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Novel Screen Printed Electrode Set for Routine EEG Recordings in Patients with Altered Mental Status

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***Abstract*—There is a growing need for an easy to use screening tool for the assessment of brain's electrical function in patients with altered mental status (AMS). The purpose of this study is to give a brief overview of the state-of-the-art in electrode technology, and to present a novel sub-hairline electrode set developed in our research group. Screen-printing technology was utilized to construct the electrode set consisting of ten electroencephalography (EEG) electrodes, two electrooculography (EOG) electrodes, two ground electrodes and two reference electrodes. Electrical characteristics of hydrogel-coated silver ink electrodes were found adequate for clinical EEG recordings as assessed by electrical impedance spectroscopy (EIS). The skin-electrode impedances remain stable and low enough at least two days enabling high-quality long-term recordings. Due to the proper material selection, thin ink layers and detachable zero insertion force (ZIF) - connector, electrode was observed to be CT- and MRI-compatible allowing imaging without removing the electrodes. Pilot EEG recordings gave very promising results and an on-going clinical trial with larger number of patients will show the true feasibility of this approach.**

I. INTRODUCTION

Electroencephalography (EEG) is a well established method for measuring the electrical activity of the brain. EEG is an irreplaceable technique in clinical epileptology for detecting epileptic seizures [1] and it plays an important role in investigation of encephalitis, head trauma, coma, stroke, drug overdose and sleep disorders [2]. Despite of EEG's indisputable role in effective diagnosis of a patient with possible acute brain injury or altered mental status (AMS) [3,4], routine recording of EEG outside neurophysiological care units has been hindered by numerous obstacles [5,6]. Firstly, traditional EEG recording systems are often costly, bulky and inconvenient to be permanently located in emergency rooms (ER), intensive care units (ICU), ambulances or in a primary care unit. Fortunately, miniature portable devices suitable for ambulatory studies, such as Trea® (Grass Technologies) or MicroEEG® (Bio-Signal Group Corp.) [6] have been recently launched. Secondly, there are difficulties of finding skilled EEG interpreters and to motivate them to be available 24/7. This challenge is expected to be relieved with wireless platform technologies in help of which a neurophysiologist can interpret EEG signal by using tablet computer or mobile phone via internet [5]. Thirdly, the time and the special expertise required to setup a full set of separate EEG electrodes according to the internationally standardized 10/20 montage is typically lacking in emergency medicine or in a primary care unit. Therefore, the development of easy, rapid-to-use electrode systems plays a crucial role in enabling EEG recordings to become routinely used with patients suffering from altered consciousness. This paper presents our innovative approach.

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II. BRIEF OVERVIEW OF STATE-OF-THE-ART

One existing approach to allow easier application of electrodes for EEG monitoring is based on the use of EEG template systems such as BraiNet (Jordan NeuroScience Inc.). These templates are disposable elastic caps with color-coded holes that indicate the proper electrode placement sites according to 10/20 system. Templates can be used with standard disc electrodes. However, these electrodes still require depositing a mound of electrode cream onto the prepared area of skin and affixing separate electrodes through the hair, being still somewhat challenging and time-consuming for a non-technologist. As an evidence, Kolls *et al.* recently published a study of the applicability of EEG template in non-technologist use, and found that only in 29% of cases, EEG recording could be started under 30 minutes, whereas in 29% of cases it took 30-40 minutes and even in 42% of cases it took over 40 minutes [7].

