Working heart off-pump cardiac repair (OPCARE) – the next step in robotic surgery?

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Abstract

The objective of the present study was to assess the feasibility of working heart off-pump cardiac repair (OPCARE), for example, for simple congenital defects or valves, with the help of a commercially available surgical robot in order to identify problem areas and to explore potential solutions. OPCARE was studied in four bovine experiments using the Zeus (Computermotion, Santa Barbara, CA, USA) surgical robot providing 3D viewing of the extra cardiac instruments in combination with two intra-cardiac ultrasound visualisation systems (Clearview Ultra, Boston Scientific, La Garenne, France) and Accunav (Accuson, Mountain View, CA, USA) allowing for two different viewing planes of the heart and identification of both, intra-cardiac structures and intra-cardiac robotic instruments. For the given experimental set-up, introduction of robotic instruments into the right atrium (typical for instrumentation during OPCARE), grabbing of the second instrument (typical for removal of intra-cardiac foreign bodies), and grabbing of relatively still atrial structures, which can be visualised by intra-cardiac ultrasound (typical for resection of specific cardiac tissue, clipping of a specific cardiac structure, steered access to other cardiac cavities) have been realised with relative ease. In contrast, grabbing of moving cardiac structures like a–v valve leaflets (typical for valve testing and absolutely necessary for valve repair) required, in general, numerous attempts, but was finally successful in the majority of test animals. Finally, introduction of self-attaching suture material (U-clips, Coalescent Surgical, Sunnyvale, CA, USA) typical for edge-to-edge valve repair could not be performed in reproducible fashion with the equipment used. We conclude that OPCARE is feasible for simple intra-cardiac lesions using current robotic instrumentation and state of the art intra-cardiac ultrasound. However, more complex procedures require further development of both robotic instrumentation and intra-cardiac visualisation.

Keywords: Beating heart surgery; Working heart surgery; Off-Pump surgery; Robotics; Telemanipulation; Intravascular ultrasound; Intra-cardiac ultrasound; Valve repair

1. Introduction

Major efforts have been made, in recent years, to develop telemanipulators for so-called robotic cardiac surgery [1]. Totally endoscopic coronary artery bypass surgery (TECAB) can now be realised with robotic help in quite reliable fashion [2], and other procedures like robot assisted mitral valve repair [3], and robot assisted pericardiectiony [4] have also been realised. For the time being, most papers dealing with robots for cardiac surgery focus on small access procedures, which can also be performed with slightly bigger incisions in very similar fashion without such heavy equipment. Pericardiectiony has been performed endoscopically, and beating heart coronary artery bypass can also be realised through quite small incisions, especially if distal mechanical connectors [5] become more widely available. Successful endoscopic mitral valve repair has also been reported [6]. However, endoscopic and/or robot assisted intra-cardiac repairs, both still require cardiopulmonary bypass, aortic cross-clamping, cardiac arrest, myocardial protection and so forth. The objective of the present study was to assess the feasibility of working heart off-pump cardiac repair (OPCARE), for example, for simple congenital defects or valves, with the help of a commercially available robot in order to identify problem areas and to explore potential solutions.
2. Material and methods

2.1. Animal experiments

Potential and limitations of working heart OPCARE was evaluated in four acute bovine experiments (60 ± 5 kg weight). After the usual pre-medication, and standard endotracheal intubation, general anaesthesia was maintained with volatile anaesthetics in accordance with the protocol, which was approved by the Lausanne Veterinary Office of the State of Vaud. Standard instrumentation included electrocardiogram (EKG), as well as venous and arterial lines for blood gas assessment as well as basic haematology and blood chemistry. After a right thoracotomy, the pericardium was opened and the usual stay sutures were placed to expose the beating heart. Systemic heparinisation was started with 100 IU of heparin per kilogram bodyweight (Liquemin, Roche, Basel, Switzerland) and the activated coagulation time (ACT, Hemochron, International Technidyne, Edison NJ, USA) was maintained above a target level of 180 s.

