Optimizing Safety and Appropriateness of Graft Use in Pelvic Reconstructive Surgery: Introduction to the 2nd IUGA Grafts Roundtable

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The most savage controversies are about matters as to which there is no good evidence either way.

Bertrand Russell, English logician and philosopher (1872–1970)

Urogynecologic surgeons, regulatory bodies, and their patients are currently embroiled in a divisive debate regarding the appropriate use of grafts in the vaginal repair of pelvic organ prolapse. This debate has spilled over onto the public and legal domains with lightning speed thanks in great part to the widespread marketing of new mesh kits by surgical device companies and prompt adoption of new techniques by pelvic surgeons, as well as widespread access to an uncensored internet. “Good evidence either way” is slow to come, as with most innovative surgical progress.

We have been keenly aware that this was likely to happen. It is reported that over 300,000 prolapse procedures are performed annually in the USA [1]. It is unknown exactly how many mesh kits are implanted per year, but it is likely a growing volume due to widespread marketing and increased surgeon training. Although the currently available kits have basic similarities, including the use of lightweight type 1 polypropylene mesh, they did not begin that way. It was our growing concern regarding the use of a wide variety of reconstructive materials—and their unknown post-implantation behavior—that led us to sponsor the initial

International Urogynecological Association (IUGA) Grafts Roundtable in 2005 [2]. The goals of that meeting included:

- To understand the current role of grafts in reconstructive pelvic surgery,
- To review current knowledge regarding the biology of available grafts,
- To assist surgeons in the rational selection of a graft for reconstructive surgery,
- To develop proposals for future research studies regarding clinical graft usage.

The proceedings of that roundtable were reported in a supplement of the *International Urogynecology Journal (IUGJ)* in 2006, and were very well received by the community of pelvic surgeons. That supplement, along with other publications and increasing clinical experience, helped surgeons realize that all surgical materials are not alike, either in their composition, construction, or post-implantation behavior.

It is now 5 years later and, indeed, many of the materials available in 2004 are now not used due to problems with what we termed “healing abnormalities” [3]. Those associated with “complex” healing abnormalities—such as Gore-Tex, IVS, Protegen, and ObTape—are no longer marketed for use in the pelvis. It can be argued that the shortcomings of those materials could have been avoided by appropriate pre-marketing testing and/or methodical post-marketing monitoring. Surgical innovation is often not systematic and, unlike medical innovation, frequently occurs as a result of small case series. As urogynecologists and pelvic surgeons, we are not alone in facing this challenge [4].

The decision to convene a second IUGA Grafts Roundtable was made after multiple discussions with experts in our field—who were all of the opinion that it is timely to

The data were presented at the 2nd IUGA Grafts Roundtable, June 2010.

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produce societal recommendations in order to improve patient outcomes associated with implanted mesh in pelvic reconstructive surgery. Various factors convinced us that it was the right time to convene a group of surgical experts and thought leaders:

- a growing volume of published literature reporting on the use of grafts and mesh [5, 6]
- a growing literature reporting on mesh-related complications and trends [7–9]
- publication of thought-leader editorial opinions [10–13]
- other societies have summarized current knowledge and aimed at making clinical use recommendations [14]
- regulatory and public awareness of complications related to mesh use has grown [15–17]
- medicolegal activity relative to mesh use has expanded significantly [18].

The 2008 FDA Public Health Notification provided further confirmation that we were on the right track in addressing issues and enhancing surgeon education regarding mesh use via a transvaginal approach [15]. On July 13, 2011, the FDA published an update expressing further, and more significant concerns regarding vaginal mesh use, focusing on identified risks and lack of recognized benefits over traditional native tissue repairs [17]. In the time period between the 2008 notification and the 2011 update, the

medical community and surgical device companies had an opportunity to address the identified concerns in 2008, and develop multiple avenues for data collection, development of prospective clinical and pre-marketing testing protocols, and other means of enhancing patient safety. Unfortunately, no organized actions were taken, while widespread marketing and adoption of surgical kits by surgeons expanded.

Once it was decided to convene the second roundtable, it became evident that simply making recommendations on the appropriate use of mesh/grafts (indications) was not sufficient to achieve an effective desirable positive impact relative to the current problems associated with vaginal mesh use. Multiple other factors have a significant degree of interplay in the current state of mesh and kit use. Thus, we realized that expanding our recommendations to: patient-related factors (appropriate candidates), material-related factors (pre-marketing testing), surgeon-related factors (appropriate training and qualifications), and the very important aspect of appropriate preoperative patient informed consent would be needed in order to more comprehensively cover the various aspects required for improving patient outcomes.

The goals of this roundtable included formulation of:

- Recommendations regarding *indications for vaginal graft usage*

Fig. 1 Flow diagram of the roundtable setup

- Recommendations regarding *minimal qualifications for surgeon training* for implantation of grafts for reconstructive surgery
- Recommendations regarding *minimal amount of basic science and clinical data expected prior to marketing* of a new reconstructive material or surgical kit
- Recommendations on the *contents of an appropriate consent form* to be used by surgeons prior to mesh implantation

Invited participants included surgeons with extensive expertise in the implantation of reconstructive mesh/grafts (and possibly a pro-mesh bias), surgeons recognized as having conservative views on mesh use, clinicians who had recently participated in methodical reviews of the current literature on this topic, influential experts in urogynecology, pelvic surgery and urology, and legal counsel to address the topics relative to the identified goals. International diversity was thought to be very important as surgical practice varies from continent to continent, and thus, international participation was included in planning and participation. On behalf of IUGA, the organizing committee comprised Linda Cardozo (UK), Michel Cosson (France), and G. Willy Davila (USA).

Interestingly, implantation of mesh abdominally for sacrocolpopexy or hernia repair, which is not devoid of recognized serious complications, has not been subjected to significant scrutiny, and does not require specific surgeon training or credentialing process. Although we did not focus on transabdominal graft placement, it may be appropriate that mesh implantation, via whatever route, be subjected to greater outcome assessment and vigilance.

The format used for this roundtable included (Fig. 1):

- Review of the current literature published in peer-reviewed journals,
- Presentations on the national guidelines currently in place—where existent,
- Breakout groups designed to address each of the four outlined goals,
- Group discussion of each breakout group's directives and goals, followed by report from each breakout group to the entire group for discussion followed by subsequent breakout group session and final reporting of recommendations to the entire group for a final review. This allowed for all participants to express their opinions and provide input on all topics being addressed.

Why IUGA? IUGA is the world's premiere professional urogynecology society, with a membership exceeding 3,000 professional members, representing 85 countries, host of the principal urogynecologic yearly scientific conference and publisher of the leading urogynecologic journal—the *IUJ*.

We of course realize the published recommendations may require individual modifications in order to be applicable to each country's medical practice structure, regulatory bodies, and the urogynecologic professional society. These recommendations are not intended to dictate surgical practice, but to share expert opinion based on current literature review and surgical experience. The published recommendations have undergone invited review by a representative segment of the IUGA membership prior to publication.

As with any clinical and professional activity, our primary goal is to improve patient well-being. In doing so, it is our wish that these recommendations will contribute to reaching this goal by helping surgeons achieve better surgical outcomes, improve surgeons' skills, reduce risks associated with prematurely marketed grafts/kits, and assist in doctor–patient communication during the preoperative informed consent process.

Conflicts of interest The author has been a speaker, consultant, and grant recipient of Astellas, CL Medical, and AMS, and a consultant for Coloplast, Teva, and Israel Biomedical Innovations.

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