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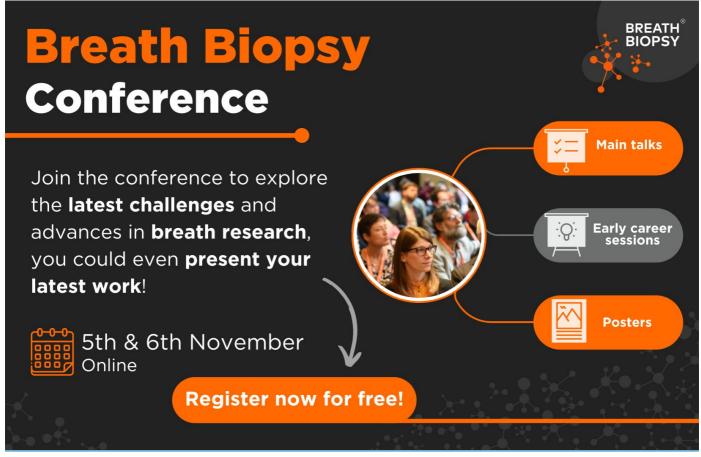
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PAPER

Intuitive control of additional prosthetic joints via electro-neuromuscular constructs improves functional and disability outcomes during home use—a case study

Jan Zbinden^{1,2}, Eric J Earley^{1,2,3,4} and Max Ortiz-Catalan^{1,2,5,6,7,*}

- Center for Bionics and Pain Research, Mölndal, Sweden
- Department of Electrical Engineering, Chalmers University of Technology, Gothenburg, Sweden
- Bone-Anchored Limb Research Group, University of Colorado, Aurora, CO, United States of America
- Department of Orthopedics, University of Colorado School of Medicine, Aurora, CO, United States of America
- Bionics Institute, Melbourne, Australia
- Medical Bionics Department, University of Melbourne, Melbourne, Australia
- Prometei Pain Rehabilitation Center, Vinnytsia, Ukraine
- Author to whom any correspondence should be addressed.

E-mail: maxortizc@outlook.com and zbinden@chalmers.se

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Supplementary material for this article is available online

Abstract

Objective. The advent of surgical reconstruction techniques has enabled the recreation of myoelectric controls sites that were previously lost due to amputation. This advancement is particularly beneficial for individuals with higher-level arm amputations, who were previously constrained to using a single degree of freedom (DoF) myoelectric prostheses due to the limited number of available muscles from which control signals could be extracted. In this study, we explore the use of surgically created electro-neuromuscular constructs to intuitively control multiple bionic joints during daily life with a participant who was implanted with a neuromusculoskeletal prosthetic interface. Approach. We sequentially increased the number of controlled joints, starting at a single DoF allowing to open and close the hand, subsequently adding control of the wrist (2 DoF) and elbow (3 DoF). Main results. We found that the surgically created electro-neuromuscular constructs allow for intuitive simultaneous and proportional control of up to three degrees of freedom using direct control. Extended home-use and the additional bionic joints resulted in improved prosthesis functionality and disability outcomes. Significance. Our findings indicate that electro-neuromuscular constructs can aid in restoring lost functionality and thereby support a person who lost their arm in daily-life tasks.

1. Introduction

The abrupt loss of functionality following amputation can be mitigated with prosthetic limbs. However, the abandonment rate of these prostheses is relatively high [1]. This is primarily because the functionality and reliability of clinically prescribed prostheses often fail to meet the user's expectations during daily use. Consequently, it is critical for researchers to move beyond laboratory testing and validate their prosthetic systems in real-world environments to ensure functionality and reliability.

The current clinical and industry standard in myoelectric prosthetic control employs surface electrodes placed on two appropriate (when possible) antagonistic muscle pairs, operating on the principle of direct control (DC). DC is a simple yet effective method where the contraction signal of a muscle is recorded via electromyography and linked to the activation of a motorized joint movement. The number of controllable motorized joints is thus restricted by the number of remaining muscles postamputation. This approach poses a particular challenge in the case of above-elbow amputations, where

often only two signal sources remain, typically the biceps and triceps. The restriction of only one controllable degree of freedom (DoF) limits a prosthesis' overall functionality [2], and forces the users to potentially harmful compensatory motions [3].

The control over additional joints can be achieved using triggers, such as co-contraction or timed pulses of a hand-open signal. These triggers can either directly influence or alter the actuated joint via a statemachine. However, the usage of these triggers is non-intuitive, in the sense that they do not mimic physiological actions, potentially leading to increased cognitive load and interruptions in action execution. This non-intuitiveness is especially evident in higher amputation levels, where even basic open/close signals, controlled by the biceps/triceps, can feel unnatural, further decreasing functionality.

Despite these challenges, DC offers exceptional reliability, given its inherent simplicity. This advantage extends to both the user and the prosthetist during the fitting procedure. When correctly tuned, the reliability of the system is primarily limited by changing signal conditions, such as electrode lift-off or increased perspiration, rather than the control system itself.

