

ULTRASOUND IMAGING AS A DIAGNOSTIC TOOL FOR ASSESSING A NEW ARTIFICIAL URINARY SPHINCTER

Hypothesis / aims of study – A new implantable artificial urinary sphincter (Flowsecure® - Barloworld Scientific Ltd, UK) is a one-piece, pre-filled and adjustable pressure-regulated device suitable for people with stress urinary incontinence. The novel feature of adjustment for occluder-cuff pressure is achieved by injecting a known volume of sterile saline through a self-sealing port in the base of a pump in the scrotum (Figure 1). The pump is used to deflate the cuff for voiding by squeezing about ten times (A) and continence is automatically restored afterwards within about ten minutes (B). A unique feature of this device is a second balloon, in line with the cuff, which transmits abdominal pressures rises directly to the cuff to help prevent stress incontinence (C).

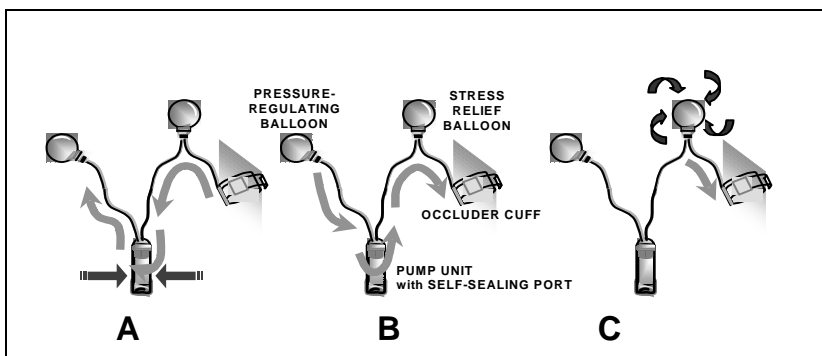


Figure 1 – Functions of the new sphincter with occluder cuff placed around the bulbar-urethra

Because the device deliberately does not contain radio-opaque solution then ultrasound was chosen as the best non-invasive diagnostic tool for assessing *in situ* mechanical performance of the new artificial sphincter. Imaging the stress balloon was determined to be the best for assessment. The aim of this study was to demonstrate the utility of ultrasound to assess 1) the intrinsic operating pressure *in situ* of the device, set by injecting known volumes of fluid and 2) the normal functions of the AUS for voiding and restoration of continence by observing the dynamic changes in intrinsic cuff pressure.

Study design, materials and methods - Three patients who had been implanted with the new sphincter to treat stress urinary incontinence following post-prostatectomy incontinence (01 aged 75, 02 aged 65) or bilateral pudendal damage (03 aged 54) were selected for this study. Each of these patients had been successfully treated (0 or 1 pad/day) for over 3 years but each with a different adjusted device pressure tailored to their individual severity of incontinence. The patients were tested supine on an examination bed and asked to relax during ultrasound imaging. To image either of the two balloons *in situ*, through the abdominal wall, a high resolution linear probe with a frequency range 6-10MHz was used. Points of maximum reflectivity at the top and bottom of each spherical balloon (outlined for clarity in Figure 2) were measured electronically on the screen and the diameters determined. The stress balloon could be identified by observing a decrease in diameter during pumping for voiding (complemented by an increase in the regulating balloon). In all patients, three repeated measurements were made of the stress balloon diameter when the device was isobaric, averaged and then compared with the experimental pressure-volume-diameter relationship (PVDR - Figure 3) to determine the balloon pressure and hence the cuff pressure. For dynamic assessment of the device the stress balloon diameters were observed in the same way immediately after pumping the cuff down with 10 squeezes and then following the recovery of pressure over time to restore continence.

