Reducing the sensation of electrical stimulation with dry electrodes by using an array of constant current sources

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Title: Reducing the sensation of electrical stimulation with dry electrodes by using an array of constant current sources

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24

25   **Abstract**

26   Hydrogel electrodes are commonly used for functional and other electrical stimulation

27   applications since the hydrogel layer has been shown to considerably reduce the

28   perception of stimulation compared to dry electrodes. However, these hydrogel

29   electrodes must be changed regularly as they dry out or become contaminated with

30   skin cells and sweat products, thus losing their adhesiveness and resistive properties.

31   Dry electrodes are longer lasting but are more uncomfortable due to unequal current

32   distribution (current hogging). We hypothesize that if current through a dry electrode

33   is equally shared amongst an array of small sub-electrodes, current hogging and thus

34   the sensitivity perceived due to stimulation will be reduced. We constructed an 8 x 8

35   array of millimetre sized dry electrodes that could either be activated as individual

36   current sources, or together as one large source. A study was performed with 13

37   participants to investigate the differences in sensation between the two modes of

38   operation. The results showed that 12 out of 13 participants found the new (distributed-

39   constant-current) approach allowed higher stimulation for the same sensation. The

40   differences in sensation between single and multiple sources became larger with

41   higher intensity levels.

42   **Keywords:** Dry electrodes; electrical stimulation; array stimulation

1. Introduction

The application of electrical current to stimulate nerves for functional and therapeutic purposes is well established [1], [2]. Electrodes play a major role in the success of stimulation since the efficacy of intervention, avoidance of tissue injury and the associated discomfort are all determined by the stimulation waveform and type of electrode used [2]. Surface electrodes are the most commonly used electrode types in typical functional electrical stimulation (FES) application for correction of foot drop caused by damage to the brain or spinal cord. Guiraud et al reported that implanted FES devices for gait restoration have been restricted to experimental concepts, and have very little follow-up data [3]. The size, shape, material and placement of surface electrodes determines how effectively the underlying muscles and nerves are stimulated with the least amount of discomfort [4]. Good surface electrodes should be comfortable during use, easy to apply, stay in place for at least a day, re- usable, cost effective and reliable [5].

In the past, carbon-rubber electrodes were commonly used. However, these require the application of electrode gel which can be messy and inconvenient. Therefore low-cost self-adhesive hydrogel electrodes are currently use as standard. As the resistivity of the hydrogel layer increases, the stimulation-induced discomfort decreases [6]. Though high resistivity hydrogel electrodes possess most of the desired properties required for good electrodes, they have poor reusability. Using old, dried out and dirty electrodes increases the chances of causing skin irritation, reduces self-adhesiveness and increase electrode-tissue impedance. Regular replacement of these electrodes increases the costs of therapy, especially when more sophisticated and costly electrodes are required [8].

Taking these issues into consideration, dry electrodes appear attractive for long-term applications. However, dry electrodes may cause pain or discomfort when high intensity electrical stimulation is applied. At low current intensities, stimulation evokes a sensory reaction without muscle contraction; as the current intensity is increased in order to evoke a muscle contraction, this sensory response increases and can cause pain and skin irritation [9]. Hair follicles, sweat pores and other structures beneath the skin form paths of low resistance for the current passing through the electrodes and thereby cause uneven current densities ("current hogging"). It is thought that the local high current densities due to current hogging lead to the greater pain associated with surface stimulation [6]. We hypothesise that if current can be more evenly distributed across the stimulated area (thus avoiding current hogging) then stimulation will be more comfortable. One way to achieve this even distribution is to use a high impedance hydrogel electrode [6]; However, Cooper et al. conducted a study on the properties of high resistivity hydrogel samples and concluded that they became contaminated with skin products and lost their desired properties if they were used for several days [7], causing significant problems in long term applications. An alternative approach to achieve equal distribution of the current within the electrode is to use multiple constant current sources, each connected to one of an array of small, adjacent mini electrodes.

2. Material and methods

Participants

Ethical approval for the study was obtained from the Sheffield Hallam University Research Ethics Committee and participants were recruited from students and staff within the University. After obtaining informed consent, thirteen adults, (11 male and

2 female) were recruited to the study. Participants were excluded if they had any prior adverse responses to any form of electrical stimulation or had any skin conditions such as eczema.