In an effort to increase intuitiveness of the control, pattern recognition has been employed to classify distinct signal patterns in higher dimensional spaces that were previously not separable in the orthogonal representation used for DC. And indeed, many laboratory experiments demonstrated that patients using pattern recognition could actuate more bionic joints [4], or change between grasps [5, 6] more intuitively, and thereby increase functionality [7–9]. These successful experiments led to the pattern recognition approach to myoelectric control to be translated outside of the laboratory and to be commercially available (e.g. Complete Control, COAPT engineering or MyoPlus, Ottobock). The increase of functionality, however, often comes at the cost of reliability. Most pattern recognition algorithms are black boxes and can display unexpected behavior when the recorded signals do not match the data the algorithms were trained on (e.g. due to electrode shift, noise disturbances, postural changes). Often the unwanted behaviour cannot easily be remedied by simply changing some settings as with DC, arguably because the parameters in pattern recognition algorithms intricately depend on each other. Especially when the algorithms also should handle proportional and/or simultaneous activation of the bionic joints. A possible remedy is to fine-tune the parameters to patient specific preferences with reinforcement learning [10-12]. Another alternative would be to train the patient to create more distinguishable signals [13, 14].

However, the number of distinguishable signals is strictly limited by the type of amputation, i.e., the number of remnant muscles. And no algorithm can make up for the lack of information in its input signals. The solution, thus, is to create more myoelectric signal sources. One approach to create new myoelectric sites is to surgically transfer nerves to native denervated muscles, known as targeted muscle reinnervation (TMR) [15]. Signals from these reinnervated native muscles lead to functional improvements thanks to intuitive control (here used in the sense of volition resulting in physiological actions) of up to 2 DoFs using a DC scheme [16, 17]. TMR even allowed for control over 3 DoFs [18], albeit non-intuitively as the wrist and hand were controlled by the same signal and a switch allowed changing between the two joints. To allow for intuitive control over 3 DoFs [19-21], pattern recognition algorithms were used to decode the motion intent from the numerically limited and nonorthogonal signals. An alternative approach to transferring a nerve to a native muscle, known as regenerative peripheral nerve interface (RPNI) [22, 23], is to dissect the nerve into several fascicles, each of them wrapped and left to innervate into a free muscle graft. The RPNI technique has so far been primarily used for creating additional myoelectric sources for people with trans-radial amputation and allowed for intuitive prosthesis control of several bionic joints or grasps

TMR is a more established procedure compared to RPNIs but only results in the creation of myoelectric sites for up to six movements in the case of a trans-humeral amputation. The diameter of the donor nerve is often much larger than the recipient nerve in the target muscle, and therefore many axons are left without a target to reinnervate. These nerve fascicles could be used to reinnervate free muscle grafts as in the case of RPNI, and thus take advantage of both procedures. In addition, if the nerve transfers to the free muscle grafts (RPNIs) would be unsuccessful, the patient would still enjoy the improved prosthetic control given by the TMR sites.

Our group recently demonstrated that combining the two surgical reconstruction techniques, meaning to concurrently nerve transfer to native and free grafted muscles, allowed a patient with transhumeral amputation to control multiple DoFs intuitively, including all fingers individually, using pattern recognition within a laboratory setting [28]. This required not only the surgical creation of new myoelectric sites but to embed implanted electrodes during the process, as some of these new myoelectric signals are too weak to be captured by electrodes on the surface of the skin. Hereafter we refer as electroneuromuscular construct to the resulting architecture of implanting an electrode in muscle tissue recipient of a nerve transfer [28]. In addition, the patient also received a bone-anchoring implant that allows both for secure attachment and routing of the signals to and from the implanted electrodes—creating a self-contained neuromusculoskeletal prosthesis fit for daily use at home [29, 30]. We hypothesized that the newly created electro-neuromuscular constructs would provide a high number of relatively independent signals—solving the underlying problem that previously prevented using a DC scheme to intuitively control multiple DoFs.

We set out to investigate if these electroneuromuscular constructs indeed allow for intuitive multi-DoF control using a DC mapping during a prolonged home-use period. We furthermore gradually increased the number of DoF over time and assessed how prosthetic functionality changed with additional myoelectric joints compared to the clinical standard of a singular DoF.

We found that the addition of electroneuromuscular constructs indeed allowed for reliable control of up to 3 DoFs (demonstration in movie S1) which led to consistent use of each DoF during home use. Prosthesis functionality and physical function increased with each added DoF. We further observed an increase in the average prosthetic use duration, indicating that increased functionality and reliable control increase prosthetic use and could potentially prevent abandonment.

