MIPS LECTURE AT UNUFU MEETING IN TESSALONIKI
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Mesh or not mesh for POP surgery

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The first decade of this century has seen the rapid development of mesh reinforcement surgery for pelvic organ prolapse. The advent of TVT in late nineties and the good vaginal tolerance of polypropylene encouraged surgeons to put large meshes to treat POP vaginally. The description of TOT was followed by the description of trans–obturator arms fixation of meshes.Tension-free Vaginal Mesh (T.V.M) and the world-wide distribution of kits with the aim of simplifying surgical techniques, thus making it accessible to every surgeon.

This popularization of synthetic meshes in POP surgery was accompanied by a rapid rise in reports of mesh related complications, with vaginal wall erosion up to 25%, chronic pain, 5.5% and sexual problems up to 17% (1). Theses complications are often difficult to treat requiring further reconstructive surgeries. In July 2011, the FDA made a Safety Communication and Update on Serious complications associated with transvaginal placement of surgical mesh for POP. This led to a wave of class action litigation law suits raised against device manufacturers by patients who have suffered mesh complications. Several major manufacturers have withdrawn their products from the market.

The FDA alert pointed out:

- lower rates of mesh complications when mesh is placed abdominally compared to transvaginally.
- no evidence that transvaginal apical or posterior repair with mesh provides any added benefit compared to traditional surgery without mesh
- transvaginal anterior repair with mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh, this anatomic benefit may not result in better symptomatic results.
- the emergence of two major complications of mesh transvaginal surgery, vaginal erosion and mesh contraction (shrinkage)

Mesh enthusiasm among surgeons as well as a high industrial lobbying led to a situation where a large number of mesh has been put for POP transvaginally and may explain the high rate of complications. One can also question about the quality of training of the surgeons who have been doing these mesh surgeries. Should mesh surgeries be reserved to surgeons specially trained in POP surgery?

The high rate of mesh contraction, shrinkage, and vaginal exposition of mesh occurred on first generation of mesh, high weight polypropylene. New generation of very light and large pores polypropylene mesh reduce vaginal exposition and stiffness of these mesh. New surgical techniques providing good apex fixation through sacrospininous

ligament by anterior route without lateral fixation of mesh (Uphold) may also reduce contraction of mesh.

Should mesh augmentation surgery be reserved to certain indications as suggested by the IUGA graft round table consensus in 2012 i.e recurrent anterior vaginal wall prolapse or situations where recurrence is high, high grade cystocele and increased intra abdominal pressure or paravaginal defect ? Meta-analysis has shown very good results on autologous tissue repair on apex fixation either USL (2) or SSF (3) and traditional posterior repair to ban mesh for apex or posterior repair.

A strict reduction policy in the use of mesh, reserving it to selected indications, may prove in the future, greater benefit compared to risk of mesh surgery.

As mandated by the FDA, one should ask for clinical pre-market studies before using new mesh and new techniques. Prior to clinical studies, tolerance of mesh in the vagina must be tested in animal models before implantation in humans.

The second part of the lecture discussed about contraction of mesh and vaginal exposition and surgical techniques of unfixed or temporary fixation of mesh which may be a solution to mesh contraction and all the related clinical effects i.e chronic pain, dyspareunia and vaginal exposition of mesh. This fact rests on our 14 years experience with vaginal POP surgery with mesh.

Fixed mesh with trans-obturator arms correct the POP and replace vaginal supports and ligaments. These mesh will support the entire abdominal pressure permanently. Due to tension on the fixed arms, intense inflammatory reactions occur in these regions with thick, rigid scarring tissues responsible of pelvic pain and dyspareunia as well as mesh exposition. On the contrary, in unfixed mesh, (fig 1) the role of the mesh is reinforcement of deficient fascia and ligaments. The POP is corrected by convenient anatomic site specific repair i.e solid apical fixation by uterosacral ligament or sacrospinous ligament vault fixation, anterior and posterior repair. In this case, the mesh can contract freely, in all directions, with less inflammatory reaction and the absence of clinical effect of contraction of mesh (fig 2)

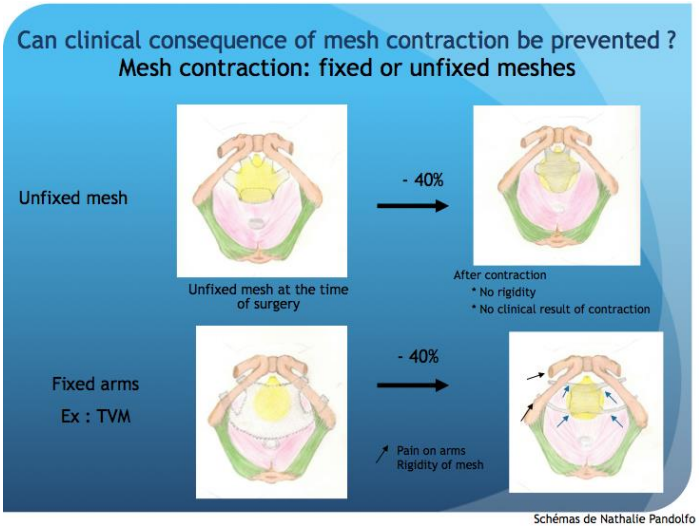

fig 1 : Comparison of contraction of mesh in unfixed and fixed trans-obturator mesh

