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Cutting Edge Bionics in Highly Impaired Individuals: A Case of Challenges and Opportunities

Cutting Edge Bionics in Highly Impaired Individuals: A Case of Challenges and Opportunities

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***Abstract*— Highly impaired individuals stand to benefit greatly from cutting-edge bionic technology, however concurrent functional deficits may complicate the adaptation of such technology. Here, we present a case in which a visually-impaired individual with bilateral burn injury amputation was provided with a novel transradial neuromusculoskeletal prosthesis comprising skeletal attachment via osseointegration and implanted electrodes in nerves and muscles for control and sensory feedback. Difficulties maintaining implant hygiene and donning and doffing the prosthesis arose due to his contralateral amputation, ipsilateral eye loss, and contralateral impaired vision necessitating continuous adaptations to the electromechanical interface. Despite these setbacks, the participant still demonstrated improvements in functional outcomes and the ability to control the prosthesis in various limb positions using the implanted electrodes. Our results demonstrate the importance of a multidisciplinary, iterative, and patient-centered approach to making cutting-edge technology accessible to patients with high levels of impairment.**

***Index Terms*— Bilateral impairment, burn injury, neural interfaces, osseointegration, prosthetic hand**

I. INTRODUCTION

FULLY integrated neuromusculoskeletal prostheses are in the nascency of their development [1-6]. This novel concept in which the prosthesis directly interfaces the user's nervous and skeletal systems is being used by a small number of individuals and improves with the insights gained from each new user. These users have reported improved functionality [6], quality of life [4], and sense of ownership and agency over the prosthesis [7]. However, until recently no users had interfering functional deficits in addition to their unilateral amputation, making adaptation of the technology to their needs relatively straightforward.

In contrast, highly impaired individuals stand to gain the most from these devices, though concurrent deficits may complicate successful implementation. These challenging cases can lead to rapid identification of shortcomings limiting translational potential of novel technologies. However, when these shortcomings are addressed, the technology becomes more reliable and robust, to the benefit of both the current user as well as future ones.

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This study was approved by the Regional Ethical Review Board in Gothenburg (Dnr. 12-769) and carried out in accordance with the Declaration of Helsinki.

Max Ortiz-Catalan has consulted for Integrum AB. Justyna Kolankowska, Alexander Thesleff, Rickard Brånemark, and Max Ortiz-Catalan hold shares in Integrum AB. Max Ortiz-Catalan and Rickard Brånemark are co-inventors on patent #US9579222B2, which is held by Integrum AB.

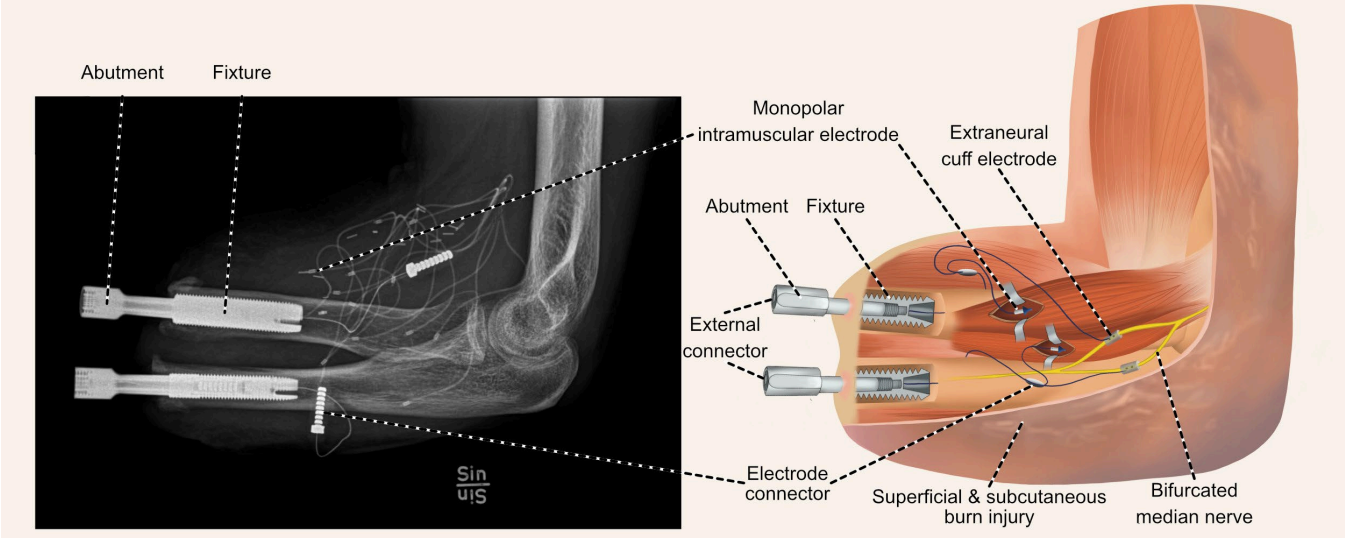

Fig. 1. The participant was implanted with a transradial neuromusculoskeletal prosthesis comprising a percutaneous titanium osseointegrated fixture in the radius and ulna and monopolar intramuscular electrodes in the residual muscles of the forearm (left). The median nerve was bifurcated and extraneural cuff electrodes were affixed to each branch (right). Leads from the intramuscular and cuff electrodes merged at the electrode connectors which featured a lead extending axially through the fixture and abutment to the external connectors, allowing for seamless electrical connection from the implanted sensors to the prosthetic system and providing direct prosthesis control and sensory feedback via direct nerve stimulation. In addition to his transradial amputation, the participant also presented several concurrent functional deficits including contralateral amputation of digits II – V, loss of one eye, and prevalent superficial and subcutaneous burn injury.

Here, we present a case in which an individual (male, born 1980) with bilateral burn injury amputation and visual impairment (sustained 1998) was provided a neuromusculoskeletal prosthesis comprising a transradial osseointegrated implant for skeletal attachment and bidirectional communication to implanted electrodes: intramuscular electrodes measuring electromyographic (EMG) signals for prosthesis control, and extraneural cuff electrodes enabling direct neural stimulation for sensory feedback (Fig. 1). This is the first such individual whose concurrent functional deficits including contralateral digital amputation ipsilateral eye loss, and contralateral visual impairment affected integration and daily use of the technology. We discuss the challenges experienced while adapting the technology to the participant, demonstrate functional improvements, and offer insights to guide future research with osseointegration and implantable prosthetic technologies such as osseointegration and neuromuscular electrodes.