2. Methods

2.1. Study design

This study investigated if neuromuscular constructs allow for multi-DoF control of a prosthesis during home use and how functionality and use of a prosthesis would change when transitioning from a 1 DoF (hand opening and closing), to a 2 DoF (adding pronation and supination), and finally to a 3 DoF (adding elbow flexion and extension) prosthesis control scheme. The main study objective was to assess whether additional prosthesis DoFs would lead to a functional benefit (as assessed by the Southampton Hand Assessment Procedure (SHAP), the refined clothespin relocation test (RCRT), and the virtual eggs test (VET)) and decrease perceived disability (as measured with the disability of the arm, shoulder, and hand (DASH) questionnaire). As second objective, we monitored changes during prosthetic home-use (as measured by logging usage data) due to the additional DoFs.

A 54 year-old male patient with a left transhumeral amputation participated in this study. He was implanted with a neuromusculoskeletal arm prosthesis in December 2018 [28]. The neuromusculoskeletal prosthesis consisted of an osseointegrated implant system (e-OPRA Implant System, Integrum AB, Sweden) for prosthesis attachment, a total of 12 implanted epimysial and intramuscular electrodes on four native muscles and in eight neuromuscular constructs (see [28] for a detailed overview of the location of the electrodes and which nerves innervate the neuromuscular constructs), and an

extraneural cuff electrode meant for somatosensory feedback (not used in this study), see figure 1. Furthermore, the prosthesis contained the Artificial Limb Controller, an embedded system for controlling prosthetic devices [31]. Prior to receiving a neuromusculoskeletal prosthesis, the participant used a conventional myoelectric prosthesis using skin surface electrodes, allowing for control over 1 DoF through a DC approach mapping biceps and triceps contractions to hand opening and closing.

Data were collected over a period of 3 years total at uneven intervals dictated by the COVID-19 pandemic. This, however, allowed the participant to familiarize himself with each new DoF for at least a year during daily home-use. Just before the participant was fitted with an additional DoF, functional tests were conducted, the questionnaire was administered, and the log data were retrieved from the memory card of the prosthesis controller. The participant started to use intuitive hand opening and closing in September 2019 (9 months after the surgical intervention). The prosthesis was equipped with wrist control in July 2020, and subsequentially elbow control was added in November 2021. To match the 1 year home-use time for the other DoFs, the end date of the 3 DoF condition was planned for November 2022. However, the elbow motor broke three months before the study termination and was in repair until March 2023, during which the participant used his previous 2 DoF prosthesis instead. The final data were thus collected in June 2023.

The study protocols were carried out in accordance with the declaration of Helsinki. Signed informed consent, as well as consent for publication, was obtained before conducting the experiments. The study was approved by the Regional Ethical Review Board in Gothenburg, Sweden (Dnr. 18-T125 and Dnr. 2020-04600).

2.2. Prosthesis control fitting

To investigate if the newly created myoelectric sites from the neuromuscular constructs would provide enough independent signals to control three bionic joints intuitively and independently, we used a DC scheme to map user intent to prosthetic movement.

The mapping for the 1 DoF control was based on the biological motor functions normally innervated by each nerve: the signal from a native muscle reinnervated by the radial nerve was mapped to intuitive open and the signal from a native muscle reinnervated by the ulnar nerve was mapped to intuitive closing of the hand. For the 2 DoF control, the signal from a free muscle graft reinnervated by the median nerve was mapped to wrist pronation and the signal from a free muscle graft reinnervated by the radial nerve was mapped to supination (see table 1 for an overview of the DC mapping). For both the 1 DoF and 2 DoF conditions, a single-DoF myoelectric hand (Greifer or



Figure 1. Detail overview of the neuromusculoskeletal prosthesis. Shown are electrodes on native muscles and in native muscles as well as free muscle grafts reinnervated by the median, radial, and ulnar nerve (i.e. electro-neuromuscular constructs). Furthermore, the attachment mechanism, where a clamp mechanism connects the prosthesis to the percutaneous part of the osseointegrated titanium implant is shown. Beneath the clamp, a housing with the embedded system is situated which decodes and translates motion intent to actuate the hand, wrist, and elbow motors of the prosthesis. Overlay surgical illustration repurposed from [28]. Adapted with permission from AAAS.

MyoHand VariPlus Speed, Ottobock) and an elbow (ErgoArm, Ottobock) with a myoelectric locking system were used. The myoelectric locking system was intuitively controlled by the lock/unlock command mapped to a signal from the native triceps. To allow for wrist rotation in the 2 DoF prosthesis, an electric wrist rotator (Ottobock) was installed. During the 2 DoF condition, the battery inside the prosthesis was exchanged for one with higher capacity to account for the increased power demand from the extra motorized joint.

