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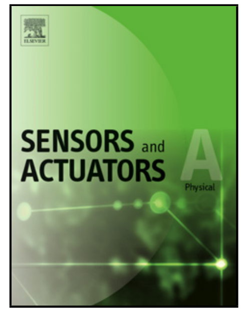

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Screen Printed Fabric Electrode Array for Wearable Functional Electrical Stimulation

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Abstract

Functional electrical stimulation (FES) activates nerves using electrical currents, and is widely used in medical applications to assist movement of patients with central nervous system lesions. The recent emergence of small electrode arrays enables greater muscle selectivity and reduces fatigue compared to the use of traditional large electrodes; however existing fabrication techniques are expensive and have limited flexibility and comfort which limits patient uptake. This work presents a screen printed flexible and breathable fabric electrode array (FEA) which consists of four printed functional layers. Successful operation has been demonstrated by stimulating an optimised selection of electrodes in order to achieve clinically relevant reference postures ('pointing', 'pinch' and 'open hand'). The materials with skin contact used in FEA have been cytotoxicity tested to establish that they are biocompatible. The FEA demonstrates the potential for printable polymer materials to realise comfortable, wearable and cost effective functional systems in healthcare applications.

Keywords: functional electrical stimulation (FES), fabric electrode array, screen printing, e-textile, biocompatibility, smart fabric

1 Introduction

Functional electrical stimulation (FES) is a technique to activate nerves using safe levels of electrical current in a coordinated manner in order to stimulate muscle activity [1]. It is widely used to assist the movement of patients with central nervous system lesions which may result from head trauma, spinal cord injury, stroke or other neurological disorders. FES uses electrodes to stimulate the neural tissues entering the muscle. The electrodes may either be implanted but are more commonly and conveniently placed on the surface of the skin. Surface electrical stimulation has widespread clinical use since the approach is non-invasive and comparatively straightforward to deploy.

Surface stimulation requires a sequence of electric charges to be delivered across an anodic and cathodic electrode pair, placed over the muscle body. Existing clinical surface electrodes are typically large and employ a self-adhesive hydrogel to improve electrical contact. The drawbacks of large electrode FES devices include insufficient selectivity and quicker patient fatigue due to the co-activation of various non-synergistic muscles [2]. Employing a large number of small surface electrodes has been found to address the lack of selectivity and a variety of different electrode arrays have recently emerged [3]. These have been found to assist patients with complex tasks through selective muscle stimulation [2-4]. In particular, electrode arrays have enabled the stimulation of functional wrist and hand gestures which are a critical component of the activities of daily living, involving at least 41 musculo-tendon units actuating a 16 joint system with 23 degrees of freedom [5].

The long-term goal is to produce wearable FES technology that provides maximum function, comfort and convenience. This necessitates exploiting the intrinsic properties of fabric (e.g. flexibility, breathability, light weight) by fabricating suitable electrode arrays directly on an appropriate fabric. To date, no fabrication technique has yet been demonstrated that can realise such an electrode array economically. Embroidery has been used by T. Keller et al. to manufacture smart fabric type electrode pads and electrode wiring on fabric for neuroprosthetic applications [6]. However, this required expensive high quality custom made silver sputtered yarns produced using plasma vapor sputtering since commercial metal coated yarns (e.g. silver coated Nylon 66 'ShieldX') showed low uniformity due to the degradation of the conductive yarn surface during the embroidery process [7]. Weaving and knitting have been used in fabricating smart fabrics for various wearable electronic applications (e.g. sensing, display, health monitoring, power generating) [8-10]. However, these methods are also not suitable for fabricating a wearable FES array. Weaving and knitting approaches impose limitations on the design of the array because the conductive path is constrained to follow the physical location of the yarns within the fabric. There is also a lack of homogeneity in the resistance of the conductive pattern due to the imprecise gaps between the conductive yarns.