II. Results

A. Rehabilitation and Impact on Physical Activity

After surgical implantation of the neuromusculoskeletal prosthesis, the participant completed a program of incremental implant loading to encourage successful osseointegration [8]. The participant faced significant limitations by not wearing a prosthesis, particularly due to his partial amputation of the right hand, which affected his independence in daily activities (ADL). Therefore, the absence of a prosthesis made the initial training phases challenging. Additionally, as a competitive marathon runner, the participant experienced difficulty running without a prosthesis, which correlates with previous research showing weight-bearing asymmetry and the risk of falls due to non-use of a prosthesis [9]. To accelerate the rehabilitation process and decrease the time of not wearing a prosthesis, the participant was suggested to increase the repetition and frequency of loading of the implant.

When the participant was later provided a lightweight prosthesis with the motors and gearing removed from the 3D-printed prosthetic shell (Prensilia, Italy), he reported a greater ease in performing ADLs (despite its non-functional nature), using it for stabilization while manipulating objects with his contralateral residual thumb and notice and improvement in balance while running.

Stable osseointegration of both screws was observed in x-rays within six months. When fitted with a fully functional prosthesis, the participant greatly appreciated the ability to have safer and stronger grips in various positions.

B. Skin Interface

Superficial infection and hypertrophic granulation at the skin-implant interface were periodically present, and the healing process was slow. The participant was encouraged to clean the stump and implant at least twice daily to prevent infection. However, he found this difficult due to his contralateral digital amputation and visual impairment. We found that an infant toothbrush was easier for the participant to grasp with his right thumb, thereafter improving compliance with the hygiene protocol. Treatment was provided once for granulation tissue and a minor superficial infection.

C. Prosthetic Interface

Each osseointegrated implant houses feedthrough connectors providing electrical access between the implanted electrodes and the artificial limb controller (ALC) [10]. External connectors were mounted in a flexible silicone housing, allowing both variable orientation between radius and ulna and precise rotational alignment for proper mating. Signal wires then ran from the external connectors to the ALC, allowing intramuscular EMG (iEMG) recording and direct

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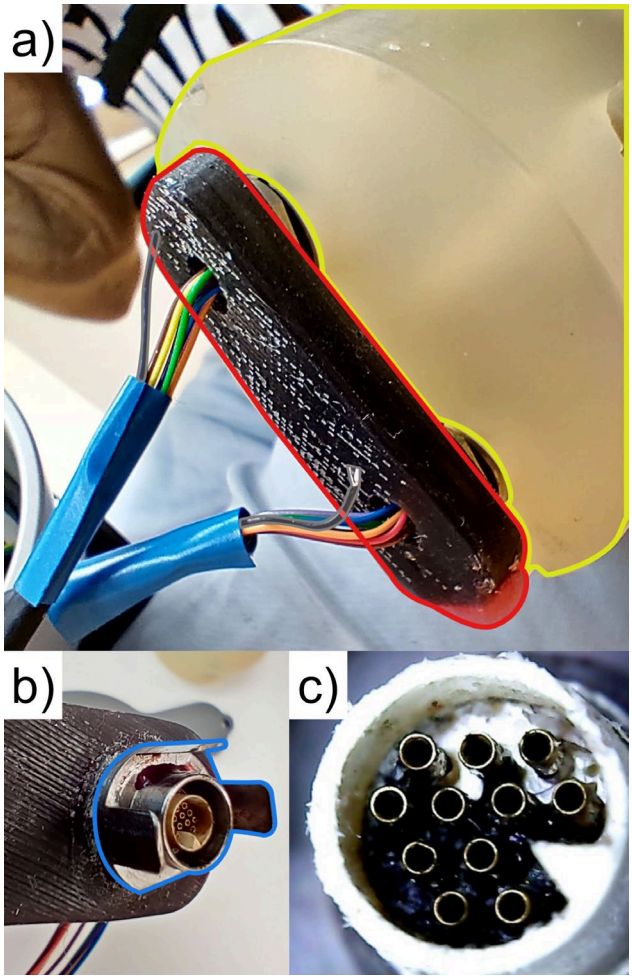

Fig. 2. (a) External connectors to the neuromuscular prosthesis were mounted in a flexible silicone lining (red), allowing both variable orientation between radius and ulna. The abutment puck (yellow) provided a clamping surface for prosthesis suspension. However, the participant had difficulty removing the connectors, resorting to pulling on the wires, resulting in frequent wire breakage (black wires, highlighted grey). (b) Metallic fins (blue) created electrical grounding contact between the abutment and the external connector. However, donning the abutment puck would cause gradual excursion of the external connector. Furthermore, bodily fluid and debris were periodically found on the external connectors and within the intermedullary connectors. (c) This fluid buildup, in combination with environmental debris such as lint, was frequently impacted into the intermedullary connector, preventing full electrical contact with the external connector and consequently deteriorating control.

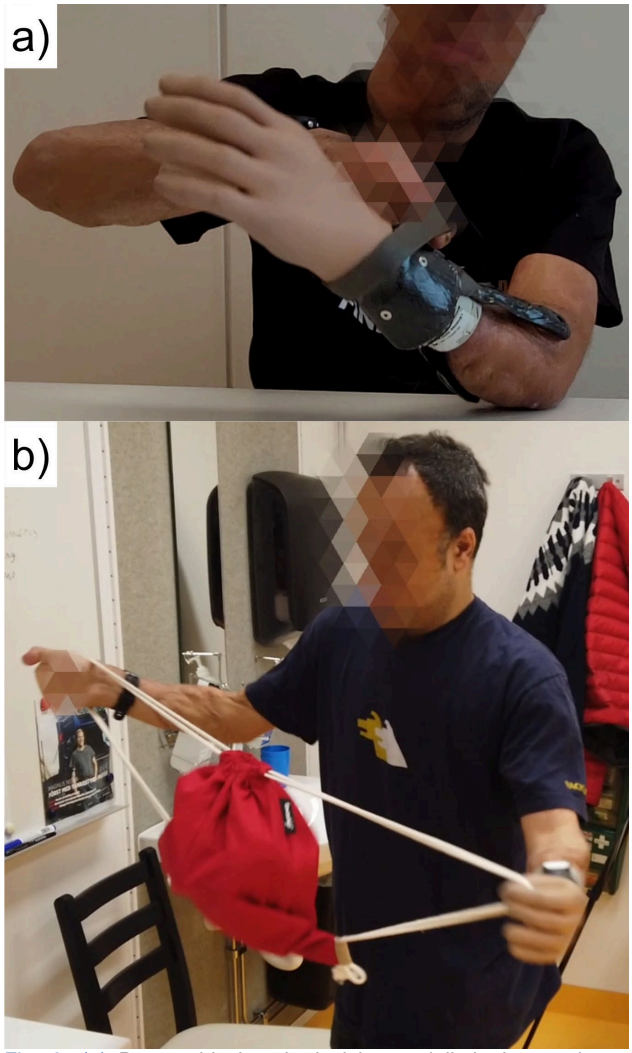

Fig. 3. (a) Due to his impaired vision and limited contralateral dexterity, the participant experienced difficulty properly aligning the external connector with the prosthesis which would normally allow for control via intramuscular EMG. Over time, the patient preferred a prosthesis which was mechanically suspended to the osseointegrated abutments but was controlled using surface EMG. (b) Despite the aforementioned challenges, functional outcomes improved 17 months post-implantation using the neuromusculoskeletal prosthesis, compared to his previous socket-suspended prosthesis, in both the ACMC (18% improvement) and the SHAP (12% improvement), with notable improvement in the modulation of grip force, ability to grasp in different positions, and coordination of both hands. We also note that the participant's impaired vision impacted his performance during standardized tasks, potentially affecting the scoring.

neurostimulation (Fig. 2a).

