„Ideal“ meshes of PVDF as the safer alternative to polypropylene ?

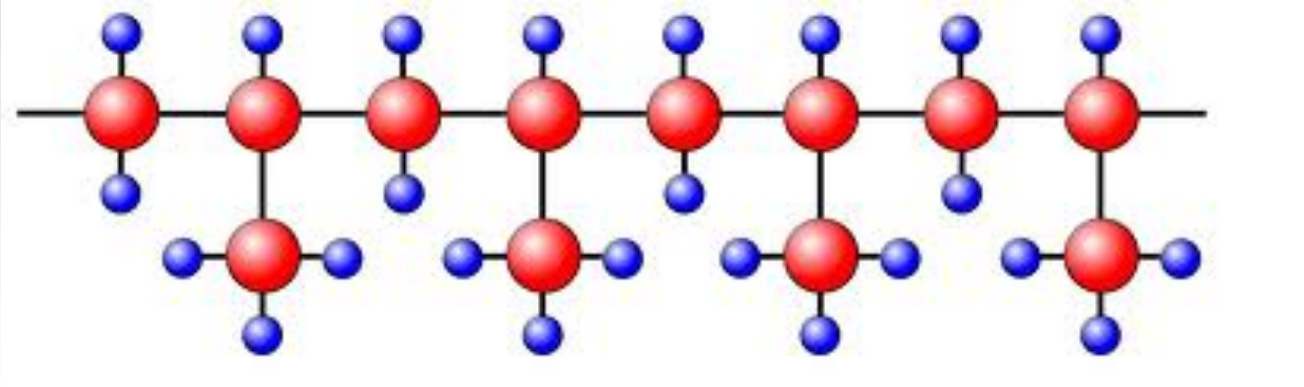
Mesh 2015,

Paris 12 juin 2015

11:30 – 12:30, 10 min

Possible conflict of interest:
Development of meshes in collaboration with Ethicon, Hamburg and FEG-Textiltechnik, Aachen; expert testimony

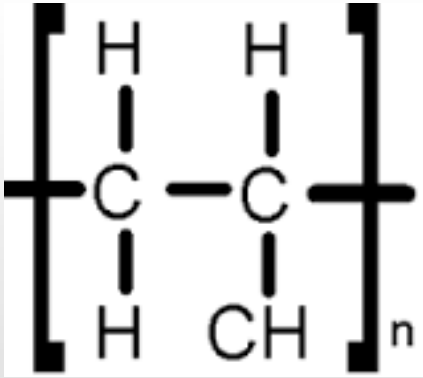
Polypropylene

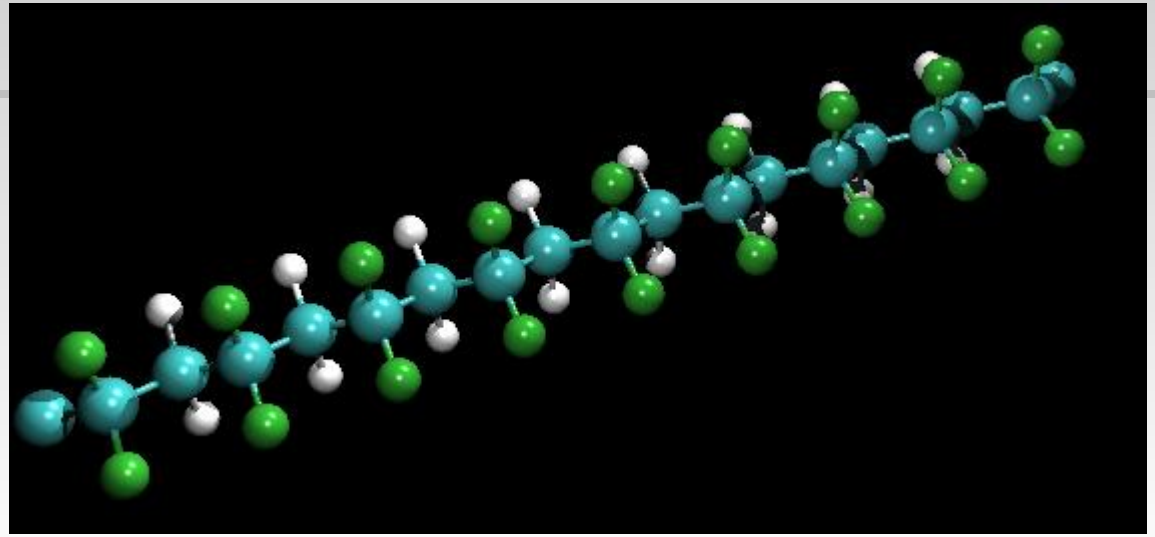


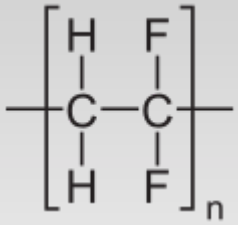
1954 developed by Hoechst

55 million tons per year

1 € per kg

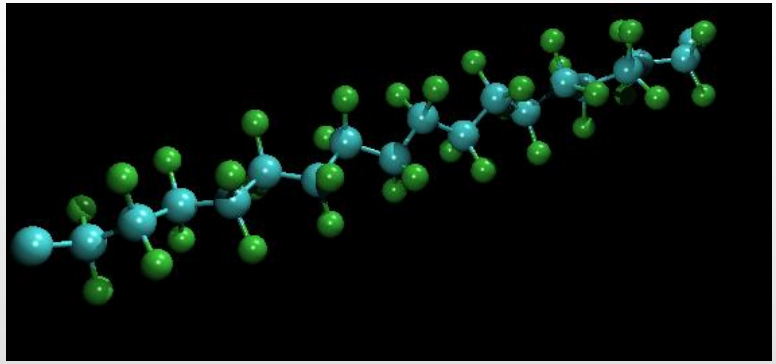






Green = fluorine
Blue = carbon
White = hydrogen

PVDF
Polyvinylidenfluoride
First application 1961
10 – 15 000 tons per year
18 € per kg



PTFE, Teflon

Universitiy of Potsdam Applied Condensed Matter Physics Prof. Dr. Reimund Gerhard


Need for PVDF meshes ?

