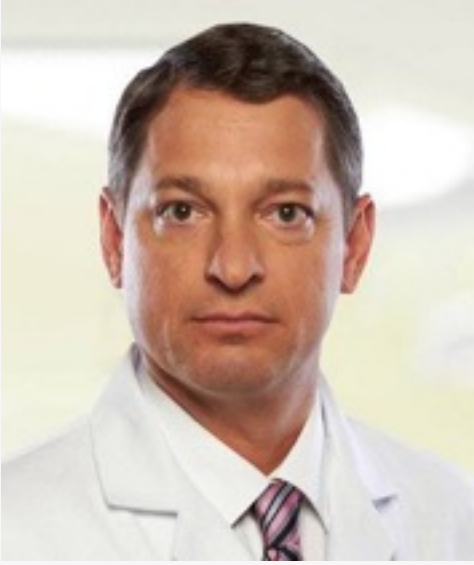
New Alternatives to Vaginal Mesh Bring Similar Dangers for Prolapse

Vaginal mesh used to treat pelvic organ prolapse and stress urinary incontinence underscores the need to move cautiously with new, unproven technologies.



SANTA BARBARA, CALIFORNIA, UNITED STATES, February 10, 2020 /EINPresswire.com/ -- According to Dr. Greg Vigna, MD, JD, practicing physician, national pharmaceutical injury attorney, and expert on vaginal mesh injuries for incontinence, “The vaginal mesh debacle to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI) underscores the critical need to move cautiously with new, unproven technologies such as the new FDA-cleared minimally invasive device/procedure to treat POP called NeuGuide. NeuGuide is a Class III device that is placed blindly through tissues close to vital blood vessels and nerves."

Even the authors of a study published in 2017 of ten women who underwent the NeuGuide procedure wrote, “However, transvaginal anchoring or placement of the fixation sutures through a deep, narrow space to the sacrospinous ligament (SSL) is technically challenging and potentially dangerous.” After only six months of follow-up, the results of this study proved successful, but this length of time is minimal due to the high recurrence of POP. Long-term studies and follow-up should continue for 5-10 years to truly demonstrate effectiveness and safety. Furthermore, there was no significant reduction in either urge or stress incontinence.

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>
> *Dr. Greg Vigna*

The NeuGuide procedure permanently implants a material into the SSL and attaches it to the back wall of the cervix with suture, thus elevating the uterus to its normal or non-prolapsed position. The alleged advantage of the NeuGuide (EnPlace) device is that it can be performed with the uterus intact and is anchored to the cervix, which is stronger tissue than the aging, estrogen-depleted vagina. The surgeon uses his or her finger as a guide to insert and deploy the anchor that is made out of Nitinol, a metal alloy with elastic and flexible properties. While Nitinol is the same material used for a new IUD (Ballerine) and sits on top of the lining of the uterus, one cannot be assured that the inflammatory reaction of the SSL and surrounding tissue will be less or that the anchor might not dislodge due to repetitive intra-abdominal forces.

These issues, among others, such as the small number of women studied (N=15) per the company website (but unvalidated via PubMed) in a follow-up study and short follow-up (less than 2-years) cannot be minimized since those were two criticisms for the vaginal mesh studies and approval process. The company also alleges a lower risk of infection because the suture is placed into the cervix, but the vagina must be cut to reach the posterior wall of the cervix, which could contaminate the site. Furthermore, the nature of the suture (permanent versus

absorbable) was not described and would reflect poorly for long term cure if absorbable.

Dr. Vigna cautions that “blind placement of a hook into the sacrospinous ligament places the pudendal neve in peril, given the known anatomical variations regarding the pudendal nerve. If a woman understands the magnitude of this risk of pudendal neuralgia that includes crippling pain that interferes with sitting and all mobility, clitoral dysfunction, pain with vaginal penetration that makes sexual relationships impossible, anorectal pain that may be described as knife like pain in the anus, painful tailbone pain, and painful bladder filling then the consent would be considered adequate."

Dr. Vigna adds, "Physicians are exposed to liability for pudendal neuralgia on a basis of 'failure of informed consent' as well as for failure to timely diagnose and treat neurological complications from this device acute injury were to occur to the pudendal nerve and the anchor is not removed.” He warns, “Pharmaceutical companies across the world will develop new devices to deal with pelvic organ prolapse since the FDA ban of the transvaginal mesh devices on April 16, 2019. The medical community must examine the risk independent of what is published as these articles are often flawed by bias.”

The second wave of transvaginal mesh litigation will focus on women who suffer from disabling pain syndromes and injuries including pudendal neuralgia, complex regional pain syndrome, obturator neuralgia, and ilioinguinal neuralgia.

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

https://www.israel21c.org/a-new-mesh-free-way-to-repair-pelvic-organ-prolapse/

Weintraub AY, Ben Zvi M, Yohay D, et al. Safety and short term outcomes of a new truly minimallyinvasive mesh-less and dissection-less anchoring system for pelvic organ prolapse apical repair. Int Braz J Urol. 2017;43(3):533–539. doi:10.1590/S1677-5538.IBJU.2016.0356

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