Due to his impaired vision and limited contralateral dexterity, the participant found it difficult to properly align and mate the external connector. Furthermore, he experienced difficulties removing the connectors, instead resorting to pulling on the wires. This resulted in frequent wire breakage and subsequent loss of prosthetic control, necessitating repairs. Furthermore, donning the abutment puck (which provides a clamping surface for prosthesis suspension) caused excursion of the external connectors, diminishing electrical connectivity and iEMG signal intensity (Fig. 2a). Using the NASA Task Load Index (TLX) questionnaire to quantify the challenge in donning and doffing the prosthesis, the participant indicated high levels of physical demand (7/7) and effort (5/7) required to connect and remove the external connector, leading to very high levels of frustration (7/7). Although the participant indicated a low temporal demand (3/7), he refused to score the mental demand and performance items, citing that he could not do so because the system "isn't working."

Additionally, bodily fluid including sweat and blood were sometimes found on the external connector (Fig. 2b). It appeared that this fluid was wicking up inside the intermedullary connector, along with environmental debris including lint, and building up at the base of the connector (Fig. 2c) This buildup of foreign material prevented full electrical contact with the external connector, increasing signal

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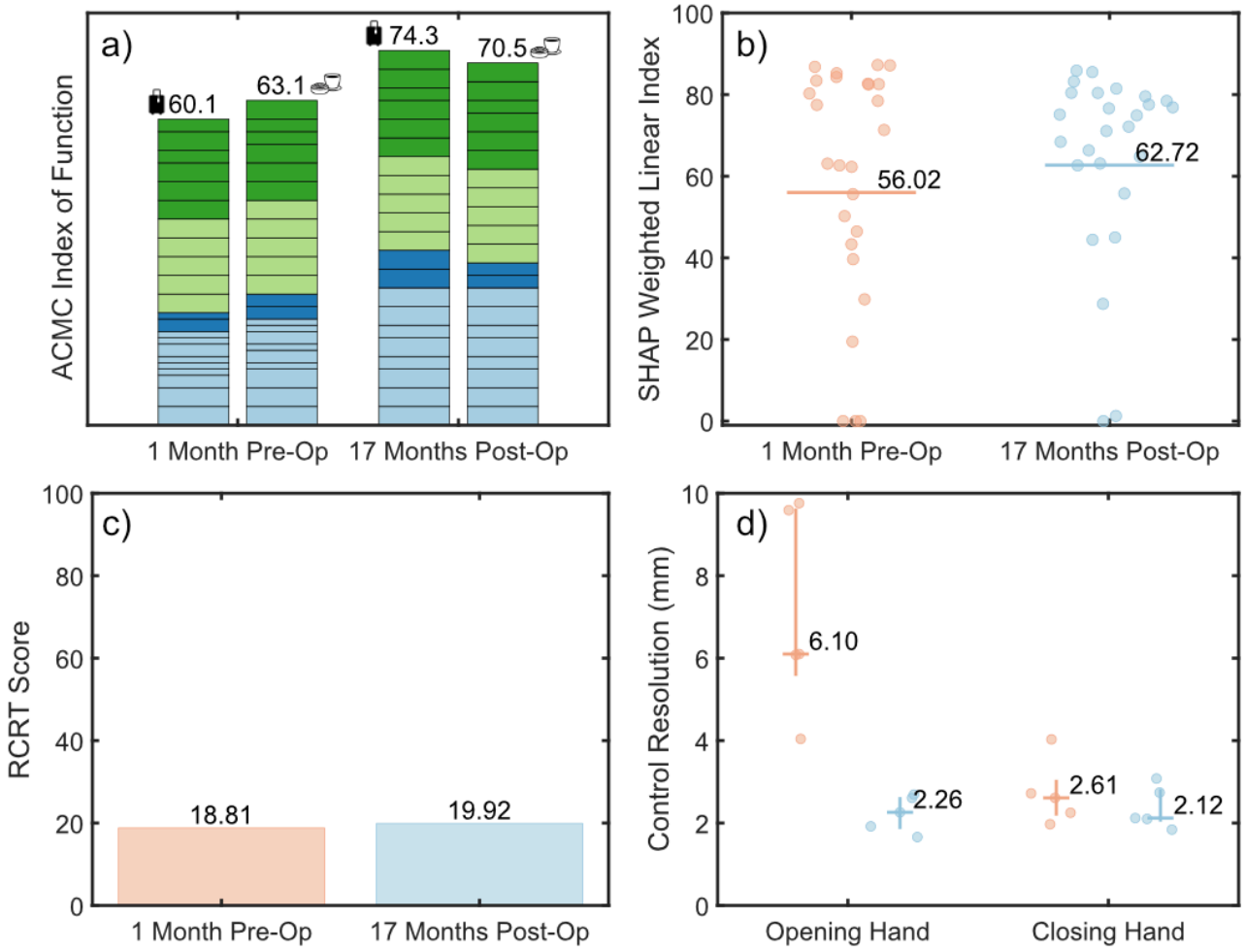

Fig. 4. The participant generally demonstrated improved control and functionality of the prosthesis after receiving the neuromusculoskeletal prosthesis (17-months post-operative, shown in blue), compared to when using his previous socket-suspended prosthesis with surface electrodes (1 month pre-operative, shown in red). Functional outcomes included (a), the suitcase packing (left bars) and table setting (right bars) tasks for the Assessment for the Capacity of Myoelectric Control (ACMC), (b) the Southampton Hand Assessment Procedure (SHAP), (c) Refined Clothespin Relocation Task (RCRT), and (d) the Prosthetic Control test. In (a), from bottom to top, color changes represent the four categories of ACMC evaluation: Grasping, Repetitive Grasp & Release, Holding, and Releasing; subdivision within each category shows the score for individual ACMC items.

impedances and consequently deteriorating control. We eventually found that soaking the intermedullary connector in a saltwater solution could loosen the impacted debris and allow for its removal.

