Cardiolock: An Active Cardiac Stabilizer

First in Vivo Experiments Using a New Robotized Device

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Abstract. Off-pump Coronary Artery Bypass Grafting (CABG) is still today a technically difficult procedure. In fact, the mechanical stabilizers used to locally suppress the heart excursion have been demonstrated to exhibit significant residual motion. We therefore propose a novel active stabilizer which is able to compensate for this residual motion. The interaction between the heart and a mechanical stabilizer is first assessed in vivo on an animal model. Then, the principle of active stabilization, based on the high speed vision-based control of a compliant mechanism, is presented. In vivo experimental results are given using a prototype which structure is compatible with a minimally invasive approach.

1 Introduction

The complex motion of the heart makes an off-pump CABG technically challenging. For example, the left anterior descending coronary artery may exhibit an excursion of 12.5 mm whereas its diameter is in the order of 1 mm [1] and the accuracy needed for suturing is in the range of 0.1 mm. Several passive mechanical stabilizers have been proposed to overcome this difficulty by reducing the anastomosis site excursion. They have been evaluated through different experiments. In [2], the residual motion of the coronary artery stabilized with a passive Medtronic Octopus device is assessed on 3 pigs using a camera coupled with a laser sensor. The residual excursion in the direction perpendicular to the cardiac tissue ranged between 0.5 mm and 2.6 mm. In [1], a 3D heart wall motion analysis during stabilization has been carried out through experiments on ten pigs. The reported systolic to diastolic heart motion is larger than 1.5 mm using three different commercial passive devices. To our knowledge, only a very few articles deal with the use of a mechanical stabilizer compatible with the even more challenging minimally invasive off-pump CABG. In [3], the authors communicate the results of robot-assisted totally endoscopic CABG experiments on human beings. One of the reported difficulties encountered by the surgeons is the significant residual motion of the passive Medtronic EndoOctopus stabilizer used during the tests.

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All these authors point out the insufficient performances of commercially available stabilizers. Experimental results are then expressed in terms of residual motion, which is the end user point of view. Nevertheless, very few information is available about the forces encountered by the stabilizer due to the heart. In [4], in vivo assessment of the cardiac forces has been carried out to design a mechanical stabilizer. However, the relationship between the forces and the physiological motions, i.e. respiratory and cardiac motions, as well as the dynamics of the interaction between the stabilizer and the heart surface, are not studied in details.

In [5,6,7,8] robotic systems are considered to compensate for the heart motion during off-pump CABG. The principle is to synchronize a robotized tool holder with the anastomosis site movement. From a safety point of view, using one robot to simultaneously perform the surgeon gesture and the stabilization task may not be satisfying. The robot has to undergo high accelerations to track the heart motion. The kinetic energy of the robot is a danger for the patient, especially when the tool is in contact with the heart surface. Moreover, the extension of this approach to minimally invasive surgery (MIS) is not obvious. One solution consists in shrinking the size of the parts moving at high speed, e.g by using a miniature robot with endocavity mobilities. This is still a technical challenge.

In this paper a novel approach is proposed, which allows the separation of the stabilization and the surgical tasks. We introduce the principle of an active cardiac stabilizer that allows to actively suppress the residual motion. The fundamental principle of our approach is similar to some extent to vibration cancellation techniques. The architecture of this new active stabilizer, called Cardiolock, is furthermore compatible with MIS.

In section 2 an experimental analysis of the interaction between the cardiac muscle and a rigid non-actuated stabilizer is presented. High-speed vision, force measurements and biological signals have been synchronously recorded during in vivo experiments on a pig. These data are of great interest for understanding the stabilizer behavior and to improve the design of the active device. In section 3, the design and principle of the active stabilizer are presented. In vivo experiments with the developed prototype are then presented, showing its efficiency, before concluding on further developments of the stabilizer.

2 Experimental Evaluation of the Heart Contact Forces

In order to complete several publications focused on the heart motion analysis [9,10], we present here an experimental evaluation of the forces applied by a passively stabilized heart. This allows a better understanding of the interaction between the cardiac muscle and a mechanical stabilizer, and provides useful information for the design of a stabilizer.

