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A Treatment for Menorrhagia and Irregular Menstruation: Free Flowing Cryo-fluid Endometrial Ablation

Julia Biddle

Virginia Commonwealth University

Hubertina Rose Tolpa

Virginia Commonwealth University

Krystal Zentgraf

Virginia Commonwealth University

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Team Members: Julia Biddle, Hubertina Rose Tolpa, Krystal Zentgraf

Faculty Advisors: Dr. Frank Gupton, Professor Rudy Krack, Dr. Ben Ward

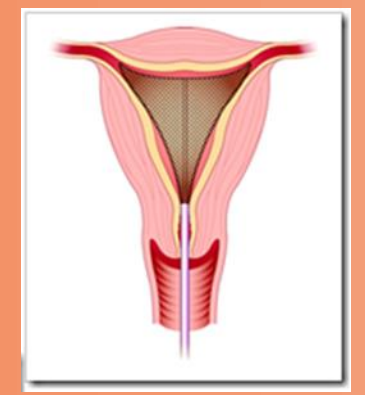
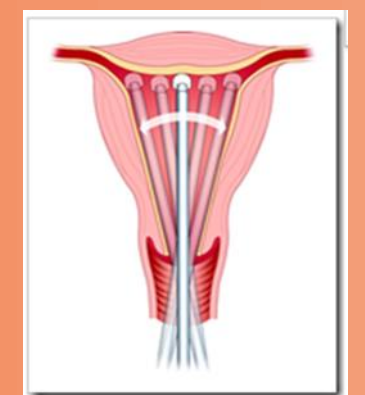
Sponsor: Dr. Philippe Girerd M.D.



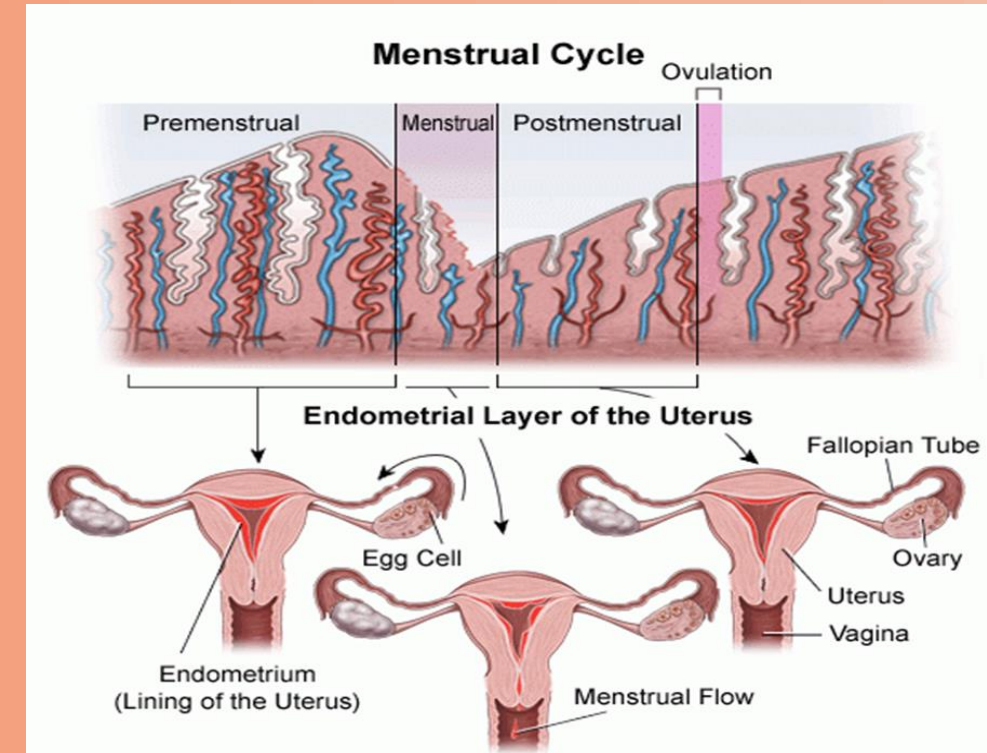
A Treatment for Menorrhagia and Irregular Menstruation: Free Flowing Cryo-fluid Endometrial Ablation



Background



- Menorrhagia is a condition defined by abnormal menstrual bleeding where flow is greater than 80 mL per cycle, 50 mL more than the average. 20% of women report suffering from this.
- Menstruation is caused by the shedding of the endometrial layer down to the regenerative basal layer; in order to permanently end menorrhagia, the basal layer must be destroyed.
- Current therapies aren't optimal for patients because the treatments are too invasive, expensive, painful or lack complete coverage of the uterus.
- A free flowing cryo-fluid system is an attractive solution to Menorrhagia due to cold's numbing properties removing need for anesthesia, and maximizing coverage of the uterine wall.



