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Design and development of a novel automatic valve system for long-term catheterized urinary incontinence patients

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Abstract: It has been estimated that over 3 million patients in the UK suffer from urinary incontinence, the result of which is often long-term catheterization. However, many catheters block prematurely through encrustation and their continuous drainage limits bladder rehabilitation. Although evidence shows that a catheter valve may overcome such weaknesses, only manual valves are currently available and many patients are not able to benefit from these owing to a lack of manual dexterity. A novel electronically controlled automatic valve system, the Shan-Lai (SL) valve system, has been designed and prototyped. The prototype is compact, reliable, and cost effective, and it has low power consumption. The mass of the overall packaged valve system is 34.2 g and it measures 4.5 cm × 4.5 cm × 1.2 cm. With an orifice of 3 mm diameter, the SL valve has achieved high flowrates with relatively low energy consumption. A flowrate–energy relationship (FER) has been introduced to assess the performance of a catheter valve, and the SL valve system prototype has achieved an FER of 0.66 m/s⁻¹ mJ⁻¹ while a commercially available electronic valve has an FER of 0.28 m/s⁻¹ mJ⁻¹. The valve demonstrated outstanding mechanical reliability after a series of performance tests and also indicated remarkable encrustation resistance in the vicinity of the valve during an *in-vitro* test.

Keywords: urinary incontinence, catheter, automatic valve

1 INTRODUCTION

The International Continence Society defines urinary incontinence as ‘the complaint of any involuntary leakage of urine’ [1]. This condition can occur in any person at any age, although it is more common in an older population. Women are also twice as likely to suffer from this condition as men [2]. This may be due to a more complex physiology for the female urological system, pregnancy, and a shorter urethra. Around 9 per cent of the population worldwide suffer from incontinence [3]. The Continence Foundation has estimated that this equates to over 3.2 million urinary incontinent patients in the UK alone.

Apart from some situations where the condition can be surgically or medically treated, urinary catheters are commonly used for management of incontinence.

The catheter is a tube, usually made of silicone, with two eyeholes to drain the urine and an inflatable balloon on one end to retain its position in the bladder, while the other end is open, allowing the user to connect to a urine collection bag. The catheter can either be inserted through the patient’s urethra (urethral catheter) or via an opening at the abdominal wall into the bladder (suprapubic catheter), as shown in Fig. 1.

Urinary catheters are far from a perfect solution and the catheters being used today have not received any major improvement since Dr Frederick E. B. Foley introduced them in the 1930s [5]. They are bulky, inconvenient, and uncomfortable, and they often cause bacterial infection. They can seriously impair the quality of the patient’s life, causing social problems and, in some cases, leading to mental depression. Catheterized patients have a 3 times higher mortality in the first year than those using other incontinence products, such as absorbent pads [6].

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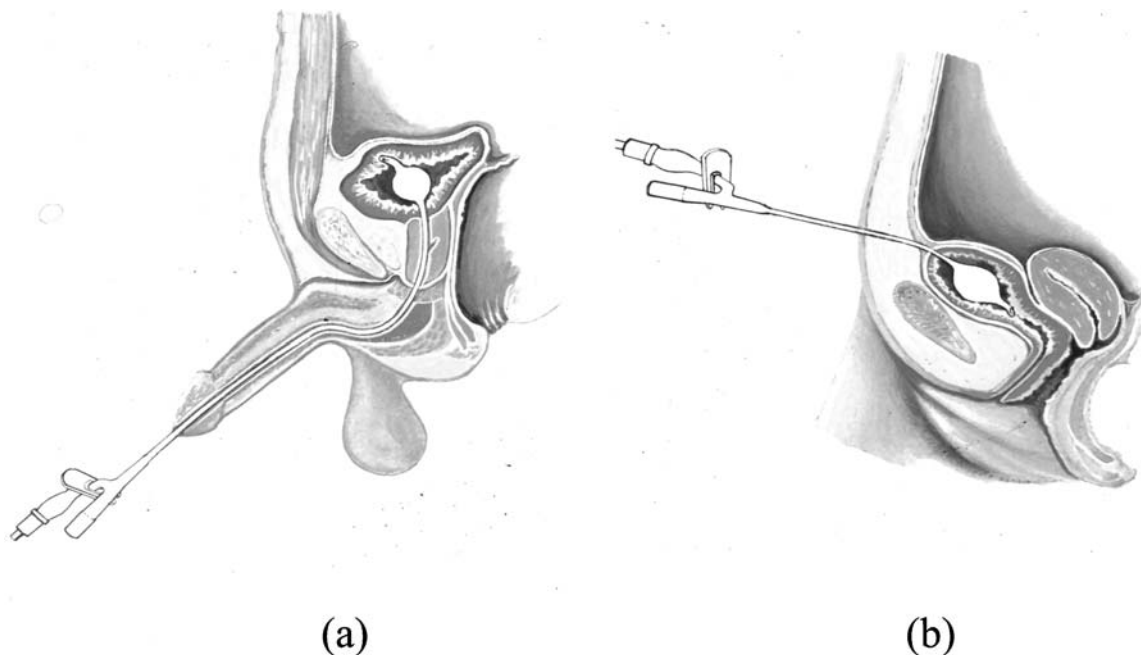


Fig. 1 Catheter and its insertion method: (a) urethral catheter; (b) suprapubic catheter [4]

Patients who use catheters long term often experience encrustation problems. This is a crystal build-up in the urine, such as calcium phosphate and/or magnesium ammonium phosphate hexahydrate. It is believed that encrustation is closely related to urinary tract infection by *Proteus mirabilis* which increases the alkalinity of the urine and encourages the formation of the encrustation [7]. Encrustation often leads to catheter blockage as the accumulating crystals will eventually fill up the eye-hole and the lumen of the catheter [8–10]. The conventional way of using a catheter is to allow the urine to be continuously draining. In this way, the flowrate of the urine is so low that it is difficult to differentiate between a flow and blockage. Hence, the patient's catheter may block at any time without the patient's knowledge until the overfilled bladder causes reflux in the kidneys. In such situations, the patient will require emergency medical attention either in hospital or in the home. This leads to a considerable financial burden.

