Tactile Feedback in Upper Limb Prosthetics: A Pilot Study on Trans-Radial Amputees Comparing Different Haptic Modalities

Federica Barontini, Alina Obermeier, Manuel Giuseppe Catalano, *Member, IEEE*,
Simone Fani, *Member, IEEE*, Giorgio Grioli, *Member, IEEE*, Matteo Bianchi, *Member, IEEE*,
Antonio Bicchi, and Eike Jakubowitz

***Abstract*—Despite technological advancements, upper limb prostheses still face high abandonment/rejection rates due to limitations in control interfaces and the absence of force/tactile feedback. Improving these aspects is crucial for enhancing user acceptance and optimizing functional performance. This pilot study, therefore, aims to understand which sensory feedback in combination with a soft robotic prosthetic hand could provide advantages for amputees, including performing everyday tasks. Tactile cues provided are contact information, grasping force, degree of hand opening, and combinations of this information. To transfer such feedback, different wearable systems are used, based on either vibrotactile or force stimulation in a non-invasive modality matching approach. Five volunteers with a trans-radial amputation controlling the new prosthetic hand SoftHand Pro performed a study protocol including everyday tasks. The results indicate the preference of amputees for a single, i.e. non-combined, feedback modality. The choice of appropriate haptic feedback seems to be subject and task-specific. Furthermore, in alignment with the participants' feedback, force feedback, with adequate granularity and clarity, could potentially be the most valuable feedback among those presented. Finally, the study suggests that prosthetic solutions should be preferred where amputees are able to choose their feedback system.**

***Index Terms*—Prosthetic hand, tactile feedback, user-centered approach, wearable haptics.**

I. Introduction

The human hand is a powerful tool to interact and operate with the environment. It allows to accomplish complex movements, from power to precision grasps and manipulation tasks. Moreover, it is an important communication vehicle for social interaction [1]. Losing a hand has devastating effects, especially concerning autonomy, limitation of capability, social life, and activities of daily living (ADLs). It changes people's life. In the last decades, the field of hand prosthetics developed rapidly with improvements in mechanics, dexterity, and control. The introduction of new myoelectrically driven hands obtained significant results for the recovery of the motoric functions actually lost with the amputation [2]. Despite this advancement, today's upper limb prosthesis users are still affected by relevant limitations that in the worst case may result in a rejection of the device. Among those, the lack of sensory feedback contributes to the limitation of an optimal control performance in everyday use [3]. According to Biddis et al. [4] and Cordella et al. [5], the need for sensory feedback is one of the most important requirements of amputees with myoelectric and body-powered prostheses. In addition, amputees expressed also their dissatisfaction with the heavy dependence on visual feedback required to control current prostheses [4], [6], [7]. Indeed, the restoration of haptic channels is an open challenge that covers several considerations. These are stimulation discomforts, the ability to relate the feedback to the grasping force and to proprioceptive information, technical constraints and pragmatic factors such as cost, weight and wearability.

Considerable efforts have been made in the last few years to find usable feedback solutions. In general, these solutions can be divided into two main categories: invasive and non-invasive feedback systems. Invasive systems interact directly with the amputee's nervous system and require surgical intervention. These systems could improve the prosthetic control and performance for amputees, however, such systems are mainly still at an experimental level since their translation into everyday life presents major challenges. For a complete review on invasive systems please refer to Kim [8] and Bensmaia et al. [9]. In

---

Manuscript received 11 November 2022; revised 19 June 2023 and 5 September 2023; accepted 9 September 2023. Date of publication 6 October 2023; date of current version 19 December 2023. This work was supported by the European Union's Horizon 2020 Research and Innovation Programme European Research Council under Grants 688857 called SoftPro and 810346 called Natural BionicS. This paper was recommended for publication by Associate Editor Hiroyuki Kajimoto. *(Corresponding author: Federica Barontini.)*

This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the Local Ethics Committee of the Hannover Medical School under Application No. 7444/18 and performed in line with the declaration of Helsinki.

Federica Barontini and Manuel Giuseppe Catalano are with the Department of Soft Robotics for Human Cooperation and Rehabilitation, Fondazione Istituto Italiano di Tecnologia, 16163 Genoa, Italy (e-mail: federicabarontini16@gmail.com; manuel.catalano@iit.it).

Alina Obermeier and Eike Jakubowitz are with the Laboratory for Biomechanics and Biomaterials, Departments of Orthopedic Surgery, Hannover Medical School, 30625 Hannover, Germany (e-mail: obermeier.alina@mh-hannover.de; jakubowitz.eike@mh-hannover.de).

Simone Fani and Matteo Bianchi are with the Department of Information Engineering, University of Pisa, 56126 Pisa, Italy, and also with the Research Center "E. Piaggio", University of Pisa, 56126 Pisa, Italy (e-mail: simonefani89@gmail.com; matteo.bianchi@unipi.it).

Giorgio Grioli and Antonio Bicchi are with the Department of Soft Robotics for Human Cooperation and Rehabilitation, Fondazione Istituto Italiano di Tecnologia, 16163 Genoa, Italy, also with the Department of Information Engineering, University of Pisa, 56126 Pisa, Italy, and also with the Research Center "E. Piaggio", University of Pisa, 56126 Pisa, Italy (e-mail: giorgio.grioli@gmail.com; antonio.bicchi@unipi.it).

Digital Object Identifier 10.1109/TOH.2023.3322559

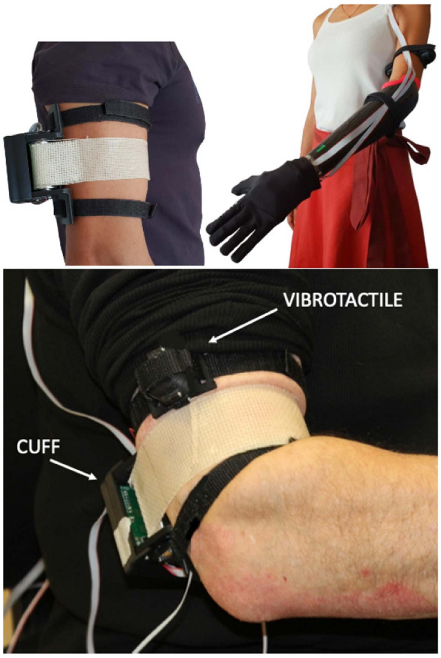


Fig. 1. CUFF, the VibroTactile devices and their combinations applied on the user's arm, during this investigation.

contrast, non-invasive solutions involve wearable haptic devices to convey various stimuli to the amputee. These systems rely on touch-mediated stimuli and can transfer information through residual limb squeeze, skin-stretch, vibration patterns and their combinations (see Dosen et al. [10], Nemah et al. [11], and Stephens-Fripp et al. [12]).

