results to stimulation in chronically implanted electrodes in amputees. Moreover, DeTOP will produce knowledge on the long-term effect of neurostimulation to produce sensory perception in activities of the daily living.

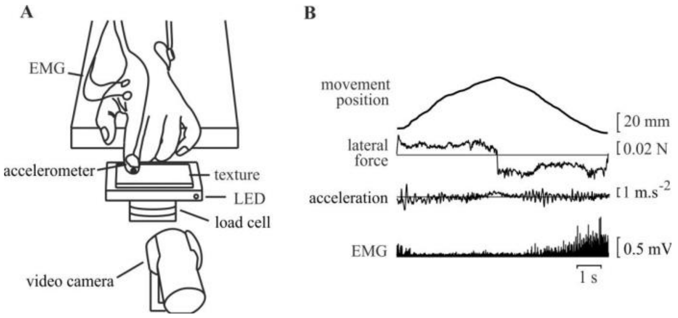

Fig. 10 *A. Experimental set-up. B. Typical result obtained for the movement position, the force and the acceleration and muscular activity of the first interosseous muscle.*

III. Conclusion

The clinical utilization of implanted neuromuscular electrodes has been hindered by the lack of a long-term stable trans-/per-cutaneous interface. The OHMG technology represents the unique clinically viable solution available today to address such issue [60], which allows more natural control and sensory feedback of prosthetic limbs using clinically ready neuromuscular interfaces. Therefore, it is important to stress, once more, that regardless of the sophistication of the neural electrodes, a realistic clinically implementation is not possible if such devices cannot be safely and reliably accessed by the prosthetic limb.

The activities of DeTOP project take advantage from the results achieved and know-how gained by the consortium's participants in decades of research. In particular, two important European technologies will be combined: the bone-anchored prosthesis technology and the robotic hand technology. This project will allow the development of an osseointegrated communication gateway for trans-radial amputees (OHMG-TR) that allows the exploitation of clinically ready neuromuscular interfaces, as well as the exploitation of the new prosthetic hand/wrist with artificial touch, the control and sensory feedback algorithms, and the wireless distributed processor architecture. This will permit the assessment of the first bone-anchored neuro-controlled bidirectional artificial transradial hand prosthesis chronically implanted in a patient.

The Consortium is in a privileged position to conduct basic research in sensory feedback and motor control, as we already have the opportunity to chronically record and stimulate the neuromuscular system, thus allowing us to explore new venues for the prediction of complex limb motions and increased understanding of tactile and proprioceptive perception. Furthermore, patients will benefit from early in this project by using the implanted electrodes to control prosthetic devices unsupervised ("take-home") in ADL. This is important, and unique, because we will deliver results of studies in long-term implanted devices (long-term stimulation and recordings), and considering the real-life utilization of prosthetic hands outside controlled laboratory environments.

The results from this project would impact not only for offering a new solution to people suffering from limb amputation, but also to those having disabling motor deficits due to other neurological diseases (stroke, brain and spinal cord trauma, brachial or lumbosacral plexus and peripheral nerve injuries etc.) which presently affect millions of patients in European countries.

References

[1] C. C. Lyon, J. Kulkarni, E. Zimersonc, E. Van Ross, and M. H. Beck, "Skin disorders in amputees," *Journal of the American Academy of Dermatology,* vol. 42, no. 3, pp. 501-507, 2000.

[2] K. Hagberg and R. Brånemark, "Consequences of non-vascular trans-femoral amputation: a survey of quality of life, prosthetic use and problems," *Prosthetics and orthotics international,* vol. 25, no. 3, pp. 186-194, 2001.

[3] N. L. Dudek, M. B. Marks, S. C. Marshall, and J. P. Chardon, "Dermatologic conditions associated with use of a lower-extremity prosthesis," *Archives of physical medicine and rehabilitation,* vol. 86, no. 4, pp. 659-663, 2005.

[4] L. E. Pezzin, T. R. Dillingham, E. J. MacKenzie, P. Ephraim, and P. Rossbach, "Use and satisfaction with prosthetic limb devices and related services," *Archives of physical medicine and rehabilitation,* vol. 85, no. 5, pp. 723-729, 2004.

