

An Access-Closure Device for Percutaneous Beating Heart Surgery¹

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1 Background

Open heart surgical procedures to treat severe cardiac disease are extremely invasive, with a high risk of surgical complications, many of which are directly related to cardiopulmonary bypass [1]. Additionally, invasive surgery is often not a viable option for the elderly or immunocompromised, necessitating minimally invasive procedures. The most common of these procedures is a transcatheter approach, where tools are threaded through the femoral or carotid artery. However, due to the small tool diameters required to fit through the vasculature, the lack of maneuverability, and the

limited force capabilities of the flexible tools, applications are limited [2].

Transapical procedures, which directly access the apex of the heart with rigid tools, are significantly less invasive than traditional open heart surgeries. The potential applications for transapical procedures are vast, but there are still many functional limitations to current devices that have resulted in a lack of widespread adoption. Many still require a minithoracotomy or a transfemoral catheterization in addition to the transapical approach or leave significant rigid hardware behind in the heart. The applications are also often limited due to the need for a specific set of tools to interface with the port and a high degree of overall complexity [3]. A simple percutaneous method of accessing the heart, as presented here, provides an optimal solution that overcomes the limited maneuverability of the transcatheter approach and allows the use of variously sized rigid tools with a minimum of trauma to the heart and surrounding tissue.

2 Device Operation

The access-closure device is composed of six primary modules, as shown in Fig. 1. An outer catheter supports the device and provides a locking mechanism to establish anchoring. A suction line runs through the catheter to a soft silicone suction cup at the distal end to provide active suction to aid in initial anchoring and sealing during insertion and serves as a soft, passive anchor once the device is through and active suction is removed. The inner catheter spans the heart wall, providing a port for tools to enter and exit the heart. A polyurethane-laminated nitinol spring anchor at its distal end provides a complete seal once deployed inside the heart, serving as an atraumatic anchoring mechanism. The spring is manipulated via pull wires accessed surgeon-side. A trileaflet non-return valve inside the catheter prevents blood backflow through the device and serves as a secondary seal in case of deployment failure. A patch system, not discussed in detail in this work, seals the incision postoperatively.

An illustration of the operating procedure is shown in Fig. 2. The outer catheter is inserted through a small incision between the ribs. Suction is applied to anchor the soft cup to the outside of the heart. The dilator and inner catheter are inserted through the outer catheter and flushed with saline solution. Once the inner catheter and dilator are through the heart wall, the nitinol anchor is deployed by releasing the pull wires. The spring is then pulled back against the heart wall by adjusting the position of the inner catheter relative to the outer catheter. The catheters are locked relative to each other to keep the device in place. The softness of the suction cup and inner anchor allows the rigid device to move with a beating heart without losing sealing.

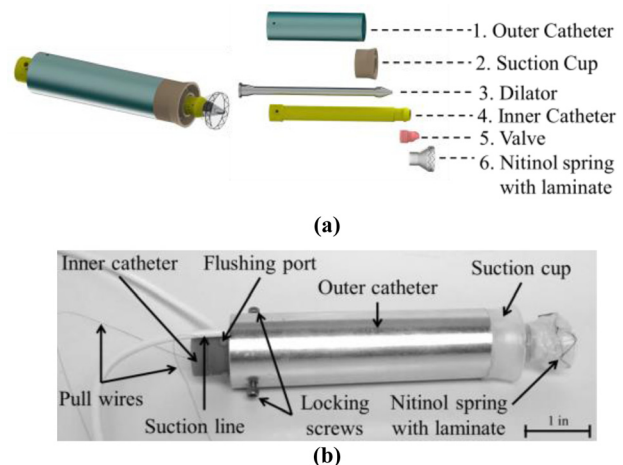


Fig. 1 (a) Computer-aided design generated exploded view of the device modules and (b) prototype used for testing (dilator not shown)

