

A technological advance in organ preservation is set to have a major impact on transplant surgery. The effect on tissue matching and organ optimisation has yet to be confirmed, but the new system must represent good news for the thousands of patients currently awaiting a transplant.

Beating heart transplantation

The UK's first successful beating heart transplant has been performed at Papworth Hospital, Cambridge. Used for the operation was state-of-the-art technology – the first technological advance in transplantation in decades – that enabled the donor heart to be kept warm and beating outside the body.

Conventional technology keeps organs waiting to be transplanted in a cold, ischaemic and non-functioning state. Use of the low-temperature method means that the maximum storage time – from removal from donor to implantation in recipient – for a heart is only four to six hours. Furthermore, this method may damage the heart and surgeons do not have an opportunity to see the organ functioning until after transplantation is complete.

Advances of the kind represented by the new technology used at Papworth Hospital recently are needed if a reduction is to be made in the number of patients dying while waiting for new organs.

Currently, more than 8000 people in the UK need an organ transplant, but fewer than 3000 transplant operations are performed annually due to a severe shortage of donated organs, and about 400 people die each year while waiting for a suitable organ to become available.

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It was noted recently that there were 104 people, including nine children, registered for a heart transplant in the UK. A further 43 patients, including two children, were waiting for a combined heart and lung transplant. In the year 1 April 2005 to 31 March 2006, a total of 146 people received a heart or heart and lung transplant, down from 170 recipients during the same period in 2004–05.

The new technology used at Papworth Hospital was the TransMedics Organ Care System. After removal from the donor, the heart was placed in the system, which has been designed to maintain human organs in a functioning state outside the body. With the system, the heart is revived immediately to a beating state, perfused with oxygenated and nutrient-rich blood and maintained at a

suitable temperature. Thus, use of the new system means that a heart is kept in its correct physiological, beating state during transport to the recipient and until transplantation.

Benefits of beating

The TransMedics' system provides surgeons with an opportunity to evaluate an organ immediately prior to transplant and to test it more extensively for existing disease. More comprehensive tissue matching may also be possible in the future, and this could lead to optimisation of organ allocation and a reduction in the risk of organ rejection.

In addition, by increasing the number of transplantable organs and decreasing the risk of post-operative complications, this technology could provide significant cost

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benefits to the healthcare system. It could reduce the period of time patients need to be maintained on costly support therapies while waiting for a donor organ, and ensure more rapid recovery and reduced hospital stays following transplantation. Furthermore, it could reduce the need for medical therapy to treat complications, and reduce the need for retransplantation.

The TransMedics Organ Care System comprises three components – a perfusion module, a portable platform with wireless monitor, and a solution set – operating together as integrated technology. At the core of the system is the perfusion module, a transparent, sterile chamber designed to protect the organ and maintain the appropriate temperature and level of humidity.

In the case of heart transplant surgery, the organ is placed in the module and revived to a beating state. The portable platform houses all elements of the system, including oxygen supply and a pump used to maintain a continuous flow of warm, nutrient-rich blood to the organ. A wireless monitor controls and displays the system functions. It also provides important information to allow visible, functional and metabolic assessment of the organ by the clinician.

