



Histopathologic Analysis of Explanted Transvaginal Polypropylene Mesh

Mathilde Rousseau¹, Chaojing Li², Kairui Wei², Yan Li², Eric Philippe¹, Yile Sun^{1,3}, Shiwei Zhao^{1,4}, Yuling Wu^{1,5}, Caroline Rhéaume⁶, Lu Wang², Ze Zhang¹, Gaëtan Brochu¹, Geneviève Nadeau⁷, Robert Guidoin¹

1. Division of Regenerative Medicine, Centre de Recherche du CHU de Québec - Université Laval, and Department of Surgery, Faculty of Medicine, Université Laval, Quebec (QC), Canada
2. Key Laboratory of Textile Science & Technology, Ministry of Education and College of Textiles, Donghua University, Shanghai, China
3. Department of Shanghai Lung Cancer Center and the Shanghai Key Laboratory of Thoracic Tumor Biotherapy, Shanghai Chest Hospital, Shanghai Jiaotong University School of Medicine, Shanghai, China
4. Department of General Surgery, Huadong Hospital, Fudan University, Shanghai, China
5. Department of Anesthesiology, Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine, Shanghai, China
6. Division of Reproduction, Maternal and Child Health, Centre de Recherche du CHU de Québec - Université Laval, and Department of Obstetrics, Gynecology and Reproduction, Faculty of Medicine, Université Laval, Quebec (QC), Canada
7. Division of Endocrinology and Nephrology, Centre de Recherche du CHU de Québec - Université Laval, and Department of Surgery, Faculty of Medicine, Université Laval, Quebec (QC), Canada

Abstract: Background: Transvaginal polypropylene (PP) meshes used to treat pelvic floor disorders have raised safety concerns due to adverse events. There is still considerable uncertainty about the causes of these complications. Objective: To identify the histological patterns that contribute to adverse events associated with PP meshes in the surgical treatment of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Study design: Eight explants were collected from seven patients (POP: four; SUI: two; POP and SUI: one), explanation due to mesh exposure or recurrent prolapse. Macroscopic and histological analyses were performed using scanning electron microscopy, light microscopy, and transmission electron microscopy. Results: Two distinct tissue responses were identified. Explants retrieved within 25 months showed rigid encapsulation by dense, well-organized collagen bundles with regular banding. In contrast, meshes removed after 33 months displayed disrupted or absent encapsulation, bacterial colonization, and significant surface degradation. Oxidative stress led to fiber fragmentation and cracking, releasing micro-debris that intensified local inflammation. Biofilm development further compromised the fibrous capsule, resulting in mesh exposure and infection in long-term cases. Conclusion: PP meshes show progressive degradation and inadequate long-term tissue integration. While early encapsulation by fibrotic tissue occurs, it fails to prevent chronic inflammation. Over time, bacterial colonization and oxidative degradation compromise the implant, often requiring removal. These findings highlight the need for alternative materials, such as polyvinylidene fluoride (PVDF), and strategies to prevent biofilm formation. Bacteriophage therapy may offer a new approach to manage mesh-related infections. Further studies with larger sample sizes are needed to confirm these results.

Keywords: Pelvic floor disorders, polypropylene mesh, adverse events, polypropylene degradation.

HIGHLIGHTS

- While transvaginal polypropylene meshes have been used to treat pelvic organ prolapse and stress urinary incontinence, concerns about their biocompatibility remain.
- After implantation, the polypropylene threads become encased in scar tissue, which can shrink as the collagen bundles contract. The presence of bacteria causes the scar tissue to undergo gradual lysis.
- A material resistant to biodegradation and stimulating sinusoidal collagen encapsulation might be the answer to mesh shrinkage.
- The detection of bacteria within the voids of mesh knots, even in microporous devices, highlights the need to explore alternative treatment strategies such as bacteriophage therapy.

INTRODUCTION

Stress urinary incontinence (SUI) and pelvic organ prolapse (POP) can be treated surgically when conservative methods fail to alleviate symptoms or enhance quality of life (1). Reconstructive surgeries are the most common approach and can be performed using various materials, from native biological tissues to synthetic devices (2). Currently, polypropylene (PP) mesh is the most used and the most firmly established material (3-4). Since 2008, medical regulatory authorities issued warnings regarding the use of PP transvaginal mesh (TVM) to treat pelvic floor disorders (PFD) due to rare but severe complications they may cause (5-6). These complications include mesh exposure/erosion, mesh contraction, dyspareunia, pain, and functional lower urinary tract sequelae (7-8). PP meshes have led to many reoperations, raising concerns about their risks while their benefits are being questioned. Since 2016, PP meshes to treat POP have been reclassified from a class II (low to moderate risk device) to class III (high-risk device) (9-10) (Figure S1A). PP meshes to treat SUI (tension free vaginal tape sling) remain in class II (Figure S1B) and is still considered and supported as the gold standard surgery by most medical organizations (11).

Numerous mechanisms have been studied to understand post-surgical adverse events, especially mesh exposure as it is a common and unique risk to mesh repair. A meta-analysis by Deng (2016) noted various patient characteristics that may contribute to mesh erosion such as parity, premenopausal/estrogen replacement therapy, diabetes, and smoking (12). Surgical experience and volume have also been identified as risk factors for mesh exposure (13). Additionally, the nature and characteristics of the biomaterial are crucial variables to consider, including brand, pore size, weight, and anatomical localization (14). In recent years, research on these external factors has enhanced the understanding of adverse events arising from reconstructive pelvic surgery using PP devices. However, uncertainties persist regarding the body's response to the foreign devices, as a non-specific inflammatory response can affect ongoing tissue remodeling during the long life of the patients. This is why a scanning electron microscopy (SEM) of the pristine devices is revisited. Building on previous advancements, this study aims to evaluate PP meshes and related adverse events along 84 months post-surgery. This histologic examination of explanted PP meshes might contribute to better understanding the lack of biocompatibility

and elucidate the mechanisms of bio-integration and/or failure of these devices, as well as their relationship with clinical histories. Specifically, we aim to identify histological patterns that could explain and predict the adverse events associated to PP meshes in the surgical treatment of POP and SUI.

MATERIALS AND METHODS

Pristine PP Meshes

Pristine devices available displayed various mesh structures for deployment as tension free vaginal tape (TVT) slings to treat SUI or POP. Devices analyzed included Restorelle (Coloplast, Humlebaek, Denmark), Avaulta (CR Bard, Becton Dickinson, Franklin Lakes, NJ, USA), Novasilk (Coloplast), and Aris Transobturator Sling System (Coloplast). Small coupons ($0.5 \times 0.5 \text{ cm}^2$) were directly examined in SEM (Jeol, JSM-6360LV, Tokyo, Japan) at accelerating voltages from 15 to 25 kV after gold palladium coating (Sputter Coater Nanotech SEMPREP2, Nanotech, Burton-on-Trent, UK). The analysis of their fabric construction was conducted according to Miao's protocol (15-16) (Table 1).

Patients

Eight PP meshes were harvested at reoperation from seven women. They were aged from 39 to 73 year old. Meshes were initially implanted to treat pelvic organ prolapses in four patients, stress urinary incontinence in two patients and both in one patient. Reoperations were due to recurrent prolapse or vaginal exposure. Patients' demographics are summarized in Table 2.

Explant Analyses

Eight tissue samples were available for biomaterial investigation after performing regular examination in pathology and obtaining patients' consent. Explants were preserved in a 10% solution of formaldehyde. According to institutional regulations, ethical review and approval for this study were waived as no patient information was included. The data were anonymous and maintained confidential.