2.2. Visualisation

Visualisation of intra-cardiac structures through the flowing blood is a key issue during beating heart OPCARE. For the present evaluation, we opted for two intra-cardiac ultrasound systems (Fig. 1) providing two different views of the working heart (Fig. 2). As previously reported [7], Clearview Ultra system (Boston Scientific, La Garenne, France) was used in combination with a 10 F, 9 MHz intra-cardiac echo probe (Sonicath ICE catheter, Meditech, Watertown, MA, USA). The latter was introduced through the left femoral vein, which was accessed through a cut down in the groin and the probe was advanced through the inferior vena cava towards the right atrium. Fig. 2 (Clearview) shows an intra-cardiac view at the level of the vena cava entering the right atrium. The sections with this probe are in the same plane as those realised with a standard CT-scan or magnetic resonance imaging (MRI). However, image acquisition and display is in real-time.

The second intra-cardiac ultrasound system Accunav (Accuson, Mountain View, CA, USA) provides a section of the heart similar to a transosophageal echocardiographic system and allows also for colour Doppler analyses. For this purpose, the right jugular vein is accessed and the 10 F flexible, and in two planes direcetable, intra-cardiac probe (Accunav 10 F, multiHertz 5–10 MHz) is advanced through the superior vena cava into the right atrium. Although the two ultrasound probes can function at different frequencies,
there are some interferences appearing on the screens if the two probes are too close to each other. Finally, the 3D video visualisation of the robotic system described below is used to follow the movements of the extra cardiac part of the instruments (Fig. 3), and also to track the responses of the heart to the movements performed.

2.3. Telemanipulation

The Zeus (Computermotion, Santa Barbara, USA) surgical robot was used for intra-cardiac telemanipulations during OPCARE (Figs. 1 and 3). For this purpose, a thoracotomy was performed and the heart was exposed in the usual fashion. Purse string sutures were placed on the right atrial wall, opposite to the target within the heart (e.g. fossa ovalis, tricuspid valve) and so-called ‘virtual ports’ were placed as close as possible to them (Fig. 4). The virtual ports have the function of the true ports usually placed at the level of the thoracic wall, which cannot be used here in order to minimise the instrument excursions at the heart entry sites. The robotic instruments were introduced into the right atrium through a small sharp incision and the purse string sutures were gently tightened.

As mentioned above, the 3D visualisation system of the robot was used to supervise the extra cardiac part of the robotic instruments (translational and rotational movements), the response of the heart to the activation of the instruments, which are in part inside of the heart, the spontaneous activity of the heart as well as the amount of bleeding.

2.4. Procedures

Bench training for robot assisted intra-cardiac surgery like edge-to-edge repair of the mitral and the tricuspid valve using self-attaching U-clips (Coalescenct Surgical, Sunnyvale, CA, USA) and other techniques was performed prior to in vivo assessment of intra-cardiac target and instrument visualisation, grabbing of intra-cardiac foreign bodies (probes and instruments) versus relatively still cardiac structures (inter-atrial septum) and moving parts (a–v valve leaflets). Finally, introduction of suture material (U-clips) into the atria was tried and valve OPCARE was evaluated.

3. Results

Two different per-procedural views with intra-cardiac ultrasound during working heart OPCARE are shown in Fig. 2. On the upper right view, the two a–v valve leaflets can be recognised and an open robotic needle holder (*) can be seen just above the coaptation zone (the atrium being on the left, the ventricle on the right side of the insert). The movements of the intra-cardiac robotic instruments, which are activated from the remote console, can be seen in Video 1 (http://www.icvts.org/elan/59/Video1.avi). Successful grabbing of an a–v valve leaflet by the means of intra-cardiac robotic instruments achieved under guidance with intra-cardiac ultrasound is shown in Video 2 (http://www.icvts.org/elan/59/Video2.avi).