According to Schofield et al. [13] three sub-categories of sensory feedback can be seen in hand prosthetics: they can be somatotopically matched, modality matched and based on a sensory substitution. Somatotopically matched feedback creates a natural signal comparable to the original sensation for the same body part. Modality matched feedback provides a stimulus similar to the original sensation, but at an alternative body site or extremity, e.g. mapping pressure at a finger on a similar pressure signal but to the forearm. Finally, a sensory substitution involves the transfer of information from a lost sense to the input channel of another sense. Usually, vibrotactile feedback systems fall into this category, since they transmit information, such as the grasping force, to the amputee's skin using frequency patterns as an alternative. Risi et al. [14] investigated the use of vibrotactile feedback to improve limb motion control and showed induced changes in motion planning after training, but also associated with cognitive costs. Shah et al. [15] investigated stimulation for body-machine interfaces to provide performance feedback to the user by conducting two psychophysical experiments to determine the effectiveness of vibrotactile perception via the arm. The results suggested that the arm could be a viable site to convey multivariate information via vibrotactile feedback for body-machine interfaces. In [16] the authors, exploiting the Discrete Event-driven Sensory feedback (DESC) policy, presented a device able to deliver short-lasting vibrotactile feedback to trans-radial amputees. The DESC-glove was tested by 5 trans-radial limb loss participants for one month at home. The results demonstrated the effectiveness of the device for prosthetic control in daily life conditions.

To the author's knowledge, only a few studies compared different feedback systems with amputees, to understand the advantages of stimuli during different ADLs. Patterson et al. [17] compared vibratory and pressure feedback during a force matching task that involved grasping with a robotic arm. They analyzed the relative error using visual plus vibration feedback and visual plus pressure feedback. The results showed that the use of visual plus pressure feedback entailed in slightly lower relative error as regards the use of visual plus vibratory feedback. Similarly, Tejeiro et al. [18] characterized the effects of vibration and pressure performance during object manipulation tasks. They demonstrated that participant performances increased with the addition of pressure or vibration stimuli compared to visual feedback alone. Bark et al. [19] compared vibration and skin stretch stimuli performance during a virtual proprioception task. The results showed that skin stretch stimuli are easier to understand as proprioception information concerning the vibration stimuli.

A limit of the previous works was the fact that the limb loss users were not involved during the experimental task and the different sensor modalities always relied on visual feedback.

Based on these groundworks, the present study aims to evaluate and identify possible advantages of different non-invasive feedback for subjects with limb loss. We adopt the modality matching approach using two wearable devices, namely the Clenching Upper Limb Force Feedback (CUFF) and the VibroTactile. In the study, we test and investigate the usefulness and performance of different feedback modalities with five trans-radial users: contact information & roughness, grasping force, hand opening degree, grasping force combined with hand opening degree, and contact information combined with grasping force. More specifically, the amputees accomplished grasping tasks using upper limb prostheses in conjunction with wearable feedback devices without relying on visual feedback. At the best of the author knowledge this is one of the first studies that evaluates and collects insight from users who tested (and finally chooses) different haptic cues in coordination with the use of a myoelectric prosthetic hand. Although it presents a relatively small number of users it anyway provides, in the author's opinion, useful findings for future development of prosthetic feedback devices.

The article is organized as follows: Section II presents the wearable devices used, while Section III describes the methods and the experimental protocol. Section IV presents the results of the experiments, and in Section V there is a discussion of the results obtained. Finally, Section VI discusses the limits of the work and the possible future developments, and Section VII is devoted to the conclusion we can draw from this work.

II. MATERIAL

This study aimed to deliver various types of stimuli (i.e., force, hand opening degree, first contact cue, and roughness) and their combinations (see Table 1) to subject with limb loss. To accomplish this, we employed two wearable haptic devices, namely the CUFF device and the Vibrotactile, which have been extensively characterized and validated in the following sources: [20] and [21]. Both of these devices can be seamlessly integrated with the robotic hand SoftHand Pro (SHP), enabling a comprehensive haptic experience for the users.

A. The Clenching Upper Limb Force Feedback Device

The Clenching Upper-Limb Force Feedback (CUFF) is a wearable device providing distributed mechano-tactile stimulation to the upper arm [22]. Briefly, the CUFF device comprises a mainframe, which can be secured fastened to the user's arm with two Velcro straps, an actuation unit composed of two DC motors (DCX16S, Maxon, Switzerland AG, Alpnach Dorf, Swiss) with a gearbox ratio of $64:1$, and a belt that interfaces featuring with the skin of the human body. The device operates by utilizing motor rotation to provide two types of stimuli: squeeze and skin-stretch. When the motors rotate in opposite directions, the belt tightens or loosens, resulting in an adjustable pressure on the arm. On the other hand, when the motors rotate in the same direction (either medially or laterally), the belt slides, producing a skin stretch sensation that corresponds to the degree of hand opening. The users were instructed to associate the stimulus from the CUFF with the grip force and the hand opening degree of the SHP. To estimate the hand position, the readings of the two magnetic encoders (AS5045, ams-Osram AG, Premstaetten, Austria) were utilized. In addition, to estimate the grip force exerted by the hand, the residual current (RC_{meas}) was calculated. This parameter represents the difference between the estimated and the real current absorbed by the hand activating motor, as defined in [23].

The process of mapping information from the robotic hand to the feedback device necessitates the establishment of a relationship between each hand value and the corresponding position value of the CUFF motor. To achieve this, a linear mapping strategy was selected to define the reference position (pos_{Cref}) of the CUFF motors. For the skin stretch stimulus, the encoder-detected motor position of the SHP $pos_{SHPmeas}$ was translated into the reference position. This translation adhered to two constraints: when $pos_{SHPmeas} = 0$ also the $pos_{Cref} = 0$ and when the $pos_{SHPmeas} = pos_{SHPmax}$, $pos_{Cref} = pos_{Cmax}$. Concerning the force stimulus, the translation of the residual current (RC_{meas}) into the reference position was conducted. Likewise, two constraints were identified: when $RC_{meas} = 0$ also the $pos_{Cref} = 0$, and when the $RC_{meas} = RC_{max}$ also the $pos_{Cref} = pos_{Cmax}$. Thus, the updated reference position of the CUFF motors can be expressed as follows:

$$pos_{Cref} = \left(\frac{pos_{SHPmeas}}{pos_{SHPmax}}\right) pos_{Cmax} \tag{1}$$

$$pos_{Cref} = RC_{meas} * gain \tag{2}$$

respectively for the skin stretch stimulus (1), and for the force stimulus (2). The *gain* was chosen heuristically equal to 0.4, while pos_{Cmax} was set at 800 ticks from the zero position as a result of testing that determined this position to be the maximum position well tolerated by a group of individuals.

