Published in final edited form as:

J Neural Eng. 2016 February ; 13(1): 016001. doi:10.1088/1741-2560/13/1/016001.

Sensory feedback by peripheral nerve stimulation improves task performance in individuals with upper limb loss using a myoelectric prosthesis

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Abstract

Objective—Tactile feedback is critical to grip and object manipulation. Its absence results in reliance on visual and auditory cues. Our objective was to assess the effect of sensory feedback on task performance in individuals with limb loss.

Approach—Stimulation of the peripheral nerves using implanted cuff electrodes provided two subjects with sensory feedback with intensity proportional to forces on the thumb, index, and middle fingers of their prosthetic hand during object manipulation. Both subjects perceived the sensation on their phantom hand at locations corresponding to the locations of the forces on the prosthetic hand. A bend sensor measured prosthetic hand span. Hand span modulated the intensity of sensory feedback perceived on the thenar eminence for subject 1 and the middle finger for subject 2. We performed three functional tests with the blindfolded subjects. First, the subject tried to determine whether or not a wooden block had been placed in his prosthetic hand. Second, the subject had to locate and remove magnetic blocks from a metal table. Third, the subject performed the Southampton Hand Assessment Procedure (SHAP). We also measured the subject's sense of embodiment with a survey and his self-confidence.

Main results—Blindfolded performance with sensory feedback was similar to sighted performance in the wooden block and magnetic block tasks. Performance on the SHAP, a measure of hand mechanical function and control, was similar with and without sensory feedback. An embodiment survey showed an improved sense of integration of the prosthesis in self body image with sensory feedback.

Significance—Sensory feedback by peripheral nerve stimulation improved object discrimination and manipulation, embodiment, and confidence. With both forms of feedback, the blindfolded subjects tended toward results obtained with visual feedback.

Keywords

electrical stimulation; electrodes; peripheral nerves; implanted nerve stimulation electrodes; neural prostheses; sensory feedback; sensation

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Introduction

The sense of touch is essential to the human experience. Touch is fundamental for adroit manipulation of objects and social interactions [1, 2]. The loss of sensation is a devastating consequence of upper extremity (UE) limb-loss. Myoelectric prostheses are not yet able to restore sensation. Without tactile and proprioceptive sensation, individuals with limb-loss rely on visual and auditory cues for task performance. The prosthesis is disassociated from the sense of self and perceived as an artificial tool independent from the body. Without sensation, prosthesis users often have difficulty gauging the position of the prosthesis in space as the phantom hand and the prosthesis are often not aligned [3]. Without ability to feel an object in the prosthesis grasp, users have a significant decrease in confidence manipulating objects with a prosthesis compared to normal [4]. Therefore, sensation is important for improved control of the prosthetic limb [5, 6], incorporation of the prosthesis into one's self-image [4, 7], and for the reduction of phantom pain [4, 8].

Existing prostheses provide minimal or no sensory feedback. Body-powered UE prostheses, used by approximately 30% of individuals with limb loss [9], provide the most sensory feedback. Feedback from tension developed on the system's cables is sensed by the user and is proportional to the pressure the system is applying to an object. However, the feedback is not a direct sensation of pressure at the end of the prosthesis. Further, it only conveys a single estimate of the entire grip pressure, but does not provide information about individual fingers' contact with objects.

Approximately 43% of individuals with limb loss use myoelectric prostheses [9], which use muscle contraction in the residual limb to control the position of the hand. While myoelectric prostheses have improved functional grip patterns and overall cosmesis compared to body-powered prostheses, they lack tactile sensory feedback, forcing users to rely entirely on visual and auditory cues. This lack of sensation and reliance on alternative sensory input is one of the primary complaints associated with myoelectric prostheses [10, 11].

Multiple strategies exist to supplement myoelectric prosthesis users with feedback. Sensory substitution provides surrogate sensation, typically vibration, somewhere on the body. The substituted sensation's intensity is proportional to the measured grasp pressure or to prosthetic hand position. Vibrotactile feedback requires modal interpretation about vibration that encodes pressure and spatial interpretation because sensations occur at locations on the body quite removed from where pressure is actually applied to the prosthesis. Sensory substitution has improved prosthetic control in laboratory settings [6, 12], but has not been widely adopted, possibly because the sensations are not natural, thus requiring additional effort to interpret the feedback. Even with sensory substitution, visual feedback was required to accurately assess hand aperture [13].

The ideal sensory feedback mechanism would be one that produces the same perception as the natural limb. In the 1970s and 1980s, researchers attempted to produce various sensations with extraneural cuff or intraneural fine wire electrodes [14–18]. Typically,

subjects reported paresthesia, vibration, or pulsing spread across the phantom hand. More recently, intrafascicular electrodes have produced additional sensations of touch, pressure, and movement at more punctate locations [19–24] but the stimulation thresholds increased over the acute 28 day study and complete loss of ability to produce sensation was reported as early as 10 days [22]. Paresthesia was associated with 30%–50% of the stimulating channels. Nonetheless, the restored sensation allowed a subject to correctly identify three different objects using sensory onset timing, illustrating the value of sensory feedback on functional control [24].

