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INTRODUCTION TO THE NEW AROYO® ARTIFICIAL URINARY SPHINCTER AND THE RELATIONSHIP OF ADJUSTABLE AND QUANTIFIABLE DEVICE PRESSURE TO PAD WEIGHT REDUCTION

Hypothesis / aims of study

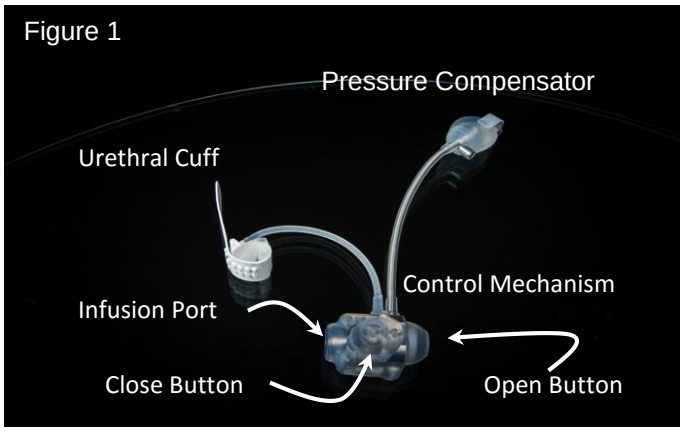
The Aroyo® Artificial Urinary Sphincter (Aroyo® AUS) was developed in response to deficiencies inherent to the AMS 800®, the current gold standard for the treatment of moderate to severe male stress urinary incontinence. When AMS 800® patients demonstrate continued or recurrent post-implant urinary leakage there is no recourse but to surgically replace the pressure regulating balloon or to down-size the cuff. AMS 800® intra-operative tubing connections require significantly greater operative time and sometimes even become disconnected post-implantation. The scrotal pump is often difficult to operate for the patient due to its small size and surrounding tissue mobility. The Zephyr® ZSI 375 and FlowSecure® AUS devices have more recently entered the clinical setting and present similar deficiencies. Although each of these two devices allow for post-implant pressure adjustment, they do not provide a reliable, quantifiable pressure adjustment method, and continued leakage or urethral erosion are frequent results. The Aroyo® AUS offers the following features and advantages over currently available AUS systems:

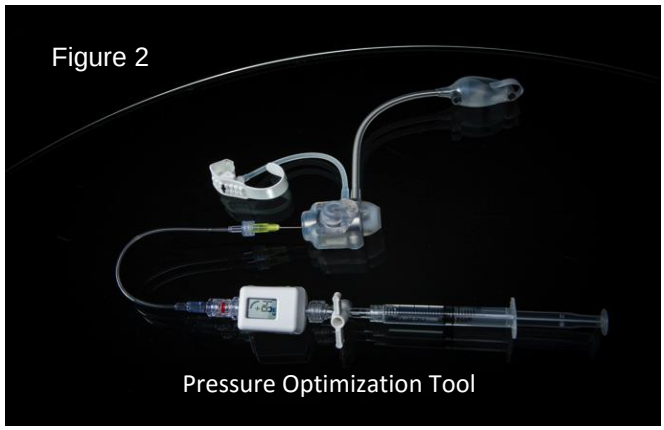
- a surgical technique requiring only a single incision
- pre-connected components, avoiding intra-operative tubing connections and reducing surgical time
- a size adjustable urethral cuff allowing Aroyo® AUS to be a 'one-size-fits-all' device, thereby avoiding stocks for the storage of different device sizes and components
- 'One Touch' open and close buttons designed to ease patient operation and encourage nocturnal deactivation
- a mechanism allowing 'ON Demand' pressure increases to counter stress urinary leakage
- quantifiable, post-implant adjustment for safe and effective personalized continence outcomes

Aroyo® AUS design and operation is presented here as well as the relationship between intra-device pressure and 24-hour pad weight reduction derived from the prospective RELIEF I and preliminary RELIEF II study results.

Study design, materials and methods

The Aroyo® AUS (**figure 1**) is a hybrid mechanical/hydraulic device consisting of an adjustable cuff accommodating 3.5 cm to 6.0 cm urethral circumferences, a scrotal control mechanism and a subcutaneous, pre-pubic pressure compensator. Peno-scrotal single incision implantation is followed by a 6-week deactivation period. Depressing the close button pressurizes the cuff and occludes the urethra. Depressing the open button deflates the cuff to allow normal voiding. Palpable clicks are felt when each button is depressed. These clicks, in conjunction with larger button geometry, aid patient operation and encourage nocturnal deactivation. The pressure compensator may be manually compressed over the pre-pubic skin to temporarily increase the intra-cuff pressure in anticipation of stress events. Removing the compression returns cuff pressure to normal intra-device baseline values.





