

## **HEART SUPPORT SYSTEMS: FROM IDEA TO CLINICAL PRACTICE**

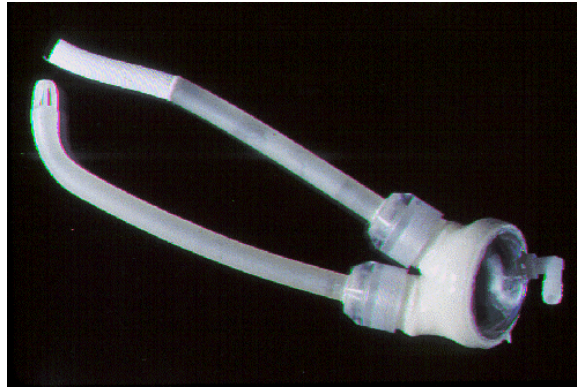
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**A b s t r a c t:** This paper describes the development of a pneumatic ventricular assist device by our group from the first steps to the clinical assay. The device, called BCM, has an input compliant cannula that improves the filling of the device. Results of the clinical assay showed that the BCM device was suitable for clinical use. New developments of our group are also mentioned.

**Key words:** Heart support systems, pneumatic ventricular assist device.

Our activities in the field of heart support systems began in 1983. At that time the Cardiovascular Surgery Department of the Hospital proposed to the Hospital's Research Committee a project on mechanical circulatory support (MCS). The experimental work started some months later with an experimental artificial ventricle (Bioimplant) obtained by the Cardiovascular Surgery Department and controlled by a very simple console built up at our unit. In 1985, and after some acute experiences with animals, we proposed the full development of a new system in Madrid. At that time a Spanish company, BIOMED S.A., showed interest in the project. We contacted other research groups to get help in the handling of plastic materials, and also in fluid mechanics. Then two more institutions became involved in the project, the Polymers Institute belonging to the Spanish Research Council (C.S.I.C.) devoted to the study of physical and chemical properties of plastics, and the Physics Department of the UNED involved in the study of problems related to fluid mechanics. The research project, called BCM, obtained financial support from the Spanish Ministries of Industry and Health.



*Figure 1 – Bioimplant prototype*

*Слика 1 –Прототип на биоимплантантот*

### *BCM Project*

The goal of the project was to develop a mechanical circulatory support system using an artificial external pneumatic ventricle. The system had to be designed for use during a short period of time.

*Development of pump prototypes:* The first prototypes developed had the same diameter for the inlet and outlet cannulae. The most important problem observed with this type of pumps was the difficulty of filling up the blood cavity of the pumping device.

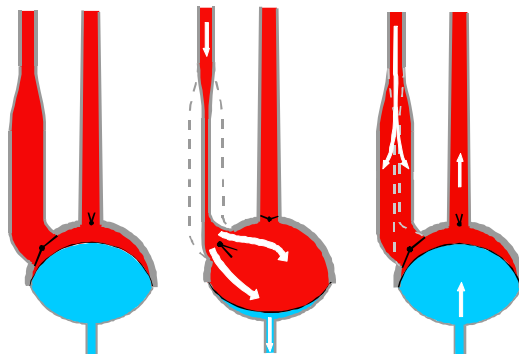
Usually, the inflow pressure gradient is significantly lower than the outflow pressure gradient. Consequently, the time required to move a given amount of blood through the inflow cannula (during diastole) is much greater than the time required to move the same amount of blood through the output cannula (during systole).

This problem becomes particularly important at high driving frequencies (100–120 bpm). During diastole, the transmission of the negative pressure through a quite rigid cannula produces the collapse of the auricle with system malfunction.

To solve these problems we designed a new elastic atrial cannula. This cannula is highly deformable, and has an enlargement that works as a blood reservoir (false auricle), located very close to the VAD. The volume of this dilation is of the same order as that of the filling volume of the blood chamber.