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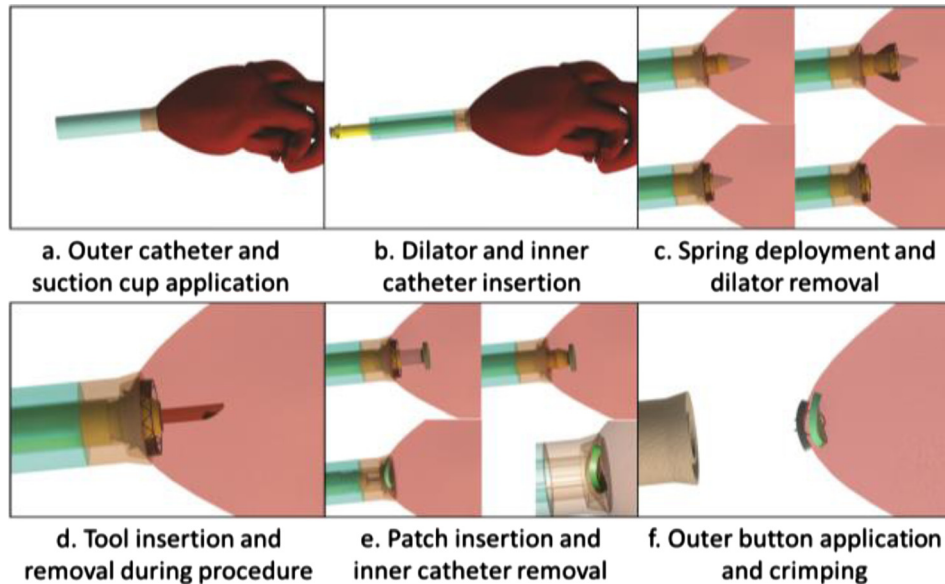


Fig. 2 Computer-aided design animation of device operation during surgical procedure

With the device fully sealed and anchored, the dilator is removed and the procedure is performed. Any tool up to 10 mm in diameter can be inserted and removed through the inner catheter, and the flexibility of the spring and the suction cup allows for a good range of tool motion while still providing secure anchoring and sealing. After the procedure, a flexible patch is inserted into the heart. The nitinol spring is collapsed by pulling on the pull wires. As the inner catheter is removed, the patch is pulled against the heart wall and pressure within the heart helps the patch temporarily seal the incision. An outer “button” is threaded over the sutures from the inner patch and crimped into place on the outside of the heart. The outer catheter is removed and the incision between the ribs is closed.

3 Results

For repeatable and controllable testing of the entire device, a testing platform to serve as a simple heart analog was created by pressurizing an acrylic box with water up to a static average systolic physiological heart pressure of 80 mm Hg, as shown in Fig. 3. A thin silicone membrane simulated the heart wall. This setup was used to test sealing capabilities of the inner catheter alone and the functionality of the fully integrated device. The inner catheter inserted through the silicone membrane showed no leaking through the seal during pressurization.

A full procedure was simulated with the apparatus fully pressurized, as shown in Fig. 4(a). The device inserted easily through the membrane, and deployment of the nitinol spring was smooth, providing complete sealing and sufficient anchoring for completing the procedure. A demonstration of the mechanism behind the spring expansion and collapse is shown in Fig. 4(b). No leaking between the inner catheter and silicon membrane occurred during any stage of the procedure. A good range of motion was demonstrated without disrupting the seal and without requiring additional attention from the operator to maintain anchoring or sealing.

The deployment of the patch and removal of the device was also successful, with the patch sealing the incision as soon as the device was removed. There was negligible leakage during this step, despite the need for coordination between device removal and sealing.

Suction cup function and internal sealing with the nitinol anchor were also tested on ex vivo animal hearts to ensure the test platform results were not biased due to the properties or shape of the silicon membrane. The suction cup was tested with active