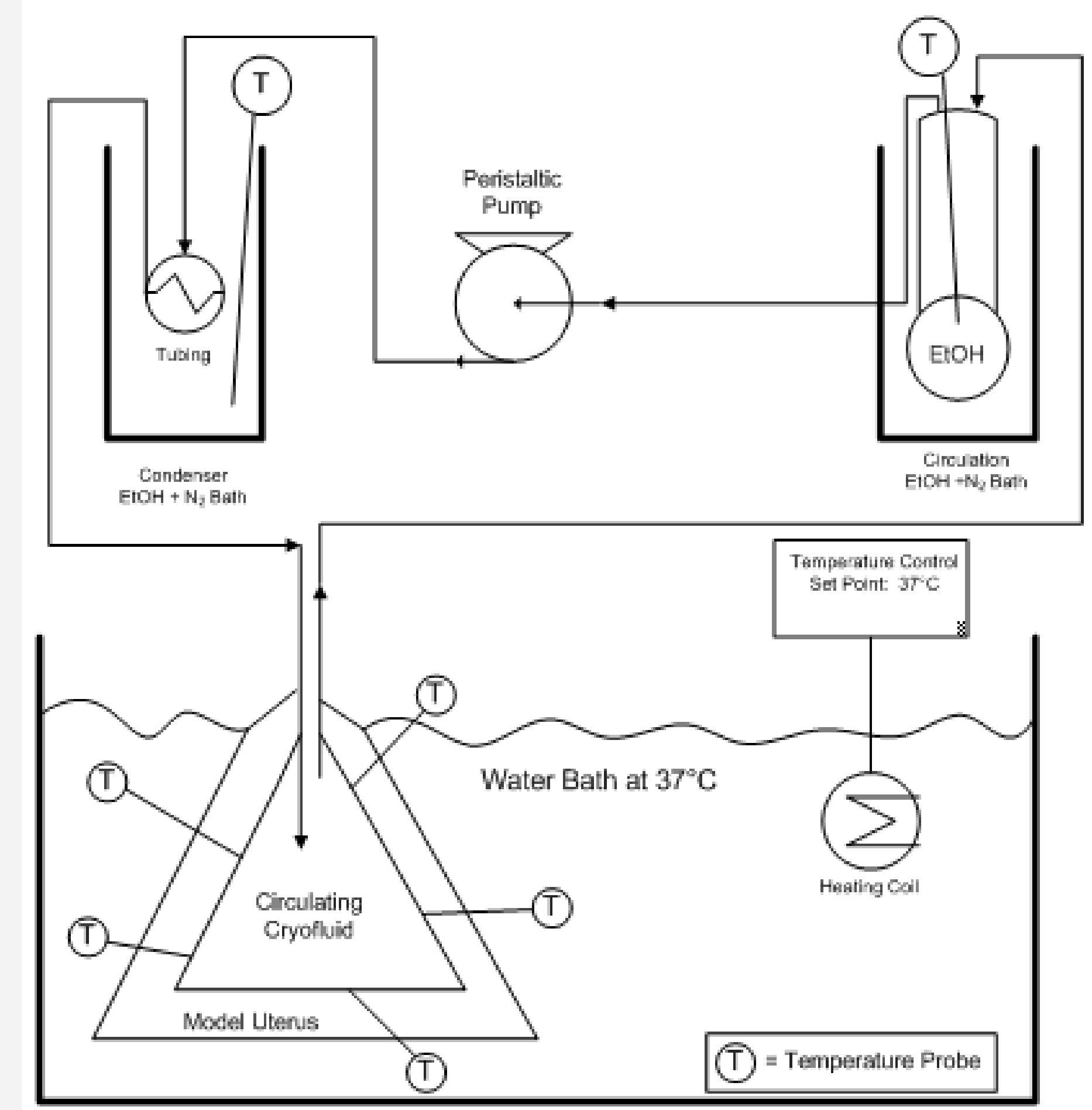
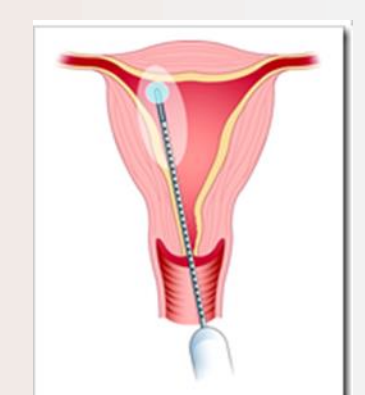
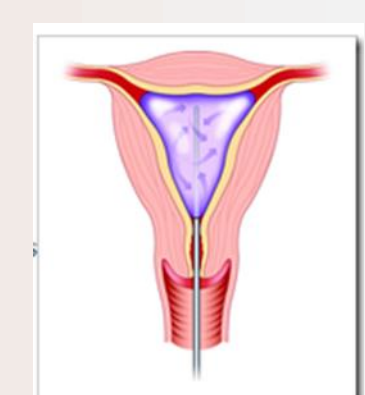
Hypothesis