During the diastolic period, the lower pressure in the blood chamber forces the blood inside the cannula to enter the VAD cavity. Simultaneously the walls of the cannula partially collapse, and the pressure drop is not fully transmitted to the atrium, avoiding the atrium collapse. During the systolic

period the elastic recuperation of the walls of the cannula forces the blood in the atrium to flow smoothly into the inflow cannula. This causes a significant increase in the efficiency of the VAD at high frequencies.



*Figure 2 – Schematic function of the input cannula*

*Слика 2 – Шематски приказ на влезната канила*

By comparing the performances of the new cannula and that of a rigid one, we show that the use of a larger, highly deformable input cannula results in higher efficiency of the system, lower driving pressure, longer systolic periods, and low haemolysis. These improvements are particularly important at high driving frequencies.

After other minor modifications the device was considered as definitive and denoted BCM 3.5. Figure 3 shows a photograph of the definitive pump. Clinical assay was performed with this model.



*Figure 3 – BCM 3.5 Artificial ventricle*

*Слика 3 – Вештачки вентрикул BCM 3.5*

*Development of driving console prototypes:* The first driving console prototype was very simple. It had a compressor and a vacuum pump. The regulated air pressure and vacuum lines were connected to a three-way valve controlled by a wave generator. With this device we could control the frequency, the duty cycle and the level of pressure and vacuum. It only worked in asynchronous mode and had no alarms at all.



*Figure 4 – Photograph of the driving console BCM 3200*  
*Слика 4 – Фотографија на подвижната конзола BCM 3200*

After that first prototype we developed two more prototypes. The second one was controlled by means of a PC computer (Intel 8086) and the third one with a Motorola 68000 microprocessor with a VME bus.

The size of these prototypes was very large, mainly due to the compressor. In 1988 we started to develop a new model of driving console that used the hospital compressed air supply and had two compressed air tanks for emergencies and transport.

This new model (BCM 3200) was equipped with two modules, each of which can drive one ventricle. The modules were mounted in a carrier with the compressed air tanks and with the battery-chargers (Figure 5). This system was very flexible and with a module and a five-litre compressed air tank, it can drive a ventricle for 40-50 minutes, depending on the working conditions.

*Characterization of pump prototypes: Figure 5 shows a graph of the output flow delivered by a 3.5 device vs frequency in a mock circulation loop with a postcharge of 100 mmHg and an input pressure of 10 mmHG. The maximal output was obtained at around 100 bps, at higher frequencies the stroke volume decreases and the output flow remains almost the same.*