To solve the above-mentioned problems, the self-adhesive EEG electrodes have been suggested for emergency medicine [8-10]. The employment of pre-gelled, disposable electrodes at the hairline are expected to allow rapid set up by staff not trained in the placement of EEG electrodes and to provide a screening tool for assessment of brain activity. However, hairline EEG with four or six channels was found to miss approximately 30% of the seizures [8, 9]. These data suggest that hairline EEG solutions based on only minimal number of electrodes might be inadequate for sensitive detection of seizures. Furthermore, these hairline studies have been performed with separate electrodes, although it is obvious that successful clinical usability would require electrode array solution in which all electrodes are embedded into a single flexible mounting film, *e.g.* using screen printing technology [11]. Some such electrode arrays have been already commercialized. The bispectral index monitor (BIS VISTA^{TM}, Aspect Medical Systems, Inc.) in assessing the depth of sedation has been on the market for over a decade with a patented bi-frontal electrode array of 4 channels. Furthermore, about two years ago, Hydrodot Inc. introduced a revolutionary StatNet^{TM} disposable EEG headpiece. In this "sandwich" construction, electrodes are pregelled elongated Ag-AgCl sensors and the electrical signals are transmitted via silver ink tracings embedded into a flexible headpiece. According to the supplier, the attachment of StatNet for a patient will take an average of only 5 minutes. However, from a demo video available online, it is clear that the attachment requires extensive experience to carry out this action so quickly, particularly in patients with long hair. Further, Brainscope Inc. also has an EEG system currently in FDA validation trials with a sub-hairline electrode system (Ahead-100) [12] for assessment of EEG at ER patients having brain injury.

III. EXPERIMENTAL PART

The second aim of this study is to introduce a novel electrode set for routine EEG studies in ER, ICU or ambulances. We hypothesize that it is possible to construct an electrode set that can be applied easily and quickly (in minutes) without neurophysiological expertise but which also allows a long-term, uninterrupted monitoring of EEG with high sensitivity and performance.

Electrodes and transmission lines of the present electrode set are composed of a thermoplastic silver ink that is screen-printed onto a polyester substrate. An UV-curable dielectric ink is printed on polyester film forming an insulation layer on all positions other than the areas of the electrodes and connection pads. Electrodes are then covered with round-shaped pieces (Ø: 18 mm) of hydrogel membrane (Amgel 603, Amgel Technologies) to improve the electrical contact enhancing the flow of charge across the skin-electrode interface. Double coated medical foam tape (7432M, 3M Company) is used at positions surrounding the hydrogel to improve the skin adherence. Finally, the electrode set is shaped using laser cutting technique. The electrode system consists of sixteen electrodes, *i.e.* ten EEG electrodes corresponding to the standard locations of Fp2, Af8, F8, Sp2, T10, Fp1, Af7, F7, Sp1, T9, two EOG electrodes, two ground electrodes, plus two reference electrodes (Fig. 1). The electrode set is designed to fit into a 16-channel zero insertion force (ZIF) connector. Small printed circuit board adapters were constructed containing the above-mentioned ZIF connector and set of soldered lead wires terminating 1.5 mm touch proof connectors thought which the electrode set could be connected to any commercial EEG device.

The electrical characteristics of electrode set were assessed using electrical impedance spectroscopy (EIS). The EIS measurements were performed after a stabilization period of 15 minutes in electrodes attached face-to-face. Measurements were carried out in the frequency band from 0.1 Hz to 10 kHz by applying a sinusoidal voltage of 10 mV without any DC offset.

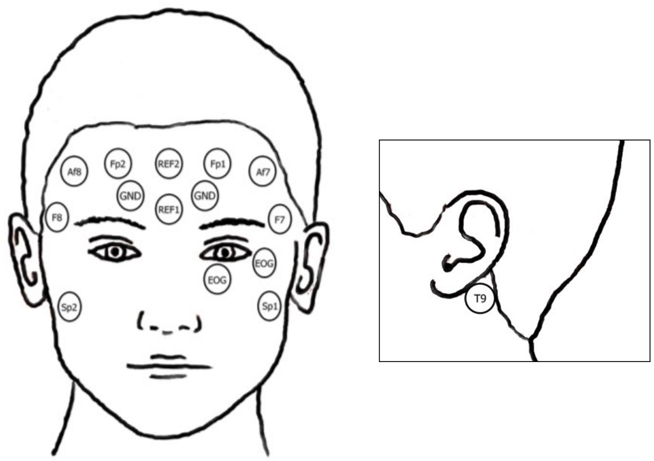

Figure 1. Sites for electrode placement. Reference electrodes (REF1, REF2) are located at centerline, and ground electrodes (GND) at both sides of them. T9 and T10 electrodes are located behind the left and right ear, respectively.