2.1 The Experimental Setup

The experiment has been carried out on a 40 kg pig which underwent full sternotomy after receiving a general anesthesia. The ventilation tidal volume was set to 600 ml with a frequency of 16 breaths/min. The recorded fundamental heart frequency was 1.81 beats/sec. A custom rigid stabilizer held by a medical robot was positioned on the myocardium (Fig.1). This stabilizer is composed of a 10 mm diameter stainless steel beam and a distal device to access the thoracic cavity. This distal device hosts a 6 degrees-of-freedom (DOF) ATI Nano-17 force sensor, that has a resolution of 0.0125 N for the force and 0.0625 Nmm for the torque. The stabilizer tip has been designed with a suction capability, and its residual displacement is measured using the position of a visual marker in the image of a 333 Hz high speed camera (DALSA CAD6) with a 256×256 CCD grayscale sensor. A Navitar Precise Eye Zoom lens was used to get a resolution of 128 pixels per mm in the experimental configuration. The ventilation was acquired through two unidirectional Honeywell Awm700 airflow sensors. The ECG signal was acquired using a 3 leads ECG cable and an electrocardiograph Schiller Cardiovit AT-6 (Fig.1). All the data acquisitions are synchronized on the camera frame rate with a sofware running under Xenomai real time operating system.

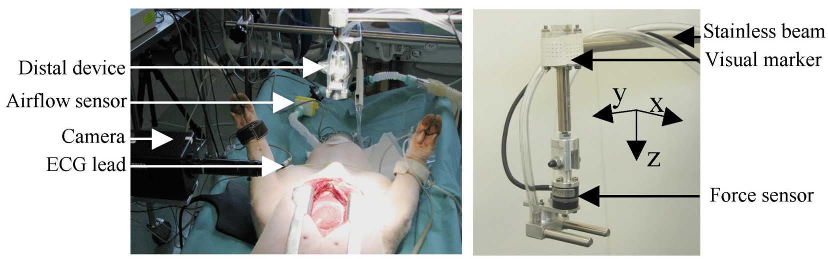

Fig. 1. The experimental setup and a close-up on the distal device

2.2 The Experimental Results

The figure 2 shows the obtained force and torque measured during one respiratory cycle for the biological parameters given above. The corresponding peak to peak values are reported in Table 1. The most significant force component is along the z axis, namely the anterior-posterior direction. The other force components are however not negligible with a ratio around 3 between the force components along x and z . Torque is of small amplitude, in the range of 15 Nmm.

It is interesting to note (Fig.3) that the peaks of the 3 force components do not occur simultaneously. Furthermore, even if the amplitude of the force components in the x and y directions is lower than in the z direction, their

Table 1. The peak to peak force and torque values

	F_x (N)	F_y (N)	F_z (N)	T_x (Nmm)	T_y (Nmm)	T_z (Nmm)
with ventilation	1.2	1	3.8	13	20	13
without ventilation	0.8	1	2	12	12	10

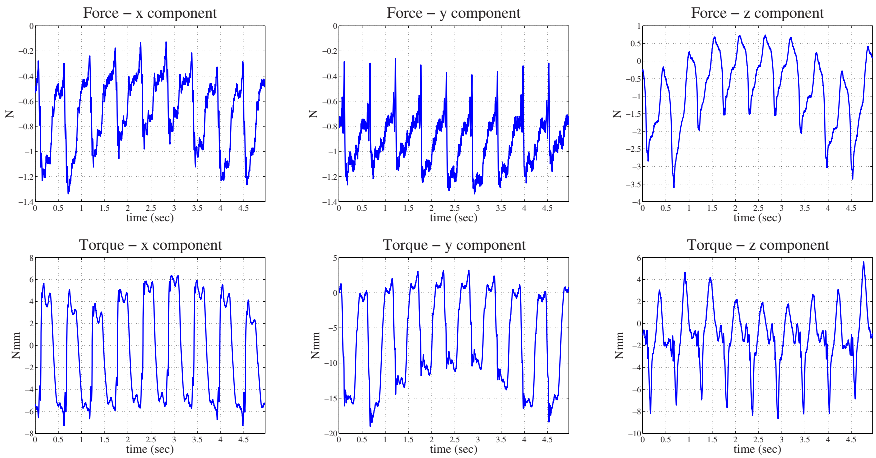

Fig. 2. Measurement of the force and torque components during one respiratory cycle

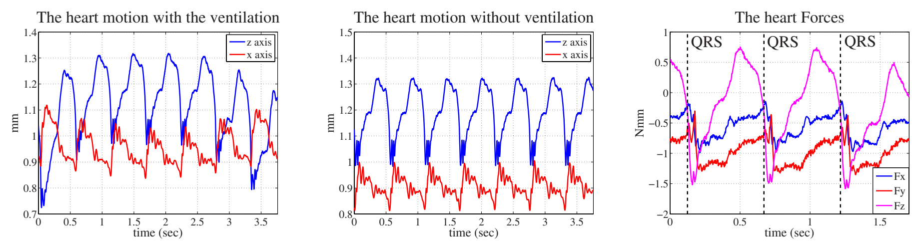

Fig. 3. From left to right: the heart motion with and without ventilation, and the heart contact force during 3 cardiac phases

transients are sharper. Figure 3 shows also that the force peaks are correlated with the physiological signals. Indeed, the peaks occur a short time (about 10 ms) after the QRS complex detection, i.e. during the systolic phase.

