Received: 31 January 2019 | Revised: 21 May 2019 | Accepted: 26 July 2019 | First published online: 20 August 2019

DOI: 10.1002/ijgo.12932

REVIEW ARTICLE

Gynecology

WILEY GYNECOLOGY OBSTETRICS FIGO

FIGO review of statements on use of synthetic mesh for pelvic organ prolapse and stress urinary incontinence

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Abstract

The use of synthetic mesh implantation for the surgical management of pelvic organ prolapse (POP) and stress urinary incontinence (SUI) has grown in popularity since mesh was marketed for widespread use in the early 1990s. As mesh usage has expanded, patterns of previously unexpected complications have become apparent. In the United States and other countries, the increase in reported outcomes (both positive and negative) has led to the initiation of medico-legal actions by patients reporting negative effects of the implanted mesh. As a result, several national and professional societies have convened expert panels to publish summaries of reported outcomes and provide clinical recommendations regarding mesh use. Despite their recommendations and further dissemination of the potential complications reported after urogynecologic mesh use, the popularity of mesh use for POP and SUI has continued to expand, with apparent geographic and national patterns. As the largest global association focusing on women's health, FIGO, via its Urogynecology and Pelvic Floor Committee, has reviewed published national recommendations regarding the use of mesh, and has summarized them for the FIGO membership to help disseminate important recommendations to surgeons who may not be aware of the existence and content of these recommendations.

KEYWORDS

Medical societies; Mesh complications; Pelvic organ prolapse; Stress urinary incontinence; Usage recommendations; Vaginal mesh

1 | INTRODUCTION

It is estimated that one in five women will need surgical treatment for stress urinary incontinence (SUI) or pelvic organ prolapse (POP) during their lifetime.[1] Subsequently, many of these women (6%–29%) will require further surgery for recurrent POP or SUI; furthermore, the frequency of repeat surgery is higher than 50% for those who have had at least two or more procedures for prolapse.[2]

As a result, much research has gone into the development of surgical techniques to decrease the high frequency of recurrence, which has led to the widespread use of synthetic mesh for POP and SUI in the past two decades. However, coupled with the increasing use of synthetic mesh has been a growing awareness of its potential risks.[3]

In follow-up to a safety notification in 2008, the Food and Drug Administration (FDA) issued a safety update in 2011 to inform the public that serious complications associated with the use of synthetic mesh for POP are not rare; this update was based on an increase in reported adverse outcomes in their adverse events database.[4] Around the same time, numerous patient reports of adverse effects after transvaginal mesh implantation posted on internet-based social media attracted widespread attention. Those events have led to marked changes in practice patterns regarding the use of synthetic mesh for treatment of SUI and POP in some parts of the world.[5,6] Furthermore,

numerous class-action lawsuits brought against mesh manufacturers in the United States have enhanced the negative press on the routine use of synthetic mesh.

Owing to these concerns about the safety of synthetic mesh, professional societies have become involved in the discussion about the value and risks of transvaginal synthetic mesh, and continue to debate whether transvaginal mesh repair should remain an option for the treatment of POP or SUI. Most recently, governmental regulatory agencies in both Australia and New Zealand carried out a national inquiry into complications reported by women in whom mesh had been implanted; on the basis of their findings, they published recommendations stating that there is no benefit of synthetic mesh over traditional repairs, essentially banning synthetic mesh use for POP in those countries.[7]

Similar reviews were carried out in Scotland[8] and by the UK National Institute for Health and Care Excellence (NICE)[9] questioning the benefits of synthetic mesh use, resulting in a "pause" in the use of synthetic mesh in the United Kingdom until at least March/April 2019. This pause applies to surgical mesh for SUI and mesh for POP where the mesh is inserted vaginally. The consequences of this stoppage of mesh use are currently unknown; nevertheless, it sends a clear message to countries outside the United Kingdom, Australia, and New Zealand regarding the need for caution when using synthetic mesh in urogynecologic surgery.