Intermittent drainage facilitated via a catheter valve in conjunction with a urine collection bag has been shown to improve encrustation resistance, extending the service lifetime of an ordinary Foley catheter by a factor of 4 [11]. The patient may be less susceptible to infection and the catheter would also provide bladder training (filling and emptying) which would allow the continuous exercise of the bladder wall tissue. This would help to maintain the urine collection function of the bladder and may assist

the rehabilitation process. Furthermore, using the catheter valve might provide an early warning of catheter blockage. If the flowrate is substantially reduced or even stopped as the valve is opened, the patient can immediately seek assistance before the problem becomes critical.

Despite all the possible benefits of an automatic catheter valve, only manual valves are commercially available. They operate by either a push button or a lever flip valve. They are inconvenient, and patients with limited manual dexterity are not able to operate them and have to rely on a personal carer or nursing staff. This paper describes the development of an automatic catheter valve system that would maintain all the benefits of the manual valve and could greatly improve patients' quality of life by additional automated features.

2 DESIGN OF THE AUTOMATIC CATHETER VALVE SYSTEM

An investigation, conducted with the Bristol Urological Institute (BUI), UK, and European Technology for Business (ETB) Ltd, UK, identified the design specifications for such a device (Table 1). The valve system, including the battery pack, must be small and lightweight in order to be hidden under clothes. The valve must be capable of a high flowrate so that it will not impair the function of the catheter. It must be safe and reliable to use. It must have high

Table 1 Design specifications of automatic catheter valve system, compared with those of a manual valve

Design specifications	Manual 'top' valve	Automatic catheter valve
Overall size	$\approx 23.5 \text{ cm}^3$	$< 30 \text{ cm}^3$
Overall mass	$\approx 13 \text{ g}$	$< 40 \text{ g}$
Flowrate at 30 cm head	$\approx 5.2 \text{ ml/s}$	$> 5 \text{ ml/s}$
Energy consumption	N/A*	$< 50 \text{ mA h}$ over 30 days
Cost	$\approx \text{£}12.00^\dagger$	$< \text{£}25.00^\dagger$
Safety measures	Self-closing mechanism	Manual override, battery monitor, fail-safe mode

*N/A, not applicable.

† Approximate retail price.

resistance to encrustation to delay blocking so that the user can replace the catheter under a normal schedule (about 4 weeks). The power consumption of the valve system must be sufficiently low to allow a small and lightweight battery to be used. Biocompatible materials must be used for the components that will come in contact with human tissue. The investigation also showed that users prefer a disposable unit as it provides maintenance-free operation throughout its service lifetime and can be used in the same way as existing manual valves. The system should also be able to attach to any existing catheters and be easy to operate. Hence, it would be accessible to all catheter users, even for those patients with limited dexterity. Furthermore, the production cost must be sufficiently low for the system to be discarded after operation for about 30 days.

2.1 The automatic Shan-Lai (SL) valve mechanism

Because of the low power requirements and compact design, only small and lightweight electronic valves are suitable for this application and, at present, there is no automatic or appropriate valve mechanism design available. Most of the commercial electronic valves have been designed for microfluidic dispensing

with a relatively high sealing pressure. However, the fundamental specification of a valve for this application is a high flowrate but low sealing pressure. A high flowrate allows the urine to drain quickly and flushes any debris in the urine to enhance resistance to encrustation of the valve. Low sealing or isolation pressure will provide additional user safety. If the valve fails to open in a malfunction, it will prevent excessive bladder pressure build-up which could damage the kidney. As the catheter valve is expected to be situated at the patients' thigh, the pressure above the valve with a fully filled bladder would be about a 30 cm head. However, additional allowance is required in the case of activities that cause abdominal pressure to increase, such as coughing.

A novel valve mechanism has been designed specifically for this catheter valve application. Based on a pinch valve mechanism with a soft diaphragmatic tube, the SL valve has been specifically developed to meet the unique requirements of a catheter valve [12]. The conceptual diagram is shown in Fig. 2. When the valve is closed, urine accumulates above the pinching point. The soft tube contains the urine to its full diameter above the pinching point but collapses below it. When the valve is opened, the entire tube deploys to its full diameter owing to

