

Comments for Annex XV restriction report. Substance name: Per- and polyfluoroalkyl substances (PFAS)

I am minimally invasive gynecological surgeon from Finland, Seinäjoki. I have implemented laparoscopic pectopexy (LP) in Finland since August 2017. I have performed over 100 laparoscopic pectopexy surgeries and for that I have used only polyvinylidene fluoride (PVDF) mesh provided by company Dynamesh.

For decades there was only native tissue repair available in the field of pelvic organ prolapse (POP) surgical treatment with a high rate of recurrences.[1] To diminish recurrences, mesh was implemented into POP surgeries in a variety of ways from the late 80's. As the use of meshes expanded, more research data was published and there was an increasing concern about unexpected complications. Vaginal meshes are now largely removed from the market because, compared to other surgeries, they have more complications[2].

However, the usage of meshes is still well accepted for vaginal apical prolapse correction through abdominal route. Abdominal and laparoscopic sacrocolpopexy (ASCP, LSCP) has been used for vaginal apical prolapse treatment for over 30 years.[3] These surgeries can be done with macroporus polypropylene (PP) mesh, but in our clinic we use PVDF meshes also for LSCP.

Laparoscopic pectopexy is an alternative way to suspend the vaginal apex bilaterally to pectineal ligaments. Laparoscopic pectopexy is widely used in Germany for vaginal apical or uterine prolapse treatment. In Europe, the surgery was first introduced by Noe et al in 2007. [4] By now, there are around 50 publications about the results of this surgical technique.

The surgeries are done according to published data and only PVDF meshes have been used.[4][5] [6] [7] [8] [9] [10] In this surgery, the mesh is anchored to pectineal ligament bilaterally to the close proximity of big blood vessels (external iliac vein) and nerves (obturator nerve). There is a study that has shown the distance from midpoint of pectineal ligament (mesh anchoring point) to iliac external vein is 1,04-1,25 cm. [11] Also according to my own experience I can say that it is impossible to avoid the contact between mesh and the wall of the vein. As the studies have been done with PVDF mesh, it is impossible to say, what complications alternative mesh materials like PP or polyester (PE) would create because of this technical detail. It is known that polypropylene is sharp from its edges and there have been reports about late bladder damages because of PP meshes used in stress-urinary incontinence surgery called tension-free vaginal tape (TVT) [12]. Polyester meshes have been abandoned in my center because they seemed to be more infections. There is currently no other company that provides PVDF meshes and there is not enough data to support PVDF meshes to be changed safely to alternative material.

According to Noe et al 2015 randomised controlled study between laparoscopic sacrocolpopexy and laparoscopic pectopexy showed a clear difference regarding de novo defecation disorders (0% in the pectopexy vs 19.5% in the sacropexy group). Also other studies have shown low rate of postoperative defecation disorders after laparoscopic pectopexy. [4] [6] [7] [10] [13] De novo lateral defect cystoceles were found after pectopexy 0% and after sacrocolpopexy 12.5%. [14] To dissect the promontorium in LSCP can be technically challenging and prone to complications, especially in obese patients. [15] Chronic low back pain can also develop in LSCP patients – for example in S. Vieillefosse et al 2015 study 25-50% of patients. [16] Some of the patients suffer from erosion of

meshes on the vaginal or intestinal side: during 9.1 years of follow-up, mesh erosion occurred in 12.5% of LSCP and 7.7% of ASCP patients (A. M. J. van Oudheusden et al 1/ 2023)[17] [18]

Based on studies, there are only few serious intraoperative or postoperative complications related to laparoscopic pectopexy.[9][10] Noe et al 2020 study reported 5/501 severe intraoperative complications: three bladder and one ureteral injury, one bleeding > 500 ml. [13] In Noe's 2021 publication, in the same material, during the 15-month follow-up period, no mesh erosions were found. Three patients developed a lymphocyst at the site of mesh attachment to the pectineal ligament, and were managed successfully by laparoscopic treatment.[19] A summary table of the complications of laparoscopic pectopexy is presented in one publication: in all studies published up to that point, a total of four bladder injuries, one ureteral injury, two major bleedings and one mesh erosion have been reported. [20]

Correction of the vaginal apical prolapse can be done with native tissues. A suspension of sacrouterine ligaments (ULS) can be used, in which stretched ligaments are shortened and sewn together. The apex of the vagina can also be suspended unilaterally or bilaterally on the sacrospinous ligament (SSF – sacrospinous ligament fixation).[21] After vaginal surgeries, it has been found that vaginal length (tvl) is shorter and the correction of the anterior wall is worse compared to abdominal sacrocolopexy (ASCP) surgeries. [22] Vaginal SSF surgery had compared to ASCP a higher risk of recurrence of prolapse (11.58% vs 8.32% respectively) and a higher risk of pain during intercourse (14.36% vs 4.67% respectively).[23] In a Cochrane review from 2016 the development of postoperative dyspareunia was reported to be 9.1% after laparoscopic and 23% (10.5 - 50.1%) after vaginal apical suspension surgeries. [24]

In the light of study data we have changed our clinical practice accordingly and started to offer laparoscopic pectopexy to vaginal vault or uterine prolapse patients as it seems more beneficial for the patients.

In case we do not have possibility to use PVDF meshes, it may be dangerous to use PP or PE meshes for laparoscopic pectopexy. LSCP has clearly bigger risk for de novo defecation disorders. Vaginal native tissue surgeries have higher recurrence and postoperative de novo symptoms rate.

To compare the environmental impact of one PVDF mesh we need to take into account the environmental impact of all the complications (reoperations, suffering of the patient, extra medications) these meshes can avoid.

I truly believe that PVDF meshes are the best meshes on the market at this moment. In my opinion, patients should only be offered the best possible surgery and the best possible foreign body material available.

Best Regards,

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