Due to the frequency of these repairs and debris buildup, a backup prosthesis was made which was mechanically connected to the osseointegrated implants but used surface instead of implanted electrodes for conventional prosthetic control (Fig. 3a). This prosthesis allowed for simple closing and opening of the prosthetic hand via contraction of the forearm flexor and extensor compartments, but did not utilize machine learning for control nor did it include electrical stimulation for sensory feedback. Over time, this backup prosthesis became preferred by the user given recurrent problems with the external electrical connector to access the implanted electrodes.

D. Functional Outcomes

Compared to his previous socket-suspended prosthesis, which he had used for many years prior to the start of this study, functional outcomes improved when using the neuromusculoskeletal prosthesis. Scores for the Assessment for the Capacity of Myoelectric Control (ACMC) improved 18% from 60.1 to 74.3 and from 63.1 to 70.5 for the suitcase packing and table setting tasks, respectively. All scores are considered "extremely capable", with post-operative improvements most notable in the ACMC evaluation categories pertaining to grip force, ability to grasp in different positions (an issue experienced with the backup prosthesis using surface EMG electrodes), coordination of both hands, and need for visual feedback (Fig. 4a). Scores for the Southampton Hand Assessment Procedure (SHAP) also improved 12% from 56.0 to 62.7 (Fig. 4b). The Refined Clothespin Relocation Test (RCRT) showed only modest improvements, increasing from a score of 18.81 to a postoperative score of 19.92 (Fig. 4c). We note that the participant's impaired vision resulted in difficulties locating and securely grasping objects, potentially degrading performance in these tests (Fig. 3b).

An additional functional test, the Prosthetic Control test, was

conducted to evaluate the resolution of the participant's control over his prosthesis. Prior to surgery, the smallest amount of movement the participant could execute was 6.10 mm of fingertip aperture while opening, and 2.61 mm while closing. 17 months after receiving and using the neuromusculoskeletal prosthesis, his smallest movements reduced to 2.26 mm of fingertip aperture while opening, and 2.12 mm while closing (Fig. 4d).

Subjectively, the participant also reported overall improvements in his daily life activities. However, it should be noted that the participant's impaired vision rendered these functional outcome measures more difficult than intended. Additionally, the participant had limited experience controlling the neuromusculoskeletal prosthesis at the time that outcomes were performed; regardless, his performance demonstrated functional improvement using the novel prosthesis, and we expect that his measured and self-perceived function may improve further with additional goal-oriented practice [11].

E. Sensory Feedback

Direct electrical stimulation of the median nerve can elicit localized and proportional sensations on the phantom hand [12]. However, the participant reported having no phantom hand prior to surgery. After surgery, he reported the elicited sensations to be perceived inside the residual arm during neurostimulation, in approximately the same location as the neural electrodes.

The participant later reported visualizing phantom finger movements within his residual arm while executing virtual movements, indicating the same location in which he reported sensation from neurostimulation. During subsequent testing, we ascertained that sensory perception could repeatably be elicited within the regions of the forearm associated with visualized movement of digits I and II (Fig. 5). We then discovered that the elicited sensory feedback was localized on the phantom hand, which is telescoped inside of the residual arm. It remains to be seen whether longitudinal neurostimulation will shift the location of the phantom hand outside of the body [3].

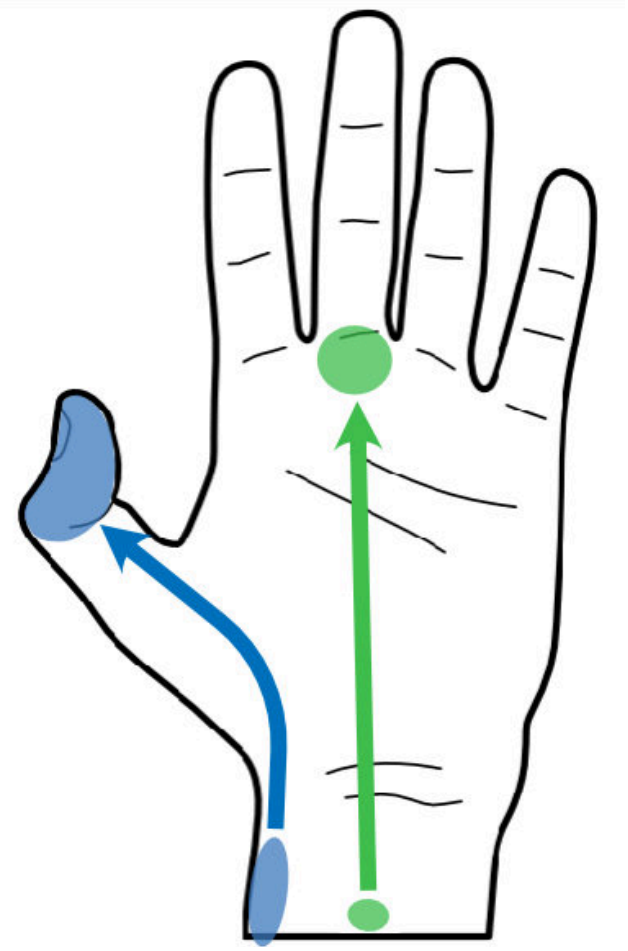

Fig. 5. The participant reported having no phantom hand sensation prior to receiving his neuromusculoskeletal prosthesis. Immediately following surgery, direct nerve stimulation of the bifurcated median nerve (represented by blue and green) elicited sensations that were reported as felt within the residual arm (further proximal than is drawn in the figure), rather than on the phantom hand as had been observed in previous studies. However, it was later ascertained that the participant's phantom hand had telescoped within his residual arm, and that direct nerve stimulation was eliciting sensations on his telescoped phantom. When asked to describe the telescoped phantom, the participant indicated that the elicited sensations were occurring in parts of the phantom associated with functions and phantom sensation of the digits.

III. Discussion

A. Summary of Outcomes

Functional outcomes demonstrate improved functionality with the neuromusculoskeletal prosthesis in comparison to his previous socket prosthesis. We additionally note that difficulties controlling the prosthesis in different limb positions and in the presence of electrical interference were also alleviated when using the neuromusculoskeletal prosthesis. Interestingly, these difficulties persist when using the osseointegration-suspended surface electrode prosthesis, demonstrating the robustness and utility of implanted electrodes for prosthesis control. However, frustration with the reliability and ease-of-use of the external electromechanical prosthetic connector has led the participant to prefer using the surface electrodes despite its limited usable range of motion and subjectively worse functionality.

