**Original article**

# Ingynious: single-incision advanced pelvic floor repair with hexapro-mesh (A.M.I.)

EMANUELA MISTRANGELO[1], FRANCESCO DELTETTO[2], GIORGIO FEBO[3]

[1]*NewMed Surgical Insitute, Albenga (SV) – Italy*
[2]*MIG Mini Invasive Gynecology, Torino – Italy*
[3]*U.O. Ginecologia e Ostetricia, Ospedale di Pescara – Italy*

*Abstract:* With the release of the FDA statement, it has become increasingly important to reduce mesh-related complications. The aim of this abstract is to describe a new generation single-incision pelvic reconstructive technique using an isoelastic ultra-light mesh (21 g/m). Between 1st March 2011 and 31st July 2012, women with pelvic organs prolapse ≥ stage II underwent repair through the InGYNious technique (AMI Agency for Medical Innovations, Austria). The surgical technique ensures the fixation of the anterior and of the posterior compartments to the sacro-spinous ligament and the recreation of lateral support to the arcus tendineus fascia pelvis (anterior) and to the iliococcygeus muscle (posterior). One-hundred-twenty-two InGYNious procedures were performed, 98 conserving the uterus and 24 in patients with vaginal vault prolapse. The only intraoperative complication was a single case of bladder lesion. At one-year follow-up 98 patients were reviewed. The objective cure rate was 93.9% (92/98) with only 2 (2.0%) cases of vaginal mesh exposure. In conclusion, the InGYNious procedure is a minimally invasive technique to treat pelvic prolapse through a single vaginal incision. Initial results show the procedure to be safe and early efficacy is promising. Longer-term follow-up is ongoing.

*Key words:* Pelvic prolapse surgery; Vaginal Mesh; Light mesh for prolapse; Single incision vaginal mesh; Prolapse conservative treatment.

## INTRODUCTION

The high recurrence rate of pelvic organ prolapse after traditional pelvic reconstructive surgery has been estimated to be up to 30%.[1] On the other hand, with the release of the FDA statement,[2] it has become fashionable to criticize the use of mesh.[3] Thus, it has become increasingly important to improve surgical strategies to decrease the incidence of surgical failure and at the same time to reduce mesh-related complications.

The aim of this manuscript is to describe a new generation single-incision pelvic reconstructive procedure using an isoelastic ultra-light mesh, which could meet the criteria described above.

## MATERIALS AND METHODS

Between 1st March 2011 and 31st July 2012, 122 InGYNious (A.M.I., Austria) procedures were performed. InGYNious is a new mini-invasive trocar-less procedural kit for pelvic floor repair, which allows to obtain a strong upper support and a complete reconstruction, combining these factors with the characteristics of one of the lightest mesh on the market (21 g/m$^2$) (Figure 1).

We reviewed the clinical records of patients who had been treated for stage II-IV pelvic organ prolapse with the InGYNious technique between March 1, 2011 and July 31, 2012.

### *Surgical technique*

The surgical technique varied according the site of the pelvic organ prolapse. These step by step instructions describe the reconstruction of the anterior compartment (using the InGYNious Anterior mesh – Fifure 2 – if conserving the uterus or the InGYNious Vault mesh – Figure 3 – in the case of vault prolapse or concomitant hysterectomy).

STEP 1: **anterior infiltration** using normal saline 40-60 ml +/- adrenalin.

STEP 2: **anterior incision,** this is a full thickness vertical incision, deep enough to reach the layer under the fascia.

STEP 3: **open the paravesical space bilaterally**, reaching the spine and identifying the sacrospinous ligament and arcus tendineus fasciae pelvis.

STEP 4: **create the anterior apical attachments**, using a non-absorbable polyester suture, which is attached bilaterally to the sacrospinous ligament, > 2 cm from the spine, using i-Stitch (A.M.I.) (Figure 5), a narrow suture instrument which can easily access the sacrospinous ligament.

STEP 5: **create the anterior lateral attachments**, placed on each side in the arcus tendineus fascia pelvis, > 2 cm from the spine, using i-Stitch (A.M.I.).

STEP 6: **create the anterior superficial attachments**, to the anterior part of arcus tendineus fasciae pelvis, using i-Stitch (A.M.I.).