The results of our attempts to act within the working heart for OPCARE by the means of robotic instruments are

<table>
<thead>
<tr>
<th>Procedure (typical for)</th>
<th>Animals</th>
<th>Attempts</th>
<th>Success</th>
<th>Success (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial introduction of robotic instruments (instrumentation)</td>
<td>4</td>
<td>8</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>Grabbing of intra-cardiac instruments (foreign body)</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>Grabbing of fixed intra-cardiac structure (border of fossa ovalis)</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>Grabbing of a–v valve leaflet (valve testing)</td>
<td>4</td>
<td>20</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Introduction of suture material (valve repair)</td>
<td>3</td>
<td>6</td>
<td>1</td>
<td>17</td>
</tr>
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</table>
summarised in Table 1. For this experimental set-up, introduction of robotic instruments into the right atrium of the working heart (typical for instrumentation during OPCARE), grabbing of the second instrument (typical for removal of intra-cardiac foreign bodies) and grabbing of relatively still atrial structures, which can be visualised by intra-cardiac ultrasound (typical for resection of specific cardiac tissue, clipping of specific cardiac structure, steered access to other cardiac cavities) have been realised with relative ease. In contrast, grabbing of moving cardiac structures like a–v valve leaflets (typical for valve testing and absolutely necessary for valve repair) required, in general, numerous attempts, but was finally successful in the majority of test animals. Finally, introduction of self-attaching suture material (U-clips: typical for edge-to-edge valve repair) could not be performed in reproducible fashion with the equipment available, the main problem being major blood loss during insertion of the loaded needle holder through the purse string suture at the level of the right atrium.

4. Discussion

Working heart OPCARE can be realised in the experimental set-up for relatively simple procedures. Provided that adequate visualisation of target lesions can be achieved in real-time (e.g. with intra-cardiac ultrasound) and access is possible with robotic instruments which move around a virtual port positioned close to the cardiac surface, grabbing and potential retrieval of foreign bodies like tips of pacemaker leads or other lost medical devices or bullets in fixed position may be realised without stopping the heart. Likewise, intra-cardiac manipulations of relatively still structures including grabbing and potential ablation of small tumours, resection of intra-cardiac obstructive material (resection of inflow or outflow stenoses, correction of restrictive atrial septal defect (ASD) in complex congenital heart disease, etc) may be within the reach of the currently available medical technology. Interestingly, we found that the right atrial wall of the beating heart could adapt quite well to two so-called ‘virtual ports’ allowing for access to the right atrium with robotic instruments without stopping the heart. This comes, in fact, less as a surprise as we initially thought. As a matter of fact, there have always been relatively rigid instruments inserted into the atria like cannulas, vents etc. For comparison, we show in Video 3 (http://www.icvts.org/elan/59/Video3.avi), a flexible right atrial cannula [8] during beating heart right ventricular outflow repair after implantation of a pulmonary autograft in aortic position (Ross procedure): major multidirectional movements are transmitted from the beating heart to the cannula and are in general quite well tolerated, even if the cannula is stabilised and made from more rigid materials like stainless steel. If, based on this evaluation, working heart OPCARE seems to be feasible for correction of relatively static intra-cardiac structures, there are, however, a number of recommendations that can be made for further development of OPCARE addressing the moving parts of the heart like valve leaflets, chordi, papillary muscles etc.

4.1. Telemanipulation

Although relatively static and moving structures within the heart can be reached with robotic instruments with the heart working, there can be no doubt that for true valve OPCARE, it is mandatory to improve the instrumentation for this purpose. An interesting approach for beating heart mitral valve surgery has been reported by Downing and colleagues using a commercially available endoscopic suturing device [9]. This group used a sealed port for accessing the mitral valve without stopping the heart and a combination with the robotic approach might be a significant step forward. For example, telemanipulated instruments allow for evaluation of various repairs of a–v valve leaflets held at the free edges in frozen position. Hence, an edge-to-edge repair can be simulated (see positioning of one leaflet in Video 2) and assessed with intra-cardiac colour Doppler measurements prior to the final consolidation.

