Optimization of a Loading Tool for a Novel Cardiac Assist Device (CAD)

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Objective

- Develop a tool or system to optimize the loading of CorInnova's CAD into a tube used for device deployment. The system must decrease loading time, maintain the CAD's outer carbothane layer positioning without damaging it, and allow the CAD to open fully during deployment.

Background

- CorInnova's CAD is a biventricular, non-blood contacting heart assist device intended to increase cardiac output in the acutely failing heart.

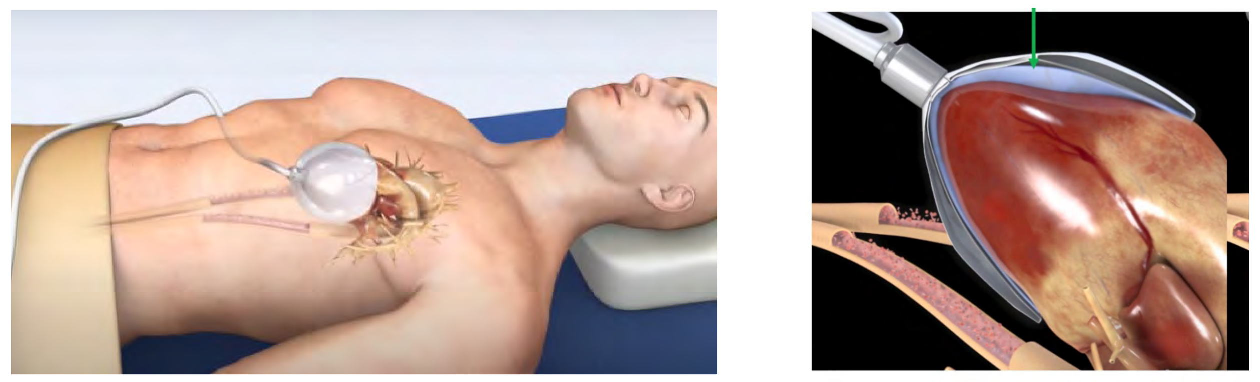

Figure 1: Device deployment

- The device is deployed through a small incision in the apex of the pericardium to self-expand around the ventricles within the pericardial sac.
- The loading method has a high impact on successful deployment. Failed deployment can result in bodily harm or unsuccessful placement.

Figure 2: CAD compressed into deployment tube

- The device is fabricated from delicate thin-film polyurethane and super elastic shape memory Nitinol wire.
- These materials allow it to be compressed into an approximately 1" diameter tube for a minimally invasive deployment and implantation.
- Current loading methods involve manually squeezing the CAD to compress and load into the deployment tube

Methods

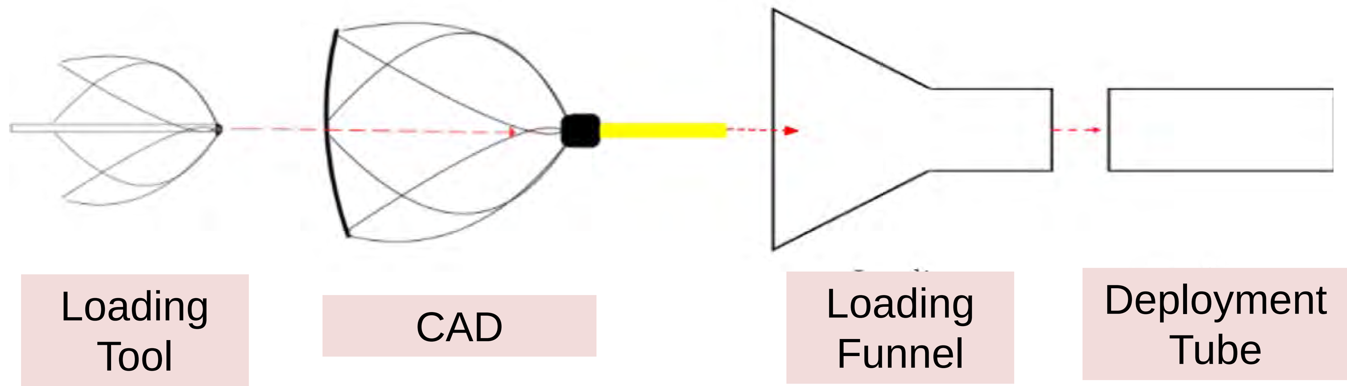

Figure 3: Loading System Components

- The loading system consists of three primary components: the loading tool, loading funnel, and deployment tube.

