



# Multi-Electrode Array for Transcutaneous Lumbar Posterior Root Stimulation

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**Abstract:** Interest in transcutaneous electrical stimulation of the lumbosacral spinal cord is increasing in human electrophysiological and clinical studies. The stimulation effects on lower limb muscles depend on the depolarization of segmentally organized posterior root afferents and, thus, the rostro-caudal stimulation site. In previous studies, selective stimulation was achieved by varying the positions of single self-adhesive electrodes over the thoracolumbar spine. Here, we developed a multi-electrode surface array consisting of  $3 \times 8$  electrode pads and tested its stimulation-site specificity. The array was placed longitudinally over the spine covering the T10–L2 vertebrae. Two different hydrogel layer configurations were utilized: a single layer adhered to all electrode pads of the array and a configuration comprised of eight separate strips attached to the three transverse electrode pads of each level. Voltage measurements demonstrated that an effectively focused field distri-

bution along the longitudinal extent of the array was not accomplished when using the single continuous hydrogel layer, and segmental selective stimulation of the posterior root afferents was not possible. The separate strips produced a focused electric field distribution at the rostro-caudal level of the electrode pads selected for stimulation. This configuration allowed for the preferential elicitation of posterior root-muscle reflexes in either the L2–L4 innervated quadriceps or the L5–S2 innervated triceps surae muscle groups. Such multi-electrode array for transcutaneous spinal cord stimulation shall allow for improved control of stimulation conditions in electrophysiological studies and time-dependent and site-specific stimulation patterns for neuromodulation applications. **Key Words:** Flexible printed circuit board—Human—Noninvasive—Selectivity—Transcutaneous spinal cord stimulation.

Therapeutic applications of epidural spinal cord stimulation (SCS) in individuals with upper motor neuron disorders can be traced back to the 1970s, when beneficial effects on spasticity and improvement of some motor function were reported (1–3). Subsequent studies in larger subject populations demonstrated more variable results (4–7), and the general enthusiasm about the technique declined. The divergence of clinical outcomes was at least partially attributable to the diversity of pathophysiological conditions of the individuals treated as well as the

wide range of applied stimulation sites and the nonstandardized stimulation parameters applied (8).

The importance of targeting specific localized neural circuitries within the lumbar spinal cord for enhancing lower limb motor control was shown in later studies in people with motor-complete spinal cord injury (SCI) (9–11). These circuitries are capable of generating sustained extension (12,13) and rhythmic flexion-extension movements of the paralyzed lower limbs (14) as well as controlling spinal spasticity (15) in response to nonpatterned SCS. To engage these functional neural circuitries, precise placement of the implanted electrode array over the upper lumbar spinal cord is required (9,15). The electrically depolarized neural structures are large-diameter afferent fibers within the posterior roots that activate the spinal neural circuitry through synaptic projections (11,14,16).

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The placement of the epidural electrode is intraoperatively guided by electrophysiological measurements of thresholds and obtainable amplitudes of muscle twitches in the lower limb muscles, so-called posterior root-muscle (PRM) reflexes (13,17,18). The availability of multiple rostro-caudally and transversely aligned contacts of the implanted electrode array is essential for further refinement of the exact stimulation sites by shifting the cathode site and selecting different bi- and multipolar electrode configurations (13,17).

The noninvasive activation of posterior root afferents and elicitation of PRM reflexes became possible with the development of transcutaneous SCS using self-adhesive electrodes (18). Preliminary studies suggest that transcutaneous stimulation applied over the upper lumbar spinal cord can be used similarly like epidural SCS as a neuromodulation tool to alleviate spasticity (19) and augment locomotor output during treadmill stepping in SCI subjects (20). Further, it allows expanding classical H-reflex studies confined to a limited number of muscles to neurophysiological studies of spinal reflexes elicited in multiple lower limb muscles simultaneously (18,21–23).

The electrode setups employed in previous studies were relatively simple and utilized paraspinal stimulating electrodes at a predefined position, with the indifferent electrodes placed over the abdomen (18,19) or the anterior superior iliac crests (22,23). The paraspinal stimulating electrodes often need to be repositioned to achieve activation of the target structures or to compensate for changes in the stimulation conditions introduced (e.g., by changes in the body position). Re-adapting the electrode position is time-consuming and may be cumbersome, particularly in SCI people studied on the treadmill and secured by an upper body harness. Also, the repeated removal of the electrodes can compromise their adhesion to the skin and may influence the stimulation conditions. Independently, multi-electrode surface arrays have been developed for functional electrical stimulation applications (e.g., for improving grasp [24–26] and for drop-foot correction [27,28] in people with upper motor neuron disorders).

