



**August 2, 2011**

## **NAFC Position Statement on the Use of Vaginal Mesh in Pelvic Surgery**

### **Background:**

Despite advances in all areas of medical technology, there continue to be few choices for women in America with stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP). The current literature reports that half of all women who have a vaginal delivery will incur some degree of disruption to the pelvic floor musculature, and 20% of those women will have symptoms that warrant intervention<sup>1</sup>. Over the lifetime of women, one in nine, or 11.1%, will have surgery for prolapse or incontinence. Nearly one in three, or 29.2%, of them undergo repeat surgery due to further failure or recurrence of prolapse or treatment of subsequent dysfunction of the pelvic floor (PFD) musculature<sup>2</sup>.

### **Stress Urinary Incontinence**

SUI is the most common type of incontinence in women younger than 60 years and accounts for at least half of incontinence in all women,<sup>3</sup> suggesting a prevalence of 15-16 million women.

Compared to the numerous non-surgical interventions available to men with benign prostate hyperplasia (BPH), such as energy thermotherapy, for example, effective non-surgical options for women with SUI have remained limited. Unlike overactive bladder (OAB) and BPH, there are no prescription medications on the market in the U.S. today with a primary indication of use for treating symptoms of SUI. While surgery may long have been considered the best ultimate solution for SUI, for some individuals surgery is not the best answer. Some women are not ideal candidates for such surgery due to other co-morbidities even if the severity of their SUI symptoms warrants it. As Americans live longer with multiple co-morbidities, this is likely to be an increasingly important consideration. Younger women may wish to become pregnant in the future, and many physicians do not recommend pelvic surgery for these women. Others may not wish to risk the possibility of complications, or simply may not be able to take the necessary time off from work or family responsibilities for recuperation.

Meanwhile, surgical outcomes do not always meet patient expectations or hopes. For example, a recently published multi-center, randomized clinical trial comparing the autologous fascial sling to the Burch colposuspension (Burch) at 2 years revealed low success rates of 66% vs. 49%, respectively, as compared with those in previous studies.<sup>4</sup> Preliminary, unpublished data from

this same study at 5 years post-op indicate a substantial decline in success rates; namely, 30% for the sling vs. 22% for the Burch group, respectively.<sup>5</sup> Although some studies have suggested that synthetic transvaginal tension-free tape results are similar, with a decline in efficacy equivalent to the Burch procedure at five years, high quality, long term follow-up data are not available and thus the ability to compare other procedures for SUI is limited. What we do know is that the inability of surgery to promise lasting results begs for continued research by expert clinicians and continued innovation by industry. Regardless, sub-urethral slings were exhaustively researched prior to their approval by the FDA in contrast to the vaginal mesh kits for prolapse. There is sufficient research and experience of over 15 years in the U.S. and close to 20 years in Europe with this product and procedure, unlike the vaginal mesh kits which are coming under increased scrutiny at this time for both their FDA approval methodology as well as their higher incidence of complications. There is no justification for withdrawing mesh used for slings in treating SUI, leaving women without long-term (5+ year) success rates of >30% with only tissue-to-tissue repair options.

## **Pelvic Organ Prolapse**

Cases involved with prolapse are often more complex and may even involve multiple organs. While minor degrees of POP affect up to half of women who have had a vaginal delivery, only 10 - 20% of them, or 1 in 10 of all women delivering vaginally, have symptomatic POP that prompts women to seek care<sup>6</sup>. However, few physicians practicing in the U.S. are trained to fit women diagnosed with POP with a pessary, and most do not discuss it encouragingly as an alternative to surgery. Doctors on whom women routinely rely for their pelvic health need to be better educated about the risk factors for POP, its symptoms, the proven treatment options and their risks, and the means of managing symptoms so they are equipped to address the problem with their patients. In addition, doctors should be more sensitive to the significance attached to POP symptoms by their patients and, if they lack the time or interest in becoming more knowledgeable, doctors should be prepared to refer patients complaining of possible POP symptoms to specialists who are trained to diagnose the problem and promptly offer non-surgical and surgical treatment options to patients. Women also lack awareness of POP, and their lack of knowledge makes their search for a provider difficult and their assessment of options weak, at best.<sup>7</sup>

Needless to say, the literature is severely lacking in long-term data comparing outcomes when mesh is used in repair versus autologous tissue, regardless of the procedural approach anatomically. Nor is there evidence of consensus among clinicians in the selection of patients for optimal procedures to perform based on a patient's symptoms, personal circumstances, health status, and medical history. This, too, is lacking in data. While there are recently published 12 month data comparing anterior colporrhaphy versus transvaginal mesh for prolapse repair in which the mesh kit resulted in a significantly higher rate of anatomical treatment success (60.8% for mesh versus 34.5% with a colporrhaphy), success rates for both deteriorated between 2 and

12 months, success rates were lower for both techniques when assessment combined objective and subjective measures, and complications both during and after surgery were markedly higher with the mesh kit<sup>8</sup>, e.g., 2.5% mesh patients experiencing pelvic pain at two months post-op versus 0.5% of colporrhaphy patients.

Especially in the case of POP, we are not at a point in our collective knowledge about patient selection and surgical techniques in treatment to arbitrarily remove all mesh from the market with the statement that all POP “can be treated successfully without mesh...”<sup>9</sup> Because of the relatively high recurrence rate in prolapse surgery, we are correct in focusing our highest priority on extending the success and longevity of the procedure, while continuing to search for innovations that can lower the incidence of complications. Women undergoing pelvic surgery and both genders undergoing hernia repair with synthetic mesh have already benefited, for example, from the evolution toward using lightweight mesh with larger pores to achieve less scar tissue formation and better blood flow<sup>10, 11, 12</sup>.

