The Universal Cardiac Introducer® for Off-pump, Closed, Beating, Intracardiac Surgery: Proof of Concept

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RESUME

Introduction: La modernization de la chirurgie intracardiaque à coeur battant fermé demande une révision de l'accès et la visualization de la cible thérapeutique. Nous rapportons notre expérience avec le Universal Cardiac Introducer® (UCI) pour un accès versatile et sans danger des cibles intracardiaques.

Méthodes: Le UCI est composé d’une collerette qui s’attache sur le coeur et une chambre d’introduction qui prévient les embolies gazeuses et le saignement et contient les instruments. Le UCI a été évaluer sur le cochon, utilisant le Flex10® micro-onde avec 13 animaux pour reproduire l’exclusion des veines pulmonaires. Le SurgiFrost® a été utiliser avec 8 animaux pour la même intervention, et 12 animaux avait l’implantation d’une prothèses mitrale.


Conclusion: L’usage d’un UCI n’a qu’une risque très faible et ne limite pas l’accès. D’autres expériences ont montré qu’ils sont utilisables pour toutes les cavités cardiaques. Cet accès n’est possible qu’avec la guidance par l’image en temps réel qui a été développé simultanément.

Mots clés: ?????.

ABSTRACT

Background: The revival of the off-pump, closed, beating, intracardiac approach requires revisitation of access to, and visualization of the target. We report our experience with the Universal Cardiac Introducer® (UCI) for safe, versatile, intracardiac access.

Method: The UCI is comprised of an attachment-cuff and an airlock-introductory chamber to prevent bleeding and air embolism. The utility of the UCI was tested in 13 acute porcine experiments by inserting a Flex 10® microwave probe into the left atrium. Exclusion of the pulmonary vein region was performed using a modified Surgifrost® probe in 7 acute pigs. In 12 acute pigs, an unmodified mitral valve prosthesis was introduced and positioned into the native mitral valve orifice.

Results: There were no complications associated with cardiac access. The pilot study, using the Flex 10® microwave probe, established the safety of UCI. Unrestricted manipulation of the Surgifrost® resulted in complete exclusion in 6 of 7 animals. The last group showed that a mitral valve prosthesis could be positioned into the mitral valve orifice.

Conclusion: We conclude that our device can safely and reliably be used to introduce various tools and devices. The feasibility of this approach requires parallel development of image-guidance and virtual reality to substitute for direct vision.

Key words: (1) Off-pump beating intracardiac surgery (2) Mini-invasive cardiac surgery. (3) Cardiac Devices. (4) Image-guidance. (5) Endocardial approach

1. Introduction

Off-pump, closed, beating intracardiac surgery, developed in the fifties [1] was abandoned after the advent of the heart-lung machine that provided intra-cardiac access and direct vision of intracardiac targets. The heart-lung machine permitted cardiac surgery to grow until it became clear that there were severe sides effects that denied the higher risk group from benefiting from surgery [2;3]. The objective of our pilot project was to modernize off-pump, closed, beating, intracardiac surgery as an alternative to the open heart approach, with the goal of duplicating the open heart intervention with fewer side effects. The
two major problems were access to and visualization of the target organ, i.e.: off-pump, intracardiac access and the substitution for direct vision. This paper focuses on access; image guidance, virtual and augmented reality are reported separately \[4-10\]. To achieve this goal, an access-device, adaptable for all heart chambers was designed with the following characteristics: safety, reliability, and versatility allowing introduction of tools and devices to duplicate the effectiveness of the open heart approach.

2. The introducer

*The Universal Cardiac Introducer*® (UCI) [5;11] was conceived as a non permanent implant, to meet the following requirements: 1) to secure an intracardiac port access that prevents bleeding without being thrombogenic; 2) to provide an effective airlock system to prevent air embolism; 3) to provide the possibility of introducing bulky tools or devices; 4) to provide easy manipulation of instruments without damaging heart port access; 5) to provide versatility and easy changing of tools and instruments to enable more than one intervention using the same port access; 6) the device should be made of non magnetic material to avoid interference with magnetic tracking systems; 7) the heart port access can be constructed either before UCI attachment or after attachment and made under UCI safe control, and 8) to make the introducer collapsible and flexible so that it occupies as little volume as possible - collapsibility should reduce mechanical stress on heart port-access and facilitate manipulation of tools.

**Impact of requirements on design:** The final design had two parts: an attachment-cuff and an airlock-introductory chamber with sleeves for tools and device holders (Fig. 1). This design addressed: 1) the need for a secure attachment of the UCI over the selected cardiac chamber, without the impediment of the presence of the heavy and obstructive UCI with the tools; 2) the necessity of easily controlling the heart port access, and 3) the need for a versatile UCI, allowing multiple interventions, because of the presence of a detachable, multi-use and versatile introductory chamber.

