Encapsulation Materials for Implantable FES Systems – a Case Study.

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Abstract - *This paper describes problems encountered with the encapsulation of an implantable receiver in epoxy resin and describes the solution adopted. The implant concerned is a receiver unit for a new peroneal nerve stimulator. The original receiver consisted of two 'D'-shaped receiver coils and associated electronic components, mounted on two ceramic substrates. The components were encapsulated in a layer of epoxy resin, coated with silicon rubber.*

Evidence was found questioning the suitability of the epoxy encapsulation. The strongest evidence came from inspection of a receiver that had been explanted from an animal 3 ½ years earlier and left in water. When the receiver was examined at the end of this period a crack was noticed in the epoxy and corrosion was found on a receiver coil. Other samples also showed similar problems with cracks.

Based on the evidence described above, it was decided to change to an alternative material, silicon rubber as the encapsulant. There is extensive experimental and theoretical evidence to show that silicon rubber adheres well to components both during manufacture and during sterilisation. The reliability of this bond between encapsulant and components has been shown to be a major factor determining the success of encapsulations. From a more practical perspective, there is also considerable clinical evidence demonstrating the effectiveness of this material as an encapsulant and this eases the regulatory problems.

Keywords: encapsulants, epoxy, silicon rubber, implant.

1. Introduction and background

This paper describes a case study of problems encountered with the encapsulation of an implantable FES device. The implant is part of a novel two channel device for the treatment of dropped foot [1]. The receiver consists of two galvanically separated channels with passive components placed inside each of two D-shaped coils. Two leads leave the receiver, each of which connects the receiver to a pair of miniature sub-epineural bipolar electrodes. One electrode pair is to be sited on the superficial peroneal nerve and the other is to be sited on the deep peroneal nerve.

The original design work began in the early 1990s and a low shrinkage epoxy resin was chosen as the main encapsulant. Overlaying the epoxy was a thin layer of silicon rubber. The original design is shown in figure 1.

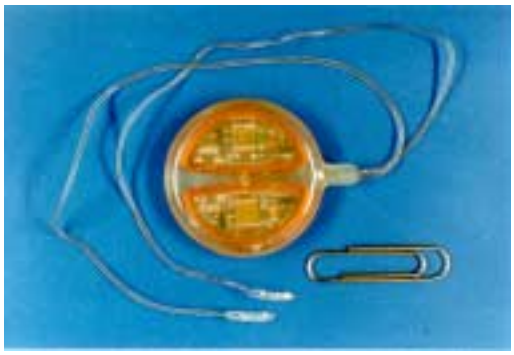

Figure 1: Original epoxy-encapsulated implant

2. Implant failure

In the early 1990s, animal testing of the new implant began. A number of implants were tested in goats and rabbits and satisfactory function was observed [2]. At the end of the animal tests, the implants were removed and histological examination of the nerve tissue was carried out. The removal entailed cutting of the lead wires between the body of the receiver and the electrodes.

Out of interest, two of the explanted receivers were placed in a beaker of water and left. In 1996, the trials were about to commence, following approval from the relevant Ethics Committees. The remaining problem was finding an authority willing to insure the trials. This proved to be extremely difficult and, due to a shortage of manpower, the project came to a halt. In December 1998 concerted work on the project began again with the appointment of a full time researcher.

It was assumed at the time of appointment that the device was more or less ready for use and hence that trials could begin within a few months. However, this proved to be a rather over-optimistic assumption. A number of outstanding practical problems quickly became apparent and a major problem with the implant

itself, the subject of this paper, was identified within the first two months. The practical problems centred around insurance and related matters. The major problem with the implant was identified when the two specimens, referred to earlier, were removed from the beaker of water in which they had been standing for at least 3.5 years. A photograph of one of the specimens is shown in figure 2.

