

# CONCUR

**Contractility: C**uff Versus **U**rodynamics Testing In  
Males With Voiding Lower Urinary Tract Symptoms

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**ii Research Reference Numbers**

IRAS number	231323
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**iv Trial Summary**

Trial Title	<b>Contractility: Cuff Versus Urodynamics Testing In Males With Voiding Lower Urinary Tract Symptoms</b>	
Short Title	<b>CONCUR</b>	
Internal ref. no.	8598 (Newcastle JRO reference number)	
Trial Design	Pilot Observational Cohort Study	
Trial Participants	Men aged 18 years old or over, who are referred for video urodynamics. They will have predominant voiding LUTS as assessed by IPSS at screening, and at least 2 voided volumes on a frequency volume chart of 250 mL	
Planned Sample Size	30	
Investigation Duration	One visit, lasting roughly 90 minutes	
Interventions Performed	Video cystometrogram, penile cuff test	
Follow up duration	N/A	
Planned Trial Period	15 months	
	<b>Objectives</b>	<b>Outcome Measures</b>
Primary	<p>To modify procedural steps of the penile cuff test</p> <p>To identify behaviour of the urethra during penile cuff inflation</p> <p>To test the basic assumption of the penile cuff test that the bladder neck remains open during flow interruption</p>	<p>Reduction in variance between <math>p_{\text{cuff.int}}</math> and <math>p_{\text{ves.isv}}</math> compared to previous data</p> <p>Qualitative description of urethral behaviour and bladder neck opening during the penile cuff test</p>
Secondary	<p>To compare non-invasive measurements from the penile cuff test against invasive indices of contractility</p> <p>To compare 2 different symptom scores for men with voiding LUTS</p> <p>To assess accuracy and inter-observer variability of ultrasound residual measurement against a known volume.</p>	<p>Comparison of <math>p_{\text{cuff.int}}</math> with other indices including BCI and Watt's Factor</p> <p>Correlation calculation to compare IPSS and ICIQ-MLUTS</p> <p>Accuracy: catheterised PVR = gold standard Inter-observer agreement: paired t-test</p>

**v Funding and Support in Kind**

<b>FUNDER(S)</b> (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	<b>FINANCIAL AND NON FINANCIAL SUPPORT GIVEN</b>
<b>Newcastle upon Tyne Hospitals NHS Foundation Trust</b> Contact: Mr Michael Drinnan Department of Medical Physics Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne NE1 4LP TEL: 0191 213 7161 Email: Michael.Drinnan@nuth.nhs.uk	100% provision of funding for project and MD studies from Trust Royalty Account
<b>Mediplus Ltd</b> Contact: Mr James Urie Sales and Marketing Director Unit 7 The Gateway Centre Coronation Road Cressex Business Park High Wycombe HP12 3SU TEL: 01494 551200 Email: James.Urie@mediplus.co.uk	Funding awarded of 2 boxes of penile cuffs

## 1. Background

Lower urinary tract symptoms (LUTS) are common in men, with population based studies estimating the prevalence of LUTS to be more than a quarter of men over the age of 60 years<sup>(1-2)</sup>. They can relate to a number of different conditions of the bladder, prostate and urethra. In particular, LUT symptoms including poor urinary flow, prolonged voiding and incomplete emptying could indicate either underactive bladder syndrome (UAB) or benign prostatic enlargement (BPE). There may be a substantial overlap in the symptoms experienced by men who may be suffering from one or both of these clinical syndromes. To aid treatment decision making, further investigations such as a bladder pressure study (urodynamics) can help to differentiate an exact cause. This may be the urodynamic diagnoses of detrusor underactivity (DU) and bladder outflow obstruction (BOO), respectively. Detrusor underactivity is currently defined by The International Continence Society (ICS) as 'a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or a failure to achieve complete bladder emptying within a normal time span'<sup>(3)</sup>. In addition, an alternative definition for UAB has been proposed by Chris Chapple et al<sup>(4)</sup> as; 'a symptom complex suggestive of detrusor underactivity and is usually characterised by prolonged urination time with or without a sensation of incomplete bladder emptying, usually with hesitancy, reduced sensation on filling, and a slow urinary stream.' These descriptive definitions are contrasted by the ICS definition of bladder outlet obstruction, which is characterised by 'increased detrusor pressure and reduced urine flow rate.' This reflects a diagnosis reached during urodynamic investigation, which has established indices/grading systems to quantify severity. The current working definitions for UAB/DU do not quantify the parameters they use. Recognising UAB/DU as the reason for a patient's LUTS is a well-documented problem<sup>(4-5)</sup>, and confusion due to the wide variety in terminology compounds this.

