Small haemodialysis machines have been developed that will allow more people to treat themselves at home. Professor Clive Buckberry FREng, Chief Technology Officer at Quanta Fluid Solutions, has been instrumental in developing a system in the UK known as SC+. He outlines the steps to design and develop a new system that is lighter, smaller and easier to use than existing machines.
Renal haemodialysis has come a long way since the 1940s, when Dutch physician Wilhelm Kolff built the first successful device using, among other items, sausage casings and parts of a washing machine. The following decades saw rapid developments in safety, effectiveness and technical sophistication. Nowadays, at any one time in the UK, more than 25,000 people are undergoing haemodialysis on account of kidney failure; some set to continue indefinitely on this treatment, others while they await a kidney transplant. Most patients receive their three-weekly, four-hour treatment in hospitals or other specialist centres – and in this lies one of the key remaining non-technical issues in contemporary haemodialysis. For over a decade, the National Institute for Health and Care Excellence (NICE) has been recommending that more patients should undergo haemodialysis at home, but still only around 3% do so.

**ONE’S ENOUGH**

Although we have two kidneys, we can get along very well with just one. This substantial over-provision means that kidney disease may already be far advanced before it is detected, often through a routine blood or urine test. With further loss of function, potential symptoms include poor appetite and loss of weight, blood in the urine, swollen ankles and feet, high blood pressure and muscle cramps. For end-stage renal failure, the final outcome of the disease process, there are two remedies: a kidney transplant, the ideal treatment, or dialysis. The latter may be used as a stopgap until a suitable donor kidney becomes available, or as a permanent solution.

The principle underlying renal haemodialysis (using an extracorporeal circuit, see diagram) is straightforward. Blood pumped from the patient flows over a semi-permeable membrane. On the other side of the membrane, and flowing in the opposite direction, is a specially prepared fluid called a dialysate. Because any dissolved substance will pass from a region of higher to one of lower concentration, waste products in the blood – urea and phosphate in particular - will move across the membrane and into the dialysate, which is free of these materials. Sodium and other substances required by the body can be retained by ensuring that the dialysate contains them at a concentration equal to that required in blood cells. Protein molecules remain in the blood, being too large to penetrate the membrane. Besides extracting impurities from the blood, haemodialysis also has to remove excess water from the patient’s body. This is achieved by ultrafiltration, which takes place across the semi-permeable membrane. If the pressure of the dialysate is kept slightly less than that of the blood, water will migrate from the latter to the former. The amount to be removed – typically two litres, but sometimes as much as four – is determined prior to treatment simply by weighing the patient. Finally, the purified blood is returned to the patient.

**PIONEERING ACHIEVEMENTS**

The engineering challenges facing the pioneers who set out to mimic the role of the kidney were considerable. They needed peristaltic pumps that would not unduly damage the delicate red and white blood cells. They needed to monitor the blood’s temperature and pressure, and they required detectors to check that potentially lethal bubbles had not formed within blood being returned to the patient. Machines had to be fitted with warning devices and backup systems to cope with any failure of the equipment.

Haemodialysis also required a considerable volume of pure water, up to 120 litres, to which were added the dialysate chemicals, principally sodium bicarbonate and acid. To avoid infections, the pipework through which the blood and the dialysate flowed needed a thorough cleaning and disinfection after each use. The first generations of the machines invented to do all this were bulky, cumbersome and required trained staff to operate them. But, step-by-step, engineering overcame these and other hurdles.

Although these early haemodialysis machines were intended for use in hospitals, the 1960s saw them beginning to be moved out into patients’ own homes. This further development threw up a new set of challenges, because they now had to be handled by patients themselves. Every session required the reassembly of the equipment. It uses generic industry standard components, and key among these is a disposable cartridge comprising some 90% of the hydraulic pipework required in haemodialysis – see picture.

The cartridge consists of a rigid rectangular polycarbonate injection moulding to which a PVC film is thermally bonded on either side. The form of the moulding, together with the film bonded to it, creates a number of fluid pathways for taking dialysate from the machine to the dialyser and back again before passing it out of the machine and onwards to the drain.

Once the cartridge has been inserted, the movement of the fluid through it is driven by the application of pneumatic pressure to various areas of the PVC film that forms the mating surface of the cartridge and the rest of the machine. Fluid is pushed and pulled through the cartridge by a programmable sequence of positive and negative pressures to four sets of pumps and valves lying behind the PVC film.

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**A NEW MACHINE**

The UK-produced SC+ portable haemodialysis machine will help to drive the trend back to performing haemodialysis at home. It aims to eradicate haemodialysis to a less demanding place in patients’ lives. It uses generic industry standard components, and key among these is a disposable cartridge comprising some 90% of the hydraulic pipework required in haemodialysis – see picture.

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One pump takes water from the mains and delivers it to the haemodialysis machine via a reverse osmosis device; this guarantees the required biological and chemical purity. Some of this purified water is delivered to another small cartridge of bicarbonate powder. The remaining bicarbonate, mixed with acid and passing through the remainder of non-disposable piping, is performed automatically when, as little as once a week, the machine goes into self-cleaning mode and flushes hot water through the remaining short length of non-disposable piping. Although SC+ is as small as a microwave oven, it still has to be as safe as machines used in hospitals, with systems in place to double check that no faults have arisen. Like its larger predecessor, the SC+ includes all the necessary devices for detecting bubbles, and for monitoring temperature, pressure and other indicators. For some of these needs, existing devices could be utilised; others had to be designed from scratch to suit the new machine. Apart from attaching themselves to the machine, the patient’s only tasks are to top up the bicarbonate and acid supplies, key in the weight of water to be removed, and change the cartridge after every session.

One section of IMI was developing equipment for dispensing drinks, including fruit juices. These are susceptible to contamination by various microorganisms, particularly during the cleaning of valves and nozzles when, for example, the machine is switched from dispensing one type of juice to another. A system was designed which enabled juice concentrate to be delivered in disposable bags already fitted with their own mechanism (also disposible) for diluting with water and dispensing. Refilling the machine, or changing the flavour being dispensed, became a procedure that required no cleaning. After consultation, it was felt that the principle of using a disposable unit would be equally applicable to haemodialysis machines. In 2006, after 18 months of development, a spin-out company to work on this was set up, Quanta Fluid Solutions. Bought were the relevant patents from IMI, which agreed to invest in the new company for a year while venture capital was sought to take the relevant patents from IMI, which agreed to invest in the new company for a year while venture capital was sought to take the project forward.

The early progress of the project was helped by Devices for Dignity (DDD), a body based at the University of Sheffield and funded by the National Institute for Health Research to encourage the development of new products, processes and services for people with chronic health conditions. Besides canvassing the views of patients, DDD was also able to offer advice on the clinical need for the system, and the required time per session from the usual four hours in hospital down to two or three and patients can even dialyse overnight.

As with any medical treatment, home haemodialysis is not entirely risk free. Besides those facing all haemodialysis patients, some events - the accidental introduction of air into the bloodstream or the failure of one of the tubes carrying blood into and out of the body - are more of a threat at home than in a clinic with experienced staff on hand. But patients and their helpers will be trained in what to do in such emergencies. The end product is a machine flexible enough to be used in hospital as well as at home. A patient developing a complication that requires haemodialysis to be performed under medical supervision could still carry out the treatment themselves, but with a nurse around to keep an eye on things. Early indications show that there is an enthusiasm among both patients and clinicians to see much more home haemodialysis, and this approach to kidney failure is likely to become more prevalent. There is a gathering momentum for the idea that those patients should be dialysing to live rather than, as is still the case for many, living to dialyse.

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