

## ***Minimally-Invasive Slings for Stress Urinary Incontinence: More Options Than Ever***

Since Ulf Ulmsten and his colleagues in Scandinavia developed and popularized the tension-free vaginal tape (TVT, Gynecare) suburethral sling in the early 1990s, American surgeons have been a little faster to accept new technology and techniques from our European colleagues. Case in point is the new trans-obturator slings, a potentially safer, and probably equally effective variant of the classic TVT sling that is growing in use quickly by gynecologist and urologists. With this new approach, whether using the “out to in” or “in to out” method, the ability to avoid the retropubic space (and the pelvic cavity, for that matter) while blindly passing the trochars may lower the risk of hematoma, bladder injury, and bowel injury. However, this new method now enters an area of the body we, as gynecologist surgeons, are not as familiar with as compared to the retropubic space of Retzius. It is important for a surgeon to not only familiarize oneself with a new procedure, but also the anatomy that is involved in the new procedure, namely the obturator foramen. Familiarity of the muscles, nerves and vessels associated on both sides of the obturator membrane is essential prior to jumping into performing these procedures. Understanding the anatomy will give one respect for the potential complications of these slings. Initial reports, as well as more recent studies (Minaglia S et al. Bladder injury during trans-obturator slings. *Urol.* 2004; 64: 376) of case series with trans-obturator slings have demonstrated that there is potential injury to the urethra and bladder, necessitating intraoperative cystourethroscopy, despite what industry representatives say. Sadly, like some random cases with the TVT, life-threatening hemorrhage has occurred with trans-obturator slings.

Another subject that abounds when discussing these new approaches to continence surgery is what patient is appropriate for what type of procedure. The answer to that is still not clear. Some experts feel that the trans-obturator slings are equally effective as conventional TVTs in patients with simple hypermobile stress incontinence, potential SUI, and SUI with prolapse. The debate come into mind more in two subsets of patients- those that have failed classic retropubic operations (MMKs, Burch) and those that may have intrinsic sphincter incompetence. The first group may benefit from a transobturator approach to avoid the retropubic space may be more scarred. The second group with more severe SUI, though, may have lower cure rates with the obturator approach as compared to the traditional transvaginal tape. . Overall, though, it is important to accept these new technologies with some air of caution, but forthcoming US studies will hopefully validate European and South American experience (and ours) that the TOT sling is a useful and safe tool in the treatment of SUI in most patients.

## **The Hormone Debate- Custom-Compounded Hormone Therapy**

The 2002 published results of the cancelled Women's Health Initiative (WHI) trials resulted in the widespread discontinuation of hormone therapy (HT) by perimenopausal and menopausal women. The ensuing symptomatology such as hot flashes, night sweats, sleep disturbances, and vaginal dryness, has turned attention toward alternative therapies to conventional HT. Proponents of custom compounded HT claim fewer related side effects and better symptom relief than conventional HT, as the compounds used are "bioidentical" to a woman's endogenous hormones. Plant hormones, usually extracted from soy and yams, are synthetically converted to chemical replicas of hormones that naturally occur in a woman's body. An individualized formulation is usually based upon a woman's current hormone levels as determined by saliva testing. Saliva is said to contain only bioavailable hormones as opposed to serum, which may not distinguish between protein-bound vs. bioavailable hormones. The promotion of these compounds as being safer due to being derived from a "natural" source is compelling for women whose quality of lives are affected by menopausal symptoms. However, to date, compounded hormones have not been tested for safety, tolerability, or effectiveness in rigorous clinical trials. Moreover, compounded hormones are not routinely tested by any regulatory agency for quality, purity, or potency. The North American Menopausal Society (NAMS) Hormone Therapy Panel concluded that bioidentical hormones should be considered in the same category as all sex steroids, which in the absence of specific safety and efficacy studies, carry the same risks and benefits as related products. A review of a woman's individualized risk panel and her informed consent is essential before initiation of any HT regimen is considered.

### **What is a "Natural" Hormone?**

Proponents of custom compounded HT claim fewer related side effects and better symptom relief than conventional HT, as the compounds used are "bioidentical" to a woman's endogenous hormones. Plant hormones, usually extracted from soy or yams, are synthetically converted to chemical replicas of hormones that naturally occur in a woman's body. They are considered natural not because of their natural source, but because they are identical to naturally occurring human hormones. An individualized formulation is usually based upon a woman's current hormone levels as determined by saliva testing. Saliva is said to only contain bioavailable hormones as opposed to serum, which may not distinguish between protein-bound vs. bioavailable hormones.