This paper presents flexible and breathable fabric electrode array (FEA, Figure 1a) fabricated entirely by screen printing the active electrode array directly onto a standard fabric. Screen printing is a straightforward and cost effective fabrication method which facilitates significant design freedom in terms of pattern geometries [11, 12]. It is a well established technology in both the textile and printed electronic fields. The printed FEA has required the development of bespoke polymer based screen printable pastes that can be processed in a manner compatible with textiles. These materials are now commercially available from Smart Fabric Inks Ltd, UK [13]. A carbon loaded silicone rubber has been applied to form the electrodes which enable dry contact via the conductive pad-skin interface and avoids the need to use the hydrogel that is typically required by existing electrodes [14]. The materials with skin contact used in the FEA are biocompatible. The performance of the FEA has been compared to that of the leading alternative, which comprises a flexible printed circuit board (PCB) array on polycarbonate with a hydrogel layer (Fatronik-Tecnalia, Spain, Figure 1b). The FEA can produce comparable angular joint movement compared to the PCB array; in addition, FEA has significant improvement on the flexibility, breathability and comfort. Critical postures of daily life have been achieved by stimulation of an optimised selection of elements.

251658240 **a** **b**

Figure 1. Fabric electrode array (a) and flexible PCB array from Fatronik-Tecnalia (b).

2 Material and Fabrication

2.1 Material

2.1.1 Fabric

The polyester/cotton (65/35, 2X1 twill, 210g/m^2, 316μm thick, provided by Klopman International) used in this study is a typical fabric for clothing. It combines the advantages of polyester fibre (e.g. wrinkle resistance, shape retention, durability, abrasion resistance, resistance to light damage) and the benefits of cotton fibre (e.g. comfort, softness, moisture absorption, light weight).

2.1.2 Pastes

The paste materials and their curing methods used in this study are shown in Table 1.

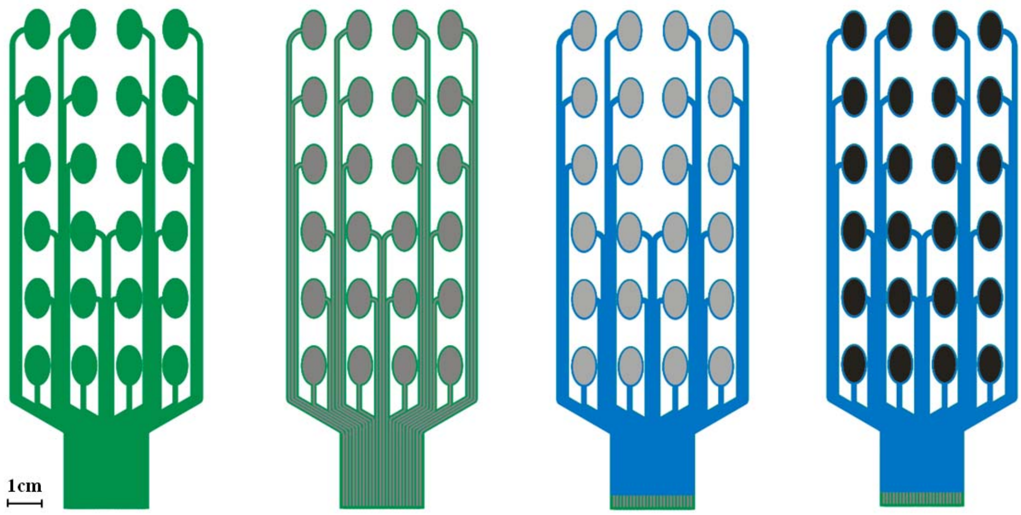
Table 1. Paste properties and curing conditions.

Pastes	Materials	Curing conditions
Fabink-UV-IF1004	Polyurethane acrylate paste	UV light
Fabink-UV-IF1044	Waterproof polyurethane acrylate paste	UV light
Fabink-TC-AG4001	Silver flake in vinyl resin polymer and solvent	10 minutes at 120°C
Carbon rubber	Carbon filled silicone polymer paste	30 minutes at 80°C

2.2 Fabrication process

Fabrication overview

A DEK248 semi-automatic screen printer was used to print the FEA which consists of four functional layers: a) an interface layer on fabric to provide a smooth surface for subsequent printing; b) a silver layer to form conductive pads and tracks; c) an encapsulation layer over the conductive tracks to provide protection and electrical insulation, which leaves the silver tracks at the end open for connection as shown in Figure 2; d) a carbon loaded silicone rubber layer over the conductive pads to provide a good electrical connection with the skin. The printing processing steps are shown in Figure 2.



