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Case Studies

Optimising annuloplasty repair rings



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Repairs to damaged heart valves have traditionally been performed with flat annuloplasty rings. Improvement of the design required data captured directly from a beating heart.

Company/Institute:

Institute of Clinical Medicine, Aarhus University Hospital, Denmark, University of Arkansas, Fayetteville, AR, USA

Industry/Application Area: Biomedical Engineering

**Products Used:** 

- Transducer Class strain gauges
- <u>Adhesives and other installation accessories</u>

## The Challenge

The human heart valve that prevents blood flow back to the lungs is called the mitral valve. This valve operates under the highest forces of any of the four valves in the heart. It can suffer damage and degradation through disease and age, which can be repaired by mounting rings around them, a procedure called annuloplasty. Unfortunately, the increased stresses can reduce valve efficiency and overall durability of the repair. New insight into the 3D dynamic behavior of the valve prompted a reevaluation of the ring design to improve the stress distribution. The hypothesis that saddle-shaped annuloplasty rings have superior uniform force distribution required confirmation through inheart force measurement, compared to flat rings.

# The Solution

Rapid prototyping was used to manufacture both flat and saddle-shaped annuloplasty rings. Strain gauges were mounted in four locations around the rings and then calibrated against force. A frequency response test was also performed to ensure they would not significantly affect the natural valve operation.



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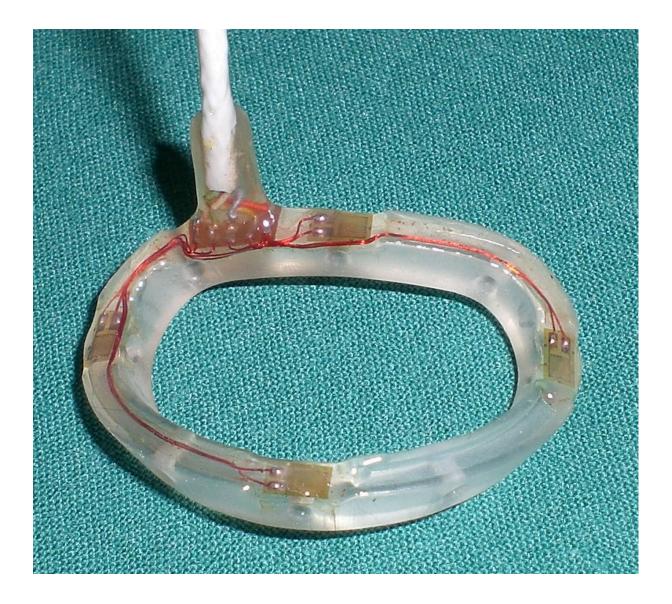
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The rings were then mounted around the mitral valve and data captured during the natural beating of the heart. In combination with other captured data it was confirmed that proper heart function was maintained with the saddle-shaped ring while maintaining forces close to zero, significantly lower than the traditional flat design. This has resulted in saddle-shaped annuloplasty rings being adopted as the primary standard for heart valve repair.

### The User Explains

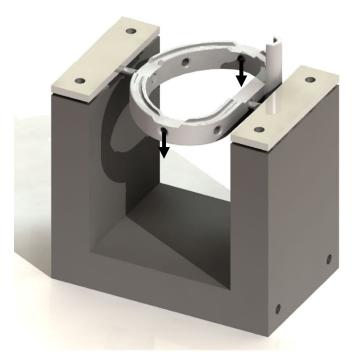
The mitral annuloplasty rings were designed based on the dimensions of the heart in an 80-kg pig, which are very similar to the adult human valve annulus. Strain gauges were mounted at four locations of the ring, as shown in the figure.







Rapid Prototyping Technology was used to create dedicated designs to measure bending strain at 4 specific locations within the mitral heart valve annulus. Strain gauge signal-to-noise ratio was increased by using plastic as material. The strain gauges were mounted by the UK-based Micro-Measurements<sup>®</sup> Technical Services Team on the ring. The strain gauges connected to the dedicated data acquisition hardware and software in quarter- bridge circuits. Testing the rings for strains from circumferential forces concluded that this component was found to be less than 10% of the strain obtained from 'bending' forces perpendicular to the plane of the ring itself. A calibration setup was designed and used to convert the regionally-measured strain to restraining force in the annuloplasty ring, see Figure below; black arrows symbolise calibration force applied to the ring.



The saddle-shaped ring experienced less restraining forces, and the results from this work are used today in designing clinically used annuloplasty rings available from large international medical device companies such as Medtronic and Edwards Lifesciences.

"The expertise from the Micro-Measurement<sup>®</sup> technical services team was a key part in this project"





#### Acknowledgement:

This work was performed at the Aarhus University Hospital, Denmark and continues at the University of Arkansas, Fayetteville, AR, USA. Aarhus University Hospital houses a world-class large animal experimentation facility. Large animal use is necessary in surgery involving experimental devices. All pigs were bred under standard laboratory animal conditions, and the experiment complied with the guidelines from the Danish Inspectorate of Animal Experimentation. The research described above was approved by this institution. Support has been provided by the Danish Heart Foundation Grants #B248-A389-30, #B248-A946-38, and #07-4-B248-A1380- 22362, the A.P. Møller Foundation for the Advancement of Medical Science, The Danish Medical Association Research Fund, National Heart, Lung, and Blood Institute (NHLBI) grant # HL 52009 and NHLBI grant K24 HL67434. For more information, please see contact information below.

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