The first step of the analysis of the specimens included the macroscopic observation of all tissue samples. Pictures were taken using a digital camera (Sony DSC 707, 5 megapixels). These images were processed using Adobe Photoshop CS4.

Tissue samples were then dissected into three sub-specimens, should size permits, for analysis in SEM (all specimens), light microscopy (LM) (six specimens), and transmission electron microscopy (TEM) (three specimens). Regretfully, the size of the explants was not sufficient to undertake textile analyses.

Specimens analyzed in SEM were rinsed in phosphate-buffered saline and then immersed in a 1% solution of osmium tetroxide. Following the post-fixation, they were rinsed in distilled water and dried sequentially in ethanol solutions of graded concentrations from 20% to absolute ethanol. Final drying was completed with hexamethyldisilazane. After gold palladium coating, specimens were ready for observation.

For LM observation, specimens were embedded in paraffin and sliced into sections of about 5 μ m in thickness with a microtome. After being mounted onto slides and eliminating paraffin, the sections were stained with hematoxylin and eosin (HE) for general observations. Masson's trichrome was employed to observe collagen and Verhoelf's staining for elastic fibers. All slides were analyzed using an Axio Imager M2 (Zeiss, Jena, Germany) and the images were processed with the AxioVision Release 4.2.2 software. For polarization microscopy, the slides were stained in red picosirius and rinsed with HCl prior to counterstaining with Harris hematoxylin. Examinations were carried out with the same microscope fitted with a Zeiss circular polarizer D.

For TEM, the samples were further stained in a 1% solution of osmium tetroxide and then in a solution of uranyl acetate. They were then embedded in Epon and sliced into thin sections using an ultramicrotome. Final staining was achieved using solutions of lead citrate and uranyl acetate. Samples were ultimately examined using a Jeol JEM-1230 TEM with an 80 kV voltage.

RESULTS

Pristine Devices

The pristine group, including Restorelle (Figure S2), Aris TOT Sling (Figure S3), Avaulta (Figure S4), and Novasilk (Figure S5), featured a range of mesh designs for the treatment of SUI or POP, depending on the specific indications of each mesh. They exhibited various constructions, from tightly compacted to widely open, showcasing different pore shapes, sizes, and distributions (Table 2).

The pristine devices analyzed in this study are representative of commercially available gynecological meshes used for pelvic repair. All are composed of a warp-knitted structure made from PP monofilament. A defining characteristic is the monofilament's configuration, which is bent and interlaced into looped structures (Figure S6). This design imparts favorable mechanical properties, including strength and a degree of elasticity. However, the overlapping loops can create points of stress concentration, making the mesh susceptible to fatigue damage post-implantation. Additionally, the tiny voids formed by these overlapping coils may serve as niches for bacterial colonization, increasing the risk of infection.

Explanted Devices

The explanted devices included eight PP meshes retrieved from seven patients. Based on macroscopic examination, the explants were categorized according to implantation duration, which ranged from 4 to 84 months. Meshes implanted for 25 months or less were found to be fully encapsulated, whereas those implanted for 33 to 84 months exhibited signs of partial to complete degradation. This time-dependent progression enabled classification of the explanted PP devices along a continuum from well-encapsulated to poorly encapsulated, depending on the duration of implantation (Figure S7).

First Group of Reaction: Complete Encapsulation

In explants retrieved after up to 25 months of implantation, SEM revealed rigid encapsulation of the PP mesh. The mesh was tightly embedded within dense collagenous scar tissue, reflecting the body's repair mechanisms aimed at restoring tissue integrity. Unlike the naturally undulating, sinusoidal collagen fibers in healthy tissue, the collagen surrounding the mesh appeared significantly stretched, indicating scar formation rather than normal remodeling.

Despite this encapsulation, the PP fibers showed early signs of degradation, including longitudinal fissures and transverse cracks, likely due to mechanical handling and surface oxidation. Notably, there was no structural integration between the collagen and the PP fibers; the polymer remained entirely isolated within the tissue. Furthermore, no bacterial colonization was detected within the voids around the mesh, as confirmed by SEM (Figure 1A&1B, Figure S8).

LM provided further insight into the biological response to the PP mesh. Two distinct reactive zones were identified surrounding the PP filaments. The first, immediately adjacent to the fibers, was characterized by an inflammatory microenvironment containing fluid, macrophages, and fibroblasts that had migrated through the mesh. This response was intensified by the fragmentation of the oxidized PP surface and led to the formation of granulation tissue, marked by increased collagen synthesis. As fibroblasts transitioned into myofibroblasts, they acquired contractile filaments, contributing to tissue contraction and volume reduction. This process brought PP fibers closer together and was further influenced by repeated mechanical stress, polymer degradation, and inflammation (Figure 1C).

The inter-filament voids became focal points for varying degrees of inflammatory response, ranging from healthy tissue interaction to intense inflammation. In cases without pronounced inflammation, a second reactive zone developed, marked by concentric layers of collagen fibers that were uniformly stretched and lacked the normal undulating structure (Figures S9, S10). These collagen arrangements were particularly evident after red picrosirius staining, which highlighted the independent, organized layering (Figure 1D).

TEM supported these findings, revealing well-organized collagen fibrils with regular banding patterns, despite being stretched (Figure 1E, 1F). However, when cells or oxidized PP debris were present, these fibrils lost their definition and appeared blurred (Figure S11).

Second Group of Reaction: Poor/Absent Encapsulation

The second group of explants showed a markedly different profile compared to the first group, characterized by poor or absent encapsulation. SEM revealed extensively damaged PP structures, with no evidence of surrounding collagen encapsulation. Collagen fibers appeared degraded at various stages of lysis, with disorganized and dispersed filaments. The degradation of the PP was more pronounced than in the first group, with numerous fractures observed along the oxidized surface layer and longitudinal axis of the fibers.

Surrounding the mesh, tissue debris were evident, along with large numbers of inflammatory cells, including white and red blood cells. Bacterial colonization was widespread, occurring in areas where the encapsulating tissue had undergone partial or complete lysis (Figure S12). This significant bacterial presence was associated with active infection. The fibrous capsule had undergone extensive fibrinolysis, marking the final stage of scar tissue breakdown. Thin, disorganized collagen bundles were scattered within the

biological debris as the structural integrity of the mesh deteriorated. In the absence of encapsulation, bacterial colonies penetrated directly into the PP fibers. The PP degradation extended both superficially and deeply, with visible features including peeled fibers, transverse cracks, fragmented surfaces, and sections of material detaching from the structure, regardless of the original mesh design (Figure 2A, 2B). The disintegrated capsules showed remnants of collagen bundles undergoing lysis, interspersed with blood debris containing bacterial colonies (Figure 2C, 2D).

TEM further illustrated this degradation. Collagen bundles appeared thin and disorganized, composed of parallel filaments lacking the normal undulating pattern. This disruption likely reflects the breakdown of collagen architecture due to infection. The external encapsulation of the fibers was lysed by bacterial activity. Although the banding pattern of collagen filaments became increasingly blurred, the individual filaments resisted aggregation (Figure 2E, 2F).

DISCUSSION

Pelvic organ prolapse and stress urinary incontinence impact the quality of life of millions of women worldwide, physically as well as psychologically. Mancuso et al. proposed a detailed analysis to better understand why there is still no gold standard treatment to cure these pathologies (17). The synthetic meshes have dramatically transformed POP and SUI repair showing superior anatomic outcomes in comparison to conservative strategies. Regretfully, adverse events have followed, such as mesh exposure, dyspareunia, pain, and functional lower urinary tract sequelae (7). Attention was paid regarding the complications that occurred with the use of synthetic meshes and the FDA issued health notifications, reclassifying these devices (10).