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a b c d

Figure 2. Top views of the FES processing after the printing of each layer, with sequence: interface layer (a), conductive silver layer (b), encapsulation layer (c) and carbon loaded silicone rubber layer (d).

2.2.1 Interface layer printing

Printing the silver conductor directly onto fabric is not ideal due to the rough surface of the fabric. In this work, the surface roughness is reduced by first printing a polyurethane based interface layer. The interface layer is made up of two different polyurethane paste compositions. These pastes (denoted Fabink-UV-IF1044 and Fabink-UV-IF1004 supplied by Smart Fabric Inks Ltd, UK) are UV curable polyurethanes which provide a flexible and smooth surface after curing. The benefit of combining a waterproof material (Fabink-UV-IF1044) and a material with good adhesion (Fabink-UV-IF1004) have been reported in our previous work [15]. UV curing is a rapid room temperature polymerisation technique. It is more environmentally friendly than the established thermal curing method due to the low release of volatile organic compounds (VOCs) and is entirely compatible with textiles.

When printing, a 250 thread/inch stainless steel screen with 40 μm emulsion thickness supplied by MCI Precision Screen Ltd was found to give the best print quality. The interface layer was formed using three prints of Fabink-IF-UV-1044 followed by one print of Fabink-IF-UV-1004. Two deposits of paste were applied for each print. UV curing was applied after each print by exposing each sample to a 400W mercury (Hg) bulb in a UV cabinet (UV Light Technology Ltd). The UV curing time was 60s for Fabink-IF-UV-1044 and 30s for the Fabink-IF-UV1004 respectively at an energy of 53 mW/cm^2 at a wavelength of 365 nm. The total thickness of the interface layer is 135 µm measured using a scanning electron microscope Zeiss EVO LS25. SEM micrographs of the bare fabric and the fabric with 1 to 4 prints of interface layer each consisting of two deposits are shown in the supplementary materials.

2.2.2 Conductive layer printing

The conductive silver paste used in this study is Fabink-TC-AG4001 which is a thermally cured polymer paste that gives a high conductivity and exhibits good adhesion to the interface and encapsulation layer. The conductive silver tracks/pads were printed using one print of a single deposit of Fabink-TC-AG4001. A 120 thread/cm polyester screen with 10 µm emulsion thickness was used. The paste was cured in a box oven at 120 °C for 8 minutes. The thickness of the silver conductor is 5 µm.

2.2.3 Encapsulation layer printing

An encapsulation layer was printed on top of the conductive tracks apart from at the connector end and the electrode pads which are left exposed for further processing. This provides physical protection and also reduces the strain in the silver track under bending by moving it closer to the neutral axis. A 250 thread/inch stainless steel screen with 30 µm emulsion thickness was used in the encapsulation layer printing. The encapsulation layer was formed using one print of Fabink-IF-UV1004 followed by two prints of Fabink-IF-UV-1044; one deposit of paste was applied for each print. The UV curing time was 30 s for the Fabink-IF-UV1004 and 60s for the Fabink-IF-UV1044 at a lower energy level, 31 mW/cm^2 at 365nm. This was because only one deposit of paste was applied for both types of paste so the curing time was shorter than the time used for the interface layer curing. The total thickness of the encapsulation layer is 75 µm.

2.2.4 Carbon rubber layer printing

Finally, one print of a single deposit of a thermally curable custom carbon loaded Viscolo 22 silicone rubber paste was printed on top of the silver electrode pads to provide the connection between the conductive silver pads and the skin [16]. A 100 µm thick stainless steel stencil screen was used in the printing. The paste was cured at 80 °C for 30 minutes leaving a dry electrode layer with a thickness of 25 µm. The use of dry electrodes eliminates potential discomfort caused by the stickiness of the hydrogel. The final FEA can therefore be reused indefinitely to provide a more cost effective and less wasteful solution.

The scanning electron microscope (SEM) micrographs of the conductive tracks and the conductive pads of the final FEA are shown in Figure 3a and b.

