



# Development and manufacture of prosthetic cardiac valves. Mexican cardiac valvular prostheses

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## ABSTRACT

A brief account of the history of the development of cardiac valvular prostheses is given. The use of these devices is analyzed. The authors describe the successive stages of the use of the various types of mechanical prosthetic valves with special reference to the experience in Mexico. They refer to the manufacture of testing and clinical results with the Biomed valves made in Mexico. It is concluded that these devices meet the highest standards and that, given their low cost, should be the option of choice for valve implantation in cardiac patients in our country.

**Key words:** Valvular prostheses, mechanical prosthetic valves, valve implantation, cardiac patients.

## RESUMEN

*Se expone un relato histórico sucinto del desarrollo de la fabricación de las prótesis valvulares cardíacas. Se analiza el uso que han tenido estas prótesis, describiendo las fases sucesivas del uso de los distintos tipos de válvulas mecánicas de prótesis, en particular la experiencia con su implantación en México. Se relata el proceso de manufactura, pruebas de funcionamiento y resultados clínicos obtenidos con las válvulas Biomed hechas en México. Se concluye que estas prótesis cumplen con las normas más altas y que en vista de su bajo costo, son la mejor opción para ser implantadas en pacientes de nuestro país.*

**Palabras clave:** Prótesis valvulares, válvulas mecánicas, implante valvular, pacientes cardíacos.

Sound medical practice and the benefit thereof for patients in developing countries as Mexico, depend on several factors such as the quality of professional university education, good hospital training, adequate equipment and the possibility to acquire the best therapeutic resources. All of these add up to explain good or bad results of medical activities.

Excellent and well informed physicians in Mexico are unable to aid the sick since they lack the adequate means to purchase expensive medical equipment. We have seen this problem during our profes-

sional lives having been involved in the practice of medical and surgical cardiology. We continue to be interested in the fate of cardiac patients who for the most part are unable to acquire costly imported cardiac valve prostheses. For these reasons we have been greatly motivated by the manufacture of prostheses by Mexican industrialists.

The specialty of cardiology in Mexico had a slow development prior to the foundation of the Instituto Nacional de Cardiología in 1944 by Dr. Ignacio Chávez-Sánchez. From then on numerous publications appeared in Mexico dealing with all aspects of cardiology.

World medical literature indicates that very early on, there was the need to develop cardiac sur-

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gery for the treatment of acquired valvular heart lesions. In 1902, Sir Thomas Lauder Brunton<sup>1</sup> experimented in cadavers and suggested that a stenotic mitral valve orifice could be enlarged by elongating the natural opening and proposed that the constriction could be "as easily divided during life as one can after death". In 1910 Carrel,<sup>2,3</sup> did experimental surgery on the aortic valve of animals. In 1913 Théodor Tuffier<sup>4</sup> dilated the stenotic aortic valve of a young patient.

In the early twenties Cutler et al.<sup>5</sup> performed operations on stenotic mitral valves with the aid of a cardiovalvulotome inserted through the apex of the left ventricle. Only one of seven patients survived. Death ensued owing to a greatly reduced cardiac output caused by iatrogenic mitral incompetence. In double mitral lesions, the stenoses were corrected but valvular incompetence remained unchanged. Davila et al.<sup>6</sup> tried to avoid this problem by tying a piece of umbilical tape around the mitral ring as a pursestring. In 1960, McGoon<sup>7</sup> reported good results in many patients on whom he "performed plication of the flail segment (mitral regurgitation). He later combined the procedure with posteromedial annuloplasty".

In 1946 Bailey<sup>8</sup> resorted to the digital technique to dilate stenotic mitral valves but again, the production of severe mitral regurgitation caused the death of four of his patients. His fifth patient whose mitral stenosis was relieved survived as no mitral incompetence occurred.

The relief of mitral stenosis was also successfully approached by Harken<sup>9</sup> with a valvulotome.

In 1954, Gibbon's outstanding contribution was the successful use of total cardiopulmonary bypass to make feasible intracardiac surgery.<sup>10</sup> In 1956 Lillehei<sup>11</sup> performed the first mitral commissurotomy with open heart surgery. The generalized practice of open heart surgery to treat damaged cardiac valves made it evident that not every valve could be repaired. This knowledge led to the need of replacing the diseased valve with prosthetic devices. Biological or synthetic materials to reproduce the morphology of native valves, or of chordae tendinae were unsuccessful partly because of the incompatibility of the materials, fatigue and rupture of the artifacts.

