366

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IN-DEPTH NANO-INVESTIGATION OF VAGINAL MESH AND TAPE FIBER EXPLANTS IN WOMEN.

Hypothesis / aims of study

Vaginal M/T implants may undergo a variety of changes, including oxidative processes, tissue ingrowth, and stress shielding over time, and thus may not be inert. This study analyzed polypropylene (PP) samples surgically explanted in women with mesh/tape (M/T) complications to investigate the effect of time on presence and extent of micro/nano structural alterations to the synthetic material.

Study design, materials and methods

Following material transfer agreement, explanted M/T synthetic materials from women requiring surgical revision for non-infectious M/T complications were extensively studied with nano-investigating tools. Explants were first freed of surrounding tissue ingrowth using a protocol based on sodium hypochlorite (1).Pristine samples were studied for baseline comparison with the same protocol to ensure no effect on PP fibers. Scanning electron microscope (SEM) sample preparation involved sputter coating with a thin layer of gold/chromium (Au/Cr) for SEM imaging. SEM imaging was performed in a Zeiss-LEO Model 1530 variable pressure SEM, under low acceleration voltage (5 keV) to minimize electron charge on the sample surface. SEM allowed to observe material defects present on the PP fiber surface. Atomic force microscope (AFM) provided surface topography and roughness of the explant samples. ATM used an Asylum MFP 3D bio-AFM in dynamic (AC) mode. Samples were imaged in air, with a soft cantilever with a nominal spring constant of k=3 N/m. Each sample was imaged for various scan sizes $5\mu m^2$ – $20\mu m^2$. Image analysis was performed using integrated Asylum software. Roughness analysis was performed on the explants and pristine samples to obtain the RMS (root mean square) roughness value on the pristine and explant samples for comparison. Finally, Raman spectroscopy was used to detect chemical signs of surface degradation. Vibrational Raman spectra were obtained using a Horiba Jobin Yvon LabRam HR800 Raman microscope using a Helium-Neon laser with a wavelength of 532 nm. Data files were extracted and analyzed using a custom MATLAB code. The spectrograph raw data collected as a text file containing the Raman shift and intensity values was utilized to plot the composite images in MATLAB. To avoid bias, details on the clinical complications, duration of implantation before removal, device manufacturer, and patient demographic information were not reviewed until after all experiments were completed.

Results

Seven explants were studied covering a range of currently M/T devices (Gynemesh, TVT, TOT, SPARC and minisling). Except for one implant removed at 175 days, all explants were removed at 4-7 years after implantation. Mean age was 66 (57-70), with mean parity at 2 (1-3) and mean BMI at 24,6 (17-33). Two women were smokers and none were diabetic. Representative SEM and AFM views are presented in Figures 1, 2, and 3. Comparison of the SEM images from explant samples with control pristine samples revealed extensive surface degradation with formation of microscopic surface cracks of several microns in length and depth, mostly formed in the radial direction of the samples. All long-term explants exhibited similar changes. The AFM image quantified the severity of PP changes by noting that the surface roughness of the explant samples was increased by several orders of magnitude compared to the smooth surface of the pristine samples (surface roughness of the pristine samples was ~ 7±2 nm, while it increased up to 485±90 nm or more for long-term explants). Raman spectroscopy did not reveal any major variation in the chemical properties of the PP fibers, especially no new peaks for oxidation.

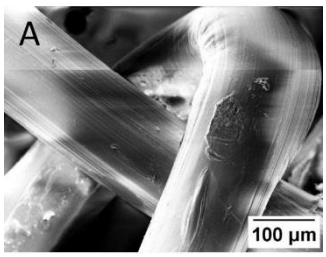
Interpretation of results

Synthetic M/T materials are being used widely for the repair of pelvic organ prolapse and incontinence. The report of serious complications with M/T has raised the interest to better understand their integration in vivo. This in-depth nano-investigation focusing on vaginal explants reaffirms one prior study (2) findings, but differs in that most explants studied were tapes and not meshes, not removed for infection, and the majority explanted after several years of implantation. The results of this study point to significant physical degradation of the meshes for all those implanted for several years, while no chemical oxidation was observed. An improved understanding of the changes affecting synthetic material when placed underneath the vaginal surface can benefit from a detailed structural analysis of explanted material so that better prosthetic material can be designed.