B. The VibroTactile Feedback Device

The VibroTactile feedback system is a wearable digital device designed to relay real-time high-frequency contact information from a robotic hand to the user through vibrotactile stimuli [21]. It consists of two main components: i) the sensing unit and ii) the actuation system. The sensing unit comprises two Inertial Measurement Units (IMUs) of type MPU-9250 (InvenSens, Inc, San Jose, USA). These IMUs are utilized to capture acceleration signals resulting from interactions with surfaces of grasping objects [24]. For our specific application, we only utilized acceleration information within the range of $\pm 2g$. The actuation unit consists of two linear voice coils (NCC01-04-001-1X, H2W Technologies, CA, USA) selected for the system. Compared to the DC motors, voice coil actuators directly generate a linear movement, which can be easily transformed into a stimulation of the skin along the normal to the surface. To support the actuators and ensure proper alignment of the moving mass with the coil, a suitable frame was designed. An elastic fabric band secures the moving mass in place, preventing it from exiting the coil shaft while enabling efficient transmission of vibrations to the amputee. The actuator's coil axis is positioned perpendicular to the residual upper arm skin of the amputees.

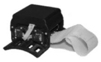
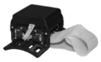
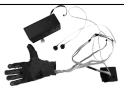
The device is capable of conveying acceleration data recorded from the fingers of the SHP, which is related to contact and surface texture, to the user. To achieve this, the IMUs were placed on the side of the nails of the little and index fingers. This placement was chosen due to the fact that these fingers collectively cover a sufficient workspace for discriminating object size and that the index finger is commonly used to explore surfaces and textures.

To convert the acceleration measurements obtained from the IMUs into a Pulse Width Modulation (PWM) signal for controlling the voice coil, digital signal processing is employed. Initially, the accelerometer measurements are filtered to eliminate low-frequency (free-hand motion) and high-frequency noise, retaining only the frequency range that specifically activates human mechanoreceptors (i.e. the Fast Adapting Type I (FA-I), and the Pacinian corpuscles [25]). The frequencies sensed by these receptors ranged between 4 to 400 Hz, with a minimum threshold below 64 Hz for FA-I and between 128-400 Hz for Pacinian corpuscles [26]. The vibrations generated by the SHP during opening and closing movements produce signals of interest within a threshold below 300 Hz. To accomplish this, a fourth-order Chebyshev Type I bandpass filter is employed, optimized for a bandwidth between 120 Hz and 230 Hz, with signal reduction in the range of 140 Hz to 210 Hz.

Furthermore, a dimensional reduction of the acceleration signal was performed. It is known that the human skin's response to vibration stimuli is independent of the acceleration direction. Therefore, we choose to stimulate the user's skin along a single direction orthogonal to the skin surface. Since acceleration is measured as a three-component vector, it needs to be reduced to a scalar value to drive the actuator. The technique used is the Sum of Components, computed as

$$a = |a_x| + |a_y| + |a_z| \tag{3}$$

TABLE I
DELIVERED INFORMATION TO THE USER, THE STIMULUS PROVIDED TO THE ARM AND USED HAPTIC DEVICE

Information to deliver	Stimulus	Haptic Feedback	Acronym
Grasping Force	Squeeze	CUFF in Force Modality 	CF
Hand Opening Degree	Skin-Stretch	CUFF in Proprioception Modality 	CP
Contact Information & Roughness	Vibration	VibroTactile 	V
Grasping Force + Hand Openining Degree	Squeeze + Skin Stretch	CUFF in Force Modality + CUFF in Proprioception Modality	CF+CP
Grasping Force + Contact information & Roughness	Squeeze + Vibration	CUFF in Force Modality + VibroTactile	CF+V

The haptic devices are referred to as follows: CF for the CUFF in force modality, CP for the cuff in proprioception modality, and V for vibrotactile. Consequently, CF + CP indicates the combination of the cuff in force modality with the cuff in proprioception modality, and CF + V indicates the combination of the CUFF in force modality with the vibrotactile. These terminology will be used also in the text.

where a is the output value, used to drive the coil, and a_x, a_y, a_z are the three components measured by the accelerometer. For more information regarding signal processing and dimensional reduction please refer to [21].

C. The SoftHand Pro

The SoftHand Pro [27] is the prosthetic version of the robotic Pisa/IIT SofHand and was used as the unique prosthetic hand for the present experiments. The Pisa/IIT SoftHand is a kinematic synergy inspired hand with 19 DOFs resulting from two ext/flex and one abd/add DOFs at the first phalange and from three ext/flex and one abd/add DOFs at each of the four remaining phalanges. All joints are manufactured as rolling contact joints with elastic ligaments ensuring an accurate closure of the hand when actuated and allowing for unharmful interactions with humans. Elastic ligaments allow for the deformation of phalanges and ensure their return to the initial position. A single cable runs through all joints to simultaneously flex and abduct the fingers upon actuation. The hand is actuated by a single 15 Watt DC motor (DCX22S, Maxon, Switzerland AG, Alpnach Dorf, Swiss) driving the cable to move the fingers on the path of the first synergy as described by Santello et al. [28]. The SHP can easily adapt to the environment as all of the fingers conform to the shape of grasped objects which augments its grasping capabilities. In addition, the SHP interfaces with commercially available surface electromyography (EMG) sensors ($13E200 = 50$ MyoBock, Otto Bock, Duderstadt, Germany). These sensors detect the action potentials of corresponding muscle fiber membranes during muscle contraction. They were placed on the flexors and extensors of the forearm to activate the closing and opening of the SHP, respectively.

III. METHODS AND EXPERIMENTAL PROTOCOL

A. Research Participants

Five trans-radial amputees S1 - S5 gave their informed consent and were initially included (mean age ± SD: 63.2 ± 11.7, 1 female). These were four unilateral and one bilateral amputee. Exclusion criteria were cognitive and neurological deficits affecting the experiments. The procedures described in this article were approved by the Local Ethics Committee of the Hannover Medical School (7444/18). The experiments were divided into two sessions: during the first session, the participants with limb loss should familiarize themselves with the SHP and test all feedback system modalities presented in Table I. At the end of the session, they should select the feedback modalities they subjectively felt most comfortable with. Later, they should test these chosen system modalities in a second session.

