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Case Studies in Neuroscience: Sensations elicited and discrimination ability from nerve cuff stimulation in an amputee over time

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The present case study details sensations elicited by electrical stimulation of peripheral nerve axons using an implanted nerve cuff electrode, in a participant with a transhumeral amputation. The participant uses an osseointegrated electromechanical interface, which enables skeletal attachment of the prosthesis and long-term, stable, bidirectional communication between the implanted electrodes and prosthetic arm. We focused on evoking somatosensory percepts, where we tracked and quantified the evolution of perceived sensations in the missing hand, which were evoked from electrical stimulation of the nerve, for over 2 years. These sensations included small, point-like areas of either vibration or pushing, to larger sensations over wider areas, indicating the recruitment of a few and many afferents, respectively. Further, we used a two-alternative forced choice paradigm to measure the level of discrimination between trains of brief electrical stimuli, to gauge what the participant could reliably distinguish between. At best, the participant was able to distinguish a 0.5 Hz difference, and on average, acquired a 3.8 Hz just-noticeable difference at a more stringent psychophysical level. The current work shows the feasibility for long-term sensory feedback in prostheses, via electrical axonal stimulation, where small and relatively stable percepts were felt that may be used to deliver graded sensory feedback. This opens up opportunities for signaling feedback during movements (e.g. for precision grip), but also for conveying more complex cutaneous sensations, such as texture.

Introduction

The restoration of cutaneous sensory signals after amputation may be accomplished through the electrical stimulation of peripheral nerves fibers. Clippinger *et al.* (1974) used electrical stimulation of the median nerve, producing sensations of paresthesia, which were used to elicit pressure sensations during grasping. More recent investigations have used the same approach to produce sensations in guiding prosthetic use (Horch *et al.* 2011; Raspopovic *et al.* 2014; Davis *et al.* 2016; Schiefer *et al.* 2016), including the transmission of more natural-feeling sensations, such as pressure and texture (Tan *et al.* 2014; Oddo *et al.* 2016).

A mechanoreceptor has the propensity to encode basic sensations, including pressure, vibration, and force (Vallbo and Johansson 1984; Johnson 2001), as well as more complex facets (Connor *et al.* 1990; Weber *et al.* 2013; Pruszynski and Johansson 2014). Single unit intra-neural microstimulation of A β mechanoreceptive afferents gives rise to a quantal tactile sensation, where the electrical stimulation of a fast-adapting type 1 (FA1) afferent produces a small sensation of vibration and a slowly-adapting type 1 (SA1) of pressure (Vallbo *et al.* 1984). Conversely, gross electrical nerve stimulation produces paresthesia and feels unnatural (Schady *et al.* 1983); however, recent advances have shown that patterned electrical stimulation of many afferents can produce more natural sensations (Tan *et al.* 2014).

Presently, we used a participant with a transhumeral amputation that was performed on the right arm in 2003. Later, an osseointegrated implant was surgically inserted into the humerus bone (OPRA Implant System; Integrum, Sweden), which provides a stable way to attach prostheses to the body. In January 2013, permanent electrodes were placed around the ulnar nerve and implanted on viable muscles. We aimed to produce perceived sensations in the missing right hand, through electrical stimulation of the ulnar

nerve. We characterized the evoked sensations in detail and assessed their stability over time. Furthermore, we sought the threshold at which perceptual differences in stimulus intensity could be distinguished, enabling us to determine an adequate intensity code that can be translated into useable signals for prosthetic feedback.

Methods

The experiment was approved by the local ethics committee and performed in accordance with the Declaration of Helsinki. The study was conducted on a single male participant (aged 40 at the start of testing; Fig. 1A), who gave written, informed consent. The ulnar nerve cuff had three electrode stimulation sites (E1, E2, E3), each with a surface area of 1 mm², with a common reference electrode (Ortiz-Catalan *et al.*, 2013; Fig. 1B). The participant was tested for perceived projected sensations from electrical stimulation through the nerve cuff in 8 experimental sessions, at 2, 3, 5, 12, 16, 18, 23, and 25 months post-surgery.