The EIS measurements with a perturbation signal of 10 mV, 0.1 Hz-100 kHz were also conducted for electrodes attached to the forearm of a human volunteer. The electrodes (n=6) similar to electrodes used in EEG electrode set as well as a larger area (50 x 40 mm) counter electrode were simultaneously attached to skin. Prior to electrode attachment, the skin was cleaned by gently wiping it with an ethanol soaked cotton pad. A Solartron 1260/1287 impedance measurement system was employed. Data acquisition and data analysis were performed with the ZPlot and ZView (Scribner Associates, Inc.) software packages.

The EEG recordings were carried out in the Department of Clinical Neurophysiology, Kuopio University Hospital. In this paper, three patient cases (Pt1: 61 yo. male; Pt2: 54 yo. male; Pt3: 71 yo. female) with AMS are shortly presented. Referral question in all these three cases was to rule out status epilepticus (SE). Recordings were conducted using a Comet XL (Grass Technologies) monitoring system. Traditional 10/20-montage EEG with twenty-one gold-over-silver scalp surface electrodes affixed with EC2® Electrode Cream was used as a reference. The skin of the patient was cleaned by gently wiping it with an ethanol soaked cotton pad. The electrode impedances were monitored and the quality of the raw signal was determined by visual inspection of the computer screen. The study protocol was reviewed by the local ethical committee (Kuopio University Hospital Ethical Committee, favourable opinion 10/2011) and VALVIRA (Finnish National Supervisory Authority for Welfare and Health, permission 166/2011).

IV. RESULTS

A prototype of a flexible screen printed EEG electrode set conforms well to the shape of the face of a volunteer (Fig. 2). The electrode set may be bended between the electrode sites to avoid having hair at the electrode contact. This is important as hair between electrodes and skin increase the contact impedance significantly. Due to the thin and flexible substrate, this procedure is not technically challenging but to ensure appropriate clinical usability with all patients, the electrode sets with different sizes are needed.

There was only minimal variation between impedance values of electrodes connected face-to-face (Fig. 3). For example, at 10 Hz, the mean impedance magnitude (|Z|) and phase (theta, θ) was 1270 ± 30 Ω and -31.2 ± 0.4°, respectively. The largest relative standard deviation (%RSD) was observed at 10 KHz (for |Z|) being only 2.7%. At other frequencies, RSD values were between 0.9% and 2.5%. Only at very low frequencies (*i.e.* below 1 Hz) the electrodes are vulnerable to significantly increased polarization effects (Fig. 3). Data from the long-term impedance testing of electrodes attached on the forearm of a human volunteer (Fig. 4) show that impedance levels, measured at 10 Hz, decreased during the first hours, and then stayed stable over 24 h of use. After 48 hours, impedances (at 10 Hz) were increased to the value measured at 15minutes time point. However, impedance value measured at 100 kHz was doubled after 48 hours and become 3.6-fold after 56 hours. Since electrode polarization impedance can be kept almost negligible at 100 kHz [13], the rise in impedances is due to the increased series resistance, *i.e.* hydrogel bulk resistance resulting from the dehydration of hydrogel membrane.

EEG recordings were performed as proof-of-concept experiments, comparing the performance of the novel electrode set to the performance of standard 10-20 montage (Fig. 5). The interpretation of both EEG recordings, performed by two specialists (AÕ, EM) gave identical reviews (Table 1). Electrode materials did not cause any skin irritation or other side effects even in long-term measurements.

Figure 2. A screen printed electrode set applied to a human volunteer.