During the DC fitting, we observed crosstalk between myoelectric sites that can be attributed to e.g. the location of the electro-neuromuscular constructs, the placement of the electrodes, or the use of monopolar electrodes. Specifically, voluntarily closing the hand resulted in a signal picked up by the electrode mapped to wrist pronation, and voluntary extension of the elbow to trigger the elbow lock/unlock functionality led to activation on the signals mapped to hand open, pronation and supination. To increase control reliability for individual movements, we masked (i.e. attenuated) these interfering signals triggering unwanted prosthesis movement. Mathematically, the masking algorithm checked whether the masking signal

exceeds a hand-tuned threshold (in our case equal to the DC movement actuation threshold of the masking signal). If the threshold is exceeded, the masked signal is multiplied with zero to remain below its own lower movement activation threshold. Doing so did limit simultaneous activation of hand closing and pronation, but considerably decreases undesired wrist rotation during hand closing movement. All other combinations of 2 DoF hand and wrist activations were, however, possible.

For the 3 DoF control, the signal from the native long head of the biceps was mapped to elbow flexion and the signal from the native lateral head of the triceps, previously used for lock/unlocking, to elbow extension. Voluntary flexion of the elbow resulted in interfering activation on the open hand signal. Thus, additional to the existing masks from the 2 DoF condition, the open hand signal was masked by the flex elbow signal. This in turn limited the simultaneous activation of elbow movements together with open hand or with wrist rotation. The previous prosthetic elbow was swapped with an elbow that allowed for active flexion and extension (Espire Pro, Steeper).

In summary, signals from six of the 12 available implanted electrodes were used, coming from two neuromuscular constructs innervated by different

Table 1. Summary of the direct control mapping showing which myoelectric source was associated with a certain movement, the used activation and saturation thresholds for each movement, and information about the masking of individual signals. The difference between the saturation and activation threshold is the possible range for proportionality. For the 2 and 3 degree of freedom (DoF) conditions, the thresholds used at the beginning and at the end of each condition are reported. The activation and saturation thresholds for the myoelectric lock/unlock were the same, thus only one number is reported. The thresholds to trigger masking were equivalent to the direct control activation threshold of the movement used for masking.

pen hand lose hand ock/ unlock	Myoelectric source Native muscle reinnervated by radial nerve Native muscle reinnervated by ulnar nerve Lateral head triceps	End: 7.7/14 mV End: 20/46 mV End: 22 mV	Masked by Lock/unlock
lose hand	radial nerve Native muscle reinnervated by ulnar nerve	End: 20/46 mV	Lock/unlock
lose hand	radial nerve Native muscle reinnervated by ulnar nerve	End: 20/46 mV	Lock/unlock
	ulnar nerve		
ock/ unlock	Lateral head triceps	End: 22 mV	
		Elia: 22 III v	
pen hand	Native muscle reinnervated by	Start: 12/17 mV	Lock/unlock
loss hand			
iose mand	•		
ronation		***	Lock/unlock and close
		End: 4.5/6.4 mV	hand
upination		Start: 6.5/7.8 mV	Lock/unlock
	radial nerve	End: 6.8/13 mV	
ock/ unlock	Lateral head triceps	Start: 21 mV	
		End: 19 mV	
pen hand	Native muscle reinnervated by	Start: 13/17 mV	Flex and extend elbow
	radial nerve	End: 10/17 mV	
lose hand	Native muscle reinnervated by	Start: 40/67 mV	
	ulnar nerve	End: 40/67 mV	
ronation	•	Start: 6.9/10 mV	Extend elbow and
			close hand
upination	•		Extend elbow
ex elbow	Long head biceps		
E-+ 1 -11	Lataral hand trianna	*** *** *	
xteria erbow	Lateral nead triceps		
	ose hand onation upination ock/ unlock pen hand ose hand	radial nerve Native muscle reinnervated by ulnar nerve Free muscle graft reinnervated by median nerve prination Free muscle graft reinnervated by radial nerve Lateral head triceps Pen hand Native muscle reinnervated by radial nerve ose hand Native muscle reinnervated by ulnar nerve Free muscle graft reinnervated by median nerve prination Free muscle graft reinnervated by radial nerve prination Free muscle graft reinnervated by radial nerve Long head biceps	radial nerve Ose hand Native muscle reinnervated by ulnar nerve Ose hand Native muscle graft reinnervated by median nerve pen hand Native muscle graft reinnervated by radial nerve pen hand Native muscle reinnervated by Start: 13/17 mV pen hand Native muscle reinnervated by Start: 40/67 mV ulnar nerve pen hand Native muscle graft reinnervated by Start: 40/67 mV pen hand The pen hand Start: 40/67 mV End: 40/67 mV End: 7.0/12 mV pen hand The pen

fascicles of the radial nerve, one neuromuscular construct innervated by a fascicle of the radial nerve, one neuromuscular construct innervated by a fascicle of the median nerve, and one each from the native biceps and triceps.

During the whole study period, only minor adjustment to the control parameters were performed. The only adjustments included changes to the activation thresholds and thereby the mask parameters in case a movement would still trigger an unwanted activation of another joint, or changes to the maximum voluntary contraction (saturation) thresholds to adjust the velocity (proportionality) of the movements in accordance with the participants preferences.