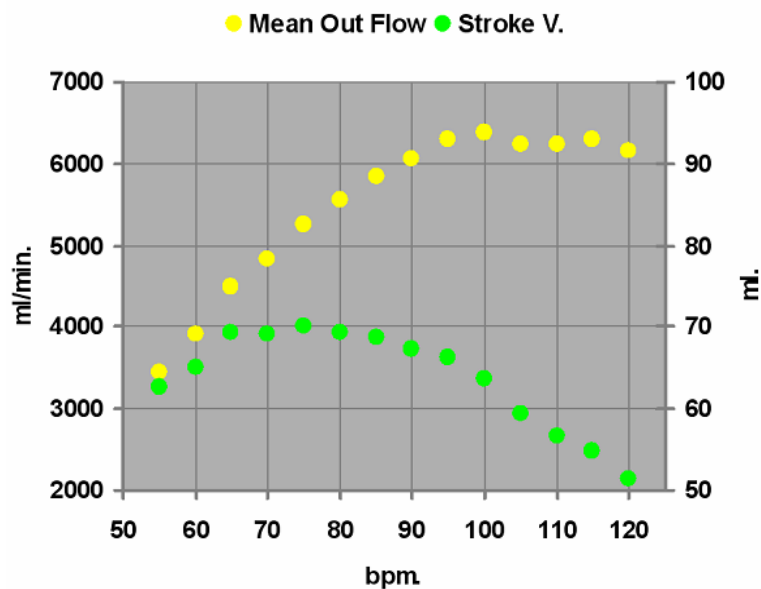
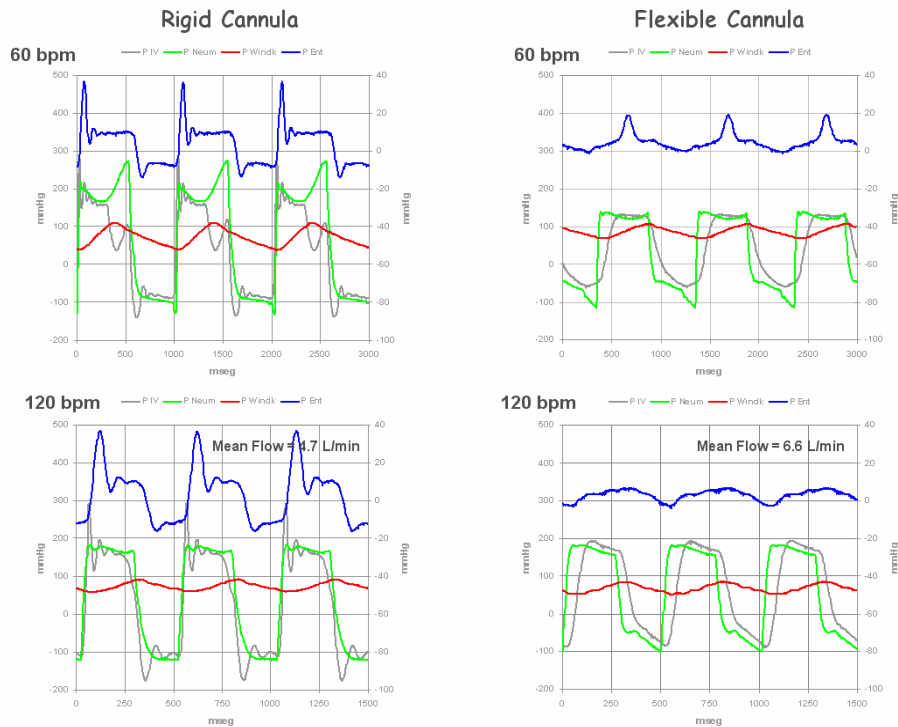


Figure 5 – "In Vitro" characterization of the BCM 3.5 ventricle  
Слика 5 – „In Vitro“ карактеристики на BCM 3.5 венстрикулот

*In order to test the influence of the compliant flexible input cannula we have compared the behaviour of the device with a rigid input cannula; Figure 6 shows the graphs obtained.*



*Figure 6 – Comparison of a BCM 3.5 device with an input rigid cannula vs a flexible cannula*  
*Слика 6 – Споредба помеѓу BCM 3.5 апаратите со ригидна и флексибилна канила*

The compliant cannula filters negative pressure and improves the hydrodynamic behaviour of the device, moreover at high frequencies (120 bpm).

#### *Experiences with animals*

To test the behavior of the VADs in real conditions we implanted the device in more than 80 sheep. The experiences were divided into acute (less than 24 hours) and chronic (around a month). In acute experiences the animal was monitored in the following way: ECG, arterial, pulmonary and left auricle pressures. We also recorded the pneumatic driving pressure. We tested the prototypes in the following conditions: switch-on and switch-off sequences, steady regimes on physiological conditions changing driving console pressure, frequency and duty cycle. Variations of arterial pressure with metoxamine and nitroglycerin were measured. A typical example of the startup of the system during a ventricular fibrillation in a sheep is shown in figure 7.