All amputees participated in the first session, but due to the COVID-19 pandemic only two of them (mean age ± SD: 53.5 ± 6.4, 1 female) could be reincluded into the second session.

B. Experimental Tests and Questionnaires

To evaluate the performance of the participants we identify specific tasks and questionnaires.

The participants were instructed to perform upper-limb dexterity test, i.e. the Activities Measure for Upper Limb Amputee (AM-ULA) [29], and the Jebsen Taylor Hand Function Test [30] using their own prosthesis. The AM-ULA test comprises 18 tasks that assess various aspects such as task completion, speed, movement quality, skill in prosthetic use, and level of independence. This measure has demonstrated excellent internal consistency, good inter-rater reliability, test-retest reliability, and showed known-group and convergent validity. Additionally, the Jebsen Taylor Hand Function Test (JTHFT) evaluates ADL performance based on the completion time of 7 simulated tasks, including writing, feeding, and manipulating both large and small objects. Redundant tasks in both tests were performed only once.

To test the feedback modalities, we design three manipulation tasks:

1) *Recognition Object task:* the participants had to recognize and grasp five objects named by the therapist, without visual feedback. The objects chosen from Table II, exhibited variation in sizes, shapes, textures and softness. All

Fig. 2. Experimental setup: on the left the investigator view, on the right and view direction of the amputee.

TABLE II
OBJECTS USED FOR RECOGNIZING OBJECT TASK

	Low	Medium	High
Stiffness	• Thin scarf • Stuffed animal • Wool ball	• Full pack of tissues • $3/4$ full 1.5 l water bottle • Carton box ($10\times 10\times 10$ cm)	• Pineapple • Hard cover book ($10\times 20\times 2$ cm) • Screwdriver • Fork
Size	• Full Pack of tissues • Thin scarf • Screwdriver • Fork	• Carton box ($10\times 10\times 10$ cm) • Wool ball • Hard cover book ($10\times 20\times 2$ cm)	• Pineapple • $3/4$ full 1.5 l water bottle • Stuffed animal
Roughness	• Full Pack of tissues • Thin scarf • Wool ball	• Pineapple • Hard cover book ($10\times 20\times 2$ cm) • Stuffed animal • Carton box ($10\times 10\times 10$ cm)	• $3/4$ full 1.5 l water bottle • Screwdriver • Fork

the objects in Table II were selected as they are commonly used in activities of daily living.

2) *Size Discrimination task:* the participants had to sort five wooden spheres (diameter of 20 mm, 40 mm, 50 mm, 60 mm and 80 mm) from the smallest to the largest.

3) *Softness Discrimination task:* the participants had to sort five balls (i.e. tennis, massage, gym balls) from the softest to the stiffest.

For all tasks, the objects were positioned inside a box ($W \times H \times D = 0.7 \times 0.5 \times 0.3$ m; see Fig. 2). The box was enclosed by a curtain on the subject's side and left open on the therapist's side. The curtain concealed the objects from the participants' view, enabling the experimenter to observe, record videos, and evaluate the exploration process. Throughout the task execution, the subjects engaged in conversation with the therapist, introducing an intentional distraction factor. During the tests, the subjects were comfortably seated at an adjustable height table, with the closed box placed in front of them. The subject wore the CUFF and the VibroTactile device on the upper arm, as shown in Fig. 1.

It is worth noticing that the CUFF device was calibrated around each user's arm before starting the task. The calibration of the CUFF involved an auto-adjustment of the fabric belt around the participant's arm in which the fabric was tightened until the two motors reached the stall condition and then released leaving the absorbed current close to zero. This process guarantees the complete contact of the belt on the arm. Thanks to the design of the frame housing the actuator, no calibration phase was required for the VibroTactile device.

Finally, the subjects accomplished two surveys: a qualitative questionnaire evaluated on a 7-point Likert scale [31], and a survey focused on the chosen feedback modality. The qualitative questionnaire consists of a series of inquiries related to the system and the experimental task. Participants were asked to assign scores ranging from 1 (totally disagree) to 7 (totally agree). This approach represents a common procedure to evaluate devices for assistive robotics and Human-Robot Interaction. The questionnaire was structured as follows:

- Questions Q1 to Q11 focus primarily on the analysis of the different feedback modalities tested by the subjects. This includes assessments of both single modality and combined modality.
- Questions Q12 to Q16 are centred around evaluating the subjects' performance with the feedback.
- Questions Q17 to Q19 explore potential applications of the various feedback modalities in everyday scenarios.
- Question Q20 investigates the perception of the current version of the feedback.
- Question Q21 pertains to the mental workload required to comprehend the stimuli conveyed by the devices.

The survey regarding the feedback was created ad hoc for the experimental session. The participants were required to answer the following questions:

1) Why did you choose this feedback device/modality?
2) In which everyday situation this feedback device could help you?
3) Which of the feedback devices presented to you would be least helpful, and why?
4) What changes would be necessary to make the devices you did not choose more useful to you?

C. *Experimental Protocol of the First Session*

The first session was divided into three days.

1) Day 1: The first day of the study was dedicated to conducting dexterity tests and familiarizing the participants with the control and usage of the SoftHand Pro. In the first phase, the participants were instructed to perform an upper-limb dexterity test, i.e., the Activities Measure for Upper Limb Amputee (AM-ULA) [29], with their own prosthesis. After this test, the SoftHand Pro was configured and attached to the user's socket. Under the supervision of a specialized physical therapist trained in prosthetic training for upper limb amputees, the participants underwent a 30-minute familiarization period. During this phase, they learned how to control and utilize the new robotic hand. The familiarization process included picking up and stacking objects including blocks and collapsible drinking cups, as well as picking up and placing down objects of different sizes, shapes, and materials. After this period, the participants repeated the AM-ULA using the SHP. The execution time was recorded for each test and each robotic hand used. In addition to evaluating dexterity, the initial day of the study also aimed to compare the agility in utilizing the SoftHand Pro relative to participants' own prostheses, as this aspect could potentially impact the outcomes of the comprehensive experiment involving the feedback devices.

2) Day 2: The second day of the study was dedicated entirely to testing all feedback system modalities in conjunction with the SHP (see Table I). A 60-minute slot was allocated per each feedback modality, and a minimum break of 30 minutes was given to the participants between tests of two feedback system modalities.