Phillips Sumika Polypropylene Company

Material Safety Data Sheet

SECTION 1 PRODUCT AND COMPANY IDENTIFICATION

Marlex® Polypropylene (All Grades)

Product Use: Extrusion and Injection Molding
Synonyms: Plastic
Product CAS No.: Mixture

Company Identification:
Phillips Sumika Polypropylene Company
10001 Six Pines Drive
The Woodlands, TX 77380

Product Information:
MSDS Requests: 1 - (800) 852-5530
Technical Information: 1 - (800) 852-5531
Responsible Party: Product Safety Group
Email:msds@cpchem.com

MEDICAL APPLICATION CAUTION: Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

Do not use this Phillips Sumika Polypropylene Company material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Phillips Sumika Polypropylene Company under an agreement which expressly acknowledges the contemplated use.

Do not use this Phillips Sumika Polypropylene Company material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Phillips Sumika Polypropylene Company under an agreement which expressly acknowledges the contemplated use.

Phillips Sumika Polypropylene Company makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for use in implantation in the human body or in contact with internal body fluids or tissues.

Not least the worst argument to discuss PP

PP versus PVDF

	PVDF	PP
Foreign body reaction	++	-
Biocompatibility	++	+
Resistance to bacterial adherence	++	-
Tensile strength	++	+
Long term stability	++	-
Purity (no additives)	++	- -
Price	-	++

+ Advantage

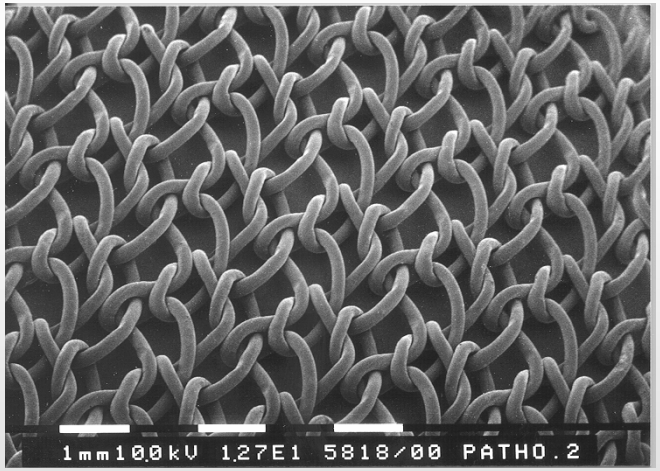
- Disadvantage

History of PVDF in Aachen:
The beginning in December 1993

Marlex appeared to be very strong

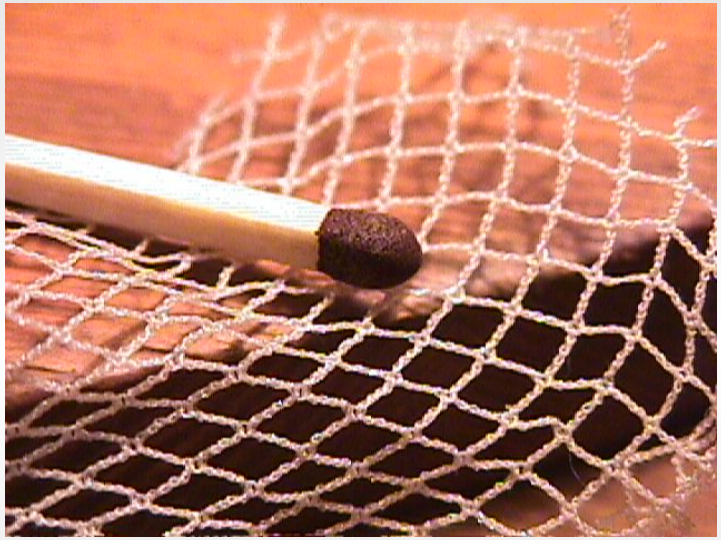
Idea:

Less material may be better for the tissues



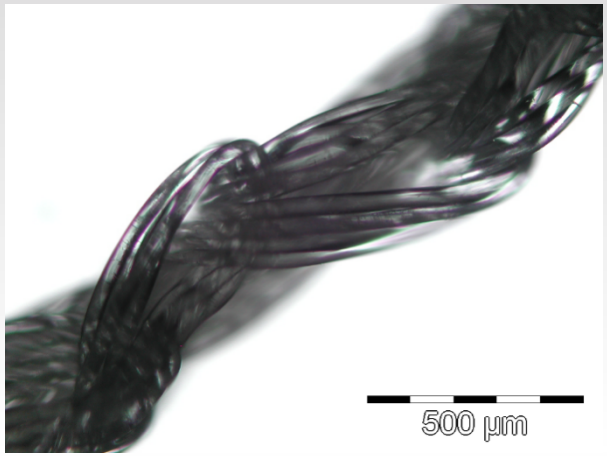
How strong meshes have to be ?
Boris Obolenski, ITA