STEP 7: **placement of the mesh**, using feeders to pass the sutures in their correct position.

STEP 8: **fix all sutures**, following the levels order.

STEP 9: **vaginal skin closure.**

For reconstruction of the posterior compartment (using the InGYNious Posterior mesh – Figure 4), we opened the pararectal space bilaterally after infiltrating and making an incision in the posterior vagina wall. Once the spine was reached, we identified the sacrospinous ligament and iliococcygeus muscles. We create the posterior apical attachments placed on each side in the sacrospinous ligament, and the posterior lateral attachments placed on each side in

Figure 1. – HexaProMesh (A.M.I.), one of the lightest mesh on the market (21 g/m$^2$).

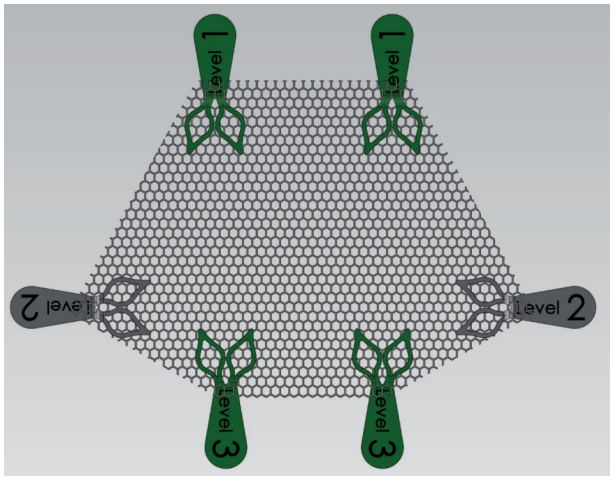


Figure 2. – InGYNious Anterior mesh (A.M.I.).

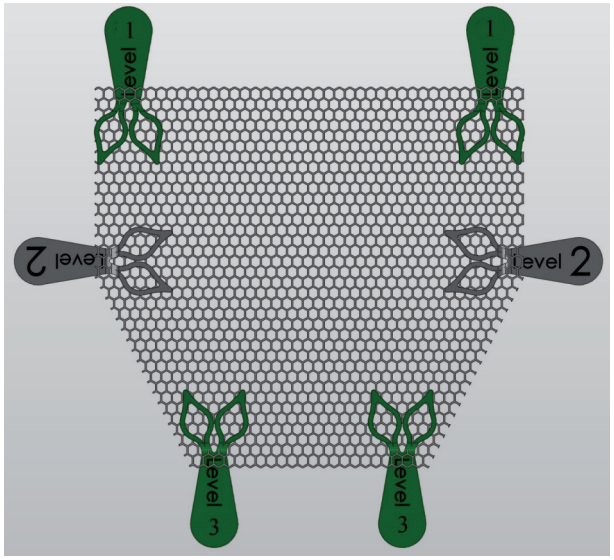


Figure 3. – InGYNious Vault mesh (A.M.I.).

the iliococcygeus muscle, 2 cm from the spine. The posterior superficial attachments are simply fixed in the perineal body.

For a complete reconstruction of both the anterior and the posterior compartment, separate incisions were performed and separate meshes were placed.

*Post-operative care*

The urinary catheter was removed 24 hours after the operation, or 48 hours post-operatively in the case of total repair. In all cases, patients were evaluated after urinary catheter removal for post-void residual volumes. If patient did not pass the voiding trial, she was sent home with an indwelling catheter and a second voiding trial was carried out on the seventh postoperative day.

All women received intravenous prophylactic antibiotic therapy for 48 hours following surgery, followed by five days of oral antibiotic therapy. All women received thromboprophylaxis with low molecular weight heparin for ten days after surgery. Post-operatively analgesics (intramuscular ketorolac) were given when requested by the patient. Post-operative reviews were performed at one month and again at one year.