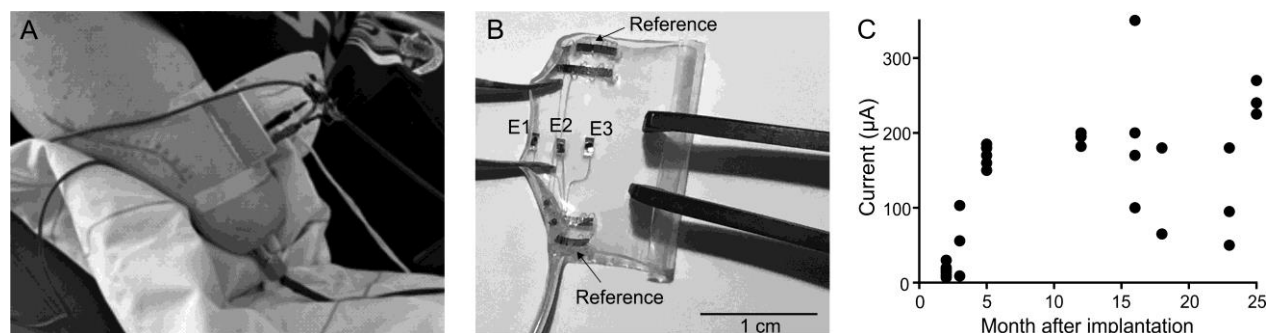


Figure 1: Set-up of electrodes and current used per experiment.

(A) The set-up of the electrodes coming out of the osseointegrated implant in the right arm. (B) Photo of the nerve cuff electrode, showing the electrode configuration (E1: electrode 1; E2: electrode 2; E3: electrode 3). Note that the common reference is interconnected at the top and bottom. (C) The current intensity used to evoke a sensation per electrode, over time.

Extra-neural electrical stimulation was delivered through the cuff electrode via a microneurography unit (Umeå University, Sweden), which received pulses from a data acquisition device (National Instruments, Austin, TX). Short, square-wave pulse trains (0.2 ms pulses at 30 Hz for 1 s) were delivered down each electrode (with the current return down the reference, Fig. 1B), while the current was increased from zero until the participant reported feeling a projected sensation in the missing hand (see Fig. 1C for current thresholds). Other electrical pulse frequencies were tested (1, 15, 30, 60, 90, 120 Hz) and both positive and negative current flows. The current was kept below 350 µA. The participant was asked to describe any sensation and its location; the experimenters noted these and drew a realistic representation of the shape/size of the perceived sensation on hand maps (Figure 2).

The sensation from electrical stimulation, for each electrode tested per experiment, was quantified using a number of measures, namely its: diameter (mm), distinctness of the border (sharp/slightly diffuse/clearly diffuse/points of intense sensation), shape (round/oval/long/irregular), if movement was present (linear/circular/no movement), and the naturalness of the sensation (completely natural/almost natural/possibly natural/rather unnatural/completely unnatural) (Vallbo *et al.* 1984). The participant was readily able to verbally ascribe these qualities to his perceptions, using a prompt-sheet that gave scale examples (Fig. 3A).

A two-alternative forced choice (2AFC) frequency discrimination protocol was used to determine the difference between two trains of electrical pulses. The participant was asked to attend to the sensation elicited and decide which of pulse trains had the higher frequency. One of the pulse trains was a constant reference frequency (15 Hz, 1.5 s), whereas the other was the test frequency, which was always higher frequency (starting at double the reference, 30 Hz for 1.5 s; Table 1). The order of the highest pulse frequency delivered first was randomized. The participant sat in front of a screen that displayed the question, 'Which is higher frequency (more intense)?'. The participant was required to answer promptly, saying '1' or '2' and he received feedback on his answer. An adaptive transformed-rule up-down staircase was used, which converged on a 67% level of correct responses (Levitt 1971). When the participant