As with any muscle, it is the ability of the individual cells to contract that governs its function. In the case of the lower urinary tract, this means that detrusor smooth muscle contractility will affect how the bladder as a whole organ performs. Currently, bladder contractility is assessed in clinical practice by urodynamics – standard pressure-flow studies (PFS). This requires insertion of fine catheters into the bladder via the urethra, and into the rectum to measure and account for changes in abdominal pressure. The patient's bladder is then filled until the patient expresses a desire to pass urine. They will then be asked to void, whilst measuring abdominal and bladder pressure. The detrusor pressure is derived by subtracting the abdominal pressure from the simultaneously measured vesical pressure. Performing PFS is time-consuming, and the invasive nature of the procedure can cause patient discomfort, as well as leading to potential morbidity.<sup>(6-7)</sup> A significant concern is the risk of introducing infection, which can lead to urinary infection despite the use of an aseptic technique<sup>(8)</sup>. Once performed, various parameters including aspects of detrusor pressure and urine flow can then be used to calculate one or more of a number of indices of bladder muscle contractility, such as the bladder contractility index (BCI) or more complex Watts Factor (WF), or used in nomograms like Schafer's LIN-PURR nomogram<sup>(9)</sup>. Isovolumetric bladder pressure – i.e. the pressure the bladder can achieve without flow of urine, is felt to reflect bladder contractility. This can be assessed in a short period at the beginning of a contraction during invasive PFS. To reduce the need for invasive investigations and improve the patient experience, various non-invasive methods of measuring isovolumetric bladder

pressure (and flow), have been proposed <sup>(10)</sup>. These include the condom catheter method <sup>(11)</sup>, as well as the penile cuff test which was developed in our unit.

The penile cuff test involves the application of a small inflatable cuff similar to a blood pressure cuff around the penile shaft. The patient is asked to void, and once voiding has commenced the machine automatically inflates at a linear rate of 10 cmH<sub>2</sub>O per second. The cuff automatically deflates 2 seconds after interruption of flow or immediately if the safety limit of 200 cmH<sub>2</sub>O is reached. Inflation-deflation cycles will continue until the void has finished. The technique relies on the principles that i) the pressure from the cuff is transmitted to the urethral lumen, ii) the bladder contraction is maintained during the period of flow interruption so that flow will recommence once the cuff pressure is released, and iii) the pressure in the penile urethra is the same as the bladder pressure (plus height difference in transducers due to hydrostatic pressure) – this requires the urethra proximal to the cuff to remain open during flow interruption to allow continuity of the urinary tract to transmit pressure between the bladder and urethra.

Previous investigation <sup>(12)</sup> of cuff interruption pressure ( $p_{\text{cuff.int}}$ ) as an estimate of isovolumetric pressure found that there is generally an overestimate of invasively measured isovolumetric bladder pressure ( $p_{\text{ves.isv}}$ ) by  $p_{\text{cuff.int}}$ . A mean difference of 16.4 cmH<sub>2</sub>O was observed, although this was reduced once the difference in transducer reference height (mean 10 cmH<sub>2</sub>O) was taken into account. There was however, a large variability in the measurements with a standard deviation of 27.5 cmH<sub>2</sub>O, which was not accounted for by abdominal straining. Two different cuff widths were used (3.8 cm (51%) or 4.8 cm (49%)) and the mean difference and standard deviation were significantly better in men tested with the larger width cuff. Test-retest reliability was found to be better in the subgroup of patients who had voided more than 150 mL on both occasions. Further investigation into these potentially modifiable factors of voided volume and cuff size is necessary to provide information that we can use to improve the accuracy of the penile cuff test.

Furthermore, preliminary work has suggested further modifiable factors which will form the basis of the investigations in the project. The analysis found:

- A reduction in the error between  $p_{\text{cuff.int}}$  and  $p_{\text{ves.isv}}$  during inflations occurring later in the void:  
In some patients this could be due to voluntary inhibition during initial inflations, which we will aim to minimise within patient coaching and introduction to the penile cuff.
- Behaviour of the urethra during cuff inflation:  
Urethrography (x-ray screening of the urethra obtained when the bladder is filled with radio-opaque contrast) performed on one test subject during the initial development of the cuff test showed distension of the urethra occurred quickly after the beginning of cuff inflation till a steady state was seen. It did however seem to demonstrate kinking of the urethra during cuff inflation, which may be another source of error in the transmission of pressure between the cuff and the urethra, or maintaining continuity of the proximal urethra with the bladder.