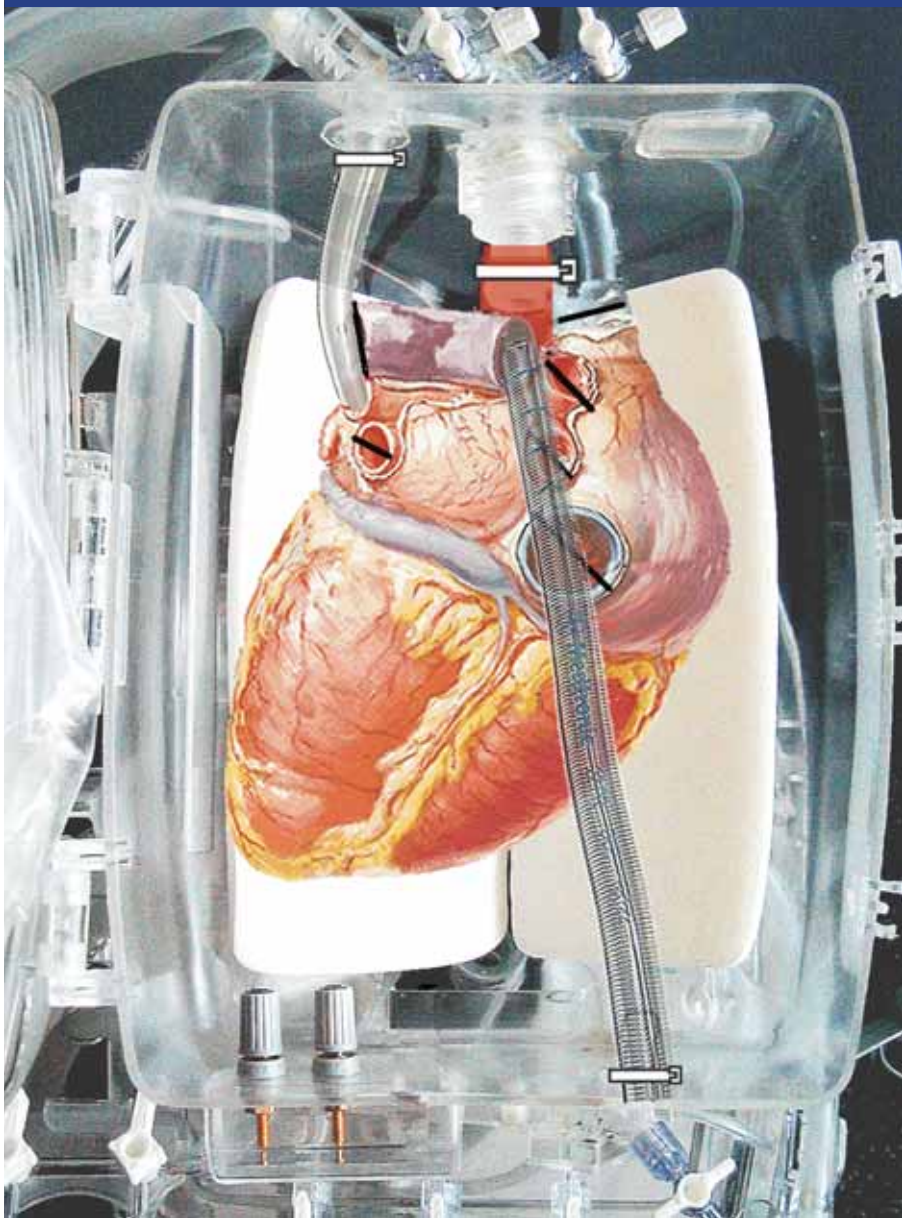
In the case of the heart, parameters such as aortic pressure, coronary flow and blood temperature are monitored. Organs that are maintained in a functioning state outside the body continue to absorb nutrients as they would *in vivo*. The TransMedics Solution Set is designed specifically to deliver the nutrients required to keep the donor organ healthy during transport.

Clinical trial

In March this year, TransMedics announced the initiation of a European multicentre clinical trial to evaluate its system’s safety and performance for heart transplants. The current trial sites are Papworth Hospital, Cambridge, and Harefield Hospital, Middlesex, in the UK, and the Clinic for Thoracic and Cardiovascular Surgery, Bad Oeynhausen, and the German Heart Institute, Berlin.

The primary endpoint is the seven-day patient survival rate following transplant. All patients will be followed for 30 days for further data. Long-term patient survival

Using the new system, the heart is kept beating, perfused with oxygenated and nutrient-rich blood and maintained at a suitable temperature.



and other outcome measures will be tracked through established registries.

“The benefits of warm versus currently utilised cold storage in preventing cell death and ensuring healthier organs have long been understood,” commented Professor Reiner Korfer of the Bad Oeynhausen Clinic for Thoracic and Cardiovascular Surgery. “The TransMedics approach is a truly revolutionary advance in a crucial surgical field.”

Chris Rudge, managing and transplant director of UK Transplant, the remit of which is to ensure that donated organs are matched and allocated in a fair and unbiased way, said: “UK Transplant welcomes any initiative to improve organ quality and availability for patients,” adding that the new approach, as it evolved, would offer “great promise not only for patients awaiting heart transplantation but also for those awaiting other donated organs.” ■

Papworth Hospital

The UK’s first successful heart transplant was performed at Papworth Hospital, the world famous heart and lung centre, in 1979. The hospital celebrated the 25th anniversary in 2004 with a garden party attended by over 400 transplant patients, their families and staff. Among those attending was Papworth’s longest surviving heart transplant patient who lives in the north of Scotland. It is now over 25 years since he had transplantation surgery. Europe’s first successful heart and lung transplant was performed at Papworth Hospital in 1984, and the world’s first heart, lung and liver transplant was performed there in 1986.