Interestingly, current practices involving the use of vaginal mesh vary greatly worldwide, from regions where meshes are (still) considered a routine (and sometimes gold standard) part of gynecologic surgery to those where extreme caution in their use has been declared. As a consequence, national professional associations and national governmental agencies have been prompted to produce recommendations and guidelines to aid pelvic surgeons working in their geographic area in the safe use of vaginal mesh.

The aim of the present review was to compile and compare existing position statements from national and international professional associations and governmental agencies on the use of synthetic mesh for POP and SUI. The dissemination of the resultant information to geographic regions where these official position statements are not readily available might help surgeons in those regions become aware of the existence of the recommendations and potentially adjust their practice patterns.

2 | MATERIALS AND METHODS

The present narrative review on use of synthetic vaginal mesh was conducted in conjunction with the FIGO Urogynecology and Pelvic Floor Committee, with coordination by a research fellow in urogynecology (AI).

A Medline/PubMed search for position statements on use of synthetic mesh for treatment of POP and SUI was performed for the period January 1, 2010, to May 31, 2017, with additional edits based on updated key documents (i.e., UK regulatory documents). Published association statements were retrieved through associations and /or government websites. Keywords included "position statements," "synthetic mesh," "transvaginal mesh," "associations," "POP," and "SUI". An experienced librarian was recruited to help identify any position statements not published in traditional references and/or not found by using standard literature search techniques.

To retrieve as many international guidelines as possible, an inquiry was sent to all committee members of the International Federation of Gynecology and Obstetrics (FIGO) and International Urogynecological Association (IUGA) leadership, including the International Advisory Board. All publications identified to have position statements regarding the use of mesh for POP and SUI were reviewed.

For inclusion in the review, a publication had to be in English (or be translatable by a designated translator of the national society), had to carry the name of the sponsoring organization or agency, and had to have been published within the past 5 years. Statements that focused solely on the management of complications resultant from mesh use were excluded.

Position statements were divided into two groups: those regarding the use of synthetic mesh for treatment of SUI (Table 1); and those regarding the use of synthetic mesh for treatment of POP (Table 2). To compile and combine the content of the different position statements, each group was separated into five categories: general, patient selection, informed consent, technical, and future aspects. In each category, statements were numbered by the frequency of mention and the interpreted importance or priority.

Most statements used wording that was understandable and clear. If the text was deemed to lack clarity, three clinicians, selected by the authors, were asked for their interpretation of the wording, and a consensus was reached.

3 | RESULTS

Position statements from 24 international professional associations and governmental agencies were included in the review.[7–26] The position statements from four major Japanese Societies, the Japan Society of Obstetrics and Gynecology (JSOG), Japanese Urological Association (JUA), Japanese Society of Female Pelvic Floor Medicine (JFPFM), and Japanese Society of Pelvic Organ Prolapse Surgery (JPOPS), and the Federaçao Brasileira das Associações de Ginecologia e Obstetricia (FEBRASGO) in Brazil were received from two members of IUGA's International Advisory Board.

Position statements were differentiated between the use of synthetic mesh in the treatment of SUI (Table 1) and its use in the repair of POP (Table 2). Some statements combining both SUI and POP mesh applications were included. In compiling the recommendations into a tabular format, the statements were organized in accordance with the five pre-determined categories.

A number of generalizations can be made when analyzing the reviewed statements. Regarding SUI mesh use, there is robust evidence to support the use of synthetic mesh mid-urethral slings in the treatment of SUI. Most of the societies emphasize the importance of a thorough informed consent process, structured surgical training,

TABLE 1 Position statements regarding the use of synthetic mesh for treatment of SUI.