answered two consecutive trials correctly, the difference between the baseline and test pulses was halved; however, a wrong answer doubled the difference (Table 1). The experiment was completed when six incorrect answers (reversals, i.e. just-noticeable difference) at a certain level were obtained. Two psychophysical levels were sought for each staircase. The first level, called the 'minimum' level, was the lowest level at which a correct answer was given, and which could not have been reached by answering randomly ($p < 0.05$, using a random-walk simulation of the full protocol). The second, called the 'just-noticeable difference', was taken to be the eventual stable level, gained after six reversals, where the participant could reliably distinguish between paired pulse trains for that sensation.

	Test pulses (100% baseline (23 pulses) + extra %)							
	← Easier		Start	More difficult →				
Baseline	+400%	+200%	+100%	+50%	+25%	+13%	+6%	+3%
15 Hz	75	45	30	22.5	18.8	16.9	15.9	15.5
23 pulses	115	69	46	35	29	26	25	24

Table 1: Comparison of frequency increases and decreases for the staircase paired pulse train discrimination protocol. The paradigm starts with the baseline pulses (15 Hz for 1.5 s = 23 pulses) compared to double this (30 Hz for 1.5 s = 46 pulses). For comparison, the frequency is given in Hertz, as well as the equivalent number of pulses.

Results

The participant was tested systematically for sensations evoked from ulnar nerve electrical stimulation per electrode (total 57 tests), up to 25 months post-surgery. The timing of the sensations coincided strictly with the duration of the train of stimulation pulses delivered. The participant was able to locate the sensation on a drawing of the hand precisely (Fig. 2). In the first session, 2 months post-surgery, low currents (mean 15 μ A) consistently gave projected sensations emanating out into the ulnar-ventral side of the missing hand. The participant described a variety of sensations, e.g. E1 gave a sensation that was 'like a pen pushing underneath the skin' at trains of 60 Hz. When the frequency was decreased to 30 Hz, this sensation became more like pulsing. The participant described it as a small (1 mm diameter), round point that felt quite natural (Fig. 2). The same tests were repeated later in the experiment and identical sensations were found. Other sensations included a warm/burning sensation (that was not unpleasant or painful) from E2, and a tactile pushing sensation that was small and point-like from E3 (Fig. 2), which turned into a line on increasing the current.