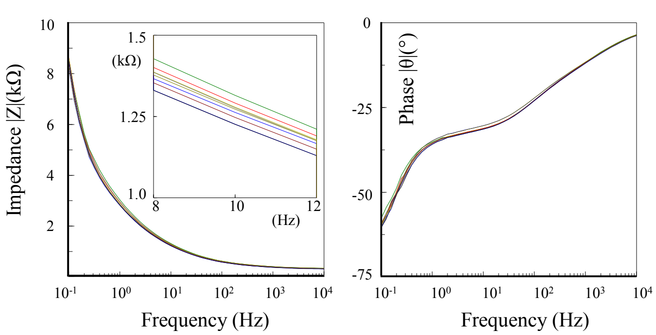

Figure 3. Bode plots of electrodes (9 pairs) attached face-to-face. Only minimal variation in impedance values of different electrode pairs is seen. At 10 Hz (see inset left), impedance values range between 1225 Ω and 1292 Ω being much less than 2000 Ω (ANSI/AAMI standard EC12). Phase data (right) show that only at very low frequencies (< 1Hz) the electrodes are vulnerable to significant polarization.

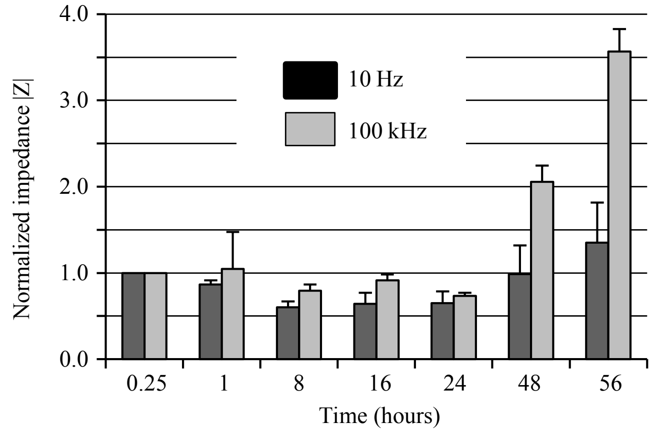

Figure 4. Normalized skin-electrode impedances of electrodes (n=6) attached on the forearm of a human volunteer, measured at 10 Hz and 100 kHz. The absolute skin-electrode impedance values 0.25 hours after electrode attachment (*i.e.* value to which measurement at other time points are normalized) at 10 Hz and 100 kHz were 4.1 ± 3.4 kΩ and 505 ± 45 Ω, respectively.

TABLE 1. EEG FINDINGS IN THREE PATIENT CASES

	with Novel EEG Set	***with 10/20 Montage***
Pt1	agree with SE, if also clinical correlates of SE	agree with SE, if also clinical correlates of SE
Pt2	SE cannot be excluded	SE cannot be excluded
Pt3	SE excluded	SE excluded

V. DISCUSSION

Recently, much effort has been put into developing electrode systems suitable for quick and easy EEG recordings allowing their employment in emergency medicine. However, commercially available solutions are still either too difficult to use, or their sensitivity and selectivity are not clinically high enough [8,9]. The solutions mimicking full 10/20 system like StatNet and BraiNet have also certain limitations. These may not be used in patients suffering from head trauma or if patient's head is unmovable due to the head or neck injury. Further, for long-term monitoring use, the dehydration of electrolyte gel leads to reduced EEG signal quality. In this study, we introduce an electrode array that is easy and rapid to attach but also allows the long-term monitoring. Material selection was optimized to permit the safe and artifact-free MRI and CT scanning of patients with attached electrodes (data not shown). Based on our pilot patient cases, the novel screen-printed EEG electrode set seems to provide reliable EEG signal suitable for diagnostic purposes, at least in clear-cut cases. However, posterior head regions are not covered, which may lead to diagnostic inaccuracy in some cases.

In our previous study [14], we tested similar electrode montage with hand-made wire electrodes. Unless being adequate in terms of electrical impedance and noise behavior [14] and also effective in detecting EEG abnormalities (unpublished data), wire electrode set suits weakly for commercial fabrication. Instead, screen printing technology used in these second generation electrodes suits well for economic mass production of disposable electrodes.