Animal studies showed that when polypropylene mesh is used to repair a fascial defect, in this case the mesh is in permanent tension, the contraction rate is 29%. (4)
On the other hand, when the mesh lies on the fascia, without defect, the mesh is not in tension, the contraction rate is 1.7% (5) . This fact may explain a different behaviour of unfixed mesh on contraction of mesh

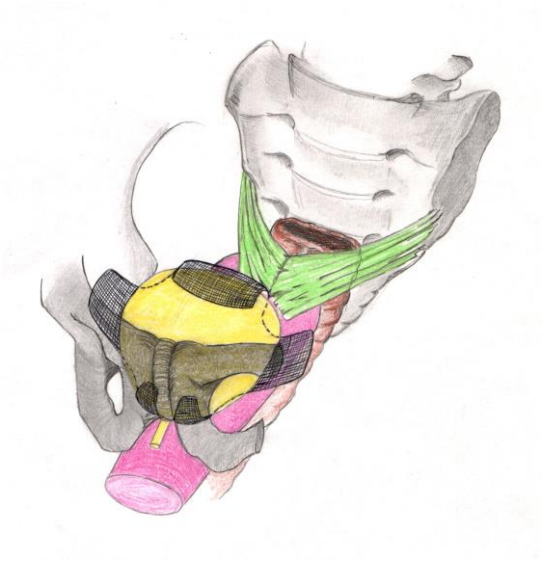

fig 2 : Unfixed anterior mesh with lateral arms in contact with arcus tendineous levator ani

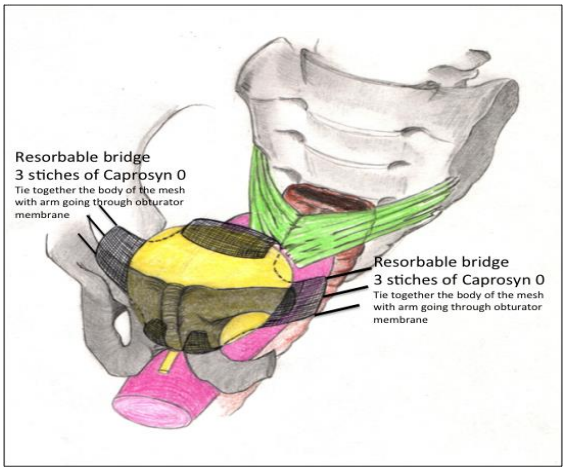

Fig 3 : Temporary fixation to arcus tendineous levator ani with absorbable sutures

Clinical evaluation has been done on unfixed anterior Prolene° mesh (80 g/m2), on 250 patients operated between 2001 and 2005. Two hundred and twenty patients had follow up with a mean of 6 years. The vaginal mesh exposition rate was 2.2%, no patient was re-operated for pelvic pain or contraction of mesh. A second cohort of 90 patients, operated

between 2006 and 2009, having an unfixed low weight PP mesh 22g/m2 , Novasilk° Coloplast was studied. Sixty patients had 6 years follow up. Vaginal mesh exposition rate was 1.7% with no patient having surgery for contraction of mesh or pelvic pain. In this series, the anatomic failure rate was high, 28 % stage 2 where as 91,7% of patients were satisfied or very satisfied. This is due to the absence of correction of the paravaginal defect in stage 3 or 4 POP prolapse. This led to a technical improvement using a trans-obturator arm on each side but with an absorbable bridge between the body of the mesh and the arms, allowing the correction of paravaginal defect. Once the mesh is integrated in the right position, the body is freed allowing contraction of mesh if necessary without tensioning on any part of the mesh. The last improvement of the technique is the abandon of the trans-obturator arms which are replaced by temporary fixations to the arcus tendineous levator ani with absorbable loops using suturing devices.(fig 3)

In conclusion, there is no need to use mesh for apical fixation nor for posterior repair. In certain indications, mainly in recurrent anterior vaginal wall prolapse or situations where recurrence is expected, i.e high grade cystocele or para vaginal defect or levator ani avulsion, anterior vaginal reinforcement mesh surgery may be helpful. Animal studies and further clinical studies performed by other teams are necessary to confirm our data of the absence of contraction of mesh if it is fixed with temporary fixations with absorbable sutures.

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