Original article

Treatment of Pelvic Organ Prolapse using a lightweight modified HexaPro Mesh

ANDREAS BRANDT[1], DANIELA ULRICH[2], ANDRZEJ KUSZKA[3], ACHIM NIESEL[4], HENRIK LUTZ[5], CHRISTIAN FÜNFGELD[6], DIRK G. KIEBACK[7]

[1] *Dept. of Obstetrics and Gynecology, Ortenau-Klinikum, Offenburg, Germany*
[2] *Dept. of Obstetrics and Gynecology, University of Graz, Graz, Austria*
[3] *Dept. of Gynecology, Ev. Hospital Hagen-Haspe, Hagen, Germany*
[4] *Dept. of Obstetrics and Gynecology, Klinik Preetz, Preetz, Germany*
[5] *Dept. of Obstetrics and Gynecology, Spital Waldshut, Waldshut-Tiengen, Germany*
[6] *Dept. of Obstetrics and Gynecology, Klinik Tettnang, Tettnang, Germany*
[7] *Dept. of Obstretrics and Gynecology, Helios Medical Center, Schleswig, Germany*

Abstract: The surgical procedure of vaginal mesh placement for the treatment of Pelvic Organ Prolapse is described. A modified ultralightweight macroporous monofilament polypropylene mesh with insertion aids at the six fixation points is placed vaginally through a single incision.

Keywords: Minimally invasive; Single incision; Six point mesh; Pelvic organ prolapse; Macroporous polypropylene; Vaginal surgery.

INTRODUCTION

Recurrence rates of Pelvic Organ Prolapse (POP) of up to 30% have been described after classical surgical procedures without prosthetic implants[1-3]. While controversy exists regarding the role of larger implants of surgical meshes, recent developments of new materials and insights regarding tissue tolerance and fibroblast proliferation warrant reevaluation of previously held concerns[4]. Advisories i.e. of the Food and Drug Administration (FDA) in 2008[5] and Health Canada in 2010 were largely based on experiences with comparably heavy meshes with microporous structure frequently using only two or four points of fixation in the pelvis with the apical sacrospinous attachment being absent[6]. Some of the early meshes that frequently caused poor tissue tolerance and erosion were much higher than the newer meshes. The surface area of only laterally fixated four-point meshes was prone to contract further compromising the therapeutic effect and necessitating secondary surgical interventions to treat complications and/or anatomical failure. With ultralight macroporous monofilament polypropylene meshes available on the market erosions have only been reported to be up to 7%[7]. In preparation for a multicenter prospective trial evaluating POP treatment by primary mesh placement, a standardized surgical method was developed for the placement of a newly modified single-incision vaginal mesh with 6 point fixation[8].

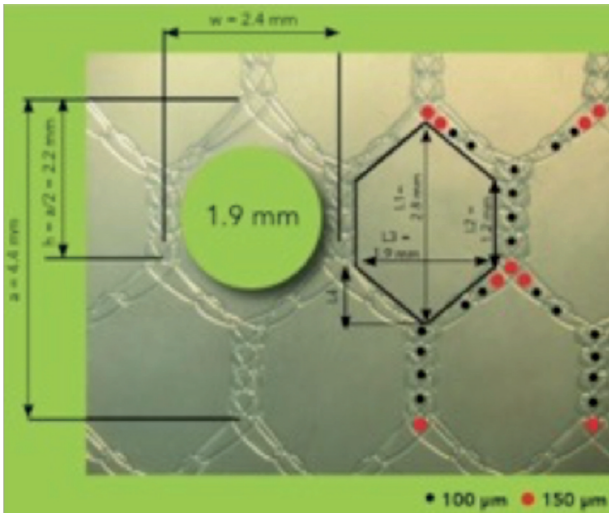

Figure 1. – HexaPro Mesh Structure and Pore Size.

MATERIALS AND METHODS

Material. An ultralightweigt monofilament polypropylene mesh (21g/m^2) was redesigned on the basis of an earlier configuration inaugurated by Mistrangelo et al.[8]. The new mesh (INGYNious®)is manufactured by A.M.I. Inc, Feldkirch, Austria and CE certification has been obtained. This mesh is characterized by large micropores of 100-150 μm and macropores of 1,9 to 2.8 mm (Fig. 1). In comparison with the earlier design the implant was markedly elongated in the direction of the sacrum while excising an arch for the passage of the rectum. The fixation points were predefined and passage aids were placed through the mesh in six positions facilitating suturing and at the same time further standardizing the surgical procedure. Two sizes were configured, a larger one for anterior mesh placement in the vesico-vaginal space and a smaller one for positioning in the recto-vaginal compartment (Fig. 2).