[5] P. Robert Gailey PhD, "Review of secondary physical conditions associated with lower-limb amputation and long-term prosthesis use," *Journal of rehabilitation research and development,* vol. 45, no. 1, p. 15, 2008.

[6] T. R. Dillingham, L. E. Pezzin, E. J. MacKenzie, and A. R. Burgess, "Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study," *American Journal of Physical Medicine & Rehabilitation,* vol. 80, no. 8, pp. 563-571, 2001.

[7] V. Mooney, P. K. Predecki, J. Renning, and J. Gray, "Skeletal extension of limb prosthetic attachments–Problems in tissue reaction," *Journal of Biomedical Materials Research,* vol. 5, no. 6, pp. 143-159, 1971.

[8] R. Branemark, P. Branemark, B. Rydevik, and R. R. Myers, "Osseointegration in skeletal reconstruction and rehabilitation: a review," *Journal of rehabilitation research and development,* vol. 38, no. 2, p. 175, 2001.

[9] P.-I. Branemark, "Vital microscopy of bone marrow in rabbit," *Scandinavian journal of clinical and laboratory investigation,* vol. 11, p. 1, 1959.

[10] M. Pitkin, "Design features of implants for direct skeletal attachment of limb prostheses," *Journal of biomedical materials research Part A,* vol. 101, no. 11, pp. 3339-3348, 2013.

[11] P. Branemark, "Osseointegrated implants in the treatment of edentulous jaw, Experience from a 10-year period," *Scand J Plast Reconstr Surg,* vol. 1, pp. 1-132, 1977.

[12] F. Snik *et al.*, "Consensus statements on the BAHA system: where do we stand at present?," *Annals of Otology, Rhinology & Laryngology,* vol. 114, no. 12_suppl, pp. 2-12, 2005.

[13] B. Håkansson, A. Tjellström, U. Rosenhall, and P. Carlsson, "The bone-anchored hearing aid: Principal design and a psychoacoustical evaluation," *Acta oto-laryngologica,* vol. 100, no. 3-4, pp. 229-239, 1985.

[14] K. Hagberg and R. Brånemark, "One hundred patients treated with osseointegrated transfemoral amputation prostheses—rehabilitation perspective," *J Rehabil Res Dev,* vol. 46, no. 3, pp. 331-44, 2009.

[15] A. Nebergall, C. Bragdon, A. Antonellis, J. Kärrholm, R. Brånemark, and H. Malchau, "Stable fixation of an osseointegated