A preliminary concern was with the attachment of the UCI to the targeted cardiac chamber. If the heart port access could be easily controlled and constructed before inserting the attachment cuff, such as for the right or left atrium via the appendages, the attachment-cuff could be directly attached onto the controlled heart port access. If not, such as for the left ventricle, the construction of a left ventricular port required the protection of the UCI. The attachment-cuff was inserted securely over the left ventricular wall, encircling the planned opening (apex) and then the left ventricular opening was performed under the protection of the UCI using a specially designed punch-tool inserted via the UCI. This method was tested for inserting the left ventricular infl ow cannula for off-pump insertion of left ventricular assist devices (G.M.Guiraudon personal communication, 2001).

The size of the heart port is determined by the
chamber anatomy, planned intervention and degree of sophistication of the tools and devices, but designed to be as small as possible, while allowing easy access and manipulation of tools without collision.

The Attachment-Cuff for controlling port access must: (a) have a secure attachment to the targeted heart chamber; (b) be made of soft, collapsible material that is easily and quickly occluded by a conventional vascular clamp; (c) have a secure connection with the main chamber of the UCI. The Introductory airlock chamber should be a tightly closed chamber to prevent air embolism. It can be exposed to a wide range of pressures, high pressure with the left ventricle, low pressure with the atria, the later with the risk of aspirating air. The sleeves that accommodate the tool holders must fit snugly to avoid blood leak or air suction. The airlock-introductory chamber also acts as a bubble trap, with its roof above the heart port allowing effective venting of air before opening the UCI into the heart. The chamber must be large to accommodate the bulky tools and devices stored before introduction. This two-part design allows the introduction of the tools or devices in a retrograde fashion, accommodating larger tools or devices, but keeping holder diameters as small as possible. The connecting system between attachment-cuff and airlock-introductory chamber must be tight, resilient, but easily disconnected.

Before manufacturing of a single use medical grade UCI, the UCI was custom made from Dacron® vascular graft material. The cuff was a cylindrical conduit - 2.0 cm long. Its diameter was determined by the planned target and necessary tools. It had the same diameter as the airlock chamber. The proximal end of the airlock introductory chamber connects with the cuff and the distal end connects with the sleeves. Up to 4 sleeves can be attached. Before use, the UCI was preclotted in usual fashion.

3. Methods:

The research protocol was approved by the Animal Care Committee of the University of Western Ontario in accordance to the Guidelines of the Canadian Council on Animal Care.

Duplication of surgery for atrial fibrillation using microwave energy via the Flex 10®. Experiments on isolated hearts obtained from the abattoir helped to conceptualize the cardiac introducer. Then, the UCI was evaluated on a series of 13 acute porcine experiments. The study addressed the feasibility of exclusion of the pulmonary vein region, via the UCI, using a Flex10® microwave probe (Afx-Inc. Fremont California). Although the Flex 10 was not designed for endocardial use, it was adequate to test the introduction and positioning of a bulky device (Fig. 2). The UCI chamber accommodated the loop and its holder, and three sleeves: the loop holder and the two ends of the loop. In two cases, a manipulator
was added via a fourth sleeve, but did not prove to be of much use. Surgery was carried out via a small left thoracotomy. The left atrial appendage was excluded using a vascular Satinski clamp, and opened. Then the UCI cuff was attached using 4-0 Prolene running suture. The airlock chamber of the UCI containing the Flex10 was attached to the cuff. Under full heparinization, the loop was introduced into the left atrium (Fig. 3), deployed and positioned under ultrasound guidance. When the loop was deemed to be well deployed and positioned, microwave energy (50 Watts-90 seconds) was delivered when possible. The animal was then terminated. Image guidance used 2D ultrasound (US) imaging; transesophageal echocardiography (TEE), an epicardial laparoscopic probe and intracardiac echocardiography (ICE). The final evaluation was based on en bloc excision of the heart with the entire device system still in place. When microwave could be delivered, lesions were identified and samples were taken for histological examination.

4. Results
There were no surgical complications associated with the introducer. Introduction and manipulation of the Flex10® provided valid information in designing the UCI. During those experiments, the two part design was definitively selected, making the attachment of the cuff easier without the impediment of the bulky chamber. The UCI allowed introduction, manipulation, positioning and deployment of the device without limitations. The loop was deemed well deployed in 7 experiments. Microwave energy could be used in only 4 animals. Image-guidance, during the first 8 animals, focused on learning the specifics of the porcine cardiac anatomy. Image guidance was more effective at the end of the series. However, the fine positioning of the loop in relation to the pulmonary vein ostium, Bachmann bundle and the coronary sinus was not possible. Macroscopic examination documented proper deployment and positioning of the loop in 5 of the 7 cases, in which the loop was deemed properly deployed: in one animal the loop was twisted, and in the other its deployment was incomplete. Microwave lesions were circumferential in 1 case and partial in 3. Histology documented transmural lesions, but with endocardial thrombus in 2 cases suggesting poor contact of the loop.