2.3. Assessments

Prosthesis functionality was assessed after around a year of home use and before adding an additional DoF (i.e. a total of three times) using the SHAP [32], RCRT [33], and VET [34] tests. The SHAP assesses the

effectiveness of how an upper limb prosthesis is used. The participant performs a total of 26 tasks, where they manipulate abstract objects and perform activities of daily living while being timed. Based on the execution times, the weighted linear index of function (W-LIF) can be calculated [35]. The W-LIF is a normed score between 0 and 100, where 100 indicates normal hand function.

The RCRT evaluates performance and assesses compensatory motion between able-bodied subjects and subjects with upper limb impairments [36]. In a total of five trials, the participant moves clothespins first from a horizontal to a vertical rod and then later back again, while being both timed and filmed. The RCRT score is calculated based on the average completion times of the trials and an average grade of bodily compensations observed during both the clothespin upward and downward conditions. During the upward condition, the trunk tilt is analyzed, and during the downward condition, the shoulder abduction is evaluated. In both

cases a score of 1 is assigned for excessive trunk tilt, shoulder abduction or excessive leg movement. A maximum score of four is assigned when no compensation was observed. The bodily compensation scores were determined by visually analyzing the experiment recordings: instances of compensatory leg movement were noted and still frames were used to assess the maximal angular compensation. The degree of compensatory motions was then referenced to the RCRT grading guidelines [36] to obtain the final compensation scores.

The VET was used to assess the proportional control performance needed when handling fragile objects. During a total of five 1 min trials, the participant was asked to transfer as many virtual egg blocks as possible without breaking them. The experiment was repeated twice, once with magnetic fuses adjusted to break at 9 N grasping force, and once with 3 N fuses. The number of total transferred blocks and non-broken blocks were recorded and reported.

To qualitatively assess the effect of adding additional DoF, the participant answered the DASH questionnaire [37], which assesses physical function and symptoms in people with any of several musculoskeletal disorders of the upper limb. The DASH comprises a total of 30 questions rated on a 5-point Likert scale. The DASH score is a weighted sum of the questionnaire answers between 100 (unable to perform physical functions with the upper limb) and 0 (no physical difficulties).

During the 1 DoF and 2 DoF laboratory assessments, the prosthetic elbow position was kept constant (at around 90° flexion) and the myoelectric locking and unlocking functionality was not used.

To analyse the prosthesis usage behavior during daily life, the predicted movements were logged on a memory card on the artificial limb controller at a 20 Hz rate. The embedded system did not feature a real-time clock and only logged a flag variable signaling every system reboot. Based on these reboot flags and the logging frequency we were able to extract usage information of known duration, hereafter defined as a 'session' [38]. As we were primarily interested in how the prosthesis is used during continued operation in daily life, we omitted any session below 30 min usage. This omission still let us capture $72 \pm 5\%$ of the total device on time for each condition. To make the extended and uneven homeuse periods comparable, only the first (initial changes during home use) and last (stabilized normal use) 75 included sessions of each condition are reported. For each session, we calculated the active total use rate (number of activations of a bionic joint direction divided by the total number of log entries for each session). For further analysis, we divided the active total use rate into the active individual use rate (only counting individual activations) and into the active simultaneous use rate (only counting simultaneous

activations). It should be noted that the active use rate is not the same as daily wear rate. Data is only logged while the prosthesis is powered on, thus time that the prosthesis is worn while being powered off (e.g. if grasping objects for a long time with the prosthesis powered off) is not included.

3. Results

The experiments and questionnaires conducted within the laboratory after each period of home-use showed an increase in functionality and reduced perceived disability. The W-LIF in the SHAP increased by 42% (from 44.6 to 63.2) after adding wrist control to the prosthesis compared to using a 1 DoF open/close hand prosthesis (see figure 2(a)). Adding the third DoF, elbow flexion and extension, resulted in an incremental improvement to a W-LIF of 65.3.

The RCRT score improved by 60% (from 9.4 to 15.0) when using the 2 DoF compared to the 1 DoF prosthesis (see figure 2(b)). And the RCRT score further increased by 46% (from 15.0 to 21.9) after adding the 3rd DoF compared to the 2 DoF prosthesis. The average completion time to place the clothespins increased with each added DoF (17.9 s/13.9 s, 17.0 s/16.3 s, and 19.1 s/17.5 s for 1, 2, and 3 DoF up/down respectively). However, the average grades evaluating reduced compensation increased with each added DoF (1.6/1.4, 3.0/2.0, and 3.6/3.6 for 1, 2, and 3 DoF up/down respectively), leading to the improved RCRT scores.

The average number of transferred 9 N blocks in the VET test were similar across the different DoF conditions (13.0 \pm 1.2, 14.6 \pm 2.1, and 14.6 \pm 1.6 for 1, 2, and 3 DoF respectively, see figure 2(c)). For the 3 N block, using the 2 DoF prosthesis led to a lower average number of transferred blocks (11.8 \pm 1.3, 8 \pm 2.1, and 11.6 \pm 1.6 for 1, 2, and 3 DoF respectively). The percentage of non-broken blocks increased with each added DoF, both for the 9 N and 3 N blocks (18%, 92%, and 94% for the 9 N block and 7%, 17%, and 24% for the 3 N blocks for 1, 2, and 3 DoF respectively).