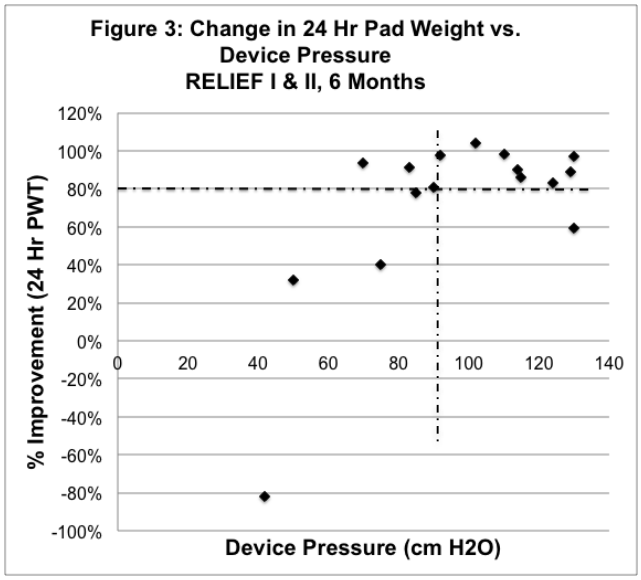
If a greater degree of continence is desired, normal saline solution can be percutaneously injected into the Aroyo® AUS through an infusion port at the side of the control assembly. A pressure optimization tool (**figure 2**) incorporates a sterile, disposable pressure transducer to quantify this intra-device pressure. RELIEF I study results established an intra-device pressure range of 80-130 cm H_2O and indicates a range in which the Aroyo® AUS operates with safety and efficacy.
RELIEF I was a pre-market, prospective, single arm, feasibility study performed in 10 men with stress urinary incontinence after radical prostatectomy or TURP in two centers between 4/2013 and 1/2015. RELIEF II is an ongoing, post-market, prospective, single arm, 18 center, multinational study intended to enroll 82 men with 48 currently implanted. Primary endpoint for both studies was the change in 24-hour pad weight from device activation to 3-month follow-up. Secondary endpoints included change in 24-hour pad weight at 6 and 12 month follow-up visits. The pressure optimization tool did not become available until the RELIEF I 6-month follow-up and RELIEF II patients, to date, have not yet reached the 12 month follow-up. Therefore, pooled analysis of 16 RELIEF I/II patients at 6-month follow-up is presented.

Results

An average 81% (± 27%) 24-hour pad weight reduction with an average 96 cm H_2O (± 20 cm H_2O) intra-device pressure (**table 1**) was calculated for this patient cohort with no serious adverse events. Data also indicate that an intra-device pressure ≥80 cm H_2O will provide a 24-hour pad weight reduction of ≥80% (**figure 3**). Additional data will be reported following RELIEF II completion to lend statistical support to this hypothesis.

Table 1: 24-hour PWT Reduction versus Device Pressure

Study	Patient Number	Device Pressure (cm H2O)	24-hour PWT reduction (%)
RELIEF I	01-001	90	81
	01-002	85	78
	02-001	129	89
	02-002	110	98
	02-005	83	91
	02-006	50	32
	02-009	42	82
RELIEF II	01-001	124	83
	01-003	130	97
	01-004	130	60
	01-005	114	90
	01-006	115	86
	01-011	**70**	94
	01-012	75	40
	07-001	102	104
	12-001	92	98
	Average	**96**	**81**
	STDev	**27**	**20**



Interpretation of results

Pooled RELIEF I and preliminary RELIEF II results indicate that Aroyo® AUS device pressures in ≥80 cm H_2O are predictive of 24-hour pad weight reductions ≥80% from pre-implant screening.

Concluding message

The new Aroyo® artificial urinary sphincter provides a quantifiable method by which post-implant pressure adjustments may be used to predictably control continence and patient safety.

Disclosures

Funding: Funding by sponsor (GT Urological) **Clinical Trial:** Yes **Registration Number:** clinicaltrials.gov NCT02288455 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Thomayer University, Prague, Czech Republice Bellberry Human Research Ethics Committee, NSW, Australia University of Wollongong Human Research Ethics Committee The University Hospital Ostrava, Ethics Committee of FN Ostrava. Czech Republic **Helsinki:** Yes **Informed Consent:** Yes