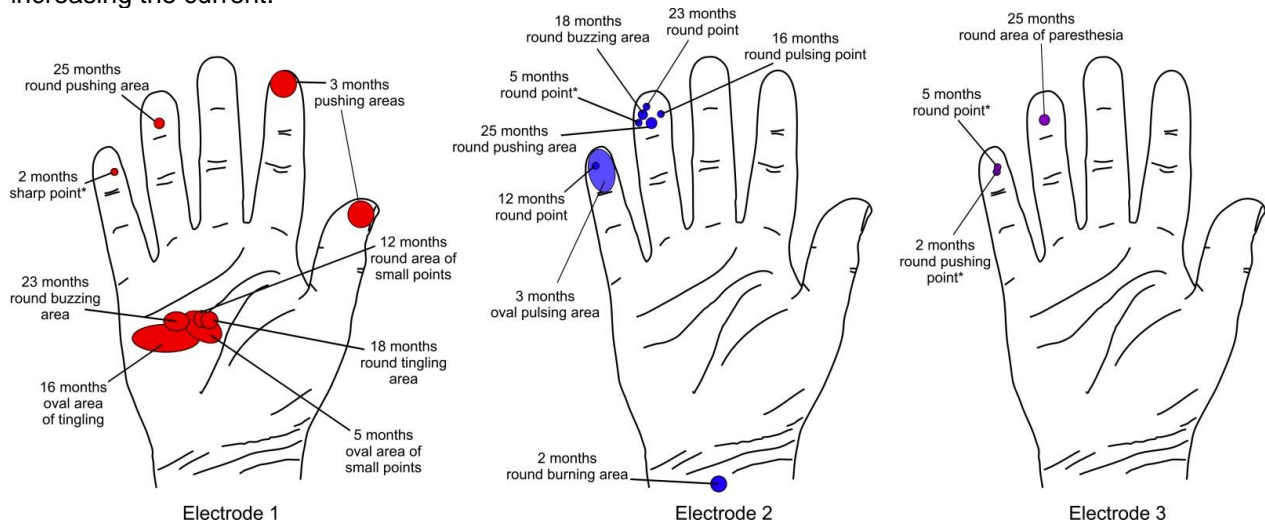


Figure 2: Perceived projected sensations over time, from each electrode.

Diagrammatic representations of the perceived sensations felt from electrical stimulation of each electrode over time (months post-surgery). The sizes and shapes represent the territories of the actual sensation felt. Note that the labels with asterisks (electrode 1, month 5; electrodes 2 and 3, month 5) showed an elongation of the sensation into lines emanating proximally down the finger when the current was increased (all $> 20 \mu$ A over the initial sensation) and that at month 25, the sensations were all in the same location (although they were of different quality).

There was some constancy between the sensations elicited over the testing sessions, with a preservation of the general innervation territory. Figure 2 shows the locations and details of evoked sensations per electrode, over time. E1 and E2 gave the most consistent sensations between sessions, where E1 typically produced a sensation in the missing palm, whereas stimulation of E2 produced sensations in the ring finger. The sensations, and the current used to evoke them (Fig. 1C), stabilized after 3 months. Different electrical pulse frequencies were tested (e.g. 1-120 Hz) and the participant consistently reported stronger sensations with higher pulse frequencies. At 2 months post-surgery, E2 gave a pushing sensation at 60 Hz stimulation that became more intense at 90 Hz; however, no sensation was felt at 30 Hz. At 3 months post-surgery, stimulation of E1 gave a small point of vibration at 30 Hz, which became stronger at 60 Hz. At 23 months post-surgery, stimulation of E1 produced a buzzing sensation at 60 Hz, which was noticeably weaker at 30 Hz, but became more pulsating at 90 Hz.

Regarding the general characteristics and quality of the projected sensations, the median size of the sensation was 3 mm diameter (min: 1 mm, max: 10 mm, mode: 1 mm), therefore the stimulation was felt as constrained and specific. The shape of the sensation was usually perceived as round or oval, and the borders of the sensations were perceived as quite-to-clearly diffuse. Typically, there was no movement associated with the sensation. The 'naturalness' of the sensation was usually described as 'almost natural' or 'possibly natural'. From 1 year post-surgery, the electrically-evoked sensations were subject to quantitative testing for the level of discrimination achievable between the intensity of pulse trains in a 2AFC paradigm. The participant was able to discriminate as low as a 0.5 Hz difference between two pulse trains (median: 0.9 Hz difference). The median just-noticeable difference was 3.8 Hz (median of 42 trials, range 39-69). Figure 3B details both discrimination levels for each electrode/experiment tested.