The DASH score decreased by 83% (from 39.2 to 21.4) going from the 1 DoF to the 2 DoF prosthesis and another 71% (from 21.4 to 12.5) going from the 2 DoF to the 3 DoF prosthesis, for a 3*x* improvement from 1 DoF to 3 DoF (see figure 2(d)).

Analysing the data log revealed that each DoF was used actively in daily life (see figure 3 and table 2). The average active total use rate of the prosthesis increased by 13% (from 0.94% to 1.07%) going from 1 DoF to 2 DoF, and by 30% (from 0.94% to 1.23%) going from 2 DoF to 3 DoF. The average active total use rate, however, decreased when comparing the beginning and the end of each of the condition, leveling of just at under 1%. The average active simultaneous

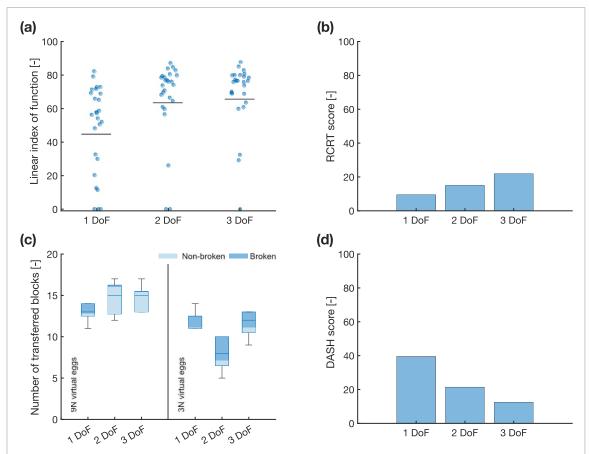


Figure 2. Results of experiments and questionnaires conducted after each home-use period where the participant used a prosthesis with a different number of active degrees of freedom (DoF). The 1 DoF prosthesis allowed for hand opening and closing, and then wrist rotation (2nd DoF) and elbow flexion and extension (3rd DoF) were added in turn. (a) Shown are the individual linear index of function scores (circles) for each of the Southampton Hand Assessment Procedure (SHAP) tasks (n=26). The horizontal black lines show the weighted linear index of function, where a higher score represents greater prosthetic functionality during activities of daily living. (b) Shown are the refined clothespin relocation test (RCRT) scores. A higher score indicates reduced compensatory motion and/or reduced time to complete the experiment. (c) Shown are the total number of transferred blocks (n=5 trials per condition) of the virtual egg test (VET), with the results of the 9 N breaking force block being depicted on the left, and the 3 N breaking force blocks on the right. The light blue overlay indicates the average percentage of non-broken blocks. (d) Shown are the scores of the disabilities of the arm shoulder and hand (DASH) questionnaire. A lower score indicates a lower perceived disability to perform upper limb activities.

use rate was constant at around 0.06%, except at the beginning of the 3 DoF condition where it increased momentarily to 0.22%.

Compared to the 1 DoF prosthesis, the 3 DoF prosthesis was used up to 40% (from 3.14 ± 1.9 h to 4.40 ± 2.4) longer per session. The total use while the prosthesis was turned on increased by 95 h from the end of the 1 DoF condition to the end of the 3 DoF condition.

4. Discussion

In this study, we found that electro-neuromuscular constructs allowed for intuitive multi DoF control over a bionic arm using a DC mapping during a prolonged home-use period in one participant with trans-humeral amputation. We further found an increase in functionality, a decrease in perceived disability, and an increase in prosthesis use during daily life after adding first wrist rotation and later elbow

control to a prosthesis that at the beginning of the study only had hand open and close actuation.

The eight surgically created electroneuromuscular constructs [28] provided access to information from the median, ulnar, and radial nerve previously inaccessible due to amputation. Together with the information from the four electrodes in native muscles, enough myoelectric sites were available to one-by-one map the myoelectric signals to the bionic joint directions, allowing for intuitive control over each joint. Although we observed enough motion intent information for controlling each of the six bionic joint directions, we did not find six signals with fully independent information for each direction. Such crosstalk or co-activation between signals is likely caused by one of multiple of the following factors: the location of the neuromuscular constructs, the placement of the electrodes, the use of monopolar electrodes, or the nature of the neuromuscular constructs themselves (fascicles of the same nerve

