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# Degradation resistance of PVDF mesh in vivo in comparison to PP mesh

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ABSTRACT

Mesh implant has been applied in hernia repair and urogynecological reconstruction. Polypropylene (PP) is now the most widely used material for non-resorbable mesh implants. A degradation phenomenon of PP mesh, which is apparent on the mesh surface as cracking, flaking and peeling, was discovered in the 1990's. This phenomenon of mesh implant has drawn attention because of mesh-related litigations. Polyvinylidene fluoride (PVDF), due to its high biocompatible performance, has been used since 2003 as an alternative material for non-resorbable mesh implants. Till now, no such degradation phenomenon of PVDF mesh has been reported, although limited study on PVDF mesh is available.

In this paper, we researched the degradation of PVDF meshes taking the degradation of PP mesh as a reference. The meshes analysed in this study were received from a previous animal experiment. To expose the surface of explanted meshes, a tissue removing method with protease was used and the result of this cleaning process was tested by X-ray Photoelectron Spectroscopy (XPS). The morphological condition of the mesh surface was compared using Scanning Electron Microscopy (SEM) and the chemical condition concerning degradation was analysed through Fourier Transform Infrared Spectroscopy (FTIR). The surface condition of PVDF mesh after 3-, 6-, 12- and 24-month implantation was illustrated and compared with two types of PP meshes.

XPS revealed an absence of nitrogen, confirming the successful removal of tissue residues using protease. SEM results presented no notable morphological surface change of the PVDF mesh and progressive surface cracking processes over time of both types of PP meshes. FTIR spectra of the implanted PVDF meshes had no considerable difference from the spectrum of the pristine mesh, while FTIR spectra of both types of PP meshes had extra chemical functional groups (carbonyl (C═O) and hydroxyl (-OH) groups) increasing with implantation time, indicating progressive degradation. This study highlights the morphological and chemical stability of the PVDF mesh and demonstrates that the PVDF mesh is more resistant to degradation in comparison to the other two types of PP meshes.

## 1. Introduction

Polyvinylidene fluoride (PVDF) has been introduced as mesh material for hernia repair and pelvic reconstruction. It is found to perform favourably in vivo concerning foreign body reaction (inflammatory infiltrate, macrophage infiltration, vessel formation, etc.) (Silva et al., 2007; Mary et al., 1998; Junge et al., 2009; Gerullis et al., 2013; Lambertz et al., 2015; Klink et al., 2011).

Currently, the most widely used mesh material is polypropylene (PP). Pure PP has poor biostability and starts to degrade after a few days of implantation (Liebert et al., 1976). PP meshes available nowadays are always manufactured in combination with various additives like an antioxidant. Incorporating antioxidant into PP meshes was believed to effectively protect PP meshes from degrading in vivo. This was however contradicted when surface cracking was found in explanted PP meshes (Iakovlev et al., 2017; Mary et al., 1998; Imel et al., 2015). Recently, there is a growing uncertainty regarding the long-term mesh safety because of the degradation phenomenon (Costello et al., 2007;

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Marcus-Braun and von Theobald, 2010; Clavé et al., 2010).

Degradation of meshes is defined morphologically as cracking, flaking and peeling on the mesh surface and is considered to be caused by mesh oxidation and hydroxylation (Talley et al., 2017). The degraded part of the mesh often present itself in histological slides as a fragmented layer around the mesh thread (see Fig. 1). Degraded mesh has reduced elastic modulus and tensile strength (Laroche et al., 1995; Mary et al., 1998; Wada et al., 2001). The reduction of the tensile strength of the mesh can weaken the tissue reinforcement ability, which is the primary function of the mesh. Zuvela et al. have reported recurrences resulting from mesh central rupture, which may be the consequence of a severe degraded mesh (Žuvela et al., 2014). Mesh with reduced elastic modulus results in stresses at the tissue-mesh interface (Velayudhan et al., 2009; Sternschuss et al., 2012; Costello et al., 2007). As a stimulator of different immune cells, mechanical stress at the interface recruits immune cells to the mesh, which can cause inflammation and fibrosis formation (Griendling and FitzGerald, 2003; Hilborn and Bjursten, 2007). Another noteworthy point is that degraded mesh releases microparticles, which can be recognized by the immune system as a foreign body, and thus the inflammation and cell differentiation are triggered. Chronic pain, stiffening of abdomen and tissue erosion are often related to chronic inflammation and fibrosis formation (Iakovlev et al., 2017). With all the above mentioned, mesh degradation is suspected to be responsible for disease recurrence as well as some delayed postoperative complications (Sternschuss et al., 2012; Costello et al., 2007).

PVDF mesh is produced without additives such as an antioxidant. Whether PVDF mesh also degrades in vivo is an interesting and important topic to discuss. So far, there are no reports of PVDF mesh degradation, yet there are few studies on the long-term behavior of PVDF mesh. The lack of study on the degradation of PVDF mesh needs to be addressed. Gerullis et al. implanted PVDF and PP meshes in a sheep model (Gerullis et al., 2013; Gerullis et al., 2014). Their experiment provided samples of long-term implanted PVDF and PP meshes under well-controlled conditions, which met the requirements for further research on mesh degradation. Using the sample of Gerullis' experiment, this study researched the degradation resistance of PVDF mesh by comparing its morphological and chemical condition with PP mesh.

## 2. Materials and methods

### 2.1. Mesh samples

Meshes researched in this study are the fascia onlay implanted meshes from the animal experiment conducted in 2010 in Hungary to analyse the incidence and adverse events prevention of mesh implantation. Surgery details and former results of this animal experiment have been published (Gerullis et al., 2013; Gerullis et al., 2014). To exclude the possibility of forming a protein-formaldehyde complex through the formalin-protein fixation process, the explanted meshes used in this study were maintained in distilled water and stored in a UV-protecting box at room temperature (approx. 22 °C) (Thames et al., 2017).