Using extraneural cuff electrodes that are effective for motor recruitment in humans [25–29] and animals [30–32], combined with novel neural stimulation paradigms in which the stimulus is time dependent [4], we have produced stable, paresthesia-free sensations [33]. Our subjects are now 40 and 32 months post-implant. In these two subjects, this study investigates the effects of sensory restoration on stereognosis, performance of functional tasks, subject confidence, and incorporation of the prosthesis into the user's sense of self.

Methods

We implanted two subjects with a UE amputation with peripheral nerve stimulation systems to restore sensory feedback (figure 1(a)). The details of this system are in [4] and [33]. Briefly, cuffs were implanted around three nerves in the forearm of subject S1 and in the upper arm of subject S2 (table 1). The nerves were the median, ulnar, and radial nerves. Cuffs were either an 8-channel flat interface nerve electrode (FINE) [34] or a 4-channel self-sizing spiral nerve cuff electrode [31] (Ardiem Medical, Indiana, PA). We routed percutaneous lead wires from the implanted cuffs to an exit site in the lateral arm. Each implant only required an outpatient surgery, performed at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC), approved by the LSCDVAMC Institutional Review Board, and studied under an FDA regulated Investigational Device Exemption. Surgery required 4–6 h for nerve dissection, lead tunneling, percutaneous lead positioning, suture, and follow-up x-ray. Cuff implantation required less than one minute per cuff. Following surgery, stimulation did not begin until after 3 weeks, during which the inflammation matured and cuffs stabilized around the nerves. S1 has been implanted for more than 3.3 years and S2 for more than 2.8 years. Over this time, S1 and S2 have participated in over 60 and 40 study sessions, respectively, marking the longest-running chronic multi-contact implant study to assess sensory restoration. The proximal location of the electrodes in S2 is the most proximal implant of multi-contact nerve cuff electrodes to restore sensation. Sensations, thresholds, and system impedance in these two subjects have remained stable through the duration of the implant [4, 33].

A custom, programmable stimulator, the UECU, delivered stimulus to one or more contacts inside the cuffs around the subject's nerves via the percutaneous leads. The stimulator delivered waveforms with a customized pulse width (PW), pulse amplitude (PA), and interpulse interval. The stimulus waveform has been found to alter the percept. Details of the stimulus and resulting percepts have been published [4]. Briefly, we selected the lowest PA that elicited a sensation at the longest PW (255 μ s) at 100 Hz. We selected a PW between

10% and 50% above the threshold PW to serve as a supra-threshold level, the ‘operating level’. We modulated the PW between the operating level and 5 μ s above the operating level using a 1 Hz sinusoidal envelope, a technique we developed known as ‘small scale offset’ modulation. Percepts varied and included sensations of pressure, tapping, vibration, moving touch, and paresthesia. For this study, the stimulus produced a sensation of pressure, which was, at times, accompanied by paresthesia. Additionally, S2 perceived kinesthesia, flexion of D3, whereas S1 did not perceive kinesthesia. Subjects received electrical stimulation for 2–4 sessions per month. Each session typically lasted 5–6 h, with breaks.

During some of these sessions, functional assays were performed. To assess functional outcomes, we instrumented the prosthetic hand with low-profile force sensors (Tekscan FlexiForce A201, Boston, MA) mounted over the pads of the thumb (D1), index (D2), and middle (D3) fingers (figure 1(b)). The sensors operated linearly within a range of 0–4.4 N. Additionally, a bend sensor (A.G.E., New York, NY) measured the hand aperture, i.e. the angle between D1 and D2.

Prior to experiments, we calibrated the force sensors by applying a range of weights and the bend sensor by having the subject close the prosthetic hand to fixed apertures. If a non-linear calibration curve was observed, we replaced the sensor. When replacing sensors, new sensors were placed prior to the start of an experiment. The force sensors on D1, D2, and D3 regulated the stimulus delivered to specific contacts in the FINE on the median nerve. As force applied to these sensors increased, the frequency of stimulation on the channels associated with each sensor increased linearly between 10 and 125 Hz [4]. The bend sensor regulated the stimulus frequency as the hand closed and was subject-specific. The bend sensor controlled stimulus on the channel that produced a kinesthetic percept in S2. With no kinesthetic percept in S1, we elicited a sense of pressure on the thenar eminence as a form of sensory substitution, similar to physical tactor arrays. Sensor sampling rate was 20 Hz. The subjects reported no distinguishable delay between physical sensor contact and the perceived sensation. The subjects used their normal myoelectric hand, standard myoelectric control settings, and prosthetic use strategies for all tests. The EMG amplitude detected by the prosthetic’s surface electrodes controls the speed of hand opening and closing. Stimulation in S1 does not result in motor recruitment, which is preferable for individuals using a myoelectric prosthesis else it may interfere with myoelectric control and adulterate intended movements or initiate unintended movements. S2 has exhibited motor recruitment on a small number of contacts, but the muscle contraction has not interfered with his normal myoelectric control. Therefore, functional tests were focused on assessing the impact of adding sensory feedback on a typical, widely-used 1-DOF prosthetic hand.