- If sub zero temperature ethanol is flown into a model uterine cavity, the heat transfer that occurs will overcome body temperature and destroy cells to a depth of 2mm, preventing regeneration.

Aims

- To provide a proof concept for an in-office procedure for the treatment of Menorrhagia by using free flowing ethanol at cryo temperatures
- To reduce temperatures inside the model uterus to below the 0° C required for cell death, without freezing the cryofluid
- Maintain cold bath temperatures between -110° C and -79° C
- Find ideal cold bath temperatures based on composition, and ethanol flow rates to achieve freezing temperatures inside the model (overcoming body temperature at 37° C)

Design



- Key Features:**
- Insulated tubing
 - Condenser (Second coiling bath) applied after pump (peristaltic)
 - Liquid nitrogen and ethanol bath
 - Free flowing 100% ethanol
 - Metal coil in which ethanol is pumped through submerged in second bath
 - Model made with Permugel mold
 - Cp=1.67 kJ/kg·K (Permugel)
 - Cp=0.36 kJ/kg·K (Uterus)

Heat Transfer

Spherical Model

Steady State Heat Equation*: $\frac{d}{dr}(r^2 \frac{dT}{dr}) = 0$

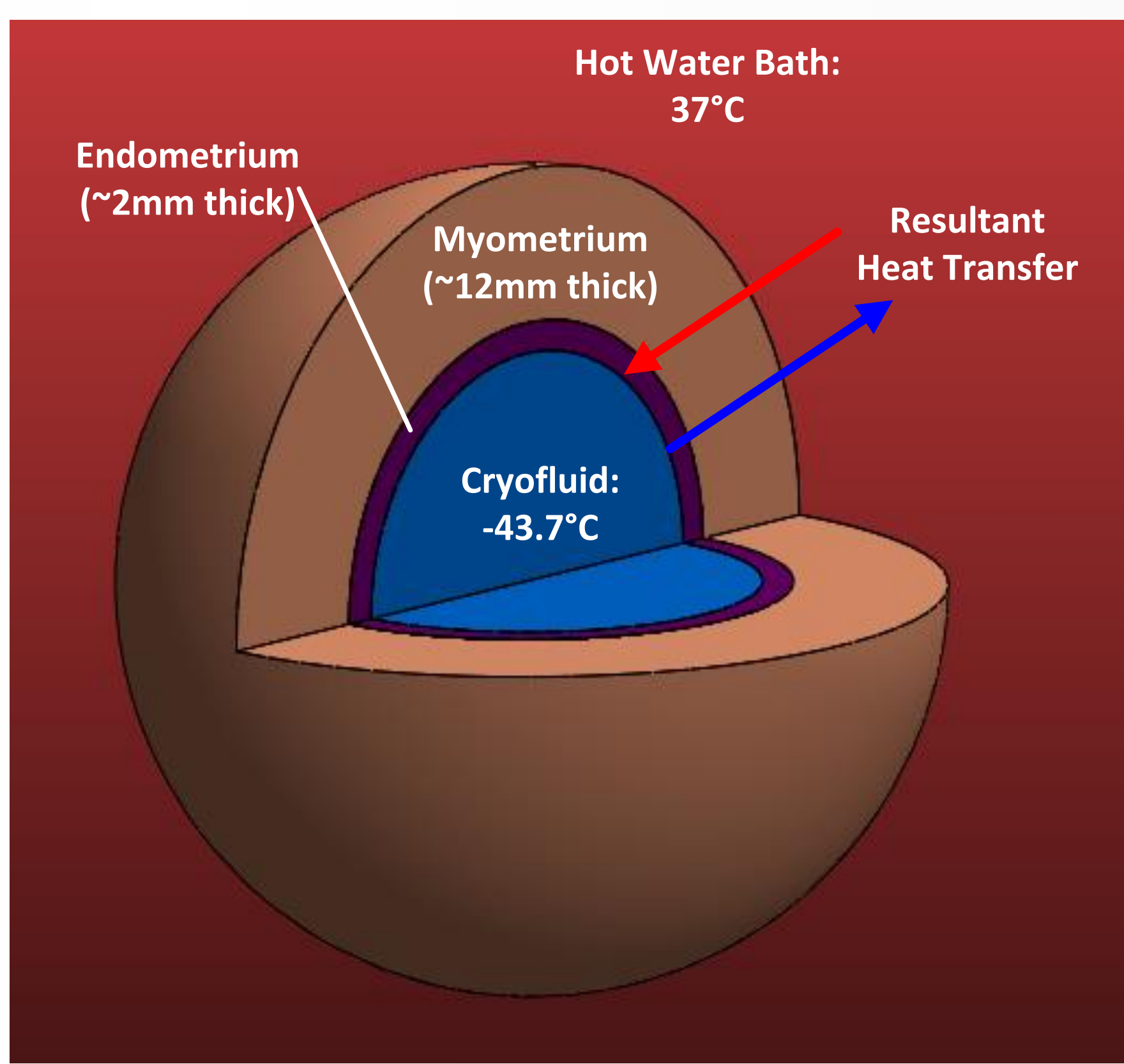
Solve: $T(r) = \frac{C_1}{r} + C_2$

Using Boundary Conditions: $T(r_1) = T_1$ $T(r_2) = T_2$

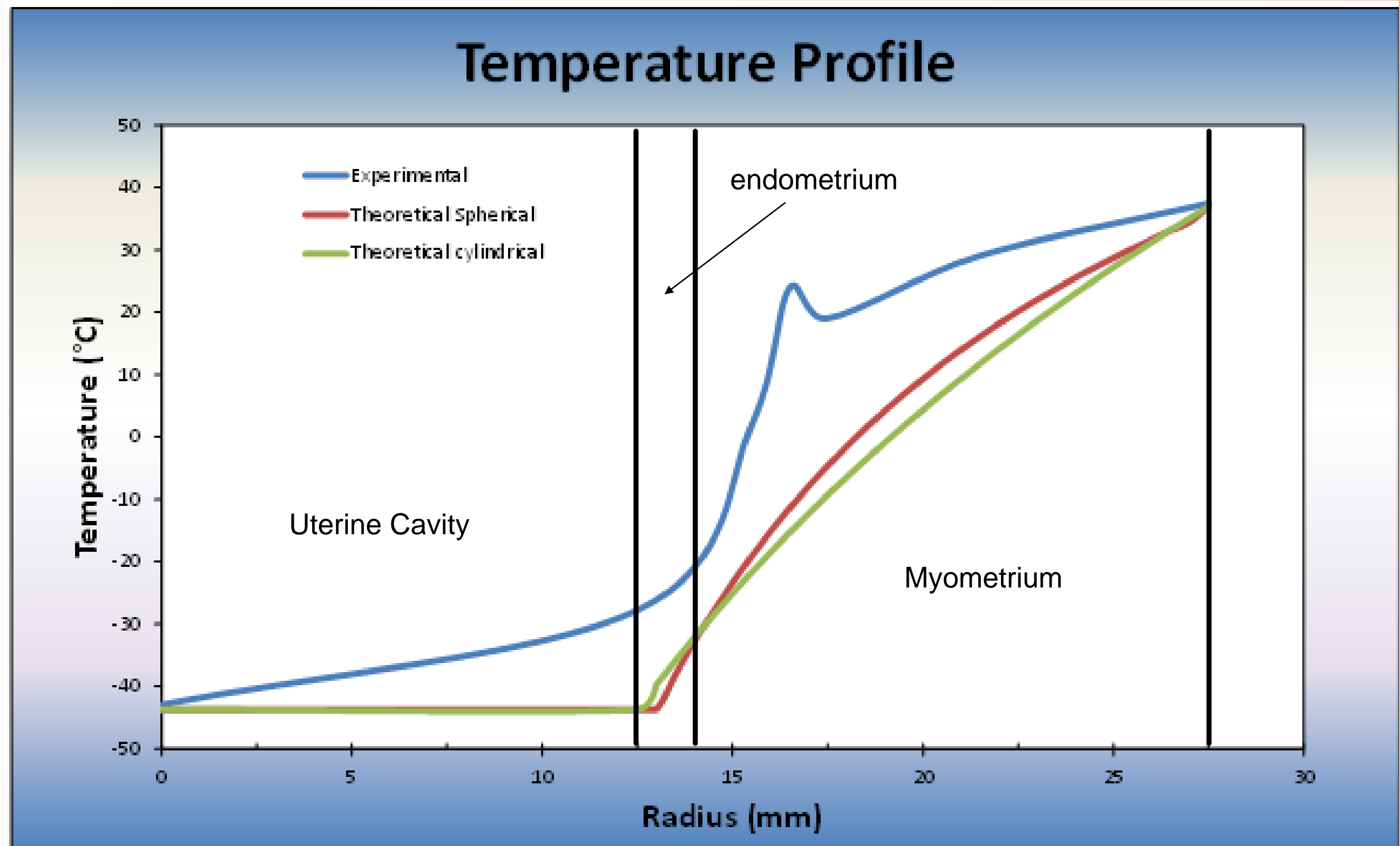
Governing Temperature Profile Equation:

$$T(r) = T_1 + \frac{T_1 - T_2}{\frac{1}{r_1} - \frac{1}{r_2}} \left(\frac{1}{r} - \frac{1}{r_1} \right)$$

*assumed steady state



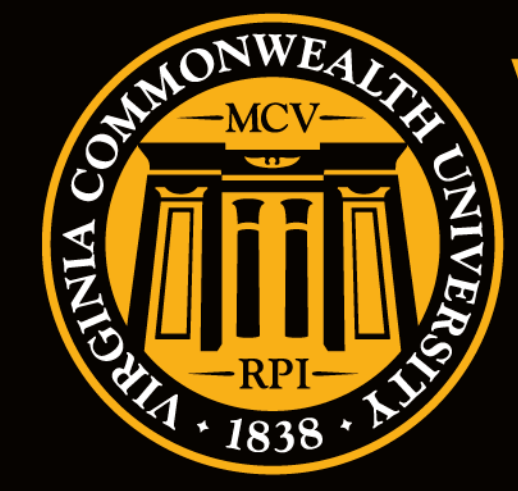
Results



Test Information	Circulation Bath Temperature Range (°C)	Condenser Bath Temperature Range (°C)	Hot Bath (°C)	Average Model Initial Temperature (°C)	Average Final Temperature at 3 mm (°C)	Coldest Temperature Achieved (°C)	Flow Rate Range (ml/min)	Time to Reach Equilibrium (min)
	-65.6 : -96.1	-69.9 : -101.8	37.0	38.0	1.2	-0.9	102 : 204	35

Conclusions & Future Work

- Cryoablation by free flowing liquid is a feasible treatment option for Menorrhagia.
- Sub -80° C ethanol can be successfully flowed in a closed system to create a -43° C environment inside a Permugel model.
- Due to the Permugel model's differing heat capacity from the endometrium, it is believed that using these cold bath temperatures in a human uterus would achieve cell death at the goal depth of 2mm.
- Flow rate adjustments were inconclusive due to peristaltic action increasing at cold temperatures causing extreme fluctuation in readings.
- Due to modeling with a steady state equation, experimental unsteady state results naturally vary from calculations.
- Cytotoxicity of ethanol on cells should be investigated. Possible treatment time could be reduced.
- Testing on tissue models with correct heat capacities will provide more definite results.



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Make it real.