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PRINCIPAL INVESTIGATOR:
DR. MARK P. ANSTADT, M.D.

CONTRACTING ORGANIZATION:
LIFEBRIDGE TECHNOLOGIES, LLC
DAYTON, OHIO 45409

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1. DR. MARK P. ANSTADT, M.D., PRINCIPAL INVESTIGATOR
2. DR. DAVID B. REYNOLDS, PhD., Co-PRINCIPAL INVESTIGATOR

E-Mail: MPANSTADT@AOL.COM beckydarner@yahoo.com

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
LIFEBRIDGE TECHNOLOGIES, LLC
30 EAST APPLE STREET,
SUITE 6252
DAYTON, OHIO 45409

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14. ABSTRACT
The FINAL annual report summarizes the salient background information and the successful completion of the proposed project with emphasis on accomplishments from 5/20/2012 to 5/19/2013. The purpose of this project was to develop a device for rapid, effective, circulatory support for remote areas. Direct mechanical ventricular actuation (DMVA) is a non-blood contacting method that can re-establish normal hemodynamics in the fibrillating (non-beating) and severely failing heart within minutes. This project's objective was to develop a portable, compact, user-friendly DMVA drive system for simplified operation. Proven, pre-existing DMVA drives were used for verifying the new drive met functional requirements. Project objectives were to develop a manual powered hand pump (HP), define optimal HP operation, design a motorized drive to power the prototype pump, and then use these inputs to construct the automated, prototype drive. In-vivo testing utilized a dedicated data acquisition system integrated with inputs selected to best interrogate the drive system's functionality and related physiologic effects. Thereby, the HP integrated with a prototype linear drive was been evaluated and reduced to a compact, automated drive (AD). The final prototype DMVA drive system was successfully constructed and tested. In-vitro bench testing on a custom mock circulatory loop (MCL) allowed final modifications to be made prior to verifying the system's functionality with in-vivo animal testing. The AD incorporates a removable HP which enables temporary acute support in the event of power failure. Final in-vitro and in-vivo testing verified the new system achieved functionality equivalent to pre-existing drive systems while providing a portable, AD useful for remote areas.

15. SUBJECT TERMS
DIRECT MECHANICAL VENTRICULAR ACTUATION, CIRCULATORY SUPPORT, HEART FAILURE, DRIVE SYSTEM

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1. INTRODUCTION

This final annual report summarized all key project goals completed to date and includes pertinent background information that justified the project. The purpose of this project was to develop a device for rapid, effective, circulatory support in remote areas. DMVA has already demonstrated its potential for providing resuscitative circulatory support with particularly relevant attributes including technically simply installation, rapid return and maintenance of perfusion to vital organs and the absence of any blood contact. This unique method of non-blood contacting biventricular support that was first described by George L. Anstadt, DVM. The method utilizes a pneumatically powered heart cup to deliver systolic and diastolic forces to the surface of the ventricular myocardium. DMVA has proven to be effective in providing total circulatory supprot to the fibrillating, or severely failing heart. This report summarizes background information pertinent to the development of DMVA and other related non-blood contacting circulatory support technologies. The background explains DMVA's unique life-saving attributes, enabling a better appreciation for the significance of the project. The report will then cover salient aspects pertaining to the project and its completion. Finally, future goals will be outlined for clinical use of the developed technology.

2. KEYWORDS

1. DMVA – DIRECT MECHANICAL VENTRICULAR ACTUATION
2. HP – HAND PUMP
3. AD – AUTOMATED DRIVE
4. MCL – MOCK CIRCULATORY LOOP
5. ECHO - ECHOCARDIOGRAPHIC
6. DCC – DIRECT CARDIAC COMPRESSION
7. RV – RIGHT VENTRICLE
8. LV – LEFT VENTRICLE
9. CPB – CARDIOPULMONARY BYPASS
10. TEE – TRANSESOPHAGEAL
11. ST – SWITCHED TANK

3. OVERALL PROJECT SUMMARY

This report represents the FOURTH AND LAST annual report for Contract # W81XWH-08-1-0484T. The original start date for this contract was 7/14/2008. However, no activity occurred until the grant was transferred to LifeBridge Technologies, LLC, with and approved start date of 5/20/2009 from USAMRAA. Our FIRST THREE annual reports reviewed activities from 5/20/2009 through 5/20/2012. This FOURTH and FINAL report summarizes subsequent project activities beginning in 5/20/2012 until 5/19/2013.

This final annual report summarized all key project goals completed to date and includes pertinent background information that justified the project. The project is further developing DMVA for use in remote areas. DMVA is a non-blood contacting method of resuscitation for support of the arrested, or severely failing heart. The project's principle goal is to develop a portable, compact, user-friendly drive system that does not require significant expertise for operation of the unit.

All proposed milestones have now been completed. Those milestones completed prior to this final report include:

(1) In-vivo studies to derive drive dynamics and pneumatic piston modifications.
(2) Design and fabrication of the HP.
(3) Design for integrating the HP into the automated system.
(4) Assembly of the prototype MCL for bench testing.
(5) Design and fabrication of the initial AD prototype.
(6) Modifications of the AD prototype system based on in-vivo testing.
(7) Final design of the AD prototype system.
(8) Fabrication/initial assembly of the automated volume regulated drive system prototype.

Milestones completed since the last quarterly report include:

(9) Analysis of interface/control and manual HP features.
(10) Final modifications of automated VRD prototype.
(11) Final testing of automated VRD prototype.

Report of Financials:

The table below summarizes the utilization of financials during the first year of the funded project period.

YEAR END FINANCIALS: 5/20/2012 – 5/19/2013

STAFF MEMBER	ROLE	% EFFORT-MONTHS 36-48
MARK P ANSTADT	PI	37.6
REBECCA DARNER	RESEARCH COORDINATOR	38.8
ANTHONY PEREZ-TAMAYO	CONSULTANT	<1
JENNIE GALLIMORE	STATISTICIAN	<1
PETER SCHIFF	LEAD ENGINEER	3
RICHARD LESLEY	ENGINEERING TECHNICIAN	23.9
KELLY SWARTZMILLER	TECHNICAL ASSISTANT	<1
NICK GARVIN	TECHNICAL ASSISTANT	8.4
MEGAN MARKL	TECHNICAL ASSISTANT	3.9
SABRINA METZGER	TECHNICAL ASSISTANT	34.6
KEVIN CARNAHAN	TECHNICAL ASSISTANT	34.6

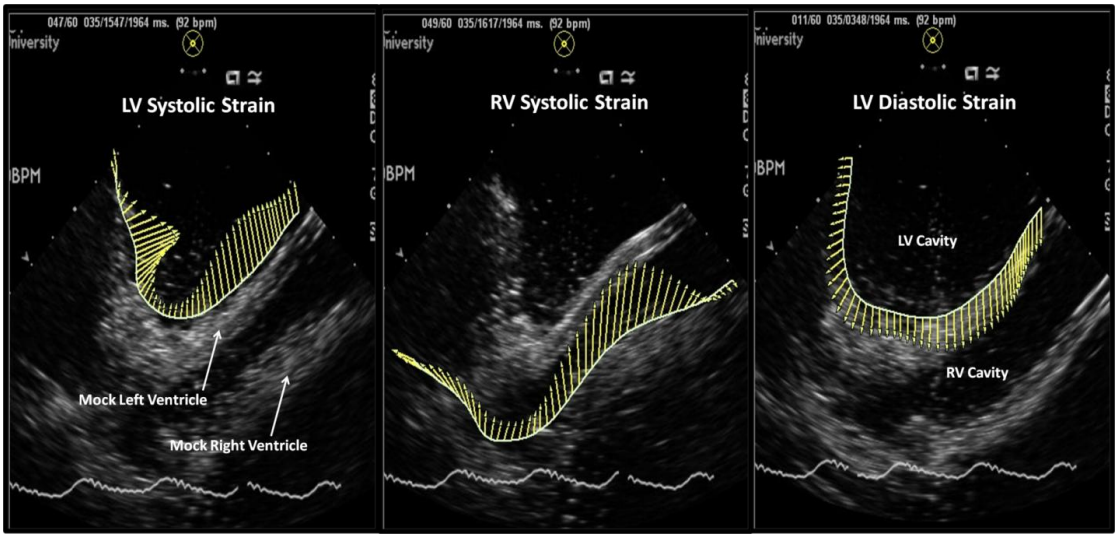
Contract expenditures to date:

COST ELEMENTS	THIS QUARTER	CUMULATIVE
Personnel	$15,762	$160,512
Fringe Benefits	0.00	0.00
Supplies	0.00	0.00
Equipment	79,197.62	203,125.25
Travel	0.00	9,774.09
Other Direct Costs	28,001.23	269,631.83
Subtotal	**$122,960.85**	**$645,206.02**
Indirect Costs	$**23,703.35**	$151,919.80

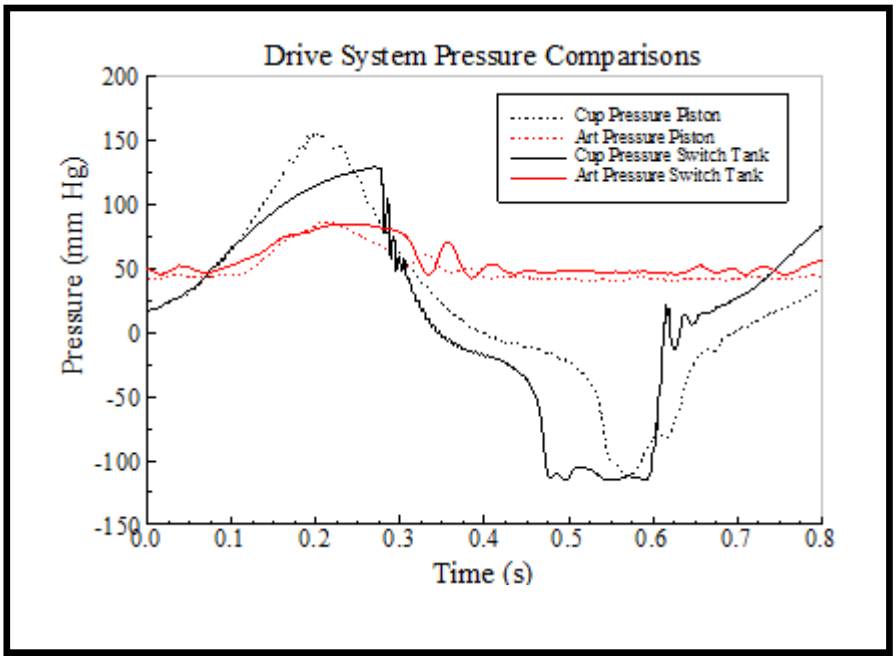
Fee	0.00	0.00
Total	**$146,664.22**	**$849,717.63**

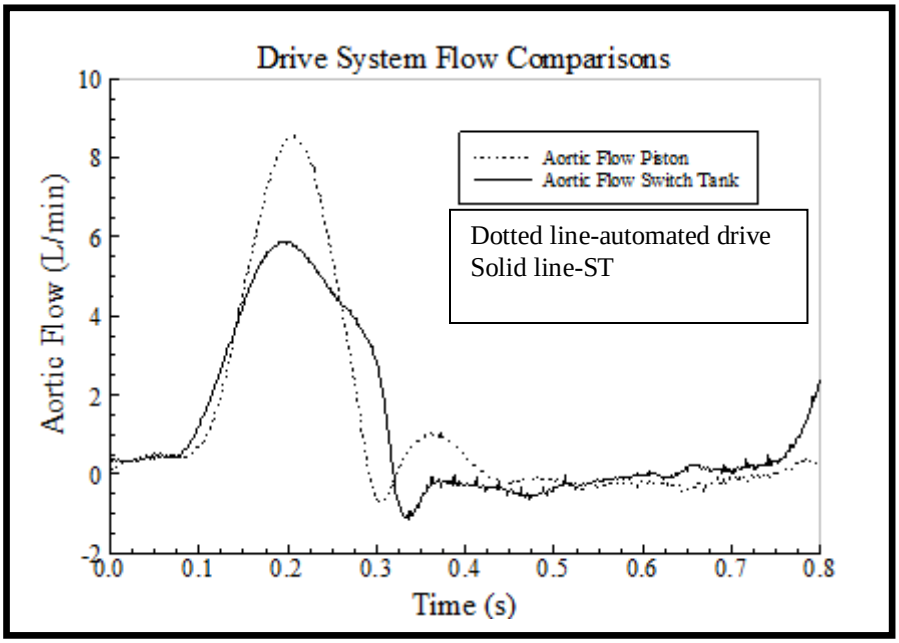
A novel, custom MCL was used to verify functionality of the drive before completing animal testing:

Echocardiographic (ECHO) interrogation of the mock ventricles was included in the analysis to verify functionality: Below are ECHO images of Mock Ventricles actuated by the AD system:

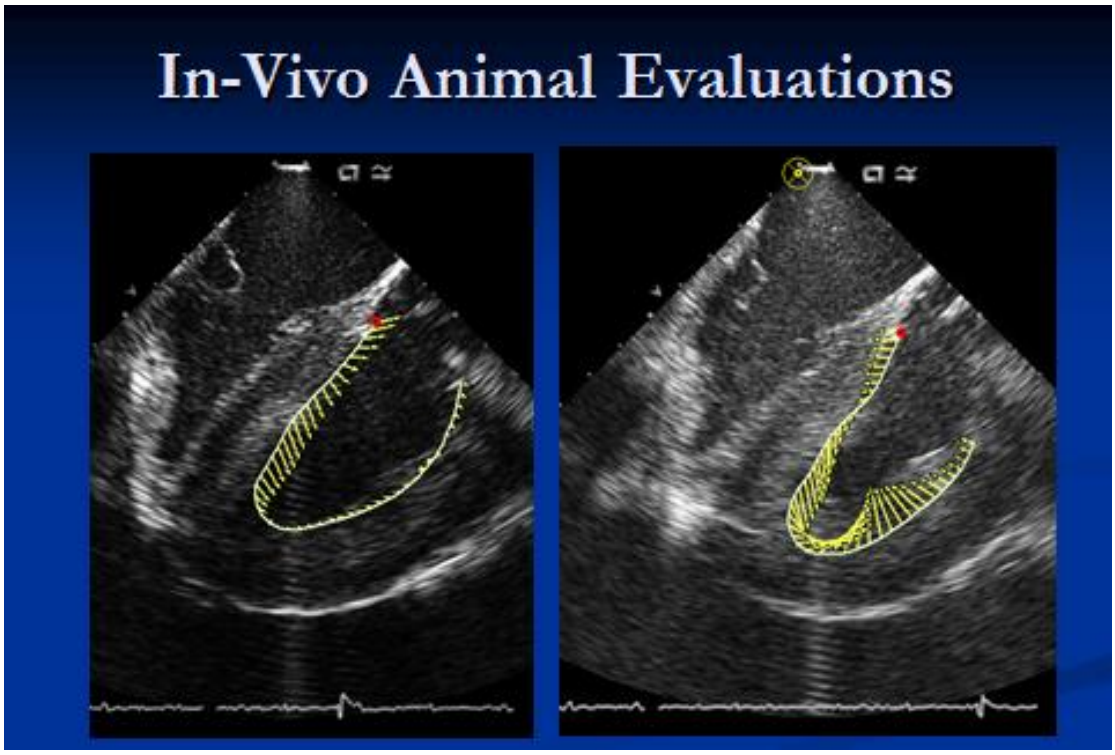


Data was compared between the switched tank (ST) and the prototype drives to verify equivalence.

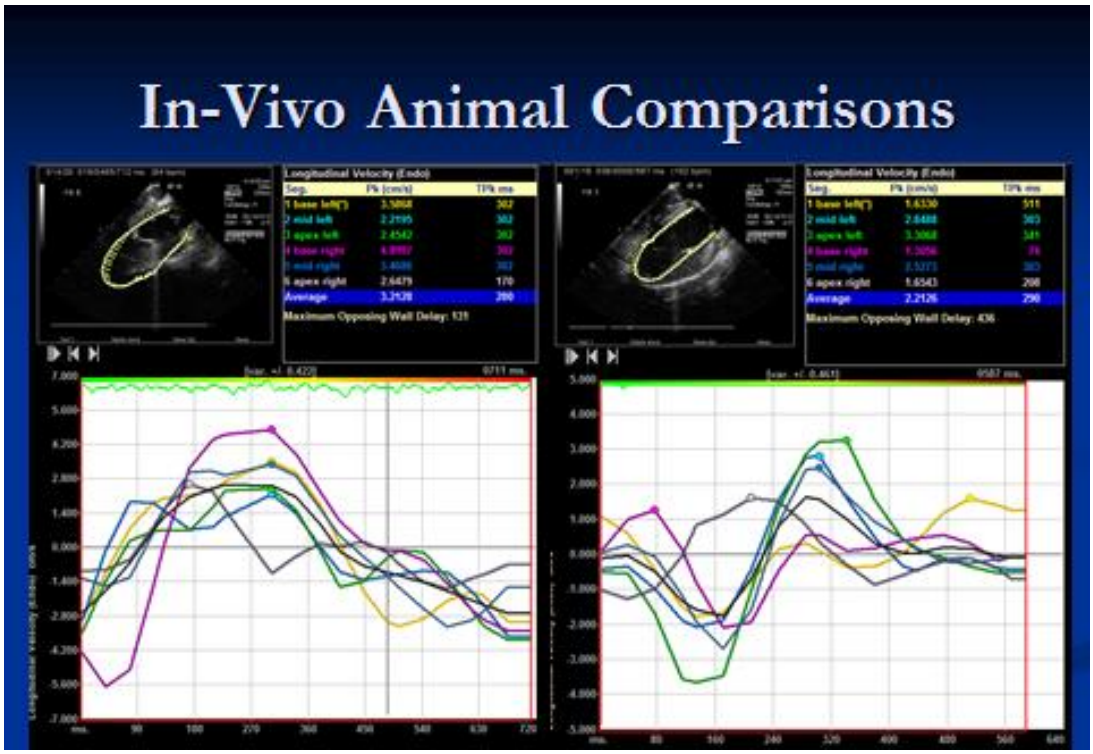




Comparisons were then made between the AD and the ST system in animals using a similar experimental algorithm. Below is an example ECHO image during DMVA support using the automated, piston drive system (left, in systolic actuation/compression) and ST system (right, during diastolic actuation) during support of the fibrillating heart:



Below are strain analysis examples of DMVA support using the automated, piston drive system (left) and the ST system (right) during support of the severely failing heart.



Data from these in-vivo experimental comparisons were averaged and mean values are provided in the below tables and graphs (piston= AD):

Drive System Mock Comparisons

Drive System	Max Cup Pressure (mm Hg)	Min Cup Pressure (mm Hg)	Integral Cup Pos Pressure (mm Hg*s)	Integral Cup Neg Pressure (mm Hg*s)
Piston	143.3	-104.0	49.3	-15.9
Switch Tank	118.4	-103.4	44.8	-27.2

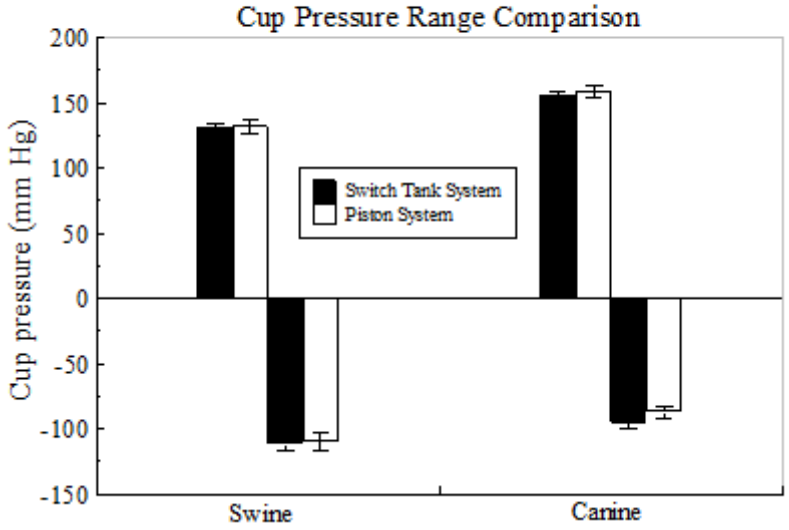
Drive System	Max LV Pressure (mm Hg)	Max RV Pressure (mm Hg)	Mean LA Pressure (mm Hg)	Mean RA Pressure (mm Hg)
Piston	98.6	103.6	18.1	9.1
Switch Tank	93.5	95.5	18.1	9.0

Drive System Mock Comparisons

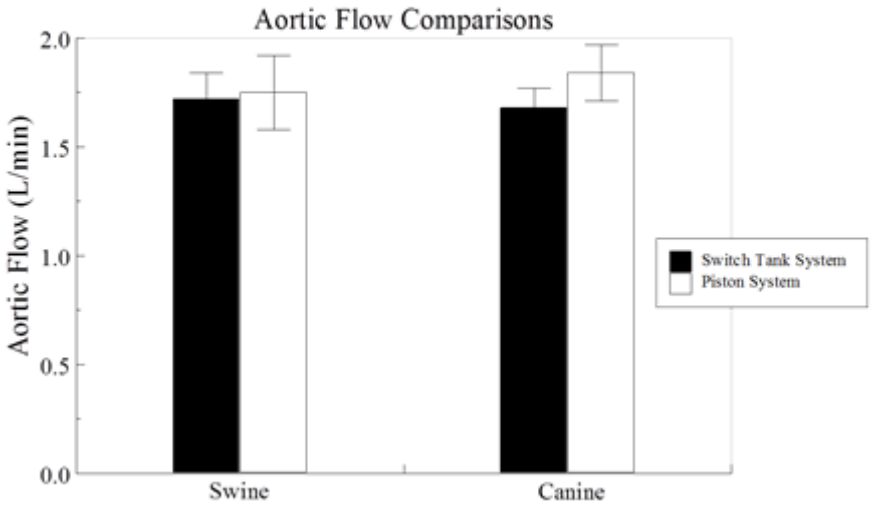
Drive System	MAP (mm Hg)	Max Arterial Pressure (mm Hg)	Min Arterial Pressure (mm Hg)	Mean Pulmonary Pressure (mm Hg)	Max Pulmonary Pressure (mm Hg)	Min Pulmonary Pressure (mm Hg)
Piston	79.3	96.8	67.4	39.2	56.3	23.3
Switch Tank	75.1	86.8	65.4	39.1	53.6	26.2

Drive System	Max Aortic Flow (L/min)	Average Aortic Flow (L/min)	Average Pulmonary Flow (L/min)	LV Stroke Volume (ml)	RV Stroke Volume (ml)
Piston	7.38	1.36	3.98	31.3	94.7
Switch Tank	4.45	1.31	4.15	33.3	99.4

