Assisted Circulation and Total Artificial Heart.
Past and Present

Prof. Domingo Liotta

I. PAST

Early Clinical Applications of Assisted Circulation and Total Artificial Heart

The Left Ventricular Assist Device –LVAD- system was created at Baylor University College of Medicine in Houston, 1962 (Liotta).

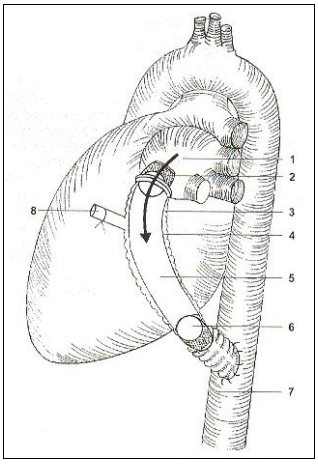
Today the implantation of LVAD is a well-established clinical procedure as:

1- A bridge for Cardiac Transplantation.

2- A bridge for Myocardial Recovery.

First Clinical Application with an Intrathoracic Pump

In the evening of July 19, 1963 D. Liotta and E. Stanley Crawford implanted the first clinical LVAD at the Methodist Hospital in Houston, bypassing the left ventricle from the left atrium to the descending thoracic aorta (DTA)[1].



Liotta-Crawford LVAS (July 19, 1963).
Drawing of the 19th July 1963 clinical prototype that was developed by Domingo Liotta at Baylor University, Houston. The pump is shown in diastole.
1= left atrium; 2= inlet valve; 3= housing of Silastic, reinforced with Dacron fabric; 4= air chamber; 5= blood chamber; 6= outlet valve; 7=descending aorta; 8= plastic tube (internal dimension, 4 mm) for air supply.

[1] *Liotta D. Early Clinical Application of assisted circulation. Texas Heart Institute Journal, 2002; 29(3): 229-30.*

The actual clinical prototype is at the Smithsonian Institution, Washington, DC.

The pneumatic powered intrathoracic pump implanted through a left thoracotomy was regulated to bypass with 1,800 to 2,500 mL of blood/min. The pulmonary edema cleared. However the anuria persisted. After 4 days of mechanical support, the pump was discontinued. The patient, who was in coma before LVAD support, continued in coma and died.

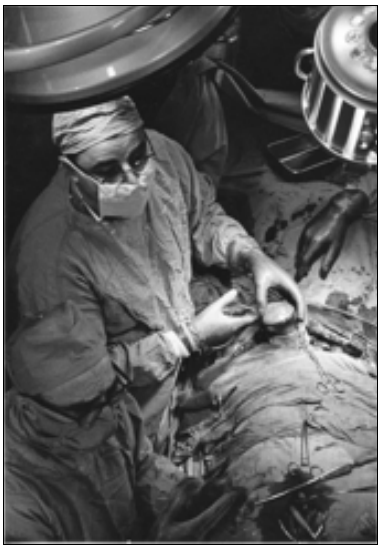
E. Stanley Crawford, MD (July 19, 1963)
At the time he and Domingo Liotta implanted an LVAD in a patient for the first time

First Clinical Application of a Paracorporeal Pump

On July 21, 1966 Michael E. DeBakey and Domingo Liotta implanted the first clinical LVAD in a paracorporeal position at the Methodist Hospital in Houston, bypassing the left ventricle from the LA to the ascending aorta in a patient in cardiogenic shock postcardiotomy. The patient developed neurological and pulmonary complications and died after few days of LVAD mechanical support.

On August 6, 1966 Liotta and DeBakey implanted an LVAD from LA to the right axillary artery. After mechanical circulatory support for 10 days the patient recovered, thus constituting:

The First successful use of an LVAD for Postcardiotomy Shock.