Each slot consists of a training session and an experimental session. During the training session, the participant used the SHP with the feedback for 30 minutes playing/grasping all the objects presented in Table II with visual feedback. They were free to grasp the different objects and test the feedback device in various everyday situations (e.g. handshake, stacking objects, grasping collapsible drinking cups). Following the training session with the visual feedback, a 10-minute training with a black box was conducted. The subject explored five objects chosen from Table II without visual feedback. The final 20 minutes of each slot were allocated to the tasks, specifically the Recognizing Objects, Size Discrimination, and Softness Discrimination tasks. Throughout the day, participants were closely accompanied by the therapist, who managed the training sessions and supervised the test sessions. The order of the feedback combinations was randomized across subjects. During the experiment we record the success, defined as the number of attempts required to retrieve the correct object, and the time of success, defined as time the participants believed that they had solved the task. At the end of each feedback modality, the subjects accomplished the qualitative survey. Corresponding questions can be taken from Table V. At the end of the day, participants were provided with an additional questionnaire to compare the different systems and choose their preferred feedback modality, stating their reasons.

TABLE III
TABLE SHOW THE RESULTS OF THE AM-ULA TEST ACCOMPLISHED IN THREE MODALITIES: WITH THEIR OWN PRSTHESIS, WITH THE SHP AND WITH THE SHP + FEEDBACK

Subject	Own Prosthesis	SHP	SHP+ Feedback
S1	11.11	14.44	13.89
S2	10.83	11.39	11.11
S4	13.33	15.00	15.00
S5	16.39	16.11	17.50

3) Day 3: On the last day, the feedback system chosen by the participant during the second day was tested more in-depth. The subjects carried out the AM-ULA and the Jebsen test with the SHP integrated with the feedback system chosen during Day 2. Subsequently, a second repetition of the two tests without feedback, aimed to assess the potential presence of learning effects during the test execution.

D. *Experimental Protocol of the Second Session*

At the end of the first experimental session, two feedback systems resulted as the preferred ones: the CUFF in force modality and the VibroTactile. The two feedback system modalities chosen during the first session were retested in this session lasting one day. Therefore, the Recognizing Object task was accomplished again with a separate use of feedback modalities. The qualitative questionnaire was finally surveyed again (Table V). The experimental setup and procedure were the same as the first session.

IV. RESULTS

A. *First Experimental Session*

From the first session of the experiment, as previously anticipated, we observed a preference for the two feedback modalities, i.e. the CUFF in force modality and the VibroTactile. Table III presents the results of the AM-ULA test conducted in three modalities: 1) with the prosthesis utilized by users in their daily lives, 2) with the SHP, and 3) with the SHP plus the haptic feedback.

Table IV displays the outcomes of the Recognizing Object task. It is worth noting that it has been decided to present only the result obtained during this task. This choice is grounded in the author's conviction that this particular task was the most informative in demonstrating how each feedback modality could be utilized to provide distinct information.

Table V provides a comprehensive overview of the qualitative questionnaire. Additionally, Table VII presents the results of the

TABLE IV
TABLE SHOWS THE RESULTS OF THE FEEDBACK TASK: # NON COMPLETED, - NON PERFORMED, S MEANS SUBJECT, CF MEANS CUFF IN FORCE MODALITY, CP MEANS CUFF IN PROPRIOCEPTION MODALITY, V VIBROTACTILE, CF+V CUFF IN FORCE PLUS THE VIBROTACTILE, CF+CP CUFF IN FORCE PLUS CUFF IN PROPRIOCEPTION

Recognizing Object Task										
	Execution Time [s]					N of errors				
S	CF	CP	V	CF+V	CF+CP	CF	CP	V	CF+V	CF+CP
S1	37	60	63	168	-	1	0	0	0	-
S2	257	154	88	110	300	2	0	0	0	3
S3	128	232	331	153	-	1	0	0	3	-
S4	132	105	126	90	152	2	0	2	0	3
S5	104	106	159	111	-	2	2	2	2	-

Jebsen test, comparing performance when using the SHP both with and without the feedback modality chosen on Day 2.

Lastly, Table VIII succinctly summarizes the impressions and comments expressed by the subjects at the end of Day 2, including an investigation into their motivations for selecting specific feedback modalities.

It is worth noticing that participant A3 has been excluded from the AM-ULA as well as from the Jebsen test, due to personal circumstances that prevented the completion of the three-day experimental session. However, we thought interesting to present the results obtained with the utilization of feedback in the Recognizing Object task. Furthermore, given the limited number of participants in the study, it was not feasible to conduct any form of statistical analysis.

B. *Second Experimental Session*

The second session of the experiment has been performed so far by only two participants with limb loss. For this reason, it was not possible to accomplish a statistical analysis. The VibroTactile and the CUFF in force modality were the feedback chosen from the first session of experiments. Table VI shows the results for the recognizing object task. At the end of the experiments, both participants underwent the qualitative questionnaire again (see *Second Session* in Table V).

V. DISCUSSION

A. *Outcomes of the First Experimental Session*

Table III presents the results of the AM-ULA test. It is noteworthy that the task execution times exhibit minimal variation between the hand commonly used by individuals in their daily lives and the SHP. This observation suggests that even with a limited amount of training, the participants were able to effectively control and utilize the SHP. However, regarding the performance of the AM-ULA test in the SHP + feedback modality, the task completion times are not significantly different from those observed when using the SHP alone. Consequently, it can be inferred that the feedback neither worsens nor improves the overall performance.

Regarding the Recognizing Object Task, due to the limited number of subjects, it was not feasible to conduct a comprehensive statistical analysis. However, from a qualitative standpoint, it can be noted that all subjects successfully completed the task when utilizing information from a single feedback modality. About the combined modalities, no significant difficulties were encountered in combining force feedback with vibration. However, it is worth mentioning that only two subjects managed to accomplish the task in the CF+CP mode. The remaining subjects expressed an inability to discern between the two stimuli and subsequently declined to proceed with the task.