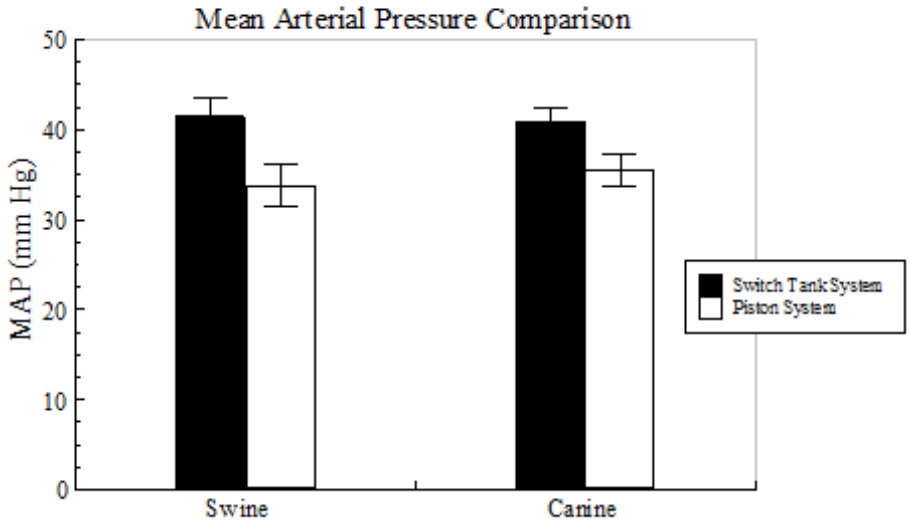
In-Vivo Cup Pressure Comparisons



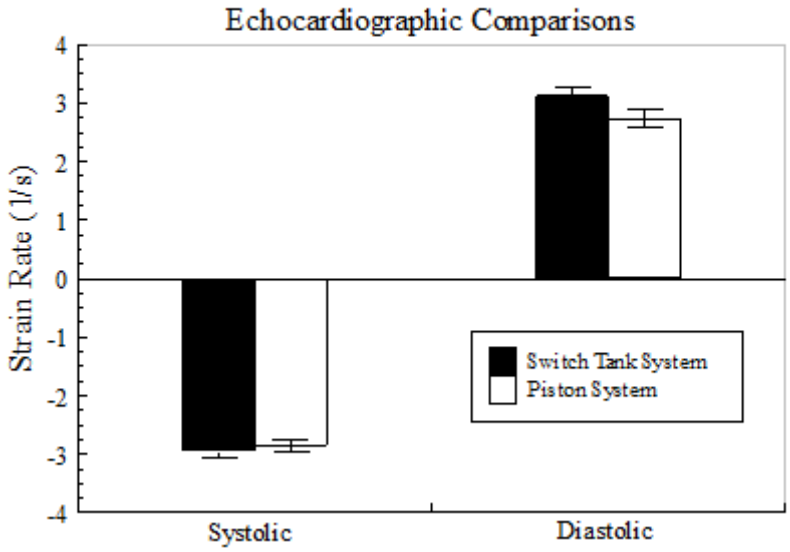
In-Vivo Cardiac Output Comparisons



In-Vivo MAP Comparisons



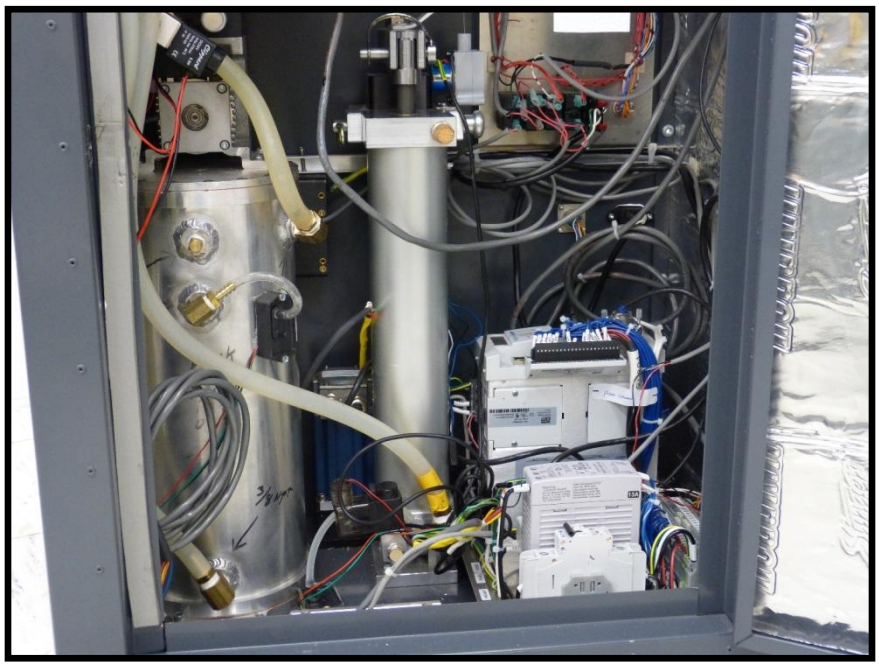
In-Vivo Strain Rate Comparisons



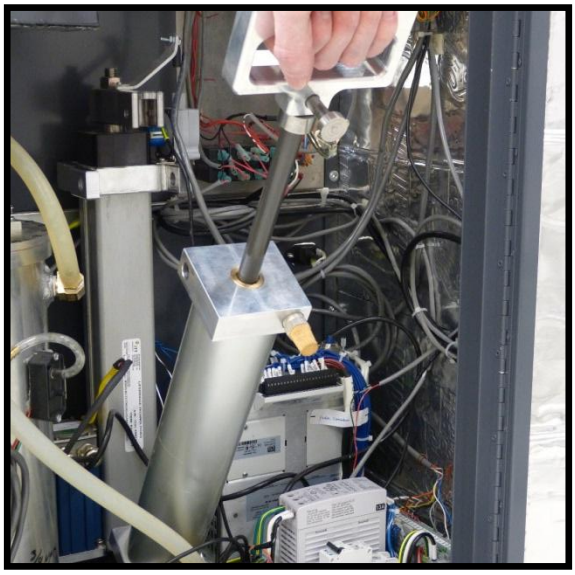
Below are pictures of the final automated, piston drive showing its housing and portable dolly features:

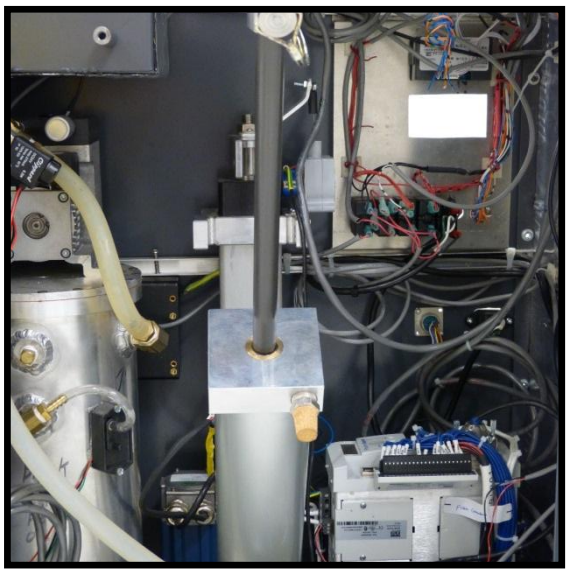
Below is an illustration showing DMVA cup attachment to the DMVA AD:

Below is a view of the internal integration of the piston and automated components:



Below is an illustration of the HP being actuated during manual operation of the AD:





The AD system was then bench tested using the MCL support system to verify functionality for cup sizes 80 thru 130. The results demonstrated the system could perform at the pre-selected drive rates with adequate actuation of DMVA cups for resuscitation in this wide range of clinically relevant heart sizes.

Future efforts will focus on reducing the current drive to an even smaller scale for use in remote areas in the field of resuscitative circulatory support and bridging to other devices.

STATEMENT OF WORK

The primary objective of this project pertains to the design and fabrication of a portable VRD for DMVA utilization in remote areas. Performance objectives were outlined with pertinent deliverables and milestones for this project. These outlined deliverables and milestones were arranged in a timeline. Therefore, achieving each consecutive milestone would provide needed conditions to proceed to the subsequent project objectives.

Year 1: A total of ten canine experiments will be performed, with a goal of six successful experiments for data analysis. Mock-loop studies will be conducted after each canine experiment, establishing the prototype drive test parameters. During the next two or three months the initial prototype design will be finalized based on specifications collected from the breadboard. Fabrication of the prototype will occur during the last six months of the year. Mock-loop testing on the prototype will begin near the end of the manufacturing in the last month of the year.

Key deliverables for year 1:

1) Completion of Breadboard In-Vivo Canine Study.
2) Completion of Breadboard In-Vitro Mock-Loop studies to establish.
3) Design of Prototype I.
4) Construction of First Prototype drive.
5) Initiation of Mock-Loop testing of First Prototype.
6) Completion and verification of appropriate documentation.

Year 1Milestones:

1) Compete Breadboard In-Vivo & Mock-Loop studies.
2) Complete design and fabrication of First Prototype drive.

Year 2: The first four months will be devoted to testing and modifying the prototype drive based on in-vitro and in-vivo testing. Mock-loop testing will finish in the first month of the year, to be followed by two to three in-vivo prototype studies. Based on in-vivo experimental data, the prototype will be modified. In-vitro testing will be conducted with the mock-loop near the end of modification to access the viability of the altered prototype model. The repeated process of in-vivo testing, prototype modifications and in-vitro testing, with 1-3 iterations likely, will lead to the development of the final prototype design and final design specifications by the end of year two**.**

Key deliverables for year 2:

1) Successful completion of mock-loop and in-vivo testing of First Prototype drive.
2) Modify Prototype as determined by mock and animal testing results (2-3 revisions).
3) Finalization of Prototype drive design.
4) Completion and verification of appropriate documentation.

Year 2 Milestones:

1) Perform in-vitro and in-vivo testing of prototypes.
2) Arrive at Final Design Prototype.

Year 3: In the first four months, six successful in-vivo experiments will be performed on the final design prototype to analyze its effectiveness. Final adjustments in the drive control system will be made in the first two or three animals. Analyses will be performed by an independent clinical investigator to assess user-friendliness and functionality. In the next two months, training algorithms will be developed prior to pre-clinical testing. In the final six months the final design prototype will undergo pre-clinical testing under an independent clinical direction. A total of six successful experiments will provide data for comparison to breadboard results obtained in year one to test the study hypothesis with a focus of developing a protocol for clinical trials.

Key Deliverables for year 3:

1) In-Vivo Final Design Prototype study.
2) Final control interface modifications of Final Design Prototype.
3) Establishment of training protocol.
4) Pre-clinical testing of Final Design Prototype.
5) Data analysis to test study hypothesis.

Year 3 Milestones:

1) Finalize user-interface/control features of final prototype.
2) Complete animal tests using independent clinical investigator.

4. KEY RESEARCH ACCOMPLISHMENTS

Progress during the 16th quarter (the final quarter of this project) focused on three critical tasks:

(1) Analysis of interface/control of the automated VRD prototype and integrated manual HP.
(2) Completion of final modifications of automated VRD prototype.
(3) Final testing of automated VRD prototype.

Two automated VRD prototype drive systems were thereby assembled with all necessary modifications to ensure functionality. The two systems were tested on the custom MCL and with in-vivo experiments following the same protocols developed during the project. Use of ultrasound imaging for novel strain analysis provided more robust validation results in both the MCL & in-vivo animal testing. This significantly enhanced the validity of the final testing to demonstrate effective drive performance. Analysis of the final automated VRD prototype demonstrated that the portable, AD system functioned as well as prior existing drive systems as anticipated.

Objectives completed during the final quarter of the project period

The final prototype AD system underwent both in-vitro (MC) and in-vitro (animal) testing with comparative analyses with the pre-existing ST system. Two prototype drives were assembled and demonstrated functionality and feasibility. The final portable, automated VRD evaluations with in-vivo experiments and in-vitro MCL testing proved the project hypothesis. All final refinements in the drive control features and user-interface were incorporated into the drive for these final evaluations.

A. Key Deliverables completed during the final quarter of the project:

(1) Assembly of the final portable automated VRD with all necessary modifications
(2) In-vivo analysis of user-interface and control, HP assembly and user-interface
(3) In-vivo and in-vitro assessment of final prototype for functionality and ease of use
(4) Data analysis to testing the study hypothesis that the portable, automated VRD drive is equivalent to pre-existing drives

B. Milestones Completed during the final quarter of the project:

(1) Fabrication/assembly of the final automated VRD prototype
(2) Final testing of VRD verifying it functionality and equivalence to pre-existing DMVA drive systems

Scientific Progress and Objectives during the 16th quarter (4/01/2013-5/19/2013) is summarized below:

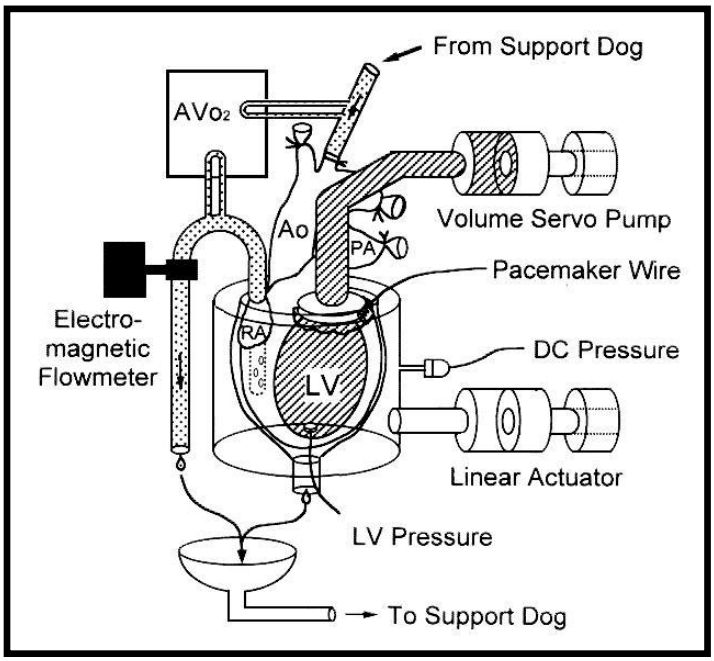
First components for the final automated VRD prototype were assembled in a custom, portable housing. Notably, this final portable, automated VRD was constructed in duplicate. The completed unit was then tested for functionality using both in-vivo, animal experiments as well as bench testing with the MCL. Animal experiments included both canine and swine models. The >50 lb canine is representative of a small human, while the >180 lb swine an average size human. The MCL platform provided a means for verifying functionality under steady-state physiologic loads pertinent to larger human. Testing of the final prototype assessed functionality, control features and user-friendliness. Final modifications were made regarding user-interface and the manual HP to improve these features. Simple training algorithms from intuitive touch-screen directions were used the final for pre-clinical testing of the final automated VRD prototype. The completed prototype then underwent in-vivo and in-vitro testing comparing it to the prior drive systems.

DMVA BACKGROUND, SALIENT ASPECTS, AND FUTURE GOALS

The study of how mechanical forces can augment cardiac pump performance has led to a large body of scientific data. These works done investigating DMVA as well as other distinctly different devices. Salient aspects of these prior studies illustrate and justify the value of advancing DMVA technology in the manner proposed by this project. It should be recognized that early work pertaining to DMVA employed rather rudimentary devices. Theses devices were desinged to compress the heart for improving systolic pump function. Devices that compress the ventricles are defined as "direct cardiac compression (DCC)" devices. DCC describes compression of the heart for the purpose of augmenting ventricular systolic pump function. Although DCC is pertinent to DMVA, it is important to understand DCC devices do not provide diastolic assist. In fact, DCC devices generally impair diastolic ventricular function. DMVA distinctly aids diastolic function which is a distinguishing feature pertaining to DMVA's efficacy.

When considering the efficacy of DMVA, one needs to also recognize the implications on the right venticle (RV). RV function is very vulnerable to the contrictive aspects of any compressive device resulting in comprised filling. This again is where DMVA's diastolic assist plays a critical role. Therefore, it is also important to appreciate that many DCC investigations focused on the the left ventricle (LV). Many times with isolated hearts preparations that excluded any considerations for RV function. Therefore, the very nature of such experiments did not account for the importance of either diastolic function or RV function both of which have implications on the efficacy of DCC.

Early isolated heart preparations utilized for evaluating DDC's effect on LV function would typically exclude the RV. Chambers were positioned around the outer surface of the heart served as the DCC plateform. These cardiac compression chambers could provide variable degress of DCC. These in-vitro plateforms provided estimates of DCC's potential impact on important physiologic variables such as LV pressure, aortic flow and pressure. Although, such experiments provided fundamental understanidng of DCC's potential effect on LV performane, these in-vitro experiments employed bulky compresion devices that could not be directly translated to practical, implantable devices. Furthermore, assessment of the RV function and/or diastolic function were typically excluded which further makes translation of the results to any practical, in-vivo method of cardiac compression limited at best.



In general, the degree of DCC applied to the left ventricle results in an equal, additive degree of LV pressure generated by the native heart. This principle is pertinent to LV and DCC pressures within the physiologic range. The diagram below illustrates LV pressure in a normal beating, isolated heart before (control) and during (DCC) application of dynamic

compression pressures timed to ventricular systole. Note the DCC pressures were additive to underlying LV pressure during the control state

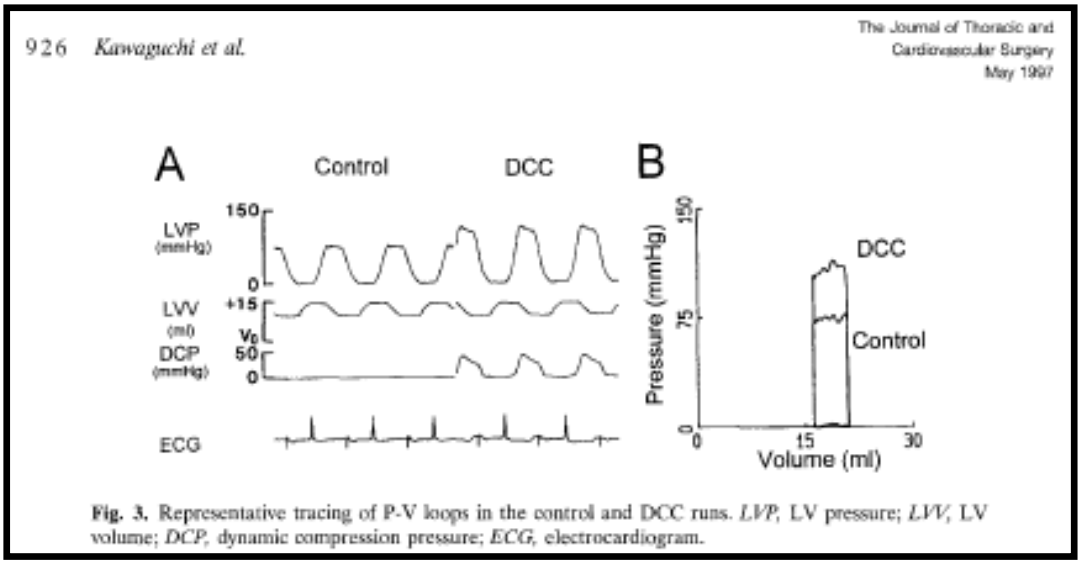
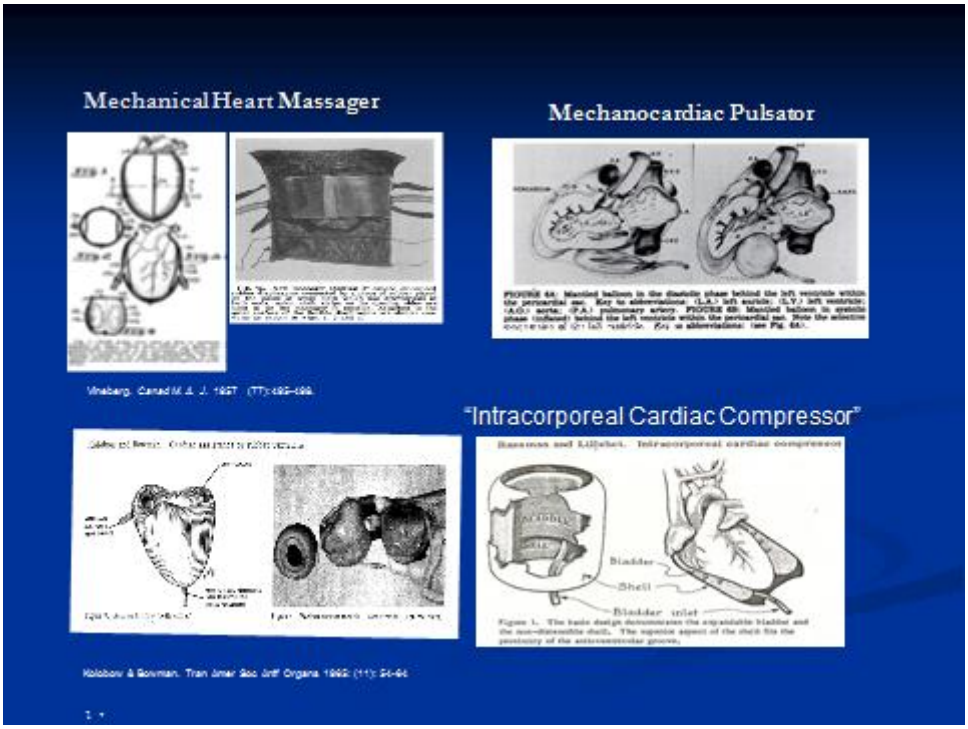


Fig. 3. Representative tracing of P-V loops in the control and DCC runs. *LVP,* LV pressure; *LVV,* LV volume; *DCP,* dynamic compression pressure; *ECG,* electrocardiogram.

Given the potential advantages of non-blood contacting circulatory support, a variety of device designs were tested to develop an effective, feasible means for applying DCC in humans. The obvious challenge was creating a device that feasibly fit the heart and effectively aided pump function. A number of devices were designed with these intentions (examples shown below).

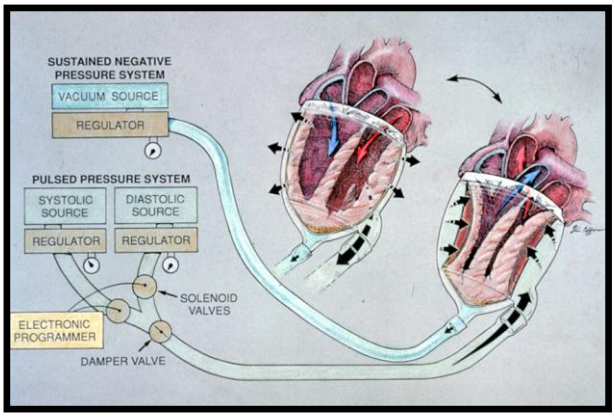


As evident from these illustrations, most of devices were relatively impractical, difficult to install and had little efficacy for providing meaningful cardiac support. Results from laboratory studies using such devices were not particularly convincing and questioned the feasibility of DCC for clinical applications. Importantly, these early devices only provided cardiac compression which only aids systolic function.

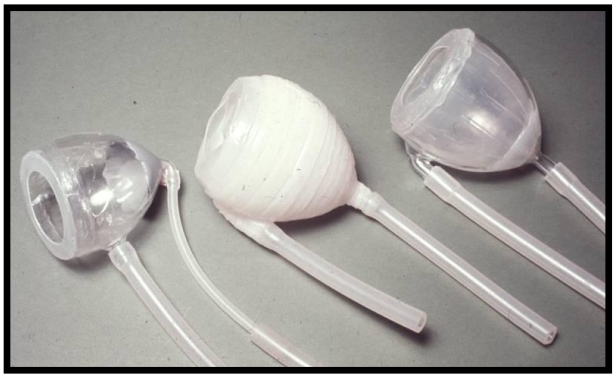
George L. Anstadt began work on a unique method of DCC circulatory support which not only compressed the heart, but also aided in ventricular filling or diastolic function. He likened this novel idea to the iron lung which altered atmospheric pressures around the chest to aid in lung ventilation

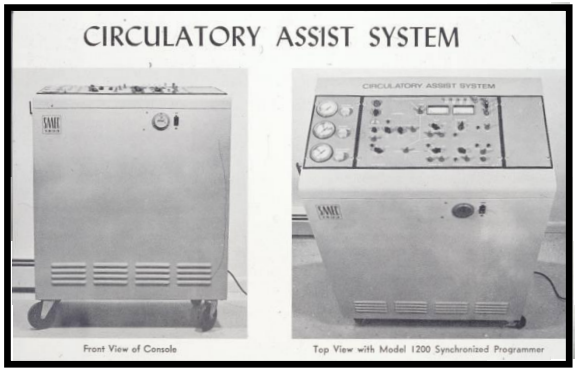
The first device he built utilized a latex diaphragm molded from casts made of the native heart. The diaphragm was bonded within a rigid Pyrex housing to allow positive and negative pneumatic forces to act on the inner latex diaphragm. The design included an opening in the apex of the housing that allowed vacuum forces to serve as a means for attaching the device non-traumatically to the heart. A picture of the first device is shown below which was successfully used to support the circulation for five hours during ventricular fibrillation.

The device utilized a pneumatic drive system to provide alternating positive and negative forces the heart cup. An illustration of the drive system and heart cup is shown below:



Work with this construct was advanced over the next 15 years with improvements in the design of the outer housing an inner flexible liner.