Central to this effort is adherence to the **3Bs principle – biofunctionality, biodurability, and biocompatibility** – which must guide the design and performance of these implants throughout the patient's lifetime. These devices are intended to restore function effectively and must withstand mechanical stress and degradation to ensure long-term safety. Preventing the release of fragments or particles is critical to avoid triggering chronic inflammatory responses.

Moreover, the mesh architecture should support healthy tissue integration by promoting a soft encapsulation process, ideally characterized by sinusoidal collagen fibers that reduce scar tissue formation. Ensuring the long-term safety and efficacy of these implants is essential for safeguarding the patient's well-being over time.

Pristine Devices

All commercial mesh devices evaluated in this study were manufactured using monofilament PP fibers via warp-knitting technology. Variations in fiber diameter and knitting architecture – including pore geometry, loop density, and stitch configuration – significantly influenced their biomechanical performance in vivo. Under mechanical stress, these structural differences resulted in diverse deformation patterns across the devices.

For example, tightly knit meshes with smaller pores showed localized stress concentrations, leading to pronounced loop distortion and a reduction in porosity when

subjected to multiaxial loading. These regional stress concentrations may intensify the host's foreign body response, potentially contributing to mesh exposure. Key properties such as porosity, anisotropy, and mechanical behavior vary widely among these meshes.

In vitro work by Feola et al. provides foundational data for characterizing prolapse meshes and their mechanical responses (16,18). Under multiaxial loading, **Restorelle** and the **Aris Transobturator Sling** maintained their structural morphology, whereas other meshes underwent significant deformation, making them unrecognizable in small, embedded explants. The concept of "gross porosity" remains poorly defined and warrants further investigation to better understand structural changes under physiological loading conditions (18). A more critical, yet underexplored issue is the presence of **voids within the mesh knots**, which often become niches for biofilm formation, harboring inflammatory cells and bacteria (19). Falagas et al. reported a 90% rate of positive bacterial cultures in hundreds of mesh explants (20). Similarly, Boulanger's study found bacterial contamination in all 16 explants analyzed, although bacterial loads were generally low (21).

These findings suggest that PP fibers can successfully integrate into host tissue **only when complete encapsulation occurs**, eliminating voids that could otherwise foster inflammation and infection.

Findings

Histological analysis of the eight explanted PP devices revealed two distinct patterns of tissue response depending on the duration of implantation and the presence or absence of bacterial infection. The **first pattern**, observed in explants retrieved after up to 25 months of implantation, was characterized by **rigid encapsulation** of the mesh within dense, stretched collagen fibers. These organized collagen bundles conferred mechanical strength and stability, forming a robust fibrotic capsule. Within each bundle, collagen filaments remained well-aligned, individualized, and displayed a regular banding pattern. In contrast, the **second pattern**, seen in long-term explants (beginning at 33 months), was marked by **disorganized or completely absent encapsulation**. Bacterial colonization was evident within the mesh structure, coinciding with significant surface degradation of the polypropylene fibers. This degradation included fragmentation and transverse cracking perpendicular to the fiber's longitudinal axis primarily due to oxidative stress on the polymer surface. The degradation process typically began with **flaking of the oxidized polypropylene**, releasing micro-fragments into the surrounding tissue. These fragments intensified the foreign body response, amplifying local inflammation. The presence of these tiny, oxidized particles triggered a sustained and exacerbated inflammatory reaction, contributing to post-surgical complications. Over time, **bacterial colonization within biofilms** played a critical role in the breakdown of the fibrous capsule. This led to full exposure of the PP mesh and established infection, as documented in this second group of reaction.

Results in the Context of what is Known

PP meshes have proven effective in the surgical management of POP and SUI (3). However, despite the clinical success of TVM procedures, the FDA has cautioned that associated risks may in some cases outweigh the benefits (9). In recent years, multiple mechanisms have

been proposed to explain these adverse outcomes. Among them, **encapsulation** has emerged as a critical factor, strongly influenced by the mesh's **material composition and structural characteristics** (22). A growing body of literature emphasizes the importance of **pore size and weight**, which play a key role in modulating the tissue response and overall mesh biocompatibility (23). Mistrangelo et al. reported that **lighter PP meshes**, characterized by reduced material density, tend to provoke a **less intense foreign body reaction** (8). Similarly, **mesh weight** significantly impacts long-term outcomes, with **heavier meshes** being more susceptible to **polymer degradation** and a heightened inflammatory response (24-25). In clinical practice, macroporous monofilament synthetic slings are generally preferred for their superior integration into host tissue. Meshes with pore sizes exceeding 75 µm enable the efficient migration of immune and structural cells, thereby promoting robust tissue ingrowth. This cellular infiltration supports better healing outcomes while reducing the risks of chronic inflammation and infection (26). Importantly, these risks are not solely determined by mesh design. The **anatomical site of implantation** also appears to influence biocompatibility. Studies suggest that the **pelvic region** is more prone to foreign body complications than the **abdominal wall**, likely due to differences in tissue environment and mechanical loading (27). Additionally, **surgical handling** of PP can have a substantial effect on the material's integrity. The use of various instruments may physically alter the mesh surface, promoting **in vivo degradation** (28-30). Finally, the **source and manufacturing quality** of the PP itself remain under-investigated and may represent an important variable in mesh performance and safety.

While significant progress has been made in understanding the external factors affecting PP mesh implantation, there remains a critical gap in studies that focus on the histological analysis of explanted devices. A notable contribution by Iakolev, involving over 164 explanted PP meshes examined using various microscopy techniques, revealed key issues such as surface degradation and persistent chronic inflammation (31,32). The body's initial response to mesh implantation is an acute inflammatory reaction. Surgical placement of the mesh creates a superficial cavity that rapidly fills with blood and interstitial fluid, forming a clot that serves as a scaffold for granulation tissue eventually leading to the formation of scar tissue (33,34). In cases where PP degradation does not occur, this scar typically manifests as a fibrous capsule encasing the mesh. However, the formation of biofilms, particularly within the voids and interstices of mesh knots, poses a serious challenge. These biofilms create protective niches for bacteria, as they compromise the immune system's access to the site. Neutrophils, for instance, are unable to migrate effectively within these environments, limiting their capacity to eliminate bacterial pathogens (35). The clinical relevance of this phenomenon is underscored by microbiological analyses showing that 44 out of 49 patient samples contained a diverse array of bacterial species (20). To address these ongoing complications, innovation in biomaterials research must be prioritized. The development of 3D in vitro biofilm models represents a promising frontier, offering a dynamic and biologically relevant platform to study host-material interactions and infection dynamics (36,37).

Clinical Implications

Considering the current controversy, it is crucial to understand and be aware of the potential adverse events that may occur after PP mesh implantation, to be able to diagnose

and address them. Identifying specific microscopic reactions from histology analysis can provide guidelines to better discriminate between factors influencing surgical outcomes, and ultimately, prevent complications. Our observations indicate that PP meshes associated with post-surgical complications do not stay intact after implantation. Instead, they experience early stages of degradation, triggering a sustained inflammatory response, regardless of the mesh construction. This lack of inertness and long-term biocompatibility in PP meshes shall be considered by both patients and doctors. It is essential that physicians provide comprehensive counseling on the potential complications associated with PP mesh implantation before any intervention.

Research Implications

Given the ongoing need for softer and more adaptive materials, polyurethane meshes produced through electrospinning have been proposed as a potential alternative to PP. However, their limited biostability raises concerns about the chemical by-products resulting from their degradation. Initiating clinical trials without robust evidence of polyurethane's long-term stability would therefore be premature. Historically, the use of polyurethane in implantable devices has sparked debate, despite its acceptance in certain cardiovascular applications (38,39).