Functional tests

We administered three tests to assess the effect of sensory feedback. The first test quantified the subject’s ability to determine whether a wooden block had been placed between D1 and D2/D3 during a pinch grip using a forced-choice object detection test (ODT). The wooden block measured 2.54 cm on each side. Both D2 and D3 sensors contacted the block as the hand closed because they travel together on the Ottobock hand and the block was wider than either finger. The ODT contained 20 presentations: 10 with a block, 10 without. Block

presentation was randomized. The blindfolded subject indicated if he believed a block had been placed in his hand and we recorded the percentage of correct responses. We administered the ODT under four conditions: (1) without sensory feedback; (2) with pressure feedback only; (3) with hand aperture feedback only; (4) with both pressure and aperture feedback. We tested each condition three times. Before each test, subjects practiced up to 10 min to familiarize themselves with the sensation they would experience during the test. We blindfolded the subject and occluded hearing by playing white noise through headphones covered by noise-canceling ear muffs during tests but not during practice. We also administered the ODT on the intact hand while visually and audibly occluded and on the prosthesis under typical use conditions. We later abandoned these two scenarios because the subjects performed these tests perfectly, which was not surprising because neither had tactile or visual deficits and had expert control of their myoelectric prosthesis. Additionally, we asked the subject to describe his chosen technique to complete the task and what feedback, if any, he relied on. S1 underwent experiments 160, 421, and 750 days post-implant, resulting in a total of 560 observations. S2 underwent experiments 123, 155, and 517 days post-implant, resulting in a total of 600 observations.

The second test, a modification of the standardized box and blocks test (mBB), quantified the subject's ability to locate and move a block. In this test, the blindfolded subject stood in front of a $34.3 \times 40.6 \times 6.3 \text{ cm}^3$ ($L \times W \times H$) metal platform that was resting on a table. The subject probed the platform by tapping its surface to locate blocks, the same used for the ODT, which were randomly positioned on the metal platform. We attached a small neodymium magnet ($0.32 \times 0.64 \times 0.16 \text{ cm}^3$) to each block using tape measuring 0.55 mm thick. The force required to lift the block and magnet off the table averaged $0.27 \pm 0.04 \text{ N}$. The magnet prevented the subject from easily knocking the block off the test platform by providing a small $0.10 \pm 0.04 \text{ N}$ resistance. The magnetic force decreased as the distance from the magnet to the platform increased and was well-described by the equation $F = -1.01 + (1.00 + 0.98/(x + 0.33))$, where x was the distance between the magnet and platform and F was the magnetic force in Newtons. The subject perceived a block when the prosthetic finger tips were stopped at a higher elevation. Once the subject located a block, he had to pick it up and remove it from the metal platform. The subject removed as many blocks as possible, up to 10, from the metal platform within the allotted 2 min. The subject assumed a comfortable posture and used his intact hand for additional balance if needed by placing it on the table without touching the metal platform. At the start of the test, the subject rested his prosthetic hand on the table to the right of the metal platform.

During each mBB test, we recorded the number of blocks that were removed, the number of failures, and the number of corrections. We defined failures as: (1) an attempt to move a block when one was not in the hand; (2) dropping a block; (3) pushing the block off the platform. We defined corrective actions as: (1) the subject closed his hand, possibly moving it toward the drop zone, but opened it and returned to get the block again because there was no block in the grasp; (2) the subject returned his hand to the drop zone again because he did not release the block. We administered the mBB three times under each of the same four conditions used for the ODT. S1 underwent experiments 160, 421, and 750 days post-implant, resulting in a total of 29 trials. S2 underwent experiments on 123, 155, and 517 days post-implant, resulting in a total of 30 trials.

The Southampton Hand Assessment Procedure (SHAP) is a validated assessment of upper limb function [35] that has been applied to myoelectric prosthetics [36]. The SHAP requires manipulation of abstract shapes and household objects. The duration of time to complete each task is used to calculate an Index of Functionality (IoF), which quantifies the prosthetic dexterity of the subject [35] and is used to assess a person's ability to perform Activities of Daily Living (ADLs) involving different grips. We administered the full SHAP test post-implant first without supplemental sensory feedback then with both pressure and aperture feedback. The subject was not blindfolded. We also administered the SHAP prior to surgical implant. The SHAP was not designed to assess sensory feedback, but it does serve as a standardized assessment within prosthetics. As such, we administered the SHAP to assess whether the process employed to provide sensory feedback reduced or otherwise interfered with myoelectric control. Both subjects performed the SHAP prior to surgery and then again 358 (S1) and 124 (S2) days post-implant.

Subject confidence

Immediately prior to and immediately after each ODT and mBB test, the subject gauged his confidence on how well he thought he would perform or believed he had performed the test, respectively. The subject reported his self-confidence on a self-selected scale, either ranging from 0% to 100% or an integer between 0 and the number of blocks being presented during the test.

Embodiment survey

We administered an adapted sense of self questionnaire (table 2) [7, 37] at the end of the day immediately following the last functional test to evaluate the subject's incorporation of the prosthesis into a sense of self during functional tasks. The questionnaire was originally used to evaluate incorporation of a fake hand into sense of self during a Rubber Hand Illusion task [37] and has been adapted for evaluating embodiment of a prosthetic limb in amputees by Marasco et al [7]. We adapted the embodiment questionnaire for functional tasks by replacing the phrase 'touch of the investigator' with 'touch of the objects' (manipulated during functional tasks). The subject scored each of the questionnaire's nine statements (table 2) between -3 and +3 corresponding to strongly disagree and strongly agree, respectively. Three statements correlate with embodiment, while 6 evaluate task compliance and suggestibility. Statements were presented in random order.

