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New mitral annular force transducer optimized to distinguish annular segments and multi-plane forces

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ABSTRACT

Limited knowledge exists about the forces acting on mitral valve annuloplasty repair devices. The aim of this study was to develop a new mitral annular force transducer to measure the forces acting on clinically used mitral valve annuloplasty devices. The design of an X-shaped transducer in the present study was optimized for simultaneous in- and out-of-plane force measurements. Each arm was mounted with strain gauges on four circumferential elements to measure out-of-plane forces, and the central parts of the X-arms were mounted with two strain gauges to measure in-plane forces. A dedicated calibration setup was developed to calibrate isolated forces with tension and compression for in- and out-of-plane measurements. With this setup, it was possible with linear equations to isolate and distinguish measured forces between the two planes and minimize transducer arm crosstalk. An in-vitro test was performed to verify the crosstalk elimination method and the assumptions behind it. The force transducer was implanted and evaluated in an 80 kg porcine in-vivo model. Following crosstalk elimination, in-plane systolic force accumulation was found to be in average 4.0 ± 0.1 N and the out-of-plane annular segments experienced an average force of 1.4 ± 0.4 N. Directions of the systolic out-of-plane forces indicated movements towards a saddle shaped annulus, and the transducer was able to measure independent directional forces in individual annular segments. Further measurements with the new transducer coupled with clinical annuloplasty rings will provide a detailed insight into the biomechanical dynamics of these devices.

1. Introduction

During the last two decades a tendency towards reconstruction of the mitral valve (MV) has been preferred as an alternative to performing total valve replacement (Gammie et al., 2009). Multiple versions of annuloplasty rings have been developed since the initial design (Carpentier et al., 1971). Persisting challenges with repair devices such as ring dehiscence and early failure of the new replacement devices require extensive multi-directional biomechanical force and displacement information of the MV.

Several strain gauge based methods have been developed in order to determine and quantify the mechanical forces within the mitral and tricuspid annulus in animal models (Hasenkam et al., 1994; Jensen et al., 2014, 2008a; Kragsnaes et al., 2013; Siefert et al., 2012b; Skov et al., 2015). All studies indicate that the forces measured throughout the heart cycle are not negligible, and that the forces vary with different left ventricular pressure and presence of ischemic heart disease (Siefert et al., 2013a, 2012a). A recent study from our group (Skov et al., 2015) addresses the issues in a full ring configuration with distinction of forces in different planes and parts of the mitral annulus. However, the issue of crosstalk between transducer segments inducing ambiguity and increasing the risk of misinterpretation of results remains in certain transducer designs.

The aim of this study was to describe the development and in-vivo implantation of a new mitral annular force transducer. The new transducer is able to distinguish out-of-plane forces

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in the different mitral annular segments and eliminate in-plane crosstalk with a novel algorithm. This will minimize the ambiguity of measured forces in the mitral annular segments and in the MV plane.

2. Methods

2.1. Mitral annular force transducer

The design of the transducer in the present study was based on a previously described concept (Siefert et al., 2013a, 2012a, 2013b). The new transducer was optimized for simultaneous in- and out-of-plane force measurements. The dimensions of the transducer were adjusted to fit the normal mitral annulus size of an 80 kg porcine model as outlined in Fig. 1. The orientation of suture holes was changed to the basal-apical direction to facilitate the calibration fixation with dedicated mounting screws (Fig. 2). The material thickness of the inner arms was increased by 1 mm to increase durability of the device. Finite element analysis (SolidWorks 2013, Dassault Systèmes, Waltham, USA) was used to optimize strain gauge positioning and to optimize transducer material selection. The position of strain gauges is outlined in Fig. 1 with four strain gauges mounted on each of the circumferential arms dedicated to measure out-of-plane forces (perpendicular to the valve annular plane), and two strain gauges mounted on the central parts of the arms to measure in-plane forces (Siefert et al., 2012b). To increase the strain signals from the commissural arms measuring out-of-plane forces, the location of the suture hole positions was optimized by computer simulation (SolidWorks, 2013) to be placed 11 mm apart resulting in a 50% increase of the strain signal.

A number of rapid prototyping technologies were tested, including stereolithography (SLA) and selective laser sintering (SLS), to find the best compromise between durability, flexibility and strain gauge mounting properties. The glass transition temperature may be as low 39 °C for some epoxy materials, but since the animal body temperature easily can reach this level it is required that the transducer material is thermally stable up to at least 10 °C above the normal animal body temperature. The material chosen was a nylon material (DuraForm PA, 3D Systems, Rock Hill, USA) printed with SLS technology (DAVINCI Development, Billund, Denmark). The transducer was mounted in a three-lead-wire 350 Ω quarter-bridge strain gauge setup (Model EA-06-031DE-350, Vishay Measurement Group UK Ltd., Basingstoke, UK) using a cyanoacrylate (superglue) covered with a thin epoxy layer to protect the gauges and wires (Fig. 3). Signals from the annular force transducer were connected to a Wheatstone Bridge completion circuit and measurements were acquired with data acquisition hardware (cDAQ model 9172 and NI-9237, National Instruments).