An acquisition without ventilation shows (Table 1) that the cardiac movement is responsible for half of the total force along the z axis, for the whole force along y and for almost the whole x component. While the remaining excursion of the stabilizer tip (Fig.3) in presence of ventilation is about 0.61 mm along the z axis and 0.3 mm along the x axis, it is reduced respectively to 0.3 mm and 0.19 mm when setting the ventilation off. The y direction corresponds to the beam axis and the displacement due to traction is therefore negligible.

One may notice that the force along z contains small positive values, indicating that the heart tries to pull the stabilizer. This is due to the stabilizer initial positioning. This positioning is therefore important since high positive force values could yield injuries to the the myocardium.

3 The Active Heart Stabilizer

3.1 The Active Compensation Principle

The necessary stabilization accuracy can be estimated to 0.1 mm with respect to the $1 - 2$ mm diameter of the coronary arteries and the 0.1 mm diameter of the stitching thread. In a MIS context, the shape of a stabilizer should be a cylinder, of maximum external diameter between 10 and 12 mm, with a length approximately equal to 300 mm, so that any heart surface can be reached by insertion through a trocar. According to the elasticity theory, the distal stabilizer deflection due to the measured cardiac force exceeds the required precision. The experiments carried out in Section 2 with a passive stabilizer confirm this analysis, showing clearly the limits of passive stabilization. In fact the displacement could then reach 0.6 mm which is far beyond the necessary accuracy.

Therefore, we introduce the principle of an active stabilization. Indeed we propose an active system composed of an actuated cardiac stabilizer and an exteroceptive measurement. Using this feedback, the actuated stabilizer can be controlled in order to cancel the residual cardiac motion. Herein we use high speed visual feedback but any kind of exteroceptive measurement could be used.

3.2 The Current Design

At the current stage of development, the aim of the proposed prototype (Fig.4) is to compensate for the anastomosis site displacement in the anterior-posterior direction, since the maximum force and residual motion are encountered in that direction. The proposed device globally consists in two parts. A first active part is composed of a one DOF closed-loop mechanism remaining outside the patient body in a MIS context. The other part is a beam of 10 mm diameter and 300 mm length. This part, which dimensions are compatible with MIS, can be simply locked on the first part. Figure 4 shows that the closed-loop mechanism is composed of a piezo actuator (Cedrat Technologies) and three revolute compliant joints. Piezo actuation is adopted to obtain high dynamics and compliant joints are used to avoid backlash. The closed-loop mechanism is designed to transform the piezo actuator translation into a rotation of the beam, as described in Figure 5. For description purpose only, the compensation is then decomposed in two sequential steps: on the left side, one can see a magnified deflection due to an external load, and on the right side the cancellation of the tip displacement by modifying the geometry of the closed-loop mechanism. Further details on the methodology to select the mechanism architecture and dimensions are given in [11].

In a MIS context, asepsy can be obtained in two steps: the first external subsystem can be wrapped in a sterile bag and the other part can be sterilized using an autoclave. To be fully compatible with MIS, a distal end will need to be designed to provide more degrees of freedom for the the placement on the myocardium. Finally, the Cardiolock will probably be held by a surgical robot to handle the trocar constraint (e.g via a Remote Center of Motion mechanism).

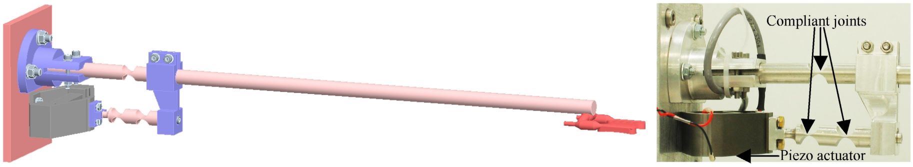

Fig. 4. The current prototype of the active stabilizer. On the left, a CAD global view and on the right the detail of the closed-loop mechanism on the current prototype.

