Hydraulic Cardiac Sleeve

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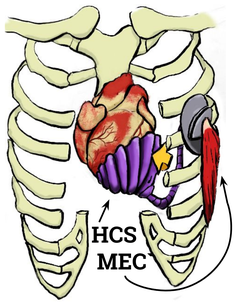
Executive Summary

Congestive heart disease (CHD) affects over 5 million Americans a year.[1] Current treatment methods are accompanied by problems and side effects for the patient.

The hydraulic cardiac sleeve (HCS) wraps around both left and right ventricles and aims to:

- Provide a long-term solution to CHD
- Be minimally invasive
- Restore the natural compressive and twisting motion of the heart
- Be internalized, alleviating the risk of a break or infection at insertion site



The HCS will use a muscle energy converter (MEC) as an internal hydraulic power source that pumps fluid into and out of a sleeve formed from an array of inflatable tubes.

Clinical Need

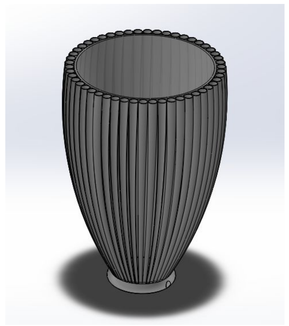
CHD encompasses any disease or disorder that reduces the heart's ability to pump blood efficiently through the body. Reduced blood flow to muscles and the organs causes fatigue among people, along with increased risk of myocardial infarction.

Three major treatment options currently available for CHD:

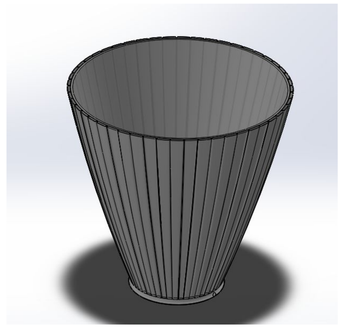
1. Pharmacologies
   - Blood thinners, cholesterol reducing drugs, etc.
   - Provides only temporary relief from symptoms
2. Ventricular Assist Devices (VADs)
   - Mechanical pump surgically implanted to assisted diseased heart
   - Short term, but requires invasive surgery
3. Heart Transplants
   - Effective, long term solution
   - Small donor pool
   - Invasive surgery
   - Requires immunosuppressive drugs

Product Design

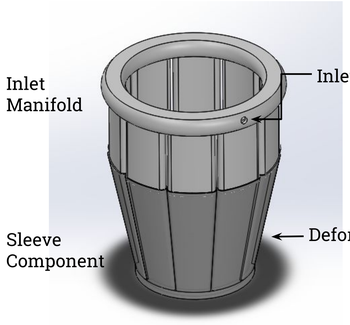
The HCS is a 3D-printed sleeve that wraps around the heart and expands/contracts according to the patient's EKG signals to improve blood circulation. The sleeve will be sutured to the surface of the heart for long-term, reliable attachment.



Systole (compressed configuration)



Diastole (expanded configuration)



Mechanism of Action

1. Muscle Energy Converter (MEC) pumps fluid into inlet of manifold
2. Fluid flows into tubes of the HCS sleeve
3. The individual tubes are inflated
   - Overall diameter of HCS decreases
   - Aids heart's contraction during systole
4. Fluid is pumped out of the HCS
   - Overall diameter of HCS increases
   - Allows heart to expand during diastole

Market Analysis

- Estimated cost of production: $1,086.00
- HCS will share market with VADs-- Market size and scope presented with graph at right
- Minimizing costs due to surgical complications-- both during and post procedure-- make it more cost effective than VADs
- Increasing demand as patients with CHD rise at faster rate than donor hearts for transplants become available

Testing Model

Requirements for product to be technically feasible:
- Ejection fraction of at least 5% of a 280 mL sac, the volume of an average heart.[4]
- Deflation that can occur immediately after inflation, to prepare for the next heartbeat
- Leakproof

Testing design:
- Fill bag with 280 mL of water, put inside sleeve
- 'Heart' assumed to be 100% full, with exit valve where the current water level is. Mark current water level.
- Inflate sleeve, mark new water level.
- Volume difference between water levels aspirated and measured with pipette to calculate ejection fraction.

Conclusions & Future Work

Our team accomplished a lot despite changing our device at the beginning of this semester, instead of continuing our design from last semester.

Accomplishments:
- Working shower curtain proof-of-concept to illustrate volumetric change
- 3D-printed sleeve with separate tubes
- 3D-printed manifold for distributing fluid

Future work could include:
- Finalization of prototype design parameters
  - Size and shape of individual tubes, overall arrangement
- Testing efficacy in aiding with blood ejection
- Testing fluid volume needed for inflating sleeve
- Testing and researching for characteristics of commercializing (biocompatible, FDA approved, covered by health insurance)

Acknowledgements

Our team thanks our advisor Dr. Dennis Trumble as well as Dr. Conrad Zapanta for their guidance on this project. Additionally, we would like to thank Elaine Soohoo and Jooli Han for their efforts in researching and producing the product, and Lauren Zemering for assistance designing and printing prototypes, and our TA Alexandria Shea for her advice on the project. Finally, we would like to thank the URO for providing funding for our research.

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