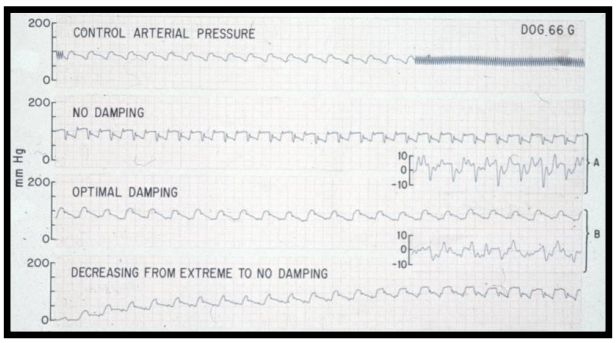


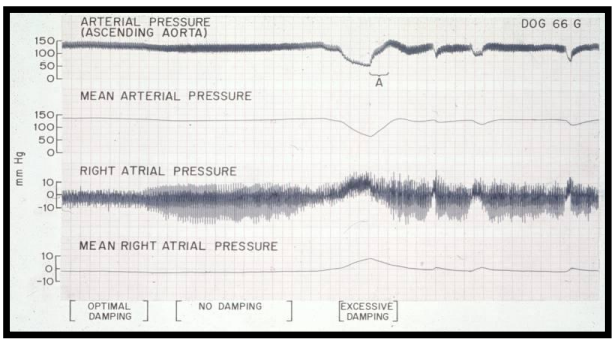


Using these devices, a pneumatic drive system was developed for controlling the manner in which DMVA actuated the heart. The systems were based on compressors that accumulated positive and negative pressures in tanks which could be switched thru a solenoid valve in a cycle manner. Control of the absolute pressure, rate of actuation and resistance in the

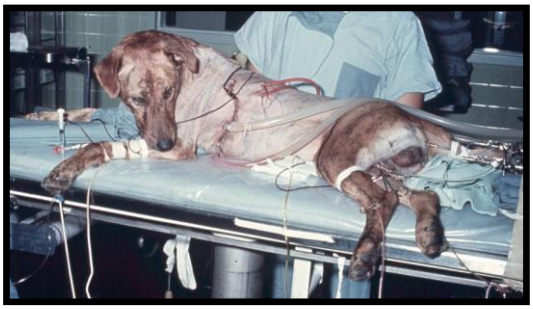
drive lines were the manner in which the operative could modulate the action of DMVA on the heart. A picture of one of these drive systems is shown above:

By regulating the "dampening" or resistance in the drive line, the operator could achieve physiologic hemodynamics that mimicked the normal physiologic state as shown below:





Most experiments were done in canine and successful support with long-term survival was achieved in animals receiving DMVA support for days in ventricular fibrillation followed by defibrillation and recovery with normal heart function. The picture below shows an animal awake during DMVA support of the fibrillating heart:



Notable, important differences existed in the characteristics of materials used in DMVA heart cups. Below is a figure illustrating the manner in which silicones versus polyurethanes behave when stretched:

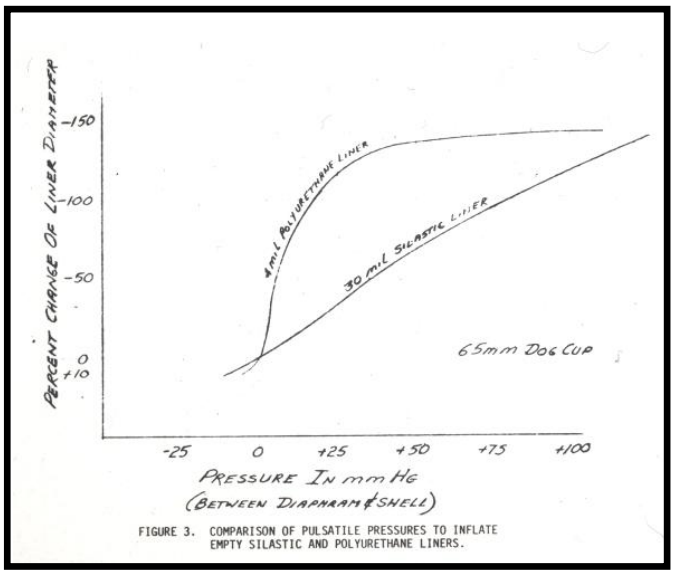
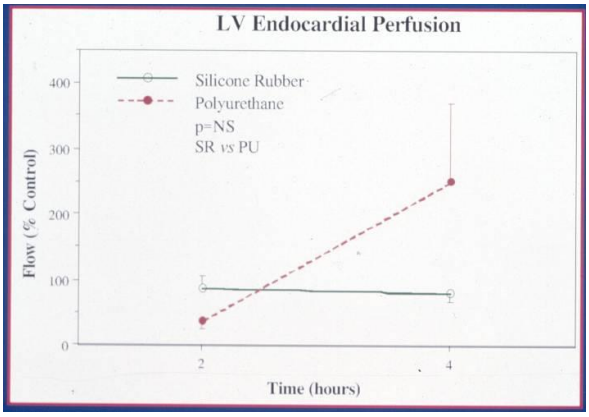


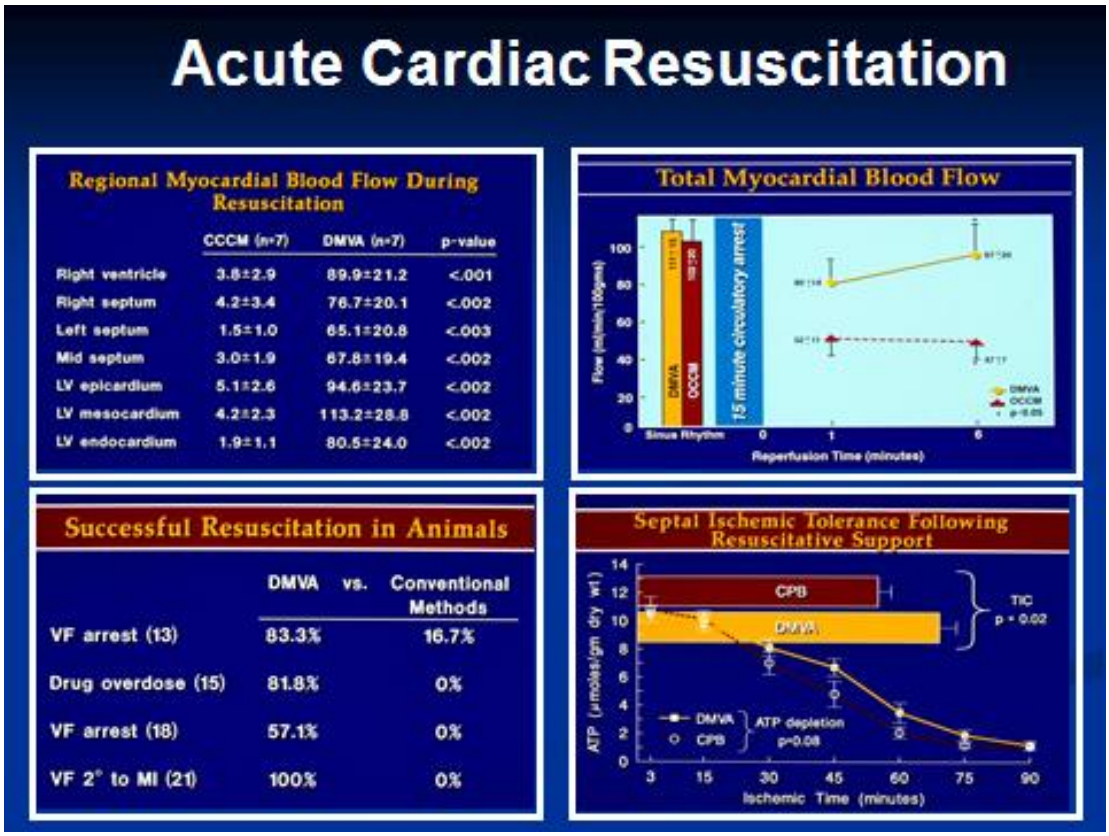
FIGURE 3. COMPARISON OF PULSATILE PRESSURES TO INFLATE EMPTY SILASTIC AND POLYURETHANE LINERS.

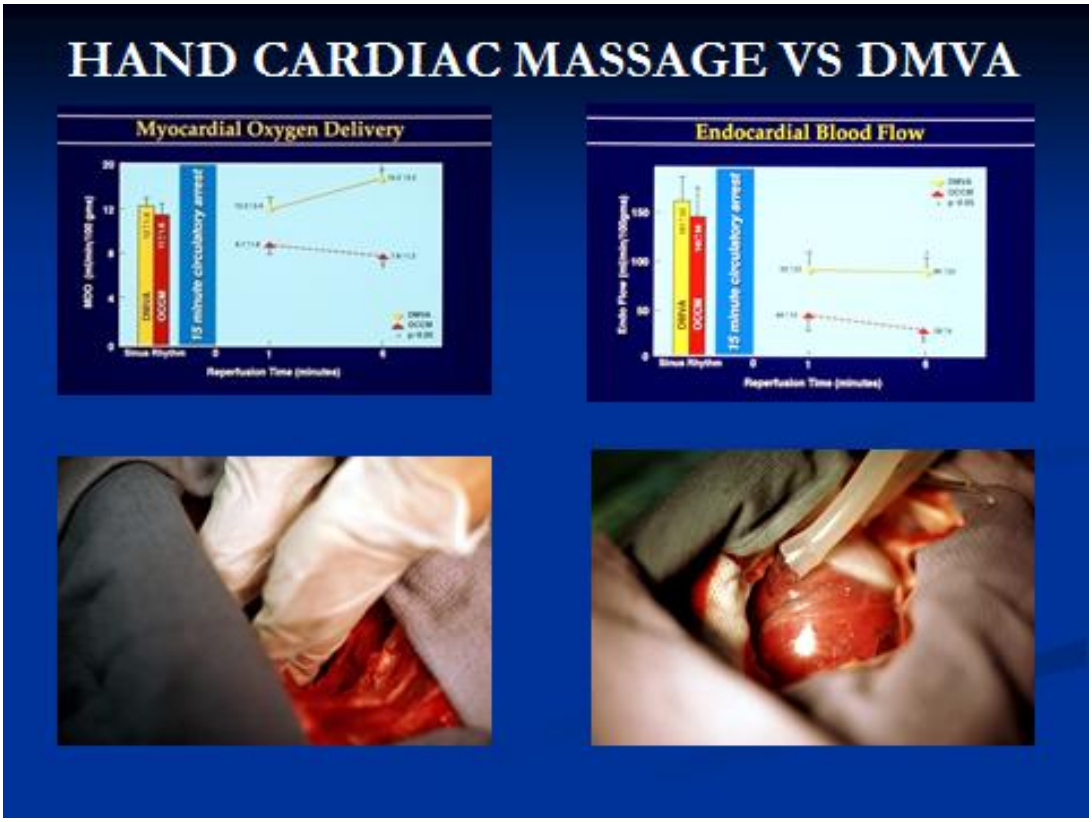
These physical characteristics were fundamentally different. I was discovered that the relatively "isotropic" behavior of silicone rubbers were the most favorable for atraumatic support of the fibrillation heart. When silicone rubber constructed DMVA cups were compared to polyurethane constructed cups, the results were dramatic. Specifically, Silicone rubber

cups resulted in hearts being preserved while the polyurethane constructed devices damaged the myocardium resulting in reduction in ATP stores that mimicked a severely injured heart, probably due to damage of the mitochondria. During support with Polyurethane devices heart became hyperemic as autoregulation led to increased blood flow to the seemingly ischemic myocardium (see graphic below):

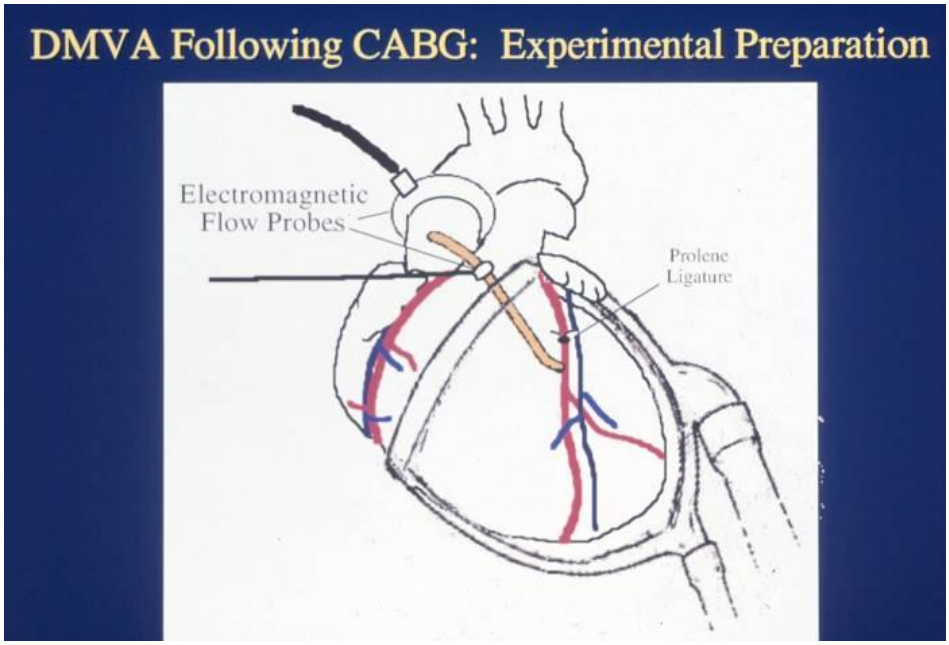


The focus with DMVA support centered around resuscitation as the device could be applied rapidly to return the circulation following cardiac arrest or sudden death. Comparisons between DMVA support and conventional methods of cardiac resuscitation such as closed-chest or open chest massage were dramatic (see below):

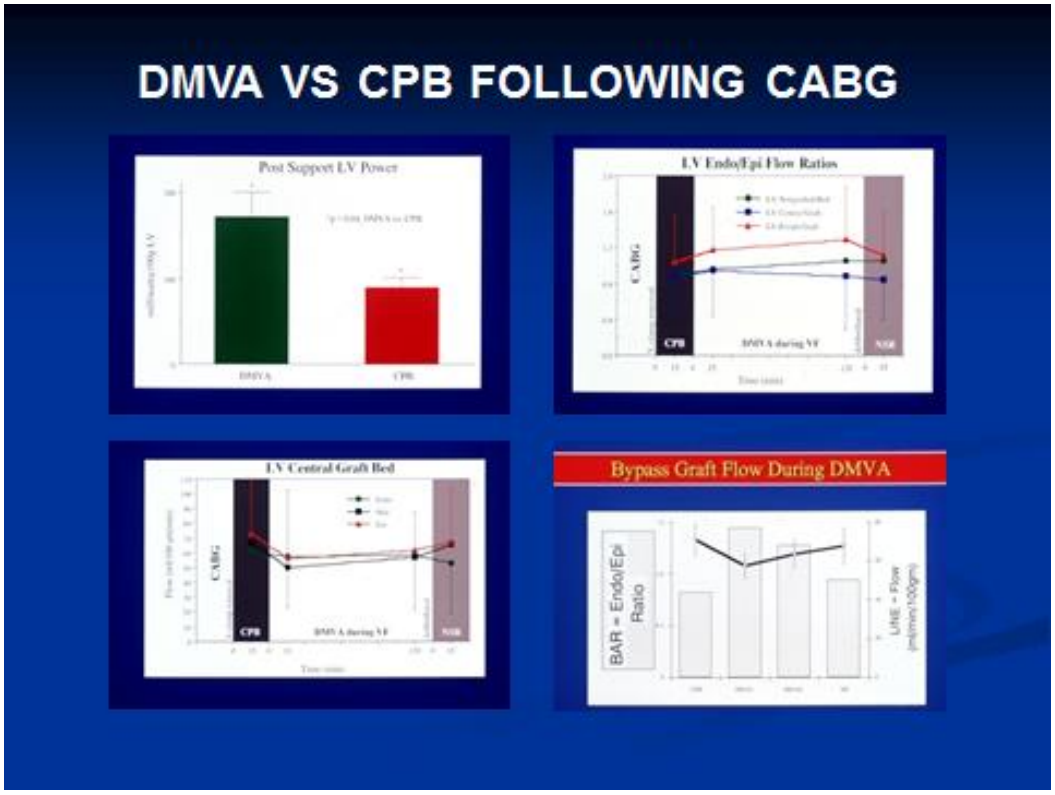




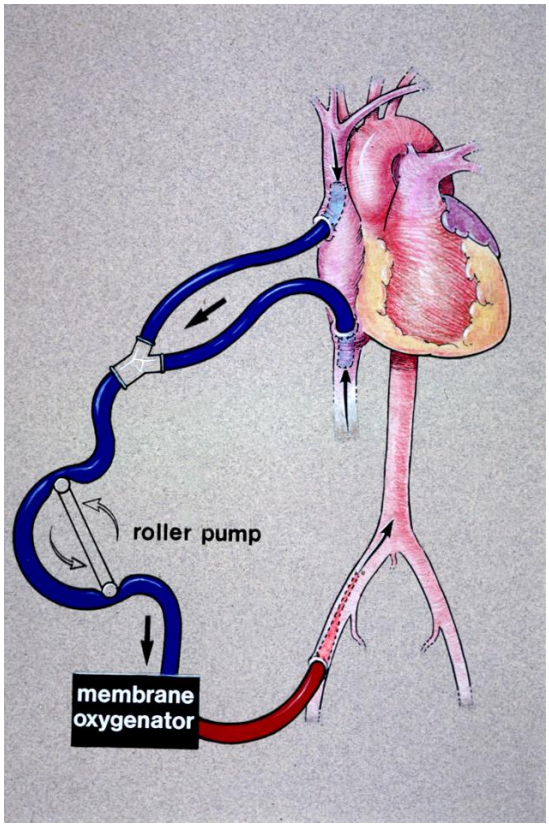
Additional work was done comparing DMVA to support of the heart following surgical revascularization of occluded coronaries using saphenous vein bypass grafts (see preparation below);



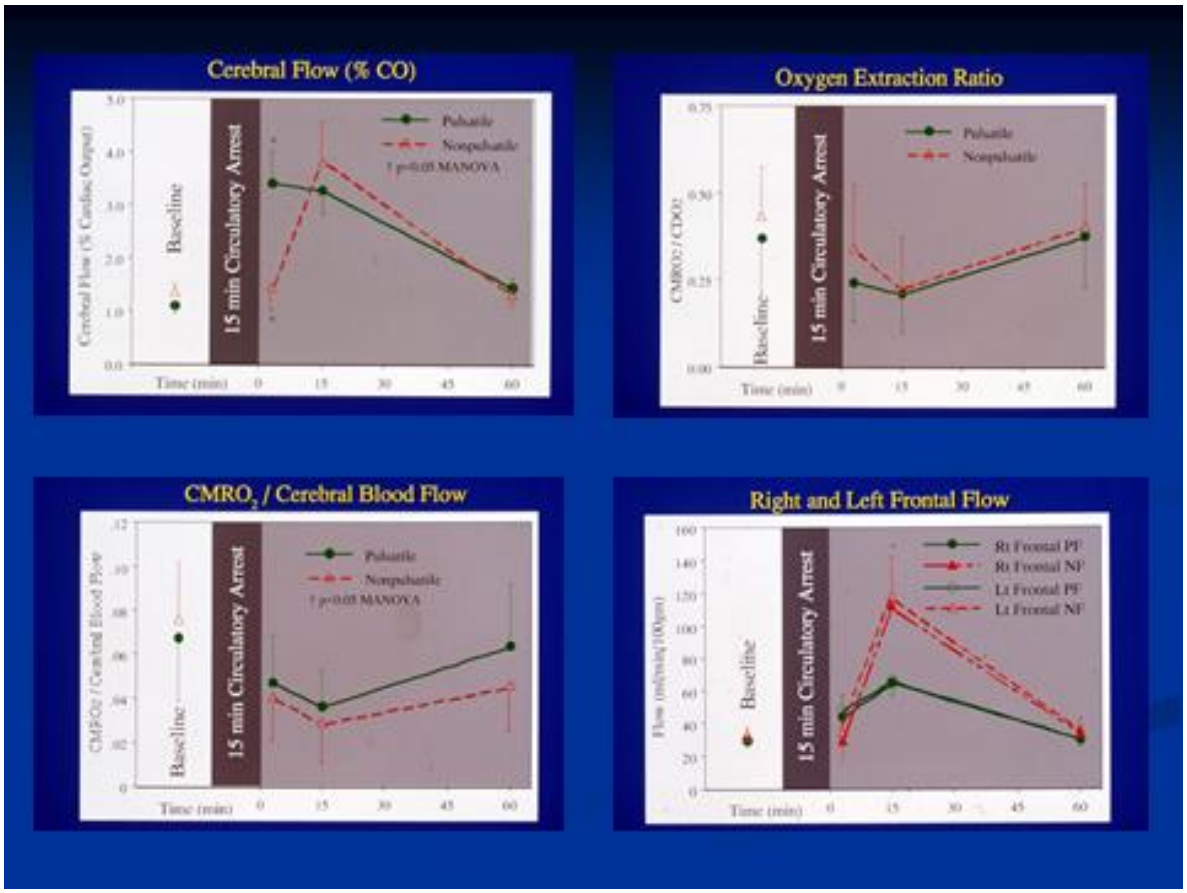
Results demonstrated that DMVA had a favorable effect on perfusion to the revascularized coronary beds with better preservation of myocardial high energy phosphates and improved post-support function (see below):



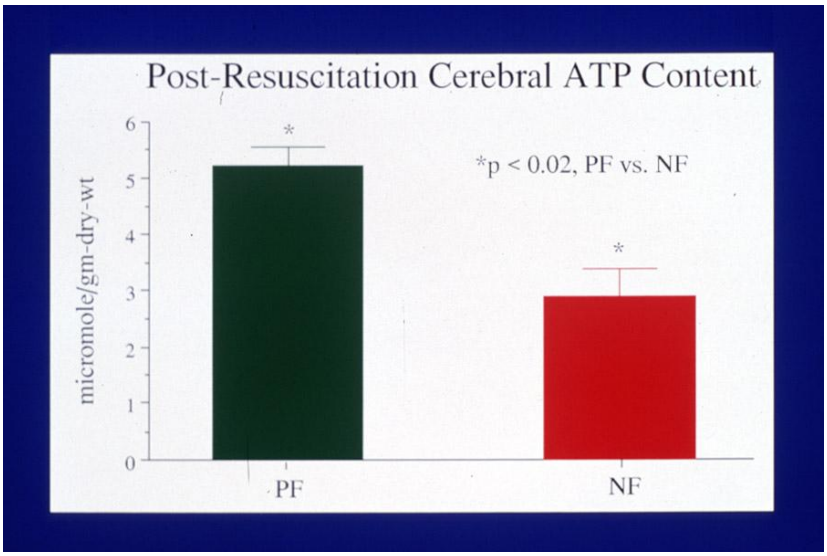
However, the most obvious role for DMVA support remained that of resuscitative circulatory support following cardiac arrest. The only other method that could generate total circulatory support in a relatively reasonable time-frame remains that of modified cardiopulmonary bypass (CPB) units. Therefore, experiments were performed comparing the best possible CPB support to DMVA following cardiac arrest. Below is an illustration of the CPB circuit used in such experiments:



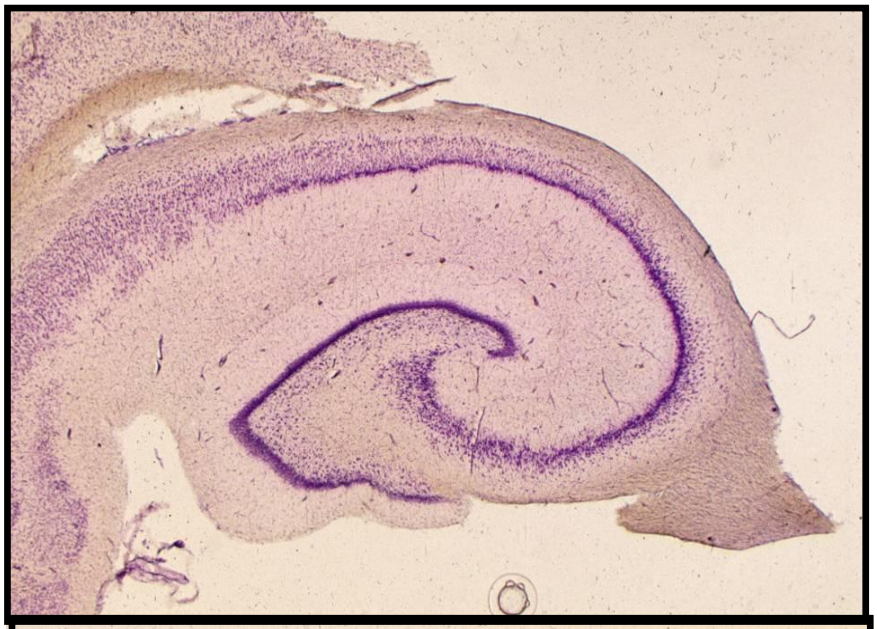
DMVA was compared to CPB following cardiac arrest to determine what differences might exist when both methods were applied after similar periods of arrest. Remember, in the clinical setting DMVA could be applied emergently in 2-3 minutes while it would normally take close 15-30 minutes to employ even partial CPB support. Therefore, these experiments biased results for more favorable CPB. Initial results demonstrated a dramatic difference regarding improved distribution of cerebral flow and resulting cerebral oxygen consumption with DMVA (pulsatile flow) versus CPB (non-pulsatile flow) shown below:



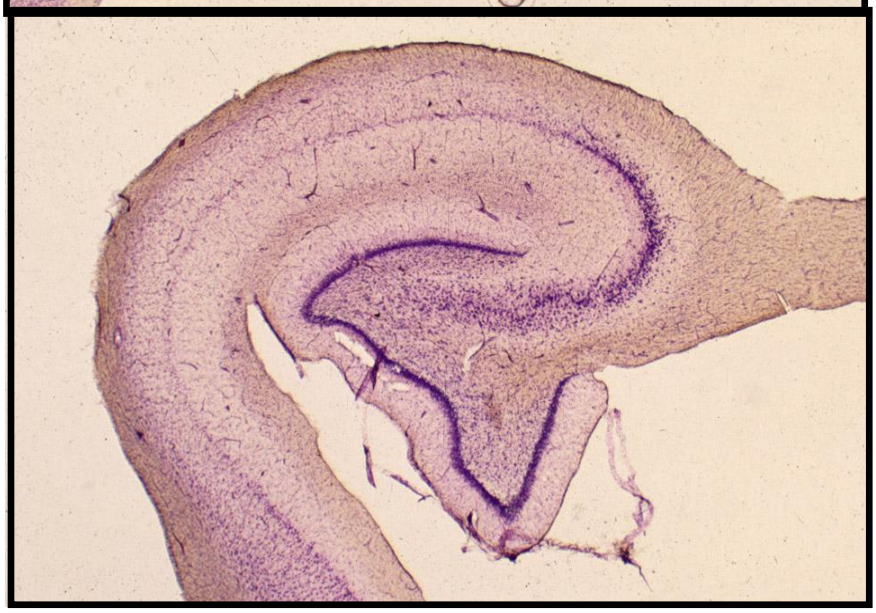
These favorable impacts on cerebral perfusion were the most likely explanation for improved cerebral ATP stores following resuscitation using DMVA (pulsatile flow-PF) versus CPB (nonpulsatile flow). It was felt that the pulsatile nature of resuscitative flow during DMVA support compared to the nonpulsatile flow of CPB might be the most important physiologic difference that could explain these dramatic discrepancies in the experimental results:



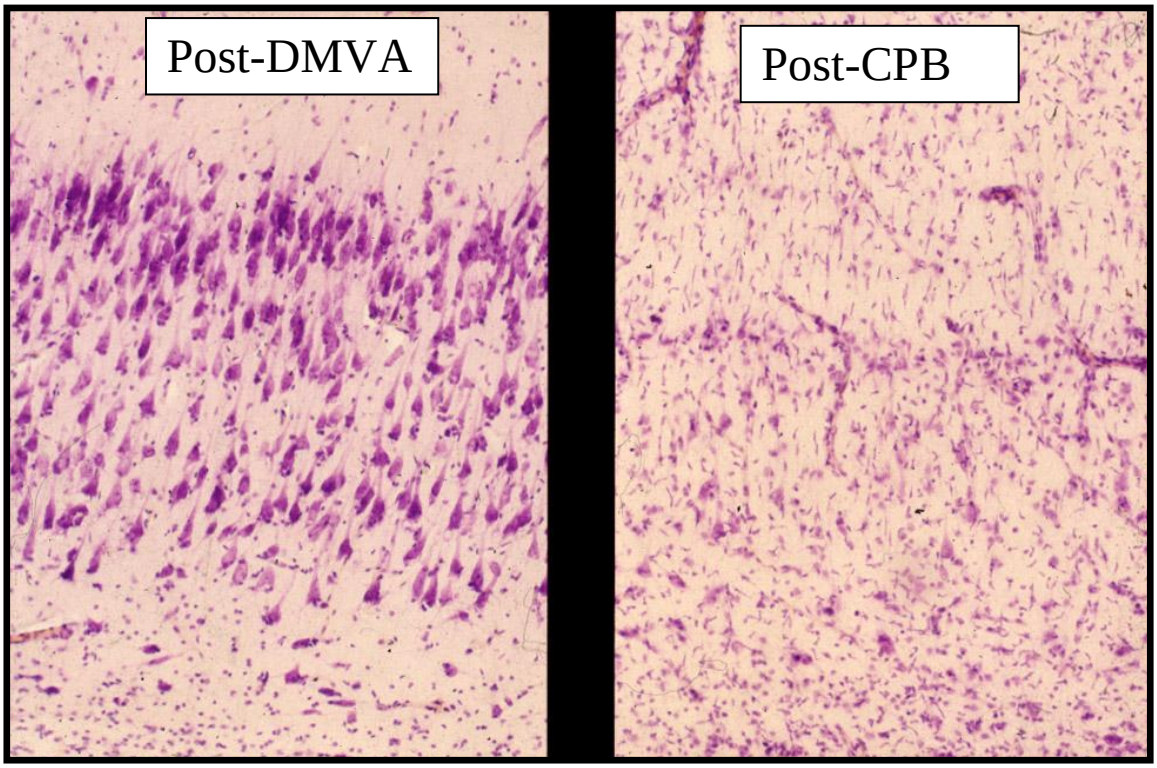
Additional work was then performed in a survival model where canine were resuscitated with DMVA (pulsatile) versus CPB (nonpulsatile) support. The surviving animals had marked improvement with respect to preservation on neurons in the Hippocampus of the brain following DMVA versus CPB as exhibited in the more pronounced purple staining in representative sections from animals following DMVA vs. CPB (see below):



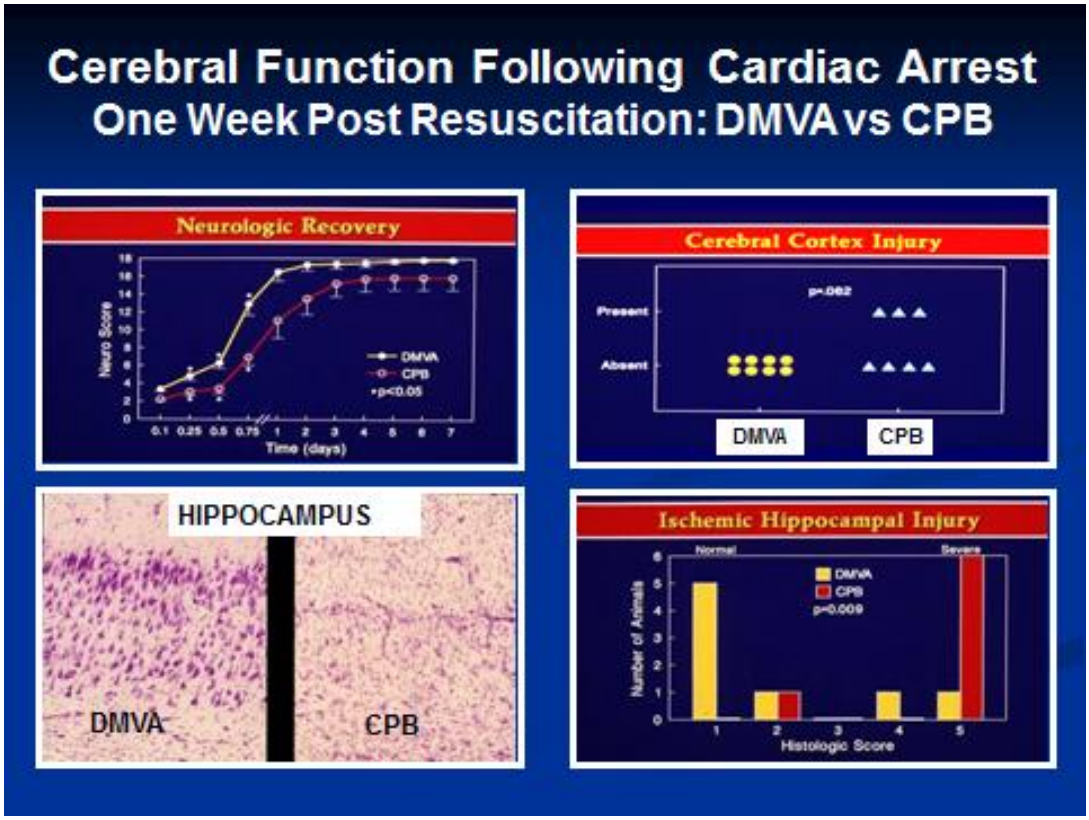
Post-DMVA



Post-CPB



The neurologic recovery and overall hippocampal scores were significantly better in animals following DMVA versus CPB in these survival studies (see below).



Clinical results were also notable using DMVA support. The first patient to receive the device at Duke University Medical Center was successfully bridged to transplantation and remains alive to date more that 10 years later (see abstract below):

First Successful Bridge to Cardiac Transplantation Using Direct Mechanical Ventricular Actuation

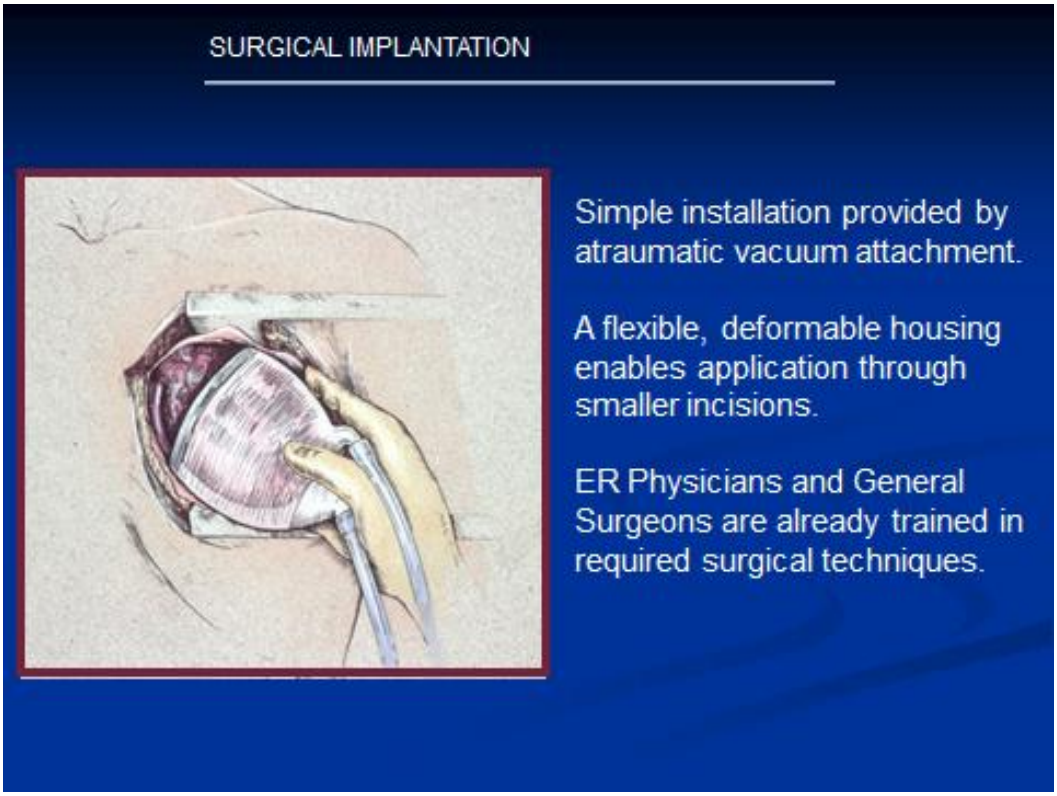
James E. Lowe, MD, Mark P. Anstadt, MD, Peter Van Trigt, MD, Peter K. Smith, MD, Paul J. Hendry, MD, Mark D. Plunkett, MD, and George L. Anstadt, VMD

Department of Surgery, Duke University Medical Center, Durham, North Carolina

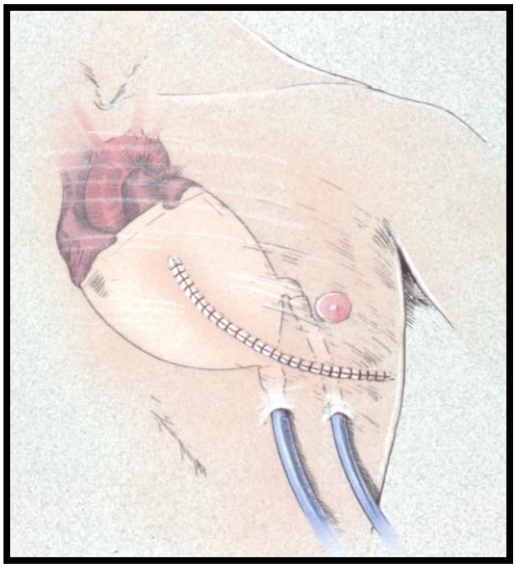
Currently available ventricular assist devices are technically difficult to implant, require continuous anticoagulation, and are associated with hemorrhagic and thromboembolic complications. Direct mechanical ventricular actuation is a biventricular assist device that can be applied in 3 to 5 minutes through a left anterior thoracotomy and has no direct blood contact or need for anticoagulation. The present study was designed to determine the effects of direct mechanical ventricular actuation in total biventricular circulatory support. Cardiogenic shock refractory to standard therapy developed in 2 patients awaiting cardiac transplantation. Direct mechanical ventricular actuation was applied and provided immediate hemodynamic stabilization in both. All inotropic agents and intraaortic balloon support were then discontinued. Fifty-six hours of circulatory support bridged the first patient to successful cardiac transplantation without complication. The patient is alive and well more than 1 year later without incident of infection or rejection. The second patient suffered cardiac arrest and required closed chest cardiopulmonary resuscitation before device application. After 45 hours of support, it was determined that irreversible neurologic injury had occurred and direct mechanical ventricular actuation was discontinued. Neither patient's native heart exhibited any histologic evidence of device-related trauma. Direct mechanical ventricular actuation has undergone limited clinical investigation since its original description 25 years ago, but in these initial trials, the device has proved effective. The concept of mechanically actuating the ventricles appears to be a valuable, yet under-utilized method of total circulatory support.

(Ann Thorac Surg 1991;52:1237–45)

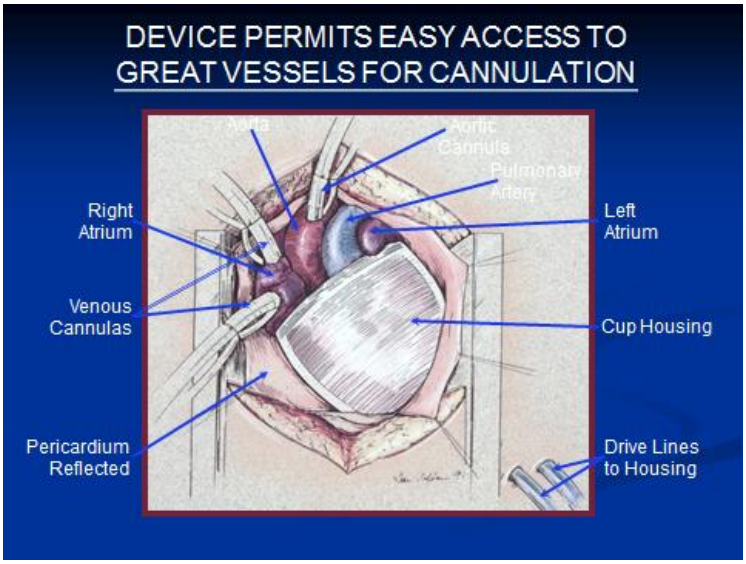
The device can be applied rapidly (2-3 minutes) thru an anterior thoracotomy (see below):



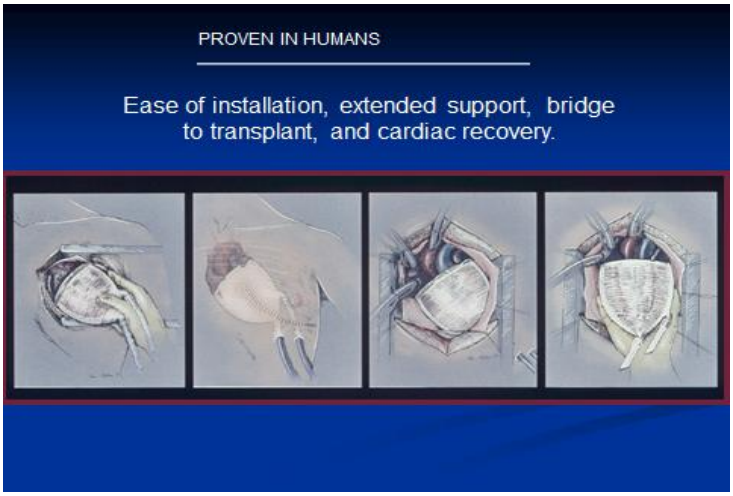
Once applied the chest can be closed for transport of the patient (see below):



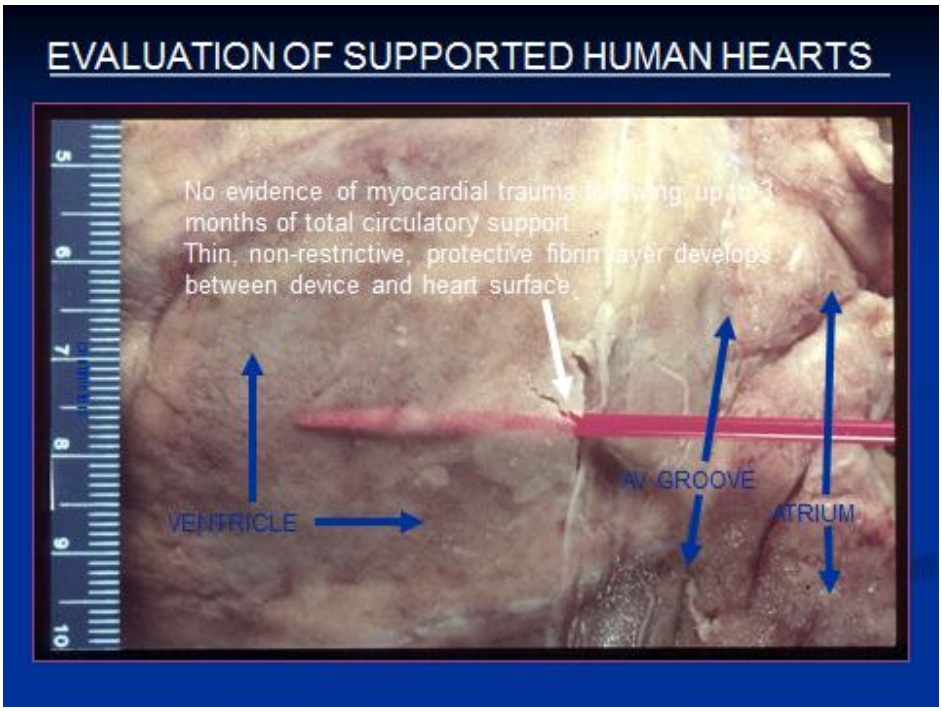
Other methods of long-term circulatory support can then be instituted by transitioning to CPB as a needed step in such considerations (see below):



This can be summarized as shown below:

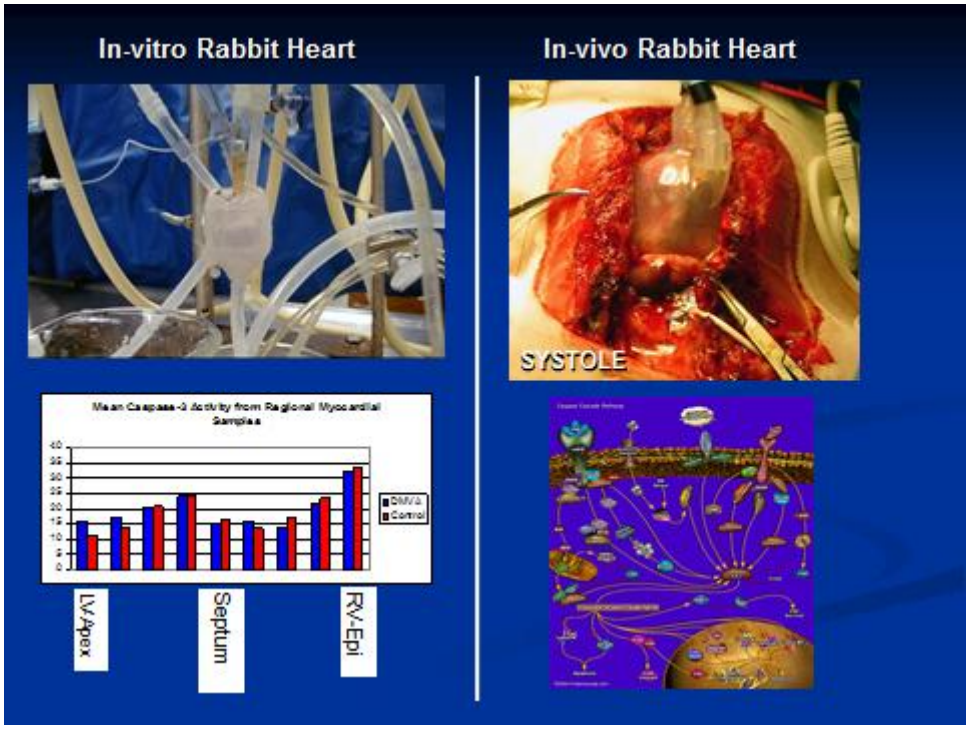


Pathologic evaluation in patients supported by DMVA has shown no evidence of myocardial damage even after up to 3 months of support (see below):

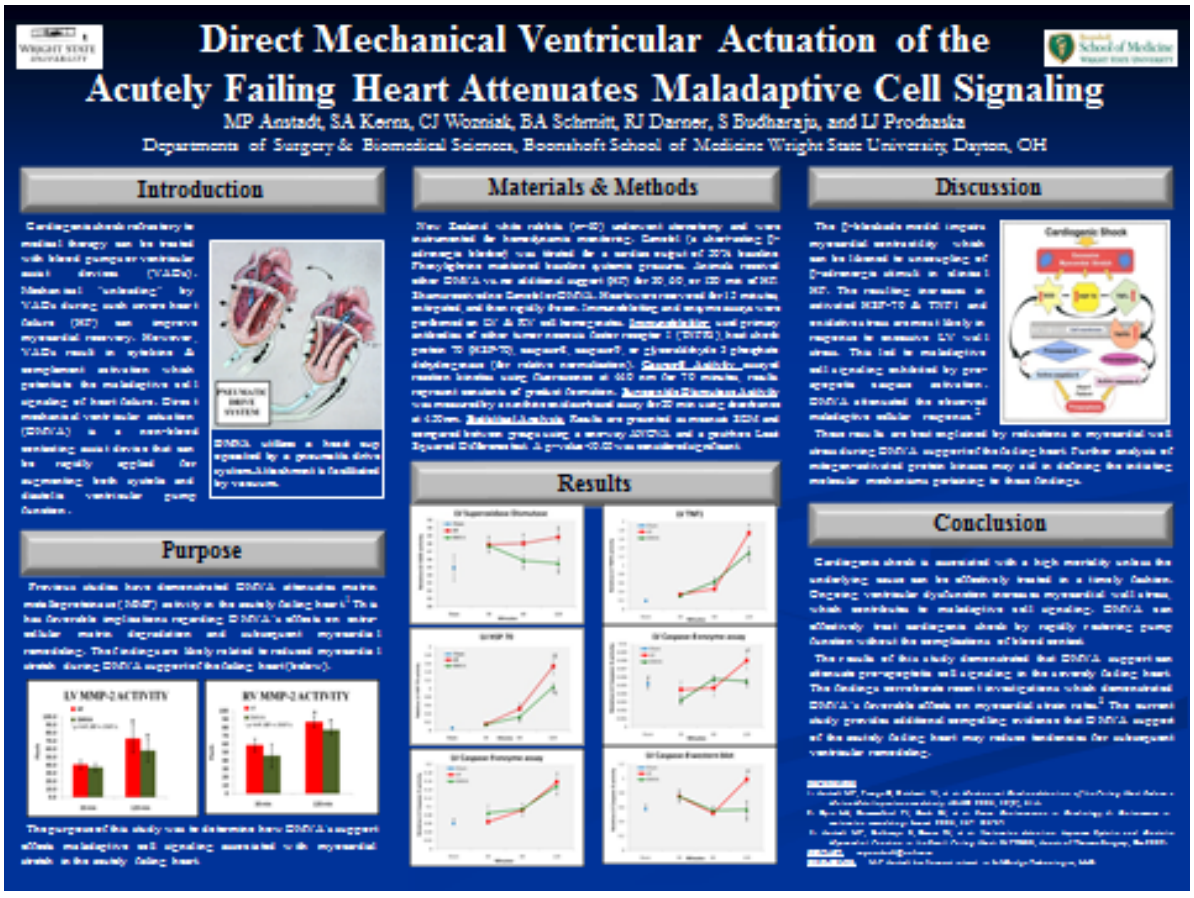


Research following these clinical findings began focusing on support of the failing heart using smaller animal models. The DMVA cup technology was reduced to smaller sizes using the same designs as proven in animal studies (see below):

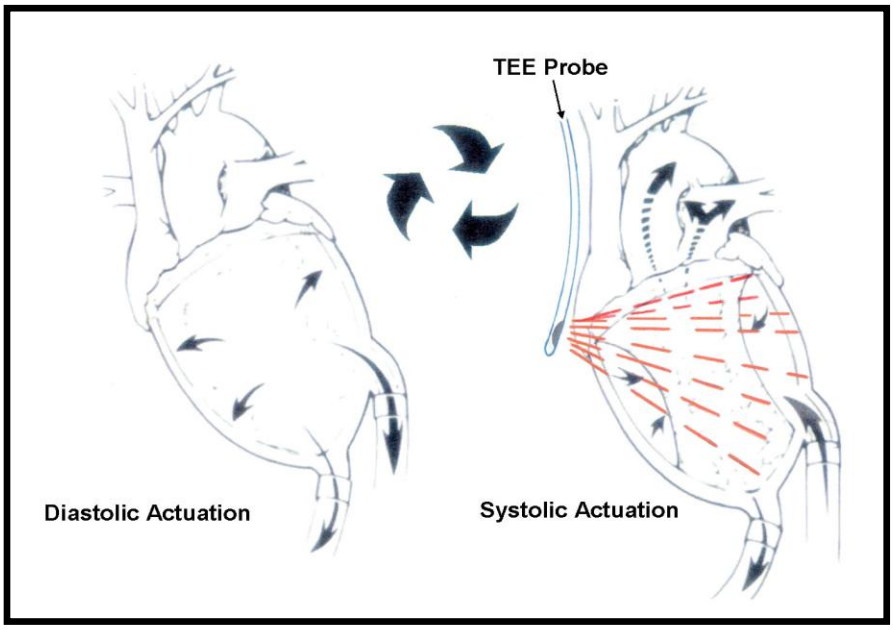
The rabbit model was the smallest animal model used for experimental DMVA support and was comparable to the human neonate with respect to hear size (see below):