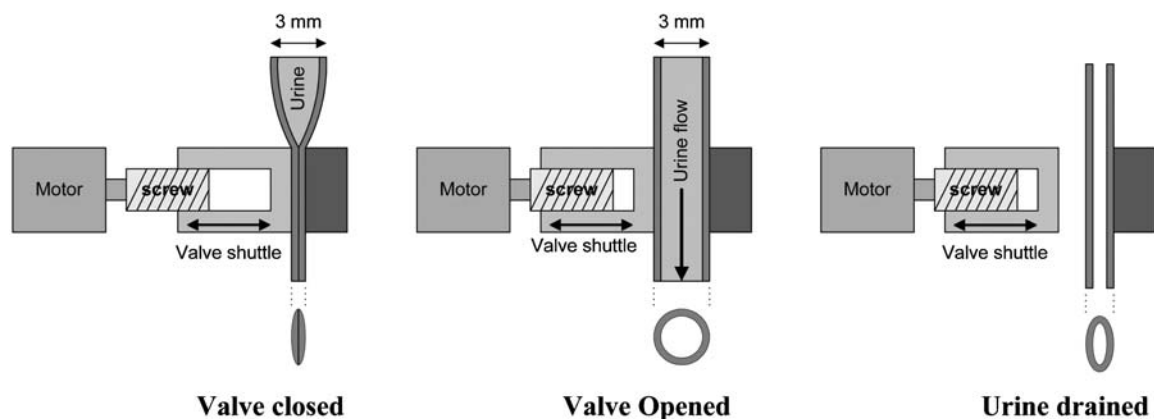


Fig. 2 Conceptual diagram of the SL valve mechanism

the pressure from the urine flow. Once the urine is drained, the tube collapses again. As the valve shuttle does not have to overcome any significant stiffness of the tube in order to shut the valve, this mechanism may operate with low actuating energy. Furthermore, it is suggested that the continuous flexing of the soft diaphragmatic tube could prevent crystallized material from adhering to the inner surface of the tube, again increasing resistance to encrustation. In addition, as all mechanisms are isolated from the urine, it would also increase the reliability of the valve.

The orifice of this proof-of-concept catheter valve has a diameter of 3 mm. It is designed to be fitted with the most commonly used 14 Ch/Fr (lumen of 2 mm diameter) catheter. As the valve does not add significantly to the drainage resistance of the catheter, the emptying flowrate of the catheter will not be affected.

2.2 The SL valve electronic control system

Apart from the unique valve requirements, the accompanying control system is equally unconventional. Urologists of the BUI found that, as the bladder wall expands when it fills up with urine, the pressure within the bladder does not substantially increase. This minimal increment is in fact less than that caused by other human activities, such as sneezing. Interpreting the bladder pressure would therefore be susceptible to error, leading to unreliable activation of the catheter valve. As a low-cost alternative and following consultation with the urologists at the BUI, a time-controlled valve system was developed. The valve opens at predetermined time intervals, ranging from 2 to 4 h, for short periods (e.g. 10 min) to empty the patient's bladder. However, the user may open the valve at any time using a manual override facility, without causing disruption to the regularity of the predetermined opening time interval.

The control system block diagram is shown in Fig. 3. An 8 bit PIC[®] microcontroller controls the operating interval of the valve, monitors the battery capacity, enables the manual override, and controls the valve status (open or closed). The valve signal-conditioning module converts the low-power control signal from the microcontroller to a driving signal for the valve mechanism.

As a disposable and maintenance-free system, the valve does not require any attention once it has been initiated. The microcontroller records the number of operations upon initiation. After a predetermined

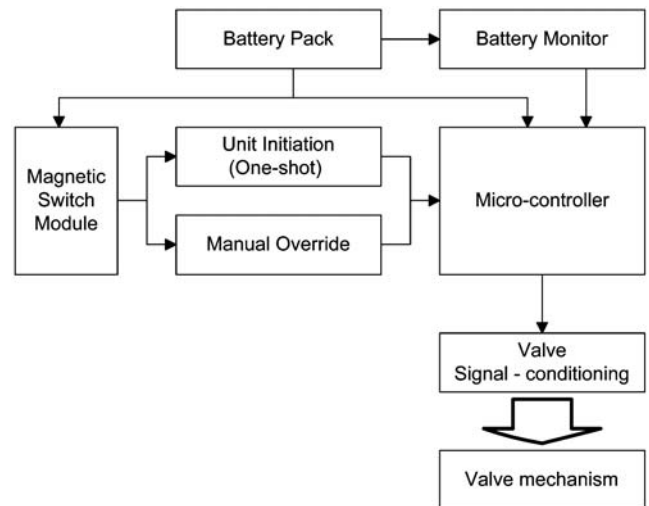


Fig. 3 Electronic control block diagram for the SL valve system

time (say, operation for 30 days), the system initiates the 'fail-safe' subroutine and the unit expires. Once the 'fail-safe' subroutine has been executed, the valve will be locked indefinitely in its open position and all system functions will be disabled. The entire valve system should then be disposed of, according to the expiry date. Any premature fail-safe activation can be identified by the lack of response after manual override.

The battery monitor constantly keeps track of the battery capacity to ensure that there is sufficient power for the operation. Otherwise, a 'STOP' signal is sent to the microcontroller and triggers the 'fail-safe' subroutine.

The magnetic reed switch module serves two functions. It is a one-shot power-on initiation switch, but all subsequent activation will act as the manual override. The reed switch can be activated by bringing a magnet close to it. This non-contact switching mechanism also allows patients with limited manual dexterity to operate the valve system.

3 THE SL VALVE SYSTEM PROTOTYPE

The valve mechanism and electronic control circuit were fabricated. They were assembled and packaged as SL valve system prototypes. Figure 4 shows the valve mechanism. It employs an ultrathin biocompatible polyurethane (PU) tube (Tecothane TT-1074A) of 3 mm diameter and a 3 V d.c. miniature motor (Faulhaber 0615) of 6 mm diameter as the actuator, driving the valve shuttle forwards and backwards, via the screw, to pinch the PU tube. The ultrathin PU tube with 30 µm wall thickness, supplied by