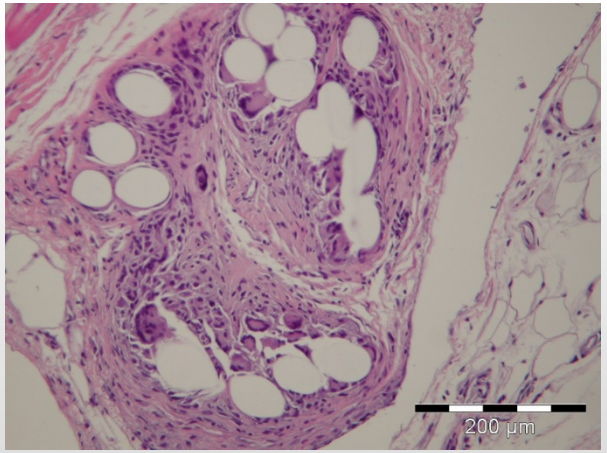
First „Hernia“ mesh



1997

Large pore meshes



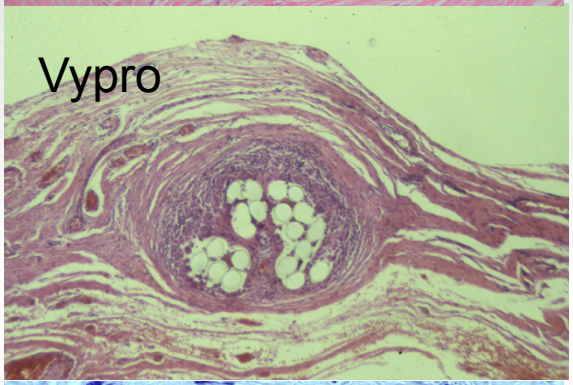


Monofilament alternative ?

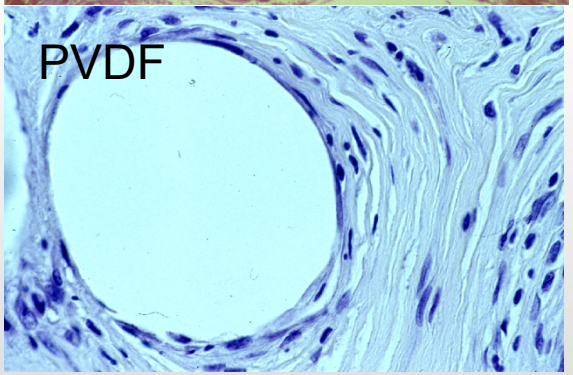
Foreign body reaction:

< 1997

1997
Collaboration with Ethicon



> 1998
granted by university

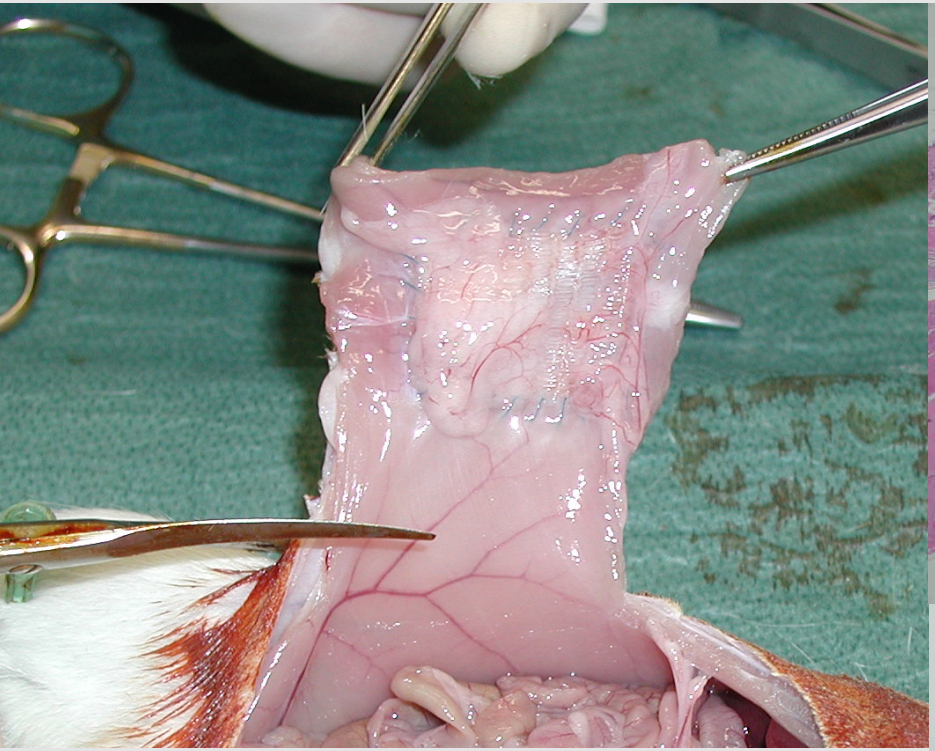


2003

patent FEG for PVDF mesh
patent Ethicon for PVDF mesh

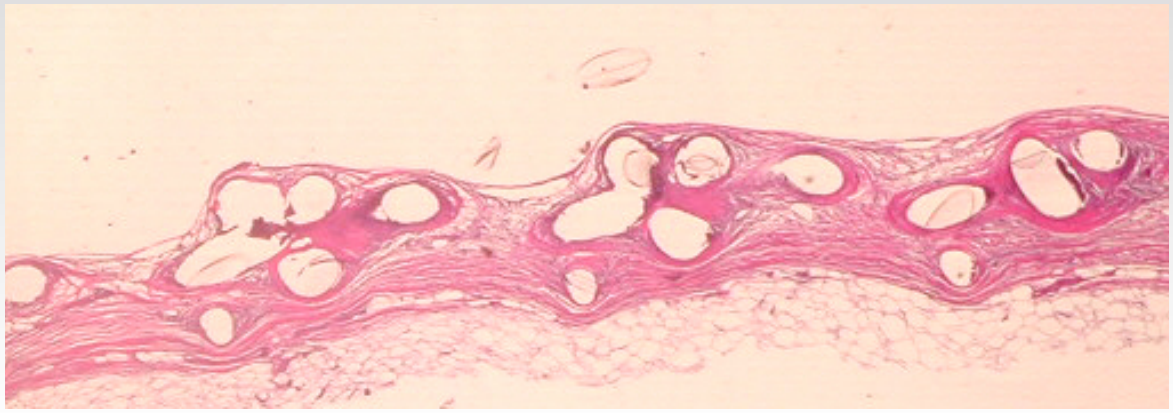
Little tissue reaction of pure PVDF

21 days, rat

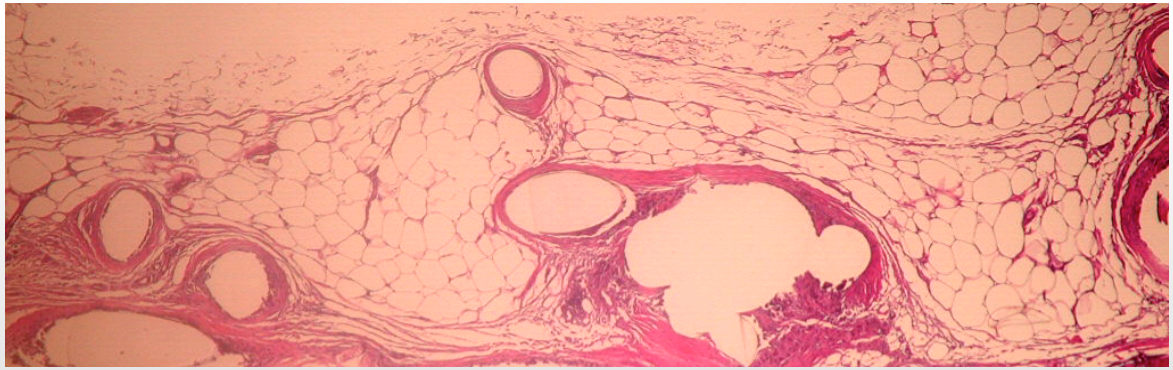


UNIKLINIK RWTH AACHEN

Biocompatibility:

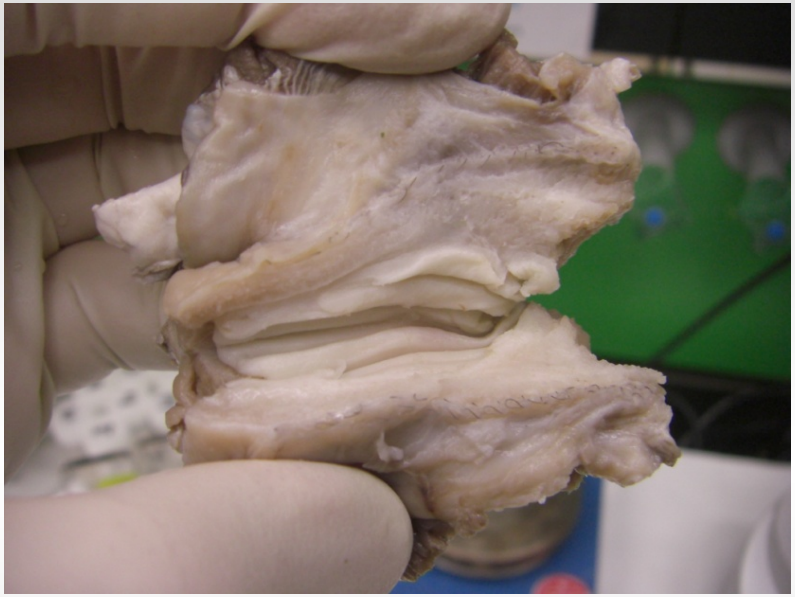


scarring



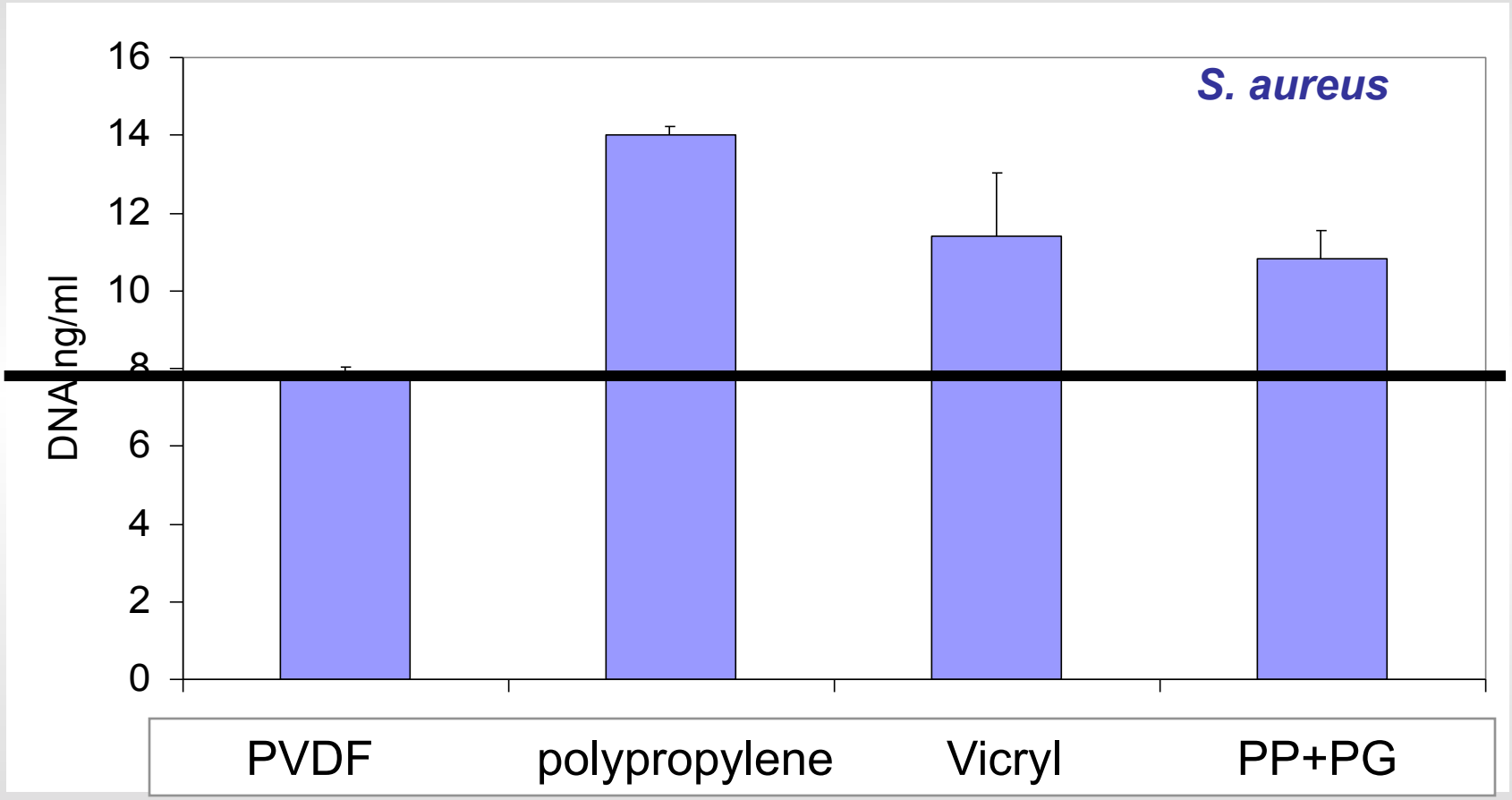
Pores filled
with local fat

Biocompatibility:
Textile structure is decisive



PVDF small pores (< 600 µm)
= fibrotic bridging

Decreased bacterial adherence



Reduced attachment of bacteria to PVDF

Tensile strength

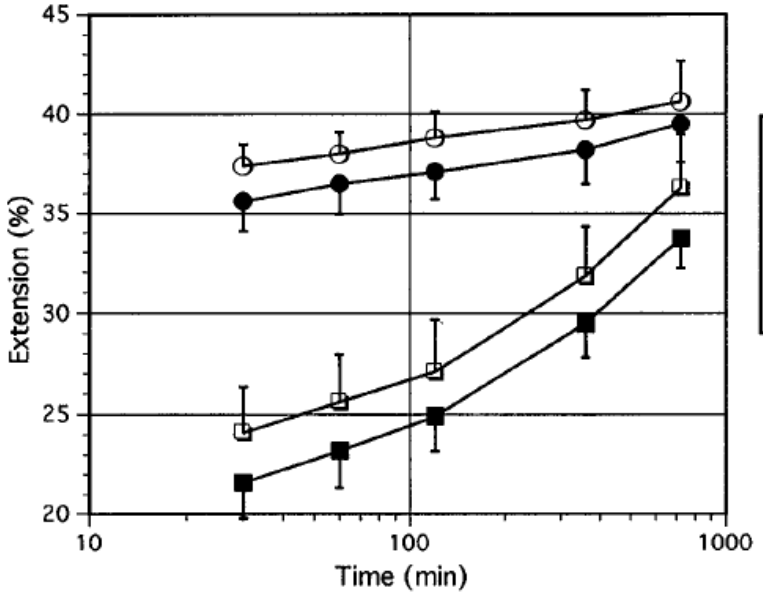


Figure 5. Creep properties of 5-0 and 6-0 PVDF and polypropylene sutures.

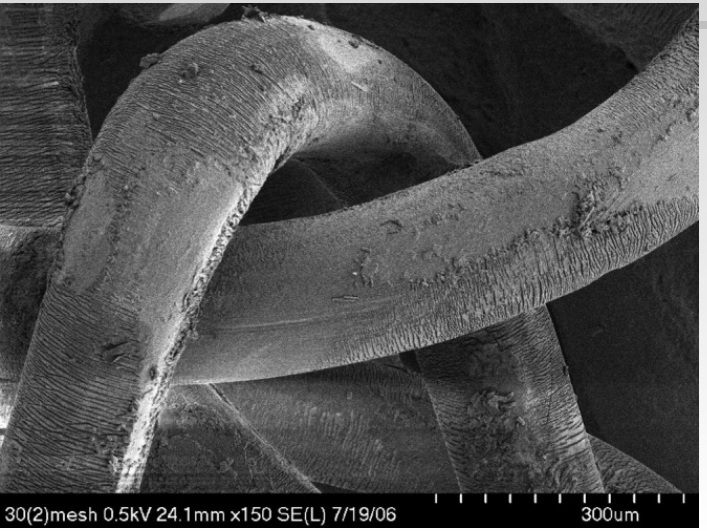
ASAIO Journal 1994

Original Articles

Why Make Monofilament Sutures Out of Polyvinylidene Fluoride?

Elisabeth Urban,*†‡ Martin W. King,*‡ Robert Guidoin,*‡ Gaetan Laroche,‡ Yves Marois,*‡ Louisette Martin,* Alain Cardou,† and Yvan Douville*

Degradation of PP



SEM of an explanted polypropylene mesh with transverse cracks.

„Our results supported our hypothesis and indicated that the explanted polypropylene meshes did undergo degradation while in vivo, most likely due to oxidation.“

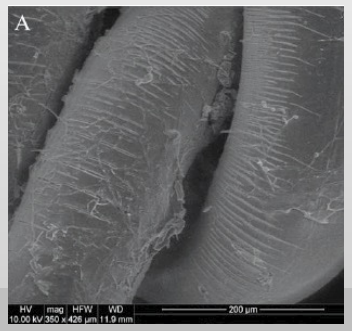
C. R. Costello, S. L. Bachman, B. J. Ramshaw, S. A. Grant:
Materials Characterization of explanted polypropylene hernia meshes
Journal of Biomedical Materials Research Part B: Applied Biomaterials, Published Online: 6 Feb 2007 *(Kugel patch)*

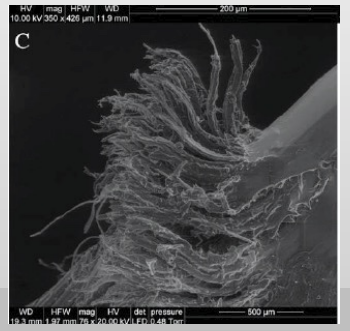
Degradation of PTFE, PP and PET

J Biomed Mater Res B Appl Biomater. 2010 Aug;94(2):455-62.
Materials characterization of explanted polypropylene, polyethylene terephthalate, and expanded polytetrafluoroethylene composites: spectral and thermal analysis.
Cozad MJ, Grant DA, Bachman SL, Grant DN, Ramshaw BJ, Grant SA.