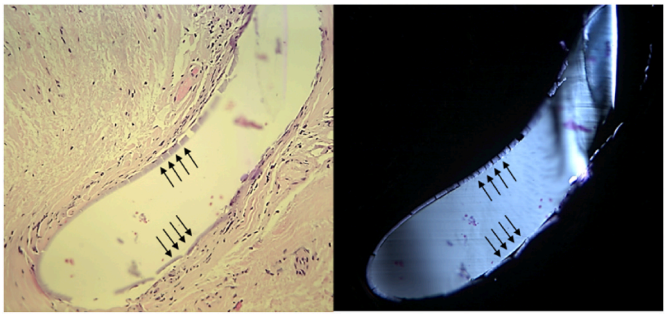

**Fig. 1.** Light microscopy of the H&E stained cross-section slides of an explanted PP mesh with degradation under normal light (left) and polarised light (right).

In brief, three different commercially available mesh products were implanted in sheep. The PVDF mesh (DynaMesh®-CICAT, FEG Textiltechnik mbH) is a tailored designed mesh for ventral hernia repair, which is made of PVDF threads (diameter: 140 μm). The two PP meshes PP1 mesh (ULTRAPRO Mesh, Ethicon™) and PP2 mesh (GYNECARE TVT™ Sling, Ethicon™) are tailored for hernia repair and pelvic floor reconstruction. PP1 mesh is a MONOCRYL®-PROLENE®-Composite mesh, which has the PP thread PROLENE® (Ethicon™, diameter: 89 μm) and the absorbable MONOCRYL® thread (Poliglecapron 25, diameter: 127 μm), which is fully absorbed within 90–120 days. PP2 mesh is made of PP thread PROLENE® (Ethicon™, diameter: 152 μm).

Twelve animals were divided into three groups according to the number of different meshes. The four animals in each group were implanted with the same mesh products. After 3, 6, 12 and 24 months, one animal of each group was randomly selected to conduct mesh explantation. Twelve mesh samples (3 mesh products each with 4 implantation times) and one pristine mesh of each mesh product were investigated in this study.

### 2.2. Mesh cleaning process

The explanted meshes went through a cleaning process to remove any biological tissue adhering to the mesh surface. The meshes were first treated with an alkaline solution (pH 8,5–9,5) containing protease (Alcalase® 2.5l) at 58 °C for 12 h. Further additives in the solution were common salt, tenside (Supralan UF, Zschimmer & Schwarz) and sodium carbonate to regulate the pH value. The protease Alcalase® is a serine endopeptidase that consists primarily of subtilisin A, which is suitable for the hydrolysis of proteins and harmless to polymers. After incubating for 12 h, meshes were rinsed with water. Shortly before XPS and FTIR tests, each sample was cleaned with 70% isopropyl alcohol to prevent environmental contamination.

### 2.3. X-ray Photoelectron Spectroscopy (XPS)

XPS was used to verify that biological tissue and other residues were sufficiently removed from the explanted mesh. The elemental composition of the mesh surface can be analysed through their energy level. As biological tissue always contains the chemical element nitrogen, it therefore differs from PP and PVDF in the chemical composition. The bond energies of carbon, nitrogen, oxygen, and fluorine are around 286, 400, 534, and 687 eV, respectively. XPS spectra were obtained with an M-PROBE surface spectrometer (Surface Science and service by Euroscan Instruments S.A.) using Al kl x-rays (1486.6 eV). The 24-month implanted meshes are analysed with XPS. Since they are the longest in tissue and have the most cracked surface, they are the most suspected to still have biological residue on them. Each of the 24-month implanted meshes was measured on three different spots with an elliptical measuring point (1 mm × 0.4 mm) and an angle of 45°. To analyse the samples, a charge neutralisation was used. Since the sample holder contains oxygen, which cannot be excluded from the measure point, this element cannot be confirmed from the tested sample by the XPS spectrum.

### 2.4. Scanning electron microscope (SEM)

SEM was used to observe the morphological surface condition of the analysed meshes. Meshes were firstly coated through Cressington Sputter-Coater 108auto at a current of 20 mA for 60 s with an ultrathin (10 nm) layer of palladium and then imaged with Zeiss DSM 982 at a voltage of 4 kV and with a magnification range from 50x to 2000x.

The extent of the mesh cracking was quantified by Cracked Area Ratio (CAR), which is defined as the ratio of the cracked area $A_c$ to the mesh area $A_m$ (see For. 1, Fig. 2).

