CATHETER SURFACE INTERACTIONS WITH HUMAN TISSUE

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Introduction to Catheters

- Usages
  - Supply or Extract Fluids
  - Open Blocked Passages
  - Diagnostics & Image
- Main Problem
  - Infection
    - Catheters Are a Conduit For Bacteria to Enter the Blood Stream
    - Human Suffering
    - Catheter Related Complications $500 Million

History

- 1844 – Claude Bernard
  - Mercury Thermometer
    - Insertion Into Artery Of a Horse
    - Documented
- 1929 – Werner Forssmann
  - German Surgical Trainee
    - Intrigued by Catheter Ease Of Use
    - Forearm to Right Atrium X-Rayed
    - Rewarded by Being Fired
- 40’s-50’s – Heart Related
  - Catheter’s Used Regularly
- 1956 – Forssmann Rewarded

Tribological Issues

- Frictional Resistance
  - Damaged tissue
    - Infection

- Biocompatibility of Catheter Material
  - Usage For Extended Time
    - Infection

Two Solutions

- Early Research
  - Antibacterial Approach
    - Kills Bacteria (anti-biotics)

- Current Research
  - Surface Roughness
    - Minimize Friction
    - Inhibits Bacteria Growth

Antibacterial Coating

- Earliest Attempt
  - Dip Coating With Antibiotics

- Presently Most Successful
  - Impregnation With Antimicrobials
    - Silver Sulfadiazine
    - Chlorohexidene
  - Catheters Release Over Time

Problems With Impregnation

- Immunodeficient Patients
  - Catheter Usage Needed But Antibiotics Incompatible With Low Immune System Patients
- Impregnation Technology Has Limitations and Barriers
  - Poor Quality Control & Manufacturing Process
  - Inability to Control The Release of The Antibiotics
    - Strong at Beginning
    - Weak at End When Patient Needs Them The Most
- Leads to Current Research In Surface Roughness Of Catheters

Catheter Surface Roughness

- Directly affects:
  - Tissue Trauma (Catheter insertion and removal)
  - Catheter surface particulate generation
    - Particulate absorption is a significant source of catheter related infection.

Catheter Materials

- Low density Polyurethane “PU” **
- Latex Rubber
- Teflon
- Silicone
- Hydrophilic Polymers

- Coated with friction reducing materials in order to reduce tissue trauma.

*** = Primary catheter material due to biocompatibility*

Effective Surface Coatings

Hydrophilic Polymers:

(similar to contact lens material)

- **Excellent lubricity properties**
- **High affinity to water**

- Hydrogel

  (Soft jelly-like material)

- Phosphoryclorine “Poly(MPC-co-BMA)”

Hydrogel Testing

- 5 Different catheters were examined for their surface profile and tested for C.O.F.:
  - Uncoated Latex
  - Silicon Coated Latex
  - Teflon Coated
  - 100% Silicon
  - Hydrogel Coated

Friction Testing

- Each catheter was cut into 2 strips "C"
- Hydrogel sheet was placed on top of catheter strips (Hydrogel doubled as human tissue) "B"
- Glass Slide "D" and Load "E" placed on top of Hydrogel sheet. (Tests were also conducted without the Hydrogel sheet)