Aspect	Position statement	Associations
General		
1	Extensive data support the use of synthetic polypropylene suburethral mesh for the treatment of female SUI	AUGS, AUA, CUA, RANZCOG, UGSA, Scottish review, RCOG, Canadian Government, SCENIHR, FDA, ACOG, FEBRASGO, Japan, NAFC, NICE, IUGA, SGS, ICS, SUFU, EAU, EUA
2	Synthetic slings are an appropriate treatment for women with stress incontinence, with similar efficacy but less morbidity as compared with conventional non-mesh sling techniques	AUA, EAU, EUA
3	Polypropylene material is safe and effective as a surgical implant	AUGS, FDA
4	The monofilament polypropylene mesh MUS is the most extensively studied anti-incontinence procedure in history	AUGS, IUGA
5	Any restriction of the use of synthetic polypropylene mesh suburethral slings would be a disservice to women who choose surgical correction of SUI	AUA
6	The complications associated with the use of surgical mesh slings currently on the market for SUI repair are not linked to a single brand of mesh	FDA
7	When surgery involving synthetic mesh tape is contemplated, a retropubic approach is recommended	Scottish review
8	If women are offered a procedure involving the transobturator approach, make them aware of the lack of long-term outcome data	NICE
9	The safety and effectiveness of mini-slings for female SUI have not been adequately demonstrated. Further evidence is required	CUA, Canadian Government, FDA, NICE
10	Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon	NICE
11	Use the "top-down" retropubic tape approach only as part of a clinical trial	NICE
Patient selection		
1	Transvaginal mesh slings should not be used for women with urethral diverticulum, urethrovaginal fistula, urethral injury, or prior transvaginal mesh complication (e.g., pain or mesh erosion)	CUA
Informed consent		
1	A thorough informed consent process should be performed prior to synthetic sling surgery	AUGS, AUA, CUA, Scottish review, Govern. Can., SCENIHR, FDA, ACOG, NAFC, NICE, SGS, ICS, SUFU, EAU, EUA
2	Provide patients with a copy of the patient labeling or brochure, if available from the manufacturer	Scottish review, Canadian Government, FDA
Technical		
1	Surgeons performing these procedures should be adequately trained in SUI surgery and capable of recognizing, diagnosing, and treating potential mesh-related complications associated with the procedure	AUA, CUA, Scottish review, RCOG, Canadian Government, SCENIHR, FDA, JSOG, JUA, JFPFM, JPOPS, NAFC, NICE, EAU, EUA
2	Intraoperative cystoscopy should be performed during all sling procedures to identify urinary tract injury	AUA
3	Be aware of the complications associated with transvaginal implantation of surgical mesh slings for the treatment of SUI. Some of these complications may require additional surgery that may not fully correct them	Canadian Government, FDA
Future aspects		
1	Improved research into the safety and effectiveness of the products; long-term outcome studies should be undertaken for existing mesh procedures	Scottish review, SCENIHR, NAFC, EAU, EUA
2	Any cases of serious or unexpected adverse incidents among patients who have received transvaginal surgical mesh devices for SUI repair should be reported	Scottish review, Canadian Government, SCENIHR, FDA, JSOG, JUA, JFPFM, JPOPS, NAFC
3	Establish European implant registries	SCENIHR

(Continues)

TABLE 1 (Continued)

Aspect	Position statement	Associations
4	Offer a follow-up appointment (including vaginal examination to exclude erosion) within 6 mo to all women who have had incontinence surgery	NICE

Abbreviations: ACOG, American Congress of Obstetricians and Gynecologists; AUA, American Urological Association; AUGS, American Urogynecological Society; CUA, Canadian Urological Association; IUGA, International Urogynecological Association; ICS, International Continence Society; FDA, Food and Drug Administration; FEBRASGO, Federaçao Brasileira das Associações de Ginecologia e Obstetricia; JSOG, Japan Society of Obstetrics and Gynecology; JUA, Japanese Urological Association; JFPFM, Japanese Society of Female Pelvic Floor Medicine; JPOPS, Japanese Society of Pelvic Organ Prolapse Surgery; MUS, mid-urethral sling; NICE, National Institute for Health and Care Excellence; NAFC, National Association for Continence; RANZCOG, Royal Australian and New Zealand College of Obstetricians and Gynaecologists; UGSA, UroGynaecological Society of Australasia; SCENIHR, Scientific Committee on Emerging and Newly Identified Health Risks; SGS, Society of Gynecologic Surgeons; SUFU, Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction; SUI, stress urinary incontinence; RCOG, Royal College of Obstetricians and Gynaecologists.

and the need to report all adverse effects and complications among patients with implanted surgical mesh (Table 1).

