The Reuse of Resterilized Fetal Scalp Electrode – An Electron Microscopic Study of Its Biocompatibility and Microbiological Culture

Soon Lean Keng, Syed Mohsin Syed Sahil Jamalullail and Farid Che Ghazali

School of Health Sciences, Universiti Sains Malaysia, Health Campus, 16150 Kubang Kerian, Kelantan Darul Naim, Malaysia

ABSTRACT

Central to intrapartum care is fetal monitoring using fetal scalp electrode that involves the placement of electrode into the infant’s scalp per vagina. This study was conducted to evaluate the surface characteristics and microbiological culture of post-inserted fetal scalp electrode. This practice has been significantly associated with common clinical problem in minimally invasive obstetric care. The collected post-inserted and resterilized fetal scalp electrode was examined for microbiological culture of gram-positive and gram-negative microorganism using Stuart media. The advantage of using VPSEM to study newly manufactured or post-inserted resterilized fetal scalp electrode are many. Characteristics and incidence of device related defect were clearly exemplified by such method as described in this study. No organism was detected in all the devices tested. The disinfecting techniques used by the HUSM for reusable fetal scalp electrode is commenable and proof effective. It is recommended that the fetal scalp electrode can be reusable subjected to it being properly cleaned using standard protocol. The findings of this research demonstrated that awareness and safety practices are important aspect to take note when reusing medical devices by all health care staffs. Biocompatibility of medical devices, detection defects and care in handling of any invasive foreign contraption into humans are, therefore paramount.

KEYWORDS: Resterilized fetal scalp electrode, Supra-variable pressure energy filter scanning electron microscope (Supra VP FESEM), Scanning electron microscopy (SEM), Variable pressure scanning electron microscopy (VPSEM) and Backscattering electrode (BSE), Microbiology culture, Defects.

INTRODUCTION

Intrapartum fetal asphyxia is an important cause of stillbirth and neonatal death. The principal screening technique for fetal distress and hypoxia during labour is the measurement of fetal heart rate. In this aspect, electronic fetal heart rate monitoring can detect fetal distress, and it is often used for routine monitoring of women in labour. This screening technique has become an accepted standard of care in the hospital for the management of labour (Shy, Larson & Luthy, 1987; Albers & Krulewitch, 1993). The measurement of fetal heart activity is performed most accurately by attaching an electrode directly to the fetal scalp per vagina, an invasive procedure requiring amniotomy and associated with occasional complications. The goal of fetal heart monitoring is to identify abnormal fetal heart patterns so that timely interventive procedures could be initiated for example in expediting birth. This effort might lower the rate of perinatal morbidity and mortality resulting from asphyxia (Albers & Krulewitch, 1993). The use of fetal scalp electrode (see Figure 1) during labour is for the detection of fetus experiencing stress due to intrauterine asphyxia, most often secondary to a compromise in the uteroplacental circulation (Santos, O’Gorman and Finster,
Single use and/or the utilization of used and resterilized fetal scalp electrode are a common practice in healthcare institutions. In the Hospital Universiti Sains Malaysia (HUSM), reusing of the resterilized post-inserted fetal electrode has been a common practice since the 1980’s to date. Reuse of disposal medical devices does occur since the late 1970s (Reports of the Council on Scientific Affairs, 2000). Medical device-related infections had and will continue to be a major concern. Bacterial colonization of devices, including orthopaedic prosthesis and catheter surfaces, can eventually lead to implant failure (Gristina, Giridhar, Gabriel, Naylor & Myrik, 1993). Formation of a conditioning film that is generally proteinaceous in nature to which bacteria can subsequently attach and secrete extracellular polymeric substances (Mittelman, 1997). Hence, these substances can eventually elicit in health problem on the infant and the mother. Bacteria associated with this ‘biofilm’ has been reported to show an increase in resistance to antibiotics when compared to their free-floating counterparts (Hoyle, Jass & Costerton, 1990; Khoury & Bruce, 1993) for reasons that are poorly understood presently. Studies by Grimshaw & Russell (1993) and ‘Implementing Clinical Practice Guidelines (1994) described that, although it has been shown in rigorous evaluations that clinical practice guideline can improve the quality of care, whether they achieve this in daily practice is less clear. This is partly because current evidence about the effectiveness of these guidelines is still debatable. On the other hand, little is known about the role of Scanning Electron Microscopy (SEM) in evaluating surface structure characteristics of fetal scalp electrode in order to explain the various recorded clinical complains associated with insertion of this small device into the female gender. Variable Pressure Scanning Electron Microscopy (VPSEM), a new highly developed model of SEM with simplified preparation of the tested material before use (Billy, 2000), has never been utilized to study the surface structure of the fetal scalp electrode previously.

The use of these electron microscopic techniques may provide evidence for the development of guidelines to minimize potential harm and are options for the improvement of quality of care received by patients. However another invaluable method is to obtain a culture to determine diversity and spatial distribution of bacterial population in ‘biofilms’ formed on the fetal scalp electrode post fetal heart monitoring. It is also important to scientifically provide evidence of the interrelationship between the evaluation of surface structure characterization of fetal scalp electrode and infection. The using of the SEM and other microscopic techniques may prove useful.