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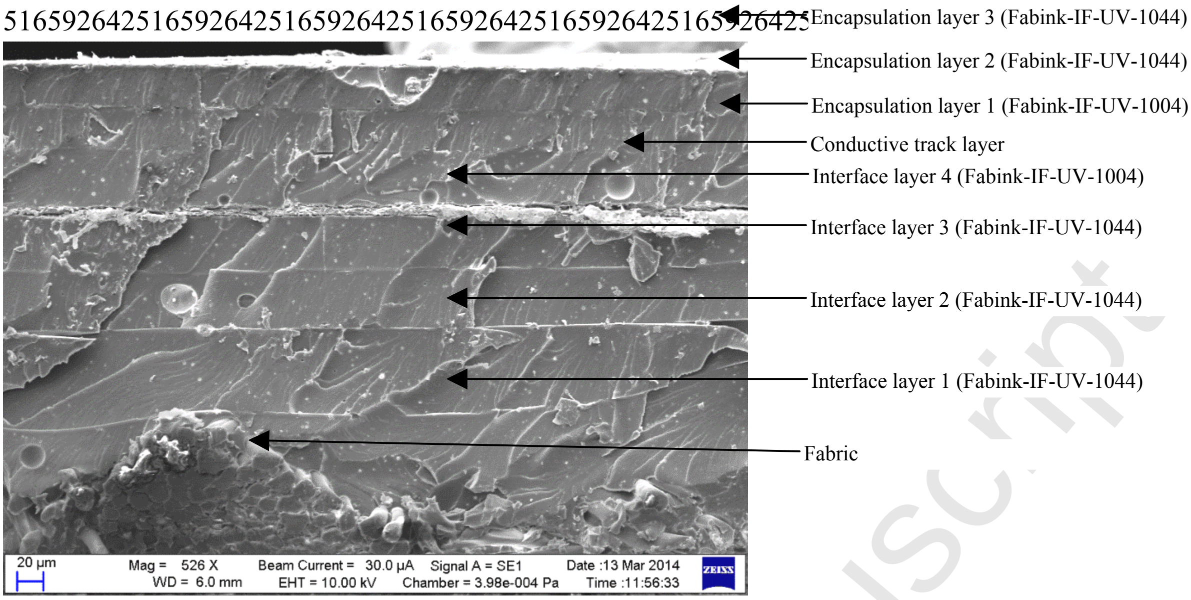

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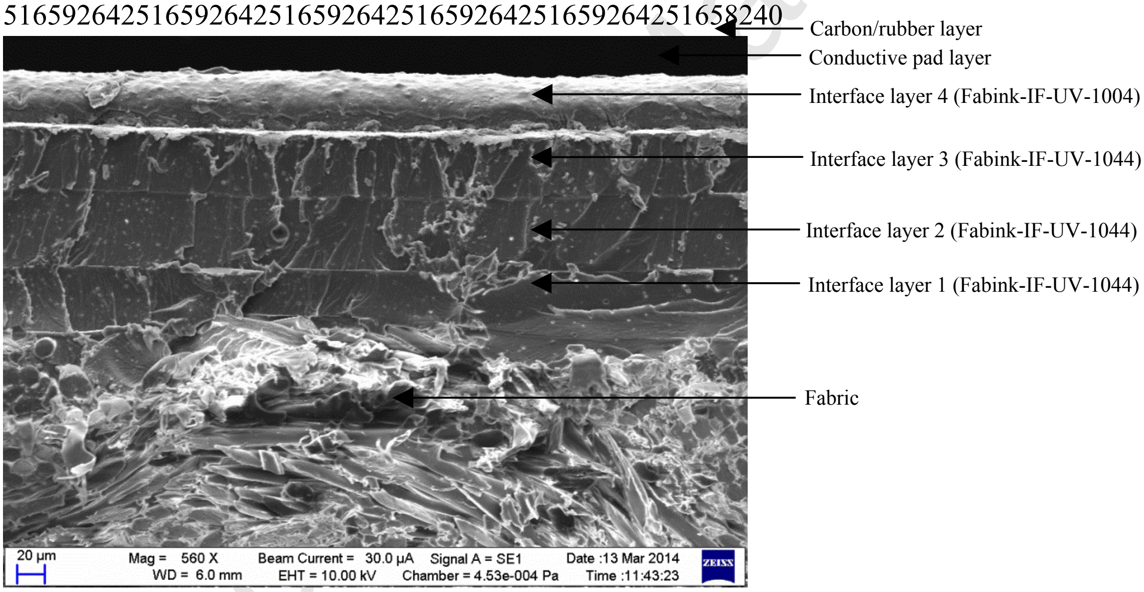

b

Figure 3. SEM micrographs of the conductive tracks (a) and conductive pads (b).