Regarding POP mesh use, the use of synthetic mesh for the treatment of POP is more controversial. Approximately half of all included associations state that POP can be successfully treated with native tissue repair in most cases, thereby avoiding the risk of mesh-related complications, and that the use of transvaginal mesh should be restricted to high-risk patients (i.e., those with recurrent prolapse, chronic cough, or chronically raised abdominal pressure). Many statements emphasize the importance of informing patients about the benefits and risks of transvaginal surgery with mesh as compared with non-surgical and non-mesh options. The importance of surgeons' expertise and the need for further research to obtain long-term results are relatively common in the statements of many associations (Table 2).

4 | DISCUSSION

The review identified a large volume of recommendation and position statements on using synthetic mesh for the treatment of SUI and/or POP. This suggests that the use of transvaginal synthetic mesh remains a highly controversial topic, where input from professional bodies has the potential to play an important role. Since the FDA's safety notification in 2008,[3] regulatory warnings about the complications associated with vaginal mesh use, growing media interest, the wide use of social media by patients, and frequent advertising by plaintiffs' attorneys have led to increased awareness among patients and surgeons. The public has thus become very skeptical about the use of vaginal mesh, especially after the more critical FDA update in 2011.[4] As a result, the usage of mesh products has markedly declined in the United States and Europe.[27]

The review found that there is much synergy and agreement among the identified statements. This strongly suggests that surgeons from parts of the world where there is no professional body producing recommendations should pay particular attention to these statements and adopt the recommendations in their clinical practice. It is beyond the scope of the present review to discuss the reasons why this situation has developed. Surgeons in the United States, Australia, New Zealand, and Europe have witnessed the events leading to this difficult situation. However, surgeons in other parts of the world may not be fully aware of the causative events, and should do their best to avoid reaching the same crisis in their countries by familiarizing themselves with the content of the published recommendations.

After evaluating the reports of adverse events and reviewing the scientific literature, the FDA concluded that the use of synthetic transvaginal placed mesh for POP surgery does not predictably improve clinical outcomes as compared with native tissue repair, and determined that serious adverse events are not rare with synthetic mesh use.[4] When comparing synthetic mesh use for POP and SUI, it has become clear that the sling procedure for SUI has much lower associated mesh-related risks[13] and it is an accepted procedure with proven efficacy and safety for most women with SUI.[12] However, the safety and efficacy of mini-slings for female SUI have not been adequately demonstrated, and further evidence is required.[14,18,21]

Vaginal mesh placement has been associated with risks such as mesh erosion and exposure, sexual dysfunction, urinary tract injury, voiding dysfunction, vaginal and pelvic pain, organ or blood vessel perforation, and bleeding.[2] As compared with native tissue repair, synthetic mesh exposure and contraction are unique issues and the most common complications of transvaginal mesh augmentation for POP repair.[2] Mesh exposure rates for vaginal POP surgery with synthetic mesh range from 4% to 19%,[28] whereas mesh exposure in synthetic sling surgery occurs in 1%–2% of cases.[29] Mesh placed abdominally for POP repair seems to result in lower rates of mesh complications as compared with transvaginal mesh placement.[4,30,31] Mesh contraction, both after POP and SUI mesh applications, may represent the most troublesome complication because it may lead to pelvic pain and/or dyspareunia and need for re-operation to explant hardened mesh.