Statistics

We applied a Test of One Proportion to ODT results with a null hypothesis that the ratio of successes to failures was equal to 0.5 versus the alternative hypothesis that the proportion was not equal to 0.5. We conducted ANOVAs with a Bonferroni correction for multiple comparisons to determine if feedback type, observation number, or test date significantly affected success rate (number of successes per number of possible successes) or subject confidence. For mBB tests, we conducted an ANOVA using a Bonferroni correction for multiple comparisons to determine if feedback type, observation number, or test date significantly affected success rate, number of failures, number of corrections, or subject confidence. We analyzed subject data independently except for when subjects were being directly compared, in which case the ANOVA included both subjects. We conducted a

Pearson correlation between the subject's confidence level and success rate for both the ODT and mBB tests, as well as between the confidence level and the number of corrections and number of failures on the mBB test. We used a paired t-test to compare SHAP results with and without sensory feedback and pre- to post-test subject confidence. We used a two-sided t-test to compare embodiment results with and without sensory feedback. In all cases, $p < 0.05$ was considered significant.

Results

Neither subject experienced complications due to the surgery, implant, or percutaneous leads. The subjects have had no complications due to infection over the 1568 percutaneous-lead-months, calculated as the product of the total number of percutaneous leads and the duration of time the leads have been implanted.

ODT

When presented with a forced-choice test to determine whether a wooden block had been placed between D1 and D2/D3 during a pinch grip, both subjects performed similarly without feedback ($p = 0.736$), with both forms of feedback ($p = 0.059$), or with pressure-only feedback ($p = 0.190$, figure 2). S2 performed significantly better than S1 when only the bend sensor was used ($p < 0.001$). Neither time nor order of observation had a significant effect.

Both subjects tended to perform best when provided with both pressure and aperture perception, achieving an accuracy of $89\% \pm 9\%$ and $96\% \pm 4\%$ in S1 and S2, respectively, which was significantly better than performance without sensory feedback ($p < 0.001$). Both subjects performed slightly better than 50% chance even without sensory feedback (Test of 1 Proportion; S1: $p = 0.030$; S2: $p = 0.007$). The type of feedback provided significantly affected the performance of S1 ($p = 0.042$) and S2 ($p < 0.001$). Aperture perception significantly improved performance in S2 ($p < 0.001$). Both subjects always identified the presence of a block with their intact hand during initial tests.

Performance significantly improved on the ODT when pressure feedback was provided ($p = 0.020$). When pressure feedback was added, the subjects did not rely solely on the transmitted vibration of the motor. Instead, they also relied on the onset of the sensation of pressure. If the sensation of pressure occurred 'sooner', there was a block in the hand. Thus, decisions were still made based on timing, but now the cue to mark the onset of finger-finger or finger-object collision was more evident. Similar strategies were used by a subject in another study to distinguish rigid objects [24].

Both subjects' confidence significantly increased with the addition of sensory feedback ($p < 0.001$). Confidence and success rate had a significant and moderately strong positive linear correlation ($\rho = 0.81$, $p < 0.001$). Without feedback, the subjects believed they would respond or had responded correctly for $35\% \pm 8\%$ of the observations. Confidence increased to $84\% \pm 6\%$ when both pressure and hand aperture feedback were presented. Confidence fell between these extremes when only one form of feedback was presented. For all tests, confidence levels did not differ significantly between subjects. Similarly, confidence did not

differ prior to and following each test (paired t-test, $p = 0.179$), suggesting neither subject gained additional information during the test.

mBB

A supplemental video illustrates an mBB test (stacks.iop.org/JNE/13/1/016001/mmedia). Both subjects removed a similar number of blocks ($p = 0.062$) and exhibited a similar number of failures ($p = 0.977$) and corrections ($p = 0.080$) when blindfolded and audibly occluded. Both subjects removed 5–6 blocks while making 0–1 error, resulting in approximately 0.1 errors per success when both pressure and aperture feedback were provided. Both subjects removed 2–3 blocks while making 6–7 errors (figure 3), resulting in approximately 2.5 errors per success without sensory feedback. Thus, sensory feedback decreased the error-to-success ratio by 96%. The type of sensory feedback significantly affected these metrics in both subjects ($p < 0.001$). The addition of one form of feedback always resulted in a success rate that was greater than or not statistically different from the success rates obtained during tests without feedback. Restoring both forms of feedback always resulted in a significantly greater success rate ($p < 0.05$). Similarly, the number of failures was reduced with one form of feedback and significantly reduced with both forms of feedback ($p < 0.001$). Both subjects removed all blocks from the platform in less than two minutes when (1) visually and audibly occluded but using the intact hand or (2) when using the prosthetic hand with visual and auditory feedback. Time did not influence subject performance on either test.

The subjects believed they would remove 4.0 ± 0.9 blocks without feedback. Confidence significantly increased by 53% to 6.1 ± 0.8 blocks ($p = 0.006$) with both pressure and hand aperture feedback. As with the ODT, subject confidence did not differ significantly prior to and immediately following the mBB test (paired t-test, $p = 0.078$), suggesting that no additional knowledge of performance was gained during the test. Confidence significantly and positively correlated with the number of corrections ($\rho = 0.46$, $p = 0.029$). Confidence positively correlated with success rate ($\rho = 0.33$, $p = 0.12$). Confidence significantly and negatively correlated with number of failures ($\rho = -0.61$, $p = 0.002$).