Likewise, development of a suitable, valved port system in combination with robotic ‘biopsy’ graspers that cannot lose their content once they are closed could allow for tumour resections in patients with papillary fibroelastoma [10] and other small excess intra-cardiac structures without stopping the heart. Robotic biopsy tools, clippers, self-tying suture material based on temperature sensitive suture material [11], etc can provide additional comfort. At this time, remote telemanipulation from a distant location seems not a viable option although there is increasing interest in telemedicine for discussion of indications [12] and external advice.

4.2. Bleeding/blood salvage

Bleeding, blood salvage and introduction of air into the cardiac cavities are a major concern during working heart OPCARE. As mentioned above, introduction of cannulas into the cardiac cavities is standard practice during on-pump procedures and it is very interesting to note that the cardiac wall is moving in quite impressive fashion (Video 3) and, in general, without significant drawback. Sealed ports for access to the working cardiac cavities are certainly of major interest, especially if they can be combined with the so-called ‘virtual ports’ which are at this time necessary to reduce the excursions of the robotic instruments at the site where the heart is entered.

In order to reduce the risk of air embolism, it might be possible to realise working heart OPCARE under water. Limited quantities of blood, over spilling from the ports and/or entry sites, can be re-transfused automatically. Such an intelligent suction system with opto-electronic trigger and individually adjustable blood level (Smart Suction...
System, Cardiosmart, Fribourg, Switzerland) has already been evaluated [13].

4.3. Visualisation

Optimal visualisation of the extra and intra-cardiac structures is a key requirement for successful working heart OPCARE. For the time being, 2D and 3D viewing of the extra cardiac structures, the extra cardiac part of surgical instruments, the response of the latter to the remote commands, their effect on the beating heart as well as the consecutive blood loss can be quite well assessed with the equipment, which is now-a-days commercially available and used here (see also Figs. 3 and 4). More difficult is, at this time, the assessment of the relevant intra-cardiac structures of the working heart as well as the relative position and status of the intra-cardiac part of the robotic instruments, which should also allow to avoid collisions. Downing and colleagues [9] have suggested transoesophageal echocardiography for beating heart mitral valve surgery. Although transoesophageal echocardiography is now-a-days the standard for pre- and postoperative assessment in clinical valve surgery, we feel that intra-cardiac ultrasound that can be used here (see also Figs. 3 and 4). More difficult is, at this time, the assessment of the relevant intra-cardiac structures of the working heart as well as the relative position and status of the intra-cardiac part of the robotic instruments, which should also allow to avoid collisions. Downing and colleagues [9] have suggested transoesophageal echocardiography for beating heart mitral valve surgery. Although transoesophageal echocardiography is now-a-days the standard for pre- and postoperative assessment in clinical valve surgery, we feel that intra-cardiac ultrasound that can be manipulated by the surgeon within the operative field has significant advantages especially if two different planes can be studied simultaneously as presented here. As a matter of fact, the two movable planes can carry all the information for 3D reconstruction of a specific intra-cardiac point of interest. Of course, real-time 3D echocardiography [14] taking in to account a multitude of serial slices is a further step, which will provide an even better overall view of the relevant cardiac structures during OPCARE.

Visualisation of the surgical instruments within the working heart, i.e. immersed in flowing blood, is an additional challenge. The currently available instruments designed for robotic surgery can usually be detected with ultrasonic imaging systems as demonstrated in Fig. 1, and Videos 1 and 2 (http://www.icvts.org/elan/59/Video1.avi, http://www.icvts.org/elan/59/Video2.avi). However, the image is burdened by a shadow originating at the instrument, which may cover other structures of interest. In the future, real-time shadow subtraction taking advantage of the images without the instruments may help to overcome such limitations.

We conclude that working heart OPCARE is feasible for simple intra-cardiac procedures like removal of foreign bodies or small tumours using current robotic instrumentation and state of the art intra-cardiac ultrasound. However, more complex procedures require further development of both robotic instrumentation and intra-cardiac visualisation.

References


Appendix A. Disclaimer

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