The hormones most commonly used in custom-compounded preparations are estrone, estradiol, estriol, progesterone, testosterone, and DHEA. Two popular estrogen formulations are Bi-Est, a combination of estradiol and estriol, and Tri-EST, a combination of estrone, estradiol and estriol. Estriol is typically the predominant estrogen in both Bi-Est and Tri-Est as it is considered to be the weakest and safest of the estrogens. Progesterone is typically used in women with or without a uterus to increase menopausal symptom relief, increase libido, and enhance a normal sleep cycle. Testosterone is sometimes added to improve libido, build bone and promote muscle tone. DHEA is touted to improve bone mineral density, burn fat, and strengthen the immune system.

### **Is Bioidentical HT Better than Conventional HT?**

The promotion of custom-compounded products as being safer than conventional products is compelling to women whose quality of lives are affected by menopausal symptoms. However, to date, compounded hormones have not been tested for safety, tolerability, or effectiveness in rigorous clinical trials. Though the compounds themselves are FDA approved there is no routine testing done by any regulatory agency for quality, purity, or potency. The North American Medical Society (NAMS) Hormone Therapy Panel concluded that bioidentical hormones should be considered in the same category as all sex steroids, which in the absence of specific safety and efficacy studies carry the same risks and benefits as related conventional products.

### **What to Prescribe?**

Reportedly, the vast majority of women who take HT do so for the relief of menopausal symptoms. Its' role in symptom relief can contribute significantly to the quality of life of the menopausal woman. Conventional or custom compounded HT should not be denied to the well-informed healthy patient. A review of a woman's individualized risk panel including family and personal history, current medical conditions, medications, and severity of symptoms are important considerations. Dietary changes, exercise, and smoking cessation can also reduce symptoms and improve quality of life. Lastly, a patient's informed consent is essential before initiation of any HT regimen is considered.

## ***New Developments in reconstructive surgery for prolapse***

As most practitioners are aware, there are several options for treatment of prolapse. Because this is a life-impacting condition and not a life-threatening condition, one option for mild to moderate prolapse is observation. However, when the prolapse worsens or affects the quality of life of a woman, and a pessary is not desired, surgery may be the best option. Sadly, in the past almost one out of three surgeries performed for prolapse and incontinence have been for failed procedures. To decrease this failure rate, many advances have been made in materials used for augmenting traditional or site specific repairs to compensate for and replace poor inherent tissue.

Additionally, new coding guidelines include a CPT code (57287) for the vaginal placement of a graft or mesh for prolapse repair. Numerous graft materials, both synthetic and biologic, are now touted by industry for use in vaginal reconstructive surgery. Although most have been proven safe in animal studies and small patient series, there is an unfortunate paucity of good data to support the use of one graft over another. In fact, no prospective comparative studies have been performed for any of the new grafts that are available for use (Table). More studies are in the pipeline and are forthcoming, hopefully with control or comparison groups.

Our personal experience has been primarily with cadaveric fascia (Tutoplast), dermal allografts, and porcine dermal xenografts used for vaginal rectocele and cystocele repair augmentation, as well as polypropylene meshes placed vaginally or laparoscopically for sacral colpopexy. The minimal problems with a synthetic mesh placed by an abdominal route for correction of prolapse have been well established. However, previous attempts at using a permanent, synthetic mesh placed vaginally have resulted in excessively high erosion and extrusion rates. This may be changing in the near future as tension-free mesh placement in both the anterior and posterior compartments is being developed and marketed by a few companies.

Preliminary results from tests centers of this total pelvic floor mesh repair are promising and our limited exposure to these trans-obturator mesh systems have been favorable. Generally high success rates over 90% are quoted for the cystocele and rectocele repair. The short term complications and long term outcomes from these mesh systems have yet to be completely elucidated. However, the data so far have demonstrated a broad range of erosion rates, generally 3-13% (and up to 20% in a few series), which gives us all cause to consider the risk-benefit balance.

Most surgeons that have experience with transvaginal mesh placement have recognized that retaining the cervix or uterus, minimizing the size of the vaginal incision, and proper surgical technique can keep the erosion rates down. Fortunately, the lessons learned from the TVT sling have made it clear that pore size of the mesh and a tension free approach appears to minimize adverse events. The most important thing to remember is that the use of interpositional graft material of whatever type in vaginal reconstructive surgery is a relatively new practice and all types of graft and mesh materials should be approached with caution. Patients should be counseled individually and it should be remembered that not one procedure or mesh kit is the right thing for every single patient- each patient should have a surgical plan individualized for their defects.