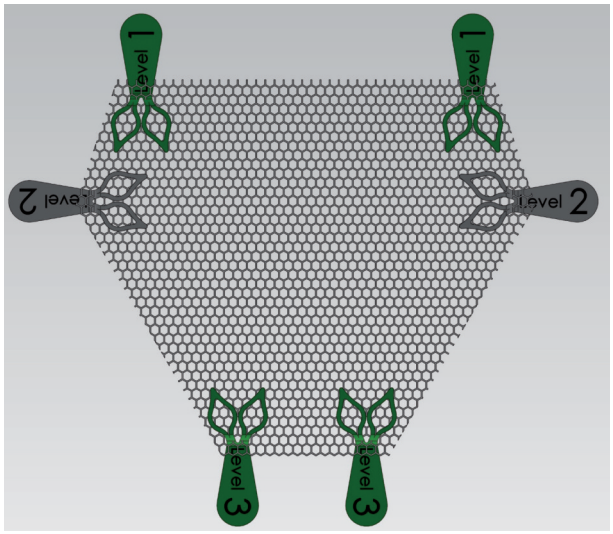


Figure 4. – InGYNious Posterior mesh (A.M.I.).


Figure 5. – i-Stitch (A.M.I.), the narrow suture instrument which can easily access the sacrospinous ligament.

## RESULTS

Of the 122 InGYNious procedures performed, in 98 patients we conserved the uterus, while 24 patients had vaginal vault prolapse. Bladder perforation occurred in one case, resolved maintaining catheter for 10 days. Thirty-one (25.4%) patients had post-operative levator myalgia, temporarily resolved with analgesic therapy. At one-year follow-up, 98 of the 122 patients were reviewed and the objective cure rate was 93.9% (92 patients completely recovered). Two (2.0%) cases of vaginal mesh exposure was observed, due to incomplete wound healing, one required partial excision of mesh with approximation of vaginal flaps, and other was treated conservatively

## CONCLUSIONS

According to the peri-operative and short-term follow up results, InGYNious seems to be a safe technique to correct pelvic organ prolapse with very good anatomical results. Moreover, the mesh of which is made Ingynious, called HexaPro-Mesh (AMI - Austria), is specifically designed to minimize fibrosis and retraction after surgery. In fact, it is a particularly soft isoelastic mesh, which has a weight of 21 g/m$^2$, less than other meshes used for the utero-vaginal prolapse, with a porosity of 93% and characteristic hexagonal pores that provide elasticity in all directions. At 1-year fol-

low-up we had only one case of mesh exposure, that was not a real erosion but it was due to incomplete wound healing.

Of course, anatomical and functional results, quality of life and sexual function questionnaires must be assessed with a long-term follow-up to evaluate the impact of the InGYNious procedure on the quality of life, but the results obtained so far are promising.

REFERENCES

1. Ming-Ping Wu. The use of prostheses in pelvic reconstructive surgery: joy or toy? Taiwan J Obstet Gynecol, 2008; 47:151-156
2. Clemons JL, Weinstein M, Guess MK, Alperin M, Moalli P, Gregory WT, Lukacz ES, Sung VW, Chen BH, Bradley CS; AUGS Research Committee. Impact of the 2011 FDA transvaginal mesh safety update on AUGS members' use of synthetic mesh and biologic grafts in pelvic reconstructive surgery. Female Pelvic Med Reconstr Surg. 2013; 19:191-8
3. Donald R. Ostergard. Evidence-based medicine for polypropylene mesh use compared with native tissue vaginal prolapse repair. Urology 2012; 79: 14.

*Correspondence to*:

Emanuela Mistrangelo
mistrangelo.e@libero.it

## Multidisciplinary Uro-Gyne-Procto Editorial Comment

To improve the integration among the three segments of the pelvic floor, some of the articles published in **Pelviperineology** are commented on by **Urologists**, **Gynecologists**, **Proctologists/Colo Rectal Surgeons** or **other Specialists** with their critical opinion and a teaching purpose. Differences, similarities and possible relationships between the data presented and what is known in the three or more fields of competence are stressed, or the absence of any analogy is indicated. The discussion is not a peer review, it concerns concepts, ideas, theories, not the methodology of the presentation.

**Urol...** The authors report their experience in the correction of vaginal prolapse by proposing a new technique that represents the evolution of the procedure proposed by Farnsworth. The possibility of correction of the prolapse with the method InGYNious which is a minimally invasive one, is certainly quite attractive. In this setting however from the surgical point of view, in terms of treating the prolapse, the opinion of the urologist is different. In fact the urologists usually prefers the vaginal approach to treat the anterior and posterior defects, independently of the use or not of meshes, but choose the abdominal approach by laparoscopy or more recently by robot-assisted laparoscopic technique for the correction of the central defect.