B. Study Limitations

As with any case study, the major limitation of this report is that it reflects the experience of a single individual; thus, functional outcomes, especially, may not translate to other users. Although no control subject is included in this study, the participant had used his socket-suspended prosthesis for many years prior to the start of the study, thus we consider his pre-operative outcomes to be a valid baseline for his performance with his original prosthetic setup. Additionally, due to the unique circumstances presented while working with this individual, some results may be considered subjective, and the timepoints at which data were collected are sometimes sporadic. The use of the backup prosthesis with surface EMG electrodes may also have affected the participant's performance while using his neuromusculoskeletal prosthesis during outcomes testing, however this unplanned intervention was deemed necessary to ensure the participant's ability to live independently and perform activities of daily living while issues with the neuromusculoskeletal prosthesis were being diagnosed.

We believe this to be an unavoidable part of working with a

highly impaired individual with multiple functional deficits. We acknowledge that the solutions presented here may not be applicable for all future cases, however we hope that our rationales presented alongside our solutions will be of use to researchers and clinicians in this and adjacent fields.

C. Lessons Learned

The participant's secondary functional deficits necessitated many adaptations to the external interface with the neuromusculoskeletal implant. Provision of a non-functional lightweight prosthesis earlier in the rehabilitation period may improve functionality and improve weight symmetry during rehabilitation. Furthermore, provision of an sEMG-controlled prosthesis with skeletal fixation is recommended as a backup device for when mechanical and control failures with the neuromusculoskeletal interface arise.

Miniaturization of the technology yielded a sleek and compact form factor for the system; however, this inadvertently limited the accessibility to those with impaired dexterity. The participant's impaired vision affected not only his ability to easily clean the implant and don the prosthesis, but also affected his performance during standardized tests of function. Adapting the system has required a multidisciplinary team of engineers, surgeons, doctors, prosthetists, and therapists, all engaged in an iterative and patient-centered approach to identifying challenges and proposing solutions, which continues beyond the scope of this report.

IV. Methods

This study was approved by the Regional Ethical Review Board in Gothenburg (Dnr. 12-769) and carried out in accordance with the Declaration of Helsinki. The participant was recruited as part of a clinical trial (NCT03178890) and provided signed and informed consent prior to participation.

A. Participant

One participant (male, born 1980) sustained severe burn injuries of the whole face, both arms and hands, and a large portion of the chest from a fire in 1998, resulting in transradial amputation of his left arm, complete phalangeal amputation of digits II through V of his right hand, and loss of his left eye. Shortly after his amputation, he was prescribed a standard myoelectric hand capable of powered opening and closing for his left arm, and did not use any prosthesis for his right hand.

The patient was and is very physically active, running routinely for exercise and frequently participating in footraces and marathons.

B. Surgical Procedure

In 2021, the participant underwent a single-stage surgery for implantation with a neuromusculoskeletal prosthesis. The median nerve was surgically split into two fascicles, and an extraneural cuff electrode were affixed to the median nerve. Intramuscular monopolar electrodes were recorded as implanted in: flexor carpi radialis, flexor carpi ulnaris, flexor digitorum profundus, flexor digitorum superficialis, pronator teres, extensor carpi radialis brevis, extensor carpi radialis longus, extensor carpi ulnaris, extensor digitorum communis, and supinator. However, due to the abundance of proximal scar tissue present during dissection, identification of muscles was sometimes uncertain.

C. Rehabilitation and Impact of Physical Activity

Following surgery, the participant followed a program of incremental axial weight implant loading to encourage successful OI [8]. The program consisted of four phases. The initial phase focused on post-surgery care, ensuring proper healing of the skin and bone while avoiding load on the implant and stump. The subsequent phase involved gradually increasing axial weight loads on the implants using the external connector and pressing against a bathroom scale twice daily with pain less than 5 in the visual analogue scale (VAS). Once the participant reached a point where he could handle a load of 5 kg, it was possible to start the lightweight prosthesis (LWP) loading phase. He was provided with a light and passive prosthesis, all internal motors and gears were removed, to gradually incorporate the prothesis in daily live activities. After using the LWP comfortably for several hours without pain, the participant was fitted with a heavier and functional prosthesis. Throughout the process, careful monitoring and documentation of the training protocol were maintained. X-rays showed signs of stable osseointegration for both screws within six months, and the participant was cleared to bear full prosthesis weight after nine months.

D. Skin Interface

After surgical implantation of the neuromusculoskeletal prosthesis, the participant was provided a standard hygiene protocol to clean the stump and implant at least twice daily, once with soap and water and once with a gauze with saline solution. However, the participant found the protocol difficult due to his contralateral digital amputation and ipsilateral visual impairment. Cleaning the skin and implants as directed was not feasible, and observing dirty areas was difficult. A solution was for the participant to clean using an infant toothbrush, which he was able to grasp with his right thumb. With practice, the participant was also able to wrap gauze around the implant using his thumb and his mouth. Signs of superficial infection in the bone-skin interface were present at times and treated with oral antibiotics. Granulation tissue around the bone-skin interface also remained present intermittently throughout the 16 months post-surgery, which was treated in an outpatient clinic. Overall, the healing process was very slow due to the difficulties in self-cleaning and care.

E. Prosthetic Interface

For the post-operative prostheses used by the participant, suspension is achieved via a puck-and-clamp attachment system [8]. A cylindrical puck is machined with two through-holes shaped to the radial and ulnar abutments, and then the puck is cut in half. These puck halves are held together with elastic bands and can be fit around the abutments, neatly encasing them and, for the functional neuromusculoskeletal prosthesis, leaving access to the intermedullary electrical connectors (described below). A clamping mechanism attached to the proximal end of the prosthetic wrist is fit around the puck and clamped shut; this secures the prosthetic wrist to the abutments, thus providing osseointegrated suspension.

Due to the impaired dexterity of the contralateral hand, care had to be taken not to over- or under-tighten the clamp. Issues arose when the participant ran while wearing the lightweight

prosthesis, where the clamp did not apply enough friction to hold the prosthesis in place, causing the puck to slide out and the prosthesis to fall to the ground. Further tightening the clamp was not an option due to discomfort in the bones from increased clamping force. The issue was identified to be the PLA material used to make the puck (via 3D printing), which experienced lower friction when clamped than the traditional low thermal conduction material used to fabricate the puck. Reverting to the traditional material resolved the issue, however the tightness of the clamp continued to be periodically adjusted to minimize discomfort for the participant.

Both the radial and the ulnar osseointegrated implants house an 11-pin intermedullary electrical connector (Omnetics Connector Corporation, Minneapolis, MN, USA). Each intermedullary connector is connected to a two-lead extraneural cuff affixed to the median nerve, and six intramuscular electrodes (3 pins are unused). Two external connectors could mate to the intermedullary connectors and provide a conduit for bidirectional communication with the ALC, an embedded system housed in the prosthetic wrist responsible for myoelectric control of the prosthesis via iEMG and direct neurostimulation for sensory feedback [10].