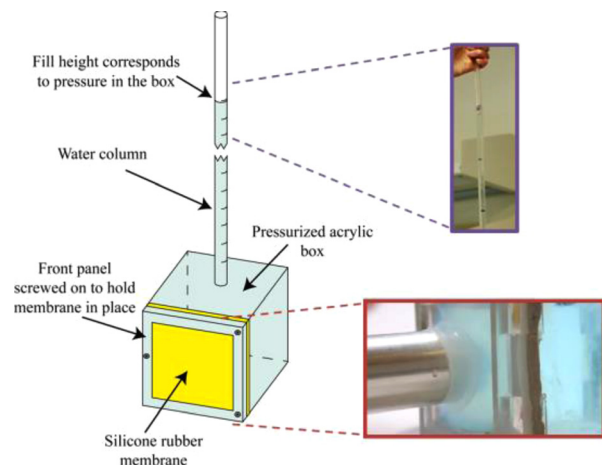


Fig. 3 Seal testing apparatus pressurized to 80 mm Hg

suction on the apex and on the external ventral walls of a pig heart, showing an adequately strong grip when applied to any tissue area. After releasing the vacuum, the suction cup was easy to remove, and signs of permanent damage or trauma to the heart wall were not observed. The expanding nitinol spring showed no leakage when inserted through the apex of a lamb heart pressurized to 80 mm Hg.

4 Interpretation

Further testing will use a more sophisticated test setup to directly cycle and measure the applied pressure at various maximum physiological pressures and the necessary forces for accidental withdrawal of the device. In vivo testing in live anesthetized pigs will also be completed to test the efficacy and ease of use of the device.

This novel percutaneous universal cardiac access-closure device addresses several of the limitations of existing transapical devices by reducing the trauma to the patient, allowing the use of a wider range of tools, and leaving minimal hardware behind. The minimally invasive direct cardiac access with varying diameter and shape tools opens up the possibility for advances in cardiac percutaneous surgical procedures.

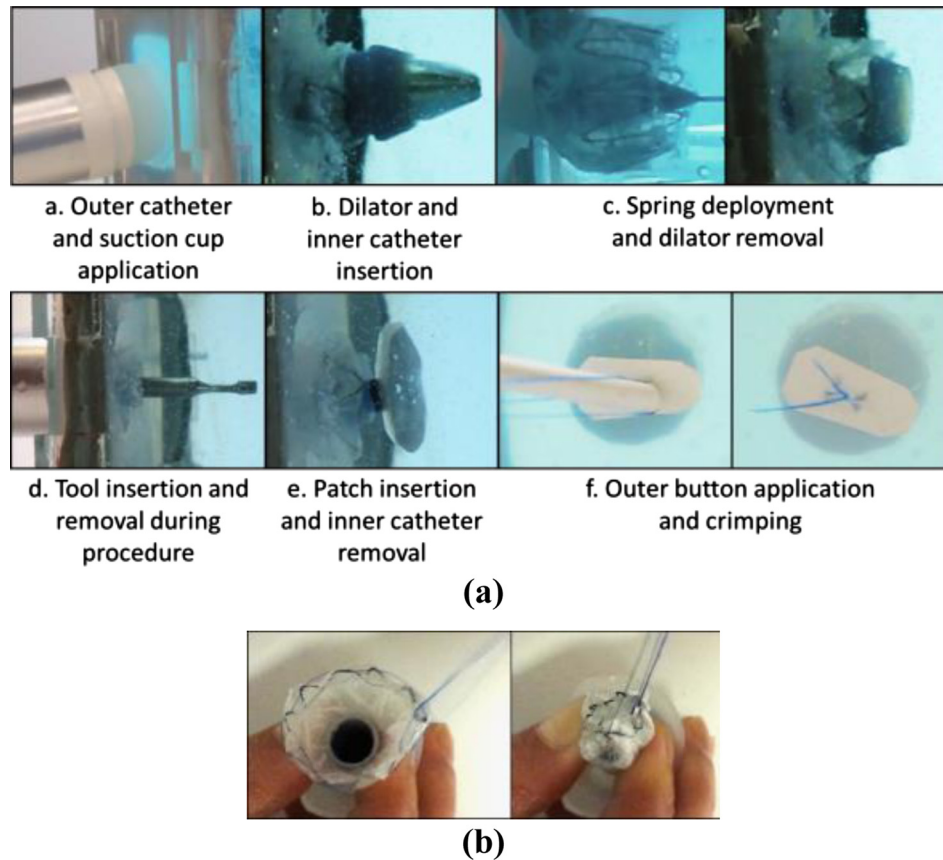


Fig. 4 (a) Screenshots from video of procedure testing on the test apparatus and (b) operation of nitinol anchor

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