Paracorporeal LVAD. *Dr. Liotta and DeBakey (foreground); Dr. Liotta (holding the pump in the picture on the right) at the historic cardiac surgery: implantation of the Liotta-DeBakey left ventricular assist device (LVAD) in a paracorporeal position at the Methodist Hospital, Houston (April 21, 1966).*

Publication – princeps on Assisted Circulation:

1 Liotta, D., E.S. Crawford, D.A.Cooley, M.E.DeBakey, M. De Urquia, L. Feldman. Prolonged partial left ventricular bypass by means of an intrathoracic pump implanted in the left chest. Trans. Am. Soc. Artif. Intern. Organs, 8 (1962): 90-9.

Early publication on Assisted Circulation:

2 Liotta, D., C.W. Hall, W.S. Henly, A.C. Beall, D.A. Cooley, M.E. DeBakey. Prolonged assisted circulation during or after cardiac and aortic surgery 1- Prolonged Left ventricular bypass by means of an intrathoracic circulatory pump. II-Diastolic pulsation of the descending thoracic. Trans. Am. Soc. Intern. Organs, 9 (1963): 182-5.

3 Liotta, D., C.W. Hall, W.S. Henly, D.A.Cooley, E.S. Crawford, M.E. DeBakey. Prolonged assisted circulation during and after cardiac or aortic surgery. Prolonged partial left ventricular bypass by means of intracorporeal circulation. American Journal of Cardiology 12 (1963): 399–405. Finalist: "*The Young Investigators Award*" of the American College of Cardiology, Denver, May 1962.

4 Liotta, D., C. W. Hall, D. A. Cooley, M. E. DeBakey. Prolonged ventricular bypass with intrathoracic pump. Trans. Am. Soc. Intern. Organs 10 (1964): 154-6.

5 Liotta, D., J. H. Maness, H. Bourland, D. Podwell, C. W. Hall, M. E. DeBakey. Recent modification in the implantable left ventricular bypass. Trans. Am. Soc. Intern. Organs 11 (1965): 284-90.

6 DeBakey, M.E., D. Liotta, C. W. Hall. Prospects for implications of the artificial heart and assistant devices. J Rehab 32 (1966): 106-7.

7 Liotta, C. W. Hall, A. Villanueva, R. M. O'Neal, M. E. DeBakey, A pseudoendocardium for implantable blood pumps. Trans. Am. Soc. Intern. Organs 12 (1966): 129-38.

8 DeBakey ME, Liotta D, Hall CW. Left heart bypass using an implantable blood pump. In: Mechanical devices to assist the failing heart, Eiseman B, ed. Washington D.C. proceedings of a conference sponsored by the Committee on Trauma, 9-10, 09, 1964, National Academy of Sciences, National Research Council, Washington 1966: 223.

9 Hall CW, Liotta D, DeBakey ME. Artificial heart -present and future. In: Research in the service of man: Biomedical knowledge, development and use. Washington D.C.: US Government Printing Office; 1967: 201-16.

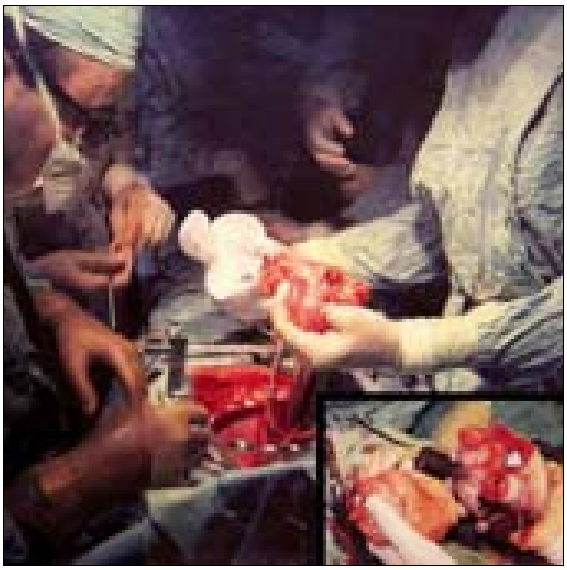
10 DeBakey ME. Left ventricular bypass pump for cardiac assistance. Am J Cardiol, 1971; 27: 3-11.