SHAP

For post-implant SHAP tests, supplementing the subject with sensory feedback improved performance (table 3). S1's IoF score improved 22.4% from 58 to 71, which was significant ($p = 0.026$). S2 had a non-significant 7.8% improvement in IoF score from 51 to 55. Without feedback, a paired t-test of the 26 SHAP tasks showed no significant difference between pre and post-implant assessments ($0.182 \leq p \leq 0.937$).

Embodiment

Both subjects indicated a greater sense of embodiment with sensory feedback according to embodiment questionnaire ratings (figure 4). Subjects significantly agreed with embodiment statements more than control statements when provided with sensory feedback ($p < 0.001$). Subjects also agreed with embodiment statements when sensory feedback was provided significantly more than when sensory feedback was not provided ($p = 0.002$). Without sensory feedback, agreement with embodiment statements and control statement did not

differ significantly ($p = 0.348$). Both subjects responded similarly and their results were pooled.

Discussion

Functional tests

Despite differences in the implant location between the subjects, they performed similarly, particularly when the test was administered without any sensory feedback or when it was administered with both pressure and aperture feedback. The ODT and mBB tests provide insight into how each subject uses sensory feedback. During the ODT tests without supplemental sensory feedback, accuracy was only slightly better than the 50% chance of success. When asked how a decision was made, both subjects indicated they relied on the time required to open and close the hand as determined by the small amount of vibration they felt through the socket as the motor operated the hand.

We did not expect pressure feedback alone to significantly improve outcomes because the response of the force sensors pushing against each other when there was no block in the hand was not distinguishable from the response when the force sensors encountered the wooden block. When provided with aperture feedback alone or in combination with pressure feedback, both subjects reported that they knew if there was a block in their hand because they knew if their hand was fully closed or partly open. While there is not enough data to prove the connection, there is strong correlation between the success rate using the bend sensor and the presence of a true kinesthetic percept. In contrast to S2, S1 did not have a kinesthetic percept and relied on timing and the intensity of pressure mapped to his thenar eminence based on the angle of the bend sensor. S1's performance with the bend sensor did not differ significantly from his performance with the force sensors, which could be because S1 only perceived a sensation of pressure whether it was pressure or aperture information being conveyed, a form of sensory substitution. It is likely that the two subjects used two different strategies to distinguish a block's presence. The results suggest that a sensation of the hand's position is sufficient to distinguish at least two sizes and, therefore, the presence or absence of an object, assuming a sufficiently tight grip and large enough object.

The improvement in performance with sensory feedback may have occurred for different reasons in the two subjects. S1's accuracy may have increased due to an additional channel of feedback pressure. S2's accuracy with both forms of feedback did not differ significantly from his accuracy with only the bend sensor, suggesting that the pressure component of the feedback contributed minimally to his performance. Indeed, S2 reported that the sensation of pressure made it harder to focus on the sensation of kinesthesia and, in contrast to S1, S2 did not rely on the timing of sensation onset when provided with both forms of feedback.

The ODT test served as the subcomponent of the MBB in which the subject identified if he had successfully squeezed a block. An accurate ODT is necessary but not sufficient to achieve a high success rate on the MBB. The MBB increases the difficulty level by requiring the subject to locate and remove the block. Similar trends occurred during both ODT and mBB tests. Restored pressure sensation alone increased successes and decreased failures on the mBB. The subjects decided if a block was present based on the sensation onset timing.

As with the ODT, a sensation of pressure alone frequently confounded the subject as it was not clear to the subject if he was squeezing an object or squeezing the fingers of the prosthetic together.

As with the ODT, use of the bend sensor alone produced different results in S1 and S2. Kinesthetic feedback in S2 significantly increased success rate and reduced failures when compared against mBBs with pressure sensation alone. Success rate and number of failures did not significantly differ for S2 when he was provided with both forms of feedback versus aperture only. S1, however, exhibited better outcomes using pressure feedback than when using hand aperture feedback.

With sensory feedback, subjects corrected their grasp on the mBB tests, which required the subjects to operate within and transition between four states: (1) locating the block, (2) grasping the block, (3) removing the block, and (4) releasing the block. Without feedback, the subjects rarely corrected for an empty grip. An empty grip often occurred because the block was pushed aside or the hand placement during state transition resulted in the block being outside of the prosthetic pinch.

Both subjects' SHAP score improved when provided with sensory feedback. The greatest improvement was observed in Power, Tip and Lateral grip tasks, consistent with the fingertip placement of force sensors and the fact that the 1-DOF myoelectric prosthesis was limited to a single power/tip grip pattern. Sensory feedback will likely demonstrate a greater improvement in SHAP scores with a more dexterous prosthesis. We conducted the SHAP with sensory feedback after the SHAP without sensory feedback. It is likely that learning contributed to improvements in performance. Interestingly, both subjects reported that they did not focus on tactile feedback but, instead, relied entirely on vision during these speed-based assessments. Randomization and inclusion of more subjects are required to assess whether the feedback affected control, perhaps, at a subconscious or reflexive level. This is a very tantalizing prospect and will be subject of further studies. Importantly, the stimulus did not interfere with or adversely affect the subject's ability to control his myoelectric prosthesis. Similarly, comparison between pre-and post-surgical trials show that the surgery, surgical implants, electrical nerve stimulation, percutaneous leads, or the additional time working in the research program did not degrade the performance results. Essentially, the addition of the neural interface did not show any adverse events related to function or stability of using the myoelectric prosthesis.