Before the era of extracorporeal circulation Campbell in 1950,<sup>12</sup> and Hufnagel in 1951<sup>13</sup> independently developed artificial valves consisting of a lucite tube and a mobile poppet, using the caged-ball principle developed and patented by Williams in 1858<sup>14</sup> for a bottle stopper. In 1952 Hufnagel<sup>15</sup> successfully implanted this device in the descending

aorta of a patient with severe aortic incompetence. The patient improved considerably and lived several years free of symptoms (*Figure 1*).

In 1960 Harken<sup>16</sup> was able to relieve aortic insufficiency with the use of prosthetic valves. In 1961 Starr<sup>17</sup> developed the highly successful caged-ball valve. Some modifications were made to this device in the following years. Thousands of these valves were implanted from then on all over the world.

In Mexico, the first Starr-Edwards valve was implanted by Benavides.<sup>18</sup> Several hundred of these valves were subsequently implanted in patients at the Instituto Nacional de Cardiología, and in the Hospital de Cardiología y Neumología (IMSS) (Martínez-Banuet et al.).<sup>19</sup>

For some time it was believed, based on isolated observations, that the caged-ball valve could dam-



**Figure 1.** Original prosthesis devised by Dr. Hufnagel. It was recovered from the aorta of a patient who died in a car accident several years later, of symptom-free life. (Courtesy of Dr. Jorge Cervantes).

age the endocardium of the left ventricle when placed in the mitral position. This prompted the creation of the "low profile" valves provided with an oscillating disk or with a double valve instead of a ball. However both the disk and the double valve model create more blood turbulence and more regurgitant volume than the ball valve and are responsible for more thromboembolic complications. While every patient with a prosthetic valve requires the use of anticoagulants, the ball valve is the least thrombogenic of all; in addition it has an excellent hydrodynamic performance, no regurgitation, a minimal transvalvular systolic gradient and a solid structure.

### HISTORY OF THE MANUFACTURE OF PROSTHETIC VALVULAR CARDIAC BIOPROSTHESES IN MEXICO

The monumental contributions of Starr and of Harken who introduced the use of valvular prostheses, kindled the interest of surgeons at the Instituto Nacional de Cardiología to design and to manufacture cardiac valvular prostheses in Mexico.

In 1973, García-Cornejo<sup>20</sup> attended a Congress in Sao Paulo, Brazil where bioprostheses made of human duramater were manufactured and implanted in cardiac valvular patients by Zerbini's group. He learned the technique and acquired the necessary specialized instruments. He suggested the manufacture and use of these valves at the Instituto Nacional de Cardiología. Unfortunately the authorities in those days consulted a physiologist who gave a negative report for the project and the proposal came to naught.

Personal communications by Zerbini<sup>21</sup> and Favalaro to one of us (F.Q.P.) indicated that duramater bioprostheses were discontinued in the aortic position due to their deterioration. Burdon et al.<sup>22</sup> reported calcification of porcine bioprostheses implanted in children and adolescents and decided to discontinue their use in patients under 18 years of age.

In 1978 Quijano-Pitman and Barragán addressed Dr. Kabelá, head of the Department of Physiology at the Instituto Nacional de Cardiología (INC) requesting the construction of a pulse duplicator<sup>23</sup> to test the performance of bioprostheses manufactured by the Department of Surgery. The duplicator attained higher standards than foreign-made duplicators.<sup>24</sup>

These bioprostheses were also implanted in other positions and used for other surgical cardiac techniques such as implants in the pulmonary valve position,<sup>25</sup> valve tubes in complex congenital

cardiopathies, patches to occlude ventricular and atrial septal defects, to expand pericardiotomy closure<sup>26</sup> and others.

During 1989 and 1981 bovine and porcine pericardium prostheses were implanted with material donated by the Hancock Laboratories to the Department of Surgery. Nearly 400 human duramater bioprostheses manufactured in the Department of Surgery at the INC were implanted from April 1976 to February 1982. Numerous papers on the subject were published and many were presented in national congresses from 1971 to 1981 attesting to their excellent performance. The accomplishment of the Department at the INC sparked the enthusiasm of other national institutions to follow suit. Palacios Macedo et al. from the Hospital de Cardiología y Neumología (IMSS) mounted duramater on Southamerican rings<sup>27</sup> and reported their long-term results in 1983.