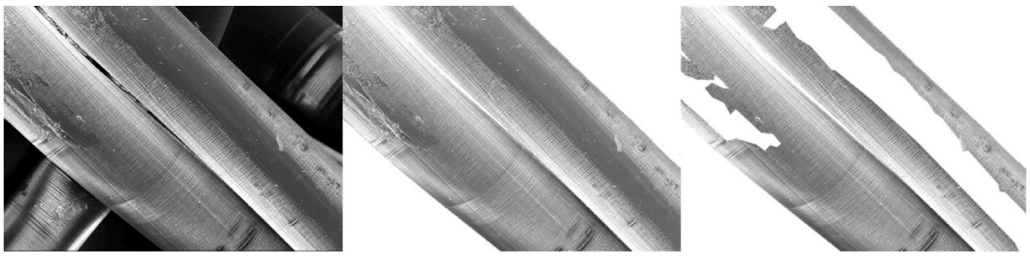

**Fig. 2.** Original SEM image (left); Mesh area $A_m$ (middle); Cracked area $A_c$ (right).

$$CAR = Ac \,/\, Am \qquad \text{(For. 1)}$$

### 2.5. Fourier-transform infrared spectroscopy (FTIR)

Degradation of PP mesh is suspected to be caused by oxidation and hydrolysis, which produces carbonyl- ('C═O') and hydroxyl ('-OH') groups (Talley et al., 2017). FTIR allows the identification of the chemical functional group of materials belonging to the carbon family by measuring the amount of light absorbed at each wavelength by each sample (Ţucureanu et al., 2016). To find the chemical change of the mesh degradation process, all the mesh samples were further examined by FTIR. Each mesh was examined three times. FTIR spectra were obtained using the Nexus 870 spectrometer from Thermo Nicolet Corporation (i.e. Thermofisher Scientific) and the software Omnic 8.2. Analyses were performed on sample surface by Attenuated Total Reflection (ATR) in the range of 3700 $cm^{-1}$ to 700 $cm^{-1}$. A weak fluctuation resulting from $H_2O$ and $CO_2$ in the measurement would appear in the range of 1900–2400 $cm^{-1}$. In the FTIR spectrum, the signal of carbonyl stretch shows as peaks in the range of 1500–1750 $cm^{-1}$ and hydroxyl stretch as wide peaks at 3200-3400 $cm^{-1}$ (Palleros, 2000; Mohrig et al., 2010).

The ratio of the Area Under the Peak (AUP) in the range of the carbonyl- and hydroxyl stretch to the corresponding reference is determined for each mesh. The reference includes only peaks standing for stable chemical functional groups such as methyl group (-$CH_3$), which are relatively consistent by the same mesh sample and not influenced by the implantation time (reference range for carbonyl- and hydroxyl stretch of PVDF mesh: 1300 - 1500 $cm^{-1}$, reference range of the two PP meshes: 1300 - 1500 $cm^{-1}$ for carbonyl stretch and 2800 - 3200 $cm^{-1}$ for hydroxyl stretch). Therefore, the AUPs of the same mesh sample with different implantation time reflect the change of the mesh over time quantitatively. In a determined range, the bigger AUP demonstrates the higher intensity of the signal.

## 3. Results

### 3.1. Mesh preparation result

Signals of carbon, oxygen and fluorine are detected in the PVDF mesh, while carbon and oxygen are present in the PP1 and PP2 meshes. The XPS result shows no signals registered around 400 eV in any of the investigated meshes, which would indicate any presence of nitrogen. The XPS spectra of the 24-month implanted PVDF, PP1 and PP2 meshes are shown in Fig. 3.

### 3.2. SEM result

Similar to the pristine mesh, none of the explanted meshes present any cleaning or biological residues on the surface. However, all of the meshes display obvious continuous extrusion lines along threads, which came from the extrusion process of the thread production process.

After 3-, 6-, 12- and 24-month implantation, PVDF mesh shows no remarkable morphological change (Fig. 4). No cracks or any kind of mesh damage are shown on the mesh surface up to 24 months after implantation (CAR: 0), while extrusion lines are visible on the smooth mesh surface.

At 3-month implantation, PP1 mesh (Fig. 4) shows no cracks or any kind of mesh damage. The MONOCRYL® part is already fully absorbed and can no longer be identified. After 6-month implantation, small and closely packed cracks perpendicular to the long axis of the thread are present with the CAR of 0.70. It should not be overlooked that extrusion lines are obvious here and continue onto the degraded layers. The cracks become deeper and wider after 12 months (CAR: 0.90). After 24 months, PP1 mesh shows very dense cracks with the CAR of 0.96, which branch

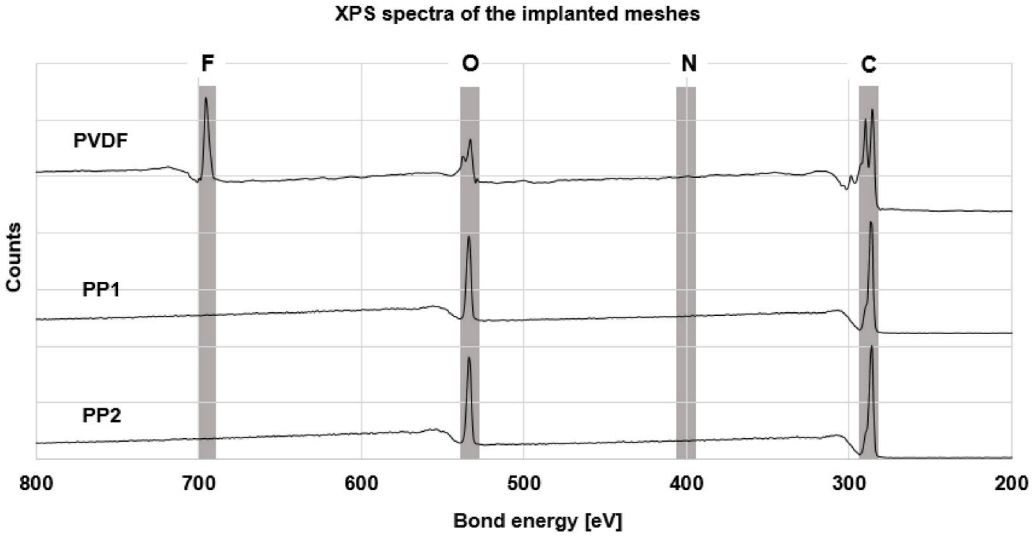


**Fig. 3.** XPS spectra of the implanted meshes: PVDF (signals of C, O and F), PP1 (signals of C and O) and PP2 (signals of C and O).