3 The benefit of using the interface layer

The silver paste penetrates into the yarns when it was printed directly onto the fabric, and results in non–conductive film after printing and curing a single deposit of silver paste on bare fabric (Figure 4a). To achieve conductivity, multiple deposits and prints of silver are required and this is expensive and time consuming [17]. The interface layer enables good conductivity using only a single print of one deposit of silver. The effectiveness of the interface can be established by comparing the resistance of the silver tracks on the interface with the resistance achieved when printing on Kapton (DuPont).

Kapton is a flexible polyimide film which has a smooth surface and is widely used in printed flexible electronics.

One deposit of the silver paste was printed on the fabric with interface layer and another on Kapton. In both cases the paste was cured at 120 °C for 8 minutes in a box oven. Figure 4d shows that for a given length of silver track, a lower resistance was obtained for the rough fabric with the interface layer compared with the Kapton. The sheet resistances of the silver tracks are 49.4 mΩ/sq on the fabric with interface layer and 54.9 mΩ/sq on Kapton respectively at a thickness of 5 μm. The underlying interface also provides protection for the conductive silver tracks from damage and sweat ingress which can occur through the underside of the fabric. The printed silver tracks have good definition and are clearly separated with a 0.4 mm gap between the silver tracks at the connector end (Figure 4c).

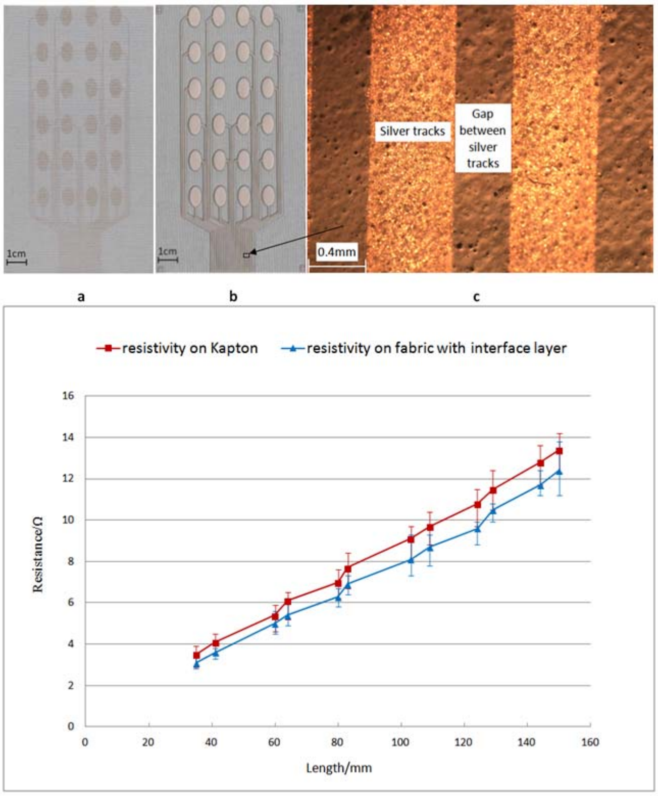

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Figure 4. Silver tracks/pads on bare fabric (a); fabric with interface layer (b); conductive track separation (c); resistivity of the conductive silver tracks on fabric interface layer and Kapton (d).

4 Material biocompatibility test

Wearable fabric arrays must be manufactured using biocompatible materials to avoid harm to the user. Cytotoxicity testing is a primary measurement method for devices and materials involving contact with the skin in medical applications. It is a rapid, standardised, sensitive and cost effective method to evaluate whether a material is harmful at significant levels and its effect on cellular components. To conduct the assessment, the cytotoxicity test (ISO 10993-5: Agar Overlay of L929 cells, 24 hrs incubation) was applied to the materials which make contact with the skin [18]. The Agar Overlay test is designed to determine the cytotoxicity of diffusible components from materials. An agar layer was added over a cell monolayer to protect the cells from damage while allowing the diffusion of the leachable materials. The test sample was placed on top of the agar layer and incubated for 24 hours at 37±1°C. The cell monolayers were examined and scored based on the degree of cellular destruction.