Currently, the only polymer fabric that may be recommended as a credible alternative to PP is polyvinylidene fluoride (PVDF). Its mechanical strength and resistance to degradation, as observed in vascular suture materials, make it a promising candidate (40). Nonetheless, PVDF does not appear to support encapsulation by wavy, sinusoidal collagen fibers and therefore cannot yet be regarded as a definitive substitute for PP (41). At present, no material in development demonstrates the ability to support sinusoidal tissue encapsulation—an essential characteristic to prevent both scar tissue formation and chronic inflammatory responses. Such a material, or potentially a bioabsorbable polymer, would need to enable collagen to organize into undulating, functional structures (42).

Preventing bacterial colonization also remains a critical concern. This issue underscores the importance of designing mesh structures that eliminate voids within the knitted knots, which can otherwise become reservoirs for biofilm formation. In cardiovascular surgery, mesh coatings that release antibiotics were explored as a method to prevent infection. However, the immobilization of antibiotics on such devices was found to interfere with tissue healing, leading to the discontinuation of these clinical trials (43).

Given these limitations, the solution may not lie solely in developing new materials. Alternative strategies should be revisited—such as bacteriophage therapy—which may offer a more targeted and sustainable approach to infection control in implantable devices (44,45).

Strengths and Limitations

This study offers a rare and detailed histological evaluation of explanted PP meshes using a combination of SEM, LM, and TEM. A key strength lies in the multi-modal imaging approach, which allowed for a comprehensive assessment of tissue-material interactions. Most

specimens were analyzed using all three microscopic techniques, strengthening the methodological rigor of the investigation.

Despite the relatively small sample size and heterogeneity of the mesh types, the explants varied in clinical indication and duration of implantation. This diversity provides a broader perspective on the behavior of PP meshes in the pelvic region across different clinical contexts.

One limitation is the absence of precise matching between pristine commercial meshes and the corresponding explanted samples. While various commercial mesh types were analyzed, they were not directly paired with the specific explants studied. Additionally, establishing a control group of explanted meshes from asymptomatic patients (i.e., without post-surgical complications) is not feasible in clinical practice.

This study should be viewed as complementary to large-scale statistical analyses of patient follow-up data. It focuses specifically on adverse outcomes and does not account for the clinical benefits of mesh implantation procedures. For a balanced interpretation, it is important to also highlight the overall success rates of such interventions and the number of complications potentially prevented through their use.

CONCLUSION

This exploratory study highlights the limitations of PP meshes in the treatment of pelvic floor disorders, raising concerns about the material long-term suitability for this application. Across all explanted devices, the PP fibers demonstrated poor resistance to oxidative stress, as evidenced by continuous surface fragmentation regardless of mesh design or manufacturer, ultimately leading to the need for surgical removal. PP meshes did not support the development of soft, functional collagen capsule with organized, sinusoidal fibers and regular banding. In more severe cases, bacterial colonization contributed to degradation of this fibrotic encapsulation, accelerating mesh degradation. These findings question the suitability of PP for long-term pelvic floor implantation. Larger studies are needed to confirm those observations. Clinical evaluation of alternative materials such as PVDF as well as strategies to limit bacterial colonization should be considered.

Acknowledgements

This work was supported in part by the Fonds de recherche du Québec (FRQ) through the research center grant for the Centre de Recherche du CHU de Québec - Université Laval, (Reference 30641), the Fundamental Research Funds for the Central University (Donghua University, NS2013, the National Nature Science Foundation (31100682 and 30972942), the III Project “Biomedical Textile Materials Science and Technology” (BO7024), the Engineering Research Center of Technical Textile Ministry of Education and the Science and Technology Commission of Shanghai Municipality (11DZ2292900).

Authors' Contribution

Lu Wang, Ze Zhang, Chaojing Li, Gaëtan Brochu, Robert Guidoin and Geneviève Nadeau conceived and designed the study and interpreted the data. Mathilde Rousseau, Kairui Wei,

Yan Li, Yile Sun, Shiwei Zhao and Yuling Wu performed the acquisition of data and the analysis of the results. Gaëtan Brochu, Caroline Rhéaume and Geneviève Nadeau obtained patients consent. Mathilde Rousseau, Chaojing Li, Eric Philippe, Ze Zhang, Robert Guidoin, Geneviève Nadeau contributed to writing the manuscript. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

All authors declare no conflict of interest.

Supplementary Data

More supporting data are available online.

Tweetable statement: Over the years, concerns have been raised over transvaginal polypropylene mesh implanted to correct stress urinary incontinence and pelvic organ prolapse. This study explores the biodurability and biocompatibility of polypropylene mesh, prompting search for safer alternatives.

REFERENCES

1. Dmochowski RR, Blaivas JM, Gormley EA, et al. Update of AUA guideline on the surgical management of female stress urinary incontinence. *J Urol*. 2010; 183(5):1906-1914.
2. Stanford EJ, Cassidenti A, Moen MD. Traditional native tissue versus mesh-augmented pelvic organ prolapse repairs: Providing an accurate interpretation of current literature. *Int Urogynecol J*. 2012; 23:19-28. doi: 10.1007/s00192-011-1584-z.
3. Cervigni M, Natale F. The use of synthetics in the treatment of pelvic organ prolapse. *Curr Opin Urol*. 2001; 11:429-435.
4. Chapple CR, Cruz F, Deffieux X, et al. Consensus statement of the European Urology Association and European Urogynaecological Association on the use of implanted materials for treating pelvic organ prolapse and stress urinary incontinence. *Eur Urol* 2017;72(3):424-431.
5. Ellington DR, Richter HE. The role of vaginal mesh procedures in pelvic organ prolapse surgery in view of complication risk. *Obstet Gynecol Int*. 2013:356960.
6. Food and Drug Administration HHS, Department of Health and Human Services - Obstetrical and Gynecological devices: reclassification of surgical mesh for transvaginal pelvic organ prolapse repair. January 2016, vol. 81, n° 2.
7. Margulies RU, Lewicky-Gaupp C, Fenner DE, et al. Complications requiring reoperation following vaginal mesh kit procedures for prolapse. *Am J Obstet Gynecol*. 2008; 199:678.e1-4.
8. Mistrangelo E, Mancuso S, Nadalini C, et al. Rising use of synthetic mesh in transvaginal pelvic reconstructive surgery: A review of the risk of vaginal erosion. *J Minim Invasive Gynecol*. 2007; 14:564-569. doi: 10.1016/j.mig.2007.04.017.
9. FDA Public Health notification: Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapsed and stress urinary incontinence, October 2008.