Concluding message

This study indicates that PP fibers from mid-urethral slings are not inert over time and offers a systematic approach to the study of PP fiber alterations over time.

Figure 1: Pristine Sample A (SEM), B (AFM)



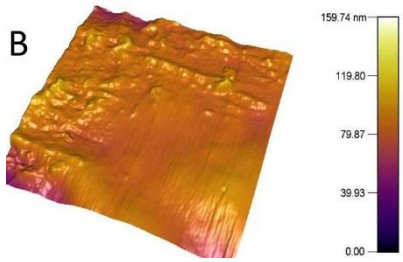


Figure 2: SEM Gynemesh™ (A, B); AFM (C)

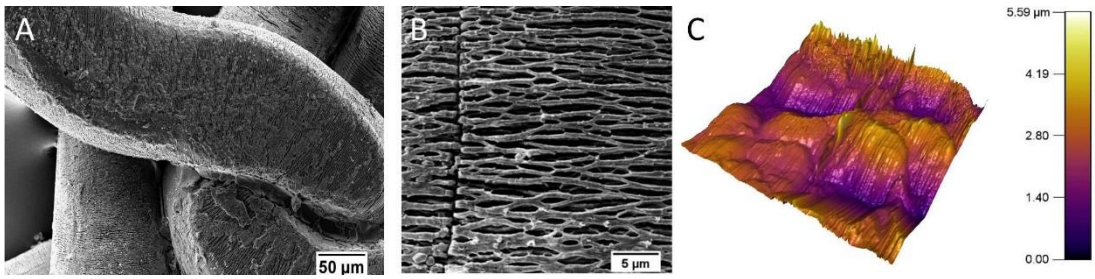
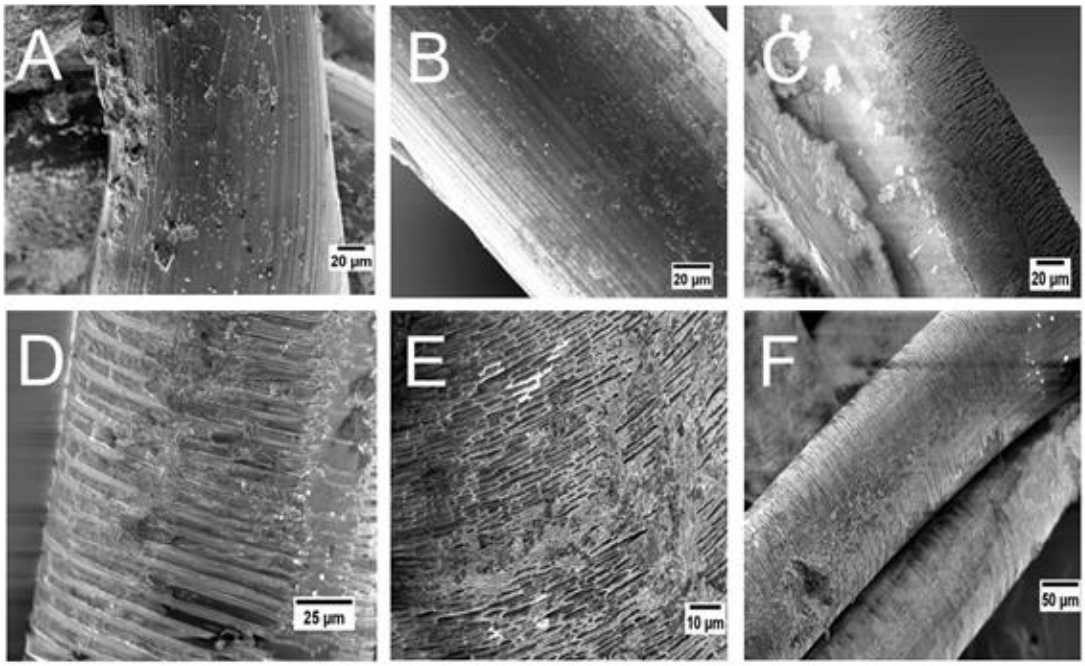


Figure 3: TVT™ (A and B); SPARC™ (C-F)



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