A patient's ability to provide informed consent prior to any surgical procedure is a key principle in surgical therapy, and patients should receive sufficient information in order to make an educated treatment decision. Patients should be informed about alternatives to surgical management, including pelvic floor muscle training, lifestyle alterations such as weight loss, limitation of exertional activities, management of significant constipation, and use of pessaries. The information should also describe alternative surgical treatments, including conventional native tissue repair and abdominal sacrocolpopexy. In addition, patients require appropriate information on the mesh procedure, including device identification, and potential benefits and complications of transvaginal mesh, and on where to report adverse events

TABLE 2 Position statements regarding the use of synthetic mesh for treatment of POP.

Aspect	Position statement	Associations
General		
1	In most cases, POP can be treated successfully without mesh, thus avoiding the risk of mesh-related complications	AUGS, AUA, CUA, RANZCOG, UGSA, Scottish review, Canadian Government, SCENIHR, FDA, ACOG, FEBRASGO, EAU, EUA
2	Based on the current state of knowledge, transvaginal operations (with mesh) for POP should be used only under carefully controlled circumstances	RCOG, NICE, EAU, EUA
3	Limit the amount of mesh used for all procedures where possible	SCENIHR, EAU, EUA
4	Transvaginal polypropylene mesh is not recommended as the first-line treatment for any vaginal prolapse	RANZCOG, EAU, EUA
5	Vaginal mesh can be used for the surgical treatment of POP and SUI. It is critically important to distinguish between these two uses of vaginal mesh	AUA, EAU, EUA
6	Serious complications associated with surgical mesh for transvaginal repair of POP are not rare	FDA
7	Outcome reporting for prolapse surgical techniques must clearly define success both objectively and subjectively. Complications and total reoperation rates should be reported as outcomes	Scottish review, RCOG, Canadian Government, FDA, ACOG, JSOG, JUA, JFPFM, JPOPS, NAFC
8	Factors to consider before using surgical mesh:	
	• Surgical mesh is a permanent implant that may make future surgical repair more challenging;	FDA, ACOG
	• A mesh procedure may put the patient at risk of requiring additional surgery or the development of new complications;	CUA, RANZCOG, UGSA, Canadian Government
	• Removal of mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life; complete removal of mesh may not be possible and may not result in complete resolution of complications, including pain;	AUA, RANZCOG, UGSA, Canadian Government
	• Mesh placed abdominally for POP repair may result in lower rates of mesh complications as compared with transvaginal mesh surgery	AUGS, RANZCOG, UGSA, RCOG, FDA
9	There is no restriction on the use of transabdominal mesh used during a minimally invasive or open sacrocolpopexy	CUA, NICE
Patient selection		
1	POP vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk:	AUA, Scottish review, SCENIHR, FDA, ACOG, IUGA, EAU, EUA
	• Recurrent prolapse where an abdominal sacrocolpopexy is contraindicated;	CUA
	• Complex cases, in particular after failed primary repair surgery;	SCENIHR, EAU, EUA
	• Recurrent prolapse (particularly of the anterior compartment);	AUGS, IUGA
	• Patients with increased risk of recurrent prolapse such as the obese, the young, those with chronically raised abdominal pressure (severe asthma, constipation), and those with stage 3 and 4 prolapse may find the risk/benefit balance of transvaginal mesh procedures acceptable	AUGS, FEBRASGO, RANZCOGJSOG, JUA, JFPFM, JPOPS
Informed consent		
1	Inform patients about the benefits and risks of non-surgical options, non-mesh surgery, surgical mesh placed abdominally, and the likely success of these alternatives vs transvaginal mesh surgery	AUGS, AUA, CUA, RANZCOG, UGSA, Scottish review, RCOG, Govern. Can., SCENIHR, FDA, ACOG, NAFC, NICE, EAU, EUA
2	For patients with postoperative symptoms that are not clearly caused by a mesh complication, removal of vaginal mesh may not improve the symptoms, and in fact may worsen their condition	AUA
3	For patients who have had vaginal mesh surgery for POP and are satisfied with their results, there is no need to take any action other than routine check-ups and follow-up care	AUA