10. FDA Executive Summary. Surgical mesh for the treatment of women with pelvic organ prolapse - Proceedings of the Obstetrics and Gynecology Devices Advisory Committee Meeting. September 2011, Gaithersburg, MD, USA.
11. Gee A, Chapman G, Paraiso MF. Where Are We Now? Urogynecologic Mesh and Present Recommendations. *J Gynecol Surg.* 2023; 39:30-35.
12. Deng T, Liao B, Luo D et al. Risk factors for mesh erosion after female pelvic floor reconstructive surgery: A systematic review and meta-analysis. *BJU Int.* 2016; 117:323-343.
13. Long CY, Lo TS, Wang CL et al. Risk factors of surgical failure following transvaginal mesh repair for the treatment of pelvic organ prolapse. *Eur J Obstet Gynecol Reprod Biol.* 2012; 161:224-227.
14. Gigliobianco G, Regueros SR, Osman NI et al. Biomaterials for pelvic floor reconstructive surgery: How can we do better? *Biomed Res Int.* 2015; 968087.
15. Miao L, Wang F, Wang L et al. Physical characteristics of medical textile prostheses designed for hernia repair: A comprehensive analysis of select commercial devices. *Materials (Basel).* 2015; 8:8148-8168.
16. Feola A, Barone W, Moalli P, Abramowitch S. Characterizing the ex vivo textile and structural properties of synthetic prolapse mesh products. *Int Urogynecol J,* 2013; 24:559-64.
17. Mancuso E, Downey C, Doxford-Hook E, et al. The use of polymeric meshes for pelvic organ prolapse: Current concepts, challenges, and future perspectives. *J Biomed Mater Res B Appl Biomater.* 2020; 108:771-789.
18. Feola AJ. Impact of vaginal synthetic prolapse meshes on the mechanics of the host tissue response. PhD dissertation, University of Pittsburg, USA, 2011.
19. Khatoon Z, McTiernan CD, Suuronen EJ et al. Bacterial biofilm formation on implantable devices and approaches to its treatment and prevention. *Heliyon,* 2018; 4:e01067.
20. Falagas ME, Velakoulis S, Iavazzo C, Athanasiou S. Mesh-related infections after pelvic organ prolapse repair surgery. *Eur J Obstet Gynecol Reprod Biol,* 2007; 134:147-156.
21. Boulanger L, Boukerrou M, Rubod C et al. Bacteriological analysis of meshes removed for complications after surgical management of urinary incontinence or pelvic organ prolapse. *Int Urogynecol J.* 2008; 19:827-831.
22. Kaelin-Gambirasio I, Jacob S, Boulvain M et al. Complications associated with transobturator sling procedures: Analysis of 233 consecutive cases with a 27 months follow-up. *BMC Women's Health.* 2009; 9:28.
23. Barone WR, Moalli PA, Abramowitch SD. Textile properties of synthetic prolapse mesh in response to uniaxial loading. *Am J Obstet Gynecol.* 2016; 215:326.e1-9.
24. Ugianskiene A, Davila GW, Su, TH. FIGO review of statements on use of synthetic mesh for pelvic organ prolapse and stress urinary incontinence. *Int J Gynaecol Obstet.* 2019; 147:147-155.
25. Chughtai B, Mao J, Buck J, et al. Use and risks of surgical mesh for pelvic organ prolapse surgery in women in New York state: Population based cohort study. *BMJ.* 2015; 350:h2685.
26. Ford AA, Rogerson L, Cody JD, et al. Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev.* 2017 Jul 31;7(7):CD006375.
27. Cervigni M, Natale F. The use of synthetics in the treatment of pelvic organ prolapse. *Curr Opin Urol.* 2001; 11:429-435.

28. Milani AL, Withagen MIJ, Vierhout ME. Outcomes and predictors of failure of trocar-guided vaginal mesh surgery for pelvic organ prolapse. *Am J Obstet Gynecol*. 2012; 206:440.el-8.
29. Azadi A, Jasinski JB, Francis SL et al. Evaluation of surgical instrument handling on polypropylene mesh using scanning electron microscopy. *Int Urogynecol J*. 2014; 25:651-656.
30. Al-Kharabsheh AM, Lo TS, Cortes EFM, et al. Conventional surgery for recurrent pelvic organ prolapse with mesh erosion after failed transvaginal mesh operation. *Gynecol Minim Invas Ther*. 2015; 4:44-46.
31. Iakovlev V, Guelcher SA, Bendavid R. Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients. *J Biomed Mater Res Part B. Appl Biomater*. 2017; 105:237-248.
32. Iakovlev V, Carey ET, Steege J. Pathology of explanted transvaginal meshes. *Intern J Med Health, Pharmac Biomed Eng*. 2014; 8:549-552.
33. Clavé A, Yahi H, Hammou JC, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. *Int Urogynecol J*. 2010; 21:261-270.
34. Diedrich CM, Verhorstert KWJ, Riool M, et al. Transvaginal mesh-related complications and the potential role of bacterial colonization: An exploratory observational study. *J Minim Invas Gynecol*, 2023; 30:205-215.
35. Guzmán-Soto I, McTiernan C, Gonzalez-Gomez M et al. Mimicking biofilm formation and development: Recent progress in in vitro and in vivo biofilm models. *iScience*. 2021; 24:102443.
36. Su Y, Yrastorza JT, Matis M et al. Biofilms: formation, research models, potential targets, and methods for prevention and treatment. *Adv Sci (Weinh)*. 2022;9:e2203291.
37. Crivello G, Fracchia L, Ciardelli G, et al. In vitro models of bacterial biofilms: Innovative tools to improve understanding and treatment of infections. *Nanomaterials (Basel)*. 2023; 13:904.
38. Stokes K, McVenes R and Anderson JM. Polyurethane elastomer biostability. *J Biomater Appl*. 1995; 9:321-54.
39. Yang M, Zhang Z, Hahn C et al. Totally implantable artificial hearts and left ventricular assist devices: Selecting impermeable polycarbonate urethane to manufacture ventricles. *J Biomed Mater Res*. 1999; 48:13-23.
40. Urban E, King MW, Guidoin R, et al. Why make monofilament sutures out of polyvinylidene fluoride? *ASAIO J*, 1992; 40:145-156.
41. Mary C, Marois Y, King MW, et al. Comparison of the in vivo behavior of polyvinylidene fluoride and polypropylene sutures used in vascular surgery. *ASAIO J*, 1998; 44:199-206.
42. Ren J, Murray R, Wong, CS, et al. Development of 3D printed biodegradable mesh with antimicrobial properties for pelvic organ prolapse. *Polymers (Basel)*. 2022; 14:763.
43. Seipelt RG, Vazquez-Jimenez JF, Seipelt IM, et al. The St. Jude "Silzone" valve: Midterm results in treatment of active endocarditis. *Ann Thorac Surg*. 2001; 72:758-762.
44. Noor I, Nasir MH, Rheman AU, et al. Medicinal and immunological aspects of bacteriophage therapy to combat antibiotic resistance. *Explor Med*. 2024; 5:215-231.
45. Fowoyo P. Phage therapy: Clinical applications, efficacy, and implementation hurdles. *Open Microbiol J*. 2024; 18:E18742858281566.

