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TWELVE-MONTH RESULTS FOR AN ADJUSTABLE SINGLE INCISION SLING IN THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Urinary incontinence has been defined as a complaint of any involuntary leakage of urine. Stress urinary incontinence (SUI) is estimated to affect 12.8-46% of women. The most common incontinence surgeries performed worldwide are the tension-free vaginal sling procedures using a transobturator or retropubic approach. Both require multiple incisions and blind needle passage. The objective of the study is to evaluate the efficacy and safety of a novel adjustable Altis® Single Incision Sling (SIS) for the treatment of SUI.

Study design, materials and methods

This prospective Investigational Device Exemption study is being conducted at 17 centers in the United States and Canada. These data represent 12-month outcomes with subject continence status measured by ≥ 50% reduction from baseline in 24-hour Pad Testing, a Negative Cough Stress Test (CST), and through validated QOL questionnaires including Urogenital Distress Inventory-6 (UDI-6), Incontinence Impact Questionnaire-7 (IIQ-7), and Patient Global Impression of Improvement (PGI-I) along with device and procedure related events. Subjects will be followed for 2 years to report on longer-term results.

Results

One hundred thirteen (113) women were implanted with the Altis SIS. Mean age was 54.5 ± 14.0 years. For subjects who had mean pad weights at baseline (n=113) and at 12-months (n=101), results were 70.6±183.8 (median 21.9, range 0.0, 1777.6) and 14.5±73.6 grams (median 1.1, range 0.0, 696.0), respectively. At 12 months, 92.1% and 93.1% had a negative CST in standing and lithotomy positions, respectively. Table 1 summarizes efficacy endpoints at post-hoc 12-month analysis. Pad weight change of at least 50% reduction occurred in 90.1% of patients. Twelve-month success rates for CST are 92.1% and 93.1% for standing and lithotomy positions (data not shown), respectively. Table 2 presents the QOL scores at baseline and 12 months. Table 3 shows the reduction in QOL scores from baseline to 12 months. Subjects responded “Very Much Better” or “Much Better” in 89.3% for the PGI-I. Eleven (11) device-related events in 8 study subjects (7.1%) were reported: 4 mesh extrusions (3.5%) and one (0.9%) case of each: urinary retention, urinary tract infection, de novo urgency, dyspareunia, inflammation, worsening overactive bladder, and voiding dysfunction. Two of the mesh extrusions were treated with mesh trimming, a third was treated with mesh trimming and later with mesh excision lateral to the urethra, and the fourth (asymptomatic) was treated with vaginal estrogen cream (see Table 4). There were no unanticipated adverse device effects. One subject underwent two incising procedures for urethral obstruction symptoms. This was reported by the site as unknown device relatedness due to bladder emptying issues diagnosed prior to implant. Two serious adverse events were reported (SAE), a pelvic hematoma where the patient was hospitalized, although the hematoma did subsequently drain spontaneously as the physician expected; and one mesh extrusion classified as an SAE due to subject withdrawal from the study prior to follow-up data collection.

Interpretation of results

For each defined success parameter, the number and percent of successful patients along with the lower 95% confidence limit for the success rate are given (Table 1). All parameters show high statistical significance to the performance goal. For both UDI and IIQ, there is a highly statistically significant reduction from baseline to 12 months (Table 3).

Concluding message

The data support a conclusion that the Altis SIS for the treatment of SUI is safe and effective.

Table 1: Efficacy Endpoints – Post-hoc Analysis at 12 Months

Endpoint	Success	Lower 95%CL	p-value*
Pad Testing[1]	90.1% (91/101)	85.2%	<0.0001
Cough Stress Test[2]	90.1% (91/101)	85.2%	<0.0001
UDI-6 Score[3]	89.3% (92/103)	84.3%	<0.0001
IIQ-7 Score[3]	90.3% (93/103)	85.5%	<0.0001
PGI-I[4]	89.3% (92/103)	84.3%	

[1]Percent of subjects with ≥ 50% reduction in pad weight at 12 months
[2]Percent of subjects with negative cough stress test at 12 months
[3]Percent of subjects with ≥ 50% reduction in UDI and IIQ Score at 12 months
[4]Percent of subjects with responses of “Very much better” or “Much better” at 12 months
*Observed success rate is greater than the performance goals of 50% for pad weight, UDI, and IIQ and 66% for CST

Table 2: Quality of Life Scores at Baseline and 12 Months

Endpoint	Mean ±SD	Median	Range	95% CL
UDI-6 at Baseline	55.6±18.8	55.5	16.7, 99.9	52.0, 59.1

UDI-6 at 12 months	9.9 ± 13.2	5.6	0.0, 66.6	7.3, 12.5
IIQ-7 at Baseline	54.3±25.4	57.0	4.0, 99.0	49.6, 59.0
IIQ-7 at 12 months	8.2±18.1	0.0	0.0, 99.0	4.7, 11.7

Table 3: Quality of Life Score Reduction from Baseline to 12 Months				
Endpoint	**Mean Reduction ±SD**	**Median**	**Range**	**95% CL**
UDI-6**	45.6±20.3	44.4	-11.1, 94.4	41.6, 49.5
IIQ-7**	47.0±26.5	47.0	-9.0, 99.0	41.8, 52.1
**Statistically significant change from baseline to 12 months; p <0.0001				

Table 4: Details of Mesh Extrusions* Requiring Treatment				
Days to onset	**Comorbidities**	**Modification**	**Location of revision**	**Current Status**
179	BMI – 33.2	Trimmed 2mm exposure in mid-portion of sling	OR (due to insurance)	Resolved
160	BMI – 30.91 Current Smoker	Simple excision, no anesthetic required. Subject scheduled for possible explant	In office	Subject withdrawn prior to additional data available
82 518	BMI – 24.41 Current Smoker	Trimmed, no anesthesia required Excised lateral to urethra	In Office Out-patient ASC	Resolved
176	BMI - 31.7 Type II Diabetic Mild vaginal atrophy	Asymptomatic - treated with estrogen cream	N/A	Resolved
* Per protocol, defined as vaginal exposure of mesh				

Disclosures
Funding: Coloplast Corp **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov NCT01272284 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Western Institutional Review Board; Greenville Hospital System IRB; Chippenham & Johnston-Willis Medical Center IRB; UIC Office for the Protection of Research Subjects; Northside Hospital IRB; CaroMont Health; Comité d'éthique de la recherche en santé chez l'humain du CHUS; Spectrum Health Research and Human Rights Committee Sentara Research Quality Assurance **Helsinki:** Yes **Informed Consent:** Yes