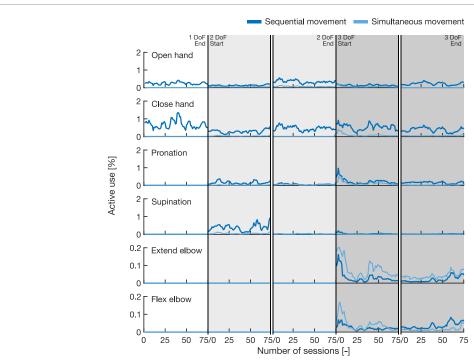


Figure 3. Active use rate of the prosthesis during daily life. Shown are the active individual use rate percentages of each of the movements (dark blue line), and the active simultaneous use rate percentages when the different movements were used in combinations with at least one other movement (light blue line). The active use rate percentages were calculated on a per session (turning the prosthesis on for at least 30 min) basis. Indicated are the 75 last sessions before coming to the laboratory, and the 75 first sessions after leaving the laboratory with an additional degree of freedom (DoF). The change of condition (adding a DoF) is indicated with a single vertical line. The double vertical line indicates a time gap within the same condition.

Table 2. Summary of usage data extracted from the data log after daily home-use. An interval between the prosthesis being turned on and off, lasting longer than 30 min, constitutes a session. Only the first 75 (initial changes during home use) and last 75 (stabilized normal use) sessions were considered per condition. The active total use rate was calculated as the number of activations of a bionic joint direction divided by the total number of log entries for each session. The average active individual use rate only includes instances of individual movements, whereas the average active simultaneous use rate only includes instances of simultaneous movement. The average active total use is the sum of the average active individual and simultaneous use.

	1 DoF end	2 DoF start	2 DoF end	3 DoF start	3 DoF end
Average use per session (h)	3.14 ± 1.9	2.63 ± 2.0	3.18 ± 2.4	3.56 ± 2.6	4.40 ± 2.4
Total use during 75 sessions (h)	235.7	197.5	238.3	266.8	330.6
Average active individual use rate (%)	0.94 ± 0.6	1.01 ± 0.6	0.88 ± 0.4	1.01 ± 0.8	0.92 ± 0.8
Average active simultaneous use rate (%)	N/A	0.06 ± 0.1	0.06 ± 0.0	0.22 ± 0.4	0.07 ± 0.01
Average active total use rate (%)	$\textbf{0.94} \pm \textbf{0.6}$	$\boldsymbol{1.07 \pm 0.7}$	0.94 ± 0.5	1.23 ± 1.1	0.99 ± 0.9

reinnervating different myoelectric sites, thus sharing neural information related to the same movements).

By changing the traditional DC scheme by adding masking of such unvoluntary active signals, we prevented unwanted simultaneous joint activations, drastically improving control reliability.

After using the system during daily life with first one, then two, and lastly three controlled DoF, the participant demonstrated a drastic functional improvement when using the prosthesis. We measured a 46% increase in the SHAP score when using the 3 DoF prosthesis compared to the 1 DoF prosthesis. The SHAP score improvement can mostly be attributed to the added wrist control. The most noteworthy decreases in task completion time were observed in tasks that require wrist rotation and cannot easily be

achieved with excessive body compensation without regripping instead, e.g. turning a key or screwing in a screw, which both received low scores in the 1 DoF condition (see figure 2(a)). As none of the SHAP tasks specifically requires changes in elbow position, only a minimal change in SHAP score was observed progressing from 2 DoF to 3 DoF. The two tasks that improved the most were pouring liquids, possibly thanks to flexing the elbow to prepositioning the hand to be level so wrist rotation would empty the container in one movement. Compared to a similar patient cohort [19] (N = 8 participants with trans-humeral amputation, a 3 DoF prosthesis, and four additional myoelectric control sites created by TMR), we observed a markedly higher SHAP outcome using 3 DoF (W-LIF of 65.3 compared to an Index of Function of 16 ± 5 and 30 ± 5 for a DC and pattern recognition-based control, respectively). We speculate that the observed improvements were mostly achieved due to the additional myoelectric sites (e.g. allowing for intuitive wrist control compared to the employed mode switching [19]) and potentially due to the longer home-use period (multiple months compared to a few weeks). It is worth noting that the maximal allotted time for the button board task (opening differently sized buttons) was exceeded and the coin collection tasks received low scores in all three conditions, respectively. For such tasks, a more dexterous hand allowing for more delicate finger positioning would be beneficial.

The RCRT score increased by a total of 133%. Adding wrist rotation and elbow control both greatly decreased body compensation—albeit at the cost of execution time (demonstration in movie S2). Although the highest measured RCRT score is still far lower compared to the median score (21.9 compared to 65) of an able-bodied comparison cohort [33], the main difference in the score stems from the task completion time and not from the compensatory motions. This is an important distinction, as one demands a bit more patience to complete tasks and the other can lead to overuse injuries. Half of prosthesis users report problems in the contralateral limb due to prolonged or repeated compensatory motions [3]. Thus, slightly increased task completion times could be a worthwhile trade-off, especially in the case of a user with unilateral amputation whose prosthesis mostly serves as support for the biological arm during bilateral tasks in daily life. In this scenario, the prosthesis is prepositioned for the task, and quick or dexterous movements are primarily performed by the biological arm.

