

## **The Use of Mesh Implants in Vaginal Prolapse Surgery:**

### Position statement and recommendations of the South African Urogynaecology Association

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#### **Introduction**

Pelvic organ prolapse (POP) is a highly prevalent condition worldwide. It is estimated to affect approximately 50% of parous women<sup>1</sup>. The lifetime risk for surgery for POP or urinary incontinence has in recent times been quoted as 11%<sup>2</sup>. New data has however shown that this is an underestimation of current trends and that the lifetime risk is currently 20% at the age of 80 years<sup>3</sup>. Although South African data are lacking, local pelvic floor surgeons are seeing an increasing number of women presenting with and requiring surgical correction of their prolapse.

The last decade has seen an increase in the use of mesh-based products with many surgeons electing to use a mesh kit device. The expanding use of mesh kits is due to ease of use, increased surgeon training and the perception that traditional native tissue vaginal pelvic floor repairs for POP have a poor long term outcome. Aggressive marketing and industry sponsored training has also played a role in the adoption of these new techniques.

In July 2011 the FDA released a document (FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse; July 12, 2011) warning surgeons to be selective when using mesh for POP repairs<sup>4</sup>. The FDA concluded that “serious complications associated with surgical mesh for transvaginal repair of POP are not rare” and that “it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair”. One of the recommendations is to “choose mesh only after weighing the risks and benefits of surgery with mesh versus all surgical and non-surgical alternatives”. It is significant to note that this warning did not include the use of abdominal mesh for POP surgery (e.g. sacrocolpopexy), nor the use of full-length midurethral mesh for the treatment of stress urinary incontinence (e.g. TVT/TOT).

In January 2012, the FDA introduced to industry mandatory post market surveillance of all mesh implanted in the vagina – so called “522 studies”, together with the gathering of comparative data between mesh kits and conventional surgery. Since then, some 88 post market study orders have been issued to 33 manufacturers of vaginal mesh kits. Given the financial burden of performing such studies, some manufacturers have withdrawn wholly (Johnson and Johnson) or partially (Boston Scientific, CR Bard) from the market and anecdotally the overall use of vaginally implanted mesh in the USA has fallen by 40 – 60% since the FDA update announcement of July 2011.

SAUGA developed this document to serve as a position statement on the use of mesh and mesh-based kits in vaginal POP surgery.

### **Rationale behind the use of transvaginal mesh for POP**

Tissue repairs have traditionally been reported as having a poor anatomical outcome. This was in part due to the definition of success based on complete anatomical correction. If the definition is revised to utilize the level of the hymen as the determinant of success; tissue repairs are successful in approximately 75-85% of cases<sup>5</sup>. Prolapse recurrence (specifically anterior compartment prolapse) is also noted as a reason for mesh use. These factors were the main initial driving force for the development of transvaginal mesh. Mesh may lead to improved long term anatomic outcomes, but not necessarily superior functional outcomes.

Transvaginal mesh has specific complications associated with its use. The type and incidence of complications are related to the patient selection, procedure selection, surgical technique, and mesh characteristics. The prudent surgeon will therefore select the appropriate technique based on the specific defect, the quality of the tissues, the age of the patient and the surgical history. We should always bear in mind that a large part of surgery remains an art and that we are required to use our training, experience and insight to make the right selection of surgical technique. It is without doubt that certain patients will benefit from the use of mesh, but this decision need to be a joint one between surgeon and patient after a *thorough* discussion. The choices are however often a personal one without current Level 1 evidence guiding this decision.

### **Evaluating the evidence for transvaginal mesh repairs**

The last few years has seen a growing body of research into these products, however, the data needs to be interpreted with care. Recent years have also seen a number of publications regarding the use of mesh kits for prolapse repairs. Note that many of the mesh kits used previously are also no longer available. There are now sufficient publications to allow systematic reviews and meta-analyses to be published<sup>6,7</sup>.

Unfortunately most case-series have significant shortcomings:

1. Inclusion criteria are often poorly specified. Various degrees of prolapse are reported grouped together in most series, including primary as well as recurrent prolapse cases.
2. Outcomes often include only anatomical description. If functional outcomes are reported, they are limited to dyspareunia, urinary and defecatory dysfunction. Occasionally pain and rarely activities

of daily living are reported. Furthermore, if validated questionnaire were used, authors tend to report solely the overall scores, making the analysis of persistent or de novo symptoms difficult.

3. Native tissue repair controls are rarely included, and when they are the surgical techniques tend to differ.
4. Most series include single and multi-site grafted repairs.
5. Apart from the use of defined mesh kits, the description of the employed mesh, its properties, how it is tailored, where it is positioned, and what it is attached or sutured to, is typically inadequate.
6. The methodology for reporting anatomical outcomes varies.
7. Follow up is usually short with most series reporting one year or less.
8. Small case series. The largest report coming from the French TVM group including nearly 800 patients. However, most series include less than 200 patients.
9. The learning curve of the surgeons enrolling patients in these studies is typically not described.
10. Different inherent properties, including weave, elasticity, total surface area and weight of type 1 polypropylene mesh is used in different kits, making complications of case series inaccurate.

### **Patient factors to be considered when using mesh**

1. Age
  - It is impossible to guarantee a perfect outcome following any type of POP surgery. Adverse outcomes following mesh repairs, specifically pain and dyspareunia, suggest that caution should be exercised when using mesh in younger sexually active women. A recurrence may be easier to manage than a mesh complication.
2. Recurrent prolapse
  - A woman who has scarred, deficient endopelvic fascia has a greater chance for a recurrence<sup>8</sup> and is therefore a good candidate for a mesh procedure<sup>9</sup>. However, these patients should be warned that there is an increase in the incidence of surgical complications such as bladder and rectal injury, and further recurrence. Realistic expectation should be raised in the pre-operative counseling.
3. Site of prolapse
  - There are clear differences in the incidence, severity and recurrence rates of prolapse in the anterior, apical and posterior compartments. Anterior prolapse is more prevalent and more prone to failure after repair<sup>9,10</sup>. Large cystoceles invariably have an apical support defect which needs to be born in mind when deciding on the surgical approach and technique<sup>11</sup>.
4. Collagen deficiency

- Currently we have limited objective or laboratory criteria to adequately assess women for collagen deficiency. However, in a patient who has a clear history of joint hypermobility, laxity or a history of hernioses, due consideration should be given to the use of a mesh product.
5. Chronic and repetitive increases in intra-abdominal pressure
    - This includes women with chronic cough, COPD, chronic constipation and occupational heavy lifting. These may be indications for the use of mesh based products, but the underlying conditions should be optimized prior to embarking on surgery.
  6. Pelvic pain and/or dyspareunia
    - Post-operative vaginal and pelvic pain following POP surgery (native tissue or mesh based) is an extremely difficult and frustrating condition to deal with. If a mesh has been used, the patient may attribute the symptoms to the product. There is also no guarantee that removal of the mesh will alleviate the symptoms. The main risk factor for the development or persistence of post-operative pain is the presence of pre-operative pain. The pain may be exacerbated by any intrinsic or extrinsic stimulus. Recovery is delayed and sometimes protracted. Pelvic surgery itself may exacerbate systemic pain. The presence of a graft may be an additional deleterious stimulus.
  7. Pregnancy
    - There are no clear data regarding pregnancy in women who have undergone transvaginal mesh repair. Women who have not completed their families should therefore not have a mesh based prolapse operation.
  8. Atrophy
    - Always treat vulvo-vaginal atrophy adequately prior to performing a vaginal mesh based prolapse repair.
  9. Immunocompromised patients (diabetes mellitus, steroid use, HIV/AIDS)
    - These women experience potential poor healing post-operatively due to an impaired or abnormal inflammatory response. This increases the risk for vaginal mesh erosions. Caution should be exercised before considering a prolapse repair with a mesh based product in these women.
  10. Smoking
    - It is associated with an increased risk of mesh erosion which is likely due to reduced vascularity. In one series, the risk for erosion was increased 7-fold in smokers<sup>11</sup>.
  11. BMI
    - Apart from being a risk factor for POP in epidemiological studies, an increased BMI has been associated with an increased risk of mesh erosion and wound infection. In one series, the risk of erosion increased 10-fold in women with a BMI > 30<sup>12</sup>.
  12. Concurrent hysterectomy

- If a vaginal hysterectomy is performed (especially if a T-incision results at the vaginal cuff from an anterior wall incision), the risk of mesh erosion increase significantly<sup>13</sup>.

### **Aspects of informed consent for vaginal mesh**

The following aspects need to be addressed in the counseling process of a patient before informed consent can be given for the use of vaginal mesh products:

1. Information on the lack of good quality evidence and long term outcomes.
2. Alternatives to surgical management (e.g. pessaries, pelvic floor exercises).
3. Specific potential benefits and complications associated with vaginal mesh products.
4. Alternatives such as traditional tissue repairs and abdominal sacrocolpopexy (open or endoscopically).
5. Complications discussed should include: mesh exposure/erosion, dyspareunia, chronic pelvic pain, vaginal scarring/stricture, fistula formation and also that the removal of mesh might not resolve the pain complications.
6. Specific information on the type of mesh to be used should be communicated to the patient.

### **Training of pelvic floor surgeons**

- It is essential that surgeons performing vaginal mesh procedures be adequately trained and possess the required anatomical knowledge, surgical skills and experience for pelvic floor reconstruction. Specific knowledge of a mesh product should be acquired, for different products demand different training and skills.
- It is essential that surgical training should be “hands on” training on multiple occasions. Simple observation of theatre cases is insufficient to demonstrate adequate expertise in performing these surgical procedures
- Prior to being trained in and performing vaginal mesh procedures, surgeons should be competent in native tissue prolapse repairs such as anterior colporrhaphy, posterior repair, and vaginal suspension procedures (sacrospinous or uterosacral ligament fixation).

### **Accepted indications for different mesh based products:**

*Before embarking on a vaginal mesh based device, consider the following:*

- Abdominal sacrocolpopexy is the gold standard for apical compartment prolapse and should be offered if possible.
- Mesh based products in the posterior compartment have not shown to be associated with significantly better outcomes than native tissue repairs.
- Primary anterior repair of Stage 1 and 2 cystoceles should ideally be performed without mesh.
- Apical suspension and/or vaginal hysterectomy is an excellent option in women with mainly uterine prolapse and mesh is usually not necessary as a 1<sup>st</sup> line treatment.

### **Anterior vaginal compartment mesh kits (Anterior Avaulta, Elevate, Nuvia, Perigee, Restorelle DirectFix, and Uphold)**

The anatomical recurrence rate is lower with mesh (synthetic or biological) compared to anterior colporrhaphy alone. There is no significant difference in quality of life outcomes or de novo dyspareunia with polypropylene mesh, however with mesh kits there is a higher re-operation rate (mostly due to complications such as erosion)<sup>5</sup>. These tend to increase with time after exposure<sup>16</sup>.

Possible indications include:

- Recurrent anterior compartment prolapse with not more than Stage 1 apical prolapse (attempt to identify the reason for recurrence to guide individual management plan).
- Primary Stage 3-4 cystocele with no more than Stage 1 apical prolapse.
- Clear evidence of a lateral (paravaginal) defect cystocele

It is essential to be aware that an advanced stage cystocele (3-4) is mostly associated with an accompanying apical support defect. It is therefore imperative that apical support be provided along with the anterior repair. In the case of mesh kits, this would imply sacrospinous ligament anchoring.

### **Posterior vaginal compartment mesh kits (Apogee, Posterior Avaulta, Elevate, Nuvia, and Restorelle DirectFix)**

There is no clear evidence supporting the use of vaginal mesh as an alternative for a posterior tissue repair<sup>5</sup>. The addition of mesh does not improve anatomic outcome or quality of life outcome measures, but may give rise to mesh associated-complications.

Possible indications include:

- Recurrent posterior compartment prolapse due to poor tissue quality
- Posterior compartment prolapse greater than Stage 2 with associated apical descent.

## Combined anterior and posterior vaginal mesh

- Vault prolapse in women not suitable for abdominal sacrocolpopexy
- In women with uterine prolapse greater than Stage 2, it may be better to perform a vaginal hysterectomy and anterior tissue repair.

## Final comment

Conservative management and native tissue repairs must be discussed as an alternative prior to using a mesh device. When anatomical evidence dictates otherwise (e.g. info gained with imaging, i.e. levator avulsion) then a mesh device may be considered. An abdominal mesh procedure (sacropexy) is better than having a vaginal mesh approach. Complications are higher in low volume mesh users (surgeons) and formal training is strongly recommended. The ongoing post-marketing studies (FDA 522) should be monitored closely.

The FDA has approved safety guidelines for surgeons who continue to make use of mesh and SAUGA strongly endorse these. The American Urogynecologic Society (AUGS) also provides an informed consent toolkit available for public use and patient education<sup>14</sup>. Most recently an IUGA round table submitted recommendations on the appropriateness of the use of mesh in vaginal surgery<sup>15</sup>. For additional resources and membership information please visit: [www.sauga.org.za](http://www.sauga.org.za)

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