The encapsulating Fabink-IF-UV1044 and carbon loaded silicone rubber materials were tested by Nelson Laboratories in the USA [19]. The criteria is negative control (polypropylene pellets) which receive a '0' reactivity grade and positive control (latex natural rubber) which receive '3-4' reactivity grades (moderate to severe). Scores of 0, 1 and 2 are pass and scores of 3 and 4 are fail. Table 2 shows the results of 3 tests with both materials passing the cytotoxicity test with an average score of '0' and '1' respectively for Fabink-UV-IF 1044 and carbon loaded silicone rubber. This is a key step towards ensuring biocompatibility of the FEA.

Table 2. Cytotoxicity test results for the printed materials in contact with skin.

Materials	Scores				Results
	#1	#2	#3	Average	
Fabink-UV-IF-1044	0	1	0	0	pass
Carbon loaded silicone rubber	1	1	1	1	pass

5 FES functions on assisting hand movement

5.1 Effects of the individual electrode

Initial functional tests of the FEA were performed to establish selectivity, comfort and achievable joint motion when applied to the forearm for hand and wrist motion. Evaluation was undertaken with two unimpaired participants (denoted P1, P2) who were instructed to provide no voluntary effort. To provide comparative validation, tests were also performed using a standard flexible PCB array manufactured by Fatronik-Tecnalia (Figure 1b) of identical size and layout. Both electrode arrays were tested using fully validated stimulation and sensing hardware that have been used in recent clinical trials with stroke patients [20]. The array was positioned as shown in Figure 5, to cover wrist and finger extensor muscles. The details of the test equipment and processing are described in the supplementary materials.

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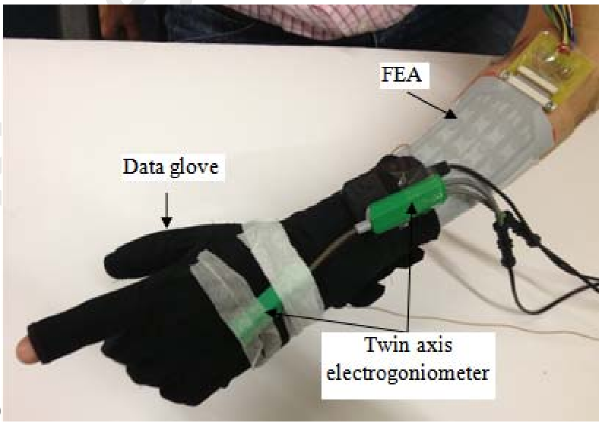

Figure 5. Monitoring system for FEA assisted hand movement.

Figure 6 presents results of individual electrode stimulation in assisting wrist extension which is a critical component in the restoration of lost hand function. These results confirm that FEA produces similar levels of movement when compared with the flexible PCB array. There is also a similar pattern of movement in each case, which confirms repeatability despite the tests being performed on an underlying biomechanical system which is extremely sensitive to physiological effects, as well as small changes in array and sensor position. No discomfort was reported by the participants during the tests.

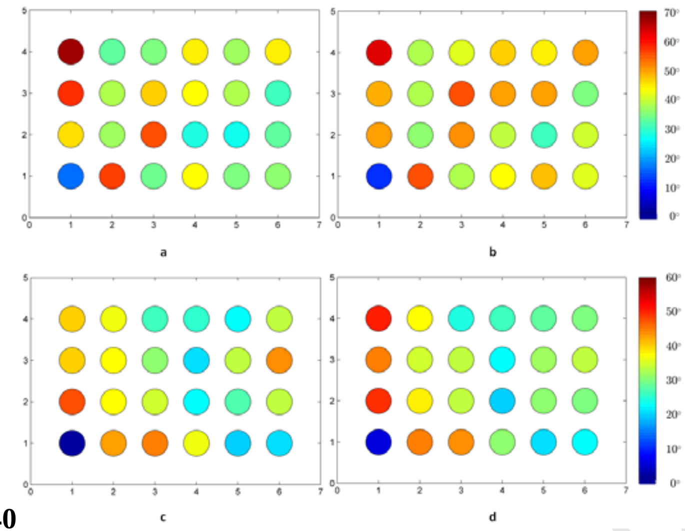

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Figure 6. Mean wrist extension using FEA for P1(a) and P2(c); flexible PCB array for P1 (b) and P2(d).