For transcutaneous SCS applications, multi-electrode arrays shall allow for a more flexible control of the stimulated neural structures and for compensation of changes in the stimulation conditions related to changes in the body position. A relatively simple setup using 24 separate surface electrodes attached to the skin in an array configuration was recently shown to selectively elicit PRM

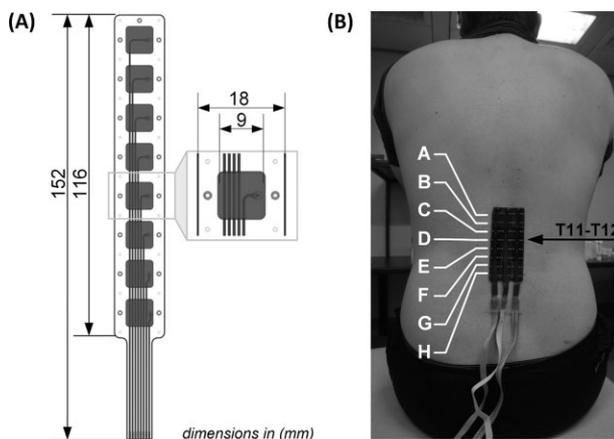
reflexes in muscles innervated by upper versus lower lumbar spinal cord segments (29,30). Motivated by these results, we developed a multi-electrode array allowing for the convenient application of transcutaneous SCS from various sites. Here, we will present the design and applicability of this multi-electrode array.

## MATERIALS AND METHODS

### Multi-electrode array

The multi-electrode array was manufactured using flexible printed circuit (FPC) technology (LeitOn GmbH, Berlin, Germany). The array had an overall size of  $116 \times 54$  mm and consisted of three separate transversely arranged FPC boards, each consisting of eight longitudinally aligned conductive pads (Fig. 1A). The base material of the FPC was polyimide with epoxy adhesive. Polyimide is a proven biocompatible material for long-term use at the electrode–tissue interface (31,32).

Each of the pads had a dimension of  $10 \times 10$  mm, with  $9 \times 9$  mm being the conductive area as the edges of the pads were covered by the stop mask to prevent loss of adhesion. The conductive surface was made of electroless nickel immersion gold which is often used for FPC boards. The thin layer of immersion gold protects the nickel and copper from oxidation. Gold is a suitable material for conductive pads because it is chemically inert, nontoxic, and has excellent electri-



**FIG. 1.** Schematic drawing of the design of the multi-electrode array and its placement over the back. (A) Dimensions of a single flexible printed circuit (FPC) board with eight longitudinally arranged individual electrode pads. Three transversely aligned FPC boards were used to form the multi-electrode array for transcutaneous spinal cord stimulation. (B) The multi-electrode array was placed over the back such that the three pads of level D were located over the T11–T12 interspinous space. A pair of interconnected indifferent electrodes were placed paraumbilically (not shown).

cal properties (33). While the bio-stability of electroless nickel immersion gold is ambivalently discussed in the literature (34), it is suitable for transcutaneous applications without permanent contact to the biological system.

Selection of active electrode pads for stimulation was realized by using an interface comprised of 24 individual mechanical on/off switches, each controlling a single electrode pad.

A hydrogel layer (model ELA-10-1500, Hollywog LLC, Chattanooga, TN, USA) was used to adhere the multi-electrode array to the skin, to reduce the impedance between skin and electrode pads, as well as to provide for a homogenous current distribution over the area of each electrode pad. The electrical resistivity of the hydrogel was  $0.54 \Omega\text{m}$  at 50 kHz.

### Transcutaneous SCS

The multi-electrode array was preliminarily tested in a subject (male, aged 22) with intact central nervous system. The study was approved by the Ethics Committee of the City of Vienna, Austria.

In the following, the eight longitudinal levels of the multi-electrode array will be referred to as A–H, A being the most rostral level. The multi-electrode array was placed symmetrically over the spine such that the three transversely aligned electrode pads of level D were located between the T11 and T12 interspinous processes (Fig. 1B). A pair of rectangular indifferent electrodes (each  $8 \times 13 \text{ cm}$ , Schwamedico GmbH, Ehringshausen, Germany) was placed over the lower abdomen, left and right of the umbilicus. The three electrode pads of each level as well as the pair of indifferent electrodes were each interconnected to function as single electrodes of larger size.

A current controlled stimulator (Stimulette r2x, Dr. Schuhfried Medizintechnik GmbH, Moedling, Austria) was set to deliver charge-balanced, symmetric, biphasic rectangular pulses of 1-ms width per phase. With reference to the indifferent electrodes, the selected electrode pads of the paraspinal array were the anode for the first and the cathode for the second pulse phase.