Dr. Luis Antonio Márquez, an indefatigable intelligent researcher who died prematurely, made valuable contributions to the manufacture of vascular prostheses, bovine pericardium cardiac bioprostheses and to the construction of a bubble oxygenator. One of us (F.Q.P.) had good results with it. His bioprostheses made with Ionescu's technique<sup>28</sup> mounted on polypropylene flexible rings were extensively used at the Hospital General SSA. In San Luis Potosí, Rosillo-Izquierdo started at this time implants of caged-ball valves made in Mexico,<sup>29</sup> the late results were published afterwards.

In 1979 a Mexican corporation began the manufacture of bovine pericardial bioprostheses and aortic porcine valves following the recommendations of Carpentier and Hancock and also mechanical Starr-type caged-ball valves; the latter have had excellent results in the hands of Rosillo-Izquierdo in San Luis Potosí. To date, this is the only mechanical cardiac valve prosthesis manufactured in Mexico.

In 1982 the INC manufactured bovine pericardium valvular prostheses following Ionescu's technique and they were initially implanted in 1983.<sup>30</sup>

The example set by the surgeons at the INC in 1975 was followed by other national institutions who manufactured their own prosthetic valves.

The same is true about oxygenators. The first type manufactured in Mexico were bubble oxygenators made of disposable plastic material by Crespo and Esperanza.<sup>30</sup> They were successfully used in about 20 patients in 1958 and 1959.

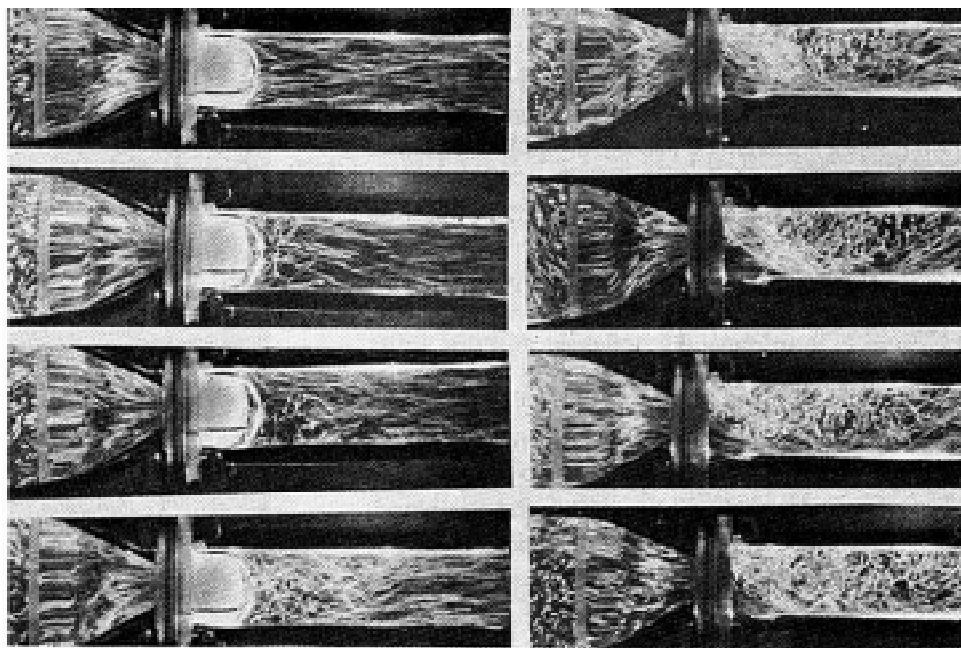
In 1973 the Director of the Instituto Nacional de Cardiología addressed the above mentioned Mexican firm, suggesting the manufacture of prosthetic

**Figure 2.**

*Post-valvular flow in a caged-ball valve (left) and in the tilting-disc valve (right).*

*There is a remarkable difference in their performance, i.e., the ball valve causes minor turbulent flow; it is streamlined for the most part.*

*In the disc valve there is a considerable turbulent flow from the very beginning, which is especially severe in the proximity of the disc.*



cardiac valves. The research team of the company began studying the designs and materials currently used for the manufacture of these valves. The following norms were taken into consideration:

1. The valves should have a proper hydrodynamic design, i.e., they should allow the blood to flow unidirectionally avoiding any reflux. Resistance to the flow of blood should be minimal with no appreciable transvalvular gradient; turbulent flow was to be avoided.
2. Biocompatible elements should be used in the manufacture of the prostheses.
3. Prosthetic valves should resist the impact equivalent to about 40 million cardiac cycles per year for a minimum of 10 years, which is the mean expected survival rate of patients having an implanted artificial valve.
4. The valves must be sterile, free of pyrogens or any harmful substances.

After studying the prostheses in use at specialized institutions it was concluded that the model to follow was the caged-ball valve type which had been in use for many years and it was the model of choice of many surgeons who obtained excellent results with it.

The ball occluder is hydrodynamically superior to a disc occluder in that it allows a laminar flow. This was demonstrated by hydrodynamic tests by G.

Muñoz in the Department of Physics at the Universidad Metropolitana de México. Experimentally the advantage of the ball valve over the disk valve showed laminar flow lines proximal and distal to the valve (*Figure 2*). The ball does not produce a turbulent flow at high speed whereas the disc causes considerable turbulence.

The best material for construction of the cage valve was Stellite-21 (Cabot Inc.). The sewing ring is made of a knitted Dacron R (Dupont de Nemours), a polyester multifilament, free of foreign substances; it contains a silicon rubber sponge ring to dampen the impact of the occluding ball.

#### TECHNICAL ASPECTS OF THE MANUFACTURE OF THE BIOMED CAGE-BALL CARDIAC VALVE PROSTHESIS

A high vacuum melting oven was used for casting. It consists of a steel dome with a powerful vacuum pump capable of lowering atmospheric pressure to between 5 and 100 microns. It contains a cast that can be heated with silicon carbide electrodes and a centrifuge which impacts metal melted at 1500 degrees centigrade into the channels to cast the cage (*Figure 3*).

Casting is done with the "lost wax" method which requires the manufacture of a model identical to the future cast. This is followed by the manufacture of silicone rubber molds into which hot wax is injected



to reproduce the exact shape of the future cage (Figure 4).

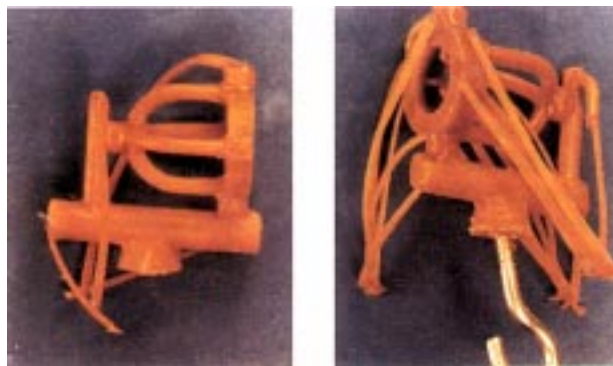
The wax cage is then incorporated into an inlet wax trunk and to the respirators which release air when the hot liquid metal fills the channels. The wax mold resembles a tree which is then embedded in a muddy ceramic mixture; when dried it withstands the casting of the metal.

Once the ceramic recipient is removed, the inlet and the other channels are eliminated with grinders. The cage is then carefully polished and the struts are carefully smoothed with high speed tools (Figure 5). Fine abrasives mixed with animal fat are required to give the cage the mirror-like finish.