Both subjects performed well in this study when provided with both forms of sensory feedback. In fact, during three trials, S1's mBB outcomes were not statistically different from those he achieved while sighted, but without sensory feedback. S2's ODT outcomes were nearly perfect. Interestingly, even with the minimal 5–10 min of training that the subjects received prior to the ODT and mBB tests, the outcomes trended toward intact hand performance. The fact that little training time was required suggests that the sensations, either their location, their mode, or both, were intuitive. The subjects provided further evidence that the sensations were intuitive. On multiple occasions, the subjects stated that the sensations felt natural and familiar. The subjects provided analogies to describe sensation, such as grasping the lid of a bottle. Nonetheless, the metrics in this study—

success rate, number of failures, number of corrections, and confidence—do not achieve the same levels of performance by the intact hand while the subject was blindfolded. Further training with a take-home system that allows the subjects to become more familiar with the nuances of their sensory feedback is expected to result in outcomes that approach those obtained with the intact hand using the metrics discussed in this study.

While the additional weight of the block due to the magnet may have provided some measure of feedback at small block-to-platform distances, it would have done so in all trials. Thus, the magnets are not expected to alter the comparisons between the different trials. On one occasion, S1 reported that he thought he could detect the *weight* of the block, either due to the weight of the block itself or the additional force created by the magnet. If a subject were able to detect the wooden block based on weight, we might expect to see corrective actions on the mBB even without tactile feedback. Indeed, S1 did make corrections (figure 3(e)) even without stimulus feedback. However, during other sessions S1 did not make corrective actions and reported being unable to detect the blocks. S2 always reported being unable to detect the blocks and never made corrective actions when sensory feedback was not provided. These data suggest that the combined weight of the block and force of the magnet relative to the weight of the prosthesis and arm falls below, but possibly near, the just noticeable difference for weight detection when lifting a block while assuming a position of 90° abduction with 90° internal rotation at the shoulder and 90° flexion at the elbow, which was the posture used by both subjects.

Embodiment and confidence

In addition to improved functional performance, the subjects exhibited increased embodiment ratings of the prosthesis. Subjects agreed more with embodiment statements than with control statements, suggesting greater embodiment of the prosthetic hand when sensory feedback was provided. Embodiment will likely increase with agency, which is the sense of control resulting from active prosthetic use [44–46], giving reason to examine both embodiment and functional tasks together. Indeed, one subject stated that when he uses one of his other prosthetic hands, a Greifer, he feels as if his hand is holding a split-hook tool, but when he uses his myoelectric hand with sensation, he feels as if he is performing a task with his actual hand. *In fact, during one experiment he stated that he had forgotten that his prosthesis was not his actual hand!*

Concurrent with their improved performance and increased embodiment, the subjects expressed increased confidence when receiving sensory feedback, consistent with previous reports [12, 47]. During a typical visit, S1 reported that he believed he had correctly identified a block in 40% of the ODT trials without sensory feedback. When supplemented with both forms of feedback, his confidence doubled to 80%. Similarly, S2 reported a confidence of 40% without sensory feedback, which increased to 98% when he was supplemented with both forms of feedback. Subject confidence reached as high as $98\% \pm 3\%$ on the ODT when both forms of feedback were restored. Without sensory feedback, neither subject was confident. On the ODT tests without sensory feedback, subject confidence was $37\% \pm 8\%$, which was below both chance (50%) and actual performance ($59\% \pm 10\%$). Therefore, it may not be surprising that both subjects report that they devoted

much of their visual attention to their prosthetic hand when undertaking tasks outside the lab, which is a sentiment expressed by many myoelectric users.

As demonstrated by this study, sensory feedback can improve standardized ADL tasks. However, there is a need to develop standardized tests that quantify the effect of sensory feedback. Current standardized tests of functional tasks, such as the SHAP, Assessment of Capacity for Myoelectric Control (ACMC; [48]), and standard box and blocks, are limited as they primarily gauge control and mechanical capability of the myoelectric prosthesis.

Alternative methods of sensory feedback

The growing body of literature in functional outcomes from sensory feedback demonstrates the importance of restoration of both pressure and proprioception. The electrodes in this and other studies [4, 33] achieve sufficient selectivity for sensory feedback [20, 22] and significantly improve functional outcome [23, 24]. Subjects with a transverse intra-fascicular microelectrode have distinguished three rigid objects: a cone, a cylinder, and a sphere [24]. The subject based decisions on the presence and timing of sensation resulting from pressure applied to sensors on D1 or D2, resulting in stimulation of the median nerve, and D5, resulting in stimulation of the ulnar nerve. Specifically, subjects distinguished objects based on the order in which force sensors were activated. In ODT and mBB tests in this study, subjects determined if a cube was present and manipulated it. When only pressure feedback was provided, the subjects' performance improved compared to tests without feedback. Because the cube activated all force sensors simultaneously, timing between force sensor onsets was not the strategy used by our subjects. Instead, they gauged the time between initiating hand closure and onset of sensation. Our subjects performed best, however, when both pressure and bend sensors were used to provide feedback and in those tests, the strategy used by our subjects was consistent with the strategy employed in the Raspopovic et al study. Specifically, our subjects used the onset of pressure as a 'trigger' at which time to gauge the aperture of the hand. Therefore, although both studies used different techniques and different neural interfaces to provide sensory feedback, both studies suggest that as few as two independent sources of information can be used by the subject to improve performance.