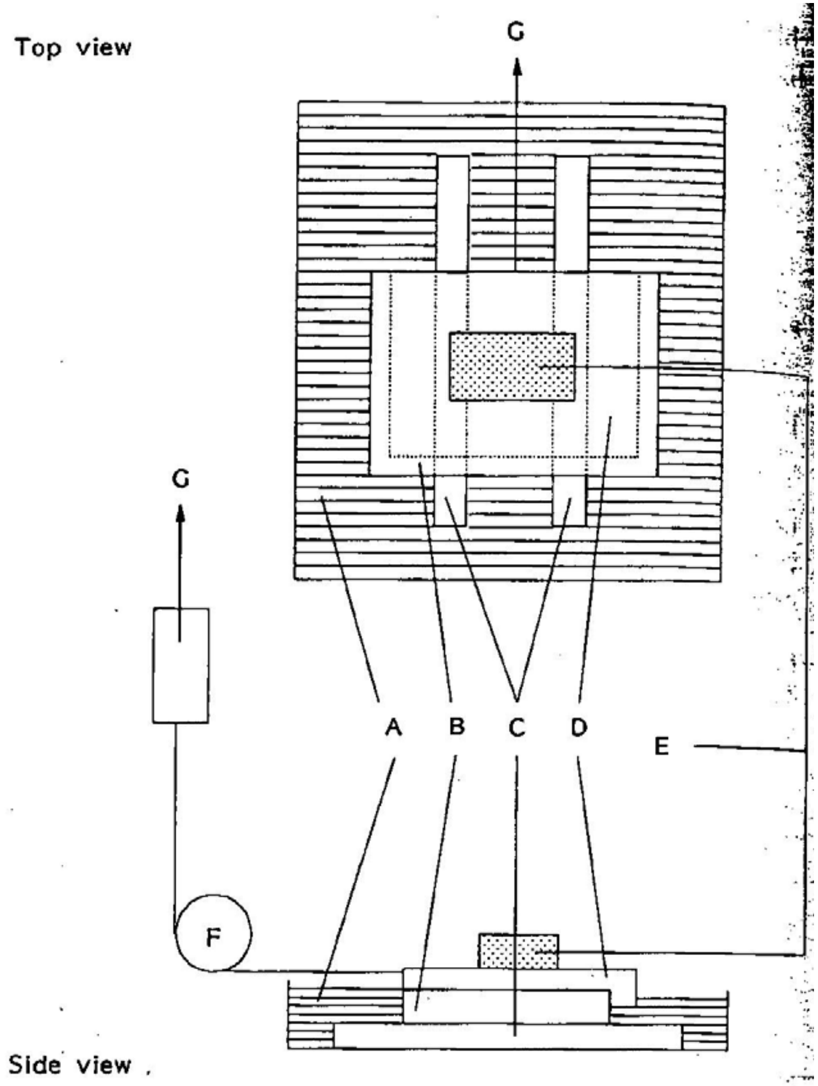


Figure 1 Schematic representation of the set-up used to determine the apparent friction coefficient. A, Water bath; B, slide surface; C, catheter sample; D, glass plate; E, load; F, low-friction pulley; G, load cell.

Hydrogel Test Results

- **Uncoated Latex:** Smooth surface but showed particulate *(.5 um Diam.)*.
- **Silicon Coated Latex:** Bumps/Hilly surface with large particulate *(3 um Diam.)*.
- **Teflon Coated:** Numerous surface cracks, which merge together.
- **100% Silicon:** Extremely bumpy with large particulate *(3 um Diam.)*.
- **Hydrogel Coated:** Smooth surface with random pores. Some infrequent particulate present.

Hydrogel Coefficient of Friction

- COF of Hydrogel is significantly lower than that of the other catheter surface materials.

Catheter	Friction surface	Apparent friction coefficient	Standard error
Natural rubber	Glass	0.470	0.0049
Natural rubber	Hydrogel	0.095	0.0057
Hydrogel-coated catheter	Hydrogel	0.054	0.0007