To quantify differences in movement, the 2-norm of movement produced in one repetition of the test sequence was calculated using equation 1:

$$\sum_{i}^{24} \|y_1(i) - y_0(i)\|_2 \qquad (1)$$

where $y_0(i)$ and $y_1(i)$ are glove and electrogoniometer joint angles at the beginning and end of each ramp test respectively for the i^{th} element. The mean and standard deviation across repetitions is shown in Table 3. The results shows that the fabric array produces an average of 96.6% and 97.5% of the angular joint movement compared with the flexible PCB for P1 and P2 respectively. It also indicates greater repeatability of movement using the fabric electrode, perhaps due to a reduction in movement associated with the absence of a hydrogel layer.

Table 3. Mean (standard deviation) of total movement 2-norm using each array type.

Participant	FEA	Flexible PCB array
P1	1929.9 (94.1)	1998.5 (189.9)
P2	1752.4 (155.0)	1797.7 (226.7)

5.2 Effects of the optimised multi electrodes

The functionality of an electrode array is highly dependent on the control strategy used to select and stimulate individual elements. Existing control methods embed simple rule-based selection of suitable sites in order to produce the greatest level of appropriate movement, while minimizing undesired effect [20-23]. Such approaches have proved capable of generating selective movement, but are slow and imprecise since they do not exploit an underlying dynamic model linking FES and resulting motion. The greatest levels of accuracy have been achieved using a technique called Iterative Learning Control (ILC) which embeds the idea of learning from past experience. This technique was used to evaluate the performance of the fabric electrodes, with full details of the ILC scheme given in [24]. Three different reference postures were selected to verify the optimization procedure; ‘pointing’ with the index finger, a ‘pinch’ hand posture and an ‘open’ hand posture. These postures are shown in Figure 7 and were performed at a wrist angle of approximately 35° extension, with each test starting from an initial wrist angle of approximately 30° flexion. The task set incorporates specific finger movement as well as extension of the fingers and wrist, comprising key elements of activities of daily living.

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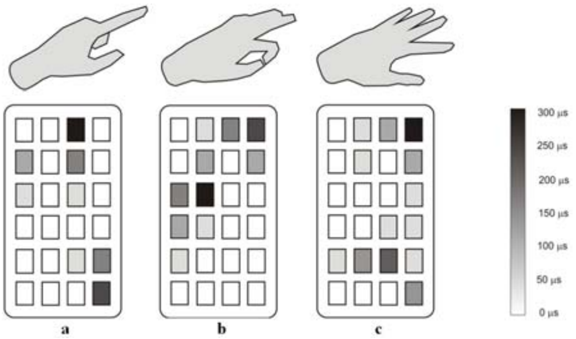

Figure 7. Stimulation patterns for pointing (a), pinching (b) and open hand (c) gestures (shading indicates the pulsewidth levels).

Three repetitions of ILC were performed for each posture. To quantify the accuracy attained the percentage error was calculated across all joints for each posture using equation 2,

$$100 \times \frac{\|e_3\|}{\|y_0\|} \quad (2)$$

where y_0 is the initial posture prior to stimulation, and e_3 is the error after 3 repetitions of ILC. The results are shown in Table 4 for each task. The ILC procedure yields results with a mean joint angle error of typically less than 7% of the initial value. It can also be seen that the FEA is able to produce slightly superior results when compared with the flexible PCB array.

Table 4. Percentage error across all joints using each array type.