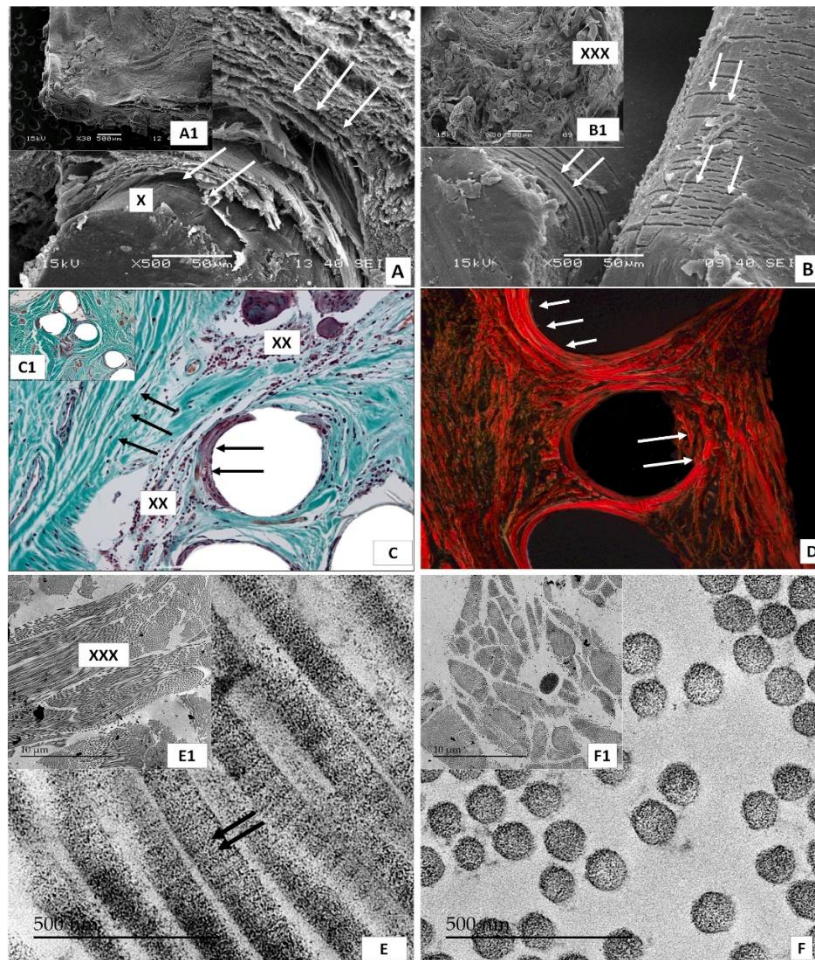
FIGURES**Figure 1**

Figure 1: Complete encapsulation: Scanning electron microscopy: encapsulation in two different devices (A, B), showing the filaments of the monolayer mesh (A1) embedded with concentric layers of collagen without any undulation (A, triple arrows), the lack of adhesion of the collagen bundles to the filament and the space between the polymer can be filled with a biofilm (A, double arrows). The polypropylene filament shows some vertical fractures (A, X). The second device is a multilayer mesh (B). The embedding of the structure is more exuberant and filaments are not fully incorporated (B1, XXX). The presence of the numerous perpendicular cracks in the oxidized layer of the polypropylene is well evidenced (B, double arrows). Light microscopy observation of embedded mesh (Masson's trichrome) (C): The encapsulation is associated with granulation tissue with a high cellularity (C, XX). The development of concentric layers of collagen fibers follows (triple arrows). The oxidized layer of polypropylene is captured in the capsule and causes inflammatory reactions (C, double arrows). Development of the scar tissue is observed in polarized microscopy after red picosirius staining (D): The collagen filaments surrounding the polypropylene fibers are stretched (D, double arrows) but there are still voids between them (D, triple arrows). Observation in TEM of a capsule whose fibers are stretched (E1, XXX). In the absence of cells, the filaments show a regular banding (E, double arrows) and are well individualized without any aggregation (F).

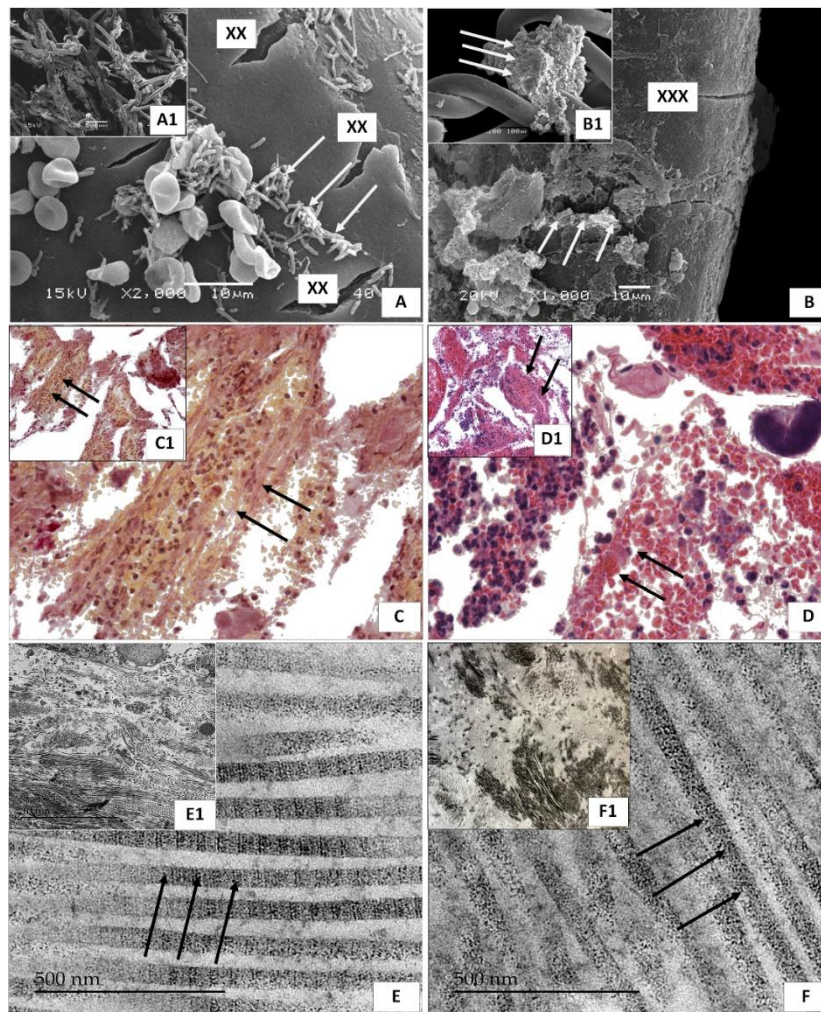


Figure 2

Figure 2. Poor/absent encapsulation: SEM images of two devices (A, B): Fracture of polypropylene filaments. The first device shows a structure devoid of full encapsulation (A1). The oxidized layer is up lifted and fractured (A, XX), and gives anchorage to bacteriemic colonization (A, tripple arrows). The fibers of the second device hold fragmented thrombi (B1, triple arrows). Blood debris are visible on the surface of the filaments (B, triple arrows) in addition to fractures perpendicular to the axis (B, XXX). Optical microscopy with HE stain (C,D): Final steps of the lysis of the capsule. The bundles of collagen fibers are dispersed (C, C1, double arrows) ending in the final step with blood debris incorporating blood cells and bacteria (D, D1, double arrows). TEM images of the collagen fibers at the last step of the lysis of the capsule (E,F): The morphology of the filaments varies from mild blurry (E, E1) to severely damaged (F, F1) according to the observation of the banding (triple arrows).

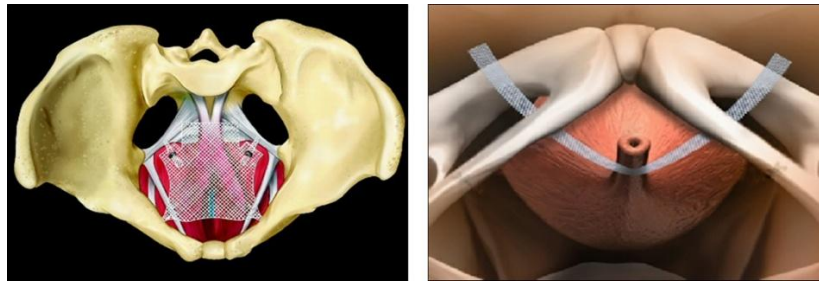


Figure S1: Deployment of surgical meshes for urogynecologic procedures: A) Transvaginal mesh to treat pelvic organ prolapse (POP). This mesh was reclassified by the FDA from Class II (low to moderate risk devices) to Class III (high risk devices); B) Mesh sling to treat stress urinary incontinence (SUI). This mesh is classified Class II by the FDA. These illustrations are adapted from <https://www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants>.