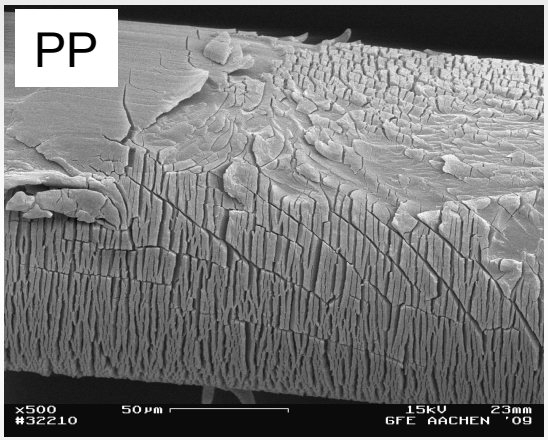
73% percent of ePTFE explants, 73% of PP explants, and only 18% of PET explants showed a decreased rate of percent weight loss as compared to pristine.
The majority of the PP and ePTFE mesh explants demonstrated oxidation and crosslinking, respectively, while the PET ring exhibited breakdown at the sites of high stress.
The results showed that all three materials exhibited varied degrees of chemical degradation suggesting that a lack of inertness in vivo contributes to hernia mesh failure.

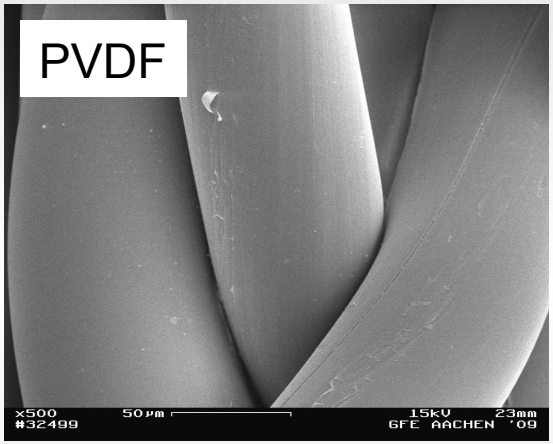
FIGURE 2. Representative explanted mesh showing the discoloration and distortion of the mesh composite.