In general, the prevailing approach adopted by the subjects involved in identifying object presence based on the feedback received during the initial contact. Once the object's position was determined, the subjects proceeded with exploration by means of grasping and manipulating the object. This strategy proved to be successful, as confirmed by the qualitative questionnaire, especially when the vibrotactile device was worn. The utilization of vibrotactile feedback for object localization was further substantiated by the responses to Question 4 (see Table V), wherein it became evident that the provided vibrations facilitated effective contact with external objects. Less strong is the result obtained with the CUFF in force modality. What emerged from questions Q4 and Q5 is that the stimulus provided was not enough strong to allow to distinguish the different levels of force. The CUFF in proprioception modality (question from Q6 to Q7) revealed that the stimulus was comfortable and easy to understand, but in general, the subjects preferred to receive information about the force grasp instead of the position of the hand. Regarding the combination of the feedback modalities, comments are more neutral without showing any good or bad opinions by the participants. More specifically questions Q8 and Q9 referred to the combination of force with the VibroTactile feedback. The subjects were able to distinguish the two stimuli with a mean score of 4.6 ± 1.4 SD, but at the same time, the combination of the two stimuli was a little bit confusing with a mean score of 3.6 ± 1.6 SD. The same conclusions could be deducted from the combination of force and proprioception modality: the stimuli were not confusing but neither easy to discriminate (4.5 ± 0.5). These outcomes were in line with the results obtained in [32] where the simultaneous display of two haptic channels did not enhance the control of the prosthesis. The participants did not feel to performed better with the working feedback device (questions Q12 3.8 ± 2.7, and Q15 3.6 ± 1.9) even if these results are in contrast with the objective results related to the time needed for task execution and the success rate (see Table IV). Moreover, the usefulness of the feedback during work, interaction with people and daily tasks received a positive score, but the design of the feedback needs to be improved. These outcomes may be explained considering the task and the experimental protocol designed. A test with longer training and an extended experimental session may be improved to understand how to use the feedback in the everyday life.

All the subjects, out of one, found the feedback potentially useful in everyday life both during work and in the interaction with others. The same four subjects stated that the feedback could be perceived even without focusing on the device output, maintaining the attention on the task. Looking at a detached comparison between devices, it can be observed that there is no

TABLE V

RESULTS OF THE QUALITATIVE QUESTIONNAIRES EVALUATED ON A 7-POINT LIKERT SCALE (1: STRONGLY DISAGREE, 7: STRONGLY AGREE). FIRST SESSION VALUES ARE MEANS AND SDS RESULTING FROM AMPUTEES S1 - S5

		First session		**Second session**	
	Questions	**Mean**	**Std. Dev.**	**A4**	**A5**
Q1	[V] The vibrations provided by the actuators were not confusing	5.0	0.9	7	5
Q2	[V] The vibrations provided by the actuators were not disturbing	6.8	0.4	7	6
Q3	[V] The vibrotactile device allowed different level of roughness to be distinguished	5.2	1.3	3	4
Q4	[V] The vibrotactile device allowed contact with the external objects to be clearly detected	4.0	1.9	5	4
Q5	[CF] I was able to distinguish different levels of force through the cutaneous device	3.0	2.1	6	4
Q6	[CF] The maximum force elicited pain	2.8	2.2	1	1
Q7	[CP] The belt generated pain when used for a long time	2.8	1.9	·	·
Q8	[CP] The proprioception feedback (sliding movement) was clear	4.6	1.4	·	·
Q9	[CP] I was able to understand the position of the hand, also after a distraction (perception retention)	5.0	1.4	·	·
Q10	[CF+V] The two stimuli (vibration and force) were clearly distinguishable	4.6	1.4	·	·
Q11	[CF+V] The stimuli together were confusing	3.6	1.6	·	·
Q12	[CF+CP] The two stimuli (force and proprioception) were clearly distinguishable	4.5	0.5	·	·
Q13	[CF+CP] The stimuli together were confusing	2.0	0.0	·	·
Q14	I felt I performed better while receiving feedback by the cutaneous device	3.8	2.7	2	4
Q15	I felt hampered by the cutaneous device	3.0	2.3	6	5
Q16	The stimulus provided by the cutaneous device was strange/weird	3.0	2.3	2	4
Q17	It was easy to perform the tasks while wearing the cutaneous device	3.6	1.9	6	4
Q18	The noise generated by the actuators interfered with the haptic perception	4.2	2.6	1	4
Q19	The feedback given was useful during the everyday life	4.6	2.0	4	3
Q20	The feedback given was useful during work	4.6	2.0	6	2
Q21	The feedback given was useful for interaction with other people	4.4	2.1	2	5
Q22	The design of haptic feedback device must be changed	6.0	1.5	7	7
Q23	I had to pay attention to the cutaneous device instead of the task to feel the stimuli	2.6	2.2	1	2

First session values are means and SDs resulting from amputees S1 - S5. Second session results are individual score values of S4 and S5 (grasping force and contact information feedback convey using the CUFF in force modality and the VibroTactile). Unperformed feedback system modalities are indicated with dots.

TABLE VI

TABLE SHOWS THE RESULTS OF THE RECOGNIZING OBJECT TASK OF THE SECOND SESSION OF EXPERIMENT ACCOMPLISHED BY TWO SUBJECTS

	Recognizing Object Task			
	Execution Time [s]		N of errors	
Subject	CF	V	CF	V
S4	96	#	0	#
S5	17	103	0	1

specific trend, but it changes greatly between subjects, suggesting that the quality of the perception of the provided feedback is very subject-dependent.

Other important information coming out from the first session are the qualitative comments of subjects. The participants agreed on the fact that the usage of the CUFF in force modality could be useful for daily-living task execution, but the main comment was related to the provided stimulus amplitude, which resulted to be not wide enough to give an appropriate granularity of the feedback. The force feedback system was unable to effectively communicate different levels of force due to the inadequate mapping of residual current values. The chosen linear mapping and the two constraints resulted in a on-off activation pattern for the belt. Consequently, participants perceived either a strong grip, regardless of the object's rigidity or softness, or the release of the belt when the hand was opening. Based on these findings, one of the future developments we have decided to pursue is the implementation of a logarithmic mapping to enable participants to distinguish between various force levels. The CUFF in proprioception modality resulted useful mainly to understand if the hand was moving or not, for the proprioception feedback on how far the hand was opened.

Among all the tasks proposed in the Jebsen test, the Small Objects Lifting task is the one in which the use of the feedback strongly improved the results with all the feedback systems. On the other side, the worst task in terms of improvement given by the feedback device is the Stacking Checkers task, where an increase in the execution time can be noted for all amputees except one.