In another study, two subjects implanted with longitudinal intrafascicular electrodes were asked to identify objects of various size and stiffness [23]. In that study, only one subject reported sensations of kinesthesia. The subject with both proprioception and pressure feedback was able to distinguish between various objects while the subject with only pressure feedback was not. While the results in this study are similar to those reported by [23], here we have demonstrated that both subjects could perform well on a variety of tests when implanted with non-penetrating electrodes driven by force and bend sensors, even when one of those subjects did not perceive a sensation of kinesthesia.

In our study, electrical stimulation at four locations significantly improved the performance of both subjects on all tests compared to no feedback. An alternative, or perhaps complement, to electrical stimulation is the use of vibratory feedback provided through tactors. No studies directly compare functional benefits achieved with a nerve cuff electrode to those achieved with vibrotactile arrays in the same population and without reliance on

visual cues. Perhaps the most similar vibrotactile studies to this study are those utilizing targeted reinnervation of peripheral sensory fibers to a proxy area, often the chest [7, 38]. In these studies, the subjects perceived sensation in the phantom, ideally at the location corresponding to pressure on the prosthetic hand. In one study, vibrotactile feedback in a subject with targeted reinnervation slightly increased performance [39]. In general, vibrotactile feedback has mixed results. In a virtual reality (VR) environment, blindfolded amputees provided with vibrotactile feedback mapped to hand aperture accurately identified three of eight discrete levels [6, 13]. In another VR study in which blindfolded subjects manipulated an arm under EMG control, performance with vibrotactile feedback did not significantly differ from performance without any feedback [40]. However, another study found that vibrotactile feedback improved object manipulation in VR [39]. In a different study, vibrotactile feedback in the absence of visual and auditory feedback did not significantly affect performance during grasp and lift tasks [41]. Other studies have found vibrotactile feedback improves control over gripping force [12, 42] and detection of state transitions, such as the transition from not touching an object to touching an object [43].

Choice of statistical methods

For multifactor ANOVA, there is a rich array of readily available and easily interpreted post-hoc comparison methods, such as Tukey honestly significant difference comparisons, in most common statistical packages. Similar post-hoc methods either do not currently exist or are not as ubiquitous for non-parametric alternatives. There is a Kruskal—Wallis one-way ANOVA on ranks that can be applied to data that is markedly non-normal. However, its comparison is not a simple mean or median, but a rather difficult-to-interpret general dominance of one distribution over the other and comparative results are non-obvious.

The ANOVA analyses of response versus feedback type, observation number, observation order, and session number in this paper all passed careful scrutiny for applicability of normal distribution assumptions of residuals prior to evaluating post-hoc comparisons. The tests for ODT and mBB in this paper result in qualitative (success rate) or count metrics (success counts). It may be argued that non-parametric statistical analyses might be more appropriate than ANOVA. The mBB and ODT success rates were based on sets of 10 blocks and will tend to be granular and limited in scale compared to the usual normal distribution assumptions. Proportions are approximately normal for np and $n(1 - p)$ sufficiently greater than 5. For proportions in the middle 50%, the robustness of the ANOVA justifies the results if the residuals do not sufficiently deviate on normal probability plots. Using an Anderson—Darling normality test, most metrics were found to be normal. Because proportions on some of the tests approached the limits of the scale, either 0% or 100%, the assumption of normality did not always hold true. However, for comparisons found to be statistically significant, the *p-value* associated with tests in which normality was not achieved never exceeded 0.013, well below the α criterion for significance.

Ultimately, because no model is perfect, all models contain error, but some are, nonetheless, applicable and useful (see page 118 of [49] and pages 74 and 424 of [50] for further discussion on applicability of models). The challenge for the field will be to continue developing test methods and metrics amenable to parametric modeling of the effect of

sensory feedback on physical tasks and cognitive, emotional, and social aspects of functional improvement.

Conclusion

Sensory feedback by peripheral nerve stimulation improves functional capability by (1) improving the individual's ability to manipulate objects; (2) increasing the individual's sense that the prosthesis is, in fact, a part of his body; and (3) improving confidence. Providing pressure and kinesthetic feedback was found to increase the success rate and confidence while decreasing the number of failures on two functional tasks in both subjects. With both forms of feedback, both subjects tended toward the results obtained with positive controls. These results suggest that it should be possible for the individual to devote less visual attention to the prosthesis, which should facilitate split-attention tasks. Continued studies are needed to directly measure visual attention during sighted tasks with and without sensory feedback or performance of task with added cognitive loading. Continued long term studies should be conducted, take-home systems should be developed, and additional subjects should be enrolled.