There is a need for further investigation within this field, given the diversity which exists in the definitions of UAB and DU. There are multiple measurements available to assess contractility, but with scant guidance and evidence on threshold values, and no consensus on which is best. This is coupled with the invasive nature of the procedure used to acquire and calculate these measurements. The concepts of the underactive bladder syndrome, detrusor underactivity and bladder contractility are felt to overlap in term of symptoms, function and aetiology respectively <sup>(4)</sup>. They are however often used interchangeably within the literature. We need to explore the relationships between the definitions and measurements, as symptoms in themselves are too non-specific for diagnosis and overlap with other conditions of the lower urinary tract. The penile cuff test has the potential to be widely used due to its non-invasive nature, but we need to refine the investigation to increase the repeatability associated with the test, and define the parameters which would be most useful.

## 2. Aims and Objectives

There are a number of confounding issues that affect the ability of  $p_{\text{cuff.int}}$  to reflect an accurate measurement of intravesical pressure. We intend to refine the procedural steps of the cuff test to improve the measurement and reduce variability with  $p_{\text{ves.isv}}$ , therefore giving a more reproducible test. By improving the penile cuff test, we can then go on to assess how our non-invasive measurements correlate with urodynamically derived indices of contractility, and we will use data from this pilot to help construct our future methodology. Our current hypotheses are that; 1) accuracy of  $p_{\text{cuff.int}}$  can be improved by modification of penile cuff test factors, 2) the number of valid inflations obtained per patient will increase with the modifications, and 3) that our non-invasive measure of contractility will correlate with pre-existing invasive indices.

Our research protocol also gives us the opportunity to explore correlation between commonly used symptom scores, and accuracy in the assessment of ultrasound residual urine volume measurement.

Our primary objectives are therefore:

- To modify procedural steps of the penile cuff test that may reduce the previously observed variability and perform a pilot study to assess a reduction in variance
- To identify behaviour of the urethra during penile cuff inflation, by performing x-ray screening during the penile cuff test, and assess whether this is another source of inaccuracy
- To test the basic assumption of the penile cuff test that the bladder neck remains open during flow interruption

Secondary objectives of the study include the following:

- To compare non-invasive measurements from the penile cuff test against invasive indices of contractility
- To compare 2 different symptom scores for men with voiding LUTS
- To assess accuracy and inter-observer variability of ultrasound residual measurement against a known volume.



### 3. Methods

Any eligible man referred for video-urodynamic investigation at the Freeman Hospital, Newcastle upon Tyne, will be invited to take part in the study.

#### *Patient Screening*

The following steps will be taken by the research team to ensure a patient is eligible for participation in this study:

- Confirm the patient's age and gender (using the investigation referral form)
- Ensure the patient has completed a frequency volume chart (FVC), and review the information contained
- Ensure the patient has completed an IPSS (International Prostate Symptom Score) questionnaire prior to attending for their appointment
- Confirm co-morbidities and past medical history with the patient and their electronic records to identify any conditions which would contra-indicate the study as per the exclusion criteria
- Assessment of capacity to give informed consent

The following criteria have been devised with regards to patient participant in the study:

- Inclusion Criteria
  - Male aged 18 years old or over
  - Referred for video urodynamics within our department
  - Predominant voiding LUTS as assessed by IPSS at screening. [The total IPSS score is out of 35, with up to 15 points for storage symptoms and 20 for voiding symptoms. If voiding symptoms as a percentage of total score is higher than storage symptoms they will be included in the study].
  - Capacity to understand study procedures and give informed consent
  - At least 2 voided volumes on FVC of 250 mL
- Exclusion Criteria
  - Female patients
  - Inability to void
  - Long term catheterisation
  - Predominant storage LUTS on IPSS at screening
  - Fewer than 2 voids on FVC  $\geq$  250 mL
  - Known pre-existing neurological cause for symptoms
  - Active urinary tract infection (UTI)