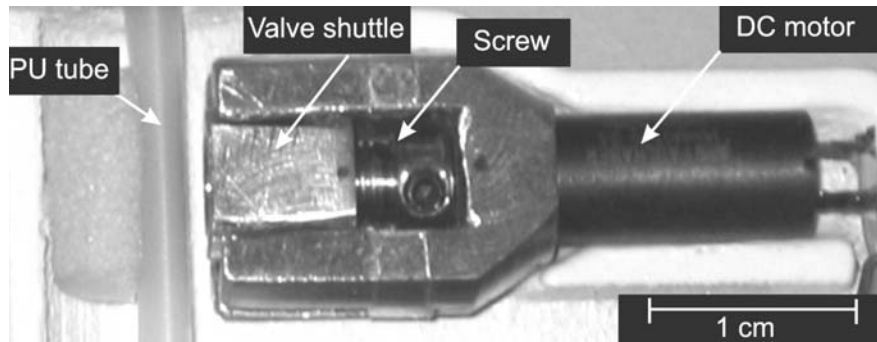


Fig. 4 The SL valve mechanism prototype, using medical-grade stainless steel

Ranier Technology Ltd, UK, has been integrated and supported on both ends by two modified Kartell polypropylene tapered 6–10 mm tube connectors (see Fig. 6(a) later). This tube connector fits all makes and sizes of common catheters. The overall length of the SL valve mechanism is 28.5 mm, its height is 8 mm, and its mass is only 7.6 g.

The maximum linear displacement of the valve shuttle is 9 mm. This valve shuttle displacement ultimately governs the maximum size of the valve orifice and hence the flowrate. The miniature d.c. motor has the distinct advantage of delivering potentially unlimited linear displacement for the valve shuttle. Hence, this implies that the identical valve mechanism can be readily expanded to produce a valve with an orifice of up to 9 mm diameter, for the negligible cost of a larger-diameter PU tube. This not only will benefit the progress of the subsequent prototyping and experimental process but also will lower the production cost by standardizing the valve components for different catheter valve sizes during manufacturing.

The SL valve system control circuit has also been fabricated using low-cost double-sided printed circuit boards, as shown in Fig. 5, with an area of only 2.8 cm × 2.8 cm. The instruction codes for the micro-controller have been written in assembly language to allow effective adjustments on the timing accuracy and to ensure efficient usage of the on-chip memory.

The power supply for the valve system is provided by two economical 3 V lithium-ion coin cell batteries (Panasonic CR2016). Although the coin cell battery has a mass of only 1.8 g, a diameter of 20 mm, and a thickness of 1.6 mm, the rated capacity is 90 mA h, delivering sufficient energy for the system to operate for up to 90 days (at 2 h operating interval). This is clearly well in excess for the targeted operating period of 30 days.

The assembled electronic control circuit board and the SL valve mechanism have been packaged into a

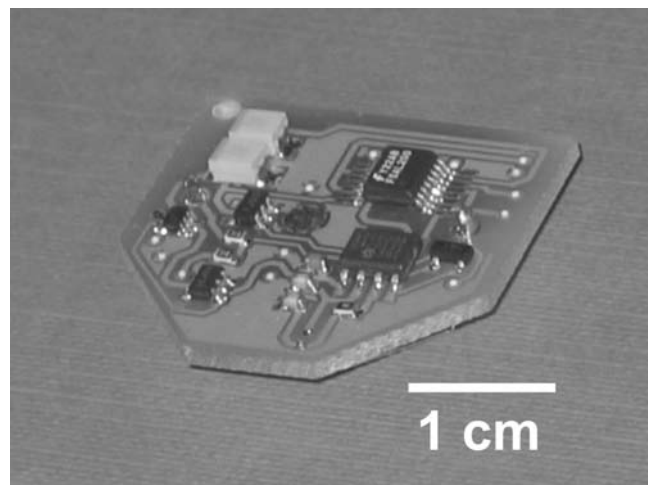


Fig. 5 The circuit board prototype for the SL valve control system

catheter valve system prototype using an ordinary low-cost rectangular enclosure, as shown in Fig. 6(a). The overall mass of the valve system is about 34.2 g. A 3 mm groove machined on the side of the SL valve package was used to mark the location of the magnetic reed switch. A neodymium disc magnet of 3 mm diameter disguised as a ring is shown in Fig. 6(b). The user swipes the magnetic activation ring along this groove for system initiation and manual override. Incorporating this magnet into a ring means that the patients or their carers can keep an activation magnet conveniently available for manual override. An observation window was also included in the prototype so that the user may instantly identify the status of the valve.

An identical system has also been packaged in a slim customized casing which was produced by rapid prototyping to demonstrate its potential as a commercial product, as shown in Fig. 6(b). This slim-packaged SL valve system fits more readily under normal clothing, giving greater comfort.