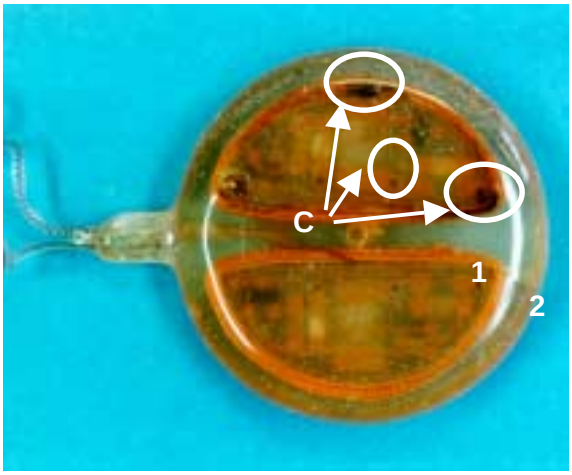

Figure 2 : Evidence of corrosion

As may be seen, black marks suggesting the presence of corrosion products, were observed at a number of points on various components (C). A crack was also noted in the epoxy resin, running from point 1 to point 2 in the figure. The other remaining implants were studied and similar cracks noted in some. Chemical analysis of the black residue and the copper wire near to the residue was carried out.

3. Possible reasons for failure.

The corrosion found in the samples required investigation. The first step taken was to send the black deposit for chemical analysis. On closer observation, the deposit took the form of dark green crystals. The deposit was taken from the largest site found on the coils. Two methods were used: X-Ray Photoelectron Spectroscopy; and Energy Dispersive X-Ray scanning. The results of these surface scans (up to a depth of 1 μm) revealed the presence of a variety of metals and metallic compounds, including not just copper compounds, but also somewhat surprisingly gold and aluminium. An example of one of the EDX scans is shown below in figure 3.

The coils themselves were of 99.9% pure copper and were surrounded by a self-fluxing polyurethane-based insulating layer. The material forming the insulating layer contained neither aluminium nor gold. Further, as far as we could determine, there was no gold or aluminium in components near to this corrosion site. Therefore, the presence of these two elements was rather surprising and remains difficult to explain. However, the scans did confirm that corrosion products were present and therefore the possible mechanisms through which this could have occurred were investigated.

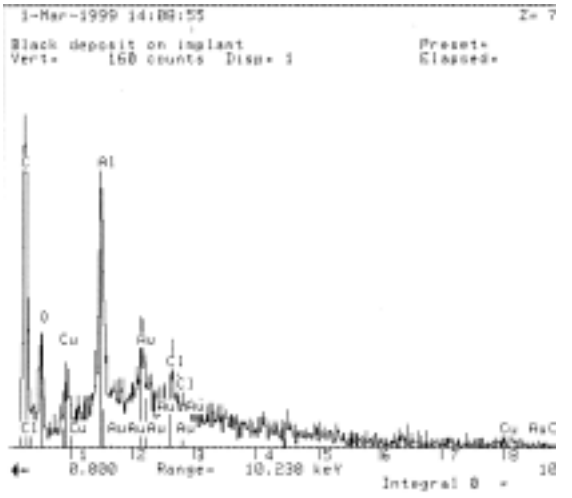

Figure 3 : EDX scan of black deposit

Epoxy resin and silicon rubber are both water vapour permeable. Nevertheless, if only water vapour had been present in the encapsulated receiver, corrosion should not have occurred. Therefore, the corrosion products indicated that water in liquid form had also been present.

There were three possible routes by which the water could have found its way to the corrosion sites. The first, and least worrying possibility, was that water entered via the cut ends of the leads. If this could be shown to be the case, then the results of the experiment could be discounted and no design changes would be needed. This route seemed unlikely, but it was impossible to confirm either way. The other two possible mechanisms were either that water had entered either via the cracks noted in the epoxy, or that water had condensed out in voids between the epoxy and the copper windings. As neither of these two explanations could be ruled out as possible failure modes for receivers manufactured in the future, a redesign was necessary.

The two options at this stage were either to investigate the existing manufacturing process or to change the entire design. There are several possible mechanisms through which voids or cracks can occur in epoxy encapsulated devices, including air trapped beneath components, bad implant shape or poor mould design [3]. However, it was extremely difficult to suggest which of the possibilities to explore. Further, if changes to the manufacturing process were to be made, a lengthy series of accelerated ageing tests would then have been necessary to confirm that the problem had indeed been solved.

4. Redesign

In our case we were fortunate to have links to the Implanted Devices Group at University College London. This group have many years experience with developing new implants and have carried out extensive work on the properties of particular silicon rubbers as encapsulants. Donaldson [4]-[7] suggests that the following properties make silicon rubber a good alternative candidate as an encapsulating material:

- It adheres well to a variety of materials typically found in implants.
- It forms a hydrothermally stable joint in many cases, thus making the bond stable under heat sterilisation
- It is impermeable to sodium and chloride ions and therefore osmosis tends to drive water out from the implant to the salty body fluids.

The other advantage of using silicon rubber is that a considerable body of knowledge exists on its properties and behaviour as an encapsulant. This does not appear to be true of epoxy resins, despite their widespread use in these types of application. This evidence can, and indeed has been used in certain circumstances, to demonstrate the safety of an encapsulating process without the need for further accelerated ageing.

Therefore it was decided the encapsulating material should be changed to silicon rubber. At this point we approached Finetech-Medical Ltd, the manufacturers of the Finetech-Brindley bladder stimulator. This stimulator was developed by Prof Brindley in conjunction with the UCL Group and the receiver is encapsulated in silicon rubber. Over 1500 patients have been implanted over almost 20 years and the encapsulation method has been shown to be very successful [8],[9]..

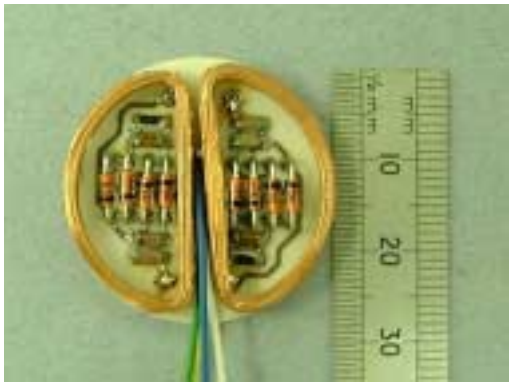

Figure 4 : Redesigned base prior to encapsulation (test leads connected)

Our receiver was functionally very similar to the receiver in the bladder stimulator and we explored the possibility of Finetech-Medical encapsulating the new implant themselves. The body of evidence demonstrating the safety of their approach to encapsulation allows for minor changes to their designs to be introduced without the need for new testing. Therefore, if our design concept could be modified in such a way that it could be viewed as a variant on their receiver, then further testing of the modified implant could be avoided. A number of small changes to the base and track material and component types were agreed and Finetech proceeded with the manufacture. The receiver base prior to encapsulation is shown in figure 4 . The leads and electrodes are shown in figure 5.

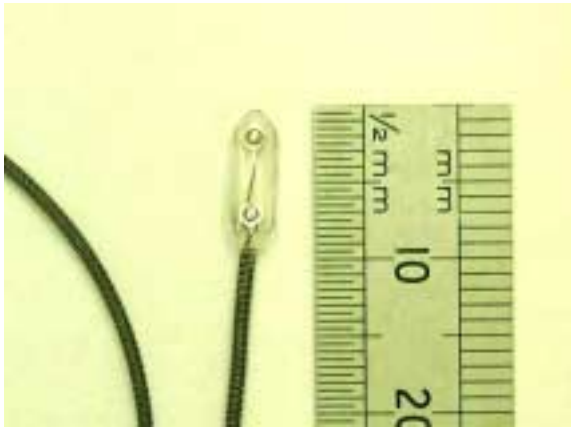

Figure 5: Sub-epineural electrodes and leads

5. Discussion and conclusions

The results have been presented of a case study of problems encountered with an epoxy-encapsulated receiver. Evidence of corrosion showed that water in liquid form had found its way to various points in the implant. It was not possible to establish whether this occurred as a result of the cut lead ends, via a crack in the epoxy, or whether it arrived in water vapour form and condensed out in a void. Having identified an encapsulation problem, but not being able to pinpoint the origin of the problem, it was decided to opt for a change of material. Extensive evidence existed to demonstrate that silicon rubber could be used in such an application and this material was chosen as the replacement for epoxy. Extensive testing of the new implant has been avoided by maintaining, wherever possible, the similarities to the well proven Finetech Brindley bladder stimulator.

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