implant system for above-the-knee amputees: titel RSA and radiographic evaluation of migration and bone remodeling in 55 cases," *Acta orthopaedica,* vol. 83, no. 2, pp. 121-128, 2012.
[16] P. J. Kyberd, "The influence of passive wrist joints on the functionality of prosthetic hands," *Prosthetics and orthotics international,* vol. 36, no. 1, pp. 33-38, 2012.
[17] E. E. Haggstrom, E. Hansson, and K. Hagberg, "Comparison of prosthetic costs and service between osseointegrated and conventional suspended transfemoral prostheses," *Prosthetics and orthotics international,* vol. 37, no. 2, pp. 152-160, 2013.
[18] M. Zecca, S. Micera, M. Carrozza, and P. Dario, "Control of multifunctional prosthetic hands by processing the electromyographic signal," *Critical Reviews™ in Biomedical Engineering,* vol. 30, no. 4-6, 2002.
[19] D. J. Atkins, D. C. Heard, and W. H. Donovan, "Epidemiologic overview of individuals with upper-limb loss and their reported research priorities," *JPO: Journal of Prosthetics and Orthotics,* vol. 8, no. 1, pp. 2-11, 1996.
[20] M. C. Carrozza *et al.*, "A cosmetic prosthetic hand with tendon driven under-actuated mechanism and compliant joints: ongoing research and preliminary results," in *Robotics and Automation, 2005. ICRA 2005. Proceedings of the 2005 IEEE International Conference on*, 2005, pp. 2661-2666: IEEE.
[21] C. M. Light, P. H. Chappell, and P. J. Kyberd, "Establishing a standardized clinical assessment tool of pathologic and prosthetic hand function: normative data, reliability, and validity," *Archives of physical medicine and rehabilitation,* vol. 83, no. 6, pp. 776-783, 2002.
[22] P. J. Kyberd *et al.*, "MARCUS: A two degree of freedom hand prosthesis with hierarchical grip control," *IEEE Transactions on Rehabilitation Engineering,* vol. 3, no. 1, pp. 70-76, 1995.
[23] P. Kyberd, N. Mustapha, F. Carnegie, and P. Chappell, "A clinical experience with a hierarchically controlled myoelectric hand prosthesis with vibro-tactile feedback," *Prosthetics and Orthotics International,* vol. 17, no. 1, pp. 56-64, 1993.
[24] J. Nightingale, "Microprocessor control of an artificial arm," *Journal of Microcomputer Applications,* vol. 8, no. 2, pp. 167-173, 1985.
[25] J. Pons *et al.*, "The MANUS-HAND dextrous robotics upper limb prosthesis: mechanical and manipulation aspects," *Autonomous Robots,* vol. 16, no. 2, pp. 143-163, 2004.
[26] C. Pylatiuk, S. Mounier, A. Kargov, S. Schulz, and G. Bretthauer, "Progress in the development of a multifunctional hand prosthesis," in *Engineering in Medicine and Biology Society, 2004. IEMBS'04. 26th Annual International Conference of the IEEE*, 2004, vol. 2, pp. 4260-4263: IEEE.
[27] C. Cipriani, M. Controzzi, and M. C. Carrozza, "The SmartHand transradial prosthesis," *Journal of neuroengineering and rehabilitation,* vol. 8, no. 1, p. 29, 2011.
[28] N. Dechev, W. Cleghorn, and S. Naumann, "Multiple finger, passive adaptive grasp prosthetic hand," *Mechanism and machine theory,* vol. 36, no. 10, pp. 1157-1173, 2001.
[29] B. Massa, S. Roccella, M. C. Carrozza, and P. Dario, "Design and development of an underactuated prosthetic hand," in *Robotics and Automation, 2002. Proceedings. ICRA'02. IEEE International Conference on*, 2002, vol. 4, pp. 3374-3379: IEEE.
[30] J.-U. Chu, D.-H. Jung, and Y.-J. Lee, "Design and control of a multifunction myoelectric hand with new adaptive grasping and self-locking mechanisms," in *Robotics and Automation, 2008. ICRA 2008. IEEE International Conference on*, 2008, pp. 743-748: IEEE.
[31] M. C. Carrozza, G. Cappiello, S. Micera, B. B. Edin, L. Beccai, and C. Cipriani, "Design of a cybernetic hand for perception and action," *Biological cybernetics,* vol. 95, no. 6, p. 629, 2006.
[32] C. Cipriani, F. Zaccone, S. Micera, and M. C. Carrozza, "On the shared control of an EMG-controlled prosthetic hand: analysis of user–prosthesis interaction," *IEEE Transactions on Robotics,* vol. 24, no. 1, pp. 170-184, 2008.
[33] Y. Ishikawa, W. Yu, H. Yokoi, and Y. Kakazu, "Development of robot hands with an adjustable power transmitting mechanism," *Intelligent Engineering Systems Through Neural Networks,* vol. 10, pp. 631-636, 2000.
[34] K. B. Fite, T. J. Withrow, X. Shen, K. W. Wait, J. E. Mitchell, and M. Goldfarb, "A gas-actuated anthropomorphic prosthesis for transhumeral amputees," *IEEE Transactions on Robotics,* vol. 24, no. 1, pp. 159-169, 2008.