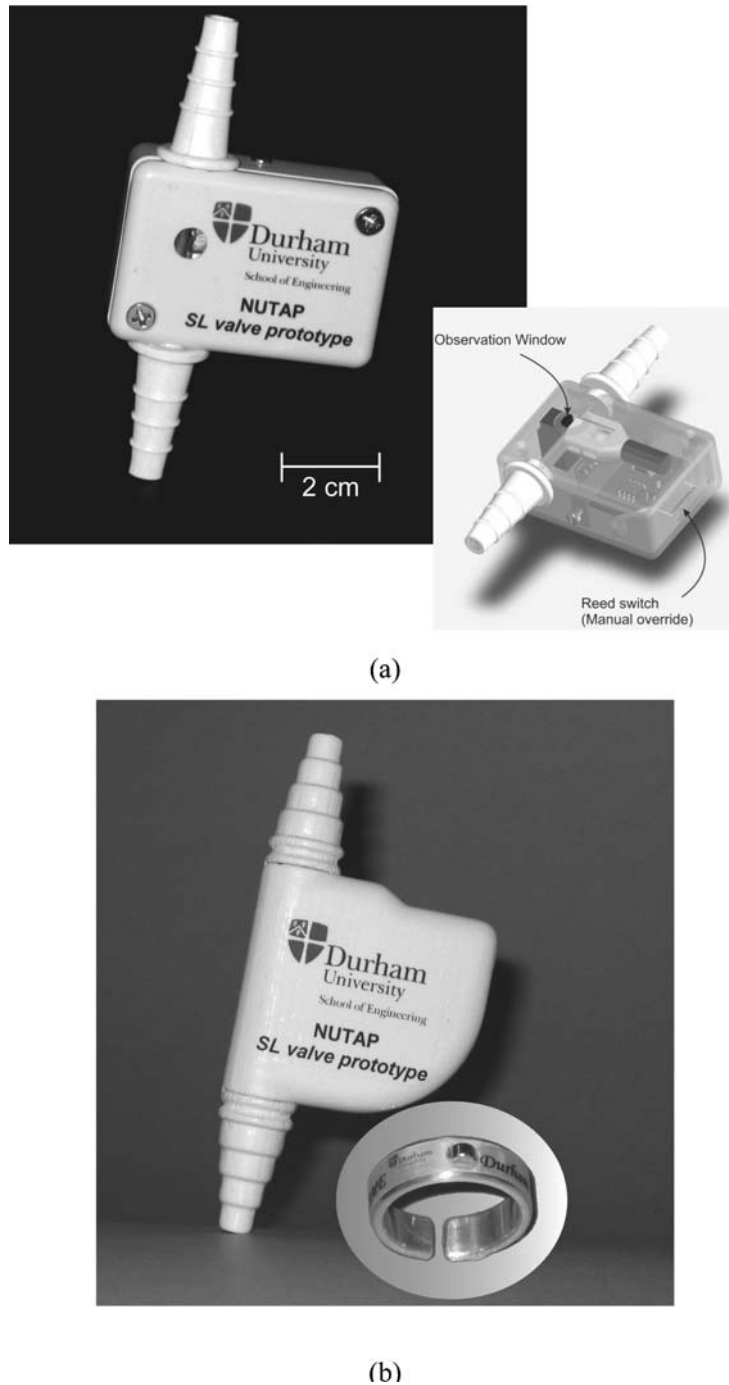


Fig. 6 (a) The SL valve system prototype (patient trial ready). (b) SL valve system prototype in a slim package and the activation ring with a magnet of 3 mm diameter at the top

4 THE PERFORMANCE OF THE SL VALVE SYSTEM PROTOTYPE

4.1 The test methods and materials

Three SL valve system prototypes were fabricated and tested at the Centre for Biomedical Engineering at Durham University. The microcontroller chips installed in these prototypes were interchangeable.

Thus the operating cycle interval could be altered for each prototype by replacing this microcontroller chip, each unit a different time interval, in order to facilitate various parametric tests.

Initially, the response time of the valve per switching was unknown. Three SL valve system prototypes with microcontrollers that were programmed with 3 min cycles (1 min open and 2 min closed) and a valve-driving pulse width of 250 ms were used to

facilitate voltage and current measurements. The voltage and current transients revealed the response time of the valve mechanism. The voltage across the valve actuator and the current (via a current-sensing circuit) were measured using an HP Infinium digital oscilloscope with a maximum 2 GHz sampling rate.

These measurements were carried out on all three valve system prototypes and three readings were taken from each prototype in order to obtain an average energy consumption of the valve mechanism. Moreover, an optimum duration of the valve-driving pulse was determined on the basis of the maximum response time of the valve mechanism. New micro-controllers were programmed to adopt this optimum driving pulse width for all subsequent experiments.

A computerized multifunctional catheter valve test station, urological simulator (UroSim), has been constructed (Fig. 7). The UroSim was designed to record the catheter valve switching time, to calculate the combined average flowrate of the catheter with the SL valve for every drainage, and to detect any missing operation. UroSim either supports one

valve prototype for testing with water, or three valve prototypes without water. The simulator consists of three main parts, namely the reservoir and bladder model, interface electronics, and the control personal computer (PC). Water was fed to the bladder model from the reservoir (Fig. 7). The water level of the bladder model was controlled by a PC via a solenoid valve. The UroSim was controlled by customized software, developed using a graphical programming tool, Agilent Technologies VEE Pro version 6, and interfacing with an Amplicon PCI 230 data acquisition card. The virtual instrument panel is shown in Fig. 8.

The flowrate of the prototype was investigated using the UroSim, as shown in Fig. 7. The bladder model was filled with 1 l of water and the valve prototype was subjected to a 30 cm static head, measured between the water level and the pinching point of the valve. The SL valve system hung vertically below the bladder model by a connecting silicone tube (i.d., 6.4 mm); the large diameter of the tube was to prevent interference with the flowrate measurement of the valve prototypes. As the valve was opened, the