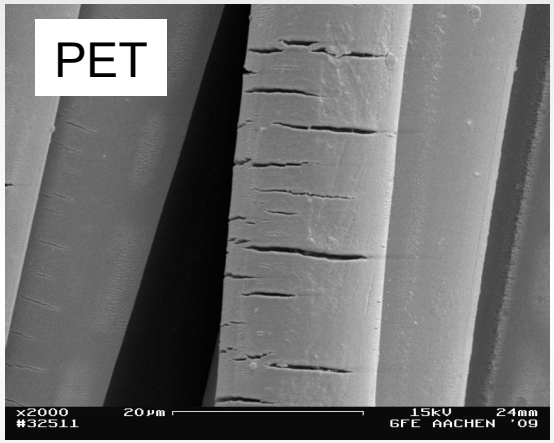




Long-term stability of PVDF

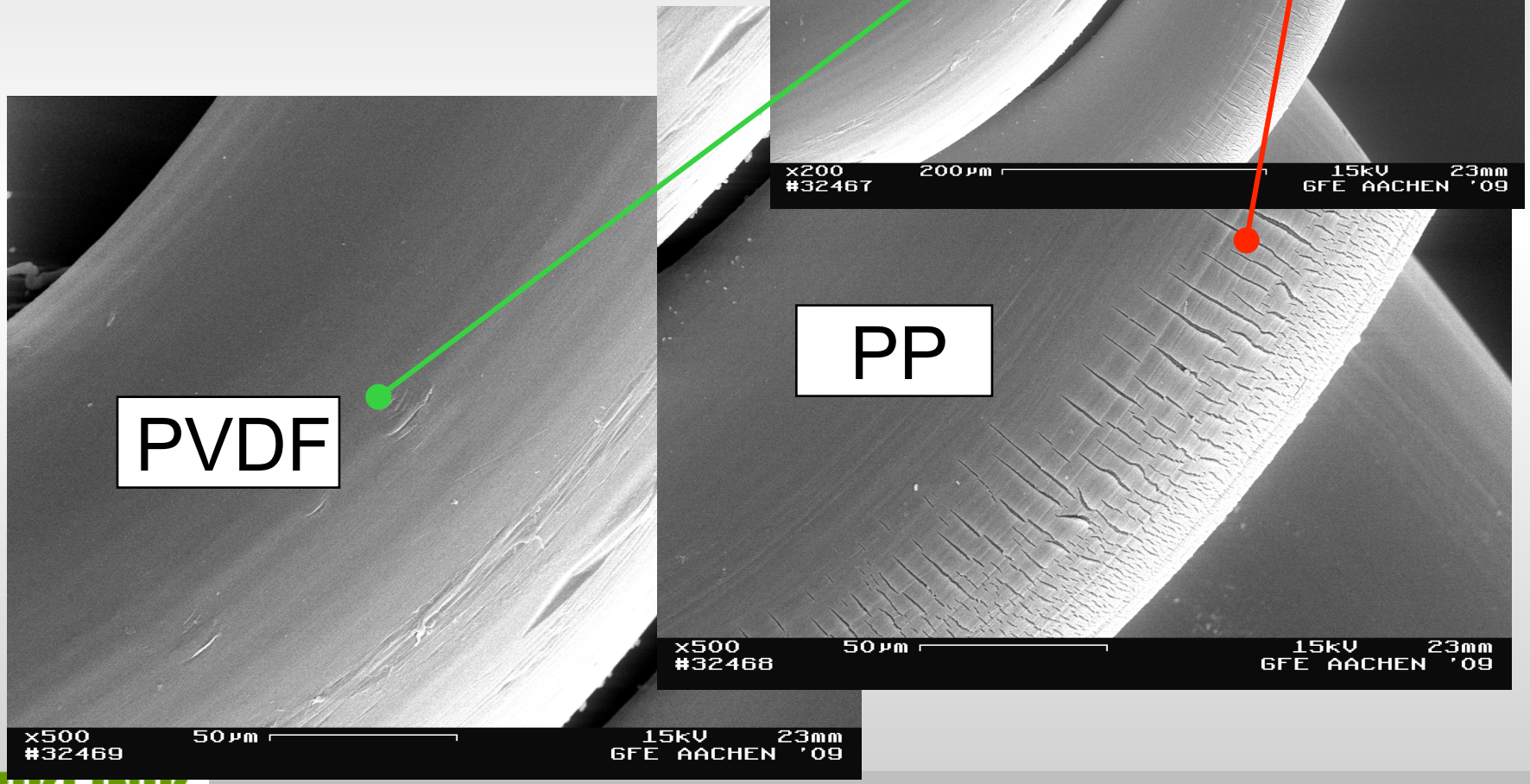






Long-term stability

21 days, rat



Polyvinylidene Fluoride Monofilament Sutures: Can They Be Used Safely for Long-Term Anastomoses in the Thoracic Aorta?

Gaétan Laroche, Yves Marois, Erwin Schwarz, Robert Guidoin, Martin W. King, Edouard Pâris, and Yvan Douville

Département de Chirurgie, Université Laval, Institut des Biomatériaux du Québec, Hôpital Saint-François d'Assise, et Département de Chirurgie, Hôpital du St. Sacrement, Québec, Canada

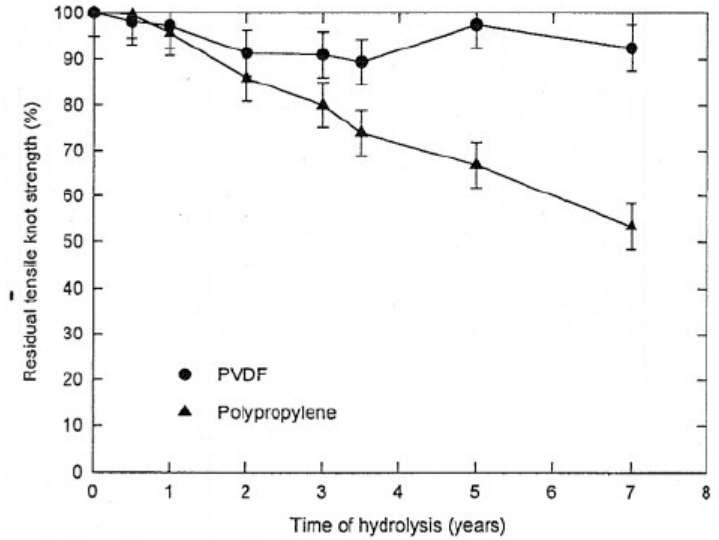


FIG. 5. The residual tensile strength of PVDF and polypropylene sutures during the 7 years of exposure to hydrolytic conditions is illustrated.

9 years. During incubation, the PVDF polymer ex-
perienced molecular rearrangements from a mixture
of
so
ec
str
showed no crystalline rearrangement but more ex-
tensive oxidation and water imbibition, which it is
believed were in part responsible for the 46.6% loss
of initial tensile strength. The tissue response of the

tensile strength after 9 years
- PVDF→92.5 %
- PP→53.4 %

Artif Organs. 1995 Nov;19(11):1190-9.

Purity (no additives) = no option for PP

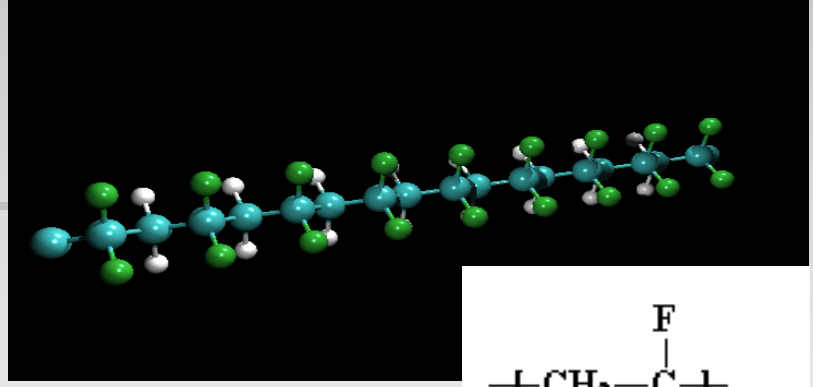
- **In its pure form polypropylene is inappropriate**
  - brittle
  - inflammable
  - shows rapid softening at higher temperatures
  - rapid degeneration
  - by UV radiation turning into powder within 1 year
- Additives = additional risks for cytotoxic effects
  = leaching out favours degradation

  stabilizers, antioxidants, antistatic agents, **makes pp**
  - resistant to heat and autoclavable
  - resistant to fatigue
  - dense and flexible
  - translucent and little inflammable
  - • Calcium stearate 0.25 – 0.35%
  - • Dilauryl thiodipropionate (DLTDP)
  - • Santonox R
  - • Polyoxyethylene lauryl ether (Luberol, Procol LA-10)
  - • Copper phthalocyanine (pigment)
- **What type of „polypropylene“ is used for your meshes ???**

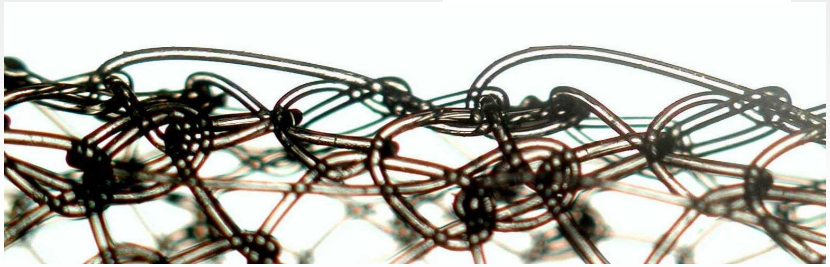
Purity (no additives)

