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Catheter-type defibrillation electrode using glassy carbon: results of electrode implantation

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Abstract—The implantable defibrillator, developed by Dr Michel Mirowski, is a remarkable electric therapeutic device which has been in clinical use since 1980 in the treatment of life-threatening arrhythmia. However, as the present life span of this device is only 3 years, research is being carried on to extend the lifetime with improved stimulation methods, circuits and electrodes. In particular, the electrode system which is inserted into the right ventricle has more than 50 times the electrode area of a pacing electrode and is prone to degradation. What is needed is biocompatibility and electrical stability, similar to that of cardiac pacemaker electrodes, which can be used for more than 10 years. For this purpose, we focused on a conductive ceramic as a new material for the defibrillation electrode instead of the previously-used metal. We selected glassy carbon as our electrode material and tested the surface condition through acute and chronic animal experiments. No clots formed around the electrodes after a 3-month implantation, nor were there surface disorders after the defibrillation stimulations. We concluded that glassy carbon is a promising material for future defibrillation electrodes.

Key words: ceramic; glassy carbon; defibrillation electrode; implantable defibrillator.

1. INTRODUCTION

The implantable defibrillator, developed by Dr Michel Mirowski, is a remarkable therapeutic device used to prevent sudden death by ventricular defibrillation which has been clinically available in the United States since 1980 [1, 2]. The defibrillator uses a catheter electrode in the right ventricle and a apical patch electrode for defibrillation shock. However, if the present 3 year life span of the defibrillator is to be extended to be similar to that of a cardiac pacemaker, the catheter electrode will have to be improved. Stokes *et al.* [3] noted problems such as corrosion and surface oxidation which cause ECG sensing failures in metal electrodes. Moreover, surface clots could increase electrode resistance and the risk of thrombosis. Therefore, a new electrode which avoids such problems would be quite beneficial.

An electrode made of titanium has been in use for defibrillation in the right ventricle. The electrode surface area (700 mm^2) [4] is 58 times greater than that of a pacing electrode (12 mm^2) [5]. However, if this electrode is implanted chronically in the right ventricle, surface oxidation may occur. In consequence, the electrode–tissue coupling becomes unreliable. This is the reason that titanium cannot be used instead of platinum or Elgiloy (Elgin Watch Company) in pacemaker electrodes. Moreover, an increase in electrical resistance caused by clots causes a higher defibrillation threshold, which leads to higher battery consumption.

In order to develop a defibrillation electrode which has high electrical stability and a low stimulation threshold, we focused on a special ceramic carbon electrode. Some kinds of carbon have been used as conductors for high electric currents, such as in the brushes of electric motors, because of its high conductance and its resistance to oxidation which gives it very good electrical stability. Among the types of carbon, glassy carbon has good biocompatibility and high conductivity [6]. We designed special carbon electrodes using this material, and observed the state of clot development after using them in three acute animal experiments with fibrillation–defibrillation episodes and in one chronic animal experiment with a 3-month implantation.

2. METHOD

Figure 1 shows the experimental electrodes for the acute animal experiments. In Fig. 1(a), the upper electrode (electrode A) is made of glassy carbon (Ringsdorff GmbH: SIGRADUR-K; surface area: 120 mm^2), and the lower electrode (electrode B) is of stainless steel (surface area: 130 mm^2 each proximal and distal). SIGRADUR-K is glass-like carbon, manufactured by carbonizing a three-dimensionally cross-linked resin at temperatures up to 1000°C.

For this experiment, the carbon was formed into tubes 20 mm in length, with 3 mm outside diameter and a 2 mm inside diameter. Figure 1(b) shows a multi-element electrode (electrode C) combined with a commercially available pacing catheter electrode and a glassy carbon tube (pacing lead: USVP #2226.20; electrode area: pacing 22 mm^2, defibrillation 180 mm^2). This electrode was designed and tested as an implantable defibrillator with a pacing function [7]. To connect the carbon tube and lead wire, stainless wire (0.5 mm in diameter) was wrapped around the tube for about 3 mm of its length and fixed with conductive adhesive (Fujikura Kasei Co Ltd, Dotite D-500). The conductivity of glassy carbon is 50 ohm μm, and the resistance between carbon and the terminal of the electrode was less than 1 ohm. Both edges of the tubes were fixed with adhesive (Ciba-Geigy Co Ltd, Araldite: 400B) and heat shrink tubing.