2.2. Calibration and crosstalk elimination

Calibration of the transducer was performed in a dedicated setup illustrated in Fig. 2. The transducer was mounted on a dedicated flat solid Plexiglas plate with 1 mm screws in the suture holes. For in-plane calibration the opposite arm from the applied calibration force was fastened with screws, and the positive force direction was defined as acting towards the center of the ring (Fig. 2, left). The transducer orientation did not influence the in-plane calibration: The applied force experienced by the strain gauge is the same, independent of which end of the transducer the force is applied to and which end the transducer is fixed due to Newton's third law of action-reaction. For out-of-plane calibration all arms were fixated except the one being calibrated, and positive force direction was defined as going downwards (apical direction, Fig. 2, right). Due to the divided circumference of the transducer (compared with a full ring shaped transducer (Jensen et al., 2008a)), strain accumulation is more isolated to each arm such that an out-of-plane force in each of the segments does not influence the strain measurements in the other arms. Similarly there is no ambiguity between the in-plane arms of the transducer due to the inherent transducer geometry. The out-of-plane strain gauges were tested with in-plane forces, but the strain accumulation was less than 10% compared to an equivalent out-of-plane force.

Simultaneous values of loading forces applied with an electronic force measuring device (Model ZP-5N, Imada, Northbrook, USA) correlated with the corresponding strain gauge voltage output was recorded with dedicated virtual instrumentation software (LabVIEW 11.0, National Instruments, Austin, TX, USA). Each strain gauge was calibrated in three independent sessions with 0.5 N steps from 0 to 5 N in both tension and compression to ensure full linearity of the transducer (Fig. 4). Intracardiac measurements usually require a flat frequency response curve up to 30 Hz (Nichols et al., 2011). A previously published frequency response curve from a similar strain gauge transducer with similar geometry and same material reported a flat curve within ± 3 dB up to 150 Hz (Jensen et al., 2008a, 2008b). We therefore assumed that this recommendation is well established with this transducer.

Finite element simulations of the calibration method revealed a significant strain accumulation for the in-plane strain gauge positions when virtually applying out-of-plane forces. This was verified during calibrations, and is illustrated for the posterior strain gauge in Fig. 5, and physically illustrated in the calibration curves in Fig. 4. This means that the in-plane strain gauges will measure significant strain originating from an out-of-plane force. If the calibrated out-of-plane force is 1 N and positive as in Fig. 5 (directed against apex) then there will be a bending of the corresponding in-plane strain gauge, which leads to a 125 times increase in strain development (red area) compared to the baseline level (blue area). Due to the geometry of the transducer, a positive in-plane force (towards the center) also creates higher strain. This means that a positive out-of-plane force would cause significant overestimation of the actual in-plane force. In the opposite case a negative out-of-plane force would decrease the in-plane strain value causing that the in-plane force would be significantly underestimated. To avoid ambiguous results for the in-plane strain gauges it is necessary to calibrate for the impact of this crosstalk between strain gauges and hence force measurements in the in- and out-of-plane transducer direction. During the calibration of each out-of-plane strain gauge the strain signal was also recorded from the nearest corresponding in-plane strain gauge (e.g. septal-lateral strain gauge when calibrating the anterior and posterior strain gauge). Fortunately this was also a linear relation as illustrated in Fig. 4C and D. From this relationship we have developed an force uncoupling method based on previous experience (Jensen et al., 2001). The principle is to eliminate the crosstalk by calculating the exact strain contribution to the in-plane strain gauges originating from an out-of-plane force, and then offset this to the measured in-plane strain gauge signal. The justification for this is that we assume a linear superposition of the strain contribution arising from both the in-plane and out-of-plane forces, which is validated in Fig. 4C and D. Before adding or subtracting the calculated crosstalk, all calibrated forces are zero adjusted to mid diastole defined as the center time point between left ventricular dp/dt max and min, equivalent to the cyclic time point with minimum myocardial activity. To increase the reliability of the method we use the mean contribution of both transducer segments affecting the in-plane strain gauge (anterior and posterior segments for the septal-lateral direction and the commissural segments for the intercommissural force direction). The anterior and posterior segments are typically considered as the fibrous and muscular segments of the annulus respectively. This asymmetric difference has been reported in terms of a significantly higher mechanical modulus in the anterior region (Gunning and Murphy, 2014). The fixation strength of the posterior part is therefore expected to be lower than the anterior part. Despite this fact we assume that the posterior contribution to the

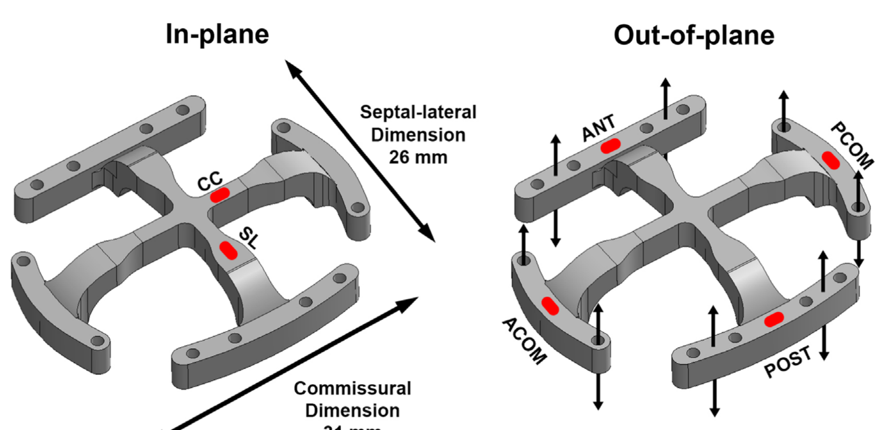

Fig. 1. Illustrations of the optimized mitral annular force transducer marked with outer dimensions and strain gauge positions for in-plane and out-of-plane measurements (Red markings). SL, Septal-lateral; CC, Commissure to commissure; ANT, Anterior; POST, Posterior; ACOM, Anterior commissure; PCOM, Posterior commissure.