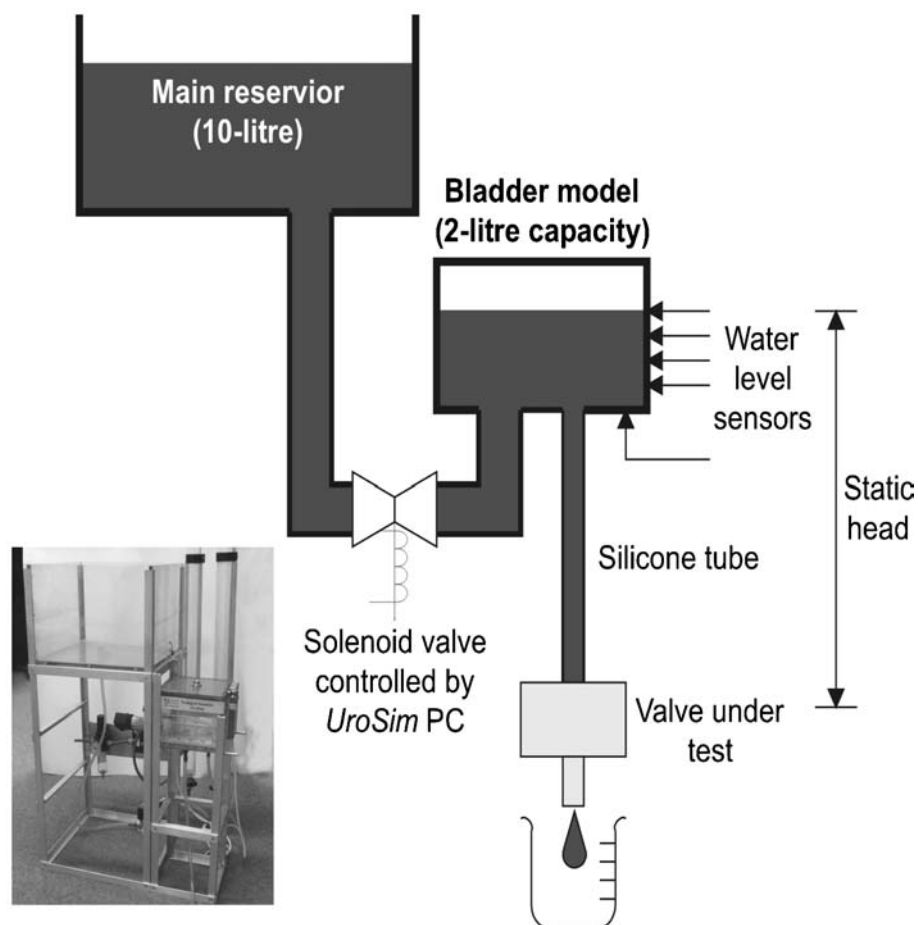


Fig. 7 Diagrams of the bladder model and the main water tank of the UroSim

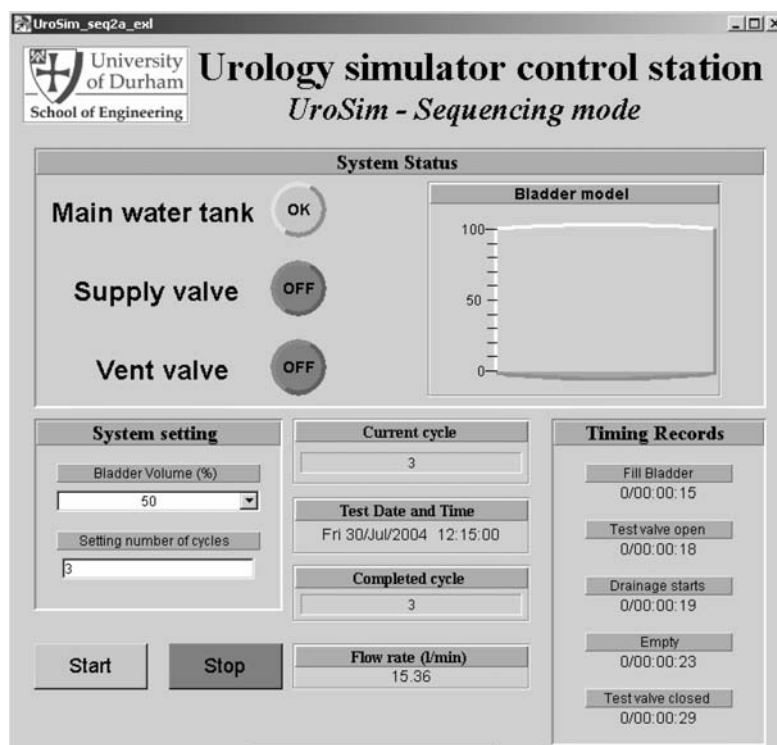


Fig. 8 The virtual instrument panel for the UroSim

water level sensors in the bladder model detected the dropping water level and recorded this start time. When 1 l of water was drained away, another sensor at the bottom of the bladder model sent a signal to the UroSim control PC, which recorded the finish time. This experiment was repeated until three consecutive drainage times were within 5 per cent tolerance for each SL valve prototype. The average of the results was taken to calculate the flowrate of the valve system.

The maximum isolation pressure of the valve system was also investigated in a similar way but the valve was closed throughout the test. The valve prototype was connected vertically below the bladder model by a 50 cm silicone tube with an inner diameter of 6.4 mm. The bladder model was then filled with water until the pressure of the water overcame the valve and began to leak. The static head, between the water level and the valve pinching point, was measured with a measuring tape. This experiment was repeated until three consecutive results were within 5 mm tolerance. The average of the results was then taken as the maximum isolation pressure.

Durability of the ultrathin PU tube was also investigated. The PU tubes in the three SL valve prototypes were constantly pinched for 7 days at room temperature. The tube was then inspected visually to ensure that it was not stuck together, obstructing the flow

path. The valve prototypes were then operated on 3 min cycles using the optimized valve-driving pulse width without water for 5000 operations. The integrity of the tube was tested similarly to the isolation pressure test, except that the static head was 1 m and the valve was opened while the output port of the valve was sealed. The PU tubes from each valve prototype were checked for leakage after this set-up had been left standing for 24 h.