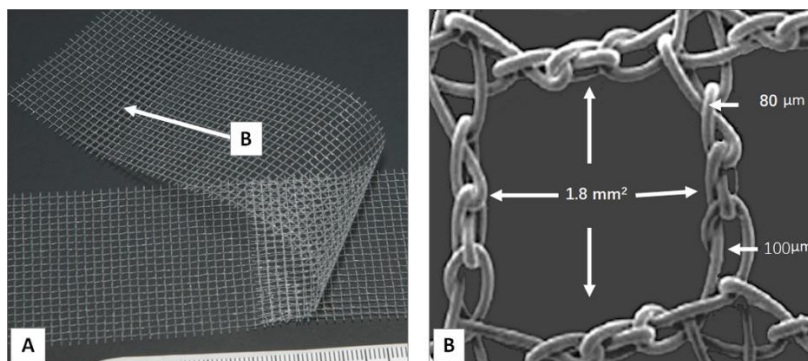


Figure S2: Restorelle mesh prosthesis specifically designed to treat pelvic organ prolapse. Its unique construction with 1.8 mm square macropores and 100 microns interstitial pores and 80 microfiber allows to maintain the structure under uniaxial textile loading (A: gross observation; B: observation in SEM). Adapted from: https://iu.coloplast.us/wp-content/upload/2017/04/USIU_CPIUwebpage_Product_Restorelle_Med_Brochure-PM-03607.pdf.

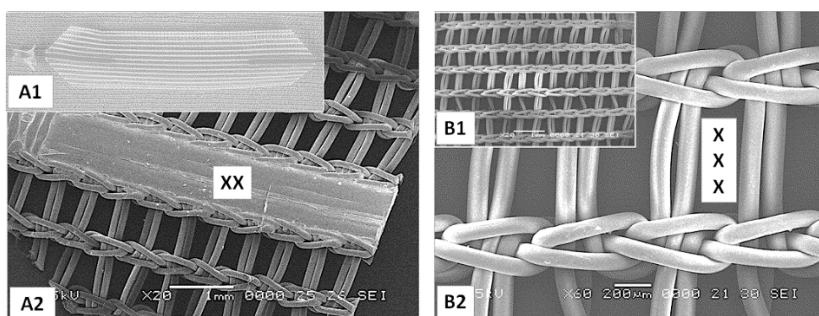


Figure S3: Aris Transobturator Sling System. (A1) SEM image highlighting the lightweight design. A reinforcing flat strip ensures uniform stress distribution and minimal deformation under load (7.5% elasticity) (A2, XX). The light weight design 70g/m² with pores 200 μ m X 400 μ m (XXX) to promote tissue integration (B1, B2).

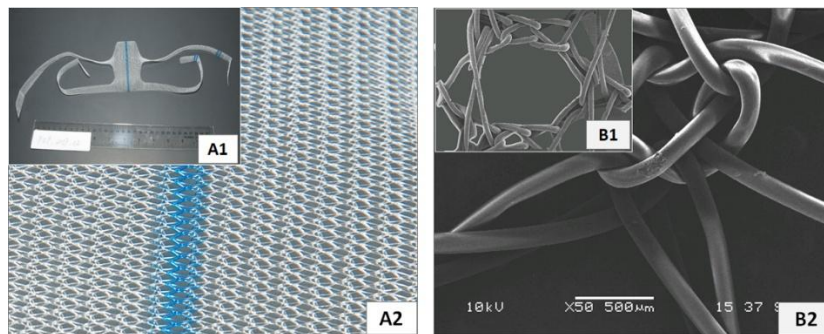


Figure S4: Avaulta mesh prosthesis(A1, A2). Scanning electron micrograph illustrating the hexagonal structure formed by warp-knitted monofilament polypropylene fibers. The mesh architecture balances mechanical strength (≥ 16 N) and biocompatibility, with a thickness of 400 μm and uniform pore distribution (B1, B2).

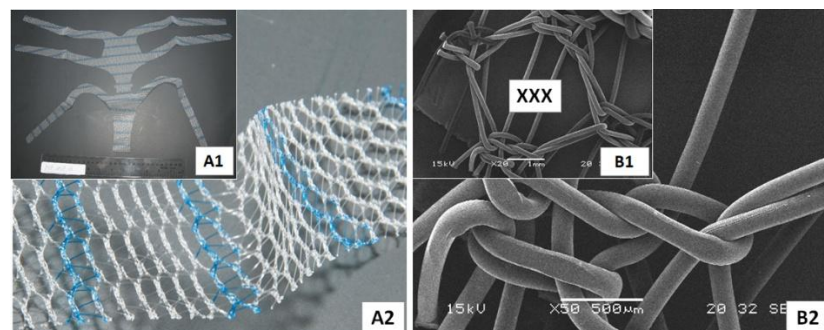


Figure S5: Novasilk with a 279 μm thickness, a fiber diameter of 75 μm , with a weight of around 70 g/m^2 (A1, A2). Monofilament here forms irregular polygonal pore shape and their several monofilament floating divided the pore to smaller size about 1.4 mm^2 (B1 XXX, B2). The failure load of this mesh is about 54 N.

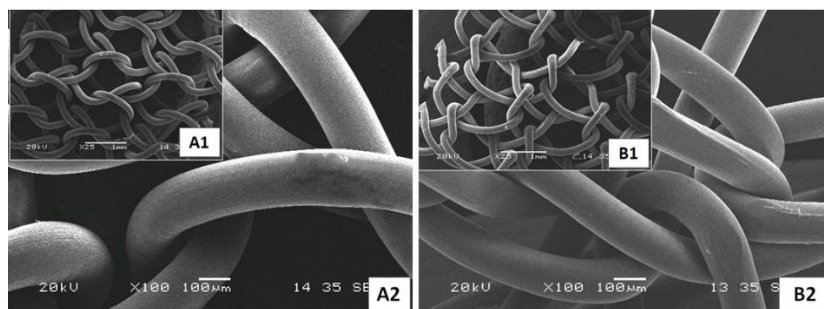


Figure S6: Representative monofilament polypropylene meshes holding a warp-knitted structure with different porosities (A, B). Such a loop structure gives the mesh good mechanical characteristics. However, upon uniaxial strain, the structures undertake major deformations and cannot be identified in small tiny explants.