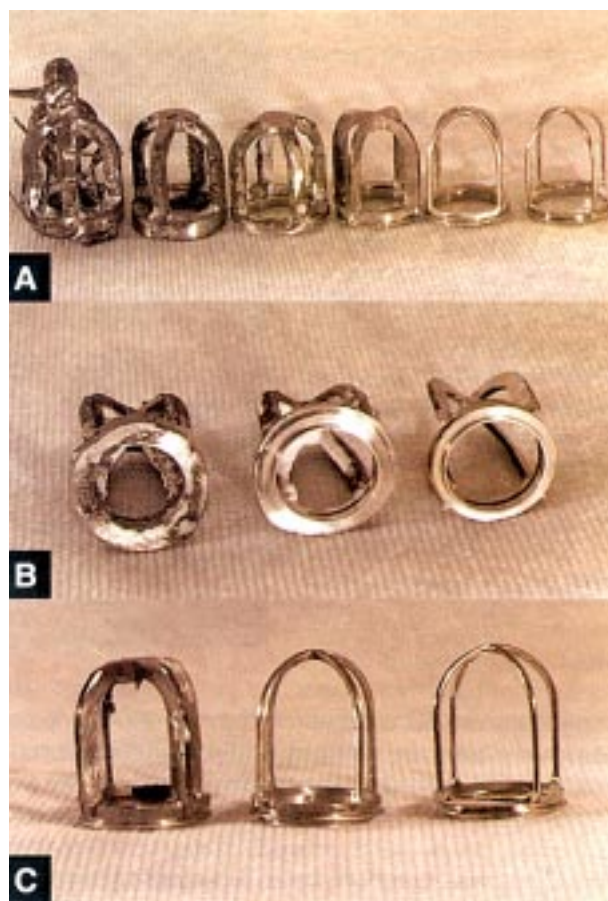
Tolerance of the blood to the Stellite-21 cage is due to an interphase between the metal and the blood, which consists of a fine layer of fatty acids. This phenomenon was demonstrated by double refraction ob-



**Figure 3.** Vacuum metal chamber in which Stellite 21 metal is melted and cast to form the cage of prosthetic valves.



**Figure 4.** A wax cage with an inlet and various ducts through which melted metal will flow. Notice the different "respirators" attached to the wax cage.

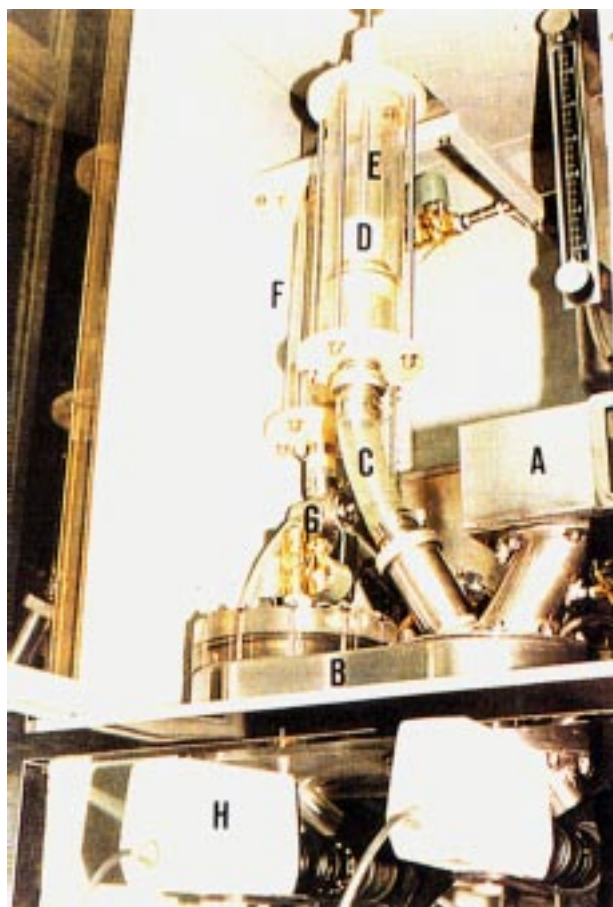


**Figure 5.** Different stages in the manufacture of the metal cage for prosthetic cardiac valves. A. Shows the cage at several stages: immediately after casting and following gradual polishing. B and C shows the bottom and lateral views respectively of the cages at different stages of polishing.