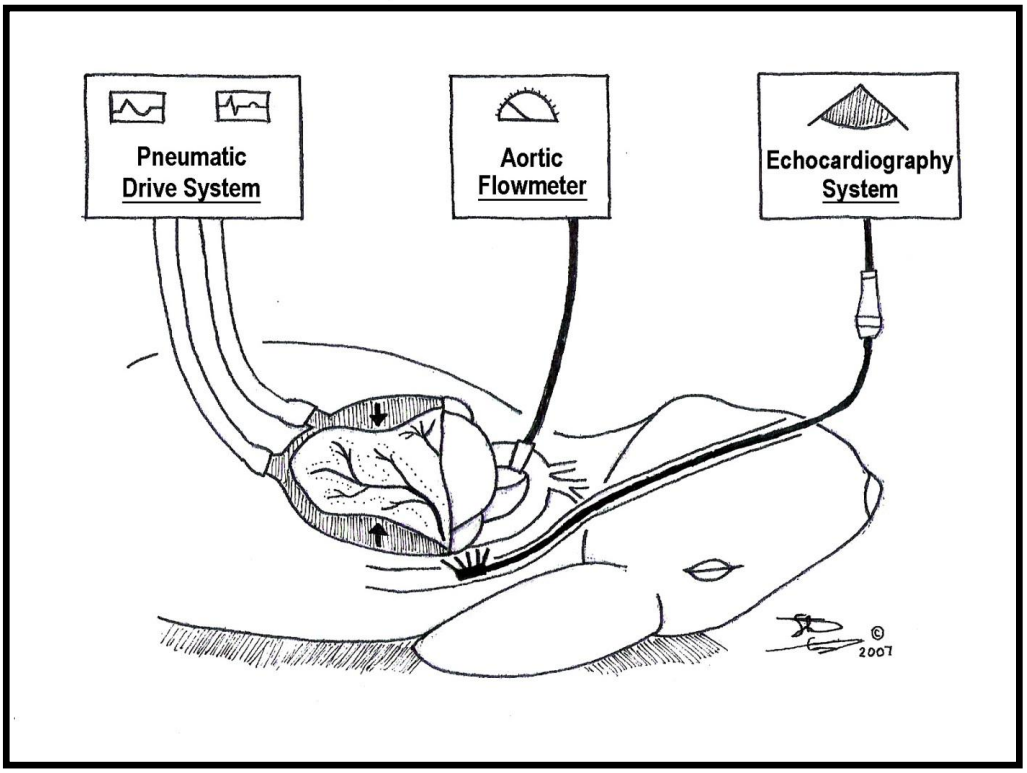
Using the rabbit model it was demonstrated that DMVA could support the failing heart with favorable effects on the myocardium with respect to cell signaling indicating a favorable impact on myocardial recovery (see results below):



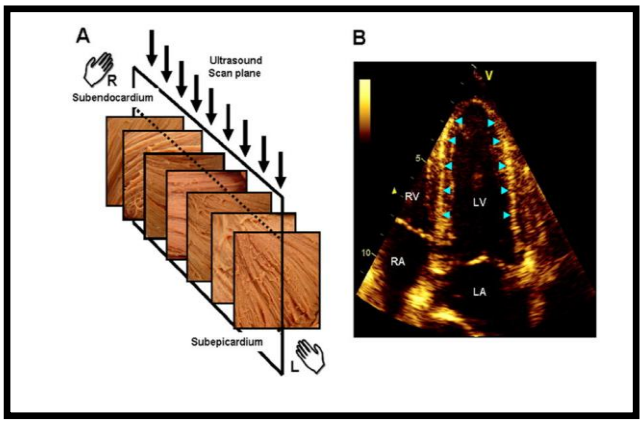
With the addition of echocardiographic, the functional aspects of how DMVA can effect myocardial contraction were enables. Transesophageal (TEE) and trans-venous ECHO imaging provided the windows for such interrogation (see below):



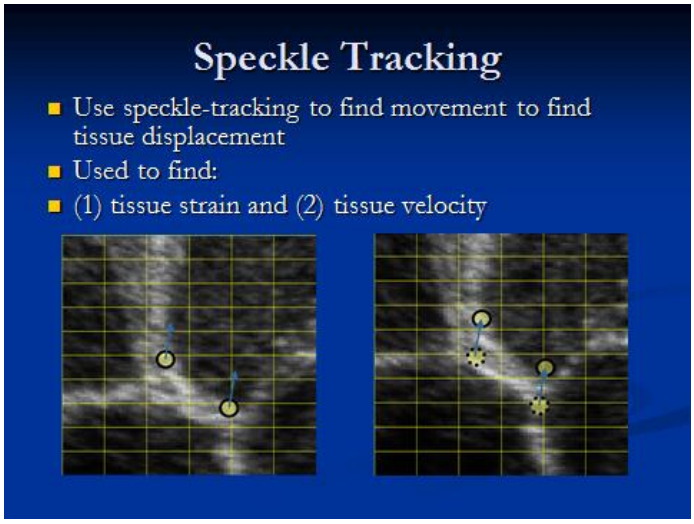
With ECHO analysis the complex manner in which myocardial contraction occurs can be characterized both graphically and with objective numeric analysis. The rabbit model was the first utilized to interrogate DMVA support of the failing heart (see below):



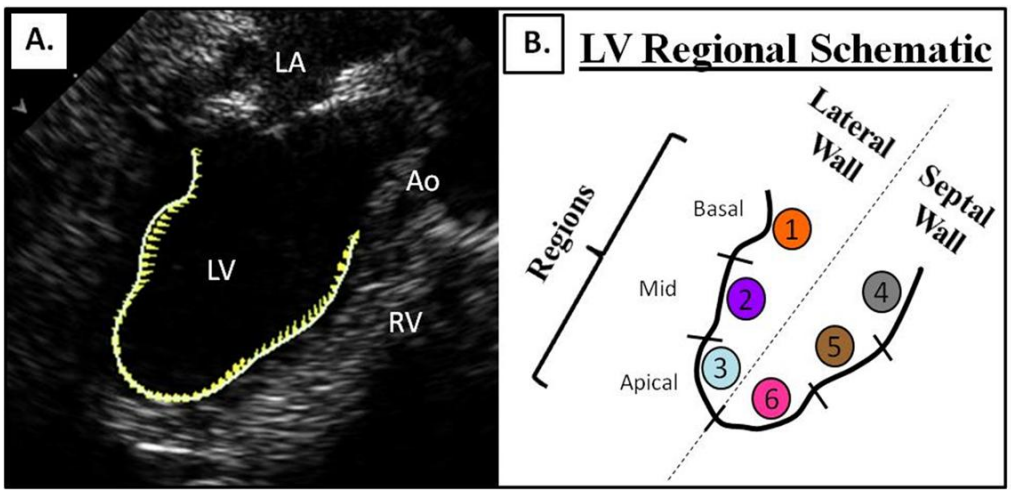
Speckle tracking using proprietary ECHO software enabled myocardial strain to be assessed in the heart before, during and after DMV support. Figure below illustrates how ultrasound imaging can visualize the myocardium to obtain strain imaging.



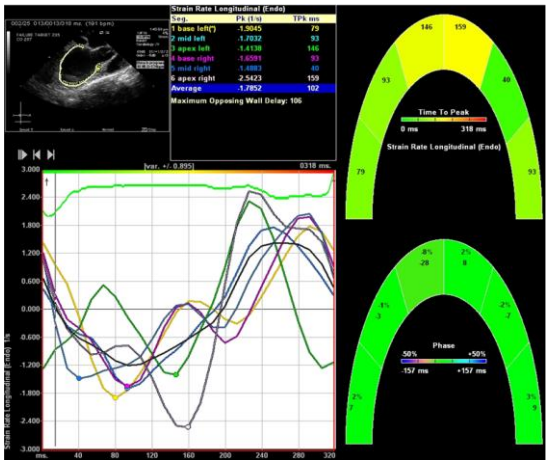
Once ECHO imaging is acquired, the technique of speckle tracking is utilized to calculate regional and global myocardial strain as depicted in the below diagram:



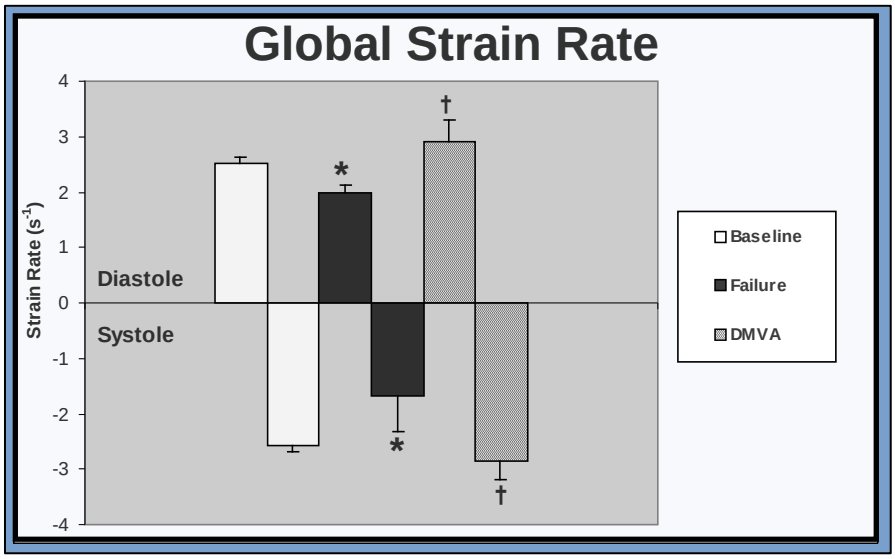
For studies carried out by our laboratory, the long axis of the left ventricle was interrogated using speckle tracking proprietary software. The left ventricle was divided into 6 regions to do analysis on both regional and global myocardial function as depicted below:



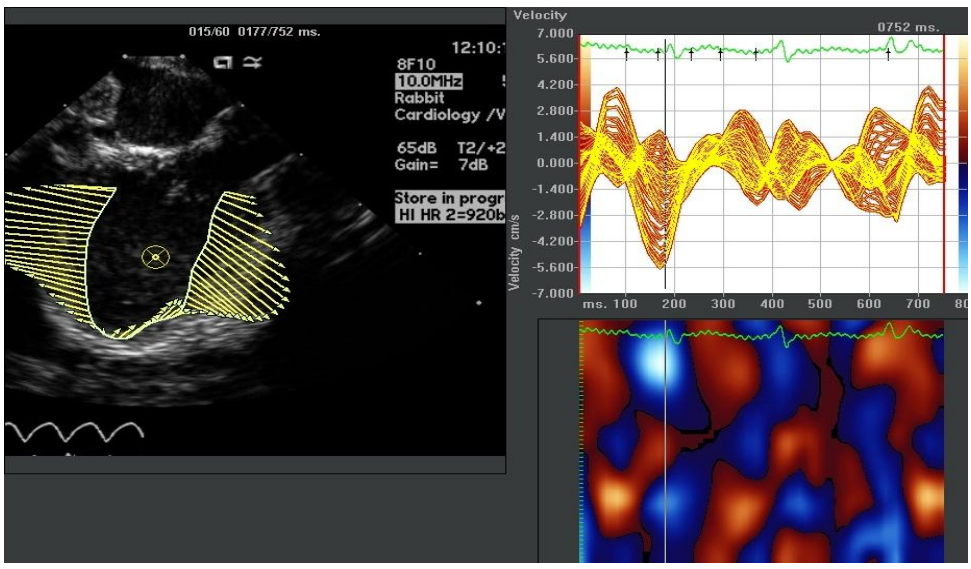
A snapshot of a representative ECHO strain image is shown below:



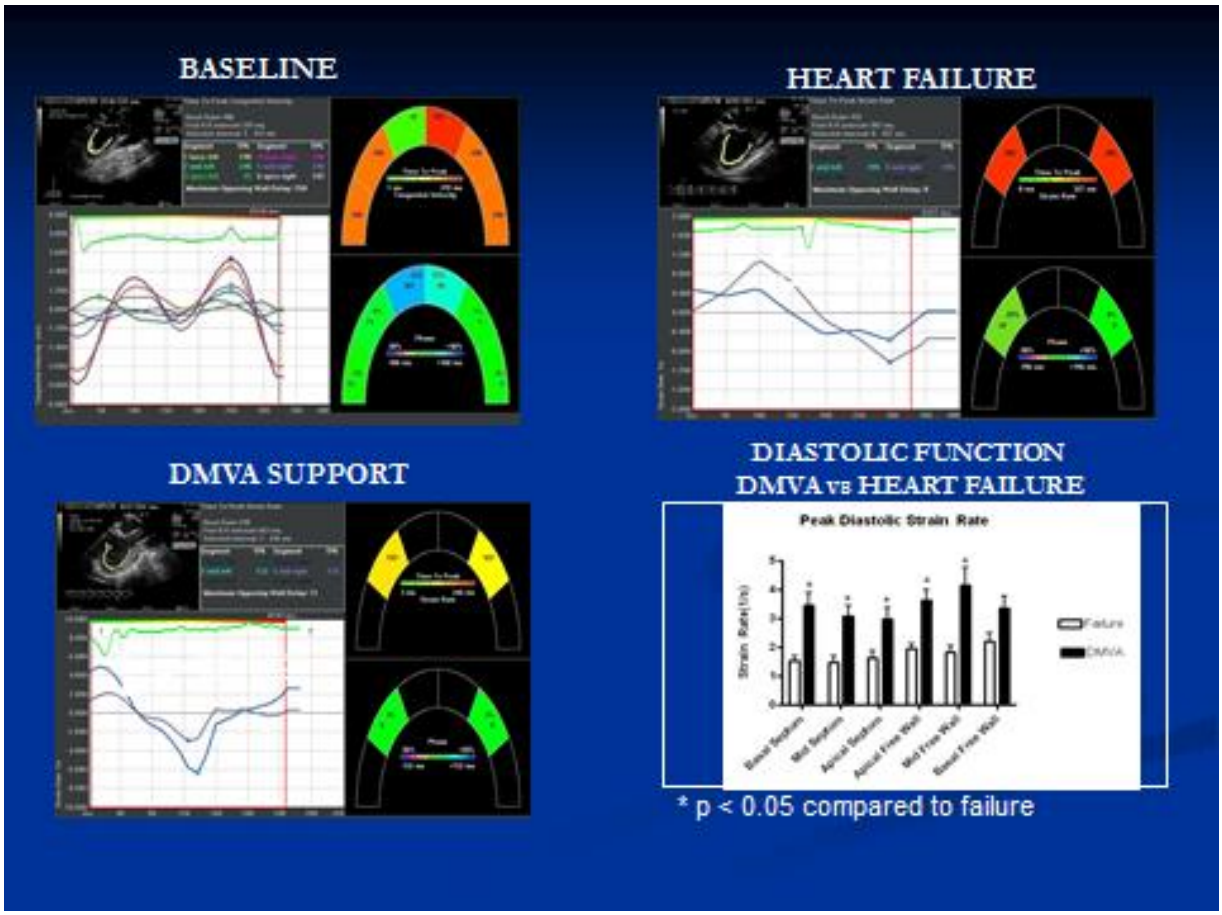
The data below compares global functions expressed as myocardial stain in rabbits during baseline, failure and subsequent DMVA support. Note DMVA returned both systolic and diastolic function to values greater than control.



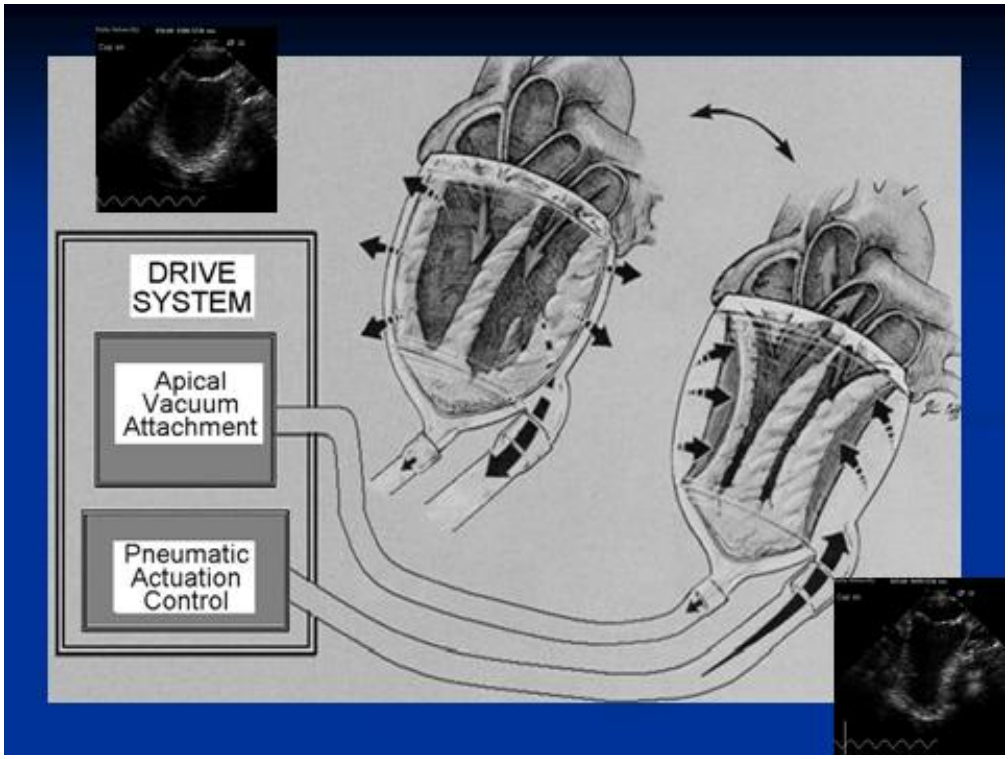
The augmentation of diastolic function, as depicted in the outward arrows of the snapshot below represent the unique capability of DMVA support compared to other DCC devices as explained earlier, see figure below:



The ability of DMVA to provide diastolic augmentation to the failing and arrested heart has now been demonstrated and published as shown below:



The use of ECHO to interrogate the heart during support with DMVA has been a primary means of analysis of DMVA drive functionality in the present project, (see below):



ECHO stain analysis has also demonstrated how DMVA not only improves myocardial function of the failing heart but also returns mechanical synchrony to a more normal state:

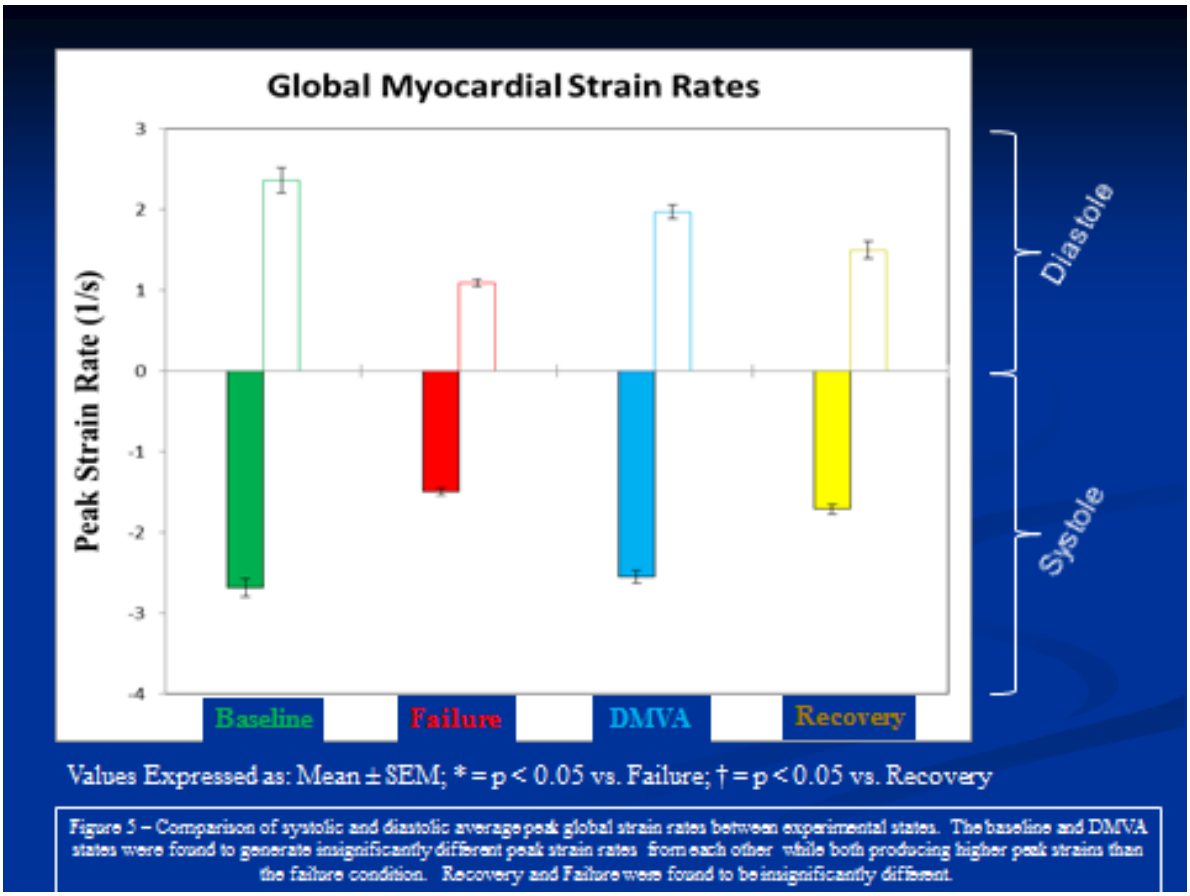


Figure 5 – Comparison of systolic and diastolic average peak global strain rates between experimental states. The baseline and DMVA states were found to generate insignificantly different peak strain rates from each other while both producing higher peak strains than the failure condition. Recovery and Failure were found to be insignificantly different.

The snapshots below demonstrate graphically how DMVA returning synchrony during failure:

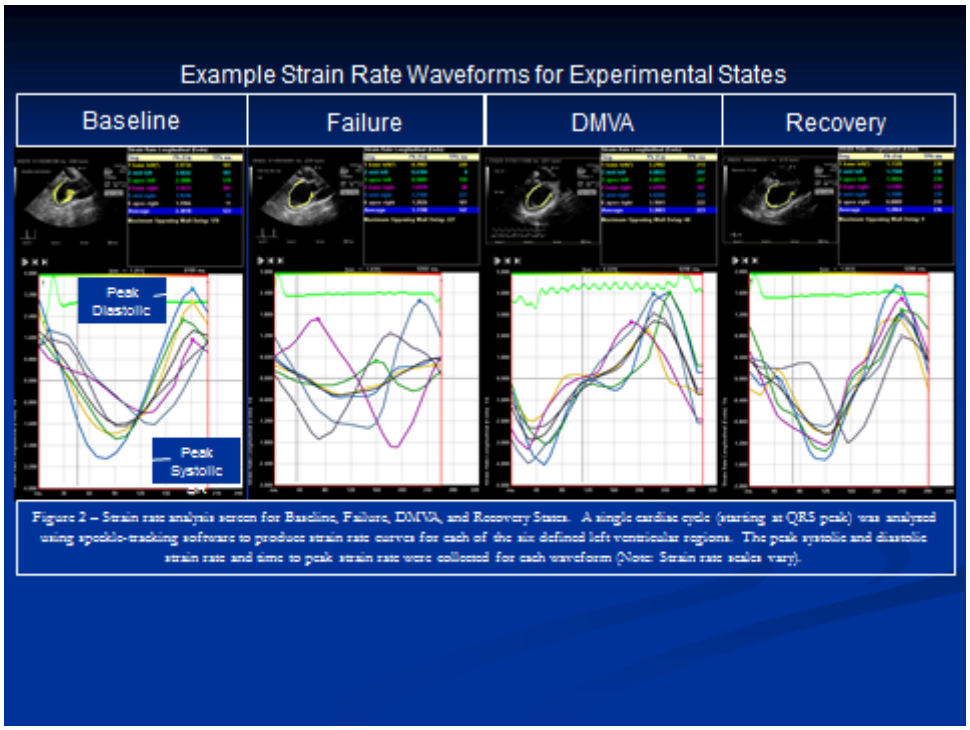
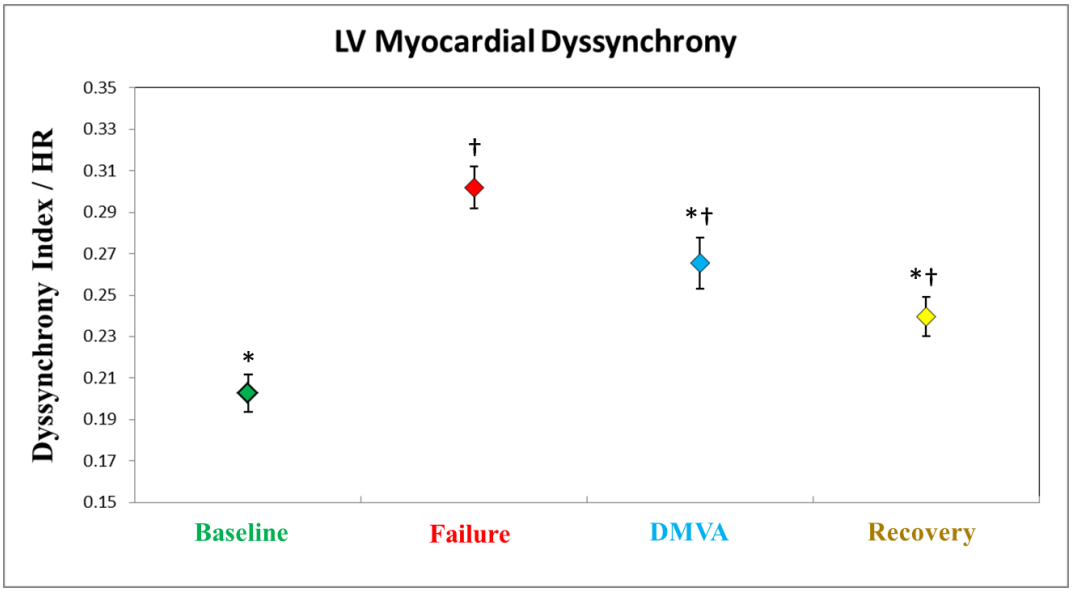
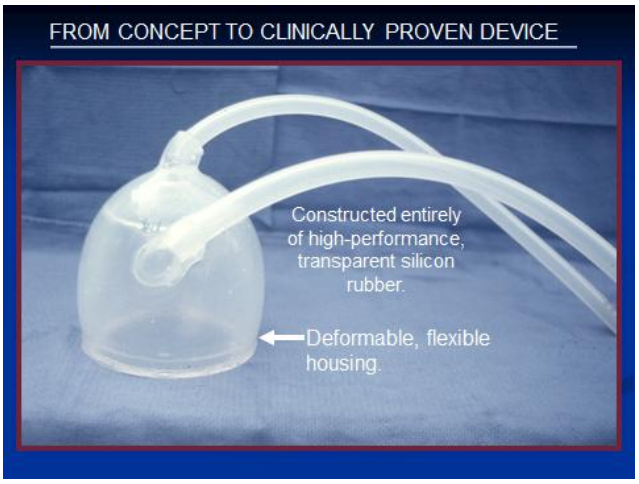


Figure 2 – Strain rate analysis screen for Baseline, Failure, DMVA, and Recovery States. A single cardiac cycle (starting at QRS peak) was analyzed using speckle-tracking software to produce strain rate curves for each of the six defined left ventricular regions. The peak systolic and diastolic strain rate and time to peak strain rate were collected for each waveform (Note: Strain rate scales vary).