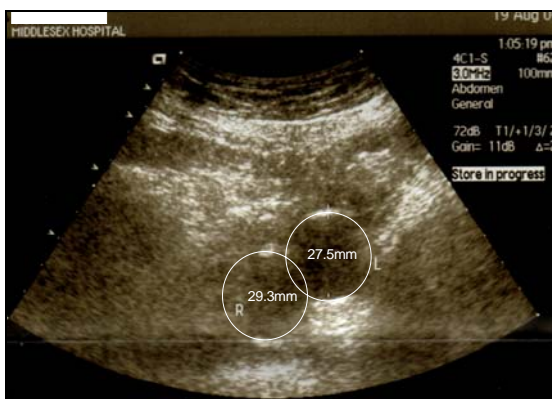


Figure 2 - Ultrasound Imaging of Balloons

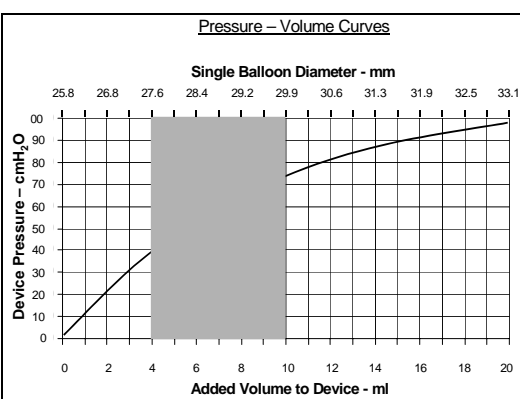


Figure 3 - PVDR for the whole device

Results –1) Table 1 shows the relationship between the diameter of the stress balloon, measured by ultrasound as described above, for each patient during the continence phase of operation (when the AUS was isobaric) together with

the pressures determined from the PVDR shown in Figure 3 above. The volumes of added sterile saline that had been injected through the self-sealing filling port to establish these operating pressures are also given.

Patient	Mean Balloon Diameter mm	Mean Device Pressure cmH ₂ O	Added Volume ml
01	28.9 (± 0.2mm)	60 (±2cmH ₂ O)	7
02	27.3 (± 0.1mm)	32 (±1cmH ₂ O)	3.5
03	26.5 (±0.15mm)	18 (±1cmH ₂ O)	1.5

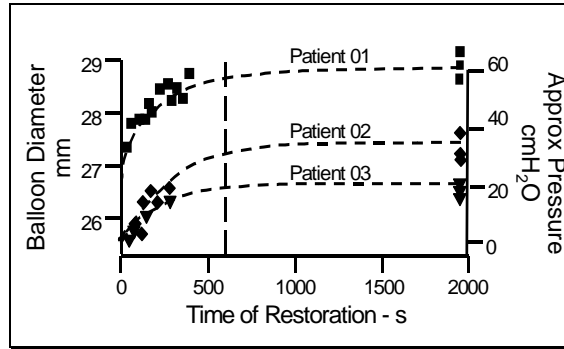


Table 1.

Figure 4 - Stress balloon recovery function

2) The graph (Figure 4) shows the data points for the ultrasound measures of diameter, in all three patients, during the recovery of the stress balloon as it refills automatically following deflation of the cuff for voiding. The full recovery is shown as dotted lines and these were the best fit curves to the data. The approximate pressures as derived from the PVDR are shown on the right hand ordinate. The data at 2000 second (~30 minutes) shows the isobaric pressures, but to reach 90% of these values the time taken was on average 6 minutes for each patient (vertical dashed line.)

Interpretation of results – As determined by non-invasive ultrasound measurement, the intrinsic pressures of this new AUS required to achieve continence in each of these three patients was shown to be different, justifying the facility for adjusting pressures *in situ* by way of a self-sealing port. Ultrasound was also able to be used for assessing proper function associated with pumping to deflate the cuff for voiding followed by automatic restoration of pressure in the cuff for continence.

Concluding message - By utilising ultrasound to non-invasively image and measure the diameter of the stress balloon of this new artificial urinary sphincter it was possible to determine more precisely the intrinsic working pressure of the occluding cuff and proper functioning of cuff-deflation for voiding and automatic re-inflation for continence. These techniques can be used for trouble shooting mal-functioning artificial sphincters and we believe also that they could also be used for functional assessment of other similar devices where spherical balloons are used to regulate pressure.

FUNDING: NONE

DISCLOSURES: NONE

HUMAN SUBJECTS: This study did not need ethical approval because It used a standard diagnostic imaging protocol for assessment but followed the Declaration of Helsinki Informed consent was obtained from the patients.