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TWO-YEAR CLINICAL OUTCOMES FOR THE ALTIS® SINGLE INCISION SLING FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

Safety and efficacy of the Altis® Single Incision Sling for treatment of women with stress urinary incontinence (SUI) was evaluated 2-years post-implant.

Study design, materials and methods

This study was conducted under an FDA Investigational Device Exemption. The study was a prospective, multi-center, single-arm clinical trial in which safety and efficacy was assessed in subjects implanted with an Altis sling for the treatment of SUI. The Altis sling is constructed of polypropylene mesh, with attached suture extending to one static and one dynamic anchor. The dynamic anchor allows intra-operative adjustability and tensioning to achieve continence. Female subjects with SUI confirmed by cough stress test or urodynamics and who were at least 18 years of age and had failed at least two non-invasive incontinence therapies for >6 months were included in the trial. Subjects were excluded if they had an infection in the region of surgery, pelvic organ prolapse ≥ stage 2, required a concomitant pelvic floor procedure, had a previous surgical SUI treatment, incontinence due to neurogenic causes, had an atonic bladder or post void residual volume consistently >100 mL or were pregnant or who planned to become pregnant in the future.

Greater than or equal to 50% reduction in 24-hour pad weight compared to baseline was the primary outcome measure. Secondary efficacy outcomes were objectively measured by cough stress testing performed in both standing and lithotomy positions, while quality of life was assessed by the use of Urogenital Distress Inventory-Short Form (UDI-6), Incontinence Impact Questionnaire-Short Form (IIQ-7), and Patient Global Impression of Improvement (PGI-I) questionnaires. Device- and procedure-related adverse events were reported as secondary safety outcomes.

Results

One hundred thirteen women with a mean age of 54.5 ± 14.0 years were implanted with an Altis sling. Procedure time averaged 12.7 ± 8.0 minutes with 52.2% (59/113) performed under general anesthesia and 45.1% (51/113) with local anesthesia. Of those subjects with paired baseline and follow-up data, 90.0% (81/90) were successful at achieving ≥50% reduction in pad weight at 2 years (**Table 1**). When subjects were evaluated for dryness (24-hour pad weight ≤ 4.0 grams), 81.1% (73/90) of subjects were dry. Cough stress test results showed that 87.9% (80/91) of subjects had a negative result in both the standing and lithotomy positions. Greater than 90% (90.4%, 85/94) of subjects rated improvement of their SUI as “very much better” or “much better” on the PGI-I questionnaire. Improved quality of life was evidenced by a statistically significant mean improvement of 80.3% in UDI-6 scores (baseline 55.6 ± 18.8, 2-years 11.1 ± 16.2, p-value <0.0001) and by 85.7% in IIQ-7 scores (baseline 54.3 ± 25.4, 2-years 7.8 ± 17.8, p-value <0.0001).

The most common procedure- and device-related adverse events consisted of hip/groin pain (7.1%, 8/113), mesh extrusion (3.5%, 4/113), pelvic/urogenital pain (3.5%, 4/113), and urinary retention (1.8%, 2/113). All 4 subjects with mesh extrusion required revision procedures, with 3 of the subjects requiring additional procedures to care for the extrusion. One subject had a severe pelvic hematoma associated with a revision procedure that required hospitalization and resolved within 2 days of onset. There were no reports of mesh erosion, migration, or foreign body reaction throughout the 2-year follow-up period.

Interpretation of results

The Altis Single Incision Sling was clinically efficacious at treating SUI in women as evidenced by 24-hour pad weight and cough stress testing. 81.1% of subjects were dry two years after surgical treatment. Cough stress test results substantiated the pad weight results with negative results obtained for almost 88% of implanted subjects. The results are consistent with data obtained as early as 3 months post-procedure, illustrating efficacy of treatment with the Altis sling through 2-years (**Table 1**).

Subject assessment of their SUI condition corroborated the objective testing measures. Greater than 90% of subjects felt they were “very much better” or “much better” two years after being implanted, which indicated a high level of satisfaction. Significant improvement of urinary symptoms, as well as subject perception of their social relationships and emotional health, was demonstrated after implant of the Altis sling based on the UDI-6 and IIQ-7 results, respectively.

The 2-year safety profile of using the Altis Single Incision Sling was consistent with earlier reports.

Concluding message

The Altis Single Incision Sling is a safe, efficacious, durable surgical option with supportive data out to 2 years for the treatment of SUI in women.

Table 1. Efficacy and Quality of Life Results

Outcome	Baseline	3 Months	6 Months	12 Months	24 Months
	24-Hour Pad Weight Testing				
>50% Reduction in 24-Hour Pad Weight (%, n/N)		82.9% (92/111)	85.4% (92/111)	90.1% (91/101)	90.0% (81/90)
Median Pad Weight (g, IQR)	21.9 g (9.4, 57.0)	1.5 g (0.2, 5.7)	1.9 g (0.2, 5.2)	1.1 g (0.3, 4.0)	1.0 g (1.0, 3.0)

Dry Pad Weight ≤4.0 grams (n/N)		66.7% (74/111)	70.9% (73/103)	77.2% (78/101)	81.1% (73/90)
	Cough Stress Testing				
Negative Cough Stress Test in standing and lithotomy position (%, n/N)	0.0% (0/112)	89.7% (96/107)	92.2% (95/103)	90.1% (91/101)	87.9% (80/91)
	Quality of Life Assessments				
UDI-6 Score (Mean ± SD)	55.6 ± 18.8	11.8 ± 13.3	11.6 ± 18.2	9.9 ± 13.2	11.1 ± 16.2
IIQ-7 Score (Mean ± SD)	54.3 ± 25.4	9.1 ± 18.4	6.9 ± 14.7	8.2 ± 18.1	7.8 ± 17.8
PGI-I “Very Much Better” or “Much Better” Responses (%, n/N)		91.8% (101/110)	87.6% (92/105)	89.3% (92/103)	90.4% (85/94)

Disclosures
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