The return of synchrony can be numerically depicted as show below:



These methods of analysis along with proven cup design (shown below) were utilized in this project:



5. CONCLUSION

This project successfully accomplished its intended goal of developing a device for rapid, effective, circulatory support for remote areas. The importance of this accomplishment is that DMVA can be made available to re-establish normal hemodynamics in patients suffering circulatory arrest in the field. The portable, compact, user-friendly DMVA drive system can be operated with minimal expertise. The AD can be utilized as a life-saving device by Military Medical Personnel in the field. A circulatory support for such application is otherwise not available to save soldiers or civilians outside the hospital environment. Reducing DMVA's operation to a user friendly, AD makes it more feasible for use in the hospital setting as well. Future goals will be to utilize the new prototype design in clinical trials to demonstrate efficacy for resuscitative circulatory support.

6. PUBLICATIONS, ABSTRACTS, and PRESENTATIONS

SCIENTIFIC PUBLICATIONS:

Anstadt MP, Budharaju S, Darner RJ, Schmitt BA, Prochaska LJ, Pothoulakis AJ, Portner PM. *Ventricular Actuation Improves Systolic and Diastolic Myocardial Function in the Small Failing Heart*, Annals Thorac Surg 2009;88:1982-8.

McConnell PI, **Anstadt MP**, del Rio CL, Preston T, Ueyama Y, Youngbood B. *Cardiac Function after Acute Support with Direct Mechanical Ventricular Actuation in Chronic Heart Failure. In PRESS: ASAIO 2014.*

ABSTRACTS/PRESENTATIONS:

Budharaju S, Pothoulakis AJ, Kerns SA, Schmitt B, Darner RJ, Prochaska LJ, Portner PM, **Anstadt MP**. *Direct Mechanical Ventricular Actuation Significantly Augments Left Ventricular Function In Failing Rabbit Heart Model*. Circ, 2008:118(18), suppl 2,12.

Anstadt MP, Kerns S, Wozniak CJ, Schmitt BA, Darner RJ, Budharaju S, Prochaska LJ. *Direct Mechanical Ventricular Actuation of the Acutely Failing Heart Attenuates Maladaptive Cell Signaling*. Circulation 2009;120:S1490.

Schmitt BA, Reynolds DB, Troche K, Gallimore JJ, Gargac SM, Darner RJ, and **Anstadt MP**. *Defining Power Specifications for Pediatric Direct Mechanical Ventricular Actuation Systems*. In: 2009 Biomedical Engineering Society Annual Meeting: October 7-10, 2009; Pittsburgh , PA.

Swartzmiller KM, Schmitt BA, Reynolds DB, Perez-Tamayo RA, Darner RJ, **Anstadt MP**. *A Simple Mock Circulatory System for Testing Direct Mechanical Ventricular Actuation.* In: 2010, Biomedical Engineering Society Annual Meeting, Oct 6-9, 2010; Austin, TX.

McConnell PI, Del Rio C, Preston T, Schmidt BA, Darner RJ, **Anstadt MP**. *Short-Term Support via Direct Mechanical Ventricular Actuation Improves Cardiac Function in Chronically Failing Hearts.* Accepted for presentation at Annual Meeting of the International Heart and Lung Society: 11/19/2010.

Swartzmiller KM, Schmitt BA, Reynolds DB, Perez-Tamayo RA, Darner RJ, **Anstadt, MP**. *A Simple Mock Circulatory System For Testing DMVA*. Presented at the 57th Annual Conference, ASAIO 2011:57(2) 115.

Schmitt BA, Swartzmiller KM, Reynolds DB, Darner RJ, Perez-Tamayo RA, **Anstadt MP**. *Pneumatic Drive Requirements for Direct Mechanical Ventricular Actuation*. Presented at the 57th Annual Conference, ASAIO 2011:57(2) 115.

McConnell PI, Del Rio C, Preston T, Schmidt BA, Darner RJ, **Anstadt MP**. *Short-Term Support Via Direct Mechanical Ventricular Actuation Improves Cardiac Function in Chronically Failing Hearts.* Journal of Heart and Lung Transplantation. April 2011:S49-S49.

Schmidt BA, Garvin NJ, Budharaju S, Reynolds DB, Darner RJ, Prochaska LJ, **Anstadt MP.** *Direct Ventricular Compression Improves Mechanical Synchrony of the Acutely Failing Heart. Circulation*. 2012. 126:A326.

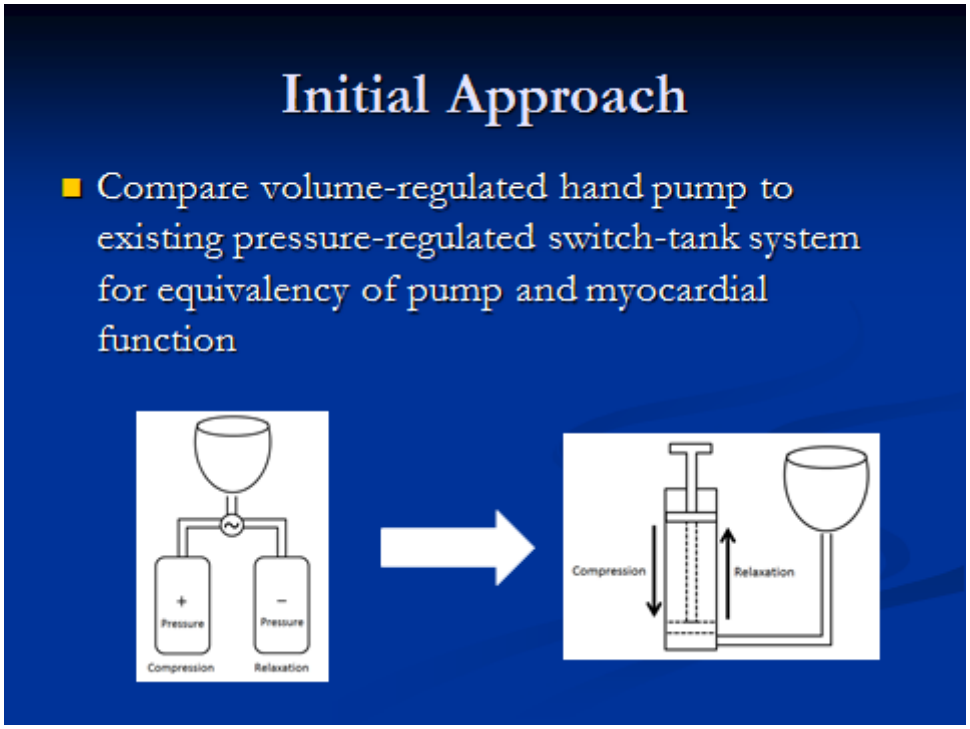
Metzger SA, Schmitt BA, Carnahan KT, Carver DE, Reynolds DB, **Anstadt MP**. *Novel Use of Ultrasound to Characterize Strain Rates in Mock Heart Ventricles*. Accepted for presentation at the 2013 Biomedical Engineering Society Annual Meeting, Seattle, Washington, September 25-28, 2013.

7. INVENTIONS, PATENTS, and LICENSES

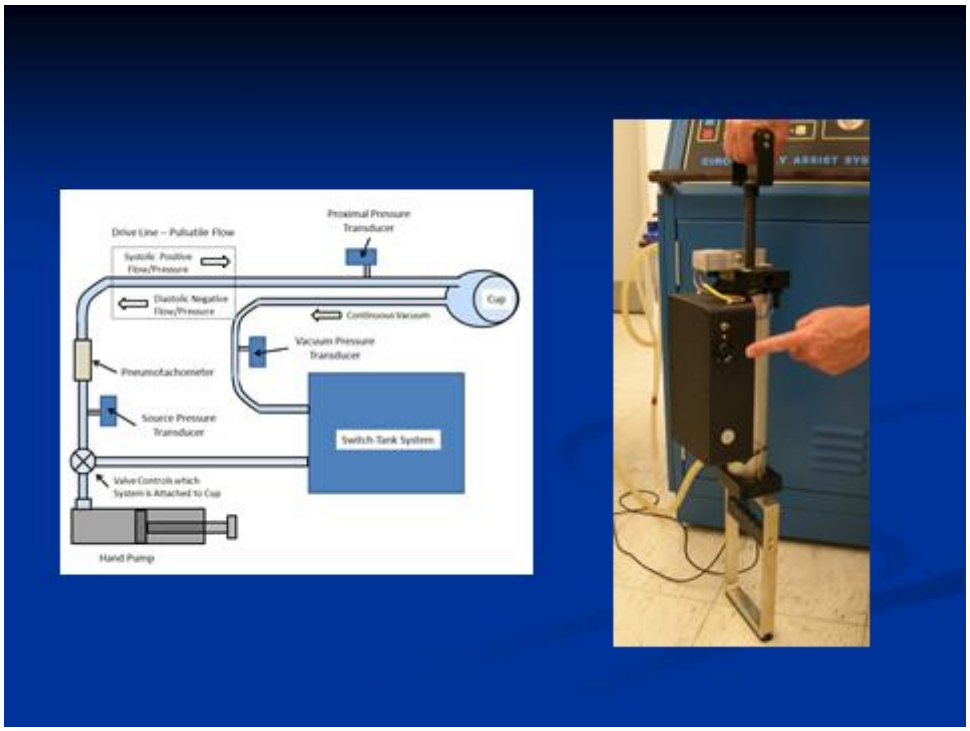
Nothing to report

8. REPORTABLE OUTCOMES

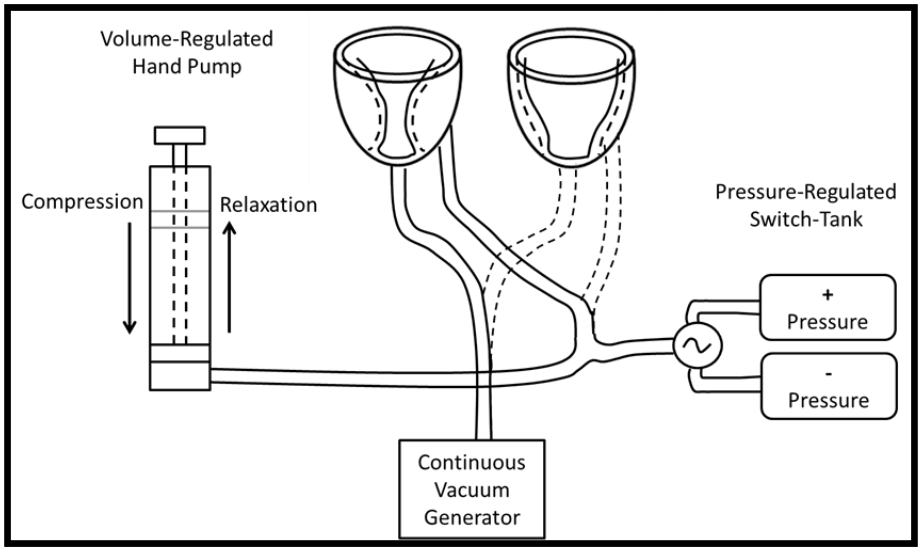
Given the understanding that a HP could achieve similar functionality as the ST drives, the project followed the below approach:



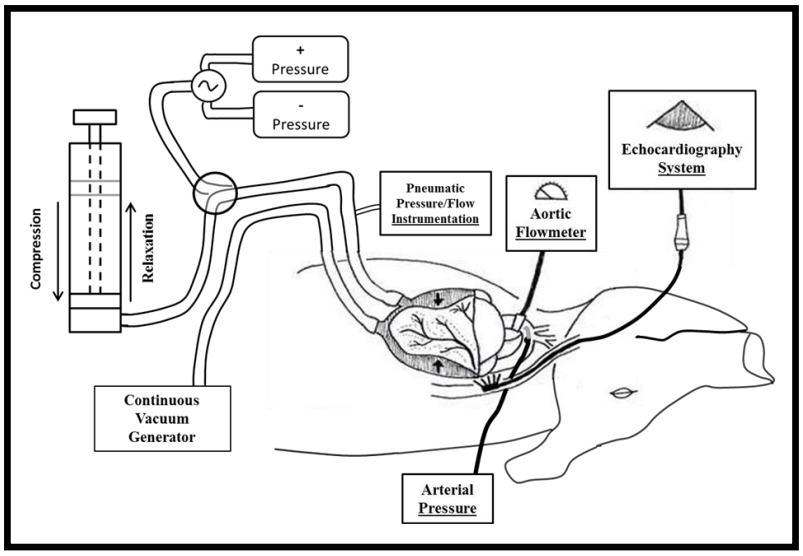
Data was acquired using the manually driven hand pump in comparison to ST system to identify optimal support dynamics.



Optimal dynamics during hand pump support were verified as similar to the optimal hemodynamics during ST support. Combined drive support analysis was used to set-up in-vivo testing.

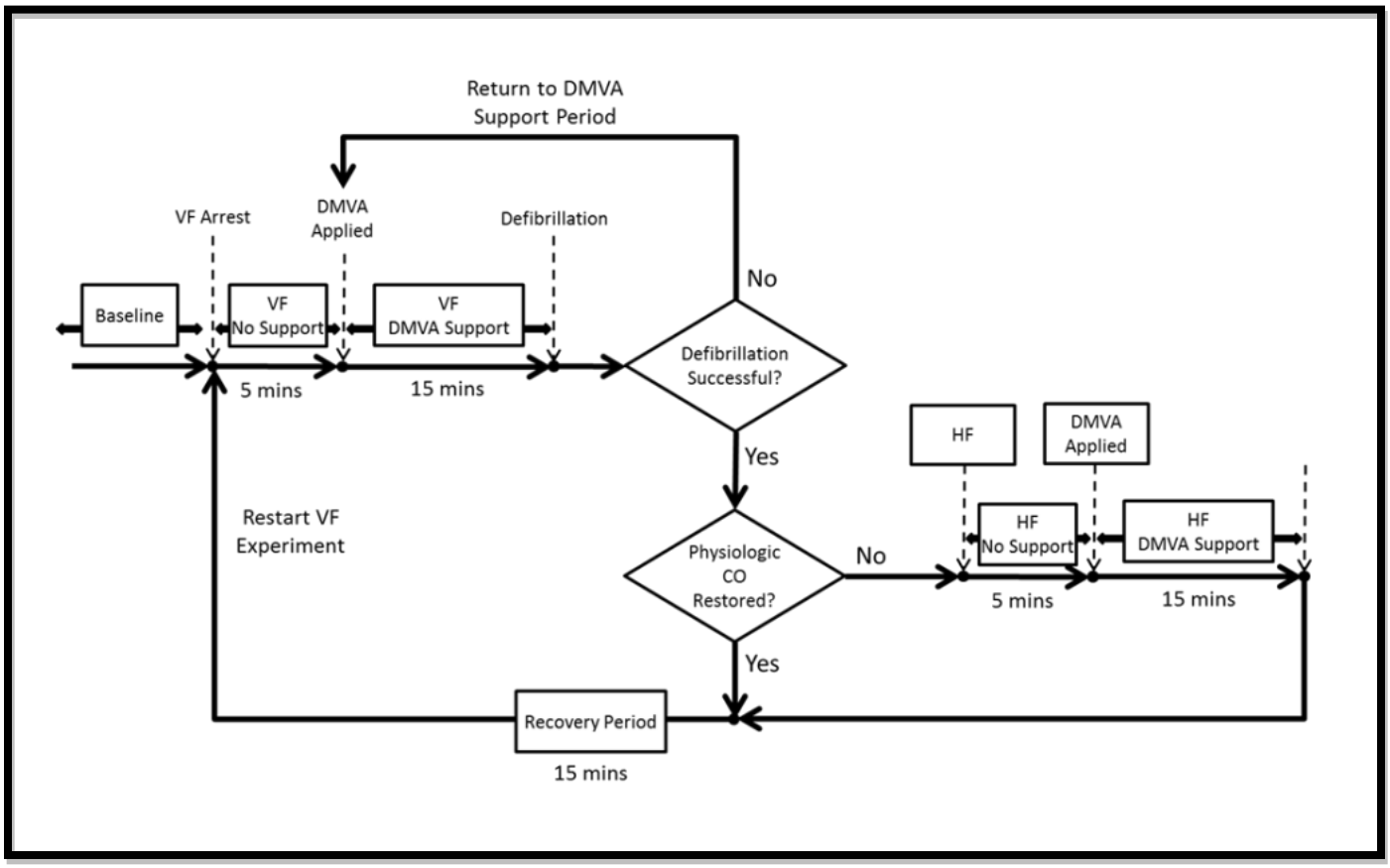


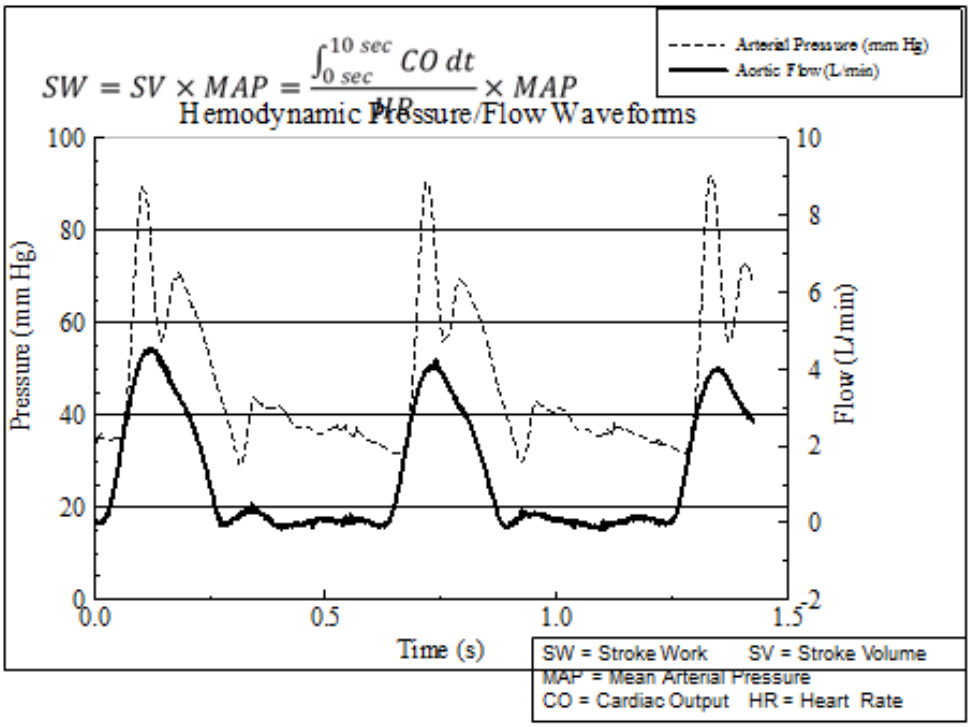
In-vivo testing used both large ovine and canine to represent clinically relevant heart sizes with the pig representative of an average adult heart:



The below support algorithm was utilized to obtain support data during periods of cardiac arrest as well as varied degrees of cardiac failure during the animal experiments.

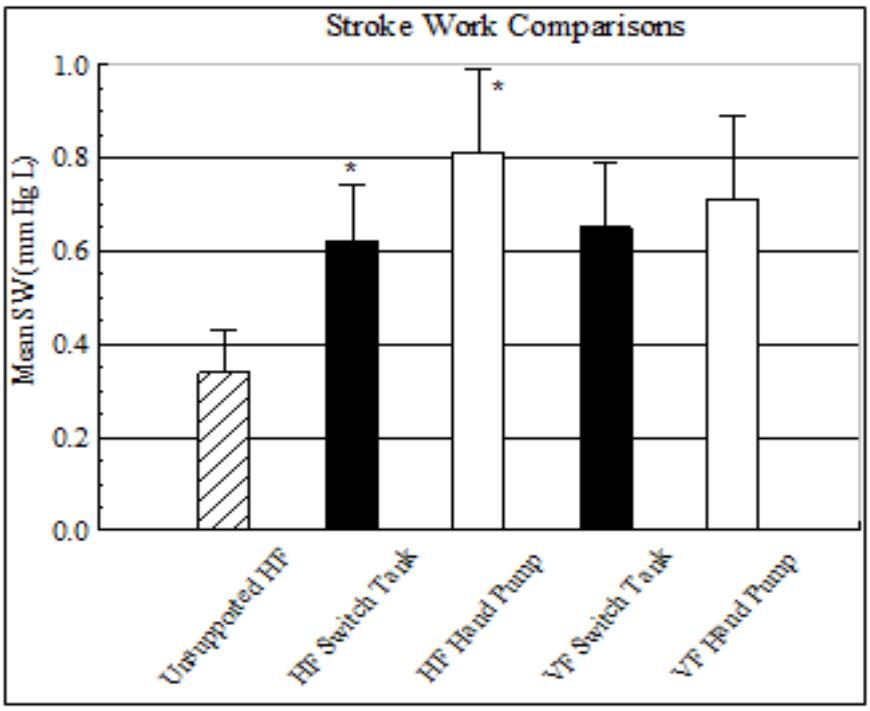
Data was collected on the custom data acquisition system to compare hemodynamics between different states of support and identify optimal drive characteristics of the HP.





Comparisons between hemodynamic states were compared during ideal settings with the ST system versus the HP indicating the HP resulted in equivalent, if not better hemodynamic results during support of either the fibrillating or failing heart.