11 Liotta D. Early clinical application of assisted circulation, Texas Heart Institute Journal, 2002; 29 (3): 229-30.

First Clinical Implantation of a Total Artificial Heart

In the afternoon of April 4, 1969 Denton A. Cooley and Domingo Liotta replaced a dying man's heart with an orthotopic mechanical heart at the Texas Heart Institute in Houston.

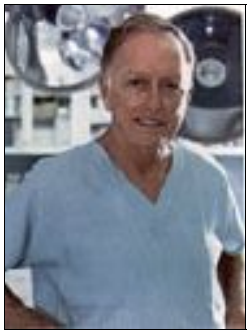
After 64 hours the pneumatic powered artificial heart was removed and replaced by a donor heart. Thirty-two hours after transplantation the patient died of what was later proved to be an acute pulmonary infection, extended to both lungs, caused by fungi.



Historical Operation. The first in medical history. Total heart replacement with an Artificial Heart *(orthotopic position). On the left, Dr. Liotta; in the center of the picture, the empty pericardial sac of the patient, Mr. H. Karp. On the right, the hands of Dr. Cooley holding Mr. Karp's heart and the artificial heart just before implantation. Texas Heart Institute, Houston (April 4, 1969). Lower right corner of the picture: Dr. Cooley is holding both the removed artificial heart and the donor heart. (April 7, 1969).*

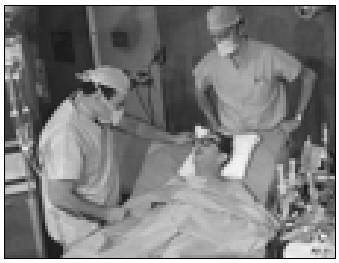
Domingo Liotta resumed his work on Total Artificial Heart (TAH) at Baylor University College of Medicine in July 1968. The straightforward objective was to use it in a patient either in irreversible cardiogenic shock postcardiotomy or in irreversible "stone heart".

The decisive objective was to prolong a patient's life by means of a mechanical heart until the implant of a donor human heart could definitively replace the artificial system. The procedure is now called two-staged cardiac transplantation.



Denton A. Cooley, M.D.

The historical operation -one of the greatest medical adventures of the XX Century- was performed for the first time in the afternoon of April 4 1969. A dying human being was able to live with the Liotta-Cooley TAH until a donor human heart replaced it. That was a medical hard time, but full of glory and courage. The original clinical prototype of Liotta-Cooley TAH was selected in 2006 to be displayed prominently in the new Smithsonian Treasures of American History. In Dr. Cooley´s opinion, "*this establishes it as a worthy part of human history*".



Dr. Liotta is talking to Mr. Karp and Dr. Cooley is observing (April 5, 1969). Right, Mrs. Shirley Karp and Mr. Haskell Karp (April 5, 1969)

References

1 Cooley D. A., Liotta D., Hallman G. L., Bloodwell R. D., Leachman R. D., Milan J. D. *First human implantation of cardiac prosthesis for total replacement of the heart.* Trans. Amer. Soc. Arts. Int. Organs, 15 (1969): 252.

2 Cooley D. A., Liotta D., Hallman G. L., Bloodwell R. D., Leachman R. D., Nora J. D., Fernbach D. J., Milan J. D. *Orthotopic cardiac prosthesis for two-staged cardiac replacement.* Am. J. Cardio, 24 (1969): 723-730.

II- PRESENT

- ***Development of Small Implantable Mechanical Assists.***

- ***Novel LVASs and Atriostomy Method that avoids Cardiac Cannulation***

Congestive heart failure remains a major public health problem all over the world. Congestive heart failure due to postischemic myocardiopathy is the leading cause of death in the industrialized world. Advanced heart failure affects approximately 5 million patients in the United States, with 400,000 new cases per year.

The treatment of patients with chronic heart failure has markedly improved over the past 25 years. The current pharmacotherapy for congestive heart failure, including neurohumoral inhibition with angiotensin converting enzyme inhibitors and beta-blockers, improves clinical outcomes.