Loading tool:

- Most significant part of the loading system.
- Used to navigate the CAD through a funnel into the deployment tube.
- Polycarbonate (PC) handle allows insertion into the CAD and force application to guide CAD.
- Nitinol frame mimics CAD shape, holding the carbothane layer in place.
- Frame is covered with a polypropylene (PP) cone to prevent carbothane pinching.

Loading funnel:

- Conical shape supports the outer wall of the CAD slowly compressing and guiding it into the deployment tube.
- Temporarily connected to the deployment tube with a rubber adapter.

Deployment tube:

- Where the device is loaded into and be deployed from.
- Retained CorInnova's 1" PTFE tube design for its low friction properties.

Results

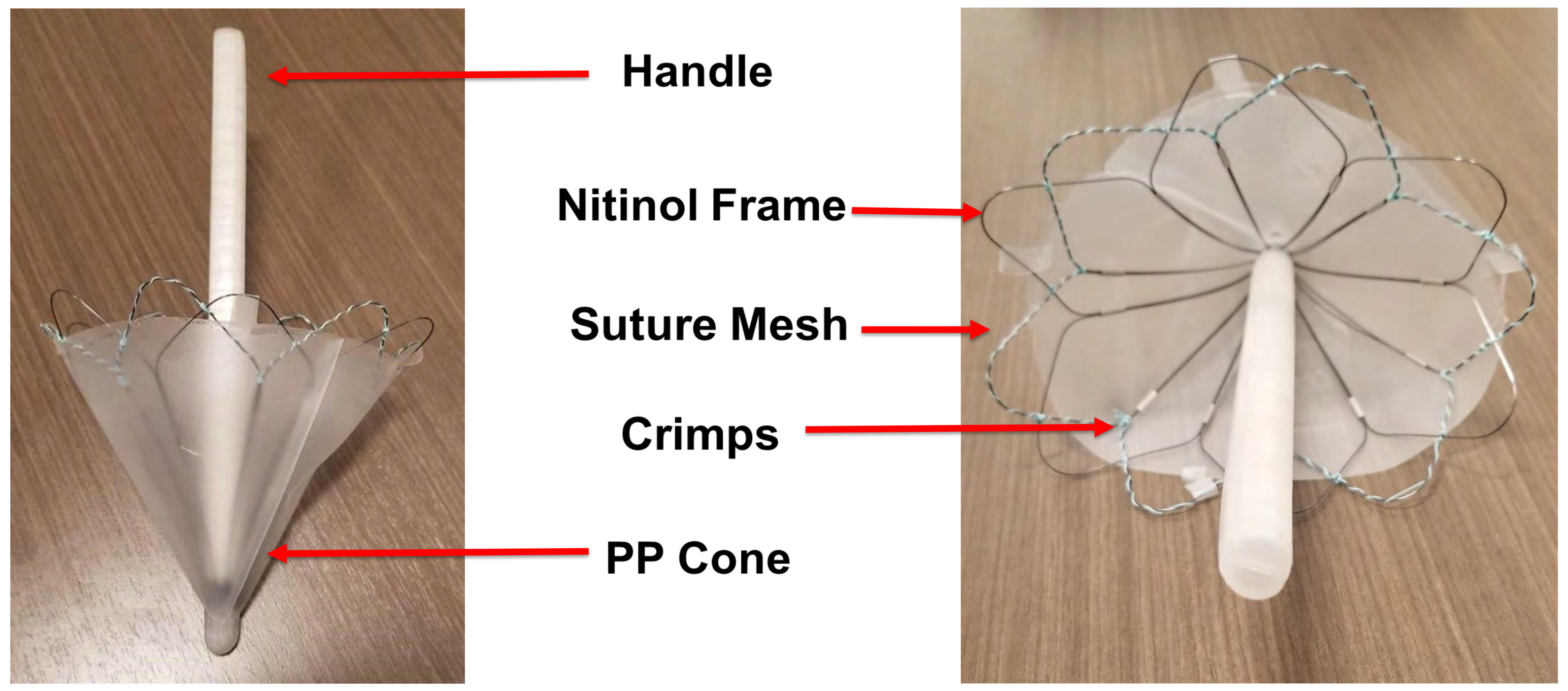

Figure 4: Loading tool

Handle: 3D printed PC rod with rounded end. Twelve holes are placed near the rounded tip for the placement of Nitinol wire ends.
Nitinol wire: Twelve compressible Nitinol wires bent in the shape of the Nitinol frame of the CAD. Free wire ends are placed into the respective holes on the handle.
Suture Mesh: Reinforces links between wires to provide stability.
Crimps: Placed on lower bend of wires to link them together.
PP cone: Surround wires to protect containment layer of CAD from damage.