B. *Outcomes of the Second Experimental Session*

Regarding the Recognizing Object task the CUFF in force modality gave the best results both in time and success rate, with a great difference for the VibroTactile, which did not allow one of the two participants to complete the task. The results showed that both subjects found the stimuli provided by the VibroTactile device not to be disturbing and easy to understand (questions Q1 and Q2). Additionally, the maximum force exerted by the CUFF did not cause any pain, as stated in question Q6. However, they expressed a need for a stronger squeezing sensation. Therefore, in line with our objectives, we aim to enhance the mapping by exploring a non-linear approach. The presence of the feedback during the execution of the task was not disrupted (see Q21), meaning that the information provided by the device does not require mental workload to be followed and integrated with the use of the prosthesis. Both amputees underlined the necessity of a design iteration. The aspects where both the participants disagreed most regarding the utility of the provided feedback: subject A4 found out more benefits using the feedback during work with respect to the interaction with people. In contrast,

TABLE VII
TABLE SHOW THE RESULTS OF THE JEBSEN TEST IN SECONDS

	SHP Post training				SHP + Feedback			
Task	S1	S2	S4	S5	S1	S2	S4	S5
Simulated page turning	35,4	22,62	28,33	34,15	31,07	26,53	27,03	36,87
Lifting small object	82	124	61,7	124,77	59,5	77	58,2	62,12
Simulated feeding	98	67	25,82	34,69	30,57	109	22,4	31,94
Stacking checkers	47	297	69,7	84,82	92	179	74,6	#
Lifting light can	13,46	16,9	12,6	16,11	19,23	16,11	13	24,05
Lifting heavy can	15,3	16,3	10,5	13,35	13,94	13,8	14,6	17,69

TABLE VIII
TABLE SHOWS THE CHOSEN FEEDBACK FOR ALL THE PARTICIPANTS

Subject	Chosen Feedback	Motivation
S1	VibroTactile	Impressed to get a feedback when touching an object. The VibroTactile provided him with a clear information/feedback. He would have chosen the force feedback, if the signal / feedback had been clearer and the range larger
S2	CUFF in Proprioception modality	The clearest and most helpful information for the use of the prosthetic hand
S3	VibroTactile	He would have chosen the force feedback, if the signal / feedback had been clearer and the range larger
S4	CUFF in Force Modality + VibroTactile	The most potential has the combination Force + VibroTactile, but he would need time to practice and to understand the feedback information
S5	VibroTactile	The CUFF was disturbing

The motivations for the choices were also presented.

subject A5 found the use of the feedback more useful during interaction with people, to work or activity of daily living.

VI. LIMITATIONS AND FUTURE WORKS

This work reports an investigation of different feedback modalities to find out which is the most effective solution. Despite we can deduce some useful information regarding the user requirements and needs, we are aware that our approach presents some limitations, which we would like to address in future work. The main aspects we would like to further develop are: 1) the cohort size, 2) the hardware architecture. Regarding the first aspect, leading an extensive campaign with limb loss participants, supported by statistical analysis, could increase the information about feedback preferences and types of stimuli required. A more in-depth analysis of the CUFF device and its mapping strategy (aspect 2), could improve the reduced capacity of the force feedback to convey squeezing stimuli. The adoption of a non-linear mapping, like a logarithmic one, could be a better choice since it can be used to obtain an amplifying effect over the mapped domain, and convey to the user a more effective squeezing sensation. Moreover, the miniaturization of the device with target integration inside the prosthesis could improve the control of the prostheses during work, daily living activities, and social interaction. Future works could include the usage of feedback with a different type of robotic hand. Furthermore, we would also like to conduct a study on the potential delay introduced in the system by the devices, comparing it to the existing delay of the EMG system.

This could suggest that the new feedback modalities are effective in delivering information without the use of visual feedback but probably, longer training is required to familiarize with the tactile stimulation. Future investigations could include performance comparisons between the use of visual feedback plus a vibration or force feedback concerning the visual feedback only.

VII. CONCLUSION

In this work, we presented a comparison between the use of vibration, skin stretch and multi modal stimuli. The target was to understand which feedback modality was preferred by limb loss participants for better control of the prosthetic hand without the use of visual feedback. Notwithstanding the small number of included amputees for the collection of further information, the results of the experiments showed that the single modality feedback is preferred to the combination of multiple feedback. The combination of different modalities do not improve the performance during the task execution and the stimuli were difficult to understand. On the other hand, the participants found the grasping force and the roughness feedback helpful to accomplish the task of daily activities, suggesting an easy integration by the user of the device. As said previously, the choice of feedback with respect to the other was very subject- and task- dependent. Finally, the qualitative evaluation underlines that prosthetic solutions could be improved where the subject can choose the type of feedback to integrate into his prosthesis.

ACKNOWLEDGMENT

The authors would like to thank the volunteers for their efforts and patience during the study; Wiebke von Kloth from John & Bamberg for physiotherapeutically trainings with the subjects; Benjamin Fleischer-Lück, Juliana Clavijo Rincón, and Carina Gempfer for assistance in data collection and processing; Cristiano Petrocelli and Mattia Poggiani for the hardware and software assistance.

REFERENCES

[1] J. B. V. Erp and A. Toet, "Social touch in human–computer interaction," *Front. Digit. Humanities*, vol. 2, 2015, Art. no. 2.

[2] C. Piazza, G. Grioli, M. Catalano, and A. Bicchi, "A century of robotic hands," *Annu. Rev. Control, Robot., Auton. Syst.*, vol. 2, pp. 1–32, 2019.

[3] H. Culbertson, S. B. Schorr, and A. M. Okamura, "Haptics: The present and future of artificial touch sensation," *Annu. Rev. Control, Robot., Auton. Syst.*, vol. 1, pp. 385–409, 2018.

[4] E. Biddiss, D. Beaton, and T. Chau, "Consumer design priorities for upper limb prosthetics," *Disabil. Rehabil.: Assistive Technol.*, vol. 2, no. 6, pp. 346–357, 2007.

[5] F. Cordella et al., "Literature review on needs of upper limb prosthesis users," *Front. Neurosci.*, vol. 10, 2016, Art. no. 209.

[6] C. Pylatiuk, S. Schulz, and L. Döderlein, "Results of an internet survey of myoelectric prosthetic hand users," *Prosthetics Orthotics Int.*, vol. 31, no. 4, pp. 362–370, 2007.

[7] J. W. Sensinger and S. Dosen, "A review of sensory feedback in upper-limb prostheses from the perspective of human motor control," *Front. Neurosci.*, vol. 14, 2020, Art. no. 345.

[8] K. Kim, "A review of haptic feedback through peripheral nerve stimulation for upper extremity prosthetics," *Curr. Opin. Biomed. Eng.*, vol. 21, 2022, Art. no. 100368.

[9] S. J. Bensmaia, D. J. Tyler, and S. Micera, "Restoration of sensory information via bionic hands," *Nature Biomed. Eng.*, vol. 7, pp. 443–455, 2020.

