

Mid-urethral Sling Update: Safer Alternative Designs Lining Up, Biodegradable Scaffold

There is a movement toward a biodegradable scaffold that causes a reduced inflammatory response and is gradually removed by the body, leaving healthy collagen

SANTA BARBARA , CALIFORNIA , UNITED STATES ,
March 19, 2024 /EINPresswire.com/ -- "Safer alternative designs for the defective polypropylene mesh that was banned in transvaginal placement for pelvic organ prolapse in 2019 and causing ongoing groin pain in women who undergo mid-urethral sling placement are lining up" ... Greg Vigna, MD, JD, national mid-urethral sling, malpractice attorney.

[Dr. Greg Vigna](#), national pharmaceutical injury attorney, states, "PVDF has been known to include less chronic inflammation and scarring when compared with polypropylene and is available most everywhere in the world, except the United States, despite favorable data when compared head-to-head with polypropylene. Now, there is finally movement toward a biodegradable scaffold called P4HB mesh that causes a reduced inflammatory response and is gradually removed by the body leaving healthy collagen that is laid down in the scaffold to support the urethra."



Dr. Greg Vigna

What did the study by Dr. Jan-Paul Roovers report in "Safety and Efficacy Report for the Use of Poly-4-Hydroxybutyrate as a Retrobuc Mid-Urethral Sling for Stress Urinary Incontinence: A Prospective 24 Months Follow-Up of New Poly-4-Hydroxybutyrate Tephaflex SUI Bioresorbable MUS" published in JMIG. Vol 31, No. 2. February 2024?

"Tephaflex SUI (Stress Urinary Incontinence) Bioresorbable Mid-Urethral Sling (MUS) is manufactured by Tephaflex, Inc as a single-layer bioresorbable mesh sling made from P4HB monofilament fiber and constructed as an 11mm by 60 cm tape enclosed in a loose polyethylene sleeve for easy insertion.

In search of an alternative for polypropylene as material for MUS surgery in women with SUI, we identified P4HB as candidate material based on the degradation profile and in vitro study results.



Polypropylene causes too robust of an inflammatory response that causes complications including pain and erosions in women when used for stress urinary incontinence. "

Greg Vigna, MD, JD

This first clinical study with 17 participants suggests that a MUS procedure with P4HB can be safely performed, based on low SAE (serious adverse events) rates and no material-related AEs (adverse events) within 24 months of follow-up.

Cure rates at 12 and 24 months were high, and a second procedure with polypropylene resulted in cure in those who had initially failed to stay continent with P4HB."

Read Dr. Roovers' article:

<https://www.sciencedirect.com/science/article/pii/S1553465023009718>

Dr. Vigna, "We are happy to see safer alternative designs finally coming to the market. There is nothing new about P4HB as it has been around since 2007 and used in sutures and this hydrophilic technology has been available since 1995. Polypropylene causes too robust of an inflammatory response that causes complications including pain and erosions in women when used for stress urinary incontinence. Clearly, there will be a movement away from polypropylene as the first line will consist of bulking agents and biodegradable scaffolds, as there appears to be a limited risk of adverse events to the material. For those who remain incontinent, PVDF slings can be considered. Polypropylene has failed as a suitable material for mesh."

Dr. Vigna concludes, "Polypropylene has failed and is a defective product when used for the treatment of stress urinary incontinence as Dejene, et al. revealed revision rates of 7.9% at 15 years, with over half of these revision surgeries for treatment of non-erosion complications that include fistulas and pain. We are investigating cases involving pain syndromes caused by mid-urethral slings for malpractice and failure of informed consent against the manufacturers."

Read Dejene: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9169553/>

Dr. Vigna RED FLAP WARNING SYMPTOMS of neurological injury or myofascial pain syndromes including Complex Regional Pain Syndrome from mid-urethral 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 the neurological injuries caused by mid-urethral slings including pudendal neuralgia, obturator neuralgia, ilioinguinal neuralgia, and complex regional pain syndrome. Ben Martin is a national pharmaceutical injury attorney in Dallas, Texas with a Pennsylvania license. The lawyers represent women in courts across the country.

To learn more, [click here](#).

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