Prolapse repair using Vaginal Mesh

National Women's Health, Auckland City hospital.

What is vaginal mesh?

Vaginal mesh are generally made of non-absorbable polypropylene, derived from non-absorbable sutures, entwined in a woven or knitted mesh construction. Some vaginal mesh implants may also have a biological or absorbable component. They are permanent implants that are not intended to be removed.

Why is vaginal mesh used?

Vaginal mesh is one of the options for the surgical repair of pelvic organ prolapse. It is an alternative to surgery where the patient's own tissue is repaired using sutures (stitches) alone. Mesh prolapse repairs can also be done via an abdominal approach which in turn can be either open abdominal or keyhole surgery. Typically vaginal mesh has been considered for use in cases where a previous operation has failed and the prolapse has recurred.

Vaginal mesh use at National Women's Health

Vaginal mesh kits were approved by the FDA (Food and Drug Administration) in the USA in 2002. Auckland City Hospital started using them in 2005. Prior to their development surgeons had used the mesh used for hernia repair in extreme cases of prolapse where other surgery had failed. This was not ideal technology and the purpose-designed mesh kits were felt to be a significant advancement for vaginal prolapse surgery.

All surgeons who place vaginal mesh at National Women's health have, as in most centres, been through specific training in these techniques. They have the surgical ability and anatomical knowledge required to place or to remove part or all of the mesh in the rare instance that this may be required.

What is the position of MedSafe, the New Zealand Medicines and Medical Devices Safety Authority at the Ministry of Health?

Medsafe continues to monitor adverse event reports relating to the use of surgical mesh implants. Some medical device regulators have raised concerns about such mesh implanted transvaginally to treat certain conditions. Medsafe has investigated surgical mesh and concluded that it is safe when used in accordance with the manufacturers' instructions by an appropriately trained surgeon. This conclusion is in line with that of other device

regulators and professional bodies. Medsafe notes that surgical mesh remains approved for use by medical device regulators globally.

The National Women's Health experience

We performed a retrospective audit of all vaginally-placed mesh used for prolapse repair between January 1st 2005 and 31st December 2013. The audit was performed as part of a trainee research project required for Obstetrics and Gynaecology specialist training.

The aim of this audit was to look at specific complication outcomes to compare with those in the international literature.

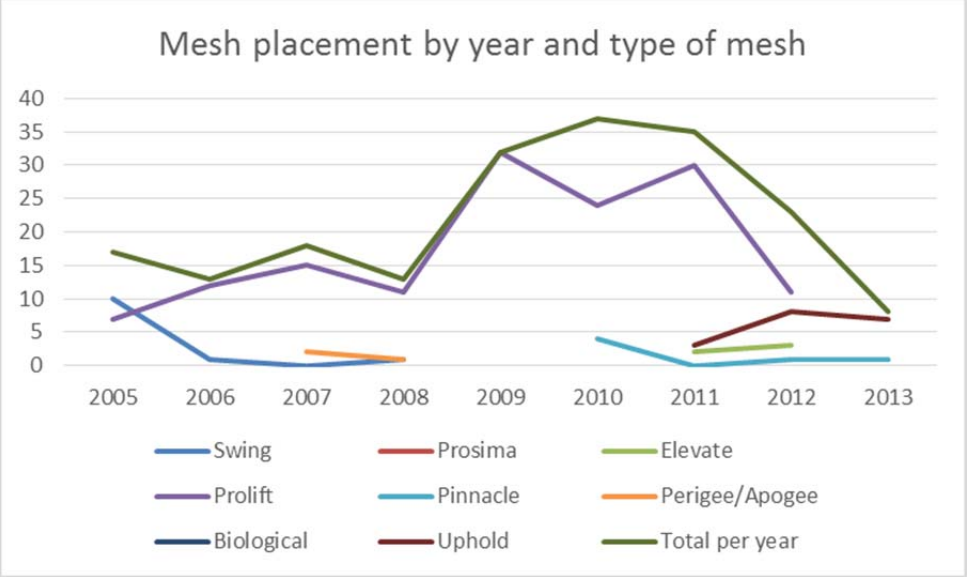

Diagram 1: This graph represents how the use of vaginal mesh kits varied over time as different types of devices and delivery systems became available and popularised. Placement of mesh during prolapse repair reached its peak between 2009-2011.The use of mesh fell sharply from 2012 onward after the FDA caution with regard to mesh specific complications.