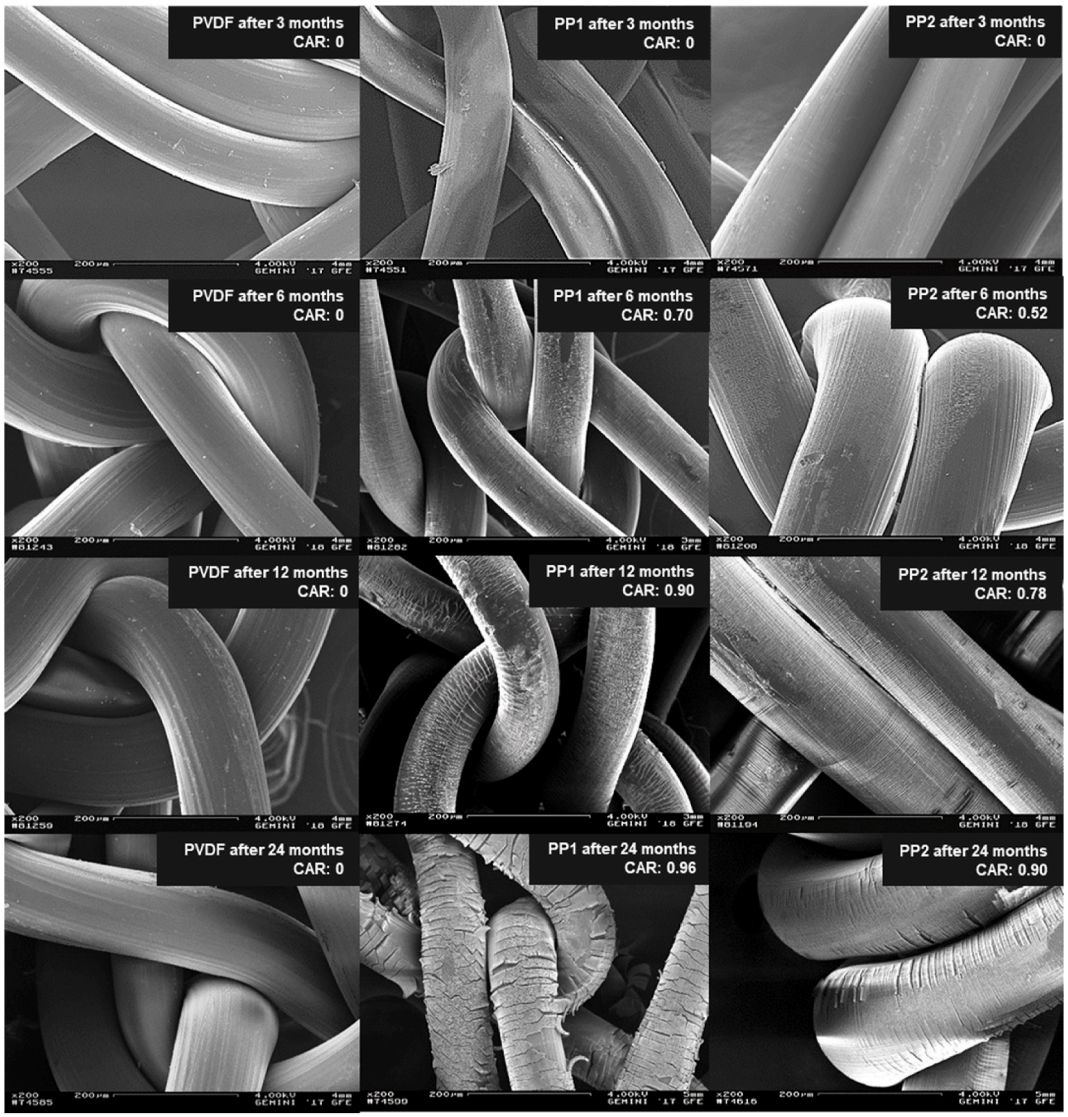


**Fig. 4.** SEM images of PVDF (first column), PP1 (second column) and PP2 (third column) each after 3-, 6-, 12- and 24-month implantation marked with the Cracked Area Ratio (CAR).

out forming larger cracks (secondary cracks). The secondary cracks have widths up to 5 μm, forming degraded layers on the surface around 5 μm thick and have partially peeled away from the thread core. The peeling phenomenon is severe.

PP2 presents a smooth surface without any cracks or damage after 3-month implantation, except for extrusion lines, which are visible and continue along the thread surface. After 6 months, small and dense cracks start to show with the CAR of 0.52. The cracks develop deeper

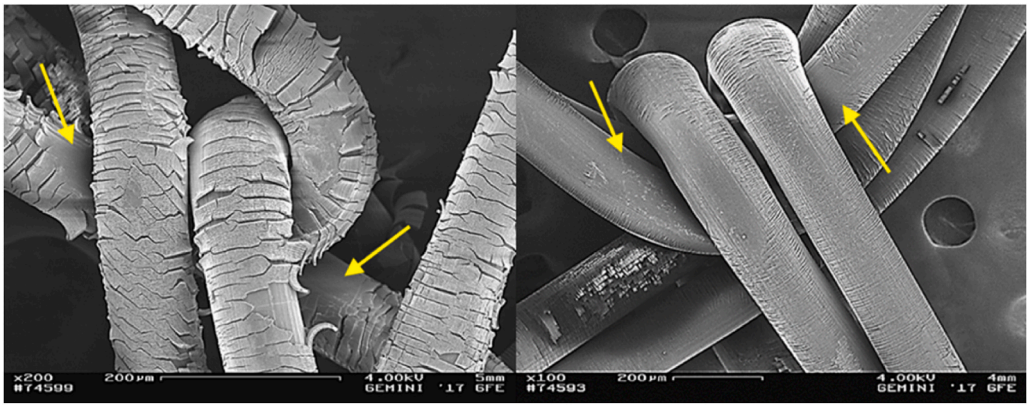

**Fig. 5.** SEM images of 24-month implanted PP1 (left) and PP2 (right), both show severe cracked surface but no cracks at the thread overlapping areas.

and wider over time, after 12 months the CAR reaches 0.78. Until 24 months, although no secondary cracks are formed, the number of primary cracks increases and the cracks cover most of the thread surface (CAR: 0.90). The degraded layer starts to peel off from the thread core after 24 months. The peeled-off layer is thinner and the particles that are on the verge of peeling are smaller compared to the explanted PP1 mesh with thinner thread (Fig. 4).