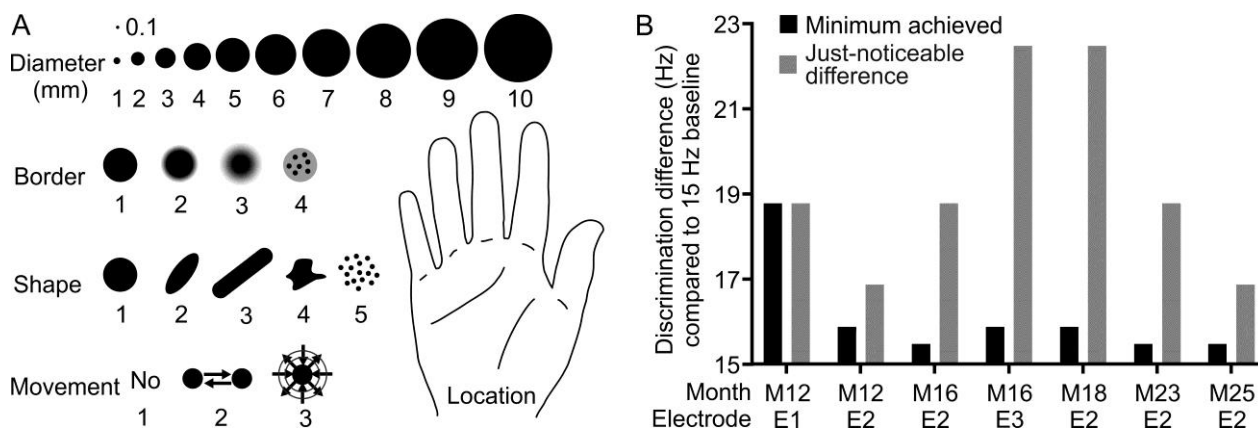


Figure 3: Perceived sensations documented through psychophysical testing.

(A) The different types of questions/responses to quantify each sensation. These were presented diagrammatically in front of the participant, who chose one response from each question that was noted by the experimenter. (B) Discrimination levels (minimum level achieved and the overall just-noticeable difference) over time. We show each level for the month (M) post-surgery and electrode (E) tested. The discrimination difference (Hz) is shown as compared to the 15 Hz (for 1.5 s) baseline.

Discussion

We performed electrical stimulation through a chronically implanted nerve cuff electrode, for over 2 years post-surgery, in an osseointegrated amputee. We found that stimulation of the ulnar nerve gave rise to confined, projected sensations, resembling the sensations generated during single unit intra-neural microstimulation (Vallbo et al. 1984). The participant could clearly indicate a sensation that was well-localized to a small point and had no problem indicating the precise location on a drawing of a hand. At lower stimulation currents, the character of the percepts resembled sensations commonly elicited when stimulating a single SA1 or FA1 afferent, namely pressure or vibration, respectively. Increasing the stimulus intensity resulted in a spatial elongation of the sensation, e.g. like a line or a larger area (Schady et al. 1983; Vallbo et al. 1984; Sanchez Panchuelo et al. 2016), as expected when more afferent nerve fibers are recruited.

We found relatively stable areas of projected sensations, over time, where there was constancy and conservation of some sensations, especially those produced from E1 in the palm, and E2 in the ring finger. During the initial testing, the sensations varied; however, they settled down from month 5 post-surgery. E3 produced some sensations in the little finger, but for the majority of testing, no particular sensations were elicited from stimulating this electrode. Overall, similarities were found in the projected sensations, but these were not always constant, which may have been due to a number of reasons, including changes at the interface, cortical plasticity, or cognitive effects. The current intensity for sensations was just above that normally used in single unit intra-neural microstimulation studies initially (Vallbo *et al.*, 1984). An increase in the threshold current occurred during the early months of testing, but from month 5, the level was stable (~165 μ A). These findings are in good correspondence with the threshold current measurements in the same patient made in a different laboratory over 11 months (Ortiz-Catalan *et al.* 2014). The increase in current after the first 3 months (not shown in Ortiz-Catalan *et al.* 2014), as well as the changes in perceived sensations, likely represented the stabilization of the electrodes around the nerve, where the formation of a fibrous membrane caused an increase in impedance. Further, the stabilization of stimulation is in agreement with different implanted electrodes in other patients (Tan *et al.* 2015), which independently validates the feasibility of providing long-term sensory feedback in prostheses.