### Measuring electric field distribution along the multi-electrode array

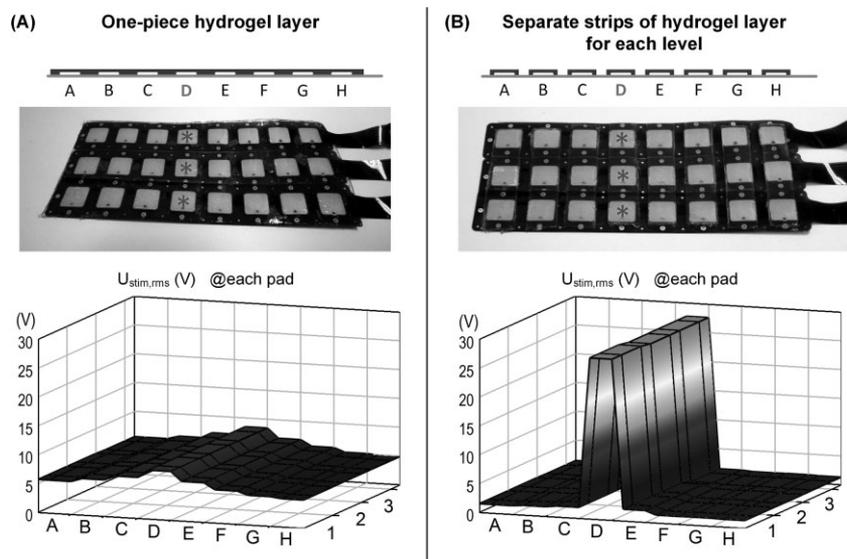
Two different hydrogel layer configurations of the multi-electrode array were tested: first, a single, larger-size layer adhered to all 24 electrode pads, and second, a configuration comprised of eight separate strips, each attached to the three electrode pads of one level and preventing conductivity in-between

neighboring levels. To evaluate the field distribution along the electrode array when using either of the two hydrogel-layer configurations, a test pulse was applied using the three interconnected electrode pads of level D with an intensity of 30 mA, and the corresponding voltage was measured for each of the 24 electrode pads of the array referenced to the abdominal electrodes. Signals were recorded using an oscilloscope (model TDS2004B, Tektronix, Inc., Beaverton, OR, USA) and analyzed offline using Matlab R2012a (The MathWorks, Inc., Natick, MA, USA) by calculating the root mean square value of the voltage pulse.

### Testing segmental selective stimulation of posterior root afferents

Single stimulation pulses applied over the lumbosacral spinal cord elicit short latency PRM reflexes in multiple lower limb muscles bilaterally in people with intact central nervous system (18,21,35) as well as SCI (19,22). Here, recordings of PRM reflexes were confined to quadriceps (Q) and triceps surae (TS). Due to their segmentally separate innervation zones (L2–L4 for Q, and L5–S2 for TS, respectively), PRM reflexes in these two muscle groups allow to distinguish upper lumbar versus lower lumbar/upper sacral roots stimulation. All recordings were conducted with the subject lying comfortably in the supine position. Both hydrogel layer configurations were tested under unchanged recording conditions. The selected electrode level of the array was varied from the most rostral (labeled as A) to the most caudal site (H). For a given stimulation site, three single pulses were applied at 0.1 Hz with intensities of 25–65 mA. PRM reflexes of Q and TS were electromyographically recorded as compound muscle action potentials using pairs of Ag/Ag-Cl surface electrodes (Intec Medizintechnik GmbH, Klagenfurt, Austria). The surface electrodes were placed centrally over the muscle bellies and oriented along the long axis of the muscles with an interelectrode distance of 3 cm (36). Reference electrodes were placed over the fibular head on both sides. Signal quality was enhanced by reducing the interelectrode impedance below  $5 \text{ k}\Omega$  using abrasive paste.

EMG signals were amplified with a gain set to 602, filtered to a bandwidth of 10–600 Hz, and digitized at 10 000 samples per second and channel with a USB-NI 6261 data acquisition card (National Instruments, Inc., Austin, TX, USA) and recorded using DasyLab 12.0 (Measurement Computing Corporation, Norton, MA, USA).



**FIG. 2.** Electric field distribution measured along the multi-electrode array using (A) a single hydrogel layer adhered to all 24 electrode pads and (B) eight separate hydrogel layer strips, each connecting the three electrodes of one level. Voltages were measured at each electrode pad, referenced to the abdominal electrodes, when a 30-mA test pulse was applied at level D; illustrated are the respective root mean squares ( $U_{stim,rms}$ ).