Another noteworthy point is that the area where the mesh threads overlap, for example inside the knots, have evidently either fewer cracks or even no cracks on both PP1 and PP2 meshes (Fig. 5). This phenomenon is observed in all meshes presenting with cracks.

### 3.3. FTIR result

The FTIR spectra of the 3-, 6-, 12- and 24-month implanted PVDF meshes (Fig. 6) show no considerable difference from the FTIR spectrum of pristine PVDF mesh. All spectra show no visible signals in the range of carbonyl- (1500-1750 $cm^{-1}$) or hydroxyl (wide peak at 3200-3400 $cm^{-1}$) stretch, which are signs of mesh degradation.

As shown in Fig. 7, the spectrum of pristine PP1 shows an additional peak at 1745 $cm^{-1}$, which although is not the sign of mesh degradation but comes from the carbonyl stretch of the absorbable part poliglecaprone 25 (MONOCRYL®). The spectrum of the 3-month implanted PP1 mesh does not show any signal of carbonyl- or hydroxyl stretch because the poliglecaprone 25 part is fully absorbed. The 6-months implanted PP1 mesh shows in the range of carbonyl stretch a relatively clear peak. In the range of hydroxyl stretch, a weak wide peak between 3200 and 3400 $cm^{-1}$ is also shown. The spectrum of 12-month implanted PP1 mesh shows slightly stronger signals of carbonyl- and hydroxyl stretch than the 6-month implanted mesh. The signals of carbonyl stretch become more intense for the 24-month implanted PP1 mesh. Four peaks in the carbonyl stretch range and a weak wide peak in the range of hydroxyl stretch are shown below.

The spectrum of pristine PP2 does not show any signal of carbonyl- or hydroxyl stretch. Compared with pristine PP2 mesh, the 3-month PP2 mesh presents a very weak signal of carbonyl stretch. The spectra of 6-, 12- and 24-month implanted meshes show clear peaks with increasing intensity in the range of carbonyl stretch and weak wide peaks with slowly increasing intensity in the range of hydroxyl stretch (Fig. 8). In the carbonyl stretch range, four peaks can be distinguished in the spectrum of 24-month implanted mesh. The FTIR spectra of the implanted PP2 meshes present a similar change process as the PP1 meshes.