In order to fix the mesh in the pelvis in a safe and reproducible manner minimizing preparatory effort and tissue trauma the i-Stitch® instrument was used (A.M.I.). This instrument consists of a stainless steel hook with a long hollow

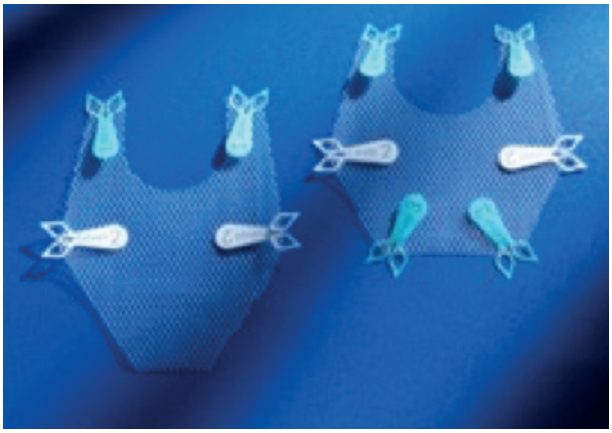

Figure 2. – InGYNious Anterior and Posterior Six-Point Meshes.

Figure 3. – i-Stitch Instrumentation for Intrapelvic Suture Placement.

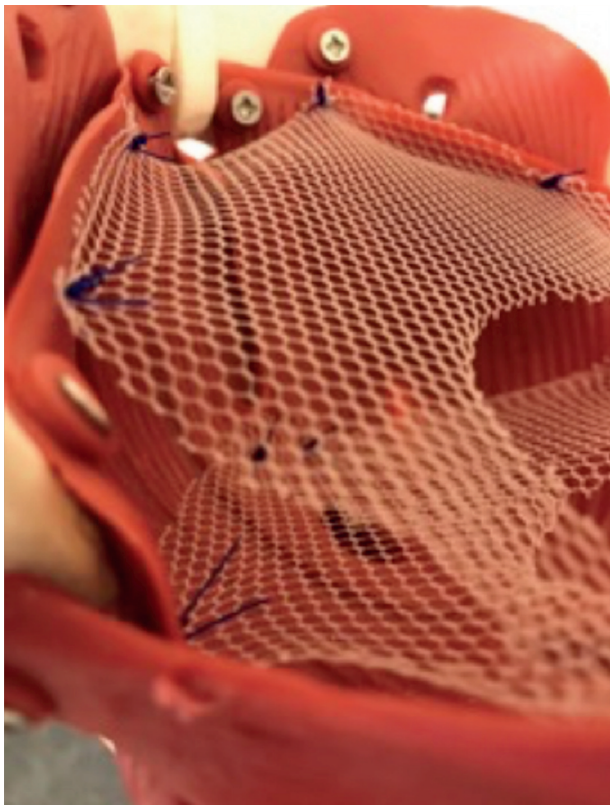

Figure 4. – Anterior and Posterior InGYNious Mesh in an Anatomical Model. View from parasacrally towards the Perineum.

handle admitting a disposable guide that advances a non-resorbable or resorbable suture towards the inner surface of the blunt hook where a pre-formed patented knot at the end of the suture is pushed into a groove first compressing it on entry and thereafter capturing it through it's re-expansion (Fig. 3). Two i-Stitch instruments are available. One with the hook pointing away from the palm of the surgeon's hand holding the handle and one with the hook pointing towards it. It is the surgeon's preference to choose the one lending itself to most comfortably placing the suture.

Methods. After single-shot antibiotic prophylaxis a single longitudinal full-thickness incision is made in the anterior or posterior wall of the vagina. The paravesical and/or pararectal spaces are opened. Three sutures of 2-0 polyester are placed on each side of the pelvis in a symmetrical fashion for a total of six sutures (Fig. 4).