## RESULTS

### Electric field distribution along the electrode array

The electric field of the electrode array with the one-piece hydrogel layer was widely distributed over its whole conductive area (Fig. 2A). The voltage measured at the electrode pads of level D selected for stimulation amounted to  $8.5 \pm 0.0$  V, and dropped by 19.5% at the neighboring level E and by 42.0% at the most distant level H. A focused electric field distribution was measured when using separate strips of hydrogel layer for each of the electrode levels (Fig. 2B). The voltage at level D was  $27.7 \pm 0.2$  V, and dropped by 77.9% and 84.3% at levels E and H, respectively. The overall electrode impedance of the electrode array with the one piece hydrogel layer was 3.3 times lower.

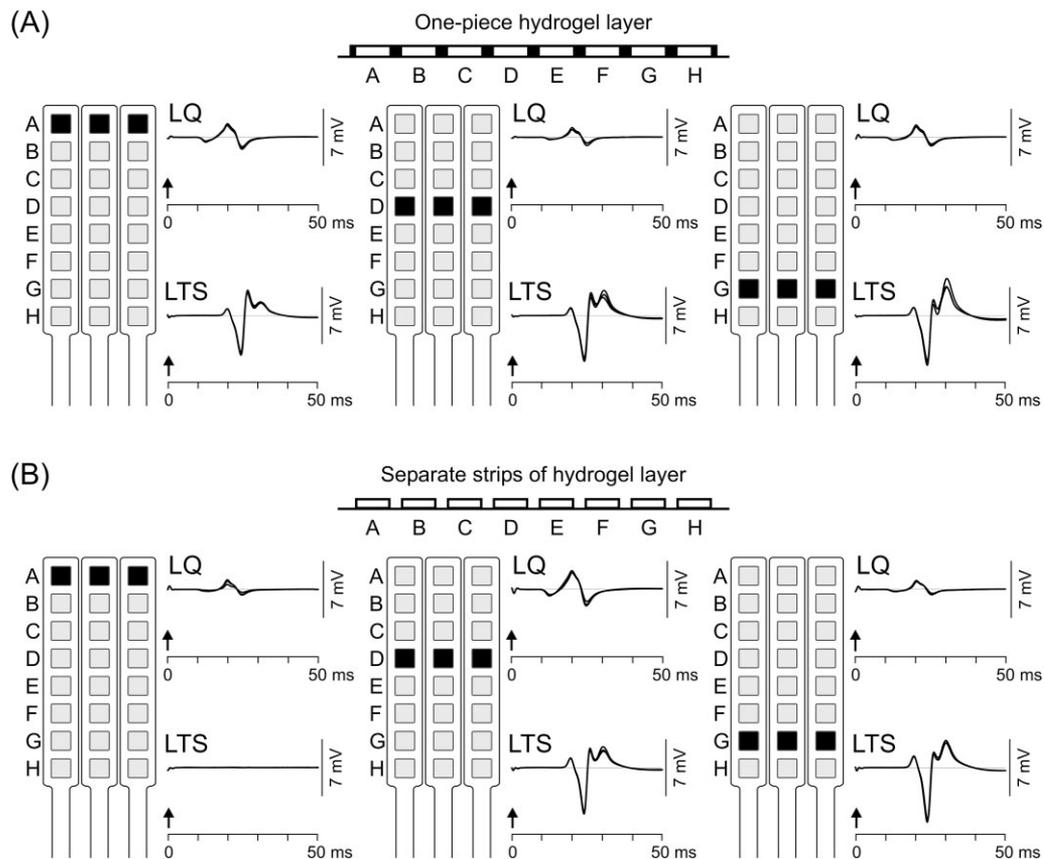
### Segmental selectivity of posterior root stimulation

Single stimulation pulses applied from the various electrode levels of the multi-electrode array with incremental intensities elicited PRM reflexes in Q and TS bilaterally for both hydrogel layer configurations. However, the recruitment of these muscle groups with varying stimulation sites was different when using either the one-piece hydrogel layer or the separate strips. The one-piece configuration led to the elicitation of PRM reflexes in Q and TS without systematic changes in the attainable response magnitudes with rostro-caudal shifts of the stimulation site (Fig. 3A). Using separate strips of hydrogel layer for each electrode level resulted in enhanced segmental selectivity of PRM-reflex elicitation (Fig. 3B). Stimulation from the most rostral site (level A) yielded

responses of considerably larger amplitudes in Q than TS. Stimulation applied over the T11–T12 interspinous space (level D) evoked large PRM reflexes in both muscle groups. The output relation as obtained from the most rostral site was reversed by shifting the stimulation sites to the more caudal positions (levels G and H).

