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EDITORIAL

While we wait for a new regulatory framework for surgical mesh

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Gynaecologists have since the 1990s used surgical mesh for transvaginal repair of pelvic organ prolapse (POP) [1]. During the past decade, introduction of new mesh and surgical "kits" (surgical mesh products that includes tools to aid in the delivery and insertion of the mesh) has been endless and ongoing. This situation has three main reasons (1) the current premarket notification program for clearance of surgical mesh, which (2) the mesh manufacturers have used to bring new products on the market without clinical data on efficacy and safety, and (3) the willingness of many gynaecologists to adopt new untried and unproved techniques into clinical practices.

The FDA cleared the first surgical mesh product specifically for use in POP in 2002 [1]. The clearance process for new surgical meshes follows the principles instituted for class II medical devices, a large group which includes a variety of devices like medical lasers, magnetic resonance imaging devices, hard contact lenses and battery-powered wheelchairs [2]. According to the 510 (k) Medical Device Amendments of 1976 approval of a new product is based on the assumption of "substantial equivalence" to a previously cleared "predicate" device and as a consequence clinical data are not required [2]. Mesh manufacturers have exploited this situation and via a massive marketing of new products promoted a "fast-food surgery" concept (many types, easy to get, not necessarily good for your health). Obviously the aim has been to earn money for the owners and shareholders, and unfortunately most companies have not been willing to sponsor clinical studies since they are expensive and delay the release of new products.

The introduction of the TVT by Ulmsten et al. in 1996 [3] heralded a new era in the treatment of stress urinary incontinence in which midurethral slings made of synthetic mesh has become the "standard of care". A similar (advantageous) situation has not developed following the introduction of mesh/mesh kits for surgical reconstruction of POP. Except for abdominal sacrocolpopexy with macroporous monofilament polypropylene, the development of POP mesh/surgical kits in general has not resulted in outstanding new products. On the contrary, product development has been limited, possibly because of the ease with which new products are approved by the FDA. Therefore, most "new contributions" are essentially "copycats".

The evidence available at the moment indicates that the use of mesh for POP reconstruction in the anterior compartment provides a statistical significant reduction in "anatomical" failure which has not been translated into improved functional or quality-of-life outcomes [4]. On the other hand, mesh/mesh kits induce a risk of erosion of about 10 % [5] and 2−6% of patients require repeated surgery under full anaesthesia [6] at a mean period of 3 years post surgery. Furthermore, approximately 10 % develop dyspareunia [5]. The use of mesh also adds to the direct cost of surgery.

The adoption of new products without relevant clinical data on efficacy and safety puts the physicians in conflict with the basic ethical principles of (1) autonomy, (2) beneficence and (3) non-maleficence [7]. Autonomy refers to the free right of the patient to make choices. This implies that the physician must fully explain the benefits, the risks and possible complications to the proposed treatment, as well as alternatives.. If sufficient data on a new product are not available, the patient must be told. This is because the physician has a fiduciary

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relationship to the patient, who (in turn) trusts that the physician is duly qualified and possesses the necessary knowledge to ensure proper *informed* consent before surgery. As a consequence of this relationship, the patient will, most often, follow the physician's advice. In practical life this implies that the gynaecologist must justify to the patient and others the use of a new product believed to improve the quality of care offered to the patient without creating undue harm [8].

Innovation in medical practice is critical to the advancement of medicine; however, new techniques should be introduced in a controlled fashion to protect our patients. Therefore, innovative activity should be changed into formal research [9] and follow recognized ethical principles: *New products without data on efficacy and safety should be rejected, or alternatively relevant data should be established within the framework of recognized methods for surgical innovation* [4, 10, 11] *and the results should be published*.

FDA has alerted practitioners for the second time to the complications associated with transvaginal placement of surgical mesh [1], and litigation is now widespread, as may be evidenced by a Google search for "transvaginal mesh". In the past, many products have been withdrawn from the market because they were harmful to the patients. This is an intolerable situation for our speciality. Hence, it is time for mesh device companies and physicians to acknowledge their mutual ethical responsibility to create relevant clinical data before new surgical procedures are fully implemented and to realize that "just because we can, does not mean we should".

The regulatory authorities also play an important role. The Institute of Medicine (IOM) has recommended a new regulatory framework for moderate-risk devices [2]. Hopefully the FDA and the European authorities will acknowledge that the present approval process is out of date in relation to surgical mesh/mesh kits and will implement some of the recommendations from IOM. In the meantime, and in respect of the altruism and confidence of the patients, which make clinical research possible, industry and academe have an obligation to act in accordance with the highest standards of scientific and ethical integrity [10].

References

1. FDA (2011) Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse. Center for Devices and Radiological Health
2. Challoner DR, Vodra WW (2011) Medical devices and health—creating a new regulatory framework for moderate-risk devices. N Engl J Med 365(11):977–979
3. Ulmsten U, Henriksson L, Johnson P et al (1996) An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogyunecol J Pelvic Floor Dysfunct 7:81–86
4. Maher CM, Feiner B, Baessler K, Glazener CMA (2011) Surgical management of pelvic organ prolapse in women: the updated summary version Cochrane review. Int Urogynecol J 22:1445–1457
5. Abed H, Rahn DD, Lowenstein L, Balk EM, Clemons JL, Rogers RG (2011) For the systematic review group of the society of gynecologic surgeons. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J 22:789–798
6. Feiner B, Jelovsek JE, Maher C (2008) Efficacy and safety of transvaginal mesh kits in the treatment of prolapse of the vaginal apex: a systematic review. BJOG 116(1):15–24
7. Ethics in Obstetrics and Gynecology, second edition. The American College of Obstetricians and Gynecologists. Women's Health Care Physicians (2004)
8. Mucowski SJ, Jurnalov C, Phelps JY (2010) Use of vaginal mesh in the face of recent FDA warnings and litigation. AJOG 203:103.e1–4
9. Innovative Practice: Ethical Guidelines. Committee Opinion, ACOG Committee on Ethics. 2006; 352: 1–7
10. Lose G (2007) Urogynaecological research: current and future developments. Int Urogynecol J 18:599–601
11. Lose G, Ostergard DR (1999) Medical technology assessment and surgery for stress incontinence. IUJ 10:351–352