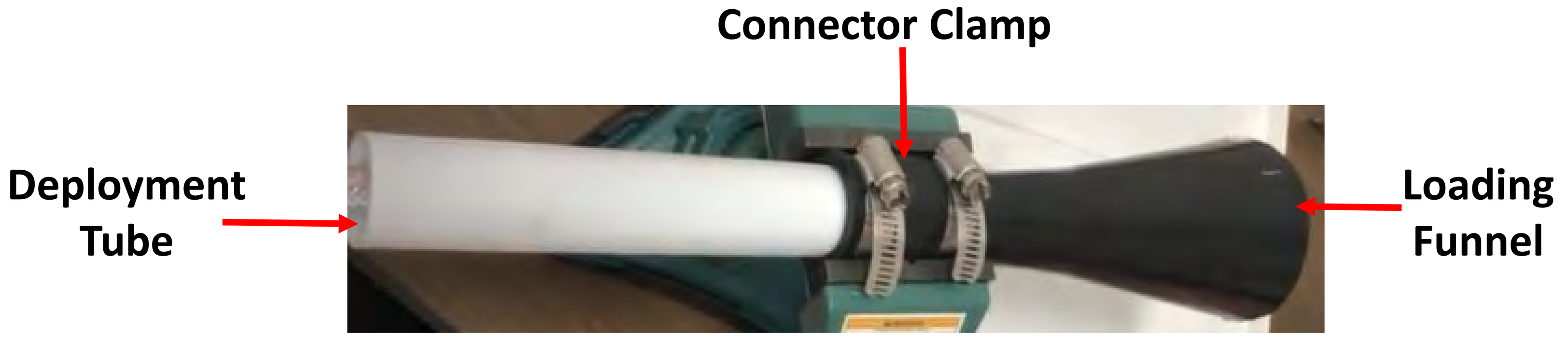

Figure 5: Funnel and deployment tube components

•Clamp connector secures funnel and deployment tube together for device loading.
•Once loading is complete, components are disconnected and the CAD is ready for surgical implantation.