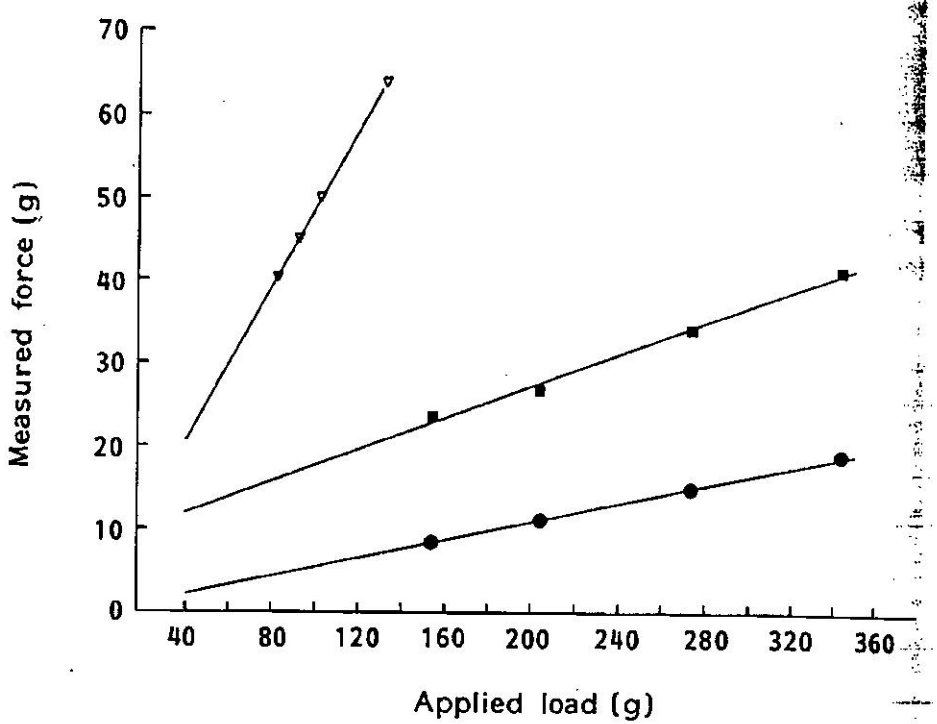


Figure 8 Force required to maintain a continuous motion under several loads. The apparent friction is determined from the slope of each set-up. △, Latex/glass; □, latex/hydrogel; ●, hydrogel-coated latex/hydrogel.

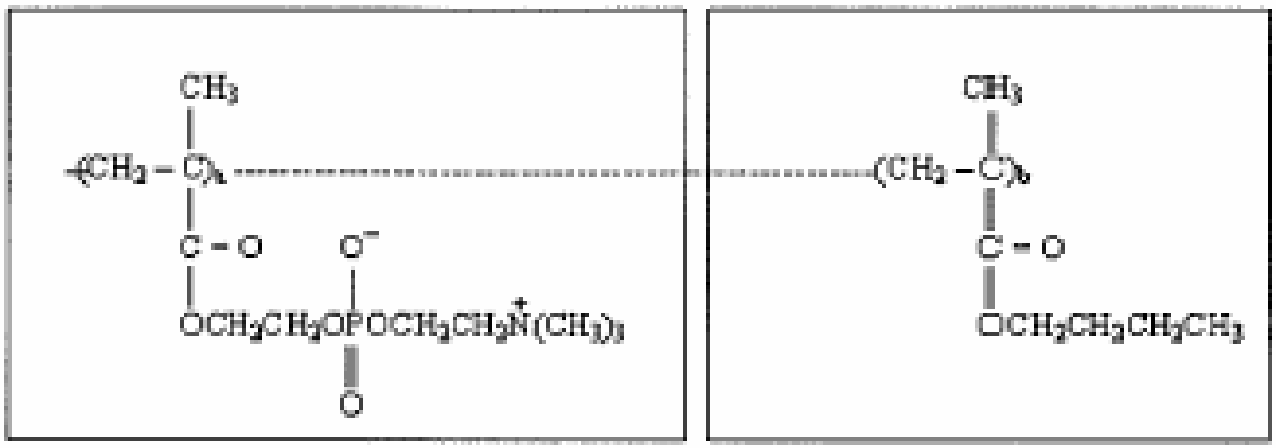
Hydrogel Pros & Cons

- Pro:
  - Softness and Porosity positively impacts lubricity and reduces tissue trauma.

- Con:
  - Hydrogel tends to delaminate due to interfacial stress. The delaminated gel leaches into the blood stream leading the way to infection and other illness.

Phosphoryclorine Catheter

- Lipid attracting copolymer
  “Poly(MPC-co-BMA)”
- Excellent coating for compliant materials due to its durability.



