Clinical Interview with Neil Harris

Date: 08/12/2014 **Time:** 15:30-16:30
Present: P. Culmer, A. Neville, W. Stokes, M. Bryant, A. Alazmani.

Neil Harris came to the University of Leeds and spent an hour discussing his identified clinical needs in the area of urology. This centred on the limitations of current urinary sphincter systems.

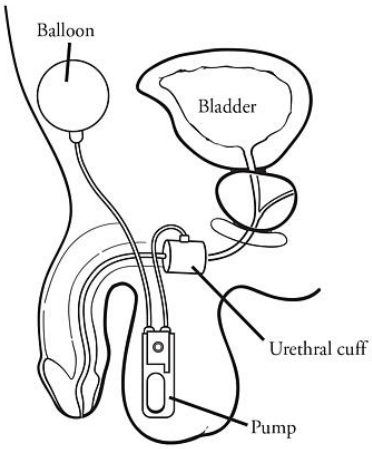
Artificial Urinary Sphincter System

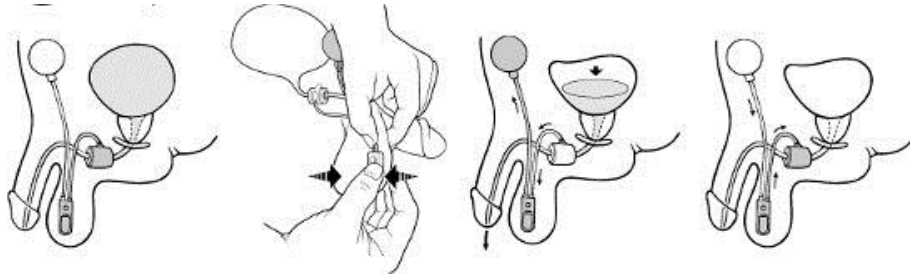
Background

The market is currently dominated by AMS (American Medical Systems) – although Coloplast produce similar systems. AMS manufacture a range of systems for male and females – they act to prevent urinary leaks by using a pneumatic compression cuff which is wrapped around the urethra. The system consists of 3 key components:

1) A cuff which is wrapped around the urethra
2) A pump enabling the user to activate the device
3) A balloon which applies a holding pressure to the urethra cuff to maintain continence

To pass urine, the patient uses the pump which is located in the testicles for males and the labia for females. This process can be problematic for some patients.
The system costs approximately £5-6K





Operation

Devices are fitted through a surgical procedure. Tissue around the urethra is dissected to create space for the cuff. The urethra is measured – with a typical circumference of 4-5cm – and a range of cuff sizes are available to suit. The cuff is wrapped around the urethra and then fixed in place. Different sized balloons are then available to provide varying pressure to close the cuff (typically 61-72 cmH_20). After time the cuff is encapsulated by a capsule of tissue. Interestingly, there is no significant restriction on the size of the cuff – currently this is 10mm wide but a bigger device could be accommodated.

Limitations of current systems

The systems are generally well tolerated by patients, with minimal erosion of internal tissues or migration of the system (~5%), which is common in artificial faecal sphincters. However, mechanical failures do occur and require refitting a new system (which is typically successful).

The main limitation of the current systems is the ability to tune/control/optimise the holding pressure applied to the cuff. This applies to both the static 'holding' pressure and dynamically adjusting the system to account for transient rises in intra-abdominal pressure (i.e. through coughing or exercise) which would result in leaks of the system. Additionally some mechanical issues exist with leaks and valve failures noted (although not particularly common)

N.B. cough pressure could vary between 30cmH2O to 100cmH2O

Opportunities

A new approach to artificial urinary sphincters would be beneficial, moving away from the current passive 3-component system. In particular opportunities were identified to

1) Use smart materials to dynamically adapt to, and resist, fast changes in pressure. (i.e. thixotropic fluids etc.)
2) Soft robotic approaches with integrated sensing and actuation (avoiding multiple components)
3) Active control of the system to modulate passive holding pressures over time (e.g. lower pressures required during the night)
4) Wireless power transmission
5) External control/tuning of the system through smartphones etc.
6) Develop an *in vitro* testing environment