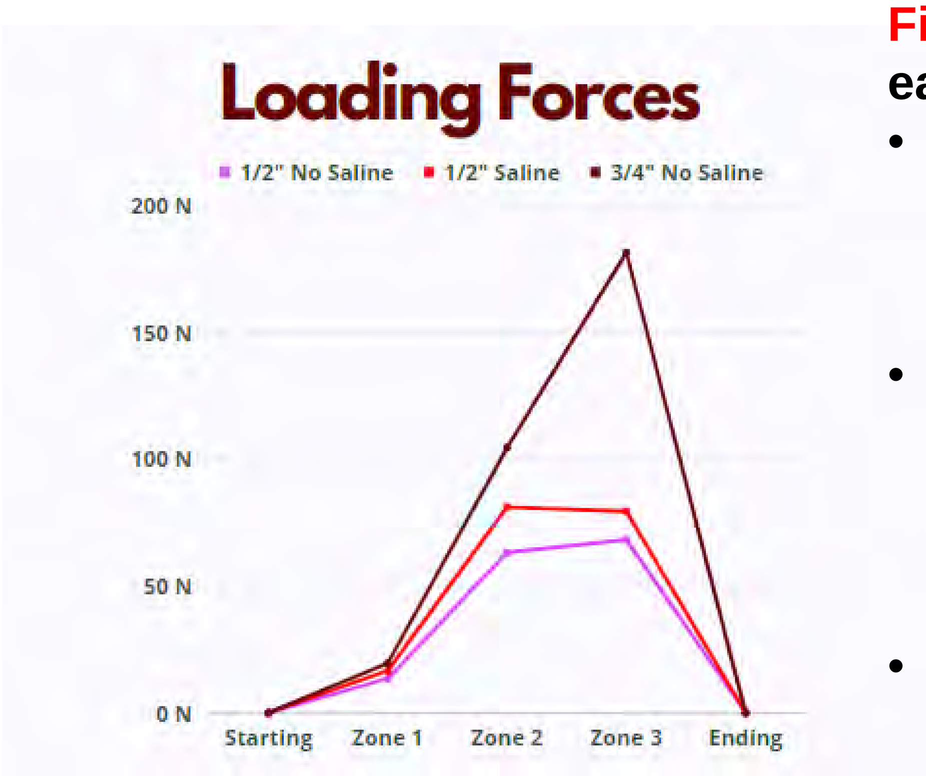

Figure 6: Loading Forces for each prototype

- The loading path was divided into 3 zones and the maximum force measured for each zone.
- Loading forces decreased with decreasing tool handle diameter and were lower without the use of saline.
- The lowest forces, or easiest loading, was with a handle of ½" diameter and no saline.

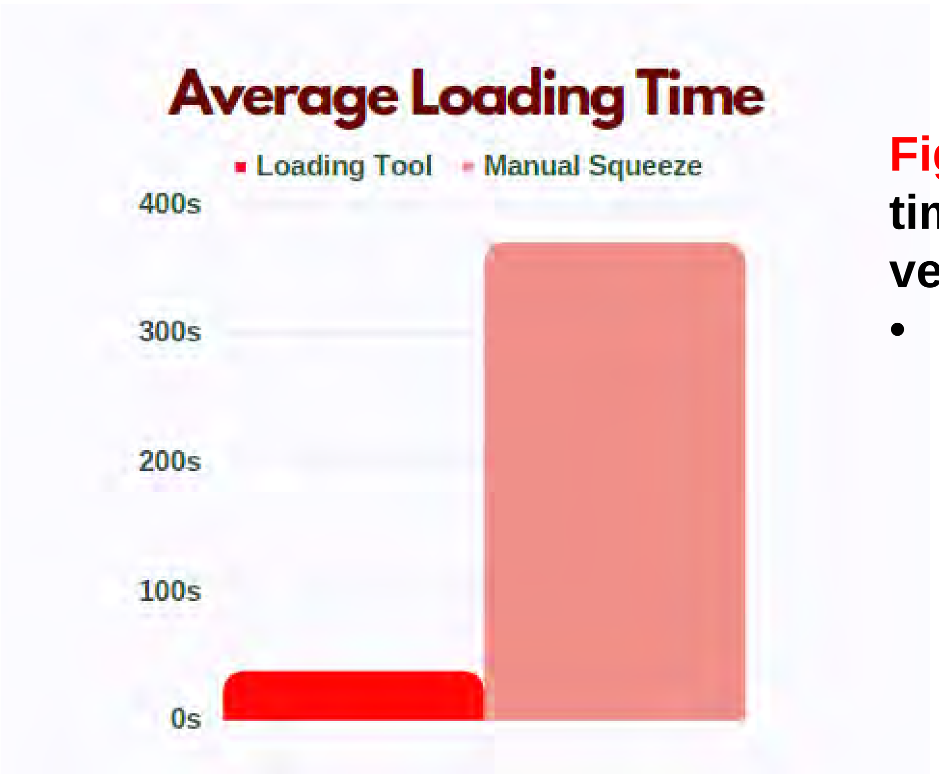

Figure 7: Average loading time for previous methods versus loading tool method

- Average loading time decreased by 85.7% when using the newly developed loading tool method compared to previous manual squeeze methods.

Containment Leak Test	
d = 1/2", Saline	PASS
d = 1/2", No Saline	PASS
d= 3/4" , No Saline	FAIL

Table 1: Carbothane Layer Leak Testing

- Following testing of loading forces for each loading tool prototype, the CAD's outer carbothane layer was checked for leaks.
- The plastic was filled with air, placed in a water bath, and inspected for the formation of bubbles. Observed bubbles indicate leaking and a failed test.
- Only the tool with the ¾" handle failed.

Conclusions

Our loading tool system is able to successfully navigate the CAD into the deployment tube while significantly reducing the loading time. Required loading force is minimized by a reduction in tool handle diameter. As a result, the CAD device is properly packed in the loading tube, allowing it to unfold in the desired orientation. Future works may include reducing the loading handle diameter while maintaining its durability. Furthermore, there is possibility for further improvement with the deployment tube and funnel component geometries.