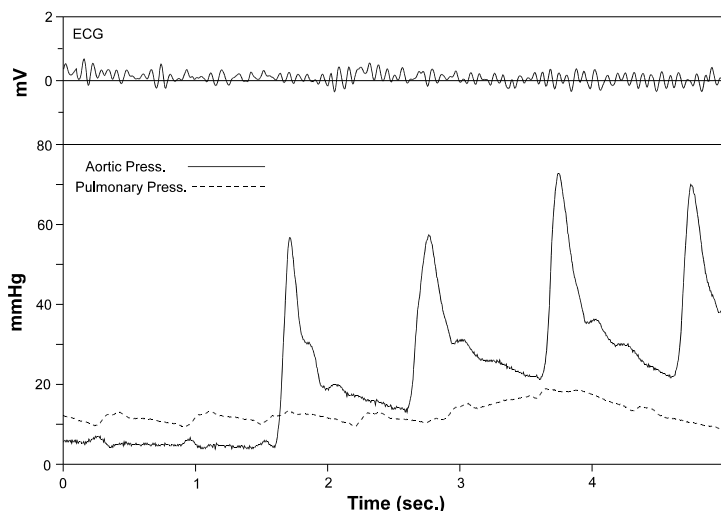


Figure 7 – Startup of the system during ventricular fibrillation  
 Слика 7 – Активирање на системот за време  
 на вентрикуларна фибрилација

*Reliability tests:* These tests must guarantee the operation of the device for a month. We performed reliability tests *in vitro* by using mock circulation loops and reliability tests *in vivo* by chronic experiences in animals.

#### *Clinical assay*

After the experiences with animals and reliability tests, the Spanish Ministry of Health authorised the clinical assay of the device on ten patients under the responsibility of our group. This clinical assay started in 1989 and finished in 1992.

Three implantations were performed in the Hospital General Gregorio Marañón, one in the Clínica Puerta de Hierro and six in the Hospital de la Princesa (all of them in Madrid). As the Hospital de la Princesa has no heart transplant programme, two patients were transferred to the Hospital General Gregorio Marañón, and two more to the Clínica Puerta de Hierro, with the device working, to perform the heart transplantation.

One of the patients was female. The other nine were males. Maximum age was 69 and minimum 45 years. Time on the device ranged from 7 hours to 18 days, with a mean of 5.8 days.

Indications of the implants were: three patients with cardiomyopathy, three post AMI, and four unweanable from ECC. All patients were intubated

before the implant, nine of them with IABP. The mean cardiac index was 1.78 l/min/m<sup>2</sup> and mean PCWP 33 mmHg.

In only nine cases was a left ventricular assist device (LVAD) needed; left and right ventricular assist devices (BVAD) were used in one case (unweanable from ECC). All of them were implanted using atrial inlet. ECC was necessary in the implantation of four patients.

Three patients died during mechanical circulatory support. Seven were transplanted, and of these two died after transplantation and five were discharged from hospital.

After the clinical assay the project was transferred to the company (Biomed S.A.).

### *New Developments*

With the experience acquired with the BCM project we started new developments keeping in mind the following rules:

- Our technology allows us only to work on short-term devices (Around 2 weeks).
- Pumps should be of tubular shape because we have never observed aggregates or thrombi in the input and output cannulae of the BCM, irrespective of shape or elasticity.
- These short-term devices should not be expensive because, otherwise, their use tends to be indicated on a very restricted basis.
- The high price of available devices is mainly due to the valves used (mechanical, biologic or polyurethane); therefore we should use active clip valves over the cannulae.

In this sense we are working now on a new tubular low-cost short-term device with active clip valves.

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#### Р е з и м е

### СИСТЕМИ ЗА ПОДДРШКА НА СРЦЕВАТА АКЦИЈА: ОД ИДЕЈА ДО КЛИНИЧКА ПРАКТИКА

*Дел Кањизо Хуан Ф.*

*Болница Грегорио Марањон, Мадрид, Шпанија*

Нашата работна група го опишува развојот на пневматскиот апарат за поддршка на вентрикулите, од првите чекори до клиничката употреба. Апаратот, наречен ВСМ, содржи влезна канила која ја зголемува неговата чувствителност. Резултатите од клиничките студии покажуваат дека ВСМ апаратот е прилагоден за клиничка практика. Наведени се и новите истражувања на работната група.

**Клучни зборови:** системи за поддршка на срцева акција, пневматски апарат за вентрикули.

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