The responses to the low blood flow in the "*heart failure peripheral milieu*" indicate the abnormal cardiac output and the most successful therapy has been attenuation of neurohumoral over activation with the antagonists of the rennin-angiotensin-aldosterone system, as well as beta-adrenergic blockade.

However, mechanical circulatory assistance has become a common method to stabilize patients with profound refractory heart failure as a bridge-to-transplantation.

The amount of information collected since Liotta´s laboratory study and early clinical applications of mechanical circulatory devices at Baylor University College of Medicine in Houston, more than 40 years ago, have been of tremendous gain.

Liotta invented (1962-66) the ***Left Ventricular Assist Device*** (LVAD) for the treatment of *cardiogenic shock postcardiotomy*, while Assistant Professor of Surgery at Baylor University College of Medicine in Houston, Tx. (1961-71).

Since 1998, the **School of Medicine of the University of Morón** has carried out the design, manufacturing, *in-vitro* testing and animal implantation (calves) of a new LVAS.[2]

Novel LVAD system may be a *bridge-to-cardiac transplantation*. However, the main indication is:

functional Heart Recovery or Destination Therapy in Advanced Heart Failure.

The Novel LVAD-III is a pneumatically activated pump positioned in the left chest. A 4-mm ID driveline attaches to the lower side of the pump, passes through a thoracic and abdominal subcutaneous tunnel and exits the body to the left of the umbilicus.

The Novel LVAD-III weight is 90 g. The housing cross section is 80 mm wide and 40 mm high.

Several basic considerations have been taken into account in the design of this new system, from bench to bedside.

A- Atriostomy Method

The cannulations of heart chambers were suppressed. Mainly it is avoided the LV apical cannula for pump's inflow, which destroys the left ventricle myocardium helical anatomy.

The Novel LVAD-III draws blood from either a 25 mm (*4.6 squared centimeters*) or a 30 mm (*7.1 squared centimeters*) diameter opening in the left atrial wall.

The atriostomy method for pump's inflow was developed. A large opening in the left atrial wall is made. Either a 25-30 mm-diameter atrial prosthesis or a porcine valve aortic root (full aortic root) is sutured on the epicardial side at the left atrial wall. **The atrial prosthesis is fitted with a metallic frame, which keeps the atriostomy permanently open.**

The blood passes through the pump implanted in the left chest and ejects through a low porosity graft that is sewn to the upper descending aorta.

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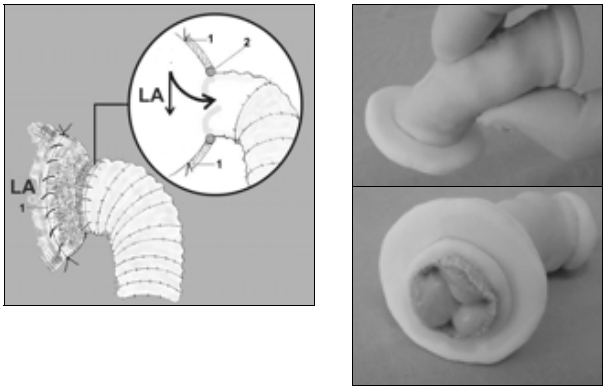
[2] *Liotta D, Novel left ventricular assist system, An electrocardiogram-synchronized LVAS that avoids cardiac cannulation, Texas Heart Institute Journal 2003, 30: 194-201.*



Atriostomy Technique.
Left, Atriostomy Areas with a 25 mm atrial prosthesis. Right, Left Atrial Prosthesis. Different views of the atrial prosthesis: porcine full aortic root covered with Dacron.