This study is an attempt to pioneer the utility of VPSEM in elucidating common clinical problems encountered in minimally invasive clinical practice. Further, this method which provides novel viable morphological and elemental analyses of various commercially available products, like the scalp electrode, can be essential in helping to understand the pathogenesis of clinical condition associated to clinical devices. This study could prove valuable in providing basic information that can act as guides to better design and improved functionality of these devices, therefore promoting effective health care practice, awareness and proper usage of such devices.

OBJECTIVES

• To examine and assess the post inserted fetal scalp electrode surface microbiologically and to examine them under high resolution scanning electron microscope.
• To detect possible remnants and contamination of resterilized post inserted fetal scalp electrode with soft tissues, microorganisms and plague using VPSEM and microbiological culture.
• To look for evidence in relation to characteristic changes of post inserted fetal scalp electrode surface using VPSEM with possible suggestion of the importance of its use as a prompt diagnostic tool.
• To examine and assess whether VPSEM can show the basic structure and to detect any manufacturing defects of the fetal scalp electrode.
• To detect types of defect in relation to the features of the fetal scalp used in HUSM by using the VPSEM.

MATERIALS AND METHODS

The fetal scalp electrode device used for this study was collected with consent from patients with post surgically implanted device at the Labour Room of the HUSM. Upon retrieval from patients, the collected scalp electrodes were prepared for high resolution microscopy investigation and microbiological culture. In high-resolution microscopical investigation, the scalp electrode was packed in a sterile plastic and then sealed. They were then kept in a refrigerator at 4ºC over a variable period of time until further investigation. The controlled sample and test fetal scalp electrode were observed directly under a stereomicroscope and were also inserted into the VPSEM peltier stage chamber by firmly placing them on the stud without the use of any cover slip with the chamber vacuum pumped to achieve a considerable Pascal pressure in accordance to the hydrated nature of the specimens. Using high-resolution VPSEM the intima surface morphology of each electrodes were investigated as unfixed sample and vacuum dried at room temperature. Each fetal scalp electrode was observed directly under the LEO1455 VPSEM at about 35kv pascal vacuum pressures and within 15 mm or shorter, working distance to enable scanning of the surface morphology with backscattering secondary electron imaging. This will be ideal for quantitative analytic work, such as quantitation of the micro-elements presence with Energy Dispersive X-ray (EDX) Analysis system at 15 Pascal vacuum pressures. The morphological evaluation was further carried out in association with recorded clinical complains (e.g. pains), and duration of insertion (hours). In the microbiological culture test, collected scalp electrodes were examined for organisms by microbiological culture of gram-positive and gram-negative microorganism. Extra efforts were also made to check microbiological culture of the reused electrodes using similar protocol as above.

RESULTS

Digital photomicrograph of a used resterilized post inserted fetal electrode (see Figure 2) show pale brownish coloured ‘biofilm’ indentation and a fetal hair follicle remaining on the surface spiral turning tip. Further probing under the VPSEM, revealed that the tip of the some of the electrodes was also observed to be double ended or of two horns (see Figures 3 & 5). Hair follicle like structures was observed present on the electrode surface (see Figures 2 & 5). The hair follicle was observed to be presented as if it was glued to the electrode. Naked eye inspection cannot reveal horns, hook-like structure, ‘bioflim’, hair follicle, indentation and/or defect (see Figures 2, 3, 4, 5, 6 & 8) on the device.

DISCUSSION AND CONCLUSION

New commercially obtained fetal scalp electrode should present with a double spiral stainless steel structure with sharp-ended tip (see Figure 1). However, blemish tips (see Figure 4 & 5) could lead to laceration of the fetal’ scalp during insertion. Minor lacerations of the fetal scalp have been mentioned in the literature as common incidents. Early study by Okada & Chow (1977) has reported that incident of minor lacerations of the fetal scalp between 1 to 4.5% usually develop into scalp ulceration or abscess. The dense connective tissue structures of the membranes protecting the women’s uterus could have caused or had played a significant role in fracture of the
electrode tip. Defects may occur due to poor technique in the polymerized tip and also possible structural inadequacies during manufacture (see Figure 4) or perhaps also defect development during insertion of the fetal scalp electrode. The defect mentioned can present a higher likelihood of causing problem like the development of embolus, retention of foreign bodies in the uterus and may also cause injury to the fetus and the mother. These electrode defects and the mentioned features of used electrode are not discernable by naked eye (see Figures 4 & 5). Hence, inspection must be done microscopically.