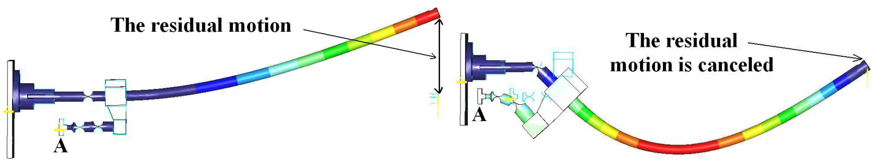

Fig. 5. A finite element analysis of the compensation. The actuator controls the horizontal position of the point A. Displacements are magnified for the sake of clarity.

3.3 High Speed Visual Servoing

The displacement of the stabilizer tip is caused by the piezo actuator action and by the external cardiac force. The measurement of this displacement is provided at 333 Hz by the high speed camera. Assuming small displacements, a linear model can be derived: $Y(z) = \mathbf{G}(z)U(z) - \mathbf{F}(z)D(z)$ where Y, U, D represent the z-transform of respectively the measured visual information, the actuator displacement, the cardiac force and $\mathbf{G}(z)$, $\mathbf{F}(z)$ are two transfer functions. The stabilization task consists in designing an appropriate feedback control law to cancel the displacement caused by the cardiac force, i.e reject the effects of $D(z)$ by controling $U(z)$. To do so, $\mathbf{G}$ has been first identified and $\mathbf{F}$ is constructed by approximation from the poles of $\mathbf{G}$ and an experimentally estimated static gain [11]. Since the previous model does not take into account the cardiac tissue mechanical properties, the control law must be robust with respect to modeling uncertainties. A H_∞ methodology is hence used to design the feedback controller, tuned to reject with high performances the cardiac force perturbation.

3.4 First in Vivo Results

The previous experimental setup was used to carry out some in vivo active stabilization experiments (Fig.6). The beam of the passive stabilizer was simply replaced by the novel actuated mechanism. The same distal device is used to provide an easy access to the thoracic cavity. Figure 7 reports the result of two stabilization tests. In both cases, the controller was switched on 6 seconds after the beginning of the experiment. The peak to peak heart excursion was then divided by 4. The RMS of the residual motion is 0.37 mm before activation of the active stabilization, which corresponds to the deflection measured in section 2,

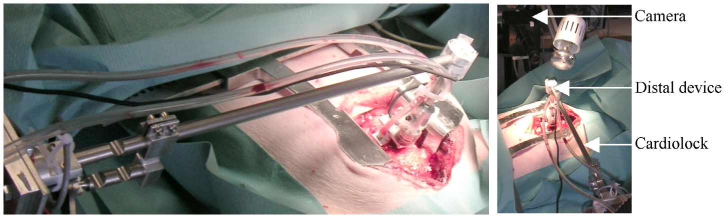

Fig. 6. The Cardiolock device during an experimental validation

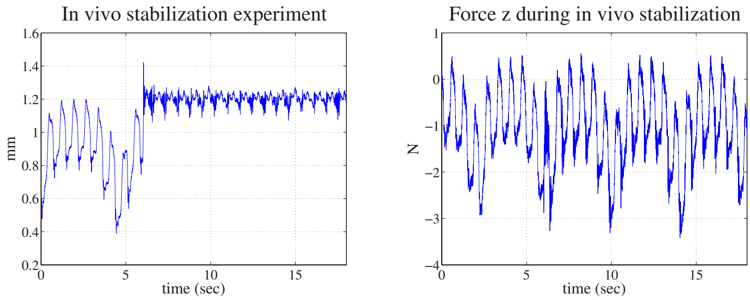

Fig. 7. In vivo stabilization results. On the left the measured motion, on the right the recorded contact force. The active stabilization starts after 6 seconds.

and 0.03 mm after activation. Since the frequency of the respiratory motion is low, it is completely suppressed, whereas the cardiac component is partially filtered. In the second experiment, the force along z was recorded (Fig.7). Only a slight variation of the force is observed. This may be explained by the little displacement, about 0.3 mm, imposed to the local area of interest in order to achieve the stabilization.

4 Conclusion

In this paper, a new robotized stabilizer, the Cardiolock device, has been proposed. After a detailed experimental assessment of the heart contact forces, stabilization experiments have been carried out showing promising performances. Future work will include a comparison of the proposed stabilizer with a commercial endoscopic stabilizer. A development of a multi DOF mechanism with the appropriate vision measurement will also be investigated in order to compensate for all possible residual motions.

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