Treatment of Menorrhagia and Irregular Menstruation: Cryo-Fluid Ablation of the Endometrium

**Background**

- Irregular Menstruation and Menorrhagia is a condition that affects reproductive and premenopausal women, characterized by:
  - Irregular/unpredictable bleeding
  - Extended menstrual periods
  - Heightened intensity of menstrual cycles
- Affects between 15% to 20% of women
- Current therapies are invasive, painful, or have low success rates. They include:
  - Hydrothermal Ablation
  - Mesh Electrode for high frequency ablation
  - Hysterectomy

- A prototype for free flowing cryo-fluid endometrial ablation as a novel treatment was developed by a 2014-2015 senior design team, as shown below:

**Project Scope**

- Improvement of the prototype to reach target temperature range, -15°C to 0°C, for 2mm endometrial ablation
- Develop a holistic mathematical model that describes the heat transfer between the endometrium of the uterus and the cryo-fluid

**Design**

- **Pennes Bioheat Equation:**
  \[ \rho c \frac{\partial T}{\partial t} = \nabla \cdot (k \nabla T) + \omega \rho b c_b (T_a - T) + q''''(r,t) \]
- **Solved in Spherical Coordinates:**
  \[ \rho c \frac{\partial T}{\partial t} = k \frac{1}{r^2} \frac{\partial}{\partial r} \left( r^2 \frac{\partial T}{\partial r} \right) + \omega \rho b c_b (T_a - T(r,t)) + q''''(r,t) \]

- As the cells transition from living to frozen state, their thermal properties change.
- The table below displays values of key parameters during this transition

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>( T_a )</td>
<td>37°C</td>
</tr>
<tr>
<td>( T_f )</td>
<td>1°C</td>
</tr>
<tr>
<td>( q'''' )</td>
<td>1 W/cm³</td>
</tr>
<tr>
<td>( \omega )</td>
<td>1 cm³/ºC-s</td>
</tr>
<tr>
<td>( \rho b c_b )</td>
<td>3.5 J/cm³-ºC</td>
</tr>
</tbody>
</table>

- Modifications:
  - 2, 1” layers of EPDM Insulation
  - Polytetrafluoroethylene (PTFE) Piping
  - Valves
  - Pressure Regulation
  - Open system to Closed system

**Results**

- The target temperature range was achieved and temperatures below that range were also reached.
- A comprehensive model for heat transfer was developed
- Enhancements to the prototype entailed regulatory devices and catheter development.
- Future work includes real tissue modeling to determine viability

**Conclusions & Future Work**

- **Catheter Development**
  - Realistic sizing
  - Balloon catheter
  - Temperature monitor
  - Removable system

**References:**


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