Array	Participant	Pointing	Pinch	Open hand
FEA	P1	5.29	5.33	6.18
	P2	3.55	6.97	5.45
Flexible PCB array	P1	6.81	7.73	7.90
	P2	4.46	6.86	6.51

6 Conclusions

The feasibility of manufacturing fabric electrode arrays (FEA) using low temperature screen printable materials has been demonstrated which establishes the potential for wearable FES technology with a high level of breathability and flexibility. Fabric surface roughness has been reduced significantly by using an interface layer between the conductor and the rough fabric. Printing a single deposit of silver on the fabric interface layer has achieved better conductivity than on Kapton when the interface layer was used on the fabric. The materials with skin contact in the FEA are biocompatible which was confirmed by cytotoxicity tests. The dry electrode provides improved comfort and lifespan compared to existing approaches which use a conductive hydrogel layer.

Tests have shown that the FEA can provide highly accurate assistance of movement. The FEA can produce over 90% of the angular joint movement generated by the leading alternative which is a flexible PCB array on polycarbonate with a hydrogel layer. Furthermore, joint movement has greater repeatability on FEA compared to the PCB plastic electrode array. Different reference postures ('pointing', 'pinch' and 'open hand') have been achieved by stimulating an optimised selection of elements. The FEA therefore has the potential for wide medical application for assistance and rehabilitation in both clinical and home environments.

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Biographies

K. Yang received the BEng in Material Engineering from Beijing Institute of Fashion Technology, China, in 2004. She obtained her Ph.D. degree in School of Chemistry from University of Leeds in 2009. Since 2009, Kai Yang has been a Research Fellow in the School of Electronics and Computer Science, University of Southampton in UK. She has worked on the printed electronic textile projects funded by EU FP7, EPSRC, DSTL and Wessex Medical Research. Dr Yang is a co-founder and director of the Smart Fabric Inks company. Her research interests include smart fabrics, ink formulation, biocompatible materials, and textile digital printing.

C. Freeman is a reader in applied control at the University of Southampton. He received the B.Sc. degree in mathematical sciences from the Open University in 2006, the B.Eng. degree in electromechanical engineering from the University of Southampton in 2000, and the Ph.D. degree in control systems from the same institution in 2004. His control research interests include iterative learning and repetitive control theory and their experimental application to industrial systems and biomedical engineering. He has led the engineering component on large UK government funded grants which have developed a range of upper limb systems using robotic and Functional Electrical Stimulation (FES) technology that have each been trialled clinically with stroke patients. In this area his current focus is on biomechanics, motor learning and control, non-contact sensing, electrode-array based FES, and touch-table technology. He has 190 publications in these fields

R. Torah graduated with a BEng (Honours) in Electronic Engineering in 1999 and an MSc in Instrumentation and Transducers in 2000, both from the University of Southampton. Between 2001 and 2004 Russel obtained a PhD in Electronics from the University of Southampton in the optimisation of thick-film piezo ceramics. Since 2005 he has been a full time researcher at the University of Southampton where he is currently a Senior Research Fellow. Dr Torah is a co-founder and director of the Smart Fabric Inks (in 2011) company specialising in printed smart fabrics. Dr Torah's research interests are currently focused on smart fabric development but he also has extensive knowledge of energy harvesting, sensors and transducers. He has over 50 publications in these fields.

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J. Tudor obtained a BSc (Eng) in electronic and electrical engineering from University College London and a PhD in physics from Surrey University. In 1987, John joined Schlumberger Industries working first at their Transducer Division in Farnborough and then their Research Centre in Paris, France. In 1990, he joined the University of Southampton as a lecturer. In 1994, John moved to ERA Technology becoming the microsystems program manager. In 2001, John returned to the School of Electronics and Computer Science, University of Southampton where he is currently a Principal Research Fellow. His research interests include smart fabrics, screen printing, dispenser printing, MEMS, microsystems, energy harvesting, sensors, resonant sensors, inkjet printing and wireless sensors. He is a co-founder of Perpetuum Ltd and a co-founder and director of two other companies Smart Fabric Inks Ltd and D4 Technology Ltd. He has 150 publications and is both a chartered physicist and engineer.

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- A flexible and breathable fabric electrode array (FEA) has been fabricated entirely by screen printing method.
- High conductivity (sheet resistance = 49.4 mΩ/sq) was achieved on fabric through use of an interface layer.
- Materials used in the FEA which make skin contact have passed the ISO cytoxocity test.
- FEA can provide highly accurate assistance of joint movement.
- Different reference postures have been achieved by stimulating an optimised selection of elements.