*Patient Pathway*

1. Urodynamic referral forms will be screened upon receipt in the department. Patients meeting initial criteria (male,  $\geq 18$  years old) will be contacted by the researcher. The study will be introduced and if he wishes to participate:
  - IPSS will be performed over the telephone
  - The study will be explained in detail
  - The patient will be given the opportunity to ask questions
  - A patient information leaflet will be sent out via post, as well as a frequency volume chart and an appointment for the investigation
2. The patient will attend the department on the day of investigation. They will be met by the researcher, who will confirm if the patient wishes to participate in the study. The FVC will be assessed at this point to ensure eligibility for the cuff test. If the patient is not eligible or no longer wishes to participate in the study, they will only undergo the test requested by their clinician. If they do wish to take part, the researcher will take written informed consent from the patient. A more detailed symptoms questionnaire (ICIQ-MLUTS) will then be performed.
3. Prior to the start of the investigation, the cuff will be shown to the patient, and the researcher will describe the steps of the procedure and need to avoid voluntary inhibition or straining. The cuff will be placed on the patient's fingers and inflated to demonstrate the test. Opportunity will be given at this point for the patient to ask any further questions about the procedure
4. The patient will undergo investigation with video-urodynamics and penile cuff test consistent with ICS Good Practice standards. In total there will be 3 fill-void cycles – 1. PFS, 2. Simultaneous PFS and cuff test and 3. Non-invasive penile cuff test. These are detailed in the following steps. Radiological screening will be performed for the 1<sup>st</sup> and 3<sup>rd</sup> cycles.
5. The PFS will be performed as per the standard clinical pathway in our department. This includes the following steps:
  - The patient will be asked to perform a free flow (if able) into a standard load cell flowmeter. If the patient is unable to perform a free flow they will move on to ultrasound volume assessment and then catheterisation at this stage.
  - If a free flow is achieved by the patient then an ultrasound examination for residual urine volume will be performed by two members of the research team, and values recorded.
  - Installation of local anaesthetic gel into the urethra.
  - Urethral catheterisation using 8Fr double lumen cystometry catheter (Digitimer Ltd, Welwyn Garden City, United Kingdom).
  - Residual urine will be aspirated via the filling line using a 50 mL luer lock syringe to confirm bladder is empty at the start of the test, and recorded against the volume measured by the ultrasound.

- Insertion of 4Fr vented manometer line into the rectum (Digitimer Ltd, Welwyn Garden City, United Kingdom).
  - The fluid filled lines will be connected to external pressure transducers (MX960P1, Smith Medical, Czech Republic) at the level of the pubic symphysis and zeroed to atmospheric pressure.
  - The bladder will be filled at a rate of 50 mL per minute with room temperature 0.9% normal saline, or Urograffin® 150 if x-ray screening to be performed. The rate may be reduced if the patient does not tolerate the standard filling rate (i.e. if it is inducing detrusor overactivity or sensory urgency)
  - Filling will continue until the patient expresses a strong desire to void, and total instilled volume noted.
  - The patient will then be asked to void, and voided volume (mL) and duration of void (seconds) recorded.
  - Throughout the test, intravesical pressure ( $p_{ves}$ ), abdominal pressure ( $p_{abd}$ ), subtracted detrusor pressure ( $p_{det}$ ) and flow rate will be recorded continuously.
6. If the patient was not able to reach a cystometric capacity of at least 200 mL, or if there is severe detrusor overactivity then they will not proceed with the next steps of the study. Our estimated attrition rate would be around 25% (we currently observe around 1/3 patients unable to achieve this, but anticipate the more stringent selection criteria for this study to reduce the value).
7. The researcher will verbally re-confirm that the patient wishes to proceed with the penile cuff test, and agreement to the use of x-ray screening.
8. The bladder will be re-filled to the same total volume as the first PFS (taking into account residual fluid volume from the first fill-void cycle). A simultaneous PFS and penile cuff test will then be performed, including the following extra steps:
- The appropriately sized penile cuff (Mediplus Ltd) will be positioned around the penis, and the distance between the mid-point of the penile cuff and the upper border of the pubic symphysis recorded.
  - Both the urethral and rectal pressure lines will remain in situ.
  - The patient will be asked to void, and the cuff will automatically inflate (at a rate of 10 cmH<sub>2</sub>O per 1 second) once flow is detected.
  - The cuff will continue to inflate until flow is interrupted, or until the safety limit of 200 cmH<sub>2</sub>O is reached.
  - The cuff will then automatically deflate, allowing flow to resume, and further inflation-deflation cycles are performed until completion of the void.
9. A final fill will then be performed, the urethral catheter will be removed, and a standard penile cuff test (as described in step 7 above) will be performed, with x-ray screening of the bladder and urethra during the periods of cuff inflation. This will be operated by an appropriately qualified radiographer.

10. Results of the standard PFS will be reported following usual departmental procedure, and returned to the responsible clinician for the patient for further management. Results from the penile cuff test will not affect standard care for the patient.