The external connectors have a triangular "key" which necessitates proper rotational alignment to match with the "notch" in the intermedullary connectors and thus properly mate all individual pins. However, to account for the participant's limited vision and contralateral dexterity, the external connectors were mounted in a flexible silicone housing to preserve rotational alignment. The flexible silicone also permitted slight variation in the axial orientation of the connectors, which was important because the intermedullary connectors are neither parallel nor coincident. Thus, connectors were mated one at a time, with the second connector needing to be "pulled" into position.

Although the connector housing was intended to aid in rotational alignment, the participant still found it difficult to properly mate the external connectors. Furthermore, we found that the puck had a tendency to translate distally during prosthesis use (for example, when the arm was in a neutral hanging position), which pressed upon the silicone housing and ultimately caused excursion of the external connectors, increasing electrical impedance within the connections and diminishing EMG signal intensity as a result.

For these reasons, the participant requested that a backup prosthesis be provided. This backup prosthesis still relied on the puck-and-clamp attachment system, but instead of using the implanted electrodes to control the terminal device, two flexible prongs extended proximally from the prosthesis, each housing an sEMG electrode which was pressed against the skin. These sEMG electrodes were aligned to permit standard direct control of the prosthetic hand via activation of the flexor (close) and extensor (open) compartments of the residual forearm.

An additional potential issue identified with the puck designed for the lightweight prosthesis and the sEMG prosthesis is that the holes for the radial and ulnar abutments did not extend through the full depth of the puck. Thus, when the puck was affixed over the abutments, the abutments were fully encased. For the lightweight prosthesis especially, which the participant typically wore while running, we hypothesized that his sweat would mix with fluid from the stoma and seep down the abutment, eventually pooling in the puck and wicking up into intermedullary connectors. When the mixed fluid dried out, foreign material would build up between the pins of the intermedullary connectors, which eventually led to difficulty fully seating the external connectors. This required periodic visits lab visits for cleaning.

At the conclusion of the rehabilitation period, the participant was fitted with a MyoHand VariPlus Speed (Ottobock, Germany) and a multifunction prosthetic hand (Prensilia, Italy); in both cases, a single-degree-of-freedom direct control scheme controlled opening and closing of the hand. The multifunction hand can contain sensorized fingertips, allowing for graded tactile sensory feedback via direct nerve stimulation whenever force is applied to the fingertip, however due to semiconductor shortages arising from the COVID-19 pandemic and the 2022 Russian invasion of Ukraine, the sensorized fingertips could not be installed in the participant's hand. At the conclusion of the study, a SensorHand Speed (Ottobock, Germany), which contains sensors in the thumb tip, was provided to the participant to allow for similar sensory feedback at home.

Signal-to-noise ratios (SNR) were calculated to determine the general strength of the acquired iEMG signals as measured from the intramuscular electrodes (Fig. 6a). 5 months after implantation, average SNR for iEMG channels was 11.36 ± 4.98, increasing to 20.26 ± 7.98 at 17 months post-implantation. Unlike in previous reports on this technology, where electro-neuromuscular constructs were created and thus signal strength was expected to grow slowly over time [6, 13], our participant in this study did not have target muscle reinnervation (TMR) or regenerative peripheral nerve interfaces (RPNIs) created when receiving his neuromusculoskeletal prosthesis – thus, no substantial increase in SNR was expected or observed.

F. Functional Outcomes

Standardized outcome measures were performed to evaluate changes in functionality resulting from using the neuromusculoskeletal prosthesis. Data were collected one month prior to implantation, and 17 months post-implantation. In both cases, a MyoHand VariPlus Speed (Ottobock, Germany) was used as the terminal device.

The Assessment for the Capacity of Myoelectric Control (ACMC) is a test of the overall skill with which a myoelectric prosthesis is controlled [14]. The participant was asked to perform two tasks: packing a suitcase, and setting a table. During both tasks, trained evaluators observed the participant's use of his prosthesis according to pre-defined guidelines. Raw scores are transformed using a Rasch scale to yield an Index of Function ranging from 0 (low skill) to 100 (high skill). ACMC scores for the pre-operative stage were 60.1 and 63.1 for the suitcase and the table, respectively. For the post-operative stage, scores in both tasks had increased to 74.3 and 70.5, an increase of 24% and 12%, respectively.

The Southampton Hand Assessment Procedure (SHAP) tests the ability to grasp objects and perform tasks using various hand grips [15]. In the first part of the procedure, objects with abstract shapes are relocated using the prosthesis; in the second part of the procedure, daily tasks are performed using both the