Equipment and Materials

A 64 channel, constant current stimulator, Shefstim, was used to provide stimulation [10]. The parameters of stimulation i.e., pulse width, amplitude and frequency were controlled by custom software and PC. A commercially available hydrogel electrode (StimTrode 5x5cm, Axelgaard Manufacturing Ltd., USA) was used as the anode. The cathode was a dry electrode array of 64 electrodes (in an 8 x 8 matrix), constructed from stainless steel paper pins. The heads of the pins were approximately 1mm in diameter and were used as the electrodes. The pins were placed through a piece of stripboard with spacing of 2.54 mm and a 5 mm thick foam backing. The pins were then soldered onto another piece of stripboard via which the electrodes were connected to the outputs of the stimulator. The whole electrode formed a square of 30 mm x 30 mm.

A breakout box was constructed so that each of the 64 channels could either act as individual electrodes (multiple sources) or all could be shorted to act as a single electrode (single source). This allowed the same electrode array to be placed on the same location and used to compare conventional (single source) and the novel (multiple sources) stimulation techniques, without having to remove the electrode. The participant was blinded as to the nature of stimulation, and the two stimulation types were delivered alternately.

Experiment design

The participants were asked to sit on a chair and rest their left arm on a table in front of them. The electrode array was placed approximately 5 cm below the elbow on the extensor aspect of the left forearm and was secured with two Velcro straps. The anode was placed on the wrist of the same arm. The experimental protocol consisted of two parts:

a) Identification of comfort threshold (CT): This was defined as the threshold at which the participant felt that the sensation was at a maximum level that would be just tolerable for long periods of stimulation. This threshold stimulation current was identified for both single and multiple sources in random order by slowly increasing the intensity of stimulation and repeated twice more for each stimulation type. The maximum current of the three measurements was taken as the comfort threshold.

b) Difference in sensation: For each participant, stimulation was applied at 25%, 50%, 75% and 100% of the largest comfort threshold current identified above, starting at the lowest intensity. Stimulation was randomly switched between single source (type A) and multiple sources (type B), whilst keeping intensity constant. The participant was asked to mark the difference in perceived sensation on the visual analogue scale provided (Figure 2). Switching between A and B was repeated until the participant was confident about his decision.

Outcome measures

a) Identification of comfort threshold (CT): After the stimulation intensity was set to the appropriate level for the measurement being made, current stimulation intensity was recorded (measured by ShefStim). At the same time the delivered charge was measured as the voltage (V_C) across a1 μF capacitor (C) connected in series with the

137 participant in the anode path using a battery operated oscilloscope (Tektronix THS

138 720). The delivered charge was calculated as Q [μC] = C [μF]$*V_C$ [V] and applied

139 current for in one pulse as $\mathrm{I\ [mA]} = \frac{Q\ [\mu C]}{t\ 200\ [\mu s]} * 10^3$

140 *b) Difference in sensation*: The perceived sensation was measured using the Visual

141 Analogue Scale (VAS). The VAS values are expressed as percentage measured on

142 10 cm line between 'no difference' and 'much more uncomfortable' for either A (single

143 source) or B (multiple sources).

144 Analysis

145 *a) Identification of comfort threshold (CT)*: The Wilcoxon matched-pair signed rank test

146 was used for the current threshold measurements. All values are expressed as mean

147 values with confidence intervals unless indicated differently on the graphs.

148 *b) Difference in sensation*: The Wilcoxon signed rank test was also used to compare

149 the differences in sensation to a hypothetical value of 0% i.e. no difference in

150 sensation.

151 **3. Results**

152 The results of the comfort threshold measurements showed that 12 out of 13

153 participants had a higher comfort threshold for multiple current sources. The median

154 comfort threshold for multiple sources was 14.5 mA (10.4 to 22.1, 97.75% CI of

155 median) in comparison to 12.4 mA (8.3 to 18.6, 97.75% CI of median) for a single

156 source. The Wilcoxon non-parametric test gave a highly-significant p value of 0.0017

157 with median difference of 2.0 mA (0.7 to 4.9 mA, 97.75% CI of median).

158 The magnitude of the differences between the comfort thresholds varied across the

159 participants (mean 19%) but was as high as 93% more current delivered for one

160   participant (Pt #8). Only one participant (Pt #7) had a higher comfort threshold for the

161   single source (6% lower for the multiple source). Figure 3 shows a graphical

162   representation of the results obtained in this test.