Hair follicle is present on the electrode surface (see Figure 8). This hair follicle seems to be glued to the electrode. We believed that this hair follicle could have been introduced per vaginal during clinical insertion of the fetal scalp electrode concerned. In this study VPSEM revealed sporadic and well organized sludge like mucous layered (biofilm layer) islands present (see Figures 2, 5 & 8). The ‘biofilm’ observed presented as if it was an integral part of and seems to be well blended to the surface electrode. Planktonic-like bacteria clumps on the ‘biofilm’ formation is known to occur avidly stuck to the inert surfaces (Costerton, et al., 1999). No organism were detected using Stuart media microbiological culture, be it neither gram-positive nor gram-negative micro-organism. Although it is a common believe that micro-organisms are present and are associated with the reusable electrode tip. Disinfecting techniques used by the HUSM for reusable fetal scalp electrode is commendable and has proven to be effective. This study suggests that the fetal electrode is reusable if subjected to thorough cleaning and sterilization protocol. Our study shows that there are various indentations or crater like features present at many areas of the spiral stainless steel loop surfaces under VPSEM. The indentations could have been due to micro-breakage, segmental or chip fractures either due to stress fractures or other undetected plastic polymerizations defects or damage during insertion. It is therefore, pertinent that equipment like the VPSEM be used to ensure quality control, biocompatibility studies (Farid, Abdul Hamid, & Jamaruddin, 2004; Farid, & Rogayah, 2004).

Elemental detection by VPSE shows the presence of iron, potassium chloride, gallium phosphorus, sodium albite, silicon dioxide, and calcium carbonate (see Figure 7 & Table 1). These substances could have been deposition of remnants of saline, mucous secretions and / or liquor amnii.

The use of fetal scalp electrode is recognized as an important procedure in obstetrics, but the microstructure of the various parts of the electrode is unknown to the health care team could pose hazards. This can be rectified by prior examination of the reusable electrodes by microscopic techniques. In this aspect in order to reused post fetal scalp electrode examination of its microstructure should be done prior to use. Understanding of its microstructure and possible build-up can be evaluated in clinical situation. Safe insertion into delicate human anatomy together with knowledge of characteristic changes of the used electrodes is vital in ensuring safe fetal cardiotocograph (CTG) monitoring. Based on this study, better product development and subsequently the use of improved product technology can be suggested. Better patient care and clinicians’ awareness and acceptance of the devices will then ensues. It can be concluded from this study that the advantage of using VPSEM for the investigation of fetal scalp electrode, be it newly manufactured or post-inserted fetal scalp electrode can reduce the incidence of device related injury or infection. The research also demonstrated the importance of health care staff awareness and their safety practices can indirectly reduce injury while improving health care. Biocompatibility of medical devices, detection of defects and care in handling of any invasive foreign contraption into (invasive) humans are paramount and must not be compromised.
Figure 1. Digital photomicrograph of a new fetal electrode with a sharp spiral turning tip.

Figure 2. Digital photomicrograph of a used resterilized post inserted fetal electrode. Note the pale brownish coloured ‘biofilm’ indentation and a fetal hair follicle remaining on the surface spiral turning tip.

Figure 3. Photomicrograph of a sharp upright pointed end tip of a fetal electrode under VPSE. Magnification 25x at working distance 8 mm.

Figure 4. Photomicrograph of a blunt end tip of a new fetal electrode observed under VPSE mode of the VPSE. Low magnification 25x at working distance 8 mm.

Figure 5. VPSEM photomicrograph showing a serrated tip of a reused fetal electrode. Some mucosal tags are also present. Magnification 89x at working distance 5mm.

Figure 6. VPSEM photomicrograph showing hook-like structure found on a new fetal scalp electrode. Magnification 37x at working distance 6mm.
Figure 7. VPSEM photomicrograph of Area 1 showing elements and substances detected in the microfilm on the fetal electrode tip. Magnification 111x at working distance 8mm.

Figure 8. Photomicrograph of used fetal scalp electrode surface observed under VPSE mode revealing the presence of hair follicle like structures and ‘biofilm’ indentations. Magnification 60x at working distance 9 mm.

Table 1 Elemental distribution detected in the microfilms at Area 1 on the fetal electrode tip

<table>
<thead>
<tr>
<th>Element</th>
<th>Standard</th>
<th>Weight %</th>
<th>Atomic %</th>
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<tbody>
<tr>
<td>C</td>
<td>CaCO$_3$</td>
<td>71.28</td>
<td>78.24</td>
</tr>
<tr>
<td>O</td>
<td>SiO$_2$</td>
<td>24.18</td>
<td>19.92</td>
</tr>
<tr>
<td>Na</td>
<td>Albite</td>
<td>1.15</td>
<td>0.66</td>
</tr>
<tr>
<td>P</td>
<td>GaP</td>
<td>0.29</td>
<td>0.13</td>
</tr>
<tr>
<td>S</td>
<td>FeS$_2$</td>
<td>0.67</td>
<td>0.28</td>
</tr>
<tr>
<td>Cl</td>
<td>KCl</td>
<td>1.51</td>
<td>0.56</td>
</tr>
<tr>
<td>Fe</td>
<td>Fe</td>
<td>0.91</td>
<td>0.22</td>
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Totals: 100.00
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