The microcontroller chip was then replaced with three valve system prototypes with 4 h cycles (10 min open and 230 min closed) for functionality tests and *in-vitro* experiments. The accuracy of the operating interval for the SL valve system had been investigated using the UroSim, without water. Three valves were tested simultaneously. High-input-impedance test probes (i.e. low current drawn, which would not affect the operation of the valve) were connected to the valve mechanism and UroSim recorded the time for each valve switching. The valve system prototypes were operated for 24 h and six cycles were collected by the UroSim. The accuracy of the operating interval for each valve prototype was statistically assessed.

The overall functionality of the SL valve system prototype was evaluated by operating it using 4 h intervals for 30 days with UroSim monitoring each switching. New batteries were installed before this test. The bladder model was filled with 250 ml of water

once the valve system under test was closed. The 10 l water reservoir was manually refilled regularly to ensure the consistency of the water volume in the bladder model. Any missing operation was detected by reviewing the switching log.

4.2 Results and discussion

Typical voltage and current profiles across the SL valve mechanism when it was switching are shown in Fig. 9(a). The transients indicated the time taken for the valve shuttle to travel to the other end of the valve mechanism. As the valve was fully closed or opened, the voltage and current profile reached steady state. The test results indicated that the maximum response time of the valve was 40 ms. Adding 20 per cent to this maximum response time to ensure reliable operation, the optimized valve-driving pulse duration per switching was determined

as 50 ms. The profile of the power consumption based on the voltage and current measurements is shown in Fig. 9(b). The energy consumption of the valve mechanism per switching was obtained by calculating the area under this curve for the 50 ms switching time. The average energy consumption was approximately 15.5 mJ (Table 2).

The results showed that the time interval for the intermittent drainage achieved an acceptable level of accuracy (Table 2). The typical standard deviation between each valve switching interval over 4 h was 139 ms. The consistency of the operating interval is important for the safety of the user and can be critical for those patients who do not have bladder sensation.

The SL valves did not show any sign of leakage, up to a pressure of 5.86 kPa (equivalent to 60 cm head) in the closed state (Table 2), exceeding the nominal operating pressure of a fully filled bladder (2.93 kPa

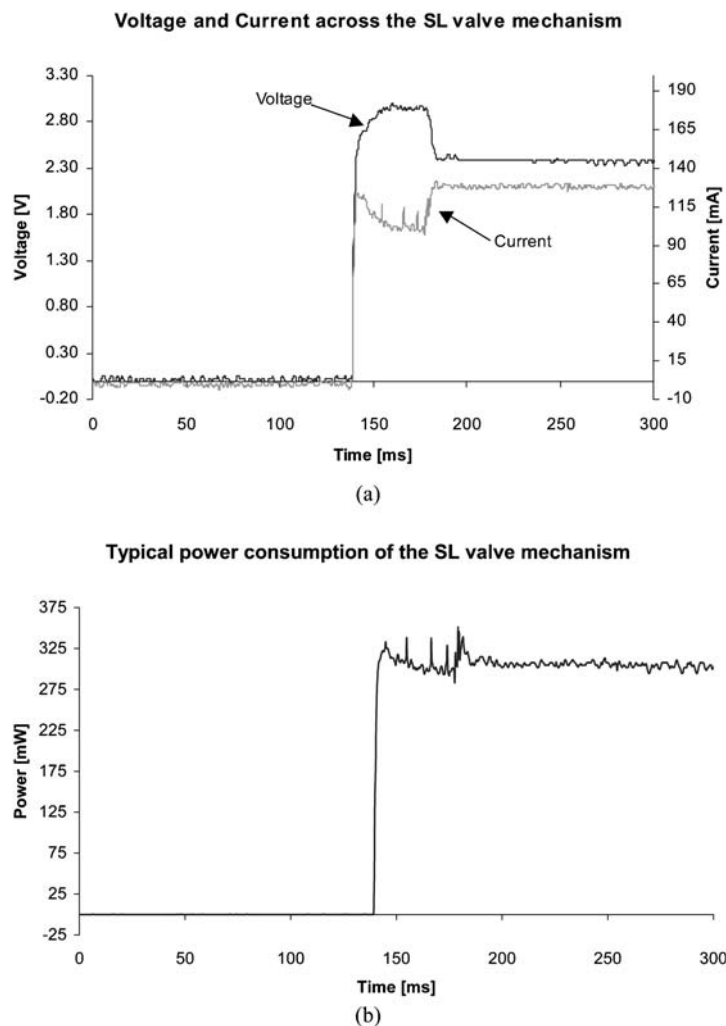


Fig. 9 (a) The typical voltage and current profile during SL valve mechanism switching; (b) the power consumption obtained from combining the voltage and current profiles

Table 2 Parametric test results of the SL valve system prototypes

Prototype number	Energy consumption of the valve mechanism (mJ)	Standard deviation of operating intervals (ms)		Maximum static head (cm)	Flowrate at 30 cm head (ml/s)
		Valve closed (230 min)	Valve open (10 min)		
SL valve system 1	15.9 ($\pm 18\%$)	139.3	31.6	60.0 \pm 0.2	10.4
SL valve system 2	15.2 ($\pm 15\%$)	139.5	32.1	60.0 \pm 0.2	10.2
SL valve system 3	15.4 ($\pm 19\%$)	138.8	31.7	60.0 \pm 0.1	10.3
Average	15.5	139.2	31.8	60 (standard deviation, 0.13)	10.3

or 30 cm head). However, this preliminary maximum valve isolation pressure setting will have to be verified by patient trials, at a later date.