[35] T. E. Wiste, S. A. Dalley, H. A. Varol, and M. Goldfarb, "Design of a multigrasp transradial prosthesis," *Journal of Medical Devices,* vol. 5, no. 3, p. 031009, 2011.
[36] R. F. Weir, P. R. Troyk, G. A. DeMichele, D. A. Kerns, J. F. Schorsch, and H. Maas, "Implantable myoelectric sensors (IMESs) for intramuscular electromyogram recording," *IEEE Transactions on Biomedical Engineering,* vol. 56, no. 1, pp. 159-171, 2009.
[37] M. Mitchell and R. F. Weir, "Development of a clinically viable multifunctional hand prosthesis," 2008: Myoelectric Symposium.
[38] G. Puchhammer, "Michelangelo 03-A versatile hand prosthesis, featuring superb controllability and sophisticated bio mimicry," 2008: Myoelectric Symposium.
[39] X. Navarro, T. B. Krueger, N. Lago, S. Micera, T. Stieglitz, and P. Dario, "A critical review of interfaces with the peripheral nervous system for the control of neuroprostheses and hybrid bionic systems," *Journal of the Peripheral Nervous System,* vol. 10, no. 3, pp. 229-258, 2005.
[40] S. Micera *et al.*, "On the use of longitudinal intrafascicular peripheral interfaces for the control of cybernetic hand prostheses in amputees," *IEEE Transactions on Neural Systems and Rehabilitation Engineering,* vol. 16, no. 5, pp. 453-472, 2008.
[41] G. S. Dhillon and K. W. Horch, "Direct neural sensory feedback and control of a prosthetic arm," *IEEE transactions on neural systems and rehabilitation engineering,* vol. 13, no. 4, pp. 468-472, 2005.
[42] L. R. Hochberg *et al.*, "Neuronal ensemble control of prosthetic devices by a human with tetraplegia," *Nature,* vol. 442, no. 7099, pp. 164-171, 2006.
[43] J. C. Sanchez and J. C. Principe, "Brain–machine interface engineering," *Synthesis Lectures on Biomedical Engineering,* vol. 2, no. 1, pp. 1-234, 2007.
[44] A. B. Schwartz, X. T. Cui, D. J. Weber, and D. W. Moran, "Brain-controlled interfaces: movement restoration with neural prosthetics," *Neuron,* vol. 52, no. 1, pp. 205-220, 2006.
[45] N. Jiang, T. Lorrain, and D. Farina, "A state-based, proportional myoelectric control method: online validation and comparison with the clinical state-of-the-art," *Journal of neuroengineering and rehabilitation,* vol. 11, no. 1, p. 1, 2014.
[46] G. R. Muller-Putz and G. Pfurtscheller, "Control of an electrical prosthesis with an SSVEP-based BCI," *IEEE Transactions on Biomedical Engineering,* vol. 55, no. 1, pp. 361-364, 2008.
[47] J. L. Collinger *et al.*, "High-performance neuroprosthetic control by an individual with tetraplegia," *The Lancet,* vol. 381, no. 9866, pp. 557-564, 2013.
[48] P. M. Rossini *et al.*, "Double nerve intraneural interface implant on a human amputee for robotic hand control," *Clinical neurophysiology,* vol. 121, no. 5, pp. 777-783, 2010.
[49] M. Ortiz-Catalan, R. Brånemark, B. Håkansson, and J. Delbeke, "On the viability of implantable electrodes for the natural control of artificial limbs: Review and discussion," *Biomedical engineering online,* vol. 11, no. 1, p. 33, 2012.
[50] T. A. Kuiken *et al.*, "Targeted reinnervation for enhanced prosthetic arm function in a woman with a proximal amputation: a case study," *The Lancet,* vol. 369, no. 9559, pp. 371-380, 2007.
[51] J. J. Baker, E. Scheme, K. Englehart, D. T. Hutchinson, and B. Greger, "Continuous detection and decoding of dexterous finger flexions with implantable myoelectric sensors," *IEEE Transactions on Neural Systems and Rehabilitation Engineering,* vol. 18, no. 4, pp. 424-432, 2010.
[52] A. Fougner, Ø. Stavdahl, P. J. Kyberd, Y. G. Losier, and P. A. Parker, "Control of upper limb prostheses: terminology and proportional myoelectric control—a review," *IEEE Transactions on neural systems and rehabilitation engineering,* vol. 20, no. 5, pp. 663-677, 2012.
[53] F. Finley and R. Wirta, "Myocoder-computer study of electromyographic patterns," *Archives of physical medicine and rehabilitation,* vol. 48, no. 1, p. 20, 1967.
[54] A. Ameri, E. N. Kamavuako, E. J. Scheme, K. B. Englehart, and P. A. Parker, "Support vector regression for improved real-time, simultaneous myoelectric control," *IEEE Transactions on Neural Systems and Rehabilitation Engineering,* vol. 22, no. 6, pp. 1198-1209, 2014.

