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
    - Chlorohexidine
  - 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)

- Phosphorylchlorine “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 (0.5 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.
COF of Hydrogel is significantly lower than that of the other catheter surface materials.
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.
**Poly(MCP-co-BMA) Testing**

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

- Test environments:
  - Vacuum Dried
  - Nanopure Water
## Poly(MCP-co-BMA) Test Results

### Average Roughness "Ra" Results

<table>
<thead>
<tr>
<th>Material</th>
<th>Ra (nm)</th>
<th>Ra Tol. (+/- nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncoated PU in Air</td>
<td>10.2</td>
<td>1.9</td>
</tr>
<tr>
<td>Uncoated PU in H2O</td>
<td>9.0</td>
<td>1.8</td>
</tr>
<tr>
<td>Coated PU in Air</td>
<td>11.7</td>
<td>1.8</td>
</tr>
<tr>
<td>Coated PU in H2O</td>
<td>3.4</td>
<td>1.0</td>
</tr>
</tbody>
</table>

(95% Confidence Interval)

### Frictional Force "Ffric" Results

<table>
<thead>
<tr>
<th>Material</th>
<th>Force (N)</th>
<th>Force Tol. (+/- N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncoated PU in Air</td>
<td>0.907</td>
<td>0.021</td>
</tr>
<tr>
<td>Uncoated PU in H2O</td>
<td>0.017</td>
<td>0.007</td>
</tr>
<tr>
<td>Coated PU in Air</td>
<td>0.930</td>
<td>0.058</td>
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<tr>
<td>Coated PU in H2O</td>
<td>0.004</td>
<td>0.001</td>
</tr>
</tbody>
</table>

(95% Confidence Interval)
Further Results

- No evidence of delamination

![Further Results Diagram](image-url)

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