Although the FDA’s July 2011 communication pertained solely to POP, the FDA stated its intent to convene the Obstetrics-Gynecology Devices Panel of the Medical Device Advisory Committee, on September 8-9, 2011, to subsequently issue recommendations regarding the safety and effectiveness of transvaginal surgical mesh for POP and SUI. This action has prompted NAFC to issue a position statement on the subject, speaking on behalf of patients.

#### **NAFC Position Statement:**

1. The complete definition of **evidence-based healthcare** should be applied in reaching a set of recommendations regarding the use of surgical mesh for POP and SUI in women. The needs and interests of individual patients must be given equal weight in decisions concerning care and treatment. The **individuality of the patient** must be recognized in all decisions made for and about the patient. NAFC stands ready to help patients find their voice and be heard, through online forums with each other and through representation as the needs and goals of women are communicated to the doctors they routinely see.
2. NAFC strongly supports the requirement of **consistent, specialized training with credentialing by societies** for all surgeons performing procedures to treat SUI and/or POP with or without mesh. The public should be educated to demand evidence of such credentials. To support improvement in the standard of care, it is **NAFC’s mission to help women identify such experts through NAFC Centers of Excellence in Continence Care** that demonstrate not only appropriately credentialed experts but also satisfaction in outcomes and care by a majority of their patients.
3. Providers and patient advocacy groups must share responsibility to educate the public to **elevate health literacy** concerning POP and SUI, with assistance from government

health agencies, so that individual patients and their involved family members can confidently participate in **shared decision-making**. **Conversational, informed consent** between the patient and her doctor must be central to the process and take place well in advance of reaching a decision for intervention. Fully informed consent includes patient education and ease of access to a provider's clinical staff regarding **post-op complications** triggering questions and concerns after hospital discharge. **Transparency in relationships** with industry must be revealed in all communications with consumers, both by individual providers, their societies, and patient advocacy organizations.

4. **Innovation** to advance knowledge, science, and treatment modalities must be continually encouraged and rewarded, especially in light of the high prevalence of SUI and POP and recurrence of pelvic floor dysfunction (PFD), to combat the current poor outcomes with established, "gold standard" procedures and the unacceptably high incidence for repeat intervention. **NAFC does not support the arbitrary withdrawal of all mesh products** from the marketplace, based on outcomes and research data to date. Despite the 1.5% incidence (1,500 reported incidents out of 100,000 procedures) of serious, adverse events from pelvic surgery for POP reported to the FDA, it is only through ongoing research and development that protocols and procedures will be improved for women in the future. Moreover, the **dynamic nature of discovery** demands ongoing review of data and input from all parties so that recommendations can be kept current and continually evolving...and most importantly, that patients may be kept safely guarded.
5. As **patient safety** is considered supreme in the search for improvement in quality outcomes, the FDA must assume greater responsibility for demanding **post-market surveillance** of all devices and drugs in use in the marketplace regardless of how they are approved initially for use, especially tracking **five-year** data on new entrants. A registry should be created in which all PFD procedures are entered so that all outcomes can be analyzed objectively, not just the casualties. Surgeon error in judgment or skill needs to be segregated as a causal factor for complications and the means for doing so identified. This effort, in conjunction with support from NIH and private industry, is essential in determining a **science-based means of patient selection** for particular procedures and implantable devices and in generating more **generalizable data** to aid in decision-making than we possess today. **NAFC considers it more valuable, from the patient's point of view, to rely on post market surveillance data in making judgments about safety and device performance than to delay or bar access to innovative options, especially in light of the poor success rates associated with non-mesh procedures and the limited PFD treatment options available to women.**
6. In the spirit of open and timely communication among all parties, the FDA is encouraged to maintain **dialogue** on an ongoing basis **with industry, providers, payers, and patient advocacy groups** for open discussion about issues affecting patient safety and patient access to innovation for improved quality outcomes in care.

## References:

- <sup>1</sup>Brown JS, Waetjen LE, Subak LL, Thoma DH, Van Den Eeden S & Vittinghoff E (2002)
- <sup>2</sup>Swift S, Woodman P, O'Boyle A et al. (2005)
- <sup>3</sup>Hannestad YS, Rortveit, Sándwich S, & Hunskaar S (2000)
- <sup>4</sup>Albo ME, Richter HE, Brubaker L, Norton PA, Kraus SR, Zimmern PE et al. (2007)
- <sup>5</sup>Brubaker L (2010)
- <sup>6</sup>Swift S (2000)
- <sup>7</sup>Muller N (2010)
- <sup>8</sup>Altman D, Väyrynen T, Ellström-Engh M, Axelsen S, & Falconer C (2011).
- <sup>9</sup>U.S. Food and Drug Administration, *FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse*, July 13, 2011.
- <sup>10</sup>Cobb WS, Kercher KW, & Heniford BT (2005).
- <sup>11</sup>Cobb WS, Burns JM, Peindl RD, Carbonell AM, Matthews BD, Kercher KW et al. (2006).
- <sup>12</sup>Novitsky YW, Harrell AG, Cristiano JA, Paton BL, Norton HJ, Peindl RD et al. (2007).

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