Cryo-Isolation of the pulmonary vein region using the Surgifrost®. This experience has been reported elsewhere [5]. Cryo-ablation was selected because it could be used safely and effectively endocardially on the closed, beating heart with a modified SurgiFrost® probe (CryoCath Inc, Kirkland, Quebec). The surgery was performed via the same access. The UCI was modified to accommodate the cryoprobe. Image-guidance: an X4 3D epicardial echocardiography was added to 2D TEE. Electrophysiological testing used two epicardial quadripolar electrode plaques attached to the right atrial appendage and the posterior wall of the left atrium (at the center of the excluded area) to test and monitor the electrical exclusion of the pulmonary vein region. The cryoprobe was positioned to circumscribe the pulmonary vein region, using a series of overlapping applications commencing at the upper left quadrant and moving counterclockwise to the left lower quadrant. Recordings from electrode plaques were used to monitor exclusion. When the probe was adequately positioned, cryoaflutteration was delivered (-110 °C for 3 min). The pig was terminated 30 to 45 minutes after completion of the study and the heart was excised for examination [5]. There were no surgical complications. Complete
electrical exclusion of the pulmonary region was obtained in 6 animals but was incomplete in one. Pathological examination showed circumferential transmural lesions with better US guidance that could detect inadvertent migration of probe into the pulmonary veins or mitral valve. However, its limited 2D field of view made the orientation of the cryoprobe difficult to evaluate. A 3D epicardial probe facilitated catheter positioning within its limited field of view, although epicardial positioning of the large transducer limits its application. All US modalities still left a large portion of the left atrium inaccessible to visualization. Access on other targets: Via the same left atrial approach, a mitral valve bio-prosthesis was positioned into the mitral valve orifice in 12 pigs (12). This mitral valve access is being developed in parallel with navigation and positioning using a 3D tracking system. It is augmented with virtual reality using a multiple image modality, registered on a tracked real-time US image, displayed on a single platform (Atamai viewer - http://www.atamai.com). The UCI was used to access the right atrium to produce an atrial septal defect (ASD) using a custom-made hole-punch device, followed by attaching a patch for the simulation of ASD closure. The UCI was used over the left ventricle apex to insert an outflow cannula of a left ventricular assist device, but can be used the same way to access the Mitral valve or the Aortic valve.

**Image Guidance: Real time visualization: navigation and positioning.**

In these pilot studies, US imaging was used because it was the sole real-time image modality readily available in the operating room. The use of 2D TEE guidance had significant limitations. Estimation of the orientation of tools and intuitive manipulation towards the target was impossible since the 2D image does not provide the global 3D context of cardiac anatomy and its limited field of view precludes seeing the same 2D cross sectional view of the target and the tool. The epicardial 3D US probe proved more effective in positioning when the tools were within its very limited field of view. However Doppler imaging
is ideal to assess positioning of a mitral valve prosthesis or a patch on an ASD. Residual flow around the valve seat, inappropriate flow through the valve, or around the ASD, is easily be identified by flow patterns.

5. Discussion
This pilot study has shown the validity of the concept. The Universal Cardiac Introducer® should make off-pump, closed, beating intracardiac surgery effective and safe.

The Universal Cardiac Introducer® is ready to be designed and produced as a medical grade device and submitted to clinical trials for safety and effectiveness. The UCI prevents blood loss and air embolism, as documented in 17 long-term animals. The UCI also allows changing tools without difficulty.

US Image guidance was indispensable as a substitute for direct vision, but has significant limitations. However, US imaging has the critical advantage of being readily available in the operating room. In addition, it provides real-time imaging for accurate registration of other image modalities for intuitive and accurate guidance for navigation and positioning. Navigation of tools requires the 3D global anatomical context, and display of the tool-device and the target on a single image. Concurrent to the UCI development, a sophisticated image-guidance system is being developed. It integrates multi-modality imaging registered on a tracked US image, using either optical or magnetic tracking system. Tracked instruments can have their virtual image integrated into the multi-modality image displayed on a single screen: the ‘AtamaiViewer’ [13;14].

New tools and devices: When access and visualization are well developed, and new operative concepts are well defined, new tools and devices can be designed for optimal results. At our University, we have strong support for tools design, haptics and robotics [15].

Conclusions:
This approach may replace open-heart surgery as the primary choice in most cases. In addition, it may offer a surgical option, when other approaches are too risky (issues of safety) or ineffective. It may be an ideal approach for re-interventions in selected cases. This new approach would also provide, an ideal surgical back-up to failures or limitations of catheter-based interventions, and may assist in catheter-based development. This approach should provide a third less invasive option to conventional open-heart surgery and catheter-based interventions, while developing technologies and experience that will be transferable to both. In other words, our project follows the same philosophy promoted for surgery for cardiac arrhythmia that paved the way for catheter-based interventions [16].

6. Reference List
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