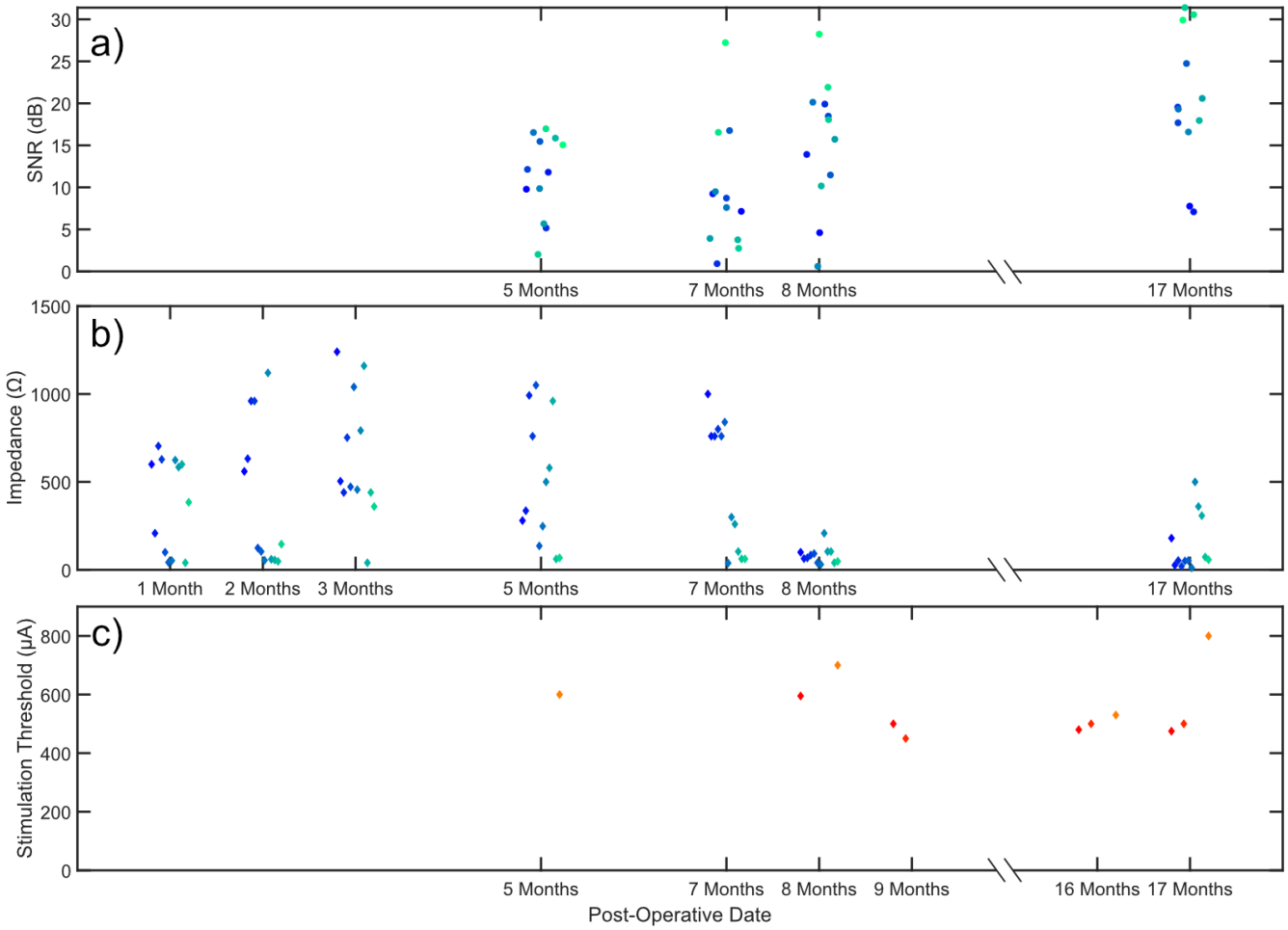

Fig. 6. Several engineering tests were conducted to verify the stability of the implanted electrodes over the course of the study. (a) Signal-to-noise ratio (SNR) measures the relative strength of iEMG signals acquired from intramuscular electrodes, and generally increased over time. (b) Electrical impedance of the implanted electrodes is a measure of how much electrical current is resisted from traveling between the electrodes and the electrical ground (in this case, the osseointegrated implant), and generally lowered over time. (c) Stimulation thresholds are the minimum current required to elicit a perceivable sensation when stimulating the extraneural cuff electrodes. Thresholds tended to vary widely, however two cuff channels (red) were identified which could reliably elicit sensations for the participant.

prosthetic and contralateral hands. The time required to complete each task is recorded, and an index of function is calculated [16]. SHAP scores increased from 56.0 pre-implantation to 62.7 post-implantation, an improvement of 12%.

The Refined Clothespin Relocation Test (RCRT) is a standardized outcome measuring postural compensation and task completion time while relocating clothespins from a horizonal bar to a vertical bar and back again [17]. A score is calculated amalgamating both the performance time and the degree of postural compensation, with a higher score reflecting higher performance [18]. RCRT scores increased from 18.81 pre-implantation to 19.92 post-implantation, and improvement of 6%.

The Prosthetic Control test measures the minimum degree of prosthetic activation in both opening and closing [4]. The subject is asked to control their prosthetic hand and to execute the smallest possible volitional movement repeatedly. The aperture of the prosthetic hand is measured with a caliper, and the process is repeated. Prior to implantation, the participant controlled his prosthesis using surface electrodes; after implantation, the implanted intramuscular electrodes were used. Prior to surgery, the participant demonstrated a median minimum voluntary opening of 6.10 mm (quartiles: 5.57 mm, 9.63 mm) and a median minimum voluntary closing of 2.61 mm (2.18 mm, 3.05 mm). After implantation with the neuromuscular prosthesis, minimum voluntary opening reduced to 2.26 mm (1.86 mm, 2.63 mm) and minimum voluntary closing reduced to 2.12 mm (2.04 mm, 2.83 mm), representing improvements of 63% and 19%, respectively.

G. Sensory Feedback

Throughout the rehabilitation and prosthesis use phases, regular engineering tests were performed to monitor neuromusculoskeletal interface stability. To monitor interface stability, the electrical impedance of implanted electrodes was calculated by applying single pulses of known current (100μA for 100μs) and measuring the voltage response. Measurements showed an average impedance 171 Ω for nerve cuffs electrodes and 141 Ω for intramuscular electrodes (Fig. 6b). Impedance measurements could periodically become significantly higher, however we believe this was due to foreign material building up between the

pins of the intermedullary connectors, which prevent full seating of the external connectors. A linear algebra approach was also used to calculate direct impedances and cross-channel impedances, however foreign material once again prevented reliable readings [19]. Impedances returned to normal following cleaning of the intermedullary connector.

Tests were also performed to quantify the detection thresholds for sensations elicited via direct nerve stimulation. Data were collected via a custom computer program written in MATLAB. Using the same setup as the impedance test, nerve cuff channels were stimulated with a pulse width of 500 μs and a pulse amplitude starting below the participant's known stimulation threshold. Using an adaptive staircase psychophysics algorithm, the nerve was stimulated at successively higher amplitudes until the participant indicated that he felt a sensation, after which the amplitude was lowered and the rate of change was decreased. After ten decision reversals, the test was stopped and the final amplitude was recorded as the detection threshold. Threshold amplitudes typically ranged between 500-600 μA over the first nine months before lowering to 450-500 μA in subsequent months (Fig. 6c).

Following identification of the detection threshold, a second graphical interface appeared to the participant which recorded the size, location, and quality of the elicited sensation. The user is asked to draw the boundaries of an elicited sensation on a representative "map" of their hand. They are then asked to identify if the sensation has tactile qualities (touch, pressure, tapping, and/or vibration) or electrical qualities (shock, zap, and/or pins & needles), and to describe the diffuseness, depth, dynamics, and naturalness of the sensation. Finally, users are offered a chance to describe the sensation in their own words. Due to the participant's visual impairment and contralateral amputation, an experimenter filled out the questionnaire on his behalf following verbal cues.

Throughout the post-operative period, sensations elicited via direct nerve stimulation were reported with electric qualities; no tactile sensations were reported, and all sensations were reported as feeling mostly unnatural (29.5% ± 21.1%, with 0% being unnatural and 100% being a sensation that one could imitate themselves). For the first year, no sensations were reported as felt within the phantom hand, as had been observed in our prior work with trans-humeral neuromusculoskeletal prostheses [4]. Instead, sensations were perceived somewhat deep within the palmar aspect of the residual limb (51.5% ± 11.8%, with 0% being deep and 100% being superficial).

