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## PERSPECTIVE

### Current Situation of Transvaginal Mesh Repair for Pelvic Organ Prolapse

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**S**URGICAL mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists. Surgical mesh has been used since the 1950s to repair abdominal hernias. In the 1970s, gynecologists began using surgical mesh products to indicate the repair of pelvic organ prolapse (POP), and in the 1990s, gynecologists began using surgical mesh for POP. Then the U.S. Food and Drug Administration (FDA) approved the first surgical mesh product specifically for use in POP. Surgical mesh materials can be divided into several categories. Most surgical mesh devices cleared for POP procedures are composed of non-absorbable synthetic polypropylene. Mesh can be placed in the anterior vaginal wall to aid in the correction of cystocele (anterior repair), in the posterior vaginal wall to aid in correction of rectocele (posterior repair), or attached to the top of the vagina to correct uterine prolapse or vaginal apical prolapse (apical repair). Over the past decades, surgical mesh products for transvaginal POP repair became incorporated into "kits" that included tools to aid in the delivery and insertion of the mesh. Surgical mesh kits continue to evolve, adding new insertion tools, tissue fixation anchors, surgical techniques, and ab-

sorbable and biological materials. This procedure has been performed popularly. It was also performed increased in China. But this new technique met some trouble recently and let shake in urogynecology.

#### **POP Reconstructive Surgery with Mesh and FDA Announcement**

In October 2008, the FDA issued a Public Health Notification (PHN) to inform clinicians and patients of adverse events related to urogynecologic use of surgical mesh, and to provide recommendations on how to mitigate risks and how to counsel patients. Following the PHN, the FDA continued to monitor the outcomes of urogynecologic use of surgical mesh. A search of the FDA's Manufacturer and User Device Experience (MAUDE) database from the last 3 years (January 1, 2008-December 31, 2010), identified 2874 Medical Device Reports (MDRs) for urogynecologic surgical meshes, including reports of injury, death, and malfunctions. Among the 2874 reports, 1503 were associated with POP repairs. So the FDA provided this update to advise the public and the medical community of complications related to transvaginal POP repair with mesh,<sup>1</sup> which included vaginal mesh erosion, pain (including painful sexual intercourse known as dyspareunia), infection, urinary problems, bleeding, and organ perforation.<sup>2, 3</sup> There were also reports of recurrent prolapse, neuro-

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muscular problems, vaginal scarring/shrinkage, and emotional problems.<sup>4</sup> Many patients need for additional intervention, including medical or surgical treatment and hospitalization (partial or complete excision of the mesh in the operating room).<sup>5,6</sup> The FDA organised an advisory panel meeting of outside experts in September 2011 to discuss. Based on evaluation of adverse event reports and assessment of the scientific literature, the FDA has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh,<sup>7,8</sup> and it may expose patients to greater risk.

### **Current Situation and Choice for POP Repair in China** *Emphasize and popularize the non-transvaginal synthesized mesh pelvic floor reconstructive surgery*

Following modern principles of reconstructive pelvic surgery, the methods using patients' own ligaments, fascia tissues (sacral anterior longitudinal ligament, sacrospinous ligament, uterosacral ligament, sciatic jujube fascia, iliococcygeus fascia, etc.) as supportive structures to repair and enforce the pelvic floor defect can be certainly effective, moreover, the cost for some operations are relatively economic. These methods involve sacral colpopexy, sacrospinous ligament fixation as well as high utersacral ligament suspension. Evidence based medicine researches indicated that uterus or vagina sacral colpopexy had a high cure but a low rate of complication for vaginal apex prolapse.<sup>9</sup> Besides, the Lefort surgery plays an inevitable role in the treatment of elder women, who are in poor health and have no requirements for sexual intercourse. We should explore management strategy suitable for Chinese population, achieving the treat goal of "effectiveness, safety, and economy".

### *Underline the functional recovery at postoperative follow-up*

With regard to surgical management effects of uterus prolapse, pelvic reconstructive operations fail to alleviate all the other pelvic floor dysfunction symptoms post-operatively (level A evidence), of which the cure rate cannot reach 100%.<sup>10</sup> So the aim of treatment should focus on relieving symptoms to different extent. As the pelvic floor dysfunction is not a lethal disease, the conception and pattern of treatment differed considerably from the past. Many doctors believe themselves to be capable of evaluating patients' life quality accurately in clinical practice, however, the level A evidence manifests that it is difficult and inaccurate for physicians to assess the influence of the pelvic floor surgery on patients' life quality. The definition of "Success of Treatment" is hard to

determine, therefore it is necessary to provide an objective methods evaluating patients' symptoms, which are designed guided by psychometrics principles with characters of repeatability and measurability, which collect data under the mode with patient as dominant and avoid subjective judgments. Through years of exploration and practice, questionnaire investigating various functions and relative symptoms is the most efficient method to test the impacts on patient's daily life and health condition affected by symptoms or disease. Hence, we advocate that urogynecologists should use patient-centered symptomatic questionnaire to assess overall postoperative situation in clinical practice. The assessments should contain patients' prolapse symptoms; patients' genital, urinary and gastrointestinal tract functions; patients' life quality and socioeconomic condition. It is recommended to use the verified Chinese version questionnaires that are introduced from international editions with level A and B evidence supported from evidence based medicine. Another important issue, sexual function, should also be highly concerned after POP repair surgery. It is reported that almost 10%-30% patients complained that their sexual function impaired after pelvic floor reconstructive surgery, especially with the implantation of transvaginal mesh.<sup>11</sup> Therefore, before carrying out the pelvic floor reconstruction, gynecologists must have a good communication with patients and their relatives, introduce the complications such as dyspareunia and persisting pain, cost and international and local clinical outcome data, then make a decision of the operative method together, finally sign the specific informed consent. Furthermore, we will spread all kinds of techniques through the new style, i.e. training assisted with constantly updated continuing education. We should establish a sound follow-up system. The best way is to set up an adverse event statistic and report system, promoting systemized management.

In the future, the establishment and development of the novo subdiscipline, urogynecology, promoted enormously specialist team building. We should explore and set up the quantification system of urogynecology specialists, the certification system and evaluation criteria of professional skills. Pelvic reconstructive surgery belongs to level IV advanced operation, which is complicated and difficult to procedure, therefore, physicians are allowed to perform this type of surgery only under the condition that doctors have already finished adequate training of theories and techniques in pelvic floor reconstruction, especially pierce training though blind zones in cadavers, meanwhile, have rich experience in transvaginal surgery.

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