The anterior vaginal mesh is fixed in the apical third of the sacrospinous ligament on boths sides. (Suture 1 is placed us-

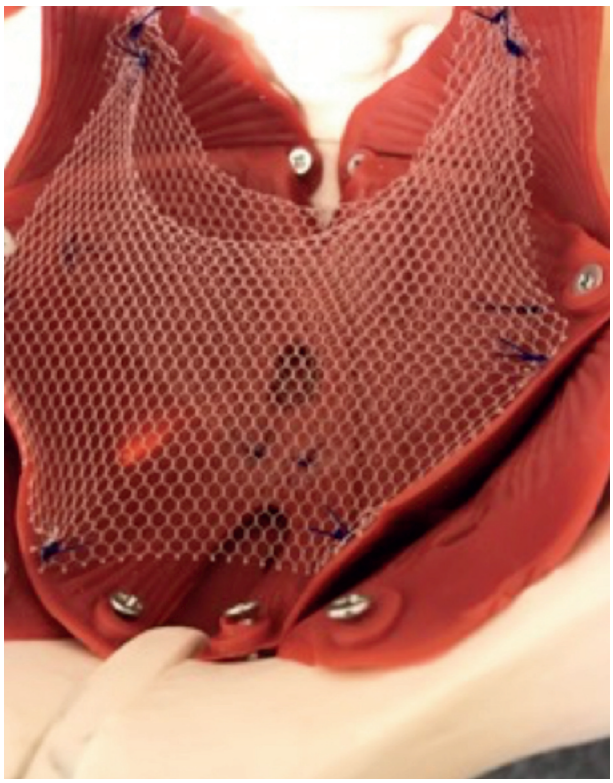

Figure 5. – Anterior and Posterior InGYNious Mesh with Six-Point Fixation in an Anatomical Model. View from the Perineum towards the Presacral Region.

ing by i-Stitch-up). The second point of fixation is the tendinous arch at the ischiadic spine on both sides. The sutures are placed through the ligament using the I-Stitch down (Suture 2). The third point of fixation by I-Stitch down is the tendinous arch of the pubic bone (Suture 3).

For posterior mesh placement in the rectovaginal space the fixation points are similar: fixation point number one is the medial part of the sacrospinous ligament on both sides, the second fixation point is the ileococcygeal muscle at the ischiadic spine on both sides. The third point of fixation is the perineal body bilaterally to keep the mesh in place.

The sutures are threaded through the mesh via the passage aids and tied starting with positions 1 followed by 2 and 3. The colpotomy is closed with a resorbable braided 2-0 suture. A vaginal pack is used and left in place for at least 24 hours.

DISCUSSION

In this paper we describe the use of a newly designed mesh with 6 point fixation and user friendly suture placement. Standardization is one of the most important features to assure high quality in surgery. This manuscript has been written in the preparation of a large multicenter study based on the surgical techniques described.

Negative experiences with first generation alloplastic meshes have lead to widely disseminated concerns regarding the use of meshes and their role in the treatment of POP leading to uncertainties in therapeutic recommendations on the part of the treating physicians and to negative preconceived notions on the part of the patients.

With the development of improved materials and standardized minimally invasive placement techniques these concerns need to be re-addressed. Clinical impression suggests that modern meshes may be well tolerated and anatomically efficient providing a good quality of life, es-

pecially also regarding sexual function. Prospective multicenter data are therefore urgently needed to test the merits and caveats of such newly designed meshes. The procedure of using the modified InGYNious mesh placement as described above provides a standardized basis for such an evaluation utilizing an advanced prosthetic material.

DISCLOSURES

All authors have received honoraria from A.M.I. for presentations at internal or scientific meetings related to pelvic floor surgery.

REFERENCES

1. Nygaard I, Barber MD, Burgio KL et al. Prevalence of symptomatic pelvic floor disorders in US women. JAMA 2008; 300 (11): 1311-6.
2. Maher C, Feiner B, Baessler K et al. Surgical management of pelvic organ prolapse in women. Cochrane Database of Systematic Reviews 2013 (4).
3. Walker GJA, Gunasekera P. Pelvic organ prolapse and incontinence in developing countries: review of prevalence and risk factors. Int Urogynecol J 2011; 22 (2): 127-35.
4. Jia XL, Glazener C, Mowatt G et al. Systematic review of the efficacy and safety of using mesh in surgery for uterine or vaginal vault prolapse. Int Urogynecol J 2010; 21 (11): 1413-31.
5. FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence 2008 [cited 2010 9 November 2010].
6. Barski D, Otto T, Gerullis H. Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair. Surg Technol Int 2014; 24: 217-24.
7. Mowat A, Maher D, Baessler K et al. Surgery for women with posterior compartment prolapse. The Cochrane database of systematic reviews 2018; 3: Cd012975.
8. Mistrangelo E. Pelvic floor reconstruction using CR-mesh (A.M.I.): past, present, future. Pelviperineology 2011; 30 (4).

Correspondence to:

Prof. Dr. med. Dirk G. Kieback
Head Department of Obstetrics and Gynecology,
Helios Medical Center, Sankt Juergener Strasse 1-3,
24837 Schleswig 24837, Germany
E-mail: dirkkieback@hotmail.de

Commentary

I am glad to read this paper written by German authors on the characteristics of "InGYNious" of which I am an inventor. It is not just a new type of mesh but a new philosophy of the prosthetic technique of repairing pelvic floor defects. Unfortunately, in the recent past the use of old meshes with transcutaneous passages have caused serious damage to the patients. Today ultralight meshes with single incision transvaginal access have completely changed the story with excellent results, lasting effectiveness over time, rapidity of intervention, spinal anesthesia, very low blood loss, reproducibility, short hospitalization.

Before providing some of the results of my 7 years experience, I must unfortunately recall that in the literature there are still studies that demonize the use of meshes by vaginal route. After the bad English study Prospect[1], recently the Prospere study appeared on European Urology[2], signed by authoritative French colleagues. It supports the superiority of the laparoscopic approach compared to the vaginal one. I have just written a letter to the editor to challenge the scientific method that leads to these conclusions. Furthermore, beyond the methodology, the authors' superficialiy is highlighted by many points of the vaginal operative technique. The heterogeneity in mesh composition (polypropylene alone / combined with absorbable components), kits and techniques for VMR (variable mesh size, with / without sacrospinous-fixation), as well as the considerable number of LS requiring a conversion to the vaginal route may affect the comparison between groups in terms of severe complications. The same thing happened for the study Prospect, published in Lancet, in which it was said that mesh should be placed "possibly" below the vaginal fascia, when it is now established that this is the key point to avoid vaginal erosion.

There are changes after years of experience in the first form of InGYNious with a 3rd level for the correction of cystocele with lateral attachment to the tissues lateral to bladder neck and then a narrower anterior part and for the correction of rectocele with a central attachment to the perineal body and laterally to the deep transversus muscle.

My experience concerns 296 patients operated in the last 3 years. I had 3 recurrence of cystocele, 1 of rectocele, 2 of hysterocele. The latter were treated with vaginal hysterectomy and with the vaginal vault attachement to the upper part of the normal-positioned mesh at the 1st level. As far as complications are concerned, there were no infections, no hematomas to be treated surgically, no extrusions, no schrinking, 4 vaginal erosions treated with the removal of part of the mesh and of eroded vagina. 10% of patients have an IUS "de novo", which is the same as that of the fascial surgery, of which only 3% has been corrected with TOT. 1% of patients had pelvic pain that lasted a month, but among active sex life only 0.5% of patients had modest dyspareunia.

Unfortunately, in Italy, due to legal sue, it is almost impossible to do randomized studies and therefore we will have only observational studies. The Italian Association of UroGinecology (AIUG), to which I belong, has been providing for two years a data collection software (SRD) on the surgical correction of pelvic floor defects that now contains more than 1000 patients. The SRD will allow an observational analysis of an appropriate number of patients operated with different techniques by 2018.

I conclude with the words of the last Cochrane 2018 on the back compartment inviting to give a precise meaning to the written words "Evidence does not support the utilization of any mesh or graft materials at the time of posterior vaginal repair", which means that, with the support of a favorable personal experience, meshes can be used.

REFERENCES

1. Glazener CMA, Breeman S, Elders A et al (for the PROSPECT study group)* Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT) www.thelancet.com Published online December 20, 2016 http://dx.doi.org/10.1016/S0140-6736(16)31596-3.
2. Lucot JP, Cosson M, Bader G et al. Safety of Vaginal Mesh Surgery Versus Laparoscopic Mesh Sacropexy for Cystocele Repair: Results of the Prosthetic Pelvic Floor Repair Randomized Controlled Trial. EURURO https://doi.org/10.1016/j.eururo.2018.01.044

FRANCESCO DEL TETTO
Dept of Gynecology, San Camillo Hospital, Trento Italy

Correspondence to:
francesco.deltetto@gmail.com