In this way, when the quality of the tissues allows it, the fascial repair of the anterior or posterior defects is in any case be preferable also because of the possibility of vaginal mesh exposure and painful contraction. These are not uncommon complications ranging between 4% and 35% and between 4% and 11% respectively.

Instead concerning the correction of the central defect by laparoscopic or robotic assisted colposacropexy, it is possible, also in this case, to restore the three levels of De Lancey with a reduced rate of intraoperative bleeding, shorter hospitalization and less wound complications. For the robotic approach there is currently not enough evidence of an impact on complication rates.

The choice of a surgical approach over another does not constitute a particular difference, provided that the surgeon observes the principle of a functional reconstructive surgery not interfering with the quality of life of the patient.

SALVATORE SIRACUSANO
*siracus@units.it*

**Gyneco...** Dr Mistrangelo reports her technique which is an evolution of the more well known mesh techniques utilized for pelvic floor repair and currently the subject of much controversy and discussion due to the FDA directives of recent years. Dr Mistrangelo addresses this controversy directly and describes her technique where a low density iso-elastic mesh specifically designed to address and minimise complications due to the prosthesis is implanted in the patient. This technique preserves the three level attachment of the original CR Mesh procedure from which this technique has evolved but utilizes a single incision and a new minimally invasive method for suspensory suture application. The results of this retrospective observational study show great promise. We look forward with anticipation to the results of a prospective study where the technique is evaluated in a controlled trial and directly compared for safety and efficacy with the other techniques that are available.

BRUCE FARNSWORTH
*Centre for Pelvic Reconstructive Surgery, Sydney Adventist Hospital, Wahroonga, 2076, Australia - drbruce505@gmail.com*

**Procto...** The procedure described in Mistrangelo's article involves all the pelvic floor compartments. In the posterior one which colorectal surgeons commonly deal with, the following anatomo-pathological entities are commonly addressed: low rectocele, which develops within the perineal body, rectal intussusception arising from the invagination either of the proximal rectum or of the medial-distal rectum, respectively as a recto-rectal or a recto-anal intussusception, and complete rectal prolapse. A rectocele must be differentiated from a posterior colpocele, which occurs in the central compartment, as a prolapse of the rectum or of the Douglas Pouch or both, into the posterior wall of the vagina. Colorectal surgeons treat these conditions with open or laparoscopic abdominal or transanal surgical procedures. During the last decade pelvic surgeons have evolved and refined the transvaginal techniques using a variety of prostheses, but despite this, the safety of these procedures is still under discussion, as delineated by the FDA 2011 advice. Nevertheless, data on transvaginal procedures have shown their efficacy in the POP repair. Farnsworth has been a pioneer in this field and when compared to laparoscopic or open surgery, data related to his technique have also highlighted an improvement of coexisting symptoms as obstructed defecation and fecal incontinence. Farnsworth described the use of prostheses (*A.M.I. CR mesh - GmbH Feldkirch-Austria*) to restore the three levels of De Lancey, thus achieving a support to the rectum and a more anatomical correction of the prolapsed pelvic organs. In more detail, Farnsworth improves posterior colpocele by recreating the 2° level of De Lancey with two trans-elevatory slings, and rectocele by recreating the 3° level of De Lancey through two posterior trans-perineal slings. Of the outmost importance from the proctologic point of view, the prosthesis placed between rectum and vagina has showed to improve also complete rectal prolapse and medial-distal rectal intussusception. InGYNious is an evolution of the Farnsworth's technique, using a smaller prostheses without the arms for the 2° and 3° level of De Lancey. Hence, though InGYNious corrects the posterior colpocele, it must be verified if the shape, dimension and lack of slings of this new device will also anatomically improve rectocele, rectal prolapse and rectal intussusception as in the CR mesh technique. Furthermore, as, the improvements of the coexisting functional symptoms that ensue with Farnsworth's procedure should be verified with a longer follow up, and randomized controlled trials could provide an interesting comparison between this promising procedure and the others available on the market of the POP treatments.

ALVISE FRASSON
*alvise.frasson@unipd.it*