Development of a Minimally Invasive Cardiac Patch Delivery Tool for Infarct Reinforcement

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1 Background

Cardiovascular heart diseases are the leading cause of worldwide mortality, with a 1.5-fold higher incidence of death than all forms of cancer combined [1]. In the U.S., a Myocardial Infarction (MI) occurs every 40 seconds, with 6.2 million adults affected each year [2]. When a patient suffers an MI, the myocardium is weakened, which may lead to irreversible heart failure [3]. In order to mitigate this risk, various types of cardiac patches have been developed to reinforce the heart at the infarct [4]. Studies suggest that these patches are most effective if deployed within a few hours of cardiac arrest [1, 5]. Nonetheless, the delivery of these patches is invasive and currently requires open-heart surgery, increasing the risk of infection and the time of convalescence [6]. This degree of invasiveness leads the patch application procedure to be unsafe, undesirable, and impractical immediately after an MI, preventing clinical use.

Medical devices have been developed which deliver cardiac reinforcements in minimally invasive procedures, but these devices are subject to constraints limiting their applications and widespread adoption. For example, a heart assist device that deploys a collapsible cardiac compression sleeve around both ventricles of the heart was developed by CorInnova [7]. However, the CorInnova device has only been designed to deliver full cardiac sleeves, which are unable to provide the localized reinforcement that cardiac patches can provide. Other delivery mechanisms include injecting or spraying therapeutics directly onto the heart, delivering patches inside the heart to repair septal defects, and delivering biomaterial patches to the epicardium to act as tissue scaffolds [8–10]. Such coatings and patch delivery tools, however, do not provide mechanical support to the epicardium.

To the knowledge of the authors, the current methods of delivering cardiac therapies do not enable epicardial delivery of newly engineered patches with a minimally invasive procedure [11]. Therefore, there is a clinical need for a device that can enable minimally invasive biodegradable patch delivery to allow more patients to benefit from cardiac reinforcement as a therapeutic measure following an MI. In order to be clinically beneficial, this delivery device should also enable interventionalists to control patch location, patch orientation, and the timing of delivery.

Adhesive patches that can be placed on the epicardial surface to provide mechanical support to the heart have been produced at the Zhao Lab and the Therapeutic Technology Design Development Lab at MIT. The size, shape, stiffness, and mechanical anisotropy of these patches can be tailored to provide customized treatments [12], so this study focuses on developing a device to work with these patches.

2 Device Design

Based on the identified clinical need, a device that could enable minimally invasive biodegradable patch delivery was designed. The following functional requirements were identified:

1. Fit a patch that is up to 50 mm in its maximum planar dimension into a 12 mm trocar.
2. Deploy multiple sizes and shapes of patches.
3. Unroll the patch and adhere it to heart tissue without creating large creases in the patch.
4. Prevent self-adhesion of patch.
5. Control timing and orientation of patch release.

Other functions during the procedure, including the creation of the entry incision, visualization, and stabilization of the heart, can be accomplished through the use of additional ports and existing technology, such as Video-Assisted Thoracoscopic Surgery (VATS) instruments or scalpels and graspers used in laparoscopic procedures [13]. Future integration of these functions through a low-profile suction line or fiber optic camera was not precluded by a delivery-only design, but the isolation of delivery enabled a focus on the development and verification of this core functionality.

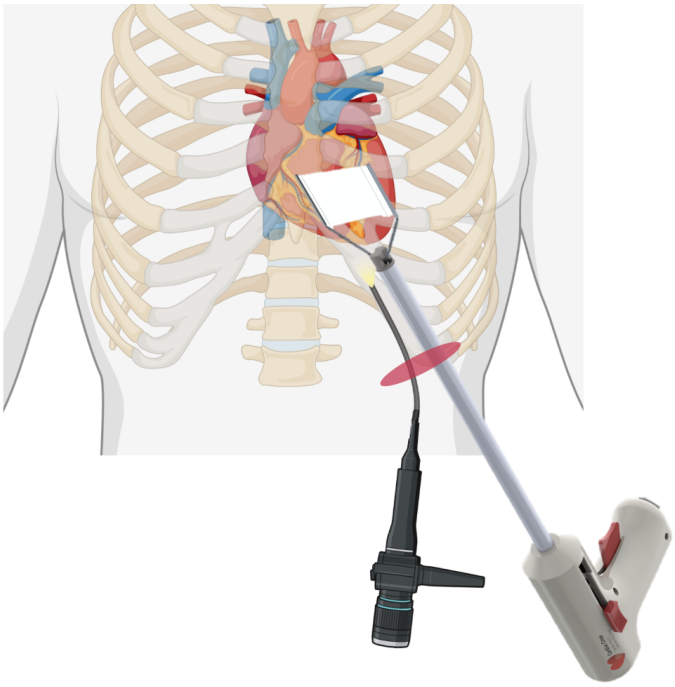

Fig. 1: Device (bottom right) and endoscope (bottom center) shown taking a subxiphoid deployment approach.

As can be seen in Fig. 1, the cardiac patch delivery device uses a subxiphoid approach for surgical access of the epicardium. An endoscope can be inserted through the same port as the delivery tool in order to increase visibility along the axis of deployment or it could enter through a different port based on the surgeon's preference and available space. An incision in the pericardium must be made near the apex of the heart and an apical heart stabilization tool may also be inserted through another port.

