



Novel annuloplasty ring solution for improved surgical quality and safety during minimally invasive mitral valve surgery

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BACKGROUND and BASICS

The future of surgical approaches lays in minimal invasive approaches due to mayor benefits for the patient. However, most minimally invasive approaches did not proof to be safer or faster than conventional surgery so far. Minimally invasive mitral valve repair or replacement procedure takes a significantly larger amount of time than the classical procedure, even when performed by someone with a great amount of specific training. Human factors engineering / Ergonomics know-how can be used beneficially in the development process of mandatory technical solutions and supports to make these minimally invasive approaches faster and safer.

“The importance of employing ergonomic principles in the design of medical devices is the way to achieve patient safety, product efficacy and business advantage“

David Hearne (Med Device Technol. 2004
May;15(4):32-33.)

CONCEPT and SOLUTION

Concept: Workflow of minimally invasive mitral valve procedures has been analyzed in order to identify main difficulties (risks) and time consuming work tasks. Main goal of these ergonomic task analysis were to detect ways to reduce CPB time (cardio pulmonary bypass) and risks related to minimally invasive approaches. Two main difficulties have been detected:

- (1) placement and monitoring of endoclamp balloon catheter in the aorta (sealing of the aorta is mandatory for CPB),
- (2) limited space, haptic feedback and vision during work at the “deepest” parts of the valve when placing the mattress of sutures to receive the reinforcement of the valve (ring annuloplasty).

Solution - Novel solution for annuloplasty ring: Design by Felipe Moraes as Medisign graduation project at IDE-TUD. All threads that hold the ring annuloplasty are pre-assembled by the assistant on one C-shaped ring. Pre-tied knots (variant of Roeder Knot) on small cylinders are used. The cylinders can be removed and the knots slide in the direction towards the annulus and can be pushed with the help of the C-shaped ring. When it reaches the desired position the threads are cut and the ring is fixated.

Benefits:

- Pre-tied and pre-arranged knots save time and lead to decreased suturing time (time on CPB)
- C-shaped ring increases stability and supports proper placement of the sutures
- Fine motor tasks (knot tying) are drastically reduced and the remaining task that need dexterity (geometrical arranging of sutures, release of Roeder Knot) can be done outside the patients body without spatial limitations and restrictions

Solution - Automatic positioning system for endoclamp catheter: Design by ARIS*ER research consortium with IDE-TUD as partner in human factor engineering / Ergonomics. Combination of information and positioning system based on augmented reality technology and robotics. Position and pressure sensors in the catheter are used to monitor and visualize catheter location and balloon efficiency. The same sensor information is used to control a pump and an actuator that control catheter position and balloon pressure.

Benefits:

- Visualization part of the system supports safe and accurate placement of the catheter
- Intelligent control secures an automatic monitoring of the catheter and keeping it in place
- No more interruptions of the surgeons during work at the valve due to displacements of catheters

STATUS and OUTLOOK

Annuloplasty ring: Actual state is a functional prototype and proofed compatibility in surgical workflow. First tests on phantom with expert surgeons are promising (proof of concept). Further R&D e.g. testing on tissue and manufacturing planning is needed. Looking for partners for R&D and commercialisation.

Catheter positioning system: Successful proof of concept on phantom studies and first animal tests. Patent of key technology is filed. Further R&D for the actuator part is needed; tracking and visualization part ready for commercialisation. Looking for partners for acquiring public funding, or partners who have readiness to invest (R&D of robotics and control part). Looking for partners for licensing monitoring and visualization part for add-on to their medical device (catheters, implants, surgical tools).

Outlook:

- Founding of start-up company
- Investigations on new application of the technology solutions (pre-knotted knots, intra-operative visualizations of sensor data)
- Further research collaboration with medical device industries that aim to improve safety and efficiency of minimally invasive approaches by design

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