CLINICAL ARTICLE SUMMARY

Mid-Term Safety and Efficacy of the ALTIS® Single-Incision Sling for Female Stress Urinary Incontinence: Less Mesh, Same Results

Eduardo Morán, MD
Javier Pérez-Ardavín, MD
Jose V. Sanchez, MD
Miguel A. Bonillo, MD
Esther Martínez-Cuenca, MD
Salvador Arlandis, MD, PhD
Enric Broseta, MD, PhD
Francisco Boronat, MD, PhD

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ABSTRACT

Study objective: To analyse the mid-term safety and efficacy of the ALTIS® single-incision sling (Coloplast Corp., Minneapolis, MN, USA) for female stress urinary incontinence (SUI).

Patients and Methods: We conducted a prospective, single-arm, unsponsored, observational single-centre trial in a cohort of patients undergoing SUI surgery with the ALTIS procedure. All patients were diagnosed according to clinical reports, physical exploration and urodynamics. Body mass index (BMI) was categorised according to World Health Organization classification. Valsalva leak-point pressure (VLPP) was categorised in three groups: <60, 60–90 and >90 cmH2O. Patients were evaluated postoperatively at 1, 6, 12 and 24 months with physical examination, International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF), and satisfaction visual scale (SVS; score 0–10). Adverse events were assessed at each visit. Multivariate analysis for risk factors of surgery failure was performed.

Results: We recruited 110 women, with a mean (SD) follow-up of 22.34 (10.34) months. Regarding efficacy, 91 patients (82.7%) were objectively cured and 97 (88.2%) were subjectively cured. Regarding VLPP and BMI, no differences were seen between groups ($P > 0.05$). There was a ~20% decrease in urge UI ($P = 0.04$). No variable showed to be an independent risk factor for ALTIS failure ($P > 0.05$). Overall, nearly 96% of the women reported 9 or 10 points on the SVS. A total of 24 patients (21.8%) had some kind of complication. No mesh erosion was reported in any patient.

Conclusions: The ALTIS sling demonstrated to be an effective and safe procedure for SUI in the mid-term setting. Objective and subjective cure rates are at least comparable to 'gold standard' procedures with a minimal rate of self-limiting non-surgical complications.

Clinical Summary Key Takeaways

- Non-industry sponsored and no author conflicts of interest.
- 0 cases of erosion at almost 24-months of follow-up (mean of 22.34-months).
- High objective cure rate of **82.7%** (91/110 pts).
- High subjective cure rate of **88.2%** (97/110 pts) defined as 0 score on ICIQ-SF.
- Similar success rates were found regardless of obesity, age or menopausal status.
- **96.0%** of patients reported high satisfaction post-op, with no patient scoring less than 8 out of 10 on the satisfaction visual scale (SVS).
- No significant decrease in success rate over time.
- The precise tension of the adjustable single incision sling allows for ideal mid-urethral support, resulting in positive treatment results for patients with hypermobility and ISD.
- Altis, compared to 5 other SIS, has the preferred anchoring system due to the low insertion force and greatest retention pullout force.

The **Altis®** Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Contraindications
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. The **Altis®** Single Incision Sling System is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Known active urinary tract infection and/or infection in operative field
- Taking anti-coagulant therapy
- Abnormal urethra (e.g., fistula, diverticulum)
- Intraoperative urethral injury
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precautions
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the warnings and precautions associated with the use of this product and the associated surgical risks.

Warnings

- The **Altis®** Single Incision Sling System should only be used by physicians familiar with the surgical procedures and techniques involving transvaginal placement of non-absorbable, synthetic mesh slings and who have adequate education and experience in the treatment of female SUI.
- A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh sling procedure.
- The patient should be counseled that alternative incontinence treatments may be appropriate, and the reason for choosing a mesh sling procedure should be explained.
- Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transvaginal mesh sling surgery.
- Patient counseling should include a discussion that the sling to be implanted is a permanent implant and that some complications associated with the implanted mesh sling may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the sling may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.
- As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.
- The risks and benefits of using **Altis®** should be considered in patients.
- Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.
- Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.
- The procedure to insert the **Altis®** sling requires good knowledge of pelvic anatomy and the correct use of the introducer needles in order to avoid damage to adjacent anatomical structures.
- Cystoscopy should be performed to confirm bladder and urethral integrity.
- Avoid placing excessive tension on the **Altis®** sling during placement and adjustment to maintain sling integrity and to avoid compression of the urethra when tensioning.

Precautions

- The **Altis®** Sling and **Altis®** introducers are provided sterile (ethylene oxide sterilization) and are for single-use only.
- Use caution to prevent intraoperative injury to adjacent pelvic structures.
- Do not let the **Altis®** sling come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the mesh, suture and anchors.

Potential Complications

- Potential complications include mesh extrusion, pelvic/urogenital pain, groin pain, hip pain (may be related to patient positioning), urinary retention, bleeding, de novo urgency, delayed wound healing, dyspareunia, hip/groin pain, inflammation, nausea, overactive bladder, pain, pelvic hematoma, reaction to antibiotic, slight discomfort upon return to work, urinary tract infection, urine stream decreased, and voiding dysfunction.
- Adverse events are known to occur with transvaginal synthetic sling procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent.
- Additional potential complications include, but are not limited to, abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh sling into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., muscles, nerves, vessels), structures, or organs (e.g., bone, bladder, urethra, ureters, vagina), seroma, sling migration, suture erosion, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), granulation tissue formation, palpable mesh (patient and/or partner), sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring or tightening.
- The occurrence of these events may require one or more revision surgeries, including removal of the sling.
- Complete removal of the sling may not always be possible, and additional surgeries may not always fully correct the complications.
- There may be unresolved pain with or without mesh sling explantation.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Ostomy Care / Continence Care / Wound & Skin Care / Interventional Urology

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Approved	FRNDU Nathalie Dampeyrou Junior Product Manager Marketing 02-Feb-2021 11:50:02 GMT+0000

Approved With Changes	FRGWG Gwénaëlle GUIDON RA Specialist Regulatory 07-Feb-2021 18:16:39 GMT+0000

Approved	FRHR Hugo Ryckebusch Head of Medical Affairs Medical/Clinical 08-Feb-2021 18:02:26 GMT+0000

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