Over this period vaginal mesh was placed in 192 women, in which there were a total of forty two recorded complications. Thirty one patients (16.1%) had what was considered to be an issue related to vaginal mesh. These included; mesh exposure through the vaginal skin in fifteen women (7.7 %); erosion of mesh into the bladder in one woman (0.5%); sixteen women (9%) developed urinary incontinence after placement of the mesh, having not previously had this problem but only eight (4.5%) required an incontinence surgery to treat this issue. Urinary stress incontinence however is a recognised problem that can occur after having a non-mesh prolapse repair as well. Among the audited cases there were eight patients (4.1%) where the bladder was entered and six (3%) where the trocars (medical instrument used to place mesh internally) entered the bladder. There were three patients (1.5%) who required blood transfusion.

Of the women with mesh exposure ten were required to return to theatre to fix the exposure and five healed with conservative treatment.

How do we compare to other international centres?

Overall these results compare favourably to the complication rates reported internationally, with the exception of bladder injury which was slightly higher. Unfortunately we have not recorded any information on the rate of chronic pain after mesh surgery and our assessment of pain with intercourse following this surgery was also limited.

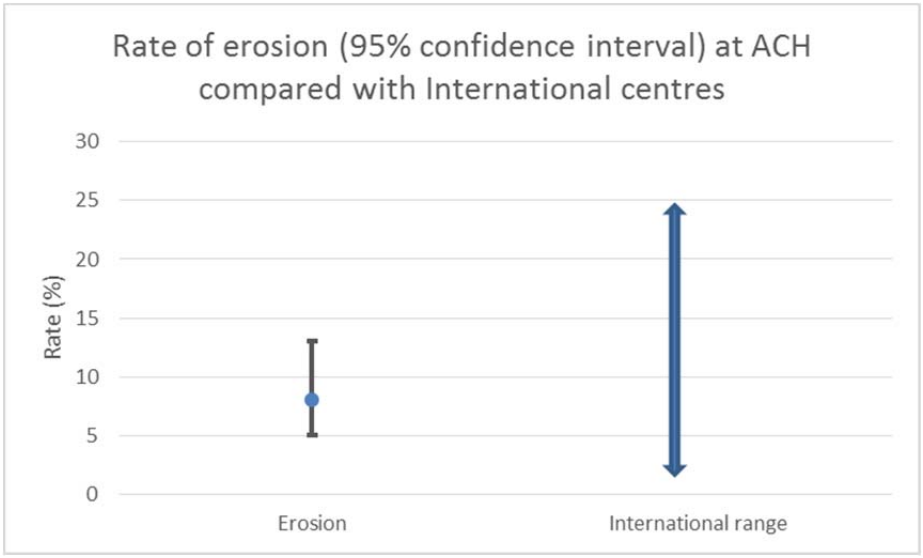

Figure1: Rate of vaginal mesh exposure/erosion (95% confidence interval) at Auckland City Hospital compared to International centres

How has our use changed over time?

As the first graph shows, our use of vaginal mesh increased from 2008 until 2011. Since then we have used it far less, in keeping with international trends. This change has come about due to a growing awareness of complications that are specific to mesh use and the subsequent advice from overseas regulatory bodies. There has also been the withdrawal of some mesh products from the market. In certain situations, there will be cases where the surgeon may believe that a vaginal mesh repair is appropriate. This will be fully discussed with the patient before a decision is made.

What should you do if you have had a vaginal mesh procedure and have questions or concerns?

If people do have concern about issues with vaginal mesh, they should in the first instance go back to the surgeon who placed the mesh. If this is not possible they should be referred to their regional hospital gynaecology department and if necessary they can be referred to the Urogynaecology clinic at Auckland City Hospital where we now run a multidisciplinary team to deal with these issues.