We initially proposed two hypotheses to explain this finding. First, that no phantom sensation was felt because no phantom representation of the hand existed. Second, that the median nerve was insensate, which would also explain why the neuroma found at the termination of the median nerve caused the participant no pain prior to surgery.

15 months after surgery, we asked the participant to provide us with more detail about the sensations elicited from nerve stimulation and his experience with his phantom hand. When asked about how he performed muscle contractions for pattern recognition of finger movements, the participant reported visualizing finger contractions within his residual arm during virtual movements, indicating the same location in which he reported sensation from neurostimulation. During subsequent testing, we ascertained that sensory perception could repeatably be elicited within the regions of the forearm associated with visualized movement of digits I-III. Specifically, sensations were associated with the distal palmar aspect of the thumb and the palmar pad of the metacarpophalangeal (MCP) joint of digits II and III.

We now hypothesize that sensory feedback is localized on the phantom hand, which is telescoped inside of the residual arm.

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VI. References

[1] M. Ortiz-Catalan, B. Håkansson, R. Brånemark, B. Hakansson, and R. Branemark, "An osseointegrated human-machine gateway for long-term sensory feedback and motor control of artificial limbs," in *Science Translational Medicine* vol. 6, ed, 2014, pp. 257re6-257re6.

[2] E. L. Graczyk, L. Resnik, M. A. Schiefer, M. S. Schmitt, and D. J. Tyler, "Home use of a neural-connected sensory prosthesis provides the functional and psychosocial experience of having a hand again," in *Scientific Reports* vol. 8, ed: Springer US, 2018, pp. 1-17.

[3] G. Valle *et al.*, "Biomimetic Intraneural Sensory Feedback Enhances Sensation Naturalness, Tactile Sensitivity, and Manual Dexterity in a Bidirectional Prosthesis," in *Neuron* vol. 100, ed: Elsevier Inc., 2018, pp. 37-45.e7.

[4] M. Ortiz-Catalan, E. Mastinu, P. Sassu, O. Aszmann, and R. Brånemark, "Self-Contained Neuromusculoskeletal Arm Prostheses," in *New England Journal of Medicine* vol. 382, ed, 2020, pp. 1732-1738.

[5] L. E. Osborn *et al.*, "Extended home use of an advanced osseointegrated prosthetic arm improves function, performance, and control efficiency," in *Journal of Neural Engineering* vol. 18, ed, 2021, p. 026020.

[6] J. Zbinden *et al.*, "Nerve transfer to native and free grafted muscles for the control of bionic limbs," *Science: Translational Medicine,* 2023.

[7] A. Middleton and M. Ortiz-Catalan, "Neuromusculoskeletal Arm Prostheses: Personal and Social Implications of Living With an Intimately Integrated Bionic Arm," (in English), *Frontiers in Neurorobotics,* Original Research vol. 14, 2020-July-24 2020, doi: 10.3389/fnbot.2020.00039.

[8] S. Jönsson, K. Caine-Winterberger, and R. Brånemark, "Osseointegration amputation prostheses on the upper limbs," *Prosthetics & Orthotics International,* vol. 35, no. 2, pp. 190-200, 2011, doi: 10.1177/0309364611409003.

[9] M. J. Major, R. Stine, T. Shirvaikar, and S. A. Gard, "Effects of Upper Limb Loss or Absence and Prosthesis Use on Postural Control of Standing Balance," *American Journal of Physical Medicine & Rehabilitation,* vol. 99, no. 5, pp. 366-371, 2020, doi: 10.1097/phm.0000000000001339.

[10] E. Mastinu, P. Doguet, Y. Botquin, B. Hakansson, and M. Ortiz-Catalan, "Embedded System for Prosthetic Control Using Implanted Neuromuscular Interfaces Accessed Via an Osseointegrated Implant," *IEEE Transactions on Biomedical Circuits and Systems,* vol. 11, no. 4, pp. 867-877, 2017-08-01 2017, doi: 10.1109/tbcas.2017.2694710.

[11] E. J. Earley, J. Zbinden, M. Munoz-Novoa, E. Mastinu, A. Smiles, and M. Ortiz-Catalan, "Competitive motivation increased home use and improved prosthesis self-perception after Cybathlon 2020 for neuromusculoskeletal prosthesis user," *Journal of NeuroEngineering and Rehabilitation,* vol. 19, no. 1, 2022, doi: 10.1186/s12984-022-01024-4.

[12] M. Ortiz-Catalan, J. Wessberg, E. Mastinu, A. Naber, and R. Brenemark, "Patterned stimulation of peripheral nerves produces natural sensations with regards to location but not quality," in *IEEE Transactions on Medical Robotics and Bionics* vol. 1, ed, 2019, pp. 1-1.

[13] M. Ortiz-Catalan *et al.*, "A highly integrated bionic hand with neural control and feedback for use in daily life," *Science Robotics,* vol. 8, no. 83, p. eadf7360, 2023, doi: doi:10.1126/scirobotics.adf7360.

[14] L. M. Hermansson, A. G. Fisher, B. Bernspång, and A. C. Eliasson, "Assessmet of Capacity for Myoelectric Control: A new Rasch-built measure of prosthetic hand control," in *Journal of Rehabilitation Medicine* vol. 37, ed, 2005, pp. 166-171.

[15] 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," in *Arch Phys Med Rehabil* vol. 83, ed, 2002, pp. 776-783.

[16] J. G. M. Burgerhof, E. Vasluian, P. U. Dijkstra, R. M. Bongers, and C. K. van der Sluis, "The Southampton Hand Assessment Procedure revisited: A transparent linear scoring system, applied to data of experienced prosthetic users," *Journal of Hand Therapy,* vol. 30, no. 1, pp. 49-57, 2017/01/01/ 2017, doi: https://doi.org/10.1016/j.jht.2016.05.001.

[17] A. Hussaini and P. Kyberd, "Refined clothespin relocation test and assessment of motion," *Prosthetics and Orthotics International,* vol. 41, no. 3, pp. 294-302, 2017, doi: 10.1177/0309364616660250.

[18] A. Hussaini, W. Hill, and P. Kyberd, "Clinical evaluation of the refined clothespin relocation test," *Prosthetics & Orthotics International,* vol. 43, no. 5, pp. 485-491, 2019, doi: 10.1177/0309364619843779.

[19] E. J. Earley, E. Mastinu, and M. Ortiz-Catalan, "Cross-Channel Impedance Measurement for Monitoring Implanted Electrodes," in *2022 44th Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC)*, 11-15 July 2022 2022, pp. 4880-4883, doi: 10.1109/EMBC48229.2022.9871954.