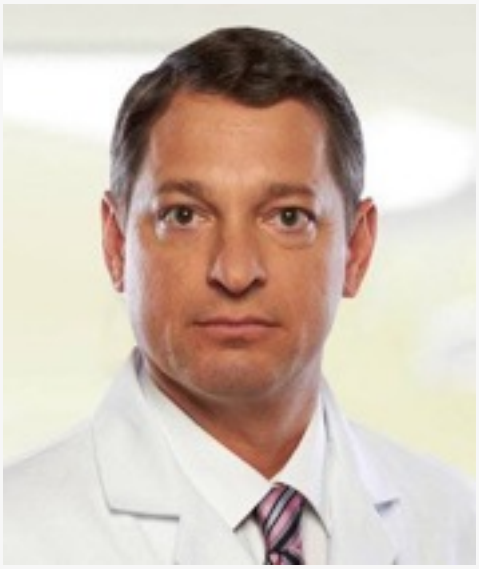
Which Poison is Worse: Outside-in vs. Inside-out Transobturator Slings

The TOT and TVT-O were developed for the management of stress urinary incontinence. Unfortunately, women's obturator nerve and its branches are in peril.



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Dr. Delorme first described the “outside-to-in” transobturator tape (TOT) in 2001 which gave birth to the Monarc sling (American Medical Systems), the Obtryx (Boston Scientific), the Align TO (Bard), and the Aris (Coloplast) and Dr. De Leval described the “inside-to-out” transobturator tape in 2003 which became the TVT-O (Ethicon). The two transobturator designs (TOT and TVT-O) were developed for the surgical management of stress urinary incontinence (SUI) to eliminate bladder and bowel injuries associated with retropubic slings. Unfortunately for a growing list of women, their obturator nerve and its branches are in peril to both acute injury and injury over time.

Which is worse, the TOT or the TVT-O?

> “Ethicon failed to act reasonably to lessen the foreseeable and unavoidable risks of their device…Instead, they placed profits over safety.”
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> *Dr. Greg Vigna*

Dr. Jean-Pierre Spinosa in June 2007 was the first physician to publish a comparative anatomical study of the TVT-O and the TOT. His finding was that the TVT-O was more dangerous than the TOT as the distances between the tape and the posterior branch of the obturator nerve was different as between the devices. That distance was less than 1 centimeter with the TVT-O compared to greater than 2.1 cm with the TOT.

Dr. Flam was troubled with the post-operative pain he observed through use of the TVT-O as well as the procedure required in the instructions for use. He was particularly concerned with the post-operative pain in the groin he observed and the long needle path required through the muscles of the groin at the obturator foramen in order to place the device. So troubled, he devised a perpendicular TVT-O needle passage through the obturator foramen which was aimed to extend the distance between the needle and obturator nerve branches. Dr. Flam claimed that he had placed over 2500 TVT-O’s with this modified placement of the device since 2005 without “clinical evidence of nerve or large vessel damage and with reduced post-operative thigh pain.”

In 2010, Dr. Menahem Neuman published an independent study and noted that the Flam Technique provided an increased safety margin when compared to the procedure called for by the TVT-O IFU between the surgical needle and the obturator nerve branches from 4 cm to 2 cm. Dr. Neuman then published results comparing cure and complication rates between the Flam

Technique and the TVT-O procedure required by the IFU and noted that post-operative thigh pain was significantly more frequent and lasted longer after the procedure required by the IFU when compared to Flam Technique (31.9% vs. 10.0%).

Which is worse, the TVT-O or the TOT? Greg Vigna, MD, JD, national pharmaceutical injury attorney, practicing physician, and Certified Life Care Planner answers:

"The verdict is still out since the manufacturers didn't bother to study long-term outcomes and didn't warn of the unavoidable and foreseeable risk of catastrophic life-altering pain related to obturator neuralgia. This is evident in that it wasn't until Dr. John Paulson, in private practice, noted that he had five patients present to his office from July 1, 2008 through June 30, 2009 who he diagnosed with pudendal neuralgia after receiving the TVT-O. Ethicon provided no reliable outcomes of their devices past one year. Ethicon had knowledge of the technique utilized by Dr. Flam whom they trusted for training physicians in the use of their devices, but Ethicon failed to study the technique that he believed was required to make their product safer at little to no cost. Ethicon failed to act reasonably to lessen the foreseeable and unavoidable risks of their device probably because it would require them to acknowledge to the FDA and the public that there are legitimate medical concerns of their device. Instead, they placed profits over safety."

"The jury is still out which is worse long-term, the TVT-O vs. the TOT as there are no reliable long-term studies. They both are unreasonably dangerous and my firm with Martin-Baughman will represent obturator and pudendal neuralgia victims until the last transobturtor device is explanted."

Ben C. Martin, Esq. of Martin Baughman states, "It was a good decision for Bard to remove their vaginal mesh products from the market, but they likely can't avoid liability for the latent injuries to the obturator and pudendal nerves their products caused as their devices continue to contract and degrade. We continue to file cases across the country including New Jersey as we did on April 10, 2020 for another catastrophically injured woman." (Case BER L 002633-20)

Ben C. Martin and Laura Baughman are national pharmaceutical injury attorneys in Dallas, Texas. Dr. Vigna is a California and Washington DC lawyer who focuses on catastrophic injuries caused by transvaginal mesh devices including pudendal neuralgia, obturator neuralgia, and complex regional pain syndrome.

For articles, video resources, and information visit the Pudendal Neuralgia Educational Portal (https://pudendalportal.lifecare123.com/) or https://tvm.lifecare123.com/.

Click here for information regarding sling related complications:
https://tvm.lifecare123.com/slingebook.html

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