[55] C. Cipriani, J. L. Segil, J. A. Birdwell, and R. F. ff Weir, "Dexterous control of a prosthetic hand using fine-wire intramuscular electrodes in targeted extrinsic muscles," *IEEE Transactions on Neural Systems and Rehabilitation Engineering,* vol. 22, no. 4, pp. 828-836, 2014.

[56] A. J. Young, L. J. Hargrove, and T. A. Kuiken, "The effects of electrode size and orientation on the sensitivity of myoelectric pattern recognition systems to electrode shift," *IEEE Transactions on Biomedical Engineering,* vol. 58, no. 9, pp. 2537-2544, 2011.

[57] D. Farina *et al.*, "The extraction of neural information from the surface EMG for the control of upper-limb prostheses: emerging avenues and challenges," *IEEE Transactions on Neural Systems and Rehabilitation Engineering,* vol. 22, no. 4, pp. 797-809, 2014.

[58] C. Antfolk *et al.*, "Using EMG for real-time prediction of joint angles to control a prosthetic hand equipped with a sensory feedback system," *Journal of Medical and Biological Engineering,* vol. 30, no. 6, pp. 399-406, 2010.

[59] M. Ortiz-Catalan, B. Håkansson, and R. Brånemark, "Real-time and simultaneous control of artificial limbs based on pattern recognition algorithms," *IEEE Transactions on Neural Systems and Rehabilitation Engineering,* vol. 22, no. 4, pp. 756-764, 2014.

[60] M. Ortiz-Catalan, B. Håkansson, and R. Brånemark, "An osseointegrated human-machine gateway for long-term sensory feedback and motor control of artificial limbs," *Science translational medicine,* vol. 6, no. 257, pp. 257re6-257re6, 2014.

[61] C. Cipriani *et al.*, "Online myoelectric control of a dexterous hand prosthesis by transradial amputees," *IEEE Transactions on Neural Systems and Rehabilitation Engineering,* vol. 19, no. 3, pp. 260-270, 2011.

[62] C. Antfolk *et al.*, "Transfer of tactile input from an artificial hand to the forearm: experiments in amputees and able-bodied volunteers," *Disability and Rehabilitation: Assistive Technology,* vol. 8, no. 3, pp. 249-254, 2013.

[63] D. W. Tan, M. A. Schiefer, M. W. Keith, J. R. Anderson, J. Tyler, and D. J. Tyler, "A neural interface provides long-term stable natural touch perception," *Science translational medicine,* vol. 6, no. 257, pp. 257ra138-257ra138, 2014.

[64] S. Raspopovic *et al.*, "Restoring natural sensory feedback in real-time bidirectional hand prostheses," *Science translational medicine,* vol. 6, no. 222, pp. 222ra19-222ra19, 2014.

[65] H. Torebjörk, Å. Vallbo, and J. Ochoa, "INTRANEURAL MICROSTIMULATION IN MANITS RELATION TO SPECIFICITY OF TACTILE SENSATIONS," *Brain,* vol. 110, no. 6, pp. 1509-1529, 1987.

[66] R. S. Johansson and I. Birznieks, "First spikes in ensembles of human tactile afferents code complex spatial fingertip events," *Nature neuroscience,* vol. 7, no. 2, pp. 170-177, 2004.

[67] B. B. Edin, L. Ascari, L. Beccai, S. Roccella, J.-J. Cabibihan, and M. Carrozza, "Bio-inspired sensorization of a biomechatronic robot hand for the grasp-and-lift task," *Brain research bulletin,* vol. 75, no. 6, pp. 785-795, 2008.

[68] F. Montagnani, M. Controzzi, and C. Cipriani, "Preliminary design and development of a two degrees of freedom passive compliant prosthetic wrist with switchable stiffness," in *Robotics and Biomimetics (ROBIO), 2013 IEEE International Conference on*, 2013, pp. 310-315: IEEE.

[69] M. Ortiz-Catalan, R. Brånemark, and B. Håkansson, "BioPatRec: A modular research platform for the control of artificial limbs based on pattern recognition algorithms," *Source code for biology and medicine,* vol. 8, no. 1, p. 11, 2013.

[70] A. M. Simon, L. J. Hargrove, B. A. Lock, and T. A. Kuiken, "A decision-based velocity ramp for minimizing the effect of misclassifications during real-time pattern recognition control," *IEEE Transactions on Biomedical Engineering,* vol. 58, no. 8, pp. 2360-2368, 2011.