163   Two out of the 52 VAS measurements were not collected due to an operator error.

164   These measurements were at 25% CT for Pt #2 and Pt #8. The values reported below

165   are differences in VAS values expressed in percent. Positive values indicate the extent

166   that multiple source stimulation is more comfortable than single source, whereas

167   negative values indicate the single source is more comfortable. The 25% of comfort

168   threshold (CT) measurements showed median difference of +5% (0% to +39%,

169   98.83% CI) and a Wilcoxon signed rank test compared the values to a hypothetical

170   value of 0 with $p = 0.089$, the 50% of CT measurement showed a median difference

171   of 16% (4% to 28%, 97.75% CI, $p = 0.0164$), the 75% CT measurement showed a

172   median of 20% (3% to 69%, 97.75% CI, $p = 0.0083$) and maximum intensity showed

173   a median of 32% difference (0% to 61%, 97.75% CI, $p = 0.0020$).

174   The differences in sensations between single and multiple sources became larger with

175   higher intensities levels (50%, 75% and max.) in participants Pt#1, Pt#,3, Pt#9 and

176   Pt#13. However in some participants the differences were consistent typically in Pt#2,

177   Pt#4, Pt#5, Pt#6 as shown on Figure 4. Participant #7 perceived the single source as

178   more comfortable than multiple sources at lower currents, but reported the opposite at

179   maximum CT, similarly Pt #8, at 25% CT.

180   **4. Discussion**

181   We hypothesised that if current is more evenly distributed across the stimulated area

182   then the stimulation will be more comfortable. The results of the study show that

183   participants were able to tolerate higher stimulation intensities with multiple sources of

184 stimulation. We expected multiple sources to be increasingly more comfortable than

185 single source stimulation as stimulation levels increased. Indeed this was the case

186 globally and some participants clearly showed this phenomena individually. However,

187 some participants did not perceive much difference between the two stimulation types

188 and two found multiple sources to be only more comfortable only at the highest levels.

189 An explanation for this could be due to differing perceptions of sensation for sub-

190 maximum stimuli. It could also be that the pitch of the electrodes was not small enough

191 to optimise the control of current hogging. Another factor that could be influential is

192 that there was no skin preparation, such as hydration of the skin, prior to the

193 application of the dry electrode to the participants' forearms, and that varying degrees

194 of skin hydration explain the wide variation in comfort thresholds. It is also possible

195 that those participants with thicker hair, more sweat glands and naturally drier skin

196 could have found multiple sources to be more comfortable, although this was not

197 measured.

198

199 Although the multiple-source constant current stimulation is more comfortable than a

200 single constant-current source, there was no attempt in this study to stimulate at

201 functional levels, so we do not know if it is comfortable enough at the currents required

202 for functional use. The minimum tolerable current intensity (Pt #2) was 9 mA, through

203 an approximate 6.25 cm^2 contact area. As electrodes in common clinical use are often

204 25 cm^2, a larger electrode area may allow a minimum of 36 mA tolerable current, which

205 is sufficient for most foot-drop applications.

206 Although the *Shefstim* stimulator is very compact for its capabilities (it measures

207 142mm x 50mm x 14mm and weighs 125 g including batteries), the necessity of having

208 64 individual constant-current sources makes it larger and more expensive than a well-

209   designed single-channel stimulator. An alternative, lower-cost approach would be to

210   use resistors to impose near constant-current for each channel. For a maximum

211   current inequality of 10%, each resistance would have to be of the order of nine times

212   greater than the maximum skin resistance presented by a single channel, so this would

213   require an approximately 10 times higher stimulation drive voltage to compensate for

214   the drop across the resistors, leading to a higher power consumption. Increasing the

215   tolerance for current inequality would lower this wasted energy.

216

217   The experimental electrode array used in this study is too bulky and inconvenient to

218   use clinically. A smaller, flexible design integrated into an elasticated garment to hold-

219   it in place on the skin would be required for this to be a clinically usable approach.

220   Further work should compare comfort levels between stimulation through multiple

221   sources and a single source using a hydrogel electrode. This will give us a clear picture

222   of whether the hydrogel electrode could be replaced with an array of dry electrodes.

223   Additional work should also investigate the tolerable level of current mismatch

224   between channels.

225   Although stimulation with multiple sources was shown to be more comfortable, it is

226   clear that there is a large difference in response between participants. Further work

227   should seek to identify the reasons for these differences, e.g., it is possible that

228   participants with thicker hair and drier skin found multiple current sources more

229   comfortable than participants with less hair and more hydrated skin. Understanding

230   these parameters may help to improve the technique further.

231   **5. Conclusions**

232

The purpose of this study was to see whether the sensation associated with the use of dry electrodes could be reduced. Stimulation through multiple sources showed improved comfort levels compared to single source stimulation in most subjects, suggesting that it may avoid current hogging.

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