Hydrophilic unit (MPC)
a = 0.3

Hydrophobic unit (BMA)
b = 0.7

Poly(MCP-co-BMA) Testing

- Test for COF, Ra, and Lubricity of
  - Polyurethane Catheter (uncoated)
  - Polyurethane coated with Poly (MCP-co-BMA) polymer

- Test enviroments:
  - Vacuum Dried
  - Nanopure Water

Poly(MCP-co-BMA) Test Results

Average Roughness "Ra" Results		
Material:	**Ra *(nm)***	**Ra Tol. *(+/- nm)***
Uncoated PU in Air	10.2	1.9
Uncoated PU in H2O	9.0	1.8
Coated PU in Air	11.7	1.8
Coated PU in H2O	3.4	1.0
(95% Confinence Interval)		

Frictional Force "Ffric" Results		
Material:	**Force *(N)***	**Force Tol. *(+/- N)***
Uncoated PU in Air	0.907	0.021
Uncoated PU in H2O	0.017	0.007
Coated PU in Air	0.930	0.058
Coated PU in H2O	0.004	0.001
(95% Confinence Interval)		

Further Results

- No evidence of delamination

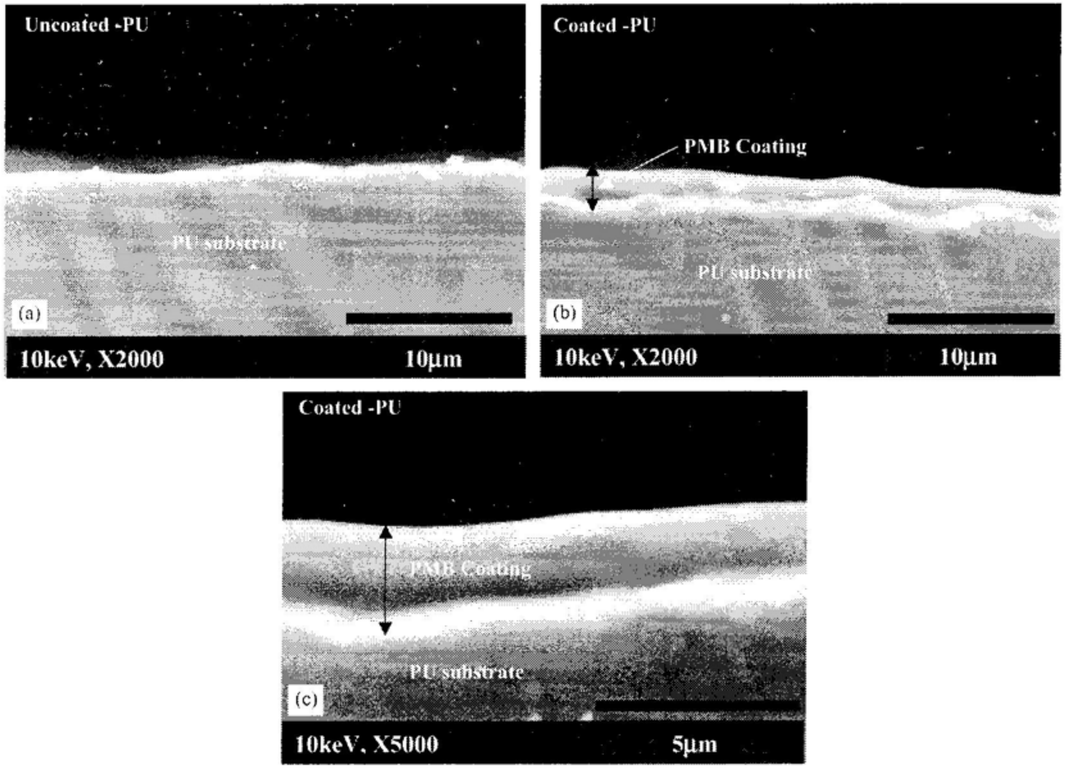


Fig. 4. Scanning electron micrographs of gold coated: (a) uncoated and (b) coated PU edges (10 keV, 2000 ×, 5000 ×).

Conclusion / Summary

- Poly(MPC-co-BMA) Polymer has the benefit of:
  - Hydrophilicity
  - No delamination
  - Excellent mechanical properties (Compliant)

Further studies show that PU catheters coated with Poly(MPC-co-BMA) cause significantly less tissue trauma and post procedural infection.