A KINDER CATHETER

Existing catheter technology leaves much to be desired. Can modern systems engineering come up with anything better?

By Christine Evans-Pughe
IT’S NOT A SUBJECT frequently talked about, but, for those with spinal injuries, some men who’ve had prostate cancer, people with multiple sclerosis, and for the very ill or elderly, long term loss of normal bladder control can be a fact of life.

Whatever the cause, the remedy tends to be the same. “You end up with a catheter and a bag and there is nothing more humiliating and depressing,” says Roger Feneley, emeritus consultant urologist to North Bristol NHS trust. “Patients rapidly lose all self-esteem and dignity and the complications are horrible,” he adds.

Feneley has spent over 10 years raising the profile of this unfashionable area of medicine, trying to stimulate research to develop better technology. As he puts it: “If people can deal with their dentures and hearing aids independently, why shouldn’t they be able to deal with their bladders?”

STATE OF THE ART
Nothing much has happened to improve catheter design since the introduction of the Foley catheter in 1937. The Foley featured the innovation of a balloon that retained the catheter in the bladder, and it has widely been employed ever since. The system works well for two or three days, but the incidence of infection rises at about 5% per day, so, after 30 days, an infection is almost inevitable. Other problems include leaks and the risk of chronic inflammation due to the bladder rubbing up against the catheter. Blockages occur in 50% of long-term catheters, which means discomfort and pain for the patient and an emergency call out for the district nurse.

The economics are equally discouraging. The basic components of a catheter cost no more than £1.50, but the ‘maintenance’ →

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alkaline, leading to the precipitation of phosphate crystals (struvite and hydroxyapatite). These encrust the catheter and block it. The crystals can also form painful bladder stones.

One method of providing a more natural flushing function is to use a manually operated release valve. Unfortunately, while lab tests have shown such valves can provide a four-fold increase in catheter lifetimes, only a small percentage of the patients requiring long-term catheters have the necessary levels of manual dexterity.

Coming up with a new electronic method to automatically control a valve to empty the bladder at regular intervals would seem to be a simple task. Unfortunately, when it comes to human biology, complications are virtually guaranteed, and it has taken ETB, working closely with the universities of Durham University and Cardiff, nearly three years to develop a prototype that fits the bill. ETB’s contribution is the overall microsystem, Durham’s school of engineering has been working on the valve and electronics, and bacteriologists at Cardiff have been testing the various prototypes to measure the growth of Proteus Mirabilis. Mediplus, the industrial partner who will make and sell the system, has also been involved as well as clinicians such as Roger Feneley.

Initially, the team thought it could fit a pressure transducer that would open a valve when the bladder was full. However, because the bladder stretches as it fills, the pressure nursing required to replace catheters at fortnightly or monthly intervals is expensive. The Royal College of Physicians estimates that supporting the three million people affected by urinary incontinence in the UK costs around £500m.

NUTAP
The idea of using electronics as one element of a wider effort to improve catheter design came about in 2000 when Feneley talked to Medilink East – a network of companies involved in medical technology. This meeting was the catalyst for Dr Diana Hodgins, director of Medilink East and managing director of ETB Ltd (a design company specialising in sensors and system design using microsystem technology), assisted by Feneley, to put together a proposal to the DTI for a Foresight Link Award. LINK is the UK Government’s principal mechanism for supporting collaborative partnerships between UK industry and researchers.

The result was the NuTap project – a multidisciplinary collaboration of seven industrial partners (ETB, Mediplus, Ranier Technology, Ellis Developments, Limbs and Things, BHR Group, Femcare, and MicroCircuit Engineering) and three academic centres (Durham, Cardiff and Southmead). The project has £2.4m funding from the DTI and the Engineering and Physical Sciences Research Council (EPSRC) and, for the last three years, the partners have been developing new types of catheter and a valve, researching into materials that discourage bacterial growth, and developing training models for catheterisation.

A BETTER VALVE
A normally functioning bladder gets filled and emptied every three hours or so – it’s this periodic flushing that keeps the bladder healthy. With a Foley catheter and bag, however, there is continuous slow drainage of the urine so the bladder never gets fully flushed out. Also, the balloon forms a sump at the bottom of the bladder. These are the main reasons why there is the build-up of bacteria and deposits that cause all the problems for patients. The chief culprit is the microbe Proteus Mirabilis, responsible for the production of ammonia. This is very
inside doesn’t alter greatly. They then chose an automatic time-release system to provide the intermittent flushing action.

“The time intervals can be set when you install the catheter and can be changed according to the person. There is also a novel form of proximity-based remote control [disguised as a ring] to activate the valve on-demand,” explains Hodgins. The design challenges have been numerous but keeping the system small and the power consumption low enough to last three months on two coin cells have been the biggest headaches. In the long term, the device has to be cheap enough to be thrown away.

The current prototype uses a microcontroller to open and close a pinch valve via a motor. Pinch valves are used in many areas of engineering, according to Professor Tony Unsworth, head of Durham University’s school of engineering, but in order to minimise power consumption, the materials and the tube sizes had to be carefully chosen. “You also need to get a very high flow rate and you need to make sure that encrustation doesn’t build up. This necessitates a system that dislodges any deposit, so we designed a method of closing the valve that dislodges debris. None of that complexity is apparent when you write your first system spec,” says Unsworth.

The prototype includes battery monitoring to provide fail-safe operation and it could include a flow sensor to activate a warning signal if there is blockage. There is also enough on-chip memory to collect data from pressure and pH monitoring if necessary, however these sensors haven’t been added yet. “There is nothing in the world like the NuTap, so we don’t want to make it more complicated than necessary at this stage,” says Hodgins.

NuTap will go into pre-clinical and then clinical trials later this year. The clinical trials will be coordinated from the Biomed centre, a unique facility within the Bristol Urological Institute that has been set up as a charity by Roger Feneley to obtain research funding for and improve the care of patients with urinary incontinence. It will take another three or four years before the system could become available as trials and subsequent CE marking typically take two years to complete and then full production can commence. First tests of the prototype by the Cardiff University team look promising, suggesting that the useful life of the catheter could be improved by at least four times using the new valve.

In the future, it may be possible to do away with catheters for some conditions and use a urinary tract implant that would replace or stimulate the function of the sphincter that opens and closes the bladder.

This idea is part of Healthy Aims, a €26m EU Framework VI project, that started last year. Healthy Aims involves 26 partners, and is aimed at developing various implants including cochlear, retina, and functional electrical stimulation implants for upper and lower limbs. Replacing or functionally stimulating the bladder sphincter looks like a tall order. “Human sphincters are basically circular cylindrical valves,” explains Diana Hodgins, managing director of microsystem design company ETB Ltd, and coordinator of Healthy Aims. “But they consume a lot of energy, are very flexible, and they respond when you want them to, so the idea of replacing them may be impossible. We might be able to stimulate the function in some manner, but we’re not sure at this stage. Currently, we’ve thrown the question back to the urologists.”

To operate implants, Healthy Aims is looking at using the MICS (Medical Implantable Communication Service) band, a frequency band between 402-405MHz dedicated to these applications. “For a urinary tract implant, you’re talking about an antenna with a diameter of 4-6mm and 10-20mm long,” explains Henry Higgins, an RF design engineer working on the project at Zarlink, one of the 26 partners. “One solution is to put a spiral helix on the outside of the implant, but one size won’t fit all so you would have to tune the antenna once it is in position,” he says.

An added complication is that the electrical properties of the body aren’t fixed, and are dependent on many factors – the position of the implant, the amount of body fat, even the way you move your arms and legs. The project has three more years to solve these challenges!