#### 4. Subjects, sample size and statistical analysis

##### *Subjects*

Any eligible man referred for video-urodynamic investigation at the Freeman Hospital, Newcastle upon Tyne, will be invited to take part in the study. Men will continue to be recruited until 30 eligible men undergo a successful penile cuff test defined as one or more valid inflations which were not excluded by previously defined quality control criteria for the test; no recovery of flow after cuff deflation, erratic flow trace resulting in ambiguity of  $p_{\text{cuff.int}}$  and continued flow above the inflation safety limit of 200 cm H<sub>2</sub>O.

##### *Sample size*

We are performing a pilot study to see if changes made to the cuff test procedure offer improvement in the observed error between  $p_{\text{cuff.int}}$  and  $p_{\text{ves.isv}}$  before proceeding with further work to compare cuff derived values to other indices of contractility. The general accepted sample size required for a pilot study to determine mean and standard deviation, and help perform power calculations for future studies is 20-30 degrees of freedom<sup>(13)</sup>, so we have chosen the upper limit of this range for number of patients to ensure we have enough values to provide reliable estimates of means and standard deviations.

##### *Valid Test Criteria*

Cuff tests will go on to further analysis if the fill volume is  $\geq 250$  mL, and if the test was performed with the standard size 4.8cm cuff.

Quality control standards were established during the development of the penile cuff test<sup>(14)</sup>, to allow observers to decide if an inflation is valid and suitable for further analysis.

Inflation cycles will be excluded from analysis if any of the conditions were met:

- There was no recovery of flow after cuff deflation (in practice this also usually includes the final inflation of a void)
- There was an erratic flow trace – giving ambiguity about the cuff pressure at flow interruption
- Flow was not interrupted before the safety limit of 200 cmH<sub>2</sub>O.

##### *Statistical analysis*

Our primary analysis will involve a comparison of the pressure required to interrupt urine flow ( $p_{\text{cuff.int}}$ ) and simultaneously measured isovolumetric bladder pressure ( $p_{\text{ves.isv}}$ ). Our hypothesis is that modifications to the procedural steps of the penile cuff test will improve the accuracy of  $p_{\text{cuff.int}}$ . Mean and standard deviation between  $p_{\text{cuff.int}}$  and  $p_{\text{ves.isv}}$  will be calculated, and compared with results from our analysis of past work using an F test to see if the variances within the two populations are different.

Analysis of the secondary outcomes will be as follows. The symptoms scores from the IPSS and ICIQ-MLUTS patient questionnaires will be compared. The frequency of symptoms will be reported, and correlation between the corresponding variables in the two scores

assessed, as well as statistical difference. We will also compare  $p_{\text{cuff.int}}$  with other indices of contractility derived from the simultaneous PFS including BCI and Watt's Factor, using a measure of difference such as a T test or ANOVA, as well as examining the correlation between the various indices. Analysis of the ultrasound residual measurements will assess accuracy and inter-observer agreement. The catheterised post void residual volume will be used as the gold standard and mean ultrasound values and difference recorded. Inter-observer agreement will be assessed using a paired t-test.

## 5. Project Timeline

With knowledge of recruitment to previous similar studies performed in the department we propose a 15 month programme as follows:

Months 1-2 Study set up  
Months 2-14 Recruitment  
Months 14-15 Data analysis

The end point for this project will be September 2019

## 6. Resources and Cost

### *Equipment*

The following equipment may be used for the pressure-flow study, covered by the department within the tariff for the patient's investigation as requested by the referring clinician:

- Disposables:
  - Catheter pack
  - STERETS® Unisept 0.05% w/v cutaneous solution (Medlock Medical Ltd., Oldham, UK)
  - Instillagel local anaesthetic jelly 11mL (FARCO-PHARMA GmbH, Cologne, Germany)
  - 50 mL luer lock syringe
  - Digitimer Ltd. Urodynamics pack – includes the 8Fr urethral double lumen catheter and the 4Fr rectal manometry line
  - Pressure transducer pack (Smith Medical)
  - Optilube Lubricating jelly 5g (Optimum Medical Solutions, Leeds, UK)
  - Sterile gloves
  - Contrast medium - Urograffin® 150 for infusion - 36.5g I per 250mL (Bayer Plc, Berkshire, UK)
  - 0.9% sodium chloride 500 mL bag (Fresenius Kabi Ltd., Cheshire, UK)

The following equipment is required for the penile cuff test (additional to standard)

- Pressure cuffs (Provided by Mediplus Ltd – distributors of cuffs and commercially available cuff machine)
- Cuff machine (existing hospital equipment)

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