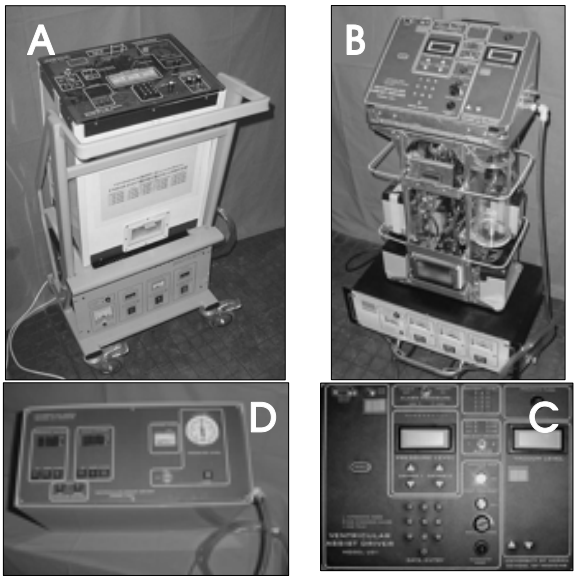
All blood contacting surfaces, except the blood pumping chamber, incorporate biological tissues. Both inflow and outflow blood paths contain a porcine valved-aortic root (full aortic root) and four centimeters of the ascending aorta as an anatomical unit.

B- Novel LVAS Driver System

The third generation of pneumatic LVAD-Driver systems has been developed.[3] The drive unit is an air-driven pulsatile system. The driving parameters can be programmed and manually preset. It incorporates two small and standalone pneumatic units. Each has its own motor compressor, electro-pneumatic valves and electronic control. A timer keeps one pneumatic system activated and the other inactivated. The timer alternates this function every 15 minutes.

The purpose of the duplication is to increase the service life of the compressors and to prevent overheating, malfunctioning of the components and component fatigue.

If one of the systems fails, an alarm will warn about the problem and the other one will continue indefinitely.



Photographs of Novel LVAS pneumatic driver system.
A, *shows the stationary driver unit for hospital use. It is 40 cm wide, 30 cm deep and 100 cm high.* ***B,*** *illustrates the ambulatory driver.* ***C,*** *shows the front view of control panel.* ***D,*** *illustrates the portable small unit, a prototype of 30 cm x 15 cm x 25 cm; its weight (without batteries) is about 1,500 gr.*

*NOVEL III LVAS´*s clinical trials allow, by entering a selected requested password, to remotely monitor the driver's functioning and the clinical parameters *on line* via Internet (from the intensive care unit or the patient's home).

The system is designed to monitor: a) ECG, systemic arterial pressure, cardiac output, body temperature, and b) several parameters of the driver's work and synchronization of the patient's ECG.

It is possible to include the clinical history and echocardiographic and X-ray studies from a Website, being feasible a teleconference with the doctors in charge of the patient's care and even with the patient himself.

C- Novel LVAS in vitro testing

The Novel LVASs work with the highest efficiency at a low frequency rate, 50 to 65 beats/min. The pump produces stroke volumes of 80 mL and, at an ideal pump low frequency of 55 to 65 beats per minute, generates flows of about 4.5-5 L/min.

[3] *Cervino C, Nasini V, Sroka, A, Diluch A, Cáceres M, Sellanes M, Malusardi A, del Río M, Pham S and Liotta D, Novel left ventricular assist system for cardiac recovery therapy: The Driver. Tex Heart Inst Journal 2005,32: 535-40.*

Conclusion

The Novel Left Ventricular Assist System (Novel LVAS) avoids cannulation of cardiac chambers, which makes the large atriostomy method the key of success, and enables its synchronization with the patient's ECG.

It is regulated the LVAS output from 4 to 4.5 L/min. The native heart ejects approximately 1.5 to 2 L/min. The flow through the aortic valve is echocardiographically measured; the aortic valve must be seen well open in each systolic ejection. The pump is synchronized with the patient's ECG, to ensure blood pump ejection in diastole.

This electro-pneumatic unit has a remarkable feature: it contains two pneumatic units that alternate in their function every 15 minutes.

This LVAS is synchronized with the patient's ECG, allowing the stroke volume to be ejected during the diastolic period, thus acting as a chronic counterpulsator.

We have designed the Novel LVAS to operate at a low-frequency rate. This fact added to the ECG synchronization offers the best prospect for myocardial recovery in patients under beta-adrenergic blocker therapy. This therapy helps adjust heart rate to the pump frequency.

End of Part II out of III

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