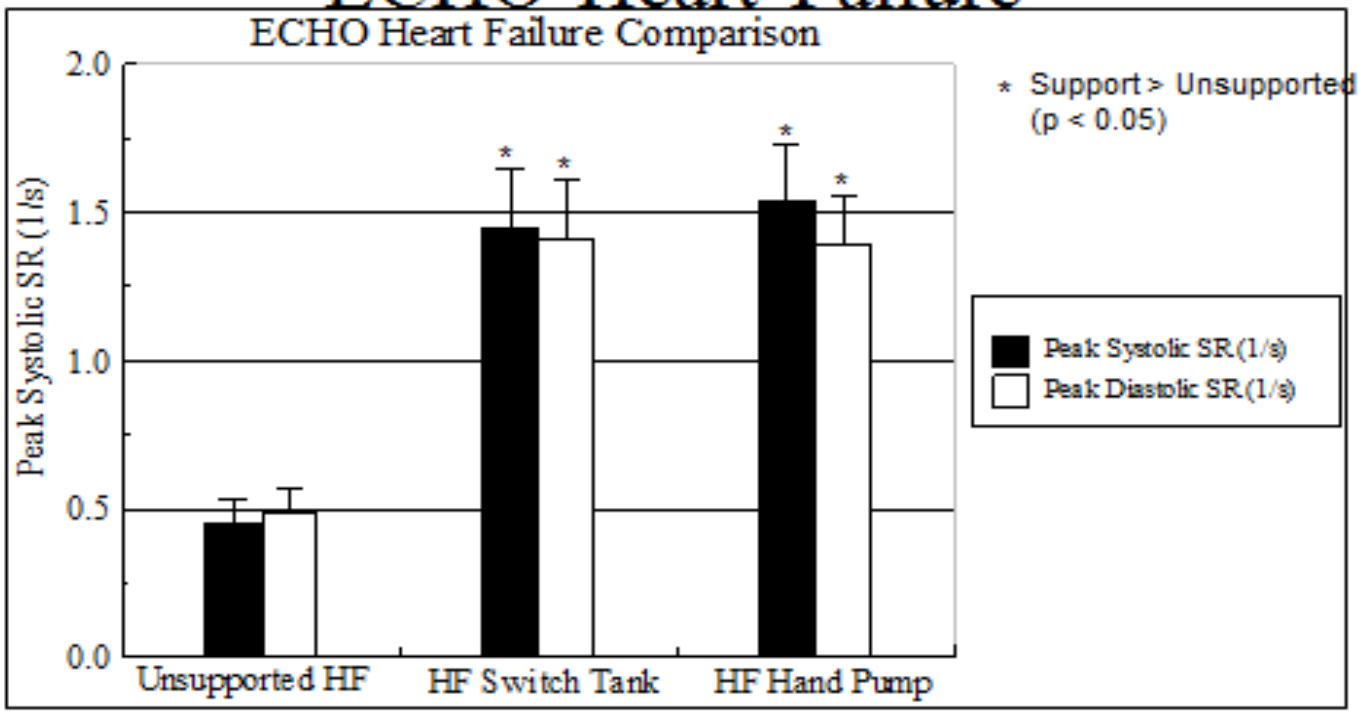
Stroke Work Calculations

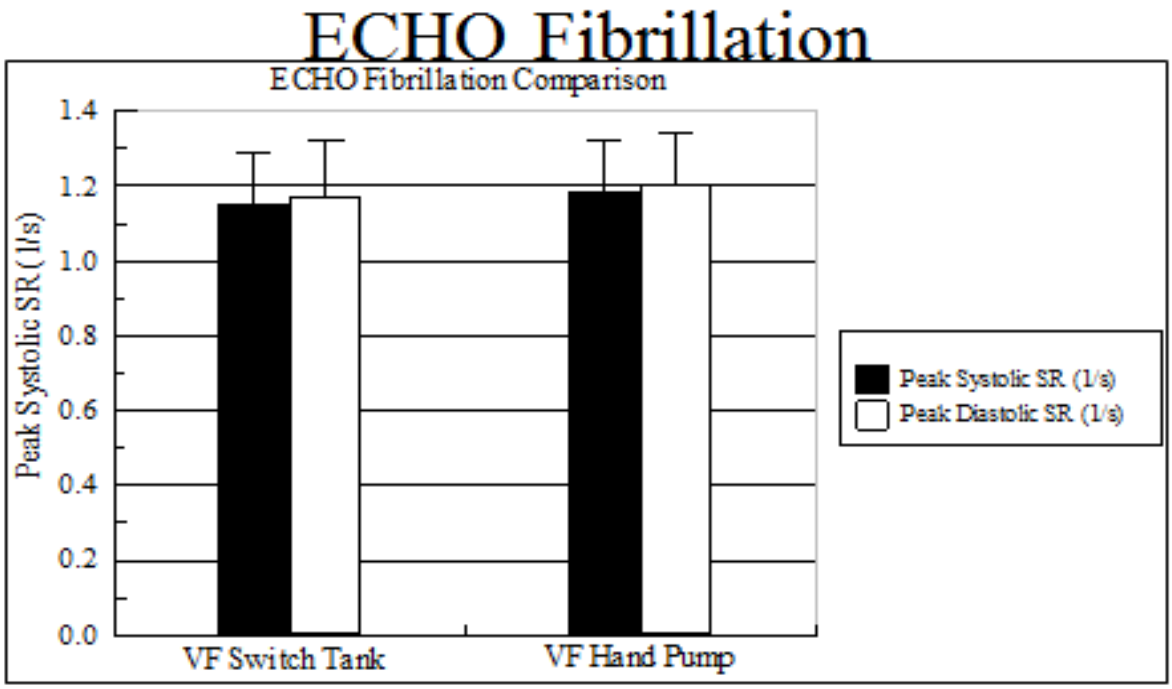


*HF Support > HF Unsupported
($p < 0.05$)

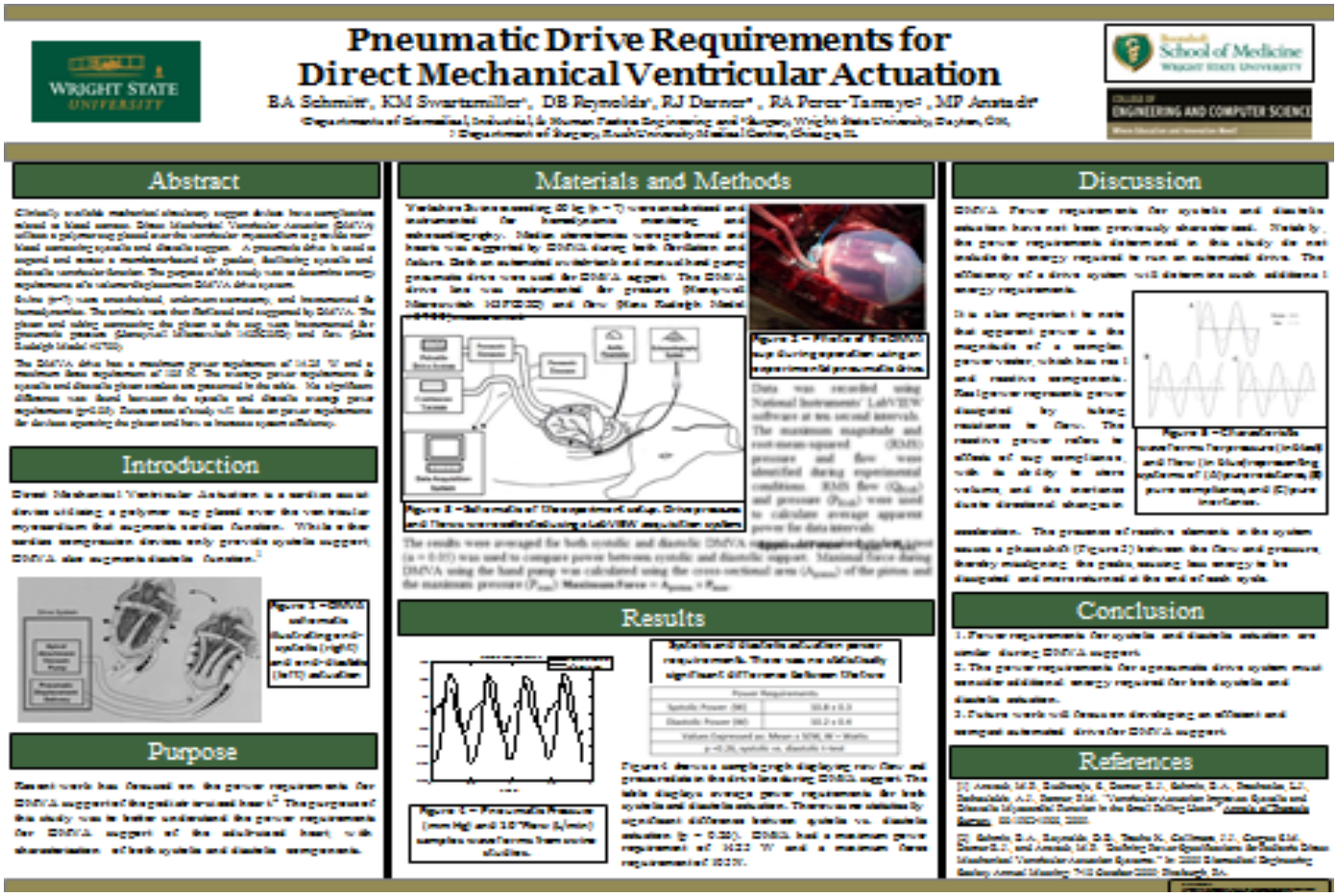
HF = Heart Failure
VF = Ventricular Fibrillation
SW = Stroke Work

ECHO Heart Failure

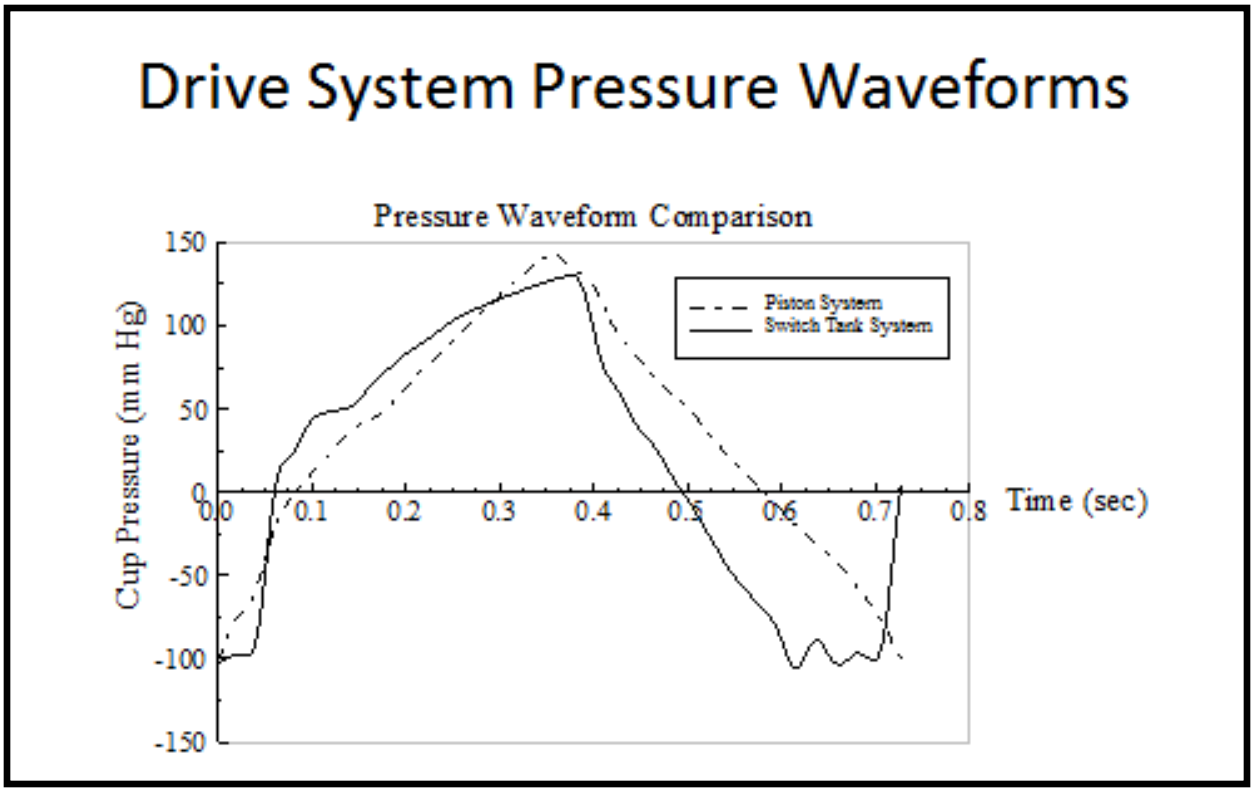




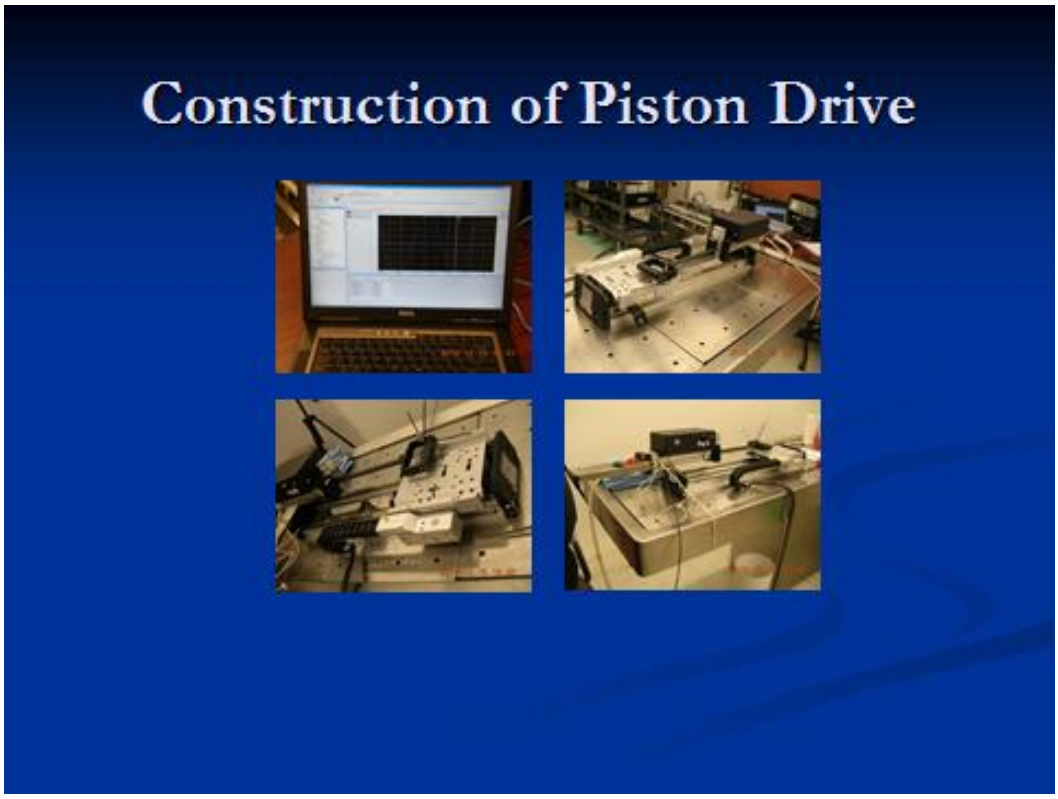
Requirements for powering the hand pump were thereby developed

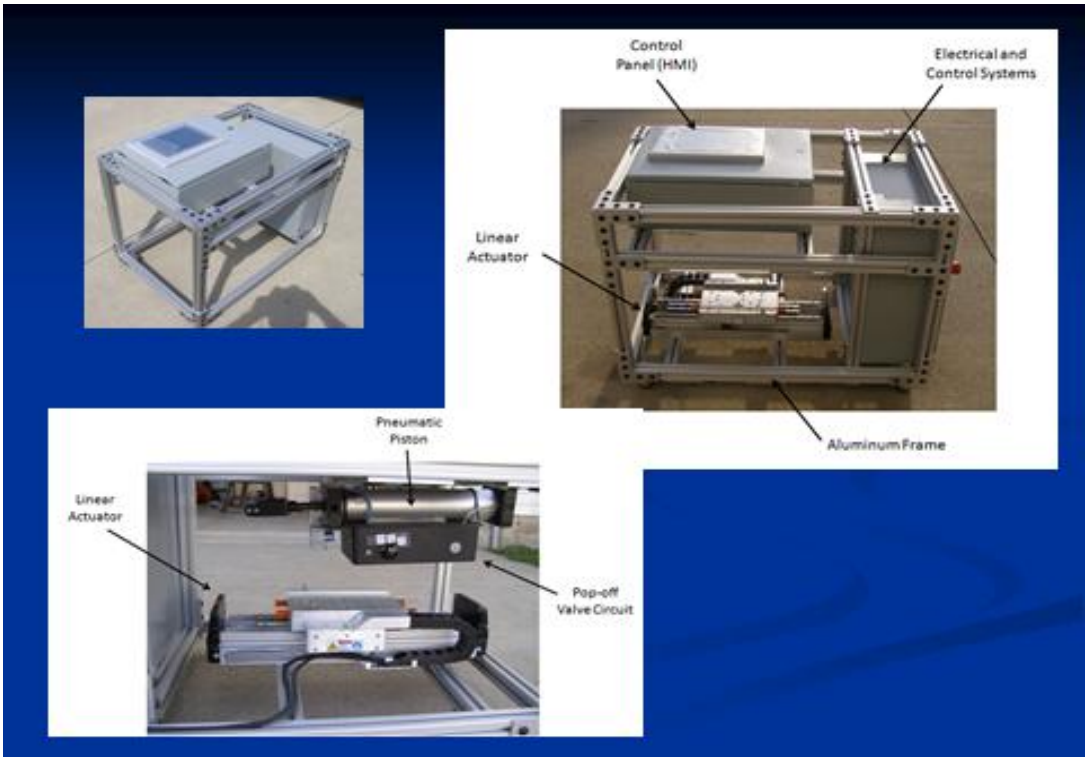


Proprietary interrogation of waveforms was also utilized for these exercises.



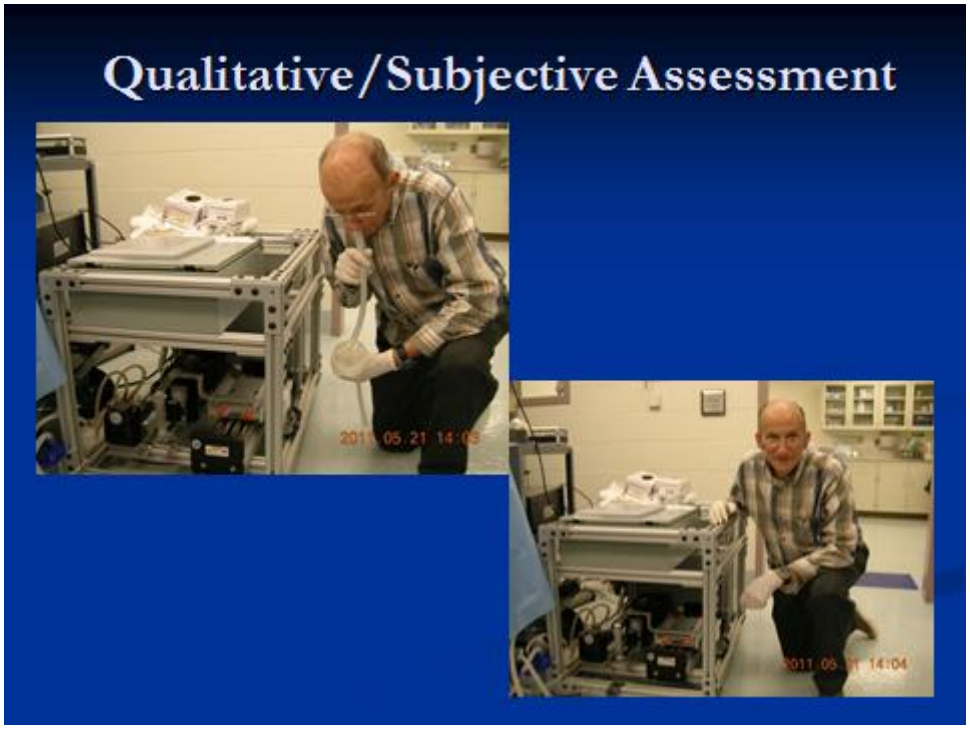
A linear actuator was selected for the first prototype drive:



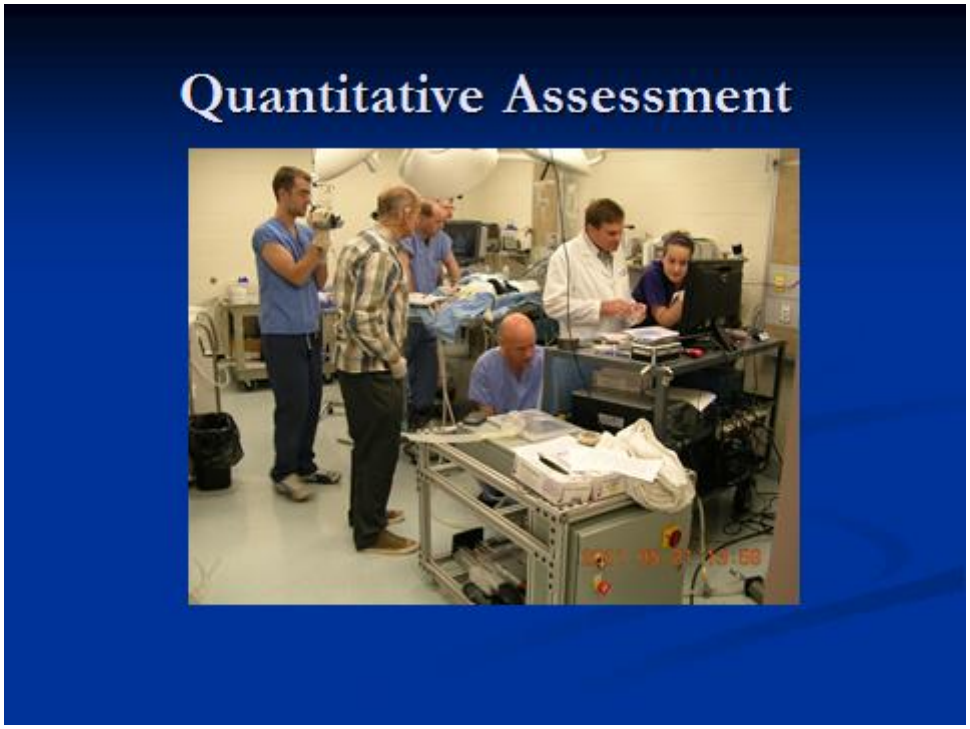


The initial system was housed along with all control components

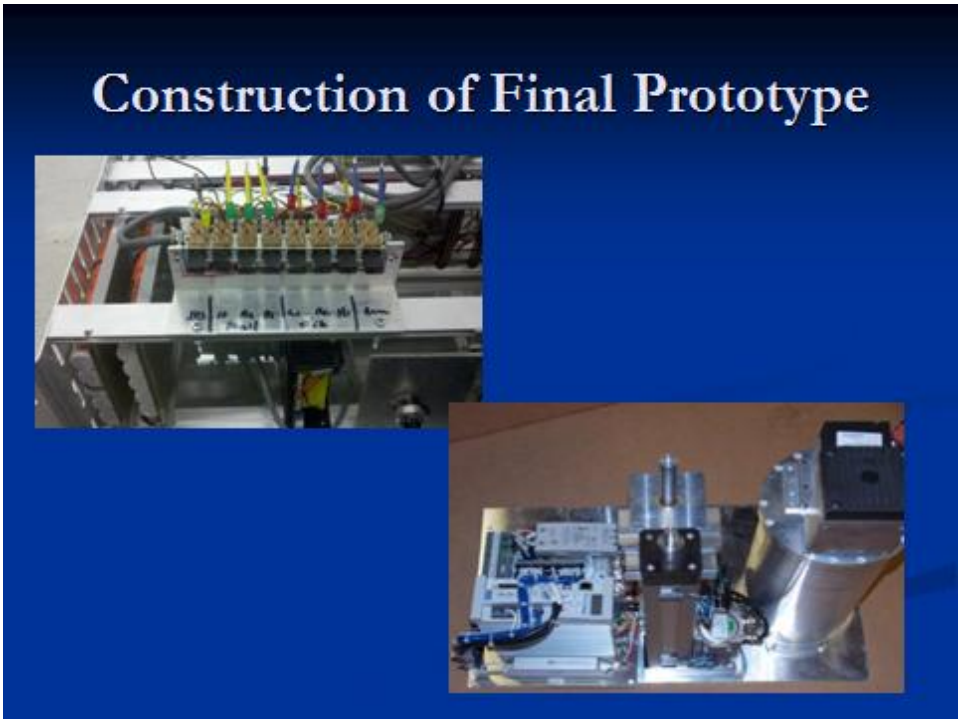
Dr. George L. Anstadt provided insight regarding quality control of all fabricated cups as well as additional verification pertaining to idealized support dynamics during the experiments.

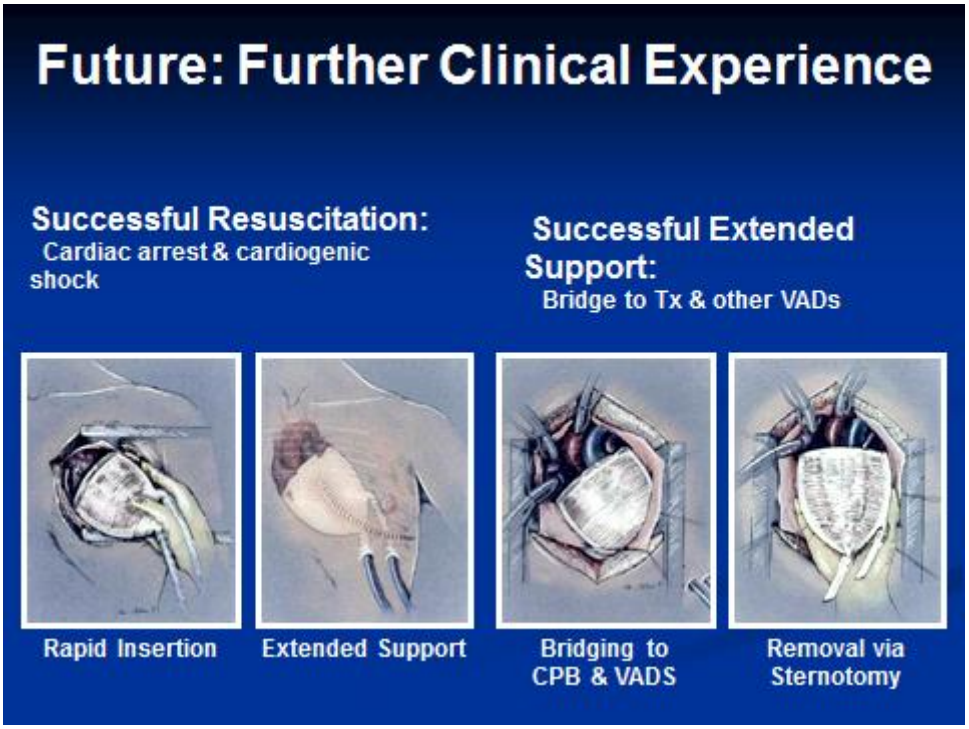


This included Dr. George L. Anstadt's oversight of device installation and optimal drive dynamics during animal experiments.



Data and performance assessments obtained from the initial prototype drive were analyzed to determine specifications for building the automated prototype drive:





9. OTHER ACHIEVEMENTS

Nothing to report.

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Lowe JE, **Anstadt MP**, Van Trigt P, Smith PK, Hendry PJ, Plunkett MD, Anstadt GL. First Successful Bridge to Cardiac Transplantation Using Direct Mechanical Ventricular Actuation. Annals of Thoracic Surgery 1991;52:1237-1245.