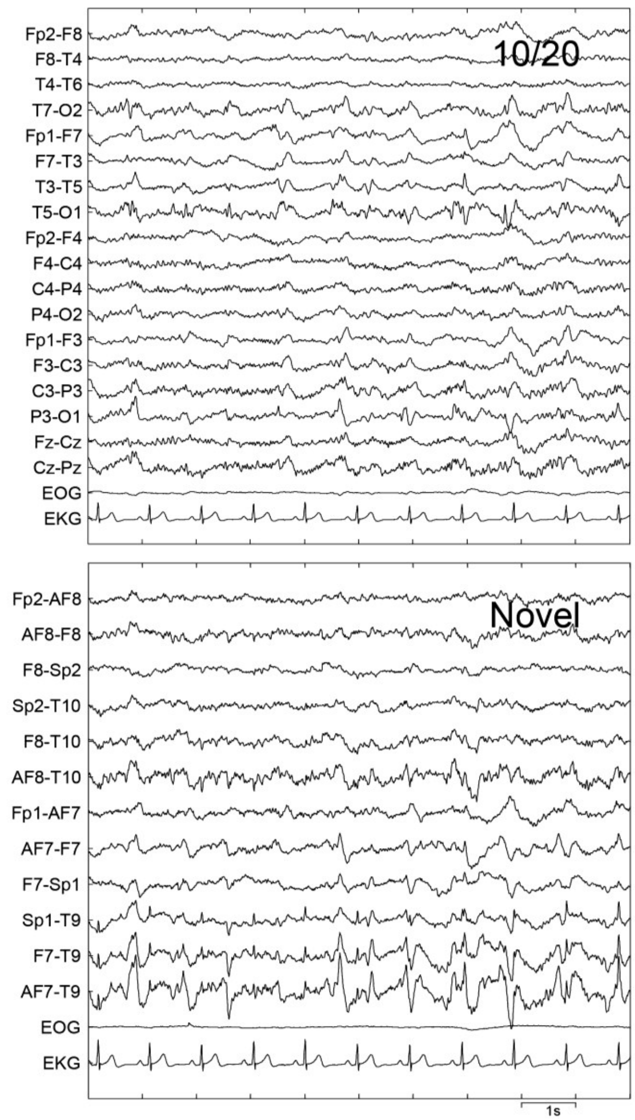

Figure 5. 61 yo. male with widespread PLEDs (periodic lateralized epileptiform discharges) over left hemisphere. EEG and clinical examination compatible with status epilepticus.

The use of screen printing technology in conjunction with electrolytic hydrogels is intriguing. It enables production of thin, highly flexible electrode arrays with accurately defined electrode areas, shapes, and inter-electrode distances for a wide range of applications [13]. Due to the mobile ions incorporated inside hydrogel, it conducts electricity moderately [13-15]. Based on the present EIS measurements, the hydrogel electrodes have relative high impedance magnitude at low frequencies (Fig. 3). However, this is not a severe problem anymore when using modern input-impedance amplifiers [16]. In accordance with previously published studies [13, 15], we observed that skin impedance is largely dependent on the nature of the skin (location, thickness, pore density), and possible pretreatments done. Thus, we reported skin-electrode impedances as normalized values (*i.e.* normalized with impedance at 15 minutes). We interestingly observed that skin impedances of hydrogel electrodes remained very stable in long-term recordings. In our 56 hour experiment, only 35% increase in impedance magnitude was noticed at 10 Hz which lies within a clinically relevant range of EEG frequencies. Further, motion artifacts primarily resulting from the mechanical disturbances of the electric charges at the skin-electrode interface are less prominent when using the hydrogel electrodes. This is due to the flexible and light-weight electrode structure that can conform to the irregularly-shaped skin surface. Moreover, self-adhesive hydrogel and foam tape materials ensure a good, mechanically firm electric contact to skin. These technical issues rise in special importance in the intended use of the electrode sets for patients with AMS.

To conclude, the preliminary results achieved with the introduced electrode set are encouraging. However, a clinical trial with large number of patients is needed to evaluate the true potential of this product.

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