



Cardiac implantable devices

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Introduction

Cardiac implantable devices are complex electronic devices that are inserted into the chest using minimally invasive surgery to regulate the beating of the heart. The devices can function as traditional pacemakers or as defibrillators. These functions may be performed by separate devices, but some modern systems have both functions within the same case. The pacemaker type speeds up a slow heart rhythm or provides the heart beat when it is missing, and the defibrillator can help control tachyarrhythmias, which are abnormal fast rhythms.

Engineers have been continuously involved with these cardiac devices from the first devices developed to the current technologies. In collaboration with cardiologists and other medical colleagues, engineers continue to make these devices perform a broader range of functions which make patients' lives safer and better.

Background

An external pacemaker was designed and built by a Canadian electrical engineer in 1950, but this device was based on vacuum valve technology, and was powered by the domestic mains supply. It was the development of the transistor and its commercial availability in 1956 that paved the way for battery-powered implantable devices. The first human pacemaker was implanted in a Swedish electrical engineer in 1958, but the device failed after just three hours. A second device was implanted in the same patient which lasted a few days. Without the pacemaker, the patient had an abnormally slow heartbeat, which led

to periods of unconsciousness and a very poor quality of life.

Initially all developments were between bioengineering departments or individual engineers and enthusiastic cardiologists. Many small companies evolved, often producing devices in garage-like conditions. This changed in the 1970s when regulation and litigation forced devices to be produced in larger, better-managed companies. Initially there were 19 major and 36 niche companies, with only one major UK contributor. Since then, the development of implantable cardiac devices has evolved at an astonishing rate, with a worldwide market now of over £1 billion, and more than 600,000 devices are implanted each year across the world. There are now only a few major players based in the US and mainland Europe but no UK industry, although UK engineers and clinicians have contributed to design and development of devices.

The technology

Cardiac implantable devices, whether for the pacemaker function or the tachyarrhythmia function, have the same major components. The device is a hermetically sealed metal case, normally made of titanium. Inside there is a lithium battery-powered pulse generator, sensing amplifiers, a microprocessor, and output power circuits. Special flexible leads from the device connect to electrodes in appropriate chambers of the heart.

Early pacemakers just stimulated, or "paced" the heart with low voltage pulses, and took no account of any spontaneous cardiac activity; health

problems were caused if a pacing stimulus occurred simultaneously with a natural beat. The devices could not change their pacing rate in accordance with physiological demand, such as running. Changing any parameters such as rate and voltage output usually involved surgical removal of the device.

Modern pacemakers are now very sophisticated and contain microprocessors and dedicated integrated circuits. They can be programmed in situ by a hand-held programmer that can also receive diagnostic information from the device.

There are three basic types of these pacemakers: single chamber, dual chamber and rate responsive.

- The single chamber devices sense (detect natural heart activity) and pace from one chamber of the heart, either the atrium, or the ventricle. They normally listen to see if a normal heart beat is present and if it is not, then they will provide a pulse to simulate the heart.

- The dual chamber devices can sense and pace in both cardiac chambers. These can help patients with many heart rhythm problems by introducing some natural physiological realism to their artificial rate, and improve the efficiency of the heart.

- Rate adaptive pacemakers use information from sensors, such as a piezoelectric crystal, to modify the patient's heart rate, so that, for example, when a patient starts running the pacemaker will sense the running activity and speed up the paced heart rate accordingly.

Tachyarrhythmias are defined as fast abnormal heart rate activity such as ventricular fibrillation and tachycardias. Ventricular fibrillation is the fast chaotic heart activity which results in no pumping activity from the heart. This can cause sudden cardiac death. Tachycardia is where the heart goes into an unnatural fast heart rate, normally classed as above 100 beats per minute (but often much higher). This can be very unpleasant for the patient and severely reduce their quality of life, and this rhythm can degenerate into ventricular fibrillation.

Implantable cardiac devices have been further developed in the last 15 years from the initial pacemakers to systems that can treat both of these conditions. The devices control tachycardia by complex pacing routines and give internal electric shocks to resolve ventricular fibrillation. The shocks are of relatively large energy, but of much less energy than the commonly available external defibrillators.

Modern devices are automatic and have complex algorithms (computer programs) that attempt to diagnose the cardiac problem and make the appropriate correcting response. They continuously monitor the activity in the heart to determine any problem and perform the appropriate action, such as fast pacing or an electric shock. This is a challenging area for the automatic device as it must recognise if the ongoing activity is pathological (ie not

wanted) or is normal cardiac activity. If the incorrect response is given, it could result in distressing consequences, such as pain, psychological damage or the rhythm rhythm degenerating to ventricular fibrillation.

Often there is no choice whether a device is used or not, but sometimes surgery (ablation) or drug therapy is an alternative.

Engineering contributions

Engineers have made and continue to make significant contributions to the development of cardiac devices. There is significant work to make batteries more efficient, reliable, and long-lasting. The electrode leads are another area where problems can occur (breakages, inefficient transmission of pulses etc) and engineers are working to create more robust leads. This is a critical area, since a broken lead could result in death of the patient.

Engineers are constantly working to improve the size and reliability of devices. They are also developing new software algorithms that will, for example, terminate fast tachycardias even more swiftly. There is a lot of work on detecting whether a fast rhythm is indeed dangerous or just the patient's natural fast rhythm due to activities such as running. There is also work to prevent abnormal rhythms in the atrium from occurring, or to convert them back to safe, sinus rhythm. Engineers are also

involved in research and clinical trials to ensure that experiments are carried out ethically and with the correct, safe equipment.

Future work

All the implantable devices are manufactured and designed in the US or mainland Europe, although many clinicians and engineers in the UK have contributed to the design and development process. There is still a large academic and NHS contribution to the development of better devices and the development, for example, of better algorithms. Some cardiac centres in the UK are world-leading in their innovations and engineers are part of this. Industrial world leaders often use the UK as a test centre for devices and for clinical trials.

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