Figure 2 shows the experimental carbon electrode (electrode D) used for the chronic experiment. The carbon tube was mounted around the catheter, and a lead wire was connected to the tube to detect the ECG during the implantation operation.

In the acute experiments, the electrode was used for defibrillation stimulation. A defibrillation pulse was applied 15 s after electrical onset of fibrillation if the fibrillation was confirmed by a drop in blood pressure. The defibrillation voltage was 600 V in pulses of 5 ms in width between the proximal and distal electrodes.

3. EXPERIMENTAL RESULTS

Acute animal experiments were performed on three mongrel dogs, and the chronic experiment on a fourth mongrel dog.

3.1. Experiment 1

Two mongrel dogs were anesthetized and mechanically ventilated. After thoracotomy, electrodes A and B were inserted into the right ventricle through the right jugular vein. We experimented with electrical defibrillation five times to confirm the efficacy of the electrodes. The electrode surfaces were observed in one dog after 1 h and in the other

(a)

(b)

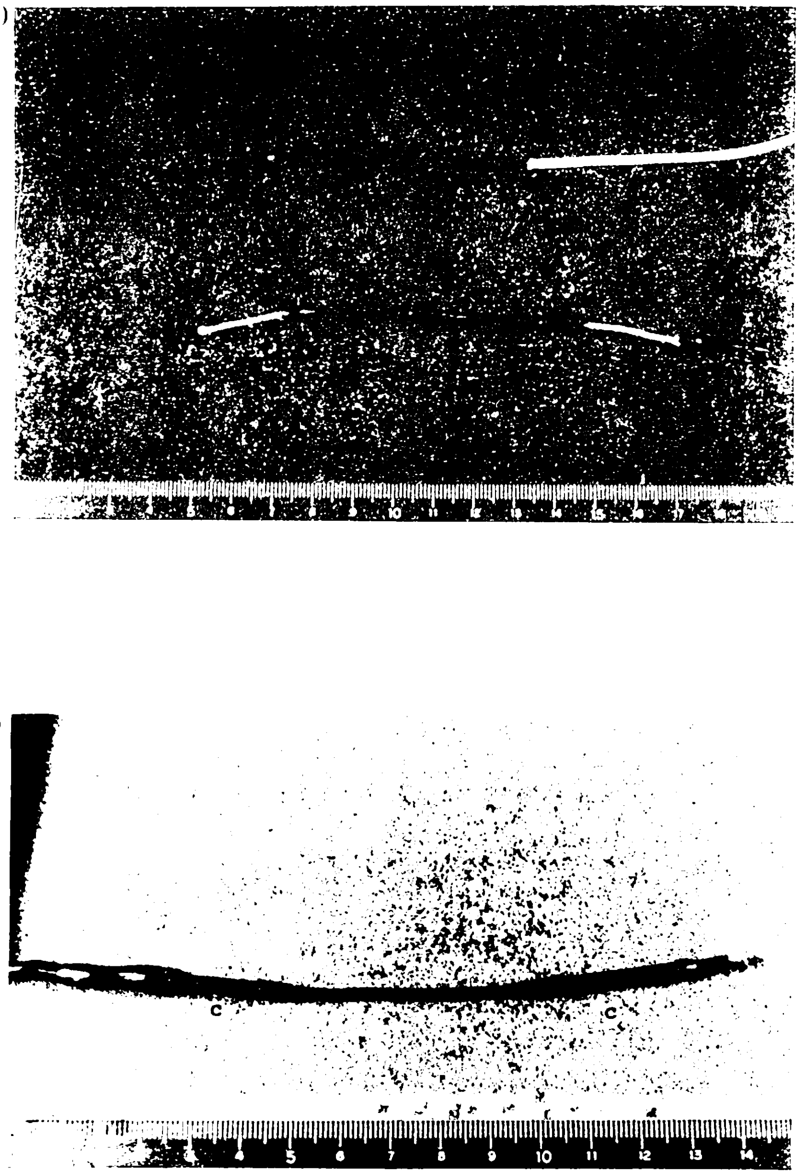

Figure 1. (a) Electrode for acute experiments: upper, glassy carbon electrode (A); lower, stainless steel electrode (B). (b) Electrode catheter for defibrillation and pacing: two carbon tips are used for defibrillation (electrode C).

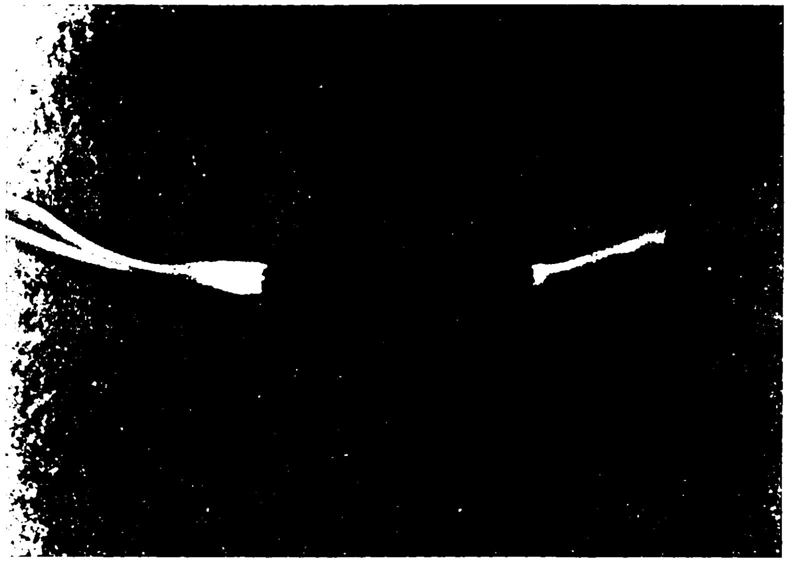

Figure 2. Carbon electrode for chronic experiment (electrode D).

after 4 h of implantation. During the defibrillation experiments, the carbon electrode in the right ventricle was used as the cathode (–) and the electrode in the superior vena cava was used as the anode (+) for a 600 V defibrillation pulse.

Figure 3 shows the results of the 1 h implantation. The electrode surface was examined immediately after the experiment. A 2 mm thick clot surrounded the stainless electrode, but no clot was observed with the naked eye around the carbon. Moreover, the carbon electrode was not deformed after the defibrillation shocks. After the 4 h implantation, the results were the same.

3.2. Experiment 2

In one anesthetized mongrel dog, two electrodes (A and C) were inserted into the right ventricle. First, we confirmed the function of the pacing and fibrillation–defibrillation sequence during implantation. After a 2 h implantation, the surface of electrode A was observed using a scanning electron microscope. The samples were fixed with 2.5% glutaraldehyde in a 0.1 M cacodylate buffer solution (pH = 7.4). The specimens were dehydrated by serial passages though an ascending concentration of ethanol (10–100%), then dried by critical point drying. Figure 4 shows a scanning electron micrograph of the carbon electrode. No clotting could be seen on the surface except for a small amount of fibrin network and protein deposition.