(Continues)

TABLE 2 (Continued)

Aspect	Position statement	Associations
4	Provide patients with a copy of the patient labeling from the surgical mesh manufacturer if available	Scottish review, Canadian Government, FDA
Technical		
1	All gynecologists should be aware of and be encouraged to make full use of the ability to report adverse events from mesh surgery	RANZCOG, UGSA, Scottish review, Govern. Can., JSOG, JUA, JFPFM, JPOPS
2	Surgeons should undergo training specific to each device and have experience with reconstructive surgical procedures and a thorough understanding of pelvic anatomy	AUGS, AUA, CUA, RANZCOG, UGSA, Scottish review, RCOG, Canadian Government, SCENIHR, FDA, ACOG, JSOG, JUA, JFPFM, JPOPS, NAFC, NICE, SGS, EAU, EUA
	Surgeons should be able to demonstrate experience and competence in non-mesh vaginal repair of prolapse including anterior colporrhaphy, posterior colporrhaphy, and vaginal colpopexy (e.g., uterosacral or sacrospinous ligament fixation) before training in and performing vaginal mesh surgery	RANZCOG, UGSA
	Surgeons should demonstrate experience and expertise in performing intraoperative cystoscopy to evaluate bladder and ureteral integrity	RANZCOG, UGSA
Future aspects		
1	Rigorous comparative effectiveness trials of synthetic mesh and native tissue repair and long-term follow-up	ACOG, NICE
2	Outcomes and complications of transvaginal placement of surgical mesh for POP should be monitored longitudinally, preferably using a statewide or national data collection mechanism so that peer comparison may be obtained	RANZCOG, UGSA, Scottish review, RCOG, NICE
3	When using the newer light-weight, transvaginal permanent meshes, consider recruiting into a clinical trial because these meshes have not been evaluated within a RCT. At minimum, extensive discussion regarding other options and referral for a second opinion should be considered. Clinical audit of all mesh procedures is encouraged	RANZCOG, UGSA, Scottish review, SCENIHR, SGS, ACOG, EAU, EUA

Abbreviations: ACOG, American Congress of Obstetricians and Gynecologists; AUA, American Urological Association; AUGS, American Urogynecological Society; CUA, Canadian Urological Association; IUGA, International Urogynecological Association; ICS, International Continence Society; EAU, European Association of Urology; EUA, European Urogynecological Association; FDA, Food and Drug Administration; FEBRASGO, Federaçao Brasileira das Associações de Ginecologia e Obstetricia; JSOG, Japan Society of Obstetrics and Gynecology; JUA, Japanese Urological Association; JFPFM, Japanese Society of Female Pelvic Floor Medicine; JPOPS, Japanese Society of Pelvic Organ Prolapse Surgery; NICE, National Institute for Health and Care Excellence; NAFC, National Association for Continence; RANZCOG, Royal Australian and New Zealand College of Obstetricians and Gynaecologists; POP, pelvic organ prolapse; SCENIHR, Scientific Committee on Emerging and Newly Identified Health Risks; RCOG, Royal College of Obstetricians and Gynaecologists; RCT, random clinical trial; SGS, Society of Gynecologic Surgeons; SUFU, Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction; UGSA, UroGynaecological Society of Australasia.

if they occur. It may be important to inform the patient if the surgeon is relatively inexperienced with a new surgical technique or device.

Clinicians should provide patients with clear written information, booklets, or access to websites that clearly describe the risks associated with the procedure and any available alternatives before women make a decision on whether they wish to proceed with surgery.[8] Various societies have prepared peer-reviewed patient information documents that are readily available to share with women. Surgeons should familiarize themselves with these resources and use them as part of the informed consent process.

The implantation of any transvaginal mesh for the treatment of POP should be considered only in complex cases, where the benefit of mesh placement justifies the recognized risks (Table 2). Such cases include recurrent POP, especially in the presence of poor-quality collagen, increased intra-abdominal pressure, and large anterior compartment prolapse, and cases with contraindication to abdominal surgery.[32] The procedure should be performed by a surgeon with a special expertise in mesh placement techniques, who is capable of recognizing, diagnosing, and treating potential mesh-related complications (Table 2). Surgical management of mesh erosion and contraction may be particularly challenging owing to the proximity of the bladder and bowel; thus, referral to a center with expertise in these techniques is recommended to avoid creating further complications such fistula formation. It is important to emphasize the importance of using intraoperative cystoscopy to evaluate bladder and ureteral integrity during any mesh-related surgery, and for implantation or revision.[12]

Long-term data are severely lacking on the efficiency and safety of synthetic mesh used in POP repair. Most recommendations are based solely on short-term data. As longer-term data become available, the recommendations may need to be modified, and surgeons should remain informed of any revision of these statements. Evidence on outcomes of the new prolapse repair mesh devices is also based on case series with relatively short-term follow-up. A retrospective multicenter

study involving the use of mesh devices (289 women) demonstrated excellent short-term cure in the management of female POP, but with significant complications: buttock pain (5.2%), vaginal erosion (10%), one case of bladder erosion, and two of serious infection.[33] Caution must therefore be employed before newer operations, materials, and devices are introduced into clinical practice. Fortunately, long-term follow-up studies have confirmed efficacy and a low complication rate for use of the synthetic mesh for SUI treatment.[34] Long-term effectiveness for up to 17 years has also been demonstrated after sling procedures.[35,36]

Randomized controlled trials with long-term follow-up would be the optimal method for evaluating the efficacy and safety of vaginal mesh surgery.[37] Owing to a lack of such studies, the outcomes and complications of transvaginal placement of synthetic mesh for POP should be followed longitudinally so that peer comparison may be obtained (Tables 1 and 2). Only through ongoing research will procedures using synthetic mesh for the treatment for SUI and POP be improved for women in the future.

Ideally, each surgeon should track their own surgical outcomes. This challenge is greatly reduced by the wide availability of self-monitoring registries that are available through professional societies such as American Urogynecological Society (AUGS), IUGA, and British Society of Urogynaecology (BSUG). Data (pre-, post-, and intra-operative) can be entered by each surgeon on all treated patients and later retrieved for analysis. Unless permitted, the collected data are confidential and not accessible to other centers.

To ensure a product's safety, mesh-related complications must be reported via well recognized regulatory agencies, such as the Medicines and Healthcare products Regulatory Agency in the United Kingdom. In 2012, the FDA introduced mandatory post-market surveillance (522 studies) for all transvaginal mesh products for POP and for mini-slings to help determine the efficiency and safety of these products. In the interim, many transvaginal polypropylene mesh products have been voluntarily removed from the market, some companies have left the POP/SUI market, and new light-weight mesh products have been introduced. Consequently, the evidence used to assess early transvaginal mesh for POP may not applicable to the newer, light-weight transvaginal permanent meshes. A recent Cochrane review noted that newer light-weight transvaginal meshes that are currently available have not been assessed by randomized clinical trials.[38] Clinicians and women should be cautious when utilizing these products because their safety, efficacy, and any unique related complications have not been established.[38]

Data from women enrolled in PROSPECT (PROlapse Surgery: Pragmatic Evaluation and randomized Controlled Trial) have been collected at 1 and 2 years post-surgery.[8] This study aimed to compare the outcomes of POP surgery when performed with native tissues, synthetic mesh inlays, or using biological grafts. Synthetic or biological graft augmentation did not improve outcomes including effectiveness, adverse effects, and quality of life in the short term, but >10% synthetic mesh complication rate was reported. In light of this, long-term follow up is important to identify any significant complications when using a synthetic or biological graft for POP surgery.[8]

Recent medical science and surgical technology related to mesh use represent a fast-moving train with few stops. It is thus likely that recently launched mesh products have not yet been evaluated in sufficient patient volumes, or have had sufficient scrutiny in non-low-risk patients to recognize the risks and benefits associated with their use. As post-marketing data are collected and experience gained, it is not uncommon for previously unreported results to be recognized. These can be positive as well as negative but, in the case of vaginal mesh use, patients have reported adverse events that are relatively disturbing to their health and quality of life. As such, governmental agencies—which are given responsibility for looking after patient wellbeing—must address these complaints and act on the patients' behalf.

Most recently, public enquiries in Scotland, the United Kingdom, and Australia have involved patient and clinician testimony. The enquiries were focused on patient input, which was highly emotional, and directed toward legislators rather than clinicians. As such, they have resulted in recommendations to halt the sales of synthetic mesh products for POP (Australia and New Zealand) and a "pause" in mesh implanted via the vaginal route usage for urogynecologic surgery (United Kingdom). It is impossible to know how this current situation will evolve; however, it is clear that mesh use in the future will continue to be scrutinized by national regulatory agencies, the legal system, and patients. Once the "pause" is completed in the United Kingdom, it is unclear whether mesh products will again be available for use by pelvic floor surgeons. The most likely situation is that mesh surgery will be performed only in tertiary referral centers by surgeons with expertise in implantation and removal, and all women will have to be enrolled in a comprehensive national registry to track clinical outcomes.

Further imposed national bans on the use of synthetic mesh may be forthcoming and would further prevent many women from accessing the full range of treatment options available to them. In addition, further anti-mesh legislation or public pressure might essentially stop or stall the surgical studies mandated by the FDA,[11] and eliminate the production of data meeting high scientific rigor. We agree with AUGS that, instead of a ban on mesh implementation, evidence-based guidelines should be established so that mesh procedures are performed only by qualified surgeons and there is a formal mechanism for patient follow-up.

The review has some limitations. It was performed with predetermined search methodology; however, it was not possible to identify any proven, validated methodology for this type of survey. In addition, because not all societies publicize their recommendations in indexed publications, some published statements may have been missed. It seems unlikely, however, that any official recommendations would differ significantly from those presented in the review. Last, international focus on mesh use for urogynecologic indications is evolving very rapidly, and further national bans might have a significant impact on other countries. Thus, by the time the present review is in print, the situation may have evolved further.

5 | CONCLUSIONS

Gynecologic surgeons worldwide should become familiarized with reported outcomes resultant from the use of synthetic mesh in pelvic surgery. Most importantly, vaginal mesh use has been recognized to

be associated with specific patterns of complications; thus, surgeons should read and follow the advice in published position statements. The present review aimed to collect all available recommendation and position statements, and to organize their content to assist pelvic surgeons worldwide in providing effective and safe care to women with pelvic floor problems. Because FIGO represents the world's largest association focused on the wellbeing of women, the present FIGO-supported review should emphasize the importance of this project to gynecologic surgeons.

The committee hopes that this document will encourage all pelvic surgeons to use synthetic mesh only for specific recognized indications among their patients with POP and SUI, clearly discuss the risks and benefits of mesh use preoperatively with their patients, track their clinical and surgical outcomes methodically, and remain familiar with any new data that become available regarding vaginal mesh use. It is only through these efforts that pelvic surgeons will be able to optimize their outcomes when treating women with POP and/or SUI.

AUTHOR CONTRIBUTIONS

DGW is the Chairman, and T-HS is the past Chairman, of the FIGO Committee on Urogynecology and Pelvic Floor. AU and DGW contributed to project development, data collection and management, and manuscript writing. T-HS contributed to manuscript writing and revision.

CONFLICTS OF INTEREST

AU and T-HS have no conflicts of interest. GWD acts as a consultant (Boston Scientific, Laborie/Cogentix, POP Medical, Alma lasers), receiving research grants (Alma lasers, Pfizer, POP Medical).

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