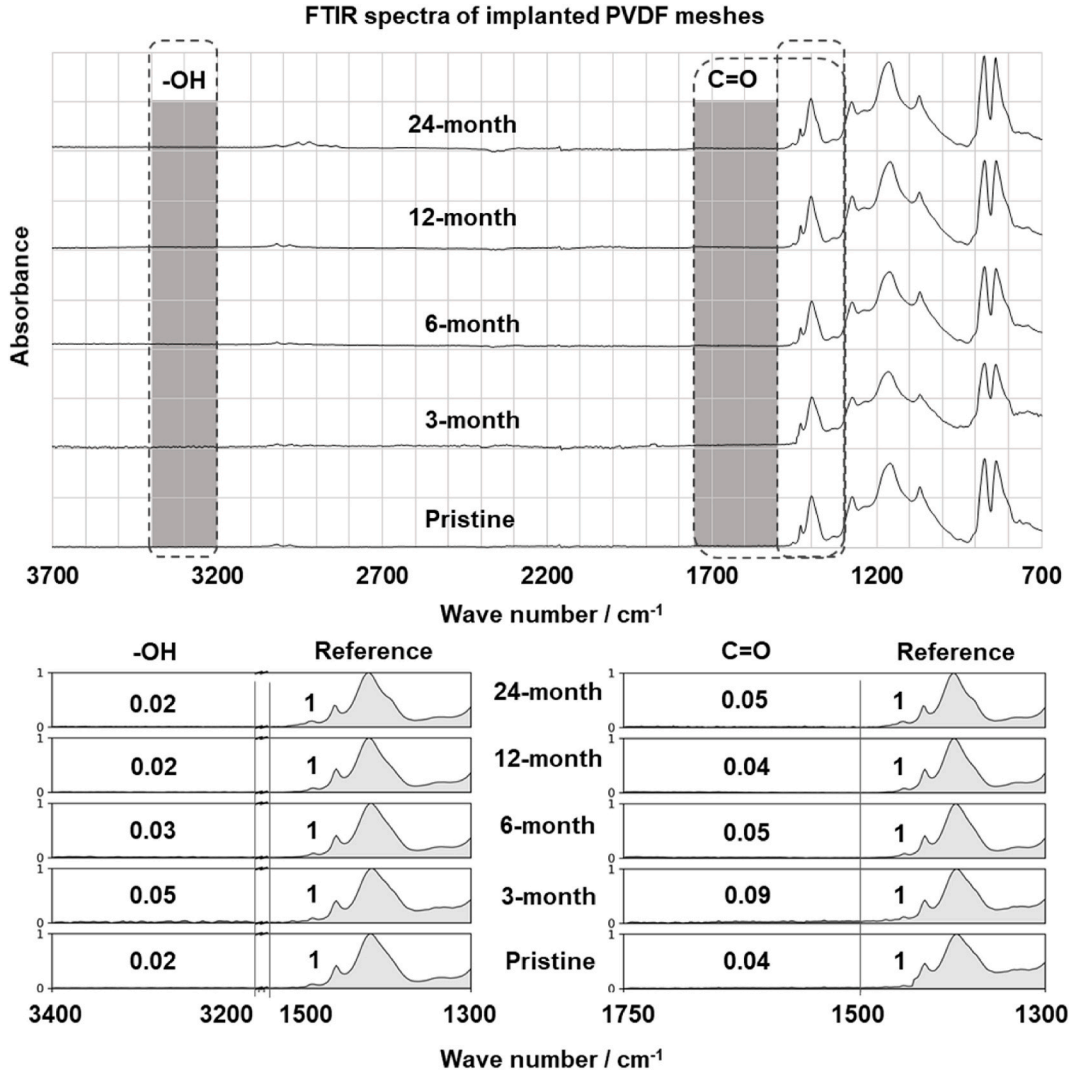


**Fig. 6.** FTIR spectra of pristine, 3-month, 6-month, 12-month and 24-month implanted PVDF meshes with zoomed ranges of hydroxyl- and carbonyl stretch presented at the bottom and marked with the AUP ratio to the reference range.

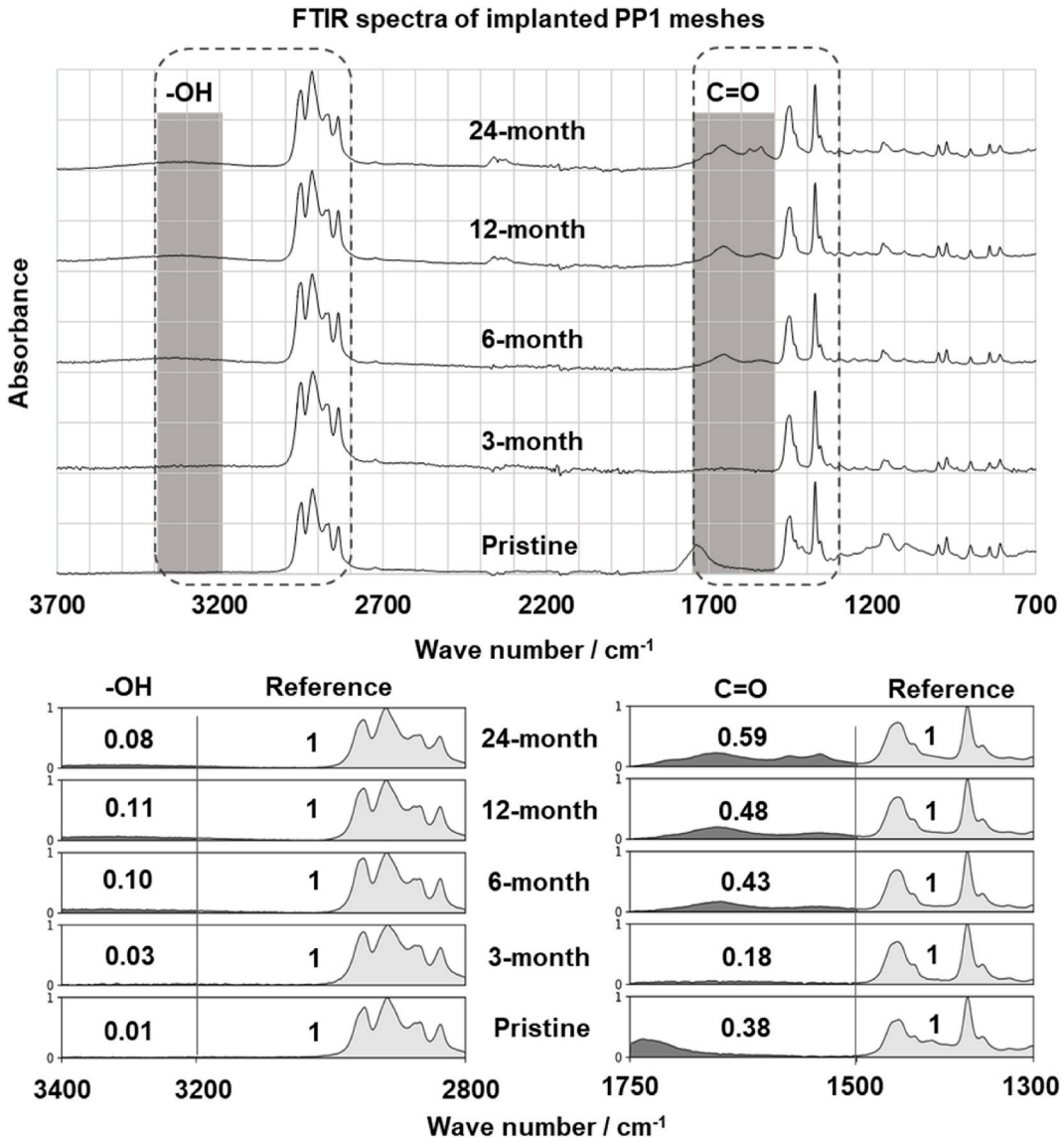


**Fig. 7.** FTIR spectra of pristine, 3-month, 6-month, 12-month and 24-month implanted PP1 meshes with zoomed ranges of hydroxyl- and carbonyl stretch presented at the bottom and marked with the AUP ratio to the reference range.