- **In its pure form PVDF is appropriate**
  - not brittle
  - not inflammable
  - High chemical resistance
  - No rapid softening at higher temperatures
  - No rapid degeneration by UV radiation turning into powder within 1 year
- **Only addition of colour pigments to pure PVDF polymer**

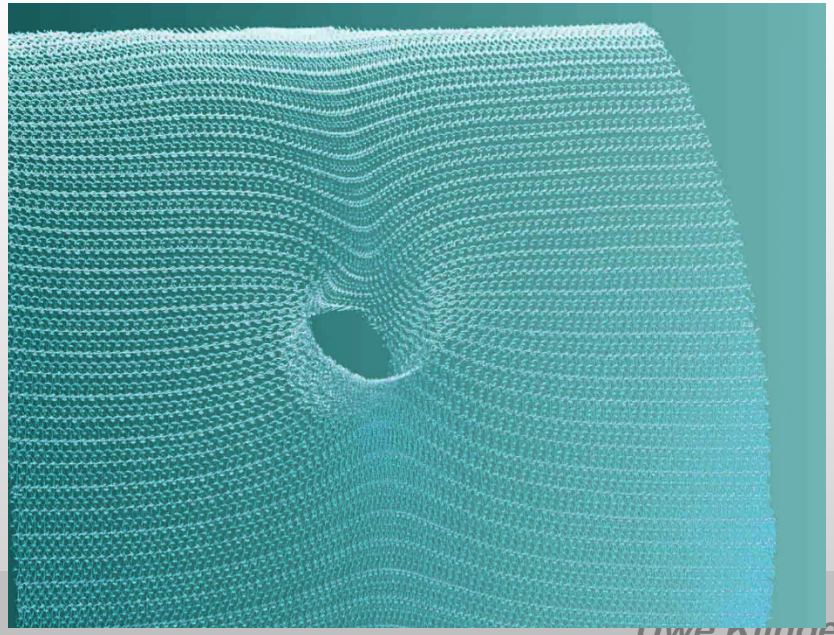
PVDF



- High specific weight
  - Polypropylene 0.9 g/cm³
  - Polyvinylidenfluoride 1.8 g/cm³
- Expensive
- Difficult to handle for engineers
- Stronger than polypropylene
- Long term stability
- lower inflammatory activity
- lowerer tendency for bridging of the scar
- reduced adherence of bacteria



= decreases the risk for <u>mesh related</u> complications

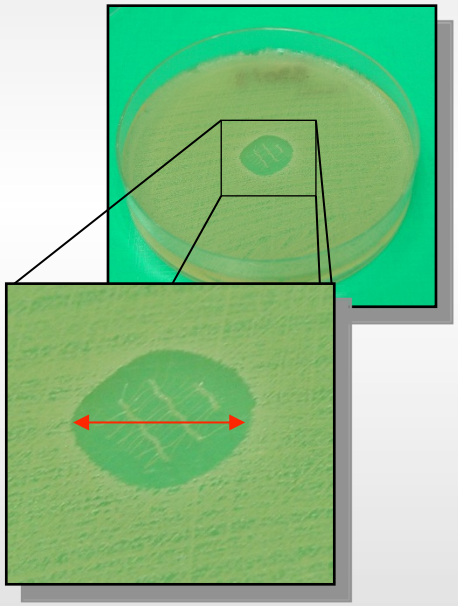


- **can be coated**
- **will be visible in MRI**

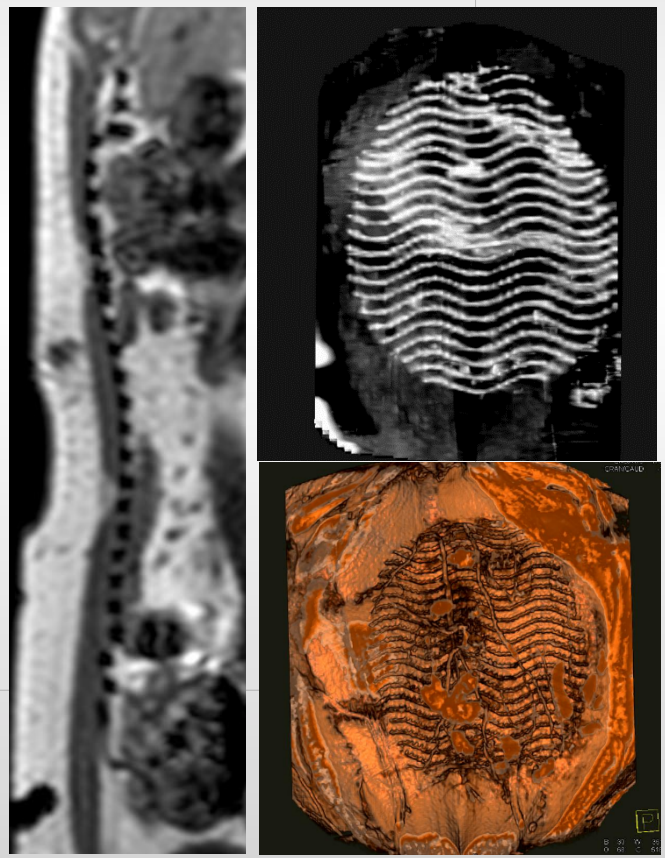
Polyvinylidene Fluoride

Impossible d'afficher l'image. Votre ordinateur manque peut-être de mémoire pour ouvrir l'image ou l'image est endommagée. Redémarrez l'ordinateur, puis ouvrez à nouveau le fichier. Si le x rouge est toujours affiché, vous devrez peut-être supprimer l'image avant de la réinsérer.

+ gentamicin



+ iron particle



F Muysoms, Gent

Thank you very much for your attention,

Your comments ?