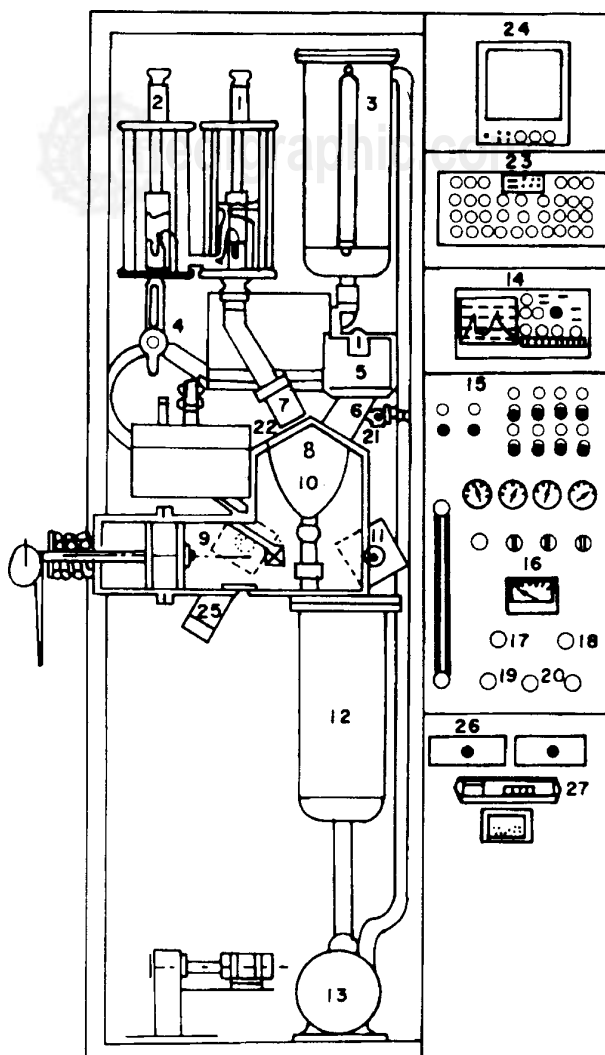
tained when the polished surface of the cage receives a luminous beam projected at an acute angle. The union of this layer to the metal is firm and cannot be broken with cleansing actions nor with detergents. Only strong abrasion or overheating may destroy this union. This union could be of a chemical nature owing to the reciprocal orientation of the charges between the sodium in the sodium hydroxide and the acid radical of fatty acids.

The occludor ball is made of silicone rubber to which barium sulphate is incorporated to render it radiopaque. It is molded by compression at a temperature of 160 °C. It is then overvulcanized for a lengthy period of time to eliminate residues and to give it the proper mechanical properties. The physical features of the balls are tested for hardness using the Shore A test and the elasticity represented by the bouncing of the balls.

The suture ring made of dacron R fabric (Dupont de Nemours) is firmly attached to the cage. It enhances endothelialization owing to the "invasion" of fibroblasts into its mesh. The ring is made of a tubular-shaped fabric containing another polypropylene ring which serves as an attachment base; the fabric is firmly held with polyester thread. The end result is a ring with a circular groove which protrudes at the inner aspect of the ring. It is to this groove that the tubular fabric is held in place by dacron R thread to another silicone medical grade rubber sponge whose purpose is to muffle the impact of the ball during the cardiac cycle. This second ring ensures a perfect adjustment between the cardiac tissue and the prosthetic valve.



**Figure 6.** Cardiac cycle duplicator built especially to test caged-ball valves. **A** represents the atrium; **B** is the ventricular chamber which is subjected to the action of a pressure piston; **C** represents the aorta; **D** is the first set of resistances; **E** is a compressible air chamber capable of storing pressure energy which is liberated during diastole; **F** represents peripheral resistances; **G** is the access of fluid returning to the atrium; **H** depicts the videocameras.



**Figure 7.** Diagram and detailed description of the components of the cardiac cycle duplicator.

#### Description:

- |                                     |  |
|-------------------------------------|--|
| 1. "Arterial" resistance;           | 15. Temperature control;               |
| 2. "Arteriolar" resistance;         | 16. Pulse/rate meter;                  |
| 3. Upper reservoir;                 | 17. Force unit control;                |
| 4. Distribution valve;              | 18. "Arterial" pressure control;       |
| 5. "Atrium";                        | 19. Systole/diastole relation control; |
| 6. "Atrial" transducer;             | 20. "Heart" rate control;              |
| 7. "Aortic" transducer;             | 21. "Mitral" valve;                    |
| 8. "Ventricular" transducer;        | 22. "Aortic" valve;                    |
| 9. Piston/cylinder;                 | 23. Preamplifiers;                     |
| 10. "Ventricle";                    | 24. TV monitor;                        |
| 11. "Ventricular" view via mirrors; | 25. TV camera;                         |
| 12. Lower reservoir;                | 26. TV camera control;                 |
| 13. Pump;                           | 27. TV camera selector.                |