## 4. Discussion

In this study, all implanted meshes were stored under the same condition and underwent the same preparation process. None of the 3-month implanted meshes show any surface damage. This proves that both the storage and the preparation with protease are harmless to the mesh. The surface cracking of the other meshes did not happen in the storage period and is not caused by the preparation with protease. The absence of nitrogen in the XPS diagrams and the presence of extrusion lines on the mesh surface in the SEM images demonstrate the adequate exposure of the mesh surface and the effectiveness of the cleaning process. Therefore, the mesh preparation with protease is considered sufficient and proper for removing biological tissues from meshes.

The SEM images reveal no morphological change on the surface of PVDF mesh after implantation time of up to 24 months. The SEM images of PP1 and PP2 show a clear tendency of the surface cracks becoming deeper and wider over time, which indicates a time-dependent progressive degradation behavior. All researched meshes were maintained in distilled water, thus the cracked mesh surface is not a protein-formaldehyde complex as described by Thames et al. (Thames et al., 2017). The FTIR result shows no considerable functional group change of PVDF mesh after implantation of up to 24-month. This indicates that PVDF mesh did not undergo any detectable chemical reactions during the implantation, such as oxidation or hydrolysis. The FTIR spectrum illustrates the chemical stability of PVDF mesh. The carbonyl- and hydroxyl stretch in the FTIR spectra of PP1 and PP2 meshes are expected to be the products of mesh oxidation and hydrolysis (Gil et al., 2018; Talley et al., 2017). Noteworthy is the intensity of the carbonyl stretch, which increases over the period of implantation time as well as the signal of hydroxyl stretch, which is more pronounced in longer implanted meshes. This tendency is compliant with the development of cracks shown in the SEM images of the PP1 and PP2 meshes, which indicates that the degradation cracks are the result of oxidation and hydrolysis of the mesh. The results of SEM and FTIR complement each other and indicate that PVDF mesh is more resistant to degradation than the two types of PP meshes.

All SEM images of the degraded mesh in this study show either fewer or even no cracks in the overlapped areas where mesh has less contact with inflammatory cells, which secret corrosive chemicals like Reactive Oxygen Species (ROS) that may degrade the mesh (Zhao et al., 1993; Hafeman et al., 2011; Martin et al., 2014; Anderson et al., 2008). SEM images show that cracks on the degraded meshes are consistently

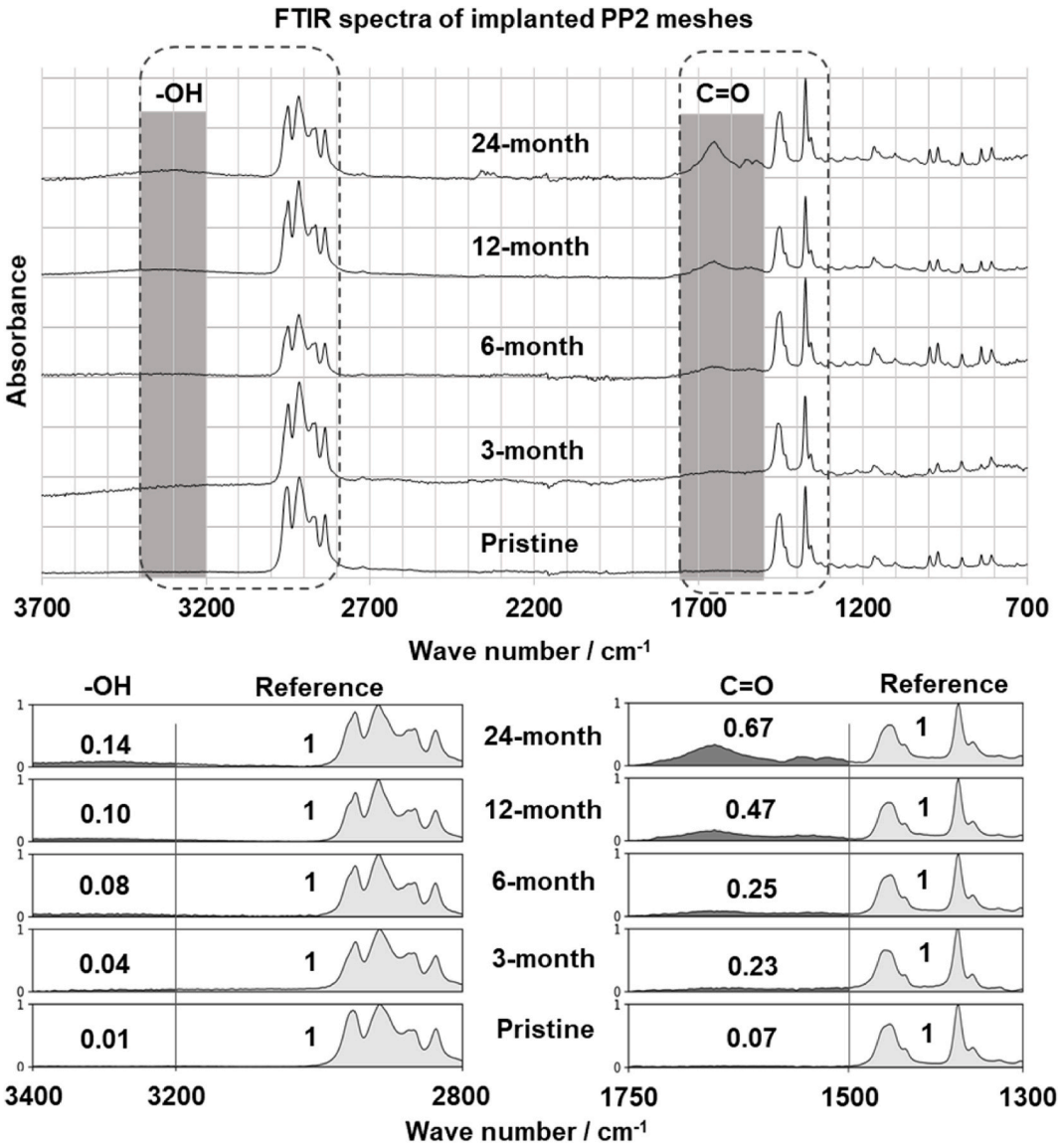


**Fig. 8.** FTIR spectra of pristine, 3-month, 6-month, 12-month and 24-month implanted PP2 meshes with zoomed ranges of hydroxyl- and carbonyl stretch presented at the bottom and marked with the AUP ratio to the reference range.

