Assessment of ErythroMer as a Ex Vivo Organ Perfusate

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Background

What is ErythroMer?

• **ErythroMer**, produced by KaloCyte, is a bioengineered synthetic cell that contains hemoglobin in a lipid nanoparticle shell. ErythroMer replicates the red blood cell's natural function of oxygen transportation

• Universally compatible with all blood types, ErythroMer is bio-digestible and stored as freeze-dried, sterilized powder, prolonging its shelf life

• Currently pending approval to begin Phase I clinical trials

Why Do We Care?

• In 2020, 20% of kidneys recovered for transplant were unused due to tissue atrophy, lowering organ quality

• 13 people die every day waiting for kidney transplants

• Ex vivo perfusion with synthetic blood particles offers a solution to challenges like compatibility and disease transmission risks.

Research Question and Goal

Our goal is to improve accessibility to and quality of donated organs through ex vivo organ perfusion with synthetic red blood cells. However, in their current state, no existing red blood cell substitute can withstand the shear stress of ex vivo organ perfusion.

How can an existing artificial red blood cell be modified to withstand ex vivo organ perfusion?

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Methods

Hypothesis 1:

If we shear the particle for ten minutes at incrementally increasing rates of shear, then we can use the percent of free hemoglobin to determine the peak shear tolerance of the particle.

Hypothesis 2:

If we shear the particle at a fixed, low shear rate for incrementally increasing amounts of time, then we can determine the prolonged shear tolerance of the particle.

The structural integrity of the particle was quantified by analyzing hemoglobin encapsulation within the particles as a function of shear tolerance, following ex vivo organ perfusion system pump specifications provided by Leiden University Medical Center.

1. Rheometer

Apply a consistent shear stress for a predetermined amount of time

2. Ultracentrifuge

Spin ErythroMer to isolate components, pelleting nanoparticles while preserving hemoglobin

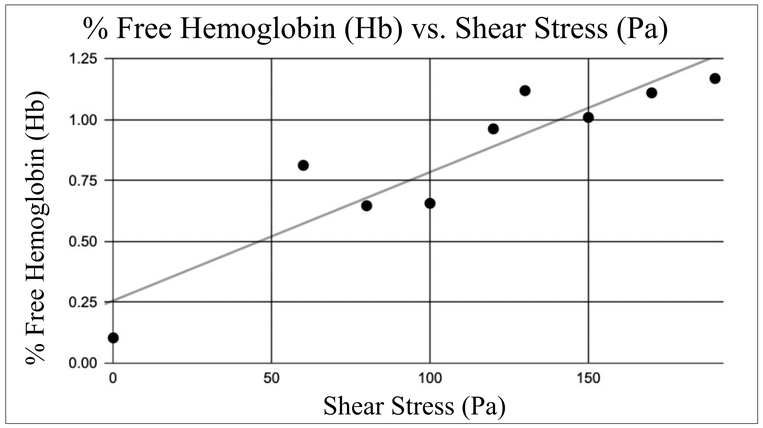
3. Spectrophotometer

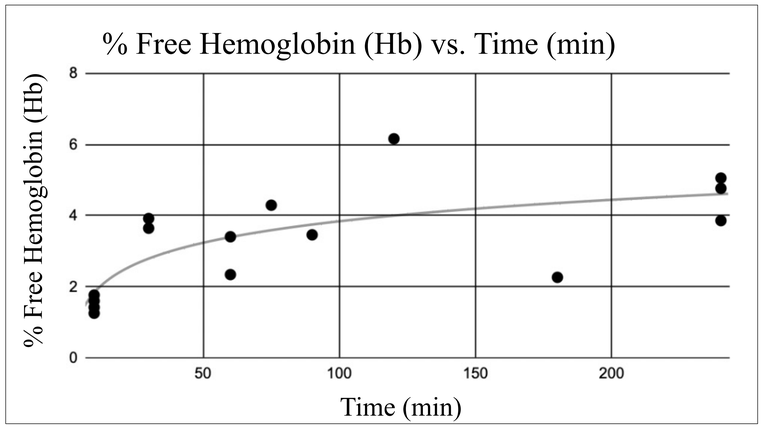
Measure absorbance wavelength for hemoglobin concentration of sheared ErythroMer

4. Calculations

Quantify free hemoglobin from absorbance, comparing sheared to unsheared samples

Current Results and Future Plans





Next Steps

• Determine physical limits of the particle and compare current limitations with pump specifications.

• Explore potential adjustments to particle aspects such as lipid component or cholesterol concentration to enhance system suitability

Acknowledgements and Citations

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