3.3. Experiment 3

In one anesthetized mongrel dog, electrode D was implanted into the right ventricle for 3 months. Figure 5 shows the experimental results. No clotting occurred on the carbon electrode surface. Figure 6 shows a micrograph of the carbon surface of the connecting rod in the catheter electrode. The upper part of the electrode shows the adhesive used

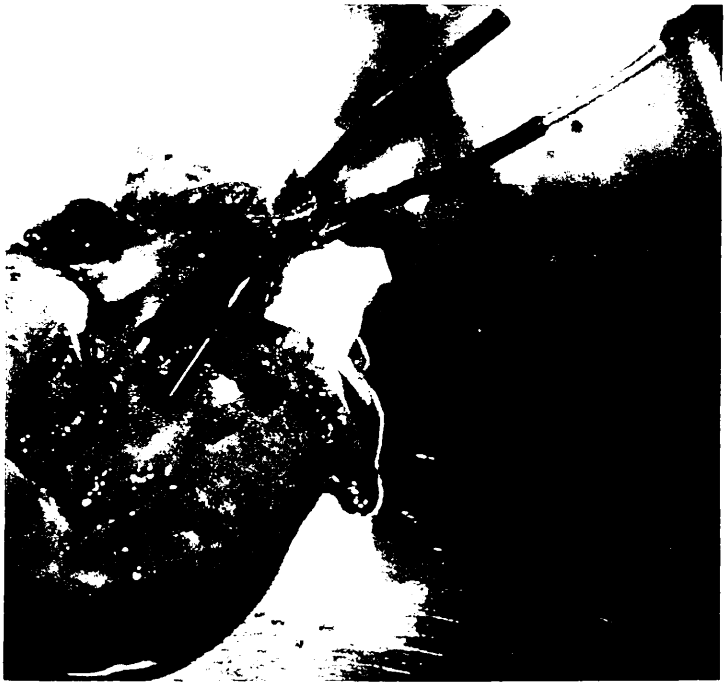

Figure 3. Experimental results of acute implantation. In the right ventricle, the carbon electrode surface (A) contrasts with the stainless steel electrode (B) covered with clots.

for fixing the carbon tube; the lower part shows the carbon surface. Although the upper part (adhesive) was covered with a clot, the lower part (carbon) remained clean.

4. DISCUSSION

Carbon material, which is chemically stable and biocompatible, has been used in artificial heart valves and artificial teeth [8–9]. Moreover, due to the excellent electrical characteristics, it has been recently used for pacing electrode tips [5]. Because of the chemical, mechanical and electrical characteristics of carbon material, we have chosen glassy carbon as the material for developing a new defibrillation electrode. As the defibrillation electrode has a wider surface than a pacing electrode, we observed its surface condition and clotting in animal experiments.

In acute experiments, we confirmed the function of glassy carbon as a defibrillation electrode material and observed the electrode surface condition for corrosion and clotting. Defibrillation using the carbon electrode was successful with a voltage of 600 V. The electrical resistance of the carbon electrode, including the lead wire, was less than 1 ohm. As myocardial impedance is about 100 ohm, this electrode resistance is low enough for a defibrillation electrode. In addition, there was no problem in the mechanical strength of the carbon electrode during defibrillation shock. Although we observed a 2 mm thick clot around the stainless wire after 1 h of implantation, there was no clot on the surface of the carbon electrode. After 2 h of implantation, we observed the carbon electrode by scanning electron micrography, and there was no electrical damage or massive clotting on the surface.

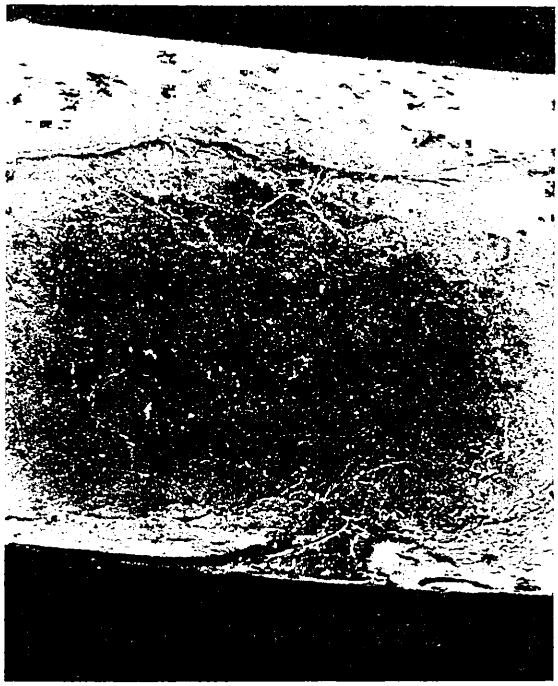

Figure 4. Electrode surface after a 2 h implantation (electrode A).