The perceptual results we present are in correspondence with results from the same participant, from tests performed independently in a different laboratory. Ortiz-Catalan *et al.* (2014) showed that the electrodes gave similar general innervation territories, where E1 showed projected sensations arising in the palm, E2 in the ring finger, and E3 in the little finger. An issue raised in the current work was the finding of sensations perceived in the index finger and thumb, which are not ulnar, but median nerve, innervation territory, which was found at month 3 (also cf. Tan *et al.* 2015). In month 2, the participant reported sensations at the wrist (paresthesia/burning), which may have been generated from general ulnar nerve stimulation. These sensations may have occurred for a number of reasons, including that the participant had not felt externally applied stimulation for over 10 years, so there may have been cortical or cognitive effects. It is likely that conflicts may have occurred between top-down vs. bottom-up information processing, where the incoming afference was novel at the time and, as described by the participant, was a welcome sensation, but may have led to a mismatch of sensation localization.

Other studies in amputees implanted with electrodes between 1 week and 3 years have shown similar feasibility for producing sensations through stimulation, although these studies have focused on more specialized activities, such as motor-functional (Horch *et al.* 2011; Raspopovic *et al.* 2014; Tan *et al.* 2014; Davis *et al.* 2016; Schiefer *et al.* 2016) and tactile-discrimination (Graczyk *et al.* 2016; Oddo *et al.* 2016) tasks. We focused on the somatosensory aspects of nerve stimulation and quantified these on a more fundamental level, using classifications of the sensations, for direct comparability over time on a number of factors (e.g. shape, naturalness), which provides a more comprehensive view of the general type and quality of sensations generated.

Our 2AFC paradigm showed that the participant could use information from electrical stimulation to distinguish differences in frequency between two pulse trains. At best, the participant distinguished 0.5 Hz (1 pulse difference) between trains of electrical stimuli. The overall just-noticeable difference equated to 3.8 Hz (6 pulse difference), which represents a more consistent measure for use in prosthetic feedback in general and can be applied to a number of areas (e.g. signaling grip pressure, texture), although this may be adapted on-line depending on the conditions. We asked which of two trains was of 'higher frequency (more intense)', which could bias the results, as modulating the frequency may have other effects than just changing the intensity of sensation. During testing, the participant felt stronger sensations at higher frequencies, although reported some changes of sensation quality at higher (>90 Hz) frequencies. As our 2AFC paradigm had a baseline frequency of 15 Hz, we do not expect that our results were biased by the question we asked; however, it is clear that modulating the frequency may lead to richer sensations. We show the feasibility of using graded levels of electrical stimulation to signal differences in intensity. For the transmission of more natural-feeling sensations (e.g. texture) it is of benefit to comprehend the minimal level that can be reliably distinguished to convey fine somatosensory qualities. Graczyk *et al.* (2016) report similar potential for discrimination abilities in amputee nerve stimulation, yet we show that this can vary

over time (cf. the minimum level distinguished and the just-noticeable difference level; Fig. 3B), which must be taken into account when using the feedback.

A long-term aim of the current work is to generate meaningful sensory feedback, to mimic tactile and proprioceptive input, and even thermal and nociceptive signals in the future (Ackerley and Kavounoudias 2015). This sensory afference would be beneficial for integrating the prosthesis, providing natural feedback, and closing the sensorimotor loop. Recent work has demonstrated the application of sensory feedback in prosthetics, especially for somatosensation (Graczyk et al. 2016; Oddo et al. 2016), and we demonstrate that tactile percepts and levels of discrimination can be signaled over long periods through osseointegration, which allows embedded electronics for closed-loop control over prosthetics (Mastinu et al. 2017) for useful feedback during everyday life (Ortiz-Catalan et al. 2017). Further work will utilize different electrical stimulation patterns to modulate these sensations for more complex sensory feedback.

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New & Noteworthy: We demonstrate the long-term stability and generation of sensations from electrical peripheral nerve stimulation in an amputee, through an osseointegrated implant. We find that perceived tactile-like sensations could be generated for over two years, in the missing hand. This is useful for prosthetic development and the implementation of feedback in artificial body parts.

Keywords: artificial touch, prosthetics, somatosensory, amputation, electrical nerve stimulation, hand