The AMPER Study: Amniotic Membrane for the Prevention of mesh Exposure in vaginal Reconstructive surgery

Sänger (Principal Investigator), Izbizky, Gelaf, Cahaud, Costanzo, Lee, Pierandrei, D'Aquino.

J.M. Penna Hospital of Buenos Aires, Argentina

NCT number: NCT07414849

Concept approval: 29 December 2025

Full-Protocol Approved: Version 2.0 13 January 2026

Last Updated: Version 2.0 December 2025

TABLE OF CONTENTS

Introduction **3**
Materials and Methods **3**
Inclusion Criteria 4
Exclusion Criteria 4
Procedures 4
Sample size 6
Variables 8
Study Flow Chart **9**
Acknowledgments **10**
References **10**
Appendix I **13**

Keywords

Pelvic organ prolapse, Transvaginal mesh, Amniotic membrane, Mesh exposure.

Introduction

Pelvic organ prolapse (POP) and urinary incontinence (UI) are common disorders affecting a large proportion of women and are frequently associated with substantial impairment in quality of life (1,2). Polypropylene meshes have become an established, fundamental tool in pelvic floor reconstructive surgery. Their application, both in prolapse repair (POP) and in suburethral slings for stress urinary incontinence (SUI), currently represents one of the most performed treatment modality, offering superior long-term anatomical and functional results and lower recurrence rates compared to native tissue repairs (3,4).

However, these clinical benefits are tempered by procedure-related complications, which led the U.S. Food and Drug Administration (FDA) to issue safety warnings in 2008 and 2011 (5,6). Among these adverse events, mesh exposure is one of the most frequently reported, with rates ranging from 5% to 42% in prolapse surgeries (7,8). In stress urinary incontinence procedures, lower exposure rates have been described, typically between 0% and 8.1% (9), although some authors have reported substantially higher rates, reaching 30.1% (10). While small vaginal exposures (<1 cm) may be managed conservatively with topical estrogen, larger or recurrent defects present a considerable clinical challenge (11).

In this context, human amniotic membrane (hAM) emerges as a promising biological alternative for exploration within the field of urogynecology. HAM exhibits key characteristics ideal for regenerative medicine applications. It expresses low or negligible levels of HLA antigens, rendering it non-immunogenic and preventing rejection after transplantation (12). Furthermore, hAM stimulates cell migration and proliferation, crucial processes for effective wound healing. This growth promotion is primarily mediated by various growth factors, including epidermal growth factor (EGF), keratinocyte growth factor (KGF), hepatocyte growth factor (HGF), and basic fibroblast growth factor (bFGF) (12).

The application of hAM across various areas of regenerative medicine—such as burn management, ophthalmologic surgery, and treatment of chronic inflammatory diseases—has demonstrated beneficial effects, attributable to its inherent anti-inflammatory, antifibrotic, antiangiogenic, antimicrobial, and immunomodulatory properties (12-17). These features suggest hAM may enhance prosthetic material integration, mitigate the local inflammatory response, and promote a more stable epithelial repair when used in pelvic floor surgery.

The present study aims to evaluate the efficacy of human amniotic membrane grafting in preventing prosthetic material exposure in vaginal surgeries employing polypropylene mesh.

Materials and Methods

The AMPER (amniotic membrane for preventing exposure in reconstructive surgery) study was a simple blind, parallel, controlled randomised trial investigating the effect of amniotic

membrane versus standard repair (1:1) following apical prolapse repair and stress urine incontinence.

This was a single-center study conducted at a tertiary care institution. The study was carried out in the Urogynecology Section of the Department of Gynecology at Hospital J. M. Penna, Buenos Aires, between March 2026 and March 2028. This is a public teaching hospital that provides specialized care for women with urogynecologic disorders. The institution performs approximately 150 urogynecologic surgeries per year and functions as a training center, hosting residents and urogynecology fellows who participate in supervised clinical and surgical activities. Our patient population predominantly consists of individuals from low-income backgrounds and with low to mid-level educational attainment.