perpendicular to the long axis of the thread, along which the mechanical stress is applied. Apart from that, PP1 has a thinner mesh thread than PP2 and therefore, bears higher mechanical stress, and show more severe cracked surface when compared with PP2 mesh. The phenomenon shown in this study indicates that the mesh surface cracking is the result of both corrosive chemicals and mechanical stress, which supports the conclusion of David Taylor's study and suggests that surface cracking of degraded meshes is Environmental Stress Crack (ESC) (Wypych, 2012; Taylor, 2018). The resistance to degradation of the PVDF mesh is owed to the high bond energy of the carbon-fluorine bond, so that PVDF has the stress bearing and antioxidant properties.

The previous histological study of this sheep experiment shows that PVDF has a favourable long-term performance than the two types of PP meshes in terms of foreign body reaction (Gerullis et al., 2013). Considering mesh degradation is a long-term process and mesh surface topography significantly influence chronic inflammation, it is reasonable to relate these results in the context that the degradation resistance of the PVDF mesh has a positive effect on the mesh performance in tissue and induces favourable foreign body reaction in the long-term compared to PP meshes.

The analysed meshes were implanted in sheep, which can only to a certain degree reflect the mesh behavior in humans. However, the degradation of PP meshes is well shown as in other studies that investigated PP degradation using human mesh implants (Iakovlev, Guelcher, and Bendavid, 2017) (Imel et al., 2015). Therefore, the result of this study should be able to reflect the mesh behavior in vivo to a proper degree in spite of the sheep model. Another limitation of this study is that the available meshes are limited in quantity. They are extremely small and come with irregular shapes. Therefore, the reduction of mechanical strength of the meshes due to degradation could unfortunately not be compared. Further work is needed to analyse more meshes, which are explanted from humans to better study mesh biostability. This study is under well-controlled conditions and therefore allows to reliably investigate mesh degradation and to directly compare PVDF and PP mesh in vivo. To our knowledge, this is the first time that PVDF mesh has been studied for its degradation resistance in vivo over such a long period.

## 5. Conclusion

PVDF mesh does not show signs of degradation up to 24 months after implantation as evidenced by morphological and chemical analyses. In

contrast, PP meshes progressively degrade with increasing time under the same conditions, which appears as worsening Environmental stress cracks. This study demonstrates the degradation resistance of the PVDF mesh relative to the two types of PP meshes in vivo.

## Declaration of interest

H.W. as Ph.D. student at the NRW Schwerpunktprofessur Biohybrid & Medical Textiles (BioTex) is employed by the FEG. B.K. had research projects and consulting fees in collaboration with the mesh manufacturers Ethicon and FEG; expert testimony at lawsuits concerned with surgical meshes. A.M. is an employee of FEG; A.D. as Ph.D. student is an employee of FEG. The financial disclosures listed result from their expertise, and none of them have tried to influence any part of the work for this manuscript. T.O and S.J have no interest to declare.

## CRediT authorship contribution statement

**Hongshi Wang:** Conceptualization, Funding acquisition, Writing – original draft, Conception and design of study, acquisition of data, analysis and/or interpretation of data, Drafting the manuscript, Approval of the version of the manuscript to be published. **Bernd Klosterhalfen:** Conceptualization, Funding acquisition, Writing – original draft, Conception and design of study, revising the manuscript critically for important intellectual content, Approval of the version of the manuscript to be published. **Andreas Müllen:** Conceptualization, Funding acquisition, Writing – original draft, Conception and design of study, analysis and/or interpretation of data, revising the manuscript critically for important intellectual content, Approval of the version of the manuscript to be published. **Thomas Otto:** Conceptualization, Funding acquisition, Writing – original draft, acquisition of data, revising the manuscript critically for important intellectual content, Approval of the version of the manuscript to be published. **Axel Dievernich:** Funding acquisition, Writing – original draft, analysis and/or interpretation of data, revising the manuscript critically for important intellectual content, Approval of the version of the manuscript to be published. **Stefan Jockenhövel:** Conceptualization, Funding acquisition, Writing – original draft, Conception and design of study, revising the manuscript critically for important intellectual content, Approval of the version of the manuscript to be published.

## Declaration of competing interest

H.W. as PhD student at the NRW Schwerpunktprofessur Biohybrid & Medical Textiles (BioTex) is employed by the FEG. B.K. had research projects and consulting fees in collaboration with the mesh manufacturers Ethicon and FEG; expert testimony at lawsuits concerned with surgical meshes. A.M. is an employee of FEG; A.D. as PhD student is an employee of FEG. The financial disclosures listed result from their expertise, and none of them have tried to influence any part of the work for this manuscript. T.O and S.J have no interest to declare.

## Acknowledgements

All persons who have made substantial contributions to the work reported in the manuscript (e.g., technical help, writing and editing assistance, general support), but who do not meet the criteria for authorship, are named in the Acknowledgements and have given us their written permission to be named. If we have not included an Acknowledgements, then that indicates that we have not received substantial contributions from non-authors.

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