

FDA Altis 522 Study 3-year Data: 8% Risk of Leg Pain vs. 0.6% in Full-length Slings

Study shows that Altis is associated with higher rates of leg pain and an increased risk of pain that requires analgesia

SANTA BARBARA, CA, UNITED STATES, September 26, 2024 / EINPresswire.com/ -- "(Full-length mid-urethral slings) are associated with significant complications, including bladder perforation and vessel injuries with RMUS (retropubic slings), and postoperative groin and thigh pain with TMUS (transobturator slings). To minimize these complications, a new generation of slings emerged: single incision slings (SIS)," states Dr. Le Mai Tu, *Neurourol Urodyn.* 2023; 42: 1722-1732.

Pain		
Pelvic/urogenital (groin) pain	7 (3.8%)	4 (2.3%)
Dyspareunia, de novo	3 (1.6%)	2 (1.2%)
Dyspareunia, worsening	1 (0.5%)	1 (0.6%)
Vaginal pain	1 (0.5%)	0 (0.0%)
Pain at incision site	0 (0.0%)	1 (0.6%)
Extremity pain		
Hip pain	7 (3.8%)	0 (0.0%)
Leg pain	4 (2.2%)	0 (0.0%)
Hip and leg pain	3 (1.6%)	0 (0.0%)
Sciatica	1 (0.5%)	0 (0.0%)
Calf pain	0 (0.0%)	1 (0.6%)

Altis 522 Study: Device and/or procedure-related adverse events through 36 months



The Altis 522 study results revealed that lower extremity pain was reported in 15 out of 184 (8%) patients in the Altis group, and 1 out of 171 patients in the full-length mid-urethral sling group."

Greg Vigna, MD, JD

[Dr. Greg Vigna, national midurethral sling attorney](#) states, "Unfortunately, the Altis single incision sling data from the Altis 522 study does not show less pain. It showed more pain. The Altis 522 study results revealed that lower extremity pain was reported in 15 out of 184 (8%) patients in the Altis group, and 1 out of 171 patients in the full-length mid-urethral sling group. Despite the Altis sling not entering the leg, it is associated with leg pain."

What did Dr. Le Mai Tu report in "Management of Female Stress Urinary Incontinence with Single-incision Mini-sling (Altis): 36-month Multicenter Outcomes" published in

Neurourol Urodyn. 2023; 42: 1722-1732?

What did the Altis 522 study show?

Dr. Vigna continues, "The Altis 522 study shows that there is an increased frequency of pelvic and leg pain when compared with full-length mid-urethral slings. Coloplast has demonstrated that its

version of the new generation does not 'minimize these complications' as the author may have expected or hoped."

Read Dr. Tu's study:

<https://onlinelibrary.wiley.com/doi/full/10.1002/nau.25256>

Dr. Vigna adds, "The SIMS (single-incision mini-slings versus standard synthetic mid-urethral slings) study from England was a three-year,

randomized control study from England which revealed that women implanted with the Altis had an increased frequency of pain that required the use of analgesia at all times when compared to the women implanted with the Bard Ajust (mini-sling) or full-length mid-urethral slings."

What did the SIMS data show?

Read the SIMS trial:

https://www.ncbi.nlm.nih.gov/books/NBK587586/pdf/Bookshelf_NBK587586.pdf

Dr. Vigna concludes, "The Altis is associated with higher rates of leg pain, which appears to be an unexpected outcome. There also appears to be an increased risk of pain that requires analgesia, which again appears to be an unexpected outcome."

Red Flag Warning Symptoms of neurological injury or myofascial pain caused by the Coloplast Altis and Aris transobturator slings, and Boston Scientific Solyx and Obtryx transobturator slings include:

- 1) Groin pain
- 2) Hip pain
- 3) Inability to wear tight pants
- 4) Clitoral pain or numbness
- 5) Severe pain that makes vaginal penetration impossible
- 6) Tailbone pain
- 7) Anorectal pain
- 8) Painful bladder
- 9) Pain with sitting

[Click here](#) for a free book on Vaginal Mesh Pain.

Dr. Vigna is a California and Washington DC lawyer who focuses on catastrophic injuries and neurological injuries caused by mid-urethral slings, including pudendal neuralgia, obturator

TABLE 17 Summary of AEs, by procedure (continued)

AEs	Procedure, n (%)			
	Ajust (N = 62)	Altis (N = 199)	RP-TVT (N = 126)	TO-TVT (N = 147)
<i>Groin or thigh pain</i>				
3 months	12 (19)	53 (27)	32 (25)	28 (19)
15 months	4 (6.5)	35 (18)	13 (10)	19 (13)
24 months	4 (6.5)	32 (16)	14 (11)	14 (10)
36 months	7 (11)	29 (15)	21 (17)	21 (14)
<i>Use of analgesia</i>				
3 months	4 (6.5)	32 (16)	13 (10)	12 (8.2)
15 months	3 (4.8)	18 (9.0)	4 (3.2)	11 (7.5)
24 months	3 (4.8)	16 (8.0)	5 (4.0)	7 (4.8)
36 months	3 (4.8)	17 (8.5)	8 (6.3)	5 (3.4)

SIMS Data: Summary of AEs, by procedure

neuralgia, ilioinguinal neuralgia, and complex regional pain syndrome. [Ben Martin](#) is a national pharmaceutical injury attorney in Dallas, Texas. The lawyers represent women in courts across the country.

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