USE OF ADJUSTABLE CONTINENCE THERAPY IN THE SPINAL CORD INJURED POPULATION:
NEW APPLICATION FOR AN EVOLVING INCONTINENCE DEVICE

Hypothesis / aims of study
Quality bladder management within the spinal cord injury (SCI) population is imperative to ensure overall health both short and long term. Renal failure was the leading cause of death for these individuals prior to improved understanding of altered physiology post injury. Today bladder dysfunction continues to impact on both morbidity and quality of life.

Patients with low thoracic or lumbar injuries may experience stress urinary incontinence due to an incompetent sphincter mechanism and lack of pelvic floor muscle support. Existing management options include periurethral bulking agents, artificial urinary sphincter (AUS) or bladder neck closure. Periurethral bulking agents are not durable; AUS is associated with a high revision and explantation rate due to infection, erosion or mechanical failure (1). Bladder neck closure is an irreversible procedure and prevents later urethral access to the bladder. The aim of this study is to evaluate the efficacy of a durable, minimally invasive and adjustable continence therapy, the ProACT balloon device, for these patients.

The ProACT device consists of two silicone balloons attached via tubing to a titanium port (fig 1). These balloons are positioned via the perineum under radiological guidance to sit adjacent to the prostatic apex. The port is sited subcutaneously within the scrotum allowing percutaneous adjustment of balloon volume after surgery in an outpatient setting.

To date numerous studies have reported the ProACT balloon to be an acceptable alternative therapy for post prostatectomy incontinence (2, 3). This is the first study to our knowledge reporting outcomes of this device in the SCI population.

Study design, materials and methods
We report our initial prospective experience of the ProACT device in three SCI patients. All patients had urodynamic proven stress urinary incontinence and were wearing pads to manage their incontinence. No patient had previous anti-incontinence surgery, urethral stricture disease, active urinary tract infection, bladder pathology or bleeding disorder.

Preoperative procedures included a detailed bladder management assessment, medical history and physical examination. Video-urodynamic (VUD) was performed to assess bladder function and abdominal leak point pressure (ALPP). All devices were implanted under a general anaesthetic. Rigid cystoscopy was performed initially and the cystoscopy sheath left in place. The bladder was then filled with 200mls of radiographic contrast medium. A transverse incision was made in the perineum and next a haemostat was used to puncture the pelvic floor and create a paraurethral tract.

Figure 1: Serial inflation of the ProACT device

Figure 2: Creation of paraurethral tract
Results

The patient demographics are demonstrated in the following table.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patient 1</th>
<th>Patient 2</th>
<th>Patient 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>53</td>
<td>52</td>
<td>32</td>
</tr>
<tr>
<td>Level of Injury</td>
<td>L1</td>
<td>T10/11</td>
<td>T12</td>
</tr>
<tr>
<td>Interval since injury (months)</td>
<td>252</td>
<td>34</td>
<td>13</td>
</tr>
<tr>
<td>ASIA score</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Present bladder management</td>
<td>CISC 4x/day with pads</td>
<td>CISC 5x/day with pads</td>
<td>CISC 4x/day with pads</td>
</tr>
<tr>
<td>Length of follow up (months)</td>
<td>17</td>
<td>17</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 1: Patient Demographics

At time of urodynamics all patients had stable bladders with filling up to 600mls. End filling pressures were less than 15cm H₂O. ALPP were 65, 55 and 40 cm H₂O for patients 1, 2 and 3 as above respectively. Imaging in all patients revealed an open bladder neck and leakage past the external sphincter. No patient could void.

No adverse events occurred intra operatively. There have been no problems with infection, device failure, migration or denovo urgency during the follow up period.

All patients have improved continence post operatively. During the follow up period two patients have required two adjustments and one patient required only one adjustment. At each adjustment 0.5-1.5 ml extra volume was added bilaterally to each balloon.

One patient is completely dry and requires no pads. Two patients are now dry overnight and require one pad per day for leakage during transfers and activities. Subjectively these patients have all reported an improved quality of life.

Interpretation of results

We believe these early results are encouraging for the ongoing evaluation and use of this device in spinal cord injury patients.

Concluding message

These patients have been selected with the characteristics of a low pressure normal volume stable bladder with normal anatomy within the bladder neck and prostatic region and willingness to intermittently self catheterise. Further patient numbers and longer term follow up will be required to better evaluate the safety and efficacy of this implant.

References