[10] S. Dosen, C. Prahm, S. Amsüss, I. Vujaklija, and D. Farina, "Prosthetic feedback systems," in *Bionic Limb Reconstruction*. Berlin, Germany: Springer, 2021, pp. 147–167.

[11] M. N. Nemah et al., "A review of non-invasive haptic feedback stimulation techniques for upper extremity prostheses," *Int. J. Integr. Eng.*, vol. 11, no. 1, 2019, Art. no. 3573.

[12] B. Stephens-Fripp, G. Alici, and R. Mutlu, "A review of non-invasive sensory feedback methods for transradial prosthetic hands," *IEEE Access*, vol. 6, pp. 6878–6899, 2018.

[13] J. S. Schofield, K. R. Evans, J. P. Carey, and J. S. Hebert, "Applications of sensory feedback in motorized upper extremity prosthesis: A review," *Expert Rev. Med. Devices*, vol. 11, no. 5, pp. 499–511, 2014.

[14] N. Risi, V. Shah, L. A. Mrotek, M. Casadio, and R. A. Scheidt, "Supplemental vibrotactile feedback of real-time limb position enhances precision of goal-directed reaching," *J. Neuriophysiol.*, vol. 122, no. 1, pp. 22–38, 2019.

[15] V. A. Shah, M. Casadio, R. A. Scheidt, and L. A. Mrotek, "Spatial and temporal influences on discrimination of vibrotactile stimuli on the arm," *Exp. Brain Res.*, vol. 237, no. 8, pp. 2075–2086, 2019.

[16] F. Clemente, M. D'Alonzo, M. Controzzi, B. B. Edin, and C. Cipriani, "Non-invasive, temporally discrete feedback of object contact and release improves grasp control of closed-loop myoelectric transradial prostheses," *IEEE Trans. Neural Syst. Rehabil. Eng.*, vol. 24, no. 12, pp. 1314–1322, Dec. 2016.

[17] P. E. Patterson and J. A. Katz, "Design and evaluation of a sensory feedback system that provides grasping pressure in a myoelectric hand," *J. Rehabil. Res. Dev.*, vol. 29, no. 1, pp. 1–8, 1992.

[18] C. Tejeiro, C. E. Stepp, M. Malhotra, E. Rombokas, and Y. Matsuoka, "Comparison of remote pressure and vibrotactile feedback for prosthetic hand control," in *Proc. IEEE 4th RAS EMBS Int. Conf. Biomed. Robot. Biomechatronics*, 2012, pp. 521–525.

[19] K. Bark, J. W. Wheeler, S. Premakumar, and M. R. Cutkosky, "Comparison of skin stretch and vibrotactile stimulation for feedback of proprioceptive information," in *Proc. Symp. Haptic Interfaces Virtual Environ. Teleoperator Syst.*, 2008, pp. 71–78.

[20] F. Barontini, M. Catalano, S. Fani, G. Grioli, M. Bianchi, and A. Bicchi, "The cuff, clenching upper-limb force feedback wearable device: Design, characterization and validation," 2023, *arXiv:2306.10413*.

[21] S. Fani, K. D. Blasio, M. Bianchi, M. G. Catalano, G. Grioli, and A. Bicchi, "Relaying the high-frequency contents of tactile feedback to robotic prosthesis users: Design, filtering, implementation, and validation," *IEEE Robot. Automat. Lett.*, vol. 4, no. 2, pp. 926–933, Apr. 2019.

[22] S. Casini, M. Morvidoni, M. Bianchi, M. Catalano, G. Grioli, and A. Bicchi, "Design and realization of the cuff-clenching upper-limb force feedback wearable device for distributed Mechano-Tactile stimulation of normal and tangential skin forces," in *Proc. IEEE/RSJ Int. Conf. Intell. Robots Syst.*, 2015, pp. 1186–1193.

[23] D. Mura, M. Barbarossa, G. Dinuzzi, G. Grioli, A. Caiti, and M. G. Catalano, "A soft modular end effector for underwater manipulation: A gentle, adaptable grasp for the ocean depths," *IEEE Robot. Automat. Mag.*, vol. 25, no. 4, pp. 45–56, Dec. 2018.

[24] K. J. Kuchenbecker et al., "Verrotouch: High-frequency acceleration feedback for telerobotic surgery," in *Proc. Haptics: Gener. Perceiving Tangible Sensations: Int. Conf.*, 2010, pp. 189–196.

[25] S. Choi and K. J. Kuchenbecker, "Vibrotactile display: Perception, technology, and applications," *Proc. IEEE*, vol. 101, no. 9, pp. 2093–2104, Sep. 2013.

[26] R. S. Johansson et al., "Responses of mechanoreceptive afferent units in the glabrous skin of the human hand to sinusoidal skin displacements," *Brain Res.*, vol. 244, no. 1, pp. 17–25, 1982.

[27] M. G. Catalano, G. Grioli, A. Serio, E. Farnioli, C. Piazza, and A. Bicchi, "Adaptive synergies for a humanoid robot hand," in *Proc. IEEE/RAS 12th Int. Conf. Humanoid Robots*, 2012, pp. 7–14.

[28] M. Santello, M. Flanders, and J. F. Soechting, "Postural hand synergies for tool use," *J. Neurosci.*, vol. 18, no. 23, pp. 10105–10115, 1998.

[29] L. Resnik et al., "Development and evaluation of the activities measure for upper limb amputees," *Arch. Phys. Med. Rehabil.*, vol. 94, no. 3, pp. 488–494, 2013.

[30] M. E. Hackel, G. A. Wolfe, S. M. Bang, and J. S. Canfield, "Changes in hand function in the aging adult as determined by the Jebsen test of hand function," *Phys. Ther.*, vol. 72, no. 5, pp. 373–377, 1992.

[31] D. Prattichizzo, F. Chinello, C. Pacchierotti, and M. Malvezzi, "Towards wearability in fingertip haptics: A 3-DoF wearable device for cutaneous force feedback," *IEEE Trans. Haptics*, vol. 6, no. 4, pp. 506–516, Oct.–Dec. 2013.

[32] K. Kim and J. E. Colgate, "Haptic feedback enhances grip force control of sEMG-controlled prosthetic hands in targeted reinnervation amputees," *IEEE Trans. Neural Syst. Rehabil. Eng.*, vol. 20, no. 6, pp. 798–805, Nov. 2012.

Open Access provided by 'Istituto Italiano di Tecnologia' within the CRUI CARE Agreement