The reliability of the ultrathin PU tube was evaluated and the result showed that all three PU tubes in the valve prototypes were unaffected; no 'sticking' or any other changes to the surface texture were detected throughout the entire test duration. Therefore, this indicated that prolonged and repeated pinching operation by the SL valve mechanism did not impair the integrity of the ultrathin PU tube. Thus the PU material is sufficiently reliable in this catheter valve application.

One SL valve system prototype was tested operating at 4 h intervals with the UroSim monitoring every switching over 30 days, and no missing switching was found throughout the entire experiment. Therefore, the SL valve system prototype has proved its reliability over the usual service lifetime of the common catheter.

The series of performance tests used primarily water instead of artificial urine. As all the moving parts and circuitry are isolated from the urine, the major safety issues associate with this automatic catheter valve are timing accuracy, reliability of the valve mechanism, and integrity of the diaphragmatic tube after repeated operations. Therefore, water is sufficient to demonstrate these characteristics. Nevertheless, an early *in-vitro* testing was carried out involving *P. Mirabilis* which was retrieved from patients who had serious encrustation to their catheters. The *P. Mirabilis*-infested artificial urine was used to test with a control catheter without the SL valve. The experiment (conducted by Sabbuba and Stickler, Biological Sciences, Cardiff University) indicated that the prototype possesses very high encrustation resistance against functional failure and might improve the service lifetime of an ordinary catheter by a factor of 4–6. Further *in-vitro* experiments will be conducted to confirm the results and a publication will be produced in the near future.

The in-line flow path design helps to maximize the valve's flowrate and the test results indicated the

average flowrate of the SL valve system prototypes reached 10.3 ml/s at 30 cm static head (Table 2). The valve flowrate and the energy required for each switching can be expressed as the flowrate–energy relationship (FER) given by

$$\text{FER} = \frac{\text{flowrate (ml/s)}}{\text{energy (mJ)}} \quad (1)$$

This relationship provides an indication of the valve performance and the appropriateness for catheter applications. Therefore, in the situation where the flowrate of a valve is comparable with the catheter in use, the higher this index value, the better the valve will function as an automatic catheter valve. The SL valve prototype resulted in an FER of 0.66 m/s⁻¹ mJ⁻¹. The flowrate experiment was repeated using a commercially available electronic valve (LHLX0500050B by Lee Products Ltd, UK) which is one of the few valves that matches the power requirements for this application. The FER and other specifications of the SL valve have been compared with this commercial valve (Table 3). Although the Lee valve consumes lower energy during switching, it is not designed for urological applications. As the solenoid actuator limits the travelling distance of the valve shuttle, its valve shuttle actually obstructs the valve inlet ports of 1.3 mm diameter and its flowrate is significantly lower than that of the SL valve prototype. Furthermore, tests conducted by ETB Ltd indicated that the Lee valve mechanism was constantly exposed in urine and subjected to encrustation, which eventually caused early functional failure. Therefore, low power consumption should not be the only consideration when sourcing or designing a valve for urological application. The FER could provide a convenient method to reflect the performance of a valve specifically for urological applications.

The prototype development has clearly met the design targets of Table 1 and in most cases has considerably surpassed them, with an overall size of 24 cm³, a mass of 34 g, a flowrate of 10 ml/s, and an energy consumption of 30 mA h in 30 days. Indeed, when these are put together with the estimated

Table 3 A comparison between the SL valve prototype and a commercial valve

Specification	Value for the following	
	SL valve prototype	LHLX0500050B Lee Products Ltd
FER ($\text{m/s}^{-1} \text{mJ}^{-1}$)	0.66	0.28
Flowrate at 30 cm head (ml/s)	10.3 ($\pm 1\%$)	1.5 ($\pm 1\%$)
Energy consumption per switching (mJ)	15.5	5.5
Orifice diameter (mm)	3	1.3
Mass (g)	7.6	3.9

production cost of around £5, the SL valve becomes a real competitor for the manual valve, irrespective of the anti-blocking benefits that it was originally intended to provide.

While this research has identified a means of preventing *P. Mirabilis* build-up and the consequent blocking of the catheter, as with the research at Cardiff [7–11] the means by which the blockage is prevented is still not fully understood. With the mechanism presented here, it is believed that two modes of prevention are in operation: firstly, the flushing of urine through the system, rather than a continuous drip, rinsing out the catheter at regular intervals; secondly, the regular crushing of the primary *P. Mirabilis* build-up site: the valve. Such suggestions remain speculation, however, until further *in-vitro* tests have been carried out. Of more importance, perhaps, is the funding required to carry out *in-vivo* tests, to ascertain the efficacy of the system against *P. Mirabilis* build-up in incontinence patients.

5 CONCLUSIONS

An automatic catheter valve system has been designed and prototyped in an attempt to prevent catheter blocking. The SL valve system prototype has overcome the technological challenges and possesses the unique characteristic required for an automatic catheter valve. It exhibits all the benefits of the manual valve plus automatic and safety features. The d.c.-motor-driven valve shuttle with the diaphragmatic PU tube harnesses the advantages of low energy consumption, prevention of encrustation, orifice expandability, and reliability. The cost-effective electronic control system has demonstrated the required functionality, reliability, and accuracy. The FER introduced is a convenient assessment for a catheter and it will assist future development of catheter valves. The SL design is realistic and low cost, and it surpasses all the design criteria provided by the clinical team, potentially making it competitive

even against a manual valve. There are several user-friendly features to ensure that the valve system prototype can be easily adoptable by existing catheter users. The valve system prototype can therefore be fabricated for further investigation including *in-vitro* tests and patient trials.

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