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Anstadt MP, Perez-Tamayo RA, Banit DM, Walthall HP, Cothran, RL, Abdel-aleem S, Anstadt GL, Jones PL, Lowe JE. Myocardial Tolerance to Mechanical Actuation is Affected by Biomaterial Characteristics. ASAIO J 1994;40:M329-334.

Perez-Tamayo RA, **Anstadt MP**, Cothran Jr, LC, Reisinger, RJ, Schenkman, DI, Hulette C, Reimer KA, Anstadt GL, Lowe JE. Prolonged Total Circulatory Support Using Direct Mechanical Ventricular Actuation. ASAIO J 1995;41:M512-517.

Idriss SF, **Anstadt MP**, Anstadt GL, Ideker RE: The Effect of Cardiac Compression on Defibrillation Efficacy and the Upper Limit of Vulnerability. J Cardio Electrophysiology 1995;6: 368-378.

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Anstadt MP, Schulte-Eistrup SA, Motomura T, Soltero E, Takano T, Mikati IA, Nonaka K, Joglar F, Nosé Y. Non-Blood Contacting Biventricular Support Synchronized to the Failing Heart. Ann Thor Surg 2002;73:556-562.

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McConnell PI, **Anstadt MP**, del Rio CL, Preston T, Ueyama Y, Youngbood B. *Cardiac Function after Acute Support with Direct Mechanical Ventricular Actuation in Chronic Heart Failure. In PRESS: ASAIO 2014.*

11. APPENDICES
CURRICULUM VITAE:

MARK P. ANSTADT, MD

Professor, Department of Surgery
Boonshoft School of Medicine, Wright State University
mark.anstadt@wright.edu

President, Miami Valley Heart & Lung Surgeons, LLC
30 E. Apple St., Suite 6252, Dayton, OH 45409
937.208.6060 o
937.208.6061 f
mpanstadt@aol.com

EDUCATION

The Pennsylvania State University State College, Pennsylvania	Animal Biosciences	B.S., 1982
Wright State University School of Medicine Dayton, Ohio	Medicine	M.D., 1986

POSTGRADUATE TRAINING

The Ohio State University Hospitals, Columbus, Ohio		
Intern	General Surgery	1986-1987
Resident	General Surgery	1987-1988
Duke University Medical Center, Durham, NC		
Research Fellow	Cardiothoracic Surgery	1988-1993
Resident	General Surgery	1993-1995
Chief Resident	General Surgery	1995-1996
Clinical Fellow	Cardiothoracic Surgery	1996-1997
Teaching Scholar	Cardiothoracic Surgery	1997-1998
Wright State University School of Graduate Studies	Healthcare Management Certificate	Jan -Dec 2013

CLINICAL APPOINTMENTS

Miami Valley Hospital	Vice- Chairman Department of Surgery	Jun 2014-Present
	Chairman, Section of Cardiothoracic Surgery	May 2007-June 2014
	Vice Chairman Section of Cardiothoracic Surgery	Jun 2004-May 2007
	Chairman Department of Surgery	Jun 2008-Jun 2010
	Vice Chairman Department of Surgery	Jun 2006-Jun 2008
	Medical Director Cardiothoracic Surgery	Dec 2004-April 2012
	Chief of Staff - Nominee	Jul 2011
Upper Valley Medical Center Troy, OH	Chief Cardiovascular & Thoracic Section	Jun 2008-Present
VA Medical Center Dayton, OH	Consultant - Thoracic Surgeon	Apr 2004-Present

The Medical College of Georgia, Augusta, GA

Section of Cardiothoracic Surgery	Chief	Jun 2002-Jul 2003
Thoracic Surgery Training Program	Director	May 2002-Aug 2003
	Associate Director	Jul 2000-May 2002

ACADEMIC APPOINTMENTS

Wright State University, Dayton, OH

Department of Surgery	Professor	Jul 2011-Present
	Associate Professor	Apr 2004-Jun 2011
Department of Pharmacology & Toxicology	Adjunct, Associate Professor	Apr 2006-Present
Department of Graduate Studies	Associate Graduate Faculty	Nov 2005-Present

The Medical College of Georgia, Augusta, GA

Department of Surgery	Assistant Professor	Jul 2000-Jun 2004
Department of Pharmacology & Toxicology	Assistant Professor	Dec 2001-Jun 2004
Vascular Biology Center	Associate Member	Jan 2001-Jun 2004

Baylor College of Medicine, Houston, TX

The Michael E. DeBakey Dept of Surgery	Assistant Professor	Jul 1998-Jul 2000

CERTIFICATIONS

Diplomat, The American Board of Surgery	Dec 1997
Recertification	Dec 2007
Diplomat, The American Board of Thoracic Surgery	Jun 1999
Recertification	Dec 2007

ACLS
ATLS
ATLS

MEDICAL LICENSURE

State of Ohio
State of NC
State of Georgia
State of Illinois

MILITARY SERVICE

U.S. Army Reserves Medical Corps — Mar 1987-Present
Colonel, 4005th U.S. Army Hospital, Houston, TX

PROFESSIONAL MEMBERSHIP

American Medical Association	1984-Present
American Society for Artificial Internal Organs	1986-Present
FACS, American College of Surgeons	1997-Present
David C. Sabiston, Surgical Society	1998-Present
Michael E. DeBakey International Surgical Society	1999-Present
Society of Thoracic Surgeons	1999-Present
American College of Surgeons Oncology Group	2000-Present
Southern Thoracic Surgical Association	2002-Present
FACCP, American College of CHEST Physicians	2002-Present
American Thoracic Society	2003-Present
American Heart Association	2005-Present

PATENTS

Sensor-Equipped and Algorithm-Controlled Direct Mechanical Ventricular Assist Device
Issued: Oct 2008

Method and Appatus for Minimally Invasive Direct Mechancial Ventricular Acutation
Issued: Jun 2010

GRANTS & AWARDS

American Heart Association, Miami Valley Chapter — May 1985-May 1986
Research Grant Investigating DMVA during Ischemic Reperfusion

Wright State University School of Medicine Research Grant — Apr 1985
An Evaluation of DMVA on Myocardial Infarct Size in an Occlusion-Reperfusion Model

Wright State University School of Medicine — Sep 1985
Golden Speculum Award for Excellence in Obstetrics & Gynecology

Wright State University School of Medicine — Jun 1986
Upjohn Achievement Award

The Ohio State University School of Medicine — Jun 1988
House Staff Teaching Award

NIH, National Research Service Award — Aug 1988-Aug 1990
Investigating Mechanical Actuation of the Heart

The American Society for Artificial Internal Organs — May 1989
Travel Fellowship Award

McGill University — Oct 1990
Heward Visiting Scientist Fellowship

Nippon Zeon Research Grant — Jan 1991
Investigating DMVA: Perfusion during Regional Myocardial Ischemia and Reperfusion

Upjohn Research Grant — Apr 1991
Investigation Lazaroids for Resuscitation

NIH, Cardiovascular Research Grant — Jul 1991-Jul 1993
Investigating Mechanical Actuation of the Heart: Laboratory and Clinical Studies,

Collaborating Investigator, NIH Project Grant — Jul 1992-Jul 1995
Non-Blood Contacting Biventricular Support Co-PI, American

Diabetes Association Research Award — Jul 1999-Jun 2002
Role of Endotheilin-1 Activation in Vascular Complications of Diabetes

PI, Medical College of Georgia Research Award — Oct 2001-Jun 2003
Endothelin Activation in Coronary Artery Grafting Surgery,
Co-PI, ONS Foundation Grant Research Award — Oct 2002-Sep 2003
Symptoms of Post Surgical Patients with Lung Cancer,
Co-PI, American Diabetes Association Research Award — Jan 2003-Dec 2005
Endothelin-1 and Vascular Mediated Remodeling in Diabetes,
PI, Research & Development Funding, Myotech, LLC — Jun 2004-Oct 2008
Developing Small Animal Models,
Outstanding Alumni Award — Feb 7, 2009
Boonshoft School of Medicine, Wright State University, Dayton, OH
PI, DOD Contract No. W81XWH-08-1-0484 — May 2009-Jun 2013
New Heart Failure Treatment Capability for Remote Environments,

RECENT COMMITTEE ACTIVITY

Miami Valley Hospital	Cancer Committee	2011-Present
	WSU Dept Surgery, Research Committee	2009-Present
	Medical Staff Executive Committee	2008-2010
	Endoscopy Committee	2008-Present
	Operating Room Committee	2007-Present
	Endovascular Stent Committee	2006-Present
	Trauma Committee	2006-Present

INDUSTRY RELATED ACTIVITIES

Consultant - SMEC, Inc., Cookeville, TN — 1976-1982
Intra-aortic Balloon Pump & Internal Defibrillator R&D and Fabrication
Consultant - Applied Sciences Inc, Dayton, OH — 1982-1988
Medical Devices; R&D
Vice President - Advanced Resuscitation Innovations, Inc, Dayton, OH — 1992-1996
Medical Devices/R&D
Chair, Industry Speaks Session — 1992-1993
Cups, Sacs, Spinners, and Rollers--Simpler Methods of Circulatory Support, 39th Annual Meeting of ASAIO
Consultant - Williamson Advisors Inc, Atlanta, GA — 1994-2003
Medical Products Ventures
Consultant & Member Board of Directors - Cardio Technologies Inc, New York, NY — 1996- 2000
DMVA R&D
Medical Director, Consultant & Member Board of Directors - Myotech, Pittsford, NY — 2003-2008
DMVA R&D
President - LifeBridge Technologies, LLC, Pittsford, NY — 2008-Present
DMVA R&D

CHAPTERS

Anstadt MP: Cardiac Assist Devices and the Artificial Heart. In ESSENTIALS OF SURGERY, Sabiston & Lyerly (eds) Second Edition: 738-746, 1994.

Anstadt MP, Lowe JE: The Coronary Circulation: Surgical Management of Coronary Artery Disease: Assisted Circulation, In SURGERY OF THE CHEST, Sixth Edition, Sabiston & Spencer (eds): 1995-2017, 1995.

Anstadt MP, Perez-Tamayo RA, Lowe JE, Anstadt GL: Recent Progress Using the Anstadt Cup for Direct Mechanical Ventricular `Actuation, In ASSISTED CIRCULATION 4, Felix Unger (ed): 394-408, 1995.

Anstadt MP, Newman MF: Use of the Intra-aortic Balloon Pump for Post-Cardiotomy Support. In INTRA-AORTIC BALLOON PUMP THERAPY, Maccioli (ed): 107-125, 1996.

Lucas WA, **Anstadt MP**: Triggering and Timing of the Intra-aortic Balloon Pump. In INTRA-AORTIC BALLOON PUMP THERAPY, Maccioli (ed): 57-68 1996.

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Anstadt GL, Schiff P, **Anstadt MP**. Umbrella Balloon for Maximum Unloading During Intra-Aortic Balloon Pumping. Trans Am Soc Artif Intern Organs 1981;27:461- 466.

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Hendry PJ, Packer DL, **Anstadt MP**, Plunkett MD, Lowe JE. Surgical Treatment of Automatic Atrial Tachycardia. Presented at the 25th Anniversary Meeting of the Society of Thoracic Surgeons, Baltimore, MD, Annals of Thoracic Surgery 1990;49:253-260.

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Hendry PJ, **Anstadt MP**, Plunkett MD, Pacifico AD, Jr., Mikat EM, Menius JA, Jr., Lowe JE. The Optimal Temperature for Preservation of Donor Myocardium. Circulation 1990;82(5):IV-306-312.

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Amato MT, Hendry PJ, **Anstadt MP**, Plunkett MD, Taber JE, Lowe JE. Effects of Amiodarone Versus Dobutamine on Subsequent Tolerance to Global Myocardial Ischemia. Surgical Forum XLII, peripheral pulses are equal and adequate throughout, no significant JVD or edema 1991;253-254.

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Thirty-third Annual Meeting, American Association for Artificial Internal Organs, May 1987: *Direct Mechanical Ventricular Assistance Promotes Salvage of Ischemic Myocardium.*

The Society of Thoracic Surgeons, Special Topics in Circulatory Support, Feb. 1988: *Bridge to Cardiac Transplantation Using Prosthetic Biventricular Circulatory Support.*

The 30th Annual University Surgical Residents Conference, The Society of University Surgeons, Feb. 1988*: Angiographic Evaluation of Direct Mechanical Ventricular Assistance.*

Annual Meeting, University Association of Emergency Medicine, May 1988: *Myocardial Hemodynamics Using Direct Mechanical Ventricular Assistance During Ventricular Fibrillation.*

Twenty-fifth Annual Spring Cardiovascular Symposium, Duke University Medical Center, April 1989: *Comparison of Direct Mechanical Ventricular Actuation (DMVA) and Cardiopulmonary Bypass (CPB).*

Thirty-fifth Annual Meeting, American Association for Artificial Internal Organs, May 1989: *Comparisons of Direct Mechanical Ventricular Actuation (DMVA) and Cardiopulmonary Bypass (CPB).*

Annual Meeting, University Association of Emergency Medicine, May 1989: *Mechanical Ventricular Assistance Following Fifteen Minutes of Ventricular Fibrillation in a Swine Model.*

62nd Scientific Sessions of American Heart Association, October 1989: *Resuscitation in Humans Using Direct Mechanical Cardiac Actuation.*

62nd Scientific Sessions of American Heart Association, October 1989: *Biventricular Mechanical Cardiac Actuation in Humans.*

31st Annual Meeting of the Society of University Surgeons, Feb. 1990: *Mechanical Cardiac Actuation Achieves Hemodynamics Similar to CPB.*

111th Annual Meeting of the American Surgical Association, April 13, 1991: *Pulsatile Reperfusion Following Cerebral Ischemia Improves Neurologic Outcome.*

37th Annual Meeting of the American Society for Artificial Internal Organs, Chicago, Illinois, April 1991: *Biventricular Cardiac Assist vs. Cardiopulmonary Bypass (CPB) for Resuscitation.*

37th Annual Meeting of the American Society for Artificial Internal Organs, Chicago, Illinois, April 1991: *Lack of Myocardial Trauma Following Acute Biventricular Cardiac Actuation for Resuscitation.*

Third Annual Meeting: The Robert M. Zollinger Ohio State University Surgical Society, May 3-4, 1991: *Direct Mechanical Ventricular Actuation (DMVA) Improves Outcome Following Cardiac Arrest Compared to Cardiopulmonary Bypass.*

Circulatory Support 1991, The Society of Thoracic Surgeons, Nov. 15-17, 1991: *State of the Art Session on Direct Mechanical Ventricular Actuation for Resuscitation.*

Circulatory Support 1991, The Society of Thoracic Surgeons, Nov. 15-17, 1991*: Centrifugal Pump Circulatory Support Following Cardiac Surgery.*

Cardiovascular Science and Technology Conference, December 2-4, 1991*: Investigating Mechanical Actuation of the Heart for Non-Blood Contacting Circulatory Support.*

41st Annual Scientific Session of the American College of Cardiology, Dallas, Texas, and April 12-16, 1992: *Thermodilution Techniques Erroneously Predict Flow Alterations during Cardiac Failure.*

38th Annual Meeting of the American Society for Artificial Internal Organs, Nashville, Tennessee, May 7-9, 1992: *Intraoperative Timing Predicts Thresholds for Assist Device Utilization.*

38th Annual Meeting of the American Society for Artificial Internal Organs, Nashville, Tennessee, May 7-9, 1992: *Clinical Results Using Direct Mechanical Ventricular Actuation.*

38th Annual Meeting of the American Society for Artificial Internal Organs, Nashville, Tennessee, May 7-9, 1992: *Ischemic Preconditioning Results from Severe Global Myocardial Ischemia.*

38th Annual Meeting of the American Society for Artificial Internal Organs, Nashville, Tennessee, May 7-9, 1992: *Pulsatile vs. Non-pulsatile Flow: Hemodynamic and Organ Perfusion during Resuscitative Circulatory Support.*

21st Scientific Symposium of the Society of Critical Care Medicine, San Antonio, Texas, May 25-29, 1992: *Myocardial Function Following Successful Cardiac Resuscitation with Mechanical Circulatory Support.*

21st Scientific Symposium of the Society of Critical Care Medicine, San Antonio, Texas, May 25-29, 1992: *Acute Myocardial Reperfusion Using Direct Mechanical Ventricular Actuation vs. Cardiac Massage.*

29th Annual Meeting of the Society of Thoracic Surgeons, San Antonio, Texas, Jan 25-27, 1993: *Pulsatile Reperfusion Improves Cerebral Flow Compared with Non-pulsatile Reperfusion after Circulatory Arrest.*

Clinical Forum Conference, The American College of Emergency Physicians, Kansas City, KS, April 19-21, 1993: *DMVA for Resuscitation.*

39th Annual Meeting of the American Society for Artificial Internal Organs, April 29-May 1, 1993: *Non-Blood Contacting Circulatory Support After CABG Does Not Impair Graft Flow.*

66th Scientific Sessions of the American Heart Association, Atlanta, Georgia, Nov 8-11, 1993: *Pulsatile Flow Attenuates Cerebral Reperfusion Injury.*

30th Annual Meeting of The Society of Thoracic Surgeons, New Orleans, LA, Jan 31-Feb 2, 1994: *Direct Mechanical Ventricular Actuation vs. Continued Cardio-pulmonary Bypass for Postcardiotomy Circulatory Support Following CABG.*

40th Annual Meeting of the American Society for Artificial Internal Organs, San Francisco, CA, April 13-14, 1994: *Cardiac Tolerance to Mechanical Actuation is Affected by Biomaterial Characteristics.*

Cardiovascular Science and Technology Conference, December 9-11, 1994: *Recent Progress Using the Anstadt Cup for Non-Blood Contacting Circulatory Support.*

41st Annual Meeting of the American Society for Artificial Internal Organs, Chicago, Ill, May 4-6, 1995: *Aorta-coronary Saphenous Vein Graft Function After Mechanical Cardiac Massage.*

42nd Annual Meeting of the American Society for Artificial Internal Organs, Washington, DC, May 2-5, 1996: Panel: *Artificial Organ Use in Emergency Cardiopulmonary Resuscitation - Use of a New Device for Direct Cardiac Compression during Open-Chest Cardiac Resuscitation.*

45th Annual Conference of the American Society for Artificial Internal Organs, San Diego, CA, June 2-5, 1999: *Analysis of External Ventricular Actuation.*

65th Annual Meeting of the American College of Chest Physicians, November 1, 1999: *Do Less Invasive Strategies Delay Optimal Treatment of Empyema Thoracis.*

The 52nd Annual Meeting of the Southwestern Surgical Conference, April 2000: *Can the Risk for Recurrent Thrombotic Thrombocytopenic Purpura be Predicted Preoperatively?*

The 5th International Conference on Circulatory Support Devices for Severe Cardiac Failure, September 15-17, 2000, NY, NY: *Non-Blood Contacting Biventricular Support of the Severely Failing Heart Using Direct Mechanical Ventricular Actuation.*

66th Annual Meeting of the American College of Chest Physicians, October 22, 1999: *Is Basaloid Lung Carcinoma a Rare and Highly Aggressive Variant of Non-Small Cell Lung Cancer?*

Grand Rounds at the German Heart Institute Berlin, September 7, 2001: *Direct Mechanical Ventricular Actuation for Non-Blood Contacting Circulatory Support.*

The 16th Annual Postgraduate Pathology Symposium, The Medical College of Georgia, March 23-24, 2002: *Current Staging Techniques for Non-Small Cell Lung Cancer.*

The 98th International Conference of the American Thoracic Society, May 17-23, 2002: *Basal Cell Carcinoma Does Not Negatively Impact Prognosis Following Surgical Resection of Non-Small Cell Cancer.*

Grand Rounds at Middlesex Hospital, University College London, Sept 13, 2002: *Direct Mechanical Ventricular Actuation for Resuscitative Circulatory Support.*

52nd Annual Conference ASAIO, Chicago, IL, June 7-10, 2006: *Mechanical Cardiac Actuation of the Failing Heart Reduces Matrix Metalloproteinases Activity.*

53rd Annual Conference ASAIO, Chicago, IL, June 7-10, 2007: *Echocardiographic Assessment of Direct Mechanical Ventricular Actuation.*

53rd Annual Conference ASAIO, Chicago, IL, June 7-10, 2007: Invited lecture. *Development of Non-blood Contacting Pumps.*

The Society of Thoracic Surgeons 45th Annual Meeting, Jan 26-28, 2009, San Francisco, CA. Oral presentation, *Non-Blood Contacting Support Device Effectively Augments Myocardial Function of the Neonatal-Sized Failing Heart*.

American Heart Association Resuscitation Science Symposium, Nov 17, 2009: Poster Presentation, #2009-R-13018-AHA. *Direct Mechanical Ventricular Actuation of the Acutely Failing Heart Attenuates Maladaptive Cell Signaling*.

Chicago Multidisciplinary Symposium in Thoracic Oncology, Dec 9-11, 2010, Chicago, IL: Paraneoplastic Cutaneous Leukocytoclastic Vasculitis and Iron Deficiency Anemia as the Presenting Features of Squamous Cell Lung Carcinoma.

American Thoracic Society Annual International Meeting, May 13-18, 2011, Denver, CO: *Lobectomy for Lung Carcinoma with Ipsilateral Pulmonary Artery Agenesis.*

American Thoracic Society Annual International Meeting, May 13-18, 2011, Denver, CO: *Recurrent Pleural Effusion as a Late Complication to Ventriculopleural Shunt*.

Annual American Heart Association Resuscitation Science Symposium, November 4, 2012. Schmidt BA, Garvin NJ, Budharaju S, Reynolds DB, Darner RJ, Prochaska LJ, **Anstadt MP.** *Direct Ventricular Compression Improves Mechanical Synchrony of the Acutely Failing Heart.*

Anstadt, MP *Esophageal Disease in the Geriatric Patient – Presented at the 24th Annual Statewide Geriatric Medicine Conference, October 11-13, 2013.*

PROFESSIONAL CONTINUING EDUCATION COURSES

The Society of Thoracic Surgeons Thoracic Endografting Symposium	Aug 26-28, 2005
Intuitive Surgical daVinci Surgical System & EndoWrist Instruments for a Console Surgeon	April 4, 2006
GORE TAG ™ Thoracic Endoprosthesis Physician Training Program	Aug 25, 2006
Edwards ONE Basic Endovascular Skills Training Program (BEST)	June 26-27, 2007
Boston Scientific Endoscopic Radial Artery Harvest Course	July 31, 2007
St. Jude Presentation & Discussion on Atrial Fibrillation	August 15, 2007 Cleveland Clinic
Transcatheter Therapy for Structural Cardiovascular Disease	October 4, 2007
Advanced Trauma Life Support Instructor Course, #31263-I	January 17-18, 2008
Advanced Trauma Life Support Course Instructor, #30873-P	June 16-17, 2008
Cook Medical Advanced Endovascular AAA Physician Workshop	June 11-13, 2008
Baylor College of Medicine Sternal Wound Management: New Surgical Strategies	June 14, 2008
Edwards Lifesciences Heart Valve Therapy, Global Mitral Summit	June 12-13, 2009
Advanced Trauma Life Support Course Instructor, #30873-P	June 17-18, 2009
Premier Health Partners Physician Leadership Series, Levels I-III, Annual Courses	2007- 2011
Minimally Invasive Thoracic VATS Course, Los Angeles, CA	Apr 6-10, 2010
Society of Thoracic Surgeons, Minimally Invasive Valve Symposium, Chicago, IL	Dec. 2-4, 2010
Endovascular Mini-Fellowship, Arizona Heart Institute, Phoenix, AZ	Apr 16-20, 2011
Synthes Rib Trauma Workshop, Grant Medical Center, Columbus, OH	Sept. 17, 2011
Coviden Minimally Invasive VATS Lobectomy Course, National Harbor, MD	Oct. 12-13, 2011
Medtronic Endovascular Therapies Peer to Peer Training EVAR, Houston, TX	Oct. 29-30, 2012
Medtronic Endovascular Therapies Peer to Peer Training TEVAR/EVAR Training, Durham, NC	April 34-25, 2013
Mini-fellowship in Thoracic VATS, Los Angeles, CA	August 19-21, 2014
Advanced Thorsicic Round-Table Discussion, New Orleans, Lo	August 15, 2014
Midwest Valve Symposium, Chicago, Ill	June 16-17, 2014
Covidien VATS Lobectomy Mini-Fellowship, Los Angeles, CA	August 19-21, 2014
Summit for Perfusion Imaging and Excellence in Surgery, Las Vegas, NV	September 13, 2014

REFERENCES

George R. Brown, MD
Cardiothoracic Surgery
937-371-4111

Mukul S. Chandra, MD
Miami Valley Cardiologists
Cardiology
937-681-0133

Marion F. Brown, MD
Miami Valley Hospital, Director Surgical Services

Cardiothoracic Surgery
937-689-1654

Steven L. Chambers, MD
Pulmonary & Critical Care Consultants
Pulmonary/Critical Care
937-271-5699

Syed Najeed, MD
Dayton Cardiology & Vascular Consultants
Cardiology
513-702-5799

Jeffrey Pence, MD
Dayton Children's Hospital
Pediatric Surgery
252-412-2697

Anthony Perez-Tamayo, MD
Cardiothoracic Surgery
708-822-3064

Paul F. Heyse, MD
Miami Valley Heart & Lung Surgeons
Vascular/General Surgery
937-475-4255