Inclusion Criteria

1. Pelvic organ prolapse (POP) stage II C or greater, defined as C ≥ +1, in women without prior hysterectomy and/or with a diagnosis of stress urinary incontinence seeking surgical treatment.
2. Ability to understand study information and provide written informed consent.
3. Availability for follow-up for a minimum of 12 months.

Exclusion Criteria

1. Previous surgery with synthetic mesh (via vaginal or abdominal approach) for POP repair.
2. Known adverse reaction to synthetic meshes.
3. Unresolved or active chronic pelvic pain.
4. History of prior abdominal or pelvic radiation.
5. Contraindication to the planned surgical procedure.
6. Current pregnancy.

Procedures

All patients in the prolapse group underwent hysteropexy using a polypropylene mesh anchored to the sacrospinous ligament (unilateral or bilateral), performed via either an anterior or posterior vaginal approach using a prepackaged anchor and mesh kit. Patients with SUI received a midurethral sling placed by either the transobturator (TOT) or retropubic (TVT) route.

The amniotic membrane was provided free of charge by AMNIOS BMA, a non-profit civil association that operates as a human amniotic membrane bank in our country. The institution is authorized by INCUCAI (National Central Institute for Ablation and Implant Coordination, resolution number: RESFC-2024-282-APN-D#INCUCAI) and by ANMAT (National Administration of Drugs, Food and Medical Technology). It carries out the processing of donated placentas through lyophilization and gamma-radiation sterilization, yielding amniotic membrane patches suitable for surgical use.

Additionally, the meshes employed in all surgical procedures were Type I, low-density, macroporous, monofilament polypropylene meshes, which have been associated with a lower rate of complications (18,19).

The primary outcome was the comparison of mesh exposure incidence between the control group and the amniotic membrane group. Postoperative follow-up assessments were conducted at 7 days and at 1, 3, 6, 9, and 12 months after surgery by a urogynecologist blinded to treatment allocation. At each follow-up visit, wound healing and the occurrence of surgical or mesh-related complications were systematically evaluated. Additionally, patients completed a self-administered, in-person questionnaire assessing postoperative satisfaction and the presence of new symptoms (Appendix I).

All surgeries are performed by the attending surgeons (I.S. and M.L.G.), who also serve as co-authors of this study. Both surgeons are authorized by INCUCAI to perform procedures involving amniotic membrane (RESFC-2025-272-APN-D#INCUCAI). Our institution holds the corresponding accreditation issued by INCUCAI (NO-2025-89427229 -APN-DCT#INCUCAI).

Standardized operative protocols were applied to all procedures. In the intervention group, a 2 × 1 cm dehydrated human amniotic membrane patch was placed over the mesh or tape prior to vaginal closure. The control group underwent the same surgical procedures without the addition of the membrane. In patients presenting with both stress urinary incontinence and pelvic organ prolapse, two separate amniotic membrane patches were used—one for each procedure.

Surgical Procedures

1. Sacrospinous Hysteropexy with Mesh

1. The patient is positioned in the dorsal lithotomy position, and the bladder is emptied via a Foley catheter.
2. Hydrodissection of the vaginal wall is performed with 1% lidocaine.
3. A longitudinal anterior vaginal incision is made between the bladder neck and the apex; a posterior incision is added when posterior prolapse predominates.
4. Blunt or sharp dissection is used to access the sacrospinous ligament extraperitoneally.
5. The ischial spine is identified.
6. Bilateral anchoring devices are inserted into the sacrospinous ligament, 2.5 cm medial to the ischial spine.
7. A polypropylene mesh is attached to the pericervical ring.
8. The mesh is suspended bilaterally using the pre-placed anchors.
9. Tension is adjusted to achieve a tension-free hysteropexy.
10. The vaginal wall is closed with 2–0 polyglactin.
11. In the intervention group, an amniotic membrane patch is placed over the mesh prior to closure.