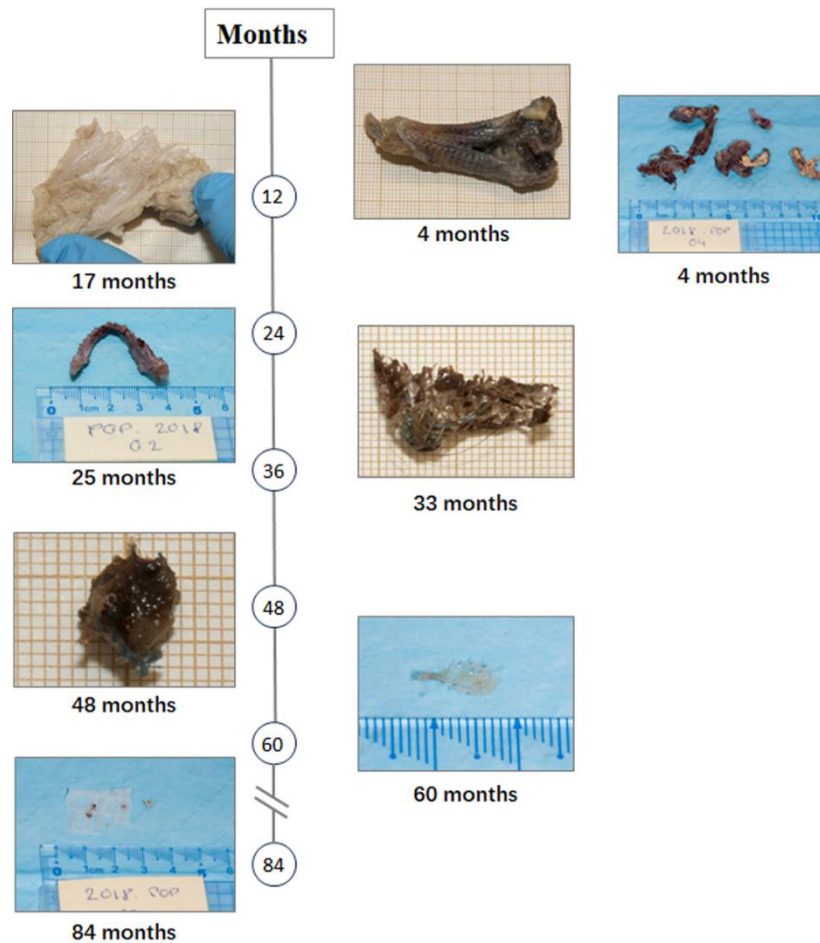
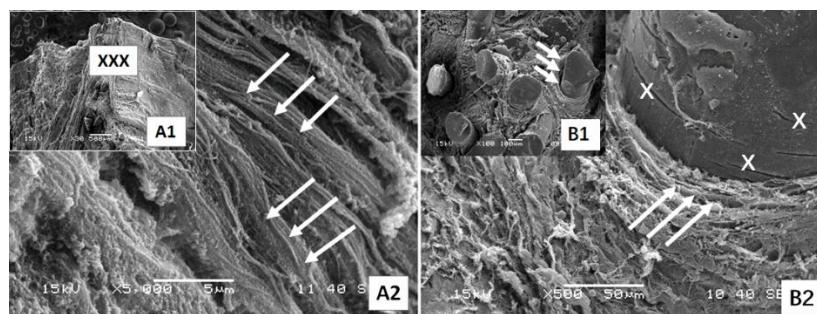


Figure S7: Gross observation of the explanted specimens. Between 4 months and 25 months, the mesh of the explant is fully encapsulated and the capsule is made of scar tissue. The specimen obtained at a second reoperation was not fully incorporated and let filaments of polypropylene visible. After 33 months and 48 months, the polypropylene mesh is visible in the middle of partially lysed scar tissue. The embedding was totally lysed in the specimens explanted after 60 months and 84 months. The structure of the mesh was visible.



FigureS8: Illustrations of a complete encapsulation of the polypropylene mesh. The development of the collagen embedding totally encases the polypropylene structure (XXX, A1). Straight and stretched bundles do not show any sinusoidal structure (triple arrows, A2). However, at the level of each polypropylene fiber, there is no adhesion of the foreign capsule (triple arrows, B1). Each fiber is surrounded with concentric layers of collagen (triple arrows, B2) and shows some fractures (X, B2).

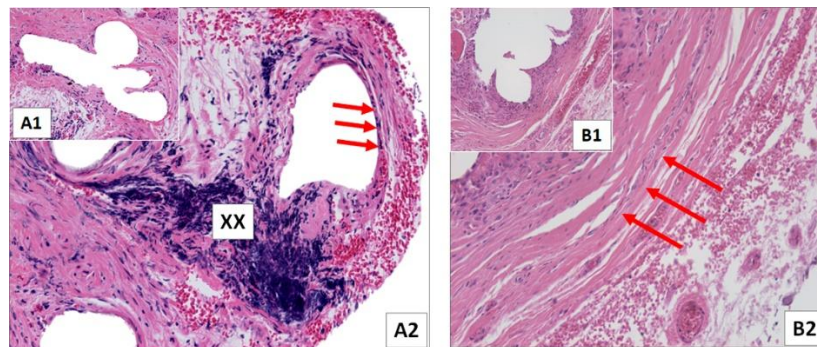


Figure S9: Pathologic encapsulation in light microscopy after HE staining. The accumulation of cells, inflammatory cells, blood cells, in the void space can initiate infection should bacteria come (XX, A2). Otherwise the exuberant development of stretched collagen fibers make the scar tissue highly stiff (triple arrows, A2, B2).

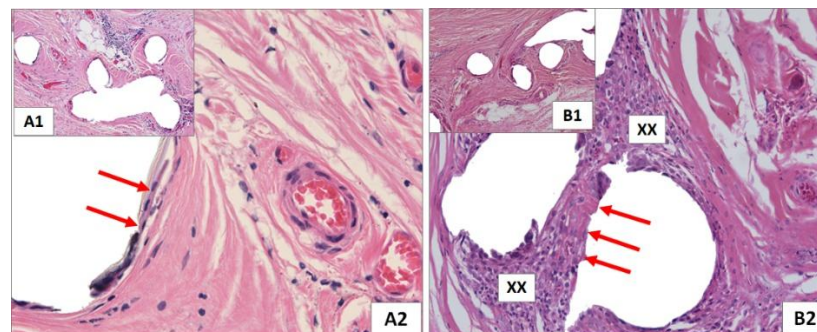


Figure S10: Voids between filaments are associated with inflammatory reactions of different intensities as illustrated in light microscopy after HE staining (XX). The presence of inflammatory cells is moderate in A (double arrows), whereas it is exacerbated in B (triple arrows).

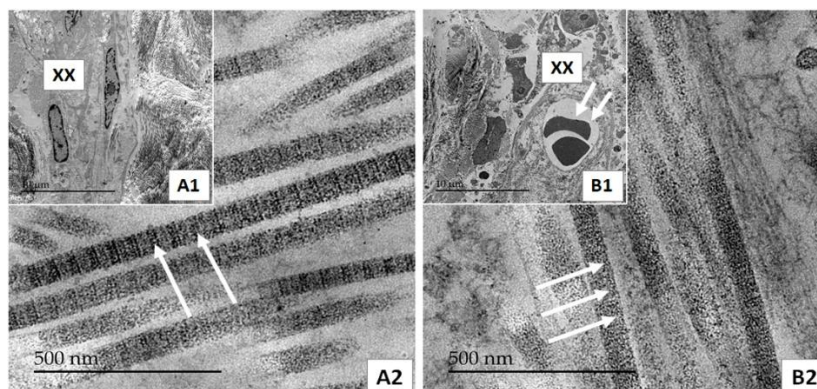


Figure S11: Observation in TEM of a capsule that is invaded with cells (XX, A1) or with oxidized polypropylene debris (XX, B1). The filaments begin dispersion with blurry morphology (triple arrows, B2).

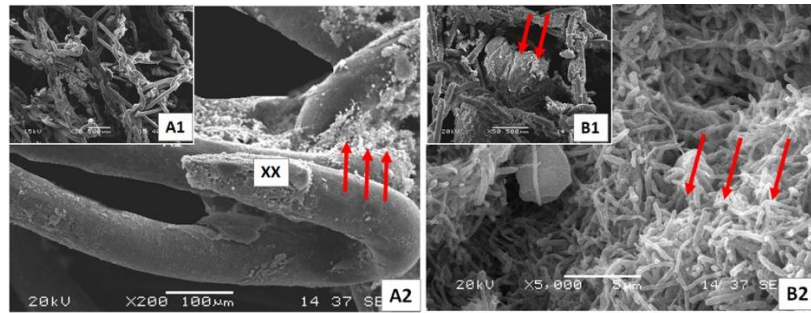


Figure S12: Polypropylene fibers in SEM. The surface shows an oxidized layer with multiple flakes holding important bacteriemic colonisation (triple arrows, A2) or a scarce infected thrombus over a fractured polypropylene filament (XX, A2). The macropores are filled with thrombotic accumulation (double arrows, B1) colonized with bacteria (triple arrows, B2).