The VET is typically used to compare different prosthetic sensory feedback strategies [34]. Though potentially less effective without specific sensory feedback provided by e.g., fingertip sensors, prosthetic users often can determine how fast their prosthesis moves from either visual or auditory feedback and adapt their control signals accordingly. However, adding additional controllable joints and thereby complexity can negatively impact how well the speed of a movement can be judged and regulated. We therefore expected VET outcomes to decrease with additional DoFs. However, the number of transferred blocks was similar in all three conditions and the percentage of non-broken blocks even increased. We hypothesize that continuous and prolonged home use improved familiarity with which voluntary inputs will results in which end-effector outputs.

Additional to the measured prosthetic functional increase, the patient reported an increase in physical function (change of DASH score of 26.7, where the minimal clinically important difference was reported to be 10–15 points [39]) after using the prosthesis

with additional DoF. One interpretation of these results is that the decrease in perceived disability could be attributed to the measured increase in functionality with each added DoF. But we also would like to highlight that, given the nature of the study, the participant was not blinded to the study outcome. Furthermore, the study allowed the participant to use expensive prosthetic parts not provided by the standard clinical care. We thus assume a certain degree of response bias within the questionnaire response.

Given the increase in functionality suggested by the laboratory experiments, we expected an increase in active use rate during home-use. However, after an initial increase in active use rate when provided with an additional DoF, the active prosthesis use following prolonged home-use returned to the same usage levels as at the beginning of the study. We did however see the use of all possible bionic joint directions during daily life (although pronation was heavily favored over supination, and since the wrist allows for continuous rotation, pronation could replace supination fully). One interpretation of these results is that additional DoF might not necessarily lead to an increased active use rate. Instead, the additional DoFs allowed the participant to accomplish the tasks more comfortably and with less compensatory motions. An alternative interpretation suggests that the increased functionality led to a decrease in time spent to perform a given task. Thus, less time is required actively controlling the prosthesis.

Regardless of how the active use rate is interpreted, we found an increasing in total use hours, indicating that additional, an intuitively controllable DoFs, could counteract prosthesis abandonment.

We found the myoelectric signals recorded by the implanted electrodes stable over time, and therefore only minor adjustment to the control parameters were necessary during our 3 year study period. This corroborates our previous findings [28, 29] that the combination of osseointegration and implanted electrodes leads to a long-term stable neuromusculoskeletal interface for controlling a prosthesis in daily life.

There are several limitations to our study. The main limitation is that only one person participated in this study. Learning effects are another limitation of the study as the DoFs were added sequentially. Although needlessly difficult for the participant, performing the study with a different condition order could have controlled for carryover learning from previous conditions. A further limitation was the deviation of the planned home-use periods. Specifically, the reparation of the active elbow and the intermittent use of the 2 DoF prosthesis might have affected the outcomes of the last study condition. However, prosthesis repair accurately portrays prosthesis home-use as it is a reoccurring constant in a prosthetic user's life. In addition, we did not compare

whether the functional improvements were a direct result of the additional degrees of freedom available or specifically attributable to the intuitive control granted by the neuromuscular constructs. Contrary to our expectations, we were limited by the independence of the myoelectric signals. There were not six signals with fully independent information available needed for the standard DC scheme. A machine learning algorithm could have been used to instead of the adapted DC scheme to improve the range of the simultaneous control—for example, a neural network could classify distinct signal patterns that were previously not separable in the orthogonal representation used for DC [40-42]. If exchanging some range for simultaneous control for the DC scheme's inherent proportional control, low computational demands and intuitive parameters for fine tuning the control is a worthwhile trad-off should, however, be determined on a per case basis.

5. Conclusion

In this case-study, we have demonstrated that neuromuscular constructs allow for intuitive simultaneous and proportional control of a prosthesis with actuated hand, wrist, and elbow joints during homeuse. Our findings indicate that additional bionic joints can increase prosthesis functionality and physical function and thereby support a person who lost their arm in daily-life tasks.

Data availability statements

All data that support the findings of this study are included within the article (and any supplementary files).

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Author contributions

J Z designed the study. M O C designed the implant system. M O C developed the electronic embedded system and J Z developed the firmware and software for the study. J Z and E J E conducted the study. J Z performed the data analysis. J Z drafted the manuscript. All authors assisted with writing the paper.

Conflict of interest

J Z and E J E declare no competing interests. M O C has consulted for Integrum AB, holds shares of Integrum AB and is co-inventors on patent # US9579222B2 entitled 'Percutaneous gateway, a fixing system for a prosthesis, a fixture and connecting means for signal transmission', which is held by Integrum AB.

ORCID iDs

Jan Zbinden • https://orcid.org/0000-0001-9535-3746

Eric J Earley https://orcid.org/0000-0002-1203-7316

Max Ortiz-Catalan https://orcid.org/0000-0002-6084-3865

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