## DISCUSSION

We presented a multi-electrode array with a design and dimensions tailored for transcutaneous stimulation of lumbosacral posterior roots. The aim was to provide for segmental selectivity of the externally delivered input by shifting the stimulation sites along the longitudinal extent of the array. Using the multi-electrode array with the continuous hydrogel layer did not provide for an effectively focused field distribution across the electrode pads. Such configuration would require a hydrogel layer with higher longitudinal resistivity (37). Longitudinal currents were limited using separate strips of hydrogel layer, one for each level of the multi-electrode array, allowing for more controlled field distributions along the array (38). With the latter setup and by selecting the more rostral levels of the array, PRM reflexes were preferentially elicited in the Q muscle group, indicating a dominant stimulation of the L2–L4 posterior roots. Selecting the more caudal levels resulted in a shift of the depolarized posterior root afferents to those of L5–S2. Thus, despite the distance of several centimeters of the stimulating paraspinal electrodes to the target neural structures and their partial insulation by the spine, a similar segmental selectivity was attained as with SCS delivered through epidural implants



**FIG. 3.** Posterior root-muscle (PRM) reflexes elicited by stimulation from different rostro-caudal sites along the multi-electrode array using (A) the one-piece hydrogel layer and (B) separate strips of hydrogel layer for each level of the array. Representative results are shown for the left (L) quadriceps (Q) and triceps surae (TS) muscle groups. Schematic drawings of the multi-electrode array illustrate levels selected for stimulation (black pads). For each stimulation site, three PRM reflexes are shown superimposed. Arrows mark times of stimulus application. Stimulation intensity was 55 mA for all examples.

(11,17). The present results are consistent with previous modeling studies that elaborated the biophysics underlying the selective depolarization of lumbosacral posterior roots by the rather unfocused electrical field produced by transcutaneous SCS (39,40). Hot spots for stimulation of posterior root fibers are at their point of entry into the spinal cord created by nonuniformities of the anatomy and changes of the fiber path direction with respect to the generated field. The current across the spine close to the stimulating paraspinal electrodes is mainly “channeled” through the electrically better conductive ligaments and vertebral discs. Employing the different levels of the multi-electrode array for stimulation, the segmental selectivity is most probably influenced by the longitudinal separation of the preferential levels of current flow given by the rostro-caudal dimensions of the vertebral bodies of 20–30 mm (41,42).

Changes in body position from lying to sitting to standing change the efficacy of transcutaneous SCS also due to variations in the curvature of the spine.

Normally, these changes of the volume conductor can be compensated by repositioning the stimulating electrodes. The multi-electrode array presented here along with a control interface allowing for the selection of individual array elements renders any removal and relocating of the electrodes unnecessary and presents an easy-to-use solution allowing for a convenient and time-efficient switch between stimulation sites.

Future studies shall test the applicability of the proposed multi-electrode array for current steering as well as selected asymmetric left–right stimulation.

## CONCLUSIONS

The possibility to provide input to multiple discrete targets of the lumbosacral spinal cord, and hence change the location and size of the activated region, shall enable finer and more efficient control of the effects on the lower limb motor outputs. Ultimately, the multi-electrode array developed here shall be

used to apply more complex, dynamic stimulation protocols. The rationale is that, in studies applying epidural spinal cord stimulation, different stimulation parameter settings were shown to generate rhythmic flexion–extension movements of the lower limbs and strong bilateral extension (9,12–14). Hence, a cycle-to-cycle modulation of the applied stimulation parameters adapted to flexion and extension phases as well as left and right sides represents a promising next step to further augment the efficacy of locomotor therapy in individuals with spinal cord injury (43).

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## SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article at the publisher's web-site and has been deposited on Dryad (44), <http://dx.doi.org/10.5061/dryad.20cs5>:

**Fig. S1.** FPC-layout (flexible printed circuit) of an 8x1 electrode array module; the conductive structures are printed on strips of flexible base foils and have means for cascading to larger arrays.

**Fig. S2.** Schematic diagram for routing of eight electrode contacts to connector pins.

**Fig. S3.** FPC-layout of a control switchboard for four 8x1 array modules; the board carries dual inline (DIL) switches, for routing connector pins to a stimulator output, and four connectors for 8x1 array modules.

**Fig. S4.** Schematic diagram of the control switchboard for four 8x1 array modules; DIL switches allow variable routing of array contacts to the stimulator output.