Altis® Single Incision Sling System

12 Month IDE Clinical Study Summary

The IDE clinical study of the Altis Single Incision Sling System is a prospective, single arm, non-randomized study. Study was conducted at 17 clinical sites in women with confirmed SUI, with follow-up through 2 years. Primary outcome is improvement in subject continence status measured by 24-hour pad weight test (PWT), with improvement defined as ≥50% reduction in PW from baseline to 6-months, and dry defined as PW less than 1.3 grams. Secondary effectiveness endpoints of negative cough stress test (CST), assessment of patient's quality of life (QOL) through validated questionnaires, and voiding diaries, were evaluated using performance goals.

113 female subjects with SUI were successfully implanted with the Altis device. Mean age is 54.5 ± 14.0 years (range 25-89). Median duration of follow-up is 12 months (range 2-23). Mean BMI was 31.2±6.8. Table 1 presents baseline characteristics for the 113 implanted subjects.

Table 1: Baseline Characteristics of Study Population

Characteristic	**N=113**
Age (years)	
N Mean±SD Median (Range)	113 54.5±14.0 54.7 (25.3, 89.3)
BMI	
N Mean±SD Median (Range)	113 31.2±6.8 29.9 (20.0, 55.8)
Stress Urinary Incontinence (SUI) History	
Hypermobility	81.4% (92/113)
Without hypermobility	19.5% (22/113)
Mixed incontinence	37.2% (42/113)
Overactive bladder	5.3% (6/113)
Previous Incontinence Treatments	
Indwelling catheter	0.0% (0/113)
Pad use	95.6% (108/113)
Biofeedback	18.6% (21/113)
Behavioral modification	69.9% (79/113)
Physical therapy	49.6% (56/113)
Smoking History	
Never	58.4% (66/113)
Current	15.9% (18/113)
Former (> 6 months)	25.7% (29/113)
Medical History	
Diabetic	9.7% (11/113)
Multiple urinary tract infections	13.3% (15/113)

Median procedure duration was 12.7±8.0 minutes (range 4-56), and nearly half of the implants were performed using spinal or local anesthesia. 40.7% of procedures took place in-office or in an ambulatory surgical center. Table 2 summarizes procedural characteristics of implanted subjects.

Table 2: Procedural Characteristics for Implanted Subjects

Parameter	**N=113**
Pre-op antibiotics	97.3% (110/113)
Pre-op estrogen	25.7% (29/113)
Procedure location	
In-patient hospital	59.3% (67/113)
Ambulatory surgical center	23.9% (27/113)
In-office	16.8% (19/113)
Anesthesia	
General	52.2% (59/113)
Spinal	2.7% (3/113)
Local	45.1% (51/113)
Procedure duration (min)	
N Mean±SD Median (Range)	113 12.7±8.0 12.0 (4.0, 56.0)
Estimated blood loss (mL)	
N Mean±SD Median (Range)	113 36.3±27.3 30.0 (0.0, 250.0)

Pad weight decreased from baseline to 12 months, as did UDI, IIQ and PGI-I scores, and more than 90% of subjects had a negative CST. 89.3% of subjects reported being “much better” or “very much better” at the 12-month visit. Changes in PWT, CST, UDI and IIQ were all statistically significant from baseline to 12 months. In addition, due to the investigational nature of the product, no learning curve for implanting physicians contributed to possible biased outcomes.

Table 3: Outcomes Data

Endpoint	Measurement	6 Months	12 months
Pad Weight (PW)	50% Reduction	85.4% (88/103)	90.1% (91/101)
Cough Stress Test (CST)	% Success in both standing and lithotomy positions	92.2% (95/103)	90.1% (91/101)
Patient Global Impression of Improvement (PGI-I)	% Very much or much better	87.6% (92/105)	89.3% (92/103)

Device-related events were reported in 8 study subjects: One (0.9%) case of each: urinary retention, UTI, decreased urine stream, dyspareunia, inflammation, worsening OAB, and voiding dysfunction and four mesh extrusions (3.5%). One additional subject underwent two incising procedures for urethral obstruction symptoms, unknown if related to device or procedure. There were no unanticipated device effects (UADEs). Three serious adverse events (SAEs) were reported: a pelvic hematoma (drained spontaneously in hospital) and two of the four mesh extrusions (one who had a surgical revision due to symptoms, and one classified as SAE due to subject withdrawal from study prior to further follow-up data collection).

Conclusions: The Altis® Single Incision Sling System met all end points of the study and its performance is consistent with the legally marketed predicate devices.

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