Team 6

[E.V.R.T]
endovascular valve resection tool

TEAM MEMBERS:
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SPONSOR:
Dr. Wei Sun
Background

- Aortic stenosis is the most common valvular heart disease in the western world.
  - Effects 2% of the population over 65, 3% of population over 75, and 4% of total population over 85.
- Endovascular procedures reduce risk of severe complications of major surgery.
  - Especially important in patients with advanced age or co-morbidities.
Background

- Project is designed to cut away calcified or diseased valve leaflet tissue from the aortic root.
- Current procedures are limited in their ability.
  - Current minimally invasive procedures only push the original tissue towards the aortic wall using a stent.
    - Limits bloodflow.
  - Open heart surgery is currently required to remove the old tissue.
Requirements

- Must consist of a highly flexible shaft that can be snaked through the femoral artery before reaching the aorta.
  - Must fit within a 24F catheter (7.6 mm).
  - Upon reaching the aorta, must expand to ~3 times as large to be effective.
- Automated opening and closing of the device.
- Hard to maneuver once in aorta.
  - Cutting force must be strong enough to cut through hardened leaflets with limited leverage.
Previous Works

- No relevant patents or current products in the USA.
- Research teams since 2005 have used a variety of techniques in attempts at a less invasive procedure.
  - High pressured water
  - Lasers
  - Metal blades
- Hauke et al. in Germany created an open heart procedure using a collapsible metal blade.
Design

- Blade and Backplate
- Shaft and Motor
- User Controls
- 5:1 Scale
Cutting Assembly

- Blade and backplate machined out of .32 in thickness 1095 steel (spring steel).
  - Allows some flexibility, not as much as Nitinol.
- Each assembly made in 4 pieces to allow more ease during compaction while closing.
- Pieces are bent to their final form, then heat treated.
  - Heated to 1400° F for 1 hour, quenched, then annealed at 700° for another hour.
Shafts

- Nested shafts used.
  - Allows rotation of cutting blade, while backplate and distal end do not move.
  - Polished and greased to minimize friction.
- For our model, flexible Nitinol shaft unnecessary.
  - Aluminum shafts used to minimize costs.
Motor and Transmission

- **Blade motor – NEMA 23 Stepper Motor.**
  - Allows blade rotation at 80-100 RPM.
  - 2” spur gear to translate motion to blade.

- **Stage motor – NEMA 17 Stepper Motor.**
  - Allows stage movement approx. 4 inches/min.

- **Parker Automation #008-3686 Linear Stage.**
  - Allows opening/closure of device.
User Controls

- Tool is operated via a computer using LABVIEW 9.0.
- Graphical User Interface allows simple control.
  - User can set linear position of blade in relation to backplate.
  - Set the blade in motion.
  - Set blade speed.
Tissue analog was used to test. Aluminum rings used with sample sutured to it. Blade exhibited reasonable cutting speed despite limitations placed on it by the motor.
# Budget

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<tr>
<th>Item</th>
<th>Cost</th>
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<tbody>
<tr>
<td>Raw Materials</td>
<td>~$150</td>
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<tr>
<td>Shaft Collars</td>
<td>~$30</td>
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<tr>
<td>Spur Gears</td>
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<tr>
<td>Motor/Linear Stage</td>
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<tr>
<td>Miscellaneous/Shipping</td>
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<td><strong>TOTAL COST</strong></td>
<td><strong>$286.88</strong></td>
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Looking Forward

- What could be next for EVRT?
- Scaled down to actual size.
- Machined out of Nitinol.
  - Allow for proper folding of the blade.
- Flexible shaft.
- Linear actuators instead of linear stage.
Thanks

- Dr. John Enderle
- Dave Kaputa
- Keiwei Li
- James Paolino
- Dr. Wei Sun
- Dr. Bi Zhang
- Special thanks to Serge, Pete, and the rest of the machine shop staff!
Questions?