Acknowledgments

Funding

This work was supported by the Department of Veterans Affairs A6156R and IK1RX00072401A1 and by the Defense Advanced Research Projects Agency's (DARPA) RENET N66001-12-C-4173.

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Figure 1.

(a) S1 was implanted with 2 FINEs and 1 spiral nerve cuff. The FINEs were implanted on the median and ulnar nerves. The spiral was implanted on the radial nerve. Leads were tunneled to the lateral upper arm, where they exit as 20 helical wires. S2's amputation is in the proximal forearm and cuffs were implanted in the arm 5–10 cm proximal to the elbow. (b) The subject's prosthetic hand was mounted with low-profile force sensors on the pads of D1–D3 as well as a bend sensor measuring the D1–D2 angle. Both subjects used their own prosthetic hand, the Ottobock SensorHand Speed, for the tests. The prosthetic hand has 1 degree of freedom (DoF) and 1 grip pattern. The internal slip sensor was disabled. The pressure and bend sensors regulated the stimulus applied to the nerves. Photo courtesy

Russell Lee/Case Western Reserve University. (c) S2 using his instrumented prosthetic to locate and remove magnetic blocks from a metal platform while blindfolded.

Figure 2.

ODT accuracy for S1 and S2. Both subjects always identified the presence of a wooden block with their intact hand (not shown). Without feedback, both subjects performed slightly above chance. Addition of one of the two forms of sensory feedback, either pressure or aperture, could significantly improve accuracy but was never significantly better than the accuracy achieved using both forms of feedback simultaneously. Both forms of feedback also resulted in significantly greater performance than with the bend sensor alone in S1 or with the force sensors alone in S2. An accuracy of 50% represented chance. ***($p < 0.001$), **($p < 0.01$), *($p < 0.05$).

Figure 3.

Results from mBB tests in S1 (left column) and S2 (right column). For both subjects, restoring both forms of feedback resulted in a significant increase in success (a) and (b) and a significant decrease in failures (c) and (d) compared to no feedback. When using the prosthetic hand while blindfolded, audibly occluded, and without additional sensory feedback, S1 and S2 removed 3.1 ± 0.8 and 2.1 ± 1.9 blocks, with 7 ± 3 and 6 ± 2 errors, and 1 ± 1 and 0 ± 0 corrections, respectively. With both pressure and aperture feedback, S1 and S2 removed 6.4 ± 2.6 ($p = 0.007$) and 5.2 ± 1.0 ($p < 0.001$) of the blocks, respectively. S1

averaged only 1 ± 1 error ($p < 0.001$) and S2 a nearly perfect 0.4 ± 0.7 ($p < 0.001$) error rate. There was no significant difference in the number of failures between the two subjects ($p = 0.610$). While S1 did not significantly vary his corrective actions (e), averaging 2 ± 1 , S2 had 4 ± 1 corrections (f), which was significantly higher ($p < 0.001$). As more feedback was provided, both subjects trended toward a perfect success rate without failures. $^{***}(p < 0.001)$, $^{**}(p < 0.01)$, $^{*}(p < 0.05)$.

Figure 4. Embodiment improved when sensory feedback was provided during functional, sighted tasks. ***($p < 0.001$), **($p < 0.01$), *($p < 0.05$).

Table 1

Subjects enrolled in the sensory restoration study.

	S1	S2
Amputation history		
Location	Wrist	Prox. forearm
Year	2010	2004
Cause	Forging hammer	Industrial shredder
Amputation outcomes		
Neuroma	No	No
Phantom pain level	Mild	Excruciating
Pain frequency	2/Week	2/Month
Phantom paresthesia	No	Yes
Implant		
Location	Mid-forearm	Upper arm
Date	May 2012	January 2013
Nerve cuffs		
Median	FINE (10.0 × 1.5 mm)	FINE (10.0 × 1.5 mm)
Ulnar	FINE (10.0 × 1.5 mm)	FINE ^a (10.0 × 1.0 mm)
Radial	Spiral (4.0 mm)	FINE (10.0 × 1.0 mm)
Total electrodes	20	16

^a Although an ulnar FINE was implanted in S2, it was found to be open after surgery upon x-ray examination. The FINE was designed to open if the lead is tugged to prevent transference of tension to the nerve. The FINE also opens if the nerve swells to prevent blood flow occlusion.

Table 2

Embodiment questions.

1	I felt the touch of the objects on the prosthetic hand.
2	It seemed as if the objects caused the touch sensations that I was experiencing.
3	It felt as if the prosthetic hand was my hand.
4	It felt as if my residual limb was moving towards the prosthetic hand.
5	It felt as if I had three arms.
6	I could sense the touch of the objects somewhere between my residual limb and the prosthetic hand.
7	My residual limb began to feel rubbery.
8	It was almost as if I could see the prosthesis moving towards my residual limb.
9	The prosthesis started to change shape, color and appearance so that it started to (visually) resemble the residual limb.

Table 3

SHAP scores before and after sensory feedback.

	S1				S2			
	No feedback		Improvement		No feedback		Improvement	
Overall Score	58	71	13		51	55	4	
Spherical	76	81	5		66	65	-1	
Power	57	76	19		54	63	9	
Tip	31	41	10		22	29	7	
Tripod	66	67	1		42	44	2	
Lateral	56	75	19		55	65	10	
Extension	40	54	14		53	50	-3	