The deployment device seen in Fig. 2 contains 0.03in diameter superelastic Nitinol wires, with a transition temperature around (37 C), heat-treated in an aluminum mold at

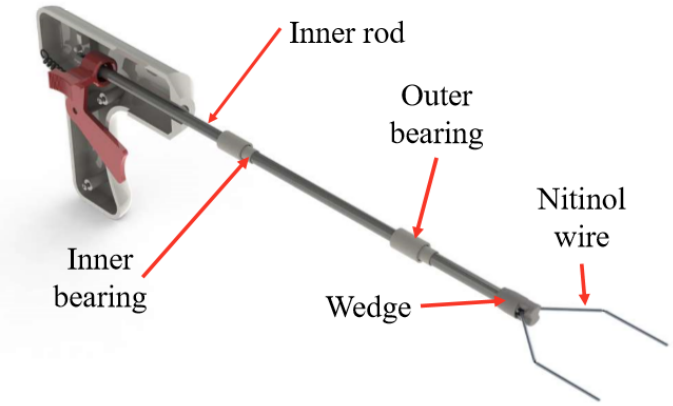

Fig. 2: Device overview in deployed position. The inner outer sheath are not shown.

(500 C) for 30 minutes to produce a final conformation with 50mm of separation between the parallel arms (the maximum target patch diameter). The wire arms were slid into pockets added to opposite edges of the patch for ease of attachment/release and versatility between different sizes and shapes of patches. The adhesive of the patch used becomes activated when it is hydrated so a protective polyvinyl acetate (PVA) backing was applied to prevent the patch from adhering prematurely during storage or deployment. The patch is rolled up around the nitinol wires in a scroll-like manner and is placed into a retractable outer sheath to keep the patch dry during deployment. When the outer sheath is pulled back, the Nitinol wires are permitted to return to their set shape. During initial rounds of testing, the Nitinol wires exerted enough force to unroll the patch when the inner sheath was retracted but did not always exert enough force for the patch to be applied in tension. To solve this, a 3D printed wedge is mechanically actuated to force the wires further apart from each other in order to increase the tensile stress of the patch. This wedge also allows our device to work with other patch materials, sizes, and shapes that could require a different amount of force to unroll. The wedge is attached to the end of the inner sheath, so retracting the inner sheath pushes the Nitinol wires apart until the patch is unrolled and in the planar conformation under the desired amount of tension. The patch can then be pressed against the heart until it is fully adhered. The outer sheath (11 mm diameter) and everything held within it fit inside of a standard surgical trocar 12 mm in diameter. Once the tool is inserted through the trocar, the delivery mechanism is slid into the pericardium and positioned over the infarct. The tool then unrolls the patch and holds it in tension at the proper location so that the patch can adhere to the heart tissue. When the patch is held on the epicardial surface, the PVA backing is hydrated and begins to dissolve, allowing the patch to adhere to the epicardium. Finally, the inner rod can be pulled back to slide the wires out of the patch pockets and retract them back into the sheaths so that the device can be removed from the body. A handheld actuation tool with an intuitive trigger mechanism allows for an easy deployment and retraction procedure. For this tool, an ergonomic study was performed to consider the anatomical measurements of an average human hand [14]. Finally, once the tool is retracted, the incision in the pericardium can be sutured, and the trocars can be removed.

3 Evaluation

3.1 In Silico Validation

ANSYS v19 software was used to simulate the deformation of the Nitinol wires during the retraction and deployment of the tool. A 2D analysis with the wedge, the outer sheath, and a Nitinol wire was performed. An intrinsic analysis with large displacements was performed to compute the force required to retract and deploy the Nitinol wires. A durability analysis was also performed to predict the number of cycles the device can undergo before failure. For the Nitinol wire, a Young's Modulus of 75 GPa and a Poisson's Raio of 0.33 were used [15].

A maximum value of force less than 50N was reported in the retraction of the tool. This value was compared to the force exerted by each human finger: from 30N in the little finger to 37-60 N for the ring, middle and index finger [16]. Therefore, the trigger can easily be actuated with any combination of two fingers.

The number of cycles before failure was also computed based on the stress-strain results obtained from the Finite Element Method (FEM) simulation. The results suggest that the tool is able to perform at least 10^3 cycles.

3.2 Ex-Vivo Validation

The delivery tool's performance was validated through deployment on an ex-vivo porcine heart with an intact pericardium. A test setup was created with an 80/20 aluminum frame to allow a subxiphoid axis approach and to impose a realistic constraint on the trocar, reflecting that of insertion through a fixed surgical port. The complete setup is shown in Fig. 3 and includes a manually actuated saline-filled balloon to simulate the beating of the heart, a suction-based heart stabilization device [17], an endoscope [18], and graspers. An incision was made in the pericardium at the apex of the heart, allowing for an apical insertion approach. While a large incision was used for testing, the incision need not be any larger than the size of the trocar (12 mm diameter).

During testing, the PVA covering was found to dissolve almost immediately after the outer sheath was removed, resulting in some cases in self-adhesion or adhesion to the pericardium prior to reaching the desired location. All other components of the delivery tool were verified successfully. Once inserted into the pericardium, the outer sheath was retracted and the Nitinol wires expanded. The inner sheath was also retracted, which caused the wedge piece to force the wires further apart, unrolling the patch and placing it in tension. The patch was then lowered such that it contacted the heart and adhered to the tissue. Releasing the pericardium allowed it to rest on top of the patch and apply downward pressure to it. Then, the wires were pulled out of the patch pockets and retracted back, allowing for the tool to be safely