Figure 5. Experimental results of chronic implantation (electrode D).

Figure 6. Electrode surface after a 3-month implantation. The adhesive part of the electrode connection covered with clots is shown in the upper part of the figure. A carbon electrode with no clots is shown below.

In the chronic experiments, the surface of the carbon electrode after a 3-month implantation was as clean as it was in a 2-h implantation. Thus, the surface condition should not cause any problem in the sensing and stimulation functions of an implantable defibrillator. However, the connecting rod between the carbon and the catheter has to be covered with a more biocompatible material such as urethane.

In past experiments by Stokes *et al.* [3], certain forms of carbon worked well as electrodes, but they sometimes suffered degradation, e.g. pitting, when they were stimulated many times. Moreover, the forms of carbon used by Stokes *et al.* were difficult to use in reliable large volume manufacturing. Thus, research is continuing to develop a better long-term electrode material. The carbon tubes we used in the experiments consist totally of carbon material with no coating or substrate. That means that carbon material does not peel from the substrate. To get the shiny outer surface of the tubes, this material has been machined to a very smooth finish and thus gives a different appearance compared to the bulk material.

To connect the carbon electrode and lead wires, conductive adhesive was used. For practical purposes, spot welding will be useful to tighten connections.

5. CONCLUSION

A catheter-type defibrillation electrode using glassy carbon tubes was developed and tested through animal experiments. The carbon electrode was found to have excellent biocompatibility and mechanical strength for use as a defibrillation electrode. Thus, glassy carbon is a possible choice as the material for long-term non-metallic electrodes for use with implantable defibrillators.

Acknowledgments

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REFERENCES

1. M. Mirowski, M. M. Mower, P. R. Reid, L. Watkins and A. Langer. The automatic implantable defibrillator. *PACE*, **5**, 384–401 (1982).
2. M. Mirowski, P. R. Reid, L. Watkins, M. L. Weisfeldt and M. M. Mower. Clinical treatment of life-threatening ventricular tachyarrhythmias with the automatic implantable defibrillator. *Am. Heart J.*, August, 265–270 (1981).
3. K. Stokes and N. L. Stephenson. The implantable cardiac pacing lead. In: *The Third Decade of Cardiac Pacing*, S. S. Barold and J. Mugica (Eds), pp. 370–371 and 386–387, Futura, New York (1982).
4. Superior Vena Cava Lead Nominal Specifications Model 0020 for VENTAK AICD, Cardiac Pacemaker Inc. Catalogue (1988).
5. 411S and 412S Vitreous-carbon-tip leads, Siemens-Elema Catalogue (1988).
6. R. Dubgen. Glassy carbon—a material for use in analytical chemistry, SIGRI GmbH, Meitingen, FRG (1985).
7. H. Makino, Y. Saitoh, Y. Mitamura and T. Mikami. Implantable defibrillator with high-output pacing function after defibrillation. *Proc. IEEE*, **76**, 1187–1193 (1988).
8. A. D. Haubold, H. S. Shim and J. C. Bokros. Carbon in medical devices. In: *Biocompatability of Clinical Implant Materials, Vol. 2*, D. F. Williams (Ed.), p. 4, CRC Press, Boca Raton, FL.
9. J. H. Dumbleton and P. Higham. Coating and surface modification. In: *Metal and Ceramic Biomaterials, Vol. 2*, P. Ducheyne and G. W. Hastings (Eds), pp. 135–139, CRC Press, Boca Raton, FL.