2. Transobturator Mid-urethral Sling (Out–In)

1. Under regional or general anesthesia, the patient is placed in the dorsal lithotomy position and the bladder is catheterized.
2. The vaginal and paraurethral tissues are infiltrated with 1% lidocaine.
3. A 2-cm midline suburethral vaginal incision is made 1 cm below the urethral meatus at the level of the mid-urethra.
4. Bilateral paraurethral dissection is performed toward the ischiopubic ramus and the obturator foramen.
5. Bilateral groin entry points are marked medial to the inguinal fold and inferior to the adductor longus tendon.
6. Small skin incisions are made at the marked entry points.
7. A helical trocar is advanced from each groin incision through the obturator musculature and membrane, exiting into the paraurethral tunnel.
8. The polypropylene tape is attached to the trocar and withdrawn through the groin on each side.
9. The tape is positioned beneath the mid-urethra without tension, verified using the Metzenbaum scissors test.
10. In the intervention group, an amniotic membrane patch is placed over the tape before closure.

3. Retropubic Mid-urethral Sling (Bottom-Up)

1. The patient is placed in the dorsal lithotomy position under regional or general anesthesia, and the bladder is catheterized.
2. Two 1-cm suprapubic incisions are marked 2 cm lateral to the midline.
3. Local anesthetic with vasoconstrictor is infiltrated into the anterior vaginal wall and paraurethral tissues.
4. A 2-cm midline anterior vaginal incision is made approximately 1 cm below the urethral meatus.
5. A paraurethral tunnel is developed toward the retropubic space.
6. Bladder drainage is confirmed.
7. The retropubic trocar is advanced bilaterally from the vaginal incision through the retropubic (Retzius) space and exteriorized at the suprapubic incisions.
8. The polypropylene tape is attached and drawn through each suprapubic exit, leaving both arms at skin level.
9. The sling is positioned below the mid-urethra without tension, confirmed using the Metzenbaum scissors test.
10. Routine cystoscopy is performed to exclude bladder or urethral injury.
11. In the intervention group, an amniotic membrane patch is placed prior to vaginal closure.

Sample size

The incidence estimate was based on observational data from our practice (unpublished), which indicated a 25% risk of mesh exposure. Because no well-established minimal clinically

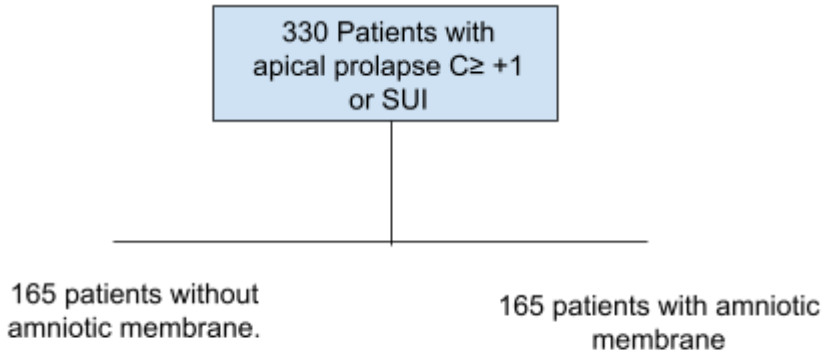
important difference exists for wound complications, we defined a 50% reduction as a clinically meaningful and achievable target for the sample-size calculation. Assuming a 10% drop-out rate, a significance level of 0.05, and 80% power, we determined that 330 women were required for inclusion, using a 1:1 allocation ratio.
Randomization was performed in a 1:1 ratio between the two main treatment groups (with amniotic membrane vs. without amniotic membrane), ensuring an equal probability of assignment to receive the amniotic membrane graft. The assignment was conducted using a system of consecutively numbered, sealed, opaque envelopes, which had been prepared in advance by an independent investigator to minimize bias. Each envelope contained the group assignment and was opened in strict numerical order immediately before the surgical procedure, in the presence of the surgeon responsible for the operation.

Due to the study design, participants were blinded to their group allocation and were not informed whether they received the amniotic membrane graft. If complications suspected to be associated with the amniotic membrane occur, unblinding will be performed.

For baseline data, absolute numbers and percentages were provided for categorical data, while continuous data were evaluated for normal distribution with visual evaluation (histograms and standardized normal probability plot) and Shapiro Wilks test. Normal distribution variables were summarized using means and standard deviations (SDs), otherwise medians with interquartile ranges were presented. Continuous variables were analyzed using the t test or Wilcoxon rank sum test according to the distribution. We used Fisher's exact test for categorical variables. Primary outcome was reported as relative risk with 95% confidence intervals (CIs). We also calculated the risk difference, and number needed to treat. Analysis was performed by intention-to-treat . A per protocol analysis was also conducted, to assess the robustness of results and to evaluate security. Logistic regression was performed to model outcomes with any identified confounders.
All the test were two-sided and P values <0.05 were considered statistically significant.

The study protocol was reviewed and approved by the Ethics Committee of Hospital J.M. Penna in Buenos Aires (Registration Code: 18099). All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards (20-23). The amniotic membrane is provided free of charge to both the patient and the hospital, and the investigators do not receive any additional remuneration for the work performed or for the time devoted to the research.

Written informed consent was obtained from all participants prior to their inclusion in the study. Each participant received both oral and written information detailing the study objectives, procedures, potential risks, and anticipated benefits. Only individuals who demonstrated adequate understanding and agreed to participate by signing the informed consent form were enrolled, with the assurance that they could withdraw at any time without any impact on their medical care



Variables

- **Alphanumeric code:** first letter of the given name, first letter of the surname, and year of birth.
- **Date of birth:** discrete quantitative variable, recorded according to the calendar format DD/MM/YYYY.
- **Date of surgery:** recorded using two digits for the day, two for the month, and four for the year (DD/MM/YYYY).
- **Number of pregnancies (gravidity):** total number of pregnancies and mode of delivery; discrete quantitative variable.
- **Prolapse stage according to the POP-Q classification.**
- **Estrogen status:** premenopausal or postmenopausal status; use of local estrogen therapy.
- **Previous treatment for pelvic organ prolapse or urinary incontinence.**
- **Smoking status.**
- **Diabetes mellitus.**
- **Current use of non-analgesic medications that may affect wound healing (such as immunosuppressants or anticoagulants) and bowel function (e.g., constipation).**

Study Flow Chart

Activity / Study Period	M-2	M-1	M 0	M1–M6	M7–M12	M13–M18	M19–M24	M25–M30	M31–M36	M37–M40
Protocol development and finalization	●	●	●							
Ethics committee approval and regulatory authorization		●	●							
Investigator training and pilot phase			●	●						
Patient recruitment and enrollment				●	●					
Surgical interventions				●	●					
Patient follow-up visits (1, 3, 6, and 12 months)				●	●	●	●	●	●	
Data collection and data entry			●	●	●	●	●	●	●	
Statistical analysis (interim and final)									●	●
Manuscript preparation and submission									●	●

Acknowledgments

We extend our sincere gratitude to the patients and their families for their trust and participation in this study. We also acknowledge AMNIOS BMA for providing the amniotic membrane patches and for their continued collaboration in supporting this research.

References

1. de Tayrac R, Antosh DD, Baessler K, Cheon C, Deffieux X, Gutman R, Lee J, Nager C, Schizas A, Sung V, Maher C. Summary: 2021 International Consultation on Incontinence Evidence-Based Surgical Pathway for Pelvic Organ Prolapse. J Clin Med. 2022 Oct 17;11(20):6106. doi: 10.3390/jcm11206106. PMID: 36294427; PMCID: PMC9605527.
2. Güler Sönmez T, Uğraş E, Gül Şahin E, Fidanci I, Aksoy H, Ayhan Başer D. The prevalence of incontinence and its impact on quality of life. Medicine (Baltimore). 2024 Dec 27;103(52):e41108. doi: 10.1097/MD.0000000000041108. PMID: 39969293; PMCID: PMC11688079.
3. Haylen BT, Freeman RM, Swift SE, Cosson M, Davila GW, Deprest J, Dwyer PL, Fatton B, Kocjancic E, Lee J, Maher C, Petri E, Rizk DE, Sand PK, Schaer GN, Webb RJ. An IUGA/ICS joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. International Urogynecology Journal. 2011;22(1):3–15.
4. Yeung E, Baessler K, Christmann-Schmid C, Haya N, Chen Z, Wallace SA, Mowat A, Maher C. Transvaginal mesh or grafts or native tissue repair for vaginal prolapse. Cochrane Database of Systematic Reviews. 2024;(3):CD012079. doi:10.1002/14651858.CD012079.pub2
5. Mao J, Chughtai B, Ibrahim S, Sedrakyan A. Food and Drug Administration Safety Communication on the Use of Transvaginal Mesh in Pelvic Organ Prolapse Repair Surgery: The Impact of Social Determinants of Health. Female Pelvic Med Reconstr Surg. 2021 Jan 1;27(1):e133-e138. doi: 10.1097/SPV.0000000000000863. PMID: 32453208; PMCID: PMC7679269.
6. U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH). Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse. July 2011. Available from: https://www.fda.gov/files/medical%20devices/published/Urogynecologic-Surgical-Mesh--Update-on-the-Safety-and-Effectiveness-of-Transvaginal-Placement-for-Pelvic-Organ-Prolapse-%28July-2011%29.pdf. Accessed 10 Nov 2025.
7. Milani AL, Damoiseaux A, IntHout J, Kluivers KB, Withagen MIJ. Long-term outcome of vaginal mesh or native tissue in recurrent prolapse: a randomized controlled trial. International Urogynecology Journal. 2018;29(6):847–858. doi:10.1007/s00192-017-3512-3.

8. Menefee SA, Richter HE, Myers D, Moalli P, Weidner AC, Harvie HS, Rahn DD, Meriwether KV, Paraiso MFR, Whitworth R, Mazloomdoost D, Thomas S; NICHD Pelvic Floor Disorders Network. Apical Suspension Repair for Vaginal Vault Prolapse: A Randomized Clinical Trial. JAMA Surgery. 2024;159(8):845–855. doi:10.1001/jamasurg.2024.1206.
9. Giusto LL, Zahner PM, Goldman HB. Management of the Exposed or Perforated Midurethral Sling. Urol Clin North Am. 2019 Feb;46(1):31-40. doi: 10.1016/j.ucl.2018.08.003. PMID: 30466700.
10. Abbott S, Unger CA, Evans JM, Jallad K, Mishra K, Karram MM, Iglesia CB, Rardin CR, Barber MD. Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. Am J Obstet Gynecol. 2014 Feb;210(2):163.e1-8. doi: 10.1016/j.ajog.2013.10.012. Epub 2013 Oct 11. PMID: 24126300.
11. Joint position statement on the management of mesh-related complications for the FPMRS specialist. International Urogynecology Journal. 2020;31:679–694. doi:10.1007/s00192-020-04248-x.
12. Jahanafrooz Z, Bakhshandeh B, Behnam Abdollahi S, Seyedjafari E. Human amniotic membrane as a multifunctional biomaterial: recent advances and applications. J Biomater Appl. 2023 Mar;37(8):1341-1354. doi: 10.1177/08853282221137609. Epub 2022 Nov 4. PMID: 36331116.
13. Jirsova K, Jones GLA. Amniotic membrane in ophthalmology: properties, preparation, storage and indications for grafting – a review. Cell and Tissue Banking. 2017;18(2):193–204. doi:10.1007/s10561-017-9618-5.
14. Elkhenany H, El-Derby A, Abd Elkodous M, Salah RA, Lotfy A, El-Badri N. Applications of the amniotic membrane in tissue engineering and regeneration: the hundred-year challenge. Stem Cell Research & Therapy. 2022;13(1):8. doi:10.1186/s13287-021-02684-0.
15. Sanders FWB, Huang J, Alió Del Barrio JL, Hamada S, McAlinden C. Amniotic membrane transplantation: structural and biological properties, tissue preparation, application and clinical indications. Eye (London). 2024;38(4):668–679. doi:10.1038/s41433-023-02777-5.
16. Hofmann N, Rennekampff HO, Salz AK, Börgel M. Preparation of human amniotic membrane for transplantation in different application areas. Front Transplant. 2023 May 5;2:1152068. doi: 10.3389/frtra.2023.1152068. PMID: 38993896; PMCID: PMC11235369.
17. Mohammed YA, Farouk HK, Gbreel MI, Ali AM, Salah AA, Nourelden AZ, Gawad MMA. Human amniotic membrane products for patients with diabetic foot ulcers: do they help? A systematic review and meta-analysis. Journal of Foot and Ankle Research. 2022;15(1):71. doi:10.1186/s13047-022-00575-y.
18. Page AS, Cattani L, Pacquée S, Claerhout F, Callewaert G, Housmans S, Van der Aa F, D'Hoore A, Deprest J. Long-term Data on Graft-Related Complications After Sacrocolpopexy With Lightweight Compared With Heavier-Weight Mesh. Obstet Gynecol. 2023 Jan 1;141(1):189-198. doi: 10.1097/AOG.0000000000005021. Epub 2022 Nov 30. PMID: 36701619.
19. Liang R, Knight K, Abramowitch S, Moalli PA. Exploring the basic science of prolapse meshes. Curr Opin Obstet Gynecol. 2016 Oct;28(5):413-9. doi: 10.1097/GCO.0000000000000313. PMID: 27517341; PMCID: PMC5161092.

20. World Medical Association (WMA). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/. Accessed 10 Nov 2025.
21. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Good Clinical Practice (GCP) Guidelines E6 (R3). 2025. Available from: https://www.aemps.gob.es/industria/inspeccionBPC/docs/normas-buena-practica-clinica-ICH-E6-R3-2025.pdf. Accessed 10 Nov 2025.
22. Argentine Republic. Personal Data Protection Law No. 25.326 – General Provisions and Principles on Data Protection, Rights of Data Subjects, and Enforcement. Available from: https://www.oas.org/juridico/pdfs/arg_ley25326.pdf. Accessed 10 Nov 2025.
23. Ministry of Health, Argentina. Resolution No. 1480/2011 – Guidelines for Research Involving Human Subjects. Available from: https://www.argentina.gob.ar/normativa/nacional/resolución-1480-2011-187206/actualizacion. Accessed 10 Nov 2025.
24. Maher CF, Yeung E, Chen Z, Masel A, Smith D, Lourie R, Devan SM, Rasch R, Uwins P, Blakey I, Boyle GM, Jones L. Pathogenesis of polypropylene mesh complications in female pelvic floor surgery. Am J Obstet Gynecol. 2025 Oct;233(4):309.e1-309.e11. doi: 10.1016/j.ajog.2025.03.009. Epub 2025 Mar 10. PMID: 40073920.
25. Six JC, Pinsard M, Guerin S, Gasmi A, Coiffic J, Richard C, Haudebert C, Nyangoh Timoh K, Hascoet J, Peyronnet B. Risk factors for stress urinary incontinence recurrence after midurethral sling revision. Int J Urol. 2023 Nov;30(11):1008-1013. doi: 10.1111/iju.15248. Epub 2023 Jul 13. PMID: 37439555; PMCID: PMC11524087.
26. Siblini T, Baracy M, Kulkarni S, Mabis C, Hagglund K, Aslam M. Midurethral Sling Mesh Exposure Confers a High Risk of Persistent Stress Urinary Incontinence. Int Urogynecol J. 2024 Jun;35(6):1177-1182. doi: 10.1007/s00192-024-05762-y. Epub 2024 May 4. PMID: 38703222.
27. Dibb B, Woodgate F, Taylor L. When things go wrong: experiences of vaginal mesh complications. Int Urogynecol J. 2023 Jul;34(7):1575-1581. doi: 10.1007/s00192-022-05422-z. Epub 2023 Jan 6. PMID: 36607398; PMCID: PMC10287809.
28. Lau HH, Jou QB, Huang WC, Su TH. Amniotic Membrane Graft in the Management of Complex Vaginal Mesh Erosion. J Clin Med. 2020 Jan 28;9(2):356. doi: 10.3390/jcm9020356. PMID: 32012905; PMCID: PMC7074329.
29. Meutia AP, Budinurdjaja P, Fauzi A, Boediono A, Djusad S, Prihartono J, Wuyung PE, Hestiantoro A, Santoso BI. Enhancing Mesh-Tissue Integration in Menopausal Models Using a Platelet-Rich Plasma-Decellularized Amnion Scaffold Sandwich: A Study on Mesh Contraction, Inflammatory Infiltrate, IL-17, CD31, and Collagen Deposition. Int Urogynecol J. 2025 May;36(5):1045-1052. doi: 10.1007/s00192-025-06084-3. Epub 2025 Mar 5. PMID: 40042603.
30. Willison N, McPhail C, Seman E, Taheri M, Aryan P, Nguyen T, Yi J, Abbott D, Dune T, Behnia-Willison F. Platelet-Rich Plasma and Fractional CO2 Laser Therapy to Reduce Surgical Intervention for Symptomatic Vaginal Mesh-Related Complications. Int Urogynecol J. 2025 Apr;36(4):903-912. doi: 10.1007/s00192-025-06123-z. Epub 2025 Apr 3. PMID: 40178545; PMCID: PMC12064601.

31. Jacquetin B, Hinoul P, Gauld J, Fatton B, Rosenthal C, Clavé H, Garbin O, Berrocal J, Villet R, Salet-Lizée D, Debodinance P, Cosson M. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study. Int Urogynecol J. 2013 Oct;24(10):1679-86. doi: 10.1007/s00192-013-2080-4. Epub 2013 Apr 6. PMID: 23563891.
32. Vu MK, Letko J, Jirschele K, Gafni-Kane A, Nguyen A, Du H, Goldberg RP. Minimal mesh repair for apical and anterior prolapse: initial anatomical and subjective outcomes. International Urogynecology Journal. 2012;23(12):1753–1761.

Appendix I

NAME: **DATE:**

Evaluation Questionnaire

Dear patient, in order to assess your current quality of life following your surgery, we kindly ask you to complete this brief questionnaire.

Global Assessment of Surgical Outcome (PGI-I)

Compared to your condition before surgery, how would you describe your current situation? Please select **one** option:

☐ Much better
☐ Better
☐ A little better
☐ No change
☐ A little worse
☐ Worse
☐ Much worse

Assessment of Postoperative Symptoms

Please indicate how much each of the following symptoms currently bothers you by selecting a number from **0 to 10**, where:

0 = not at all
10 = very much

Vaginal bleeding
0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐

Vaginal discharge
0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐

Dyspareunia (pain during sexual intercourse)
0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐
☐ Does not engage in sexual intercourse

Hispareunia (pain experienced by the partner during sexual intercourse)
0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐
☐ Does not engage in sexual intercourse / Not applicable

Vaginal pain
0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐

Sensation of a vaginal bulge
0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