The vaginal mesh saga and solutions with MESH FREE SURGERY

The Vaginal Mesh Misadventures
The Therapeutic Goods Association (TGA) has been monitoring surgical meshes in Australia since 2008. A literature search of published materials since 2009 found the overall quality of the literature to be poor. The literature did identify the known adverse outcomes associated with their use. However, there was little evidence to support the overall effectiveness in trans vaginal pelvic prolapse repair. The use of mesh for treatment of stress urinary incontinence and abdominal pelvic organ prolapse repair was adequately supported by evidence.

Because of adverse outcomes, Shine Lawyers in Australia has commenced a class action against mesh manufacturers on behalf of over 500 plaintiffs. As a result of court action and Regulatory authority intervention manufacturers worldwide have voluntarily withdrawn products.

The number of meshes available for clinical use in Australia has shrunk over four years from over 100 products to less than 5 manufacturers providing meshes. Only a few pelvic organ prolapse mesh repairs are still being performed by Australian surgeons. The less robust traditional native tissue plication repairs have been on the uptake.

Currently, an increasing number of patients are requesting a surgical solution without mesh.

Mesh Free Pelvic Organ Prolapse Surgery
With a better understanding of the anatomy and function of the pelvic support mechanism, surgical techniques have been refined to result in improved restorative anatomical outcomes. Long term data is currently being collected.

Surgery has been further modified by the utilisation of general surgery hernia principles, meticulous attention to restoring the anatomic ligamentous and muscular supports where possible and the judicious use of third generation collagen scaffold remodelling biografts.

Techniques and advances in imaging especially dynamic MRI, MRI defaecogram, and 3D/4D trans perineal ultrasonography have provided a better understanding of the pelvic anatomy and the function of the pelvic supports. Delineation of the anatomical structures in the pelvic support zones and delineation of the actual damage to the supports has enhanced surgical planning and prognoses.

No single procedure fits all. Each patient undergoes operative procedures individually selected to correct each particular anatomical disruption.

In Summary
This medical practice sees no call for synthetic mesh. Native tissue repair with the judicious use of third generation collagen scaffold remodelling biograft provides superior outcomes with less morbidity.

Mesh Free Cure of Stress Urinary Incontinence
Those patients who are desirous of a durable and robust polypropylene mesh free repair of stress urinary incontinence with success rates equal to or exceeding the existing TVT can be offered a bladder neck sling utilising their own autologous fascia. By moving attention from the mid-urethra to the bladder neck excellent results can be achieved elevating this “Sling on a String” procedure or pubo vaginal autologous rectus sling to the status of the Gold Standard.

A 7 cm strip of rectus sheath is harvested through a transverse 5cm supra pubic incision. Delayed absorbable sutures attached to the distal ends of the harvested rectus sheath strip are fed through a vaginal incision to exit above the restored rectus sheath. An air suture secures the sling above the rectus sheath. Hospital stay is generally 48 hours. Indications for the procedure include:

- Primary repair in young women
- Primary repair in hyperallergic individuals
- Patients with intrinsic sphincter deficiency
- Repeat and salvage procedures

Complications
The material complication is outflow obstruction. Fine tuning of surgical techniques has significantly reduced this incidence. Less than 4% of patients require return to the operating theatre to remove the superficial skin sutures to allow access to loosen the air suture and thus relieve the obstruction.

Outcomes

Patient satisfaction: 73% initially claim good quality of life decreasing with longer follow up.

Fate of the Implanted Rectus Sheath
Post implantation biopsies have been taken at 3 weeks, 5 weeks, 8 weeks, 17 weeks and 4 years.

Fibroblast proliferation, neovascularisation and extensive graft remodelling occurs. There is no inflammatory reaction nor graft degeneration. Fibroblast proliferation with linear orientation of connective tissue and fibroblast provide adequate tensile strength for the physiological role.

Understanding Biografts
Misconceptions abound about the understanding and the defining of biografts. The term biograft encompasses all grafts and meshes implanted in a patient.

The first generation biografts from the 1950’s on were required to have minimal interaction or reaction with human tissues. These grafts mainly included industrial products such as polymers and alloplastic meshes, elastomers and pyrolytic carbons. These grafts include hernia meshes, vaginal meshes, and tension free vaginal tapes (TVT). The goal was to insert a product that was bioinert.

The second generation biografts from 1980’s on had a goal of bioactivity and included resorbable bio materials such as polyglycolic acid (PGA) sutures, Vicryl sutures or involved a controlled reaction with the physiological
environment involving bone bonding, controlled drug released products such as Mirena and drug eluting stents.

The third generation from 2000 on had the goal to regenerate functional tissue. These grafts included Cook Medical SurgiSIS, Boston Scientific Xenform and autologous rectus sheath pubo vaginal slings. These products are required to be bio-interactive, integrative, resorbable and have the capability to stimulate specific cellular responses at a molecular level involving proliferation and differentiation of tissues and extra cellular matrix production and organisation. This is a basic bio engineering principle known as Dynamic Reciprocity.

The key concept to these third generation bio grafts or bio degradeable scaffolds is that these acellular scaffolds usually of collagen contain or attract specific chemical and structural information in the form of signalling proteins and growth factors to control tissue formation analogous to cell to cell communication and patterning during embryological development with a highly precise reaction with proteins at a molecular level.

These scaffolds are of two types
1. Extracorporeal seeding of scaffolds with cells then undergoing subsequent implantation.
2. Scaffolds implanted to specifically attract endogenous functional cells invivo. Three to six months following implantation the scaffold is replaced by fibroblast, endothial cells epithelial cells and native collagen. No residual implant products be they porcine, bovine or autologous remain in this remodelled and regenerated native tissue.

Religious objections to animal derived products are misconstrued. The American medical literature states “there is no prohibition in Islam to the use of porcine, bovine or allogenic products in surgery” – Professor Abdul Aziz Sachedina, Professor of religious studies, University of Virginia (Enochs et al 2005 j med ethics).

Australian surgeons L.C.Easterbrook and G. Madden evaluated the current Australian literature up to 2008 in an article published in Arch Surg entitled “Porcine and Bovine Products – Jewish, Muslim and Hindu perspectives in Australia.”

The authors sought the opinion of religious leaders in Australia concerning the religious beliefs among persons of Jewish, Muslim and Hindu perspectives in Australia to determine if animal-derived surgical implants were permitted for use in these religious.

The authors found that dietary restrictions in these religions do not translate to tissue implantation. There is however a rider that there are scholars and religious leaders who would prohibit the use of porcine products in surgery unless there were no other options for treatment.

Provided proper informed consent is collected there can be no opposition to their use.

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**INSURED PATIENTS**

- Insured patients are fully covered by their health insurance with no out of pocket expenses for doctors fees.
- Insured patients should check with their private health insurance as to whether they are covered for day hospital expenses.
- Private facilities include:
  - Sunnybank Urodynamics
  - Caboolture Urodynamics

**SERVICES PROVIDED**

- Detailed urogynaecological history and examination
- Office cysto-urethroscopy
- Multichannel urodynamics with pudendal ultrasonography
- Uroflowmetry
- Prolapse and pelvic floor assessment
- Diagnosis
- Detailed management plans
- Surgical training, preceptorships and mentoring

**UNINSURED PATIENTS**

- Uninsured patients are fully covered by the Medicare rebate. There is no out of pocket expenses to the patient.
- Uninsured patient facilities include:
  - Silverton Urodynamics
  - Noosa Urodynamics
  - Gympie Urodynamics
  - Maryborough Urodynamics
  - Toowoomba Urodynamics
  - Bribie Urodynamics

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**URODYNAMIC CLINICS**

- **Silverton Urodynamics**
  101 Wickham Tce
  BRISBANE
- **Sunnybank Urodynamics**
  Sunnybank Private Hospital
  245 McCullough St
  SUNNYBANK
- **Maryborough Urodynamics**
  St Stephens Medical Centre
  10/166 John St
  MARYBOROUGH
- **Gympie Urodynamics**
  Sunshine Health
  67 Channon St
  GYMPIE
- **Noosa Urodynamics**
  Sullivan Nicolaides Centre
  90 Goodchap St
  NOOSAVILLE
- **Toowoomba Urodynamics**
  St Andrew’s Hospital
  Suite 35 BLDG 4 North St
  TOOWOOMBA
- **Caboolture Urodynamics**
  Caboolture Private Hospital
  McKean St
  CABOOLTURE
- **Bribie Urodynamics**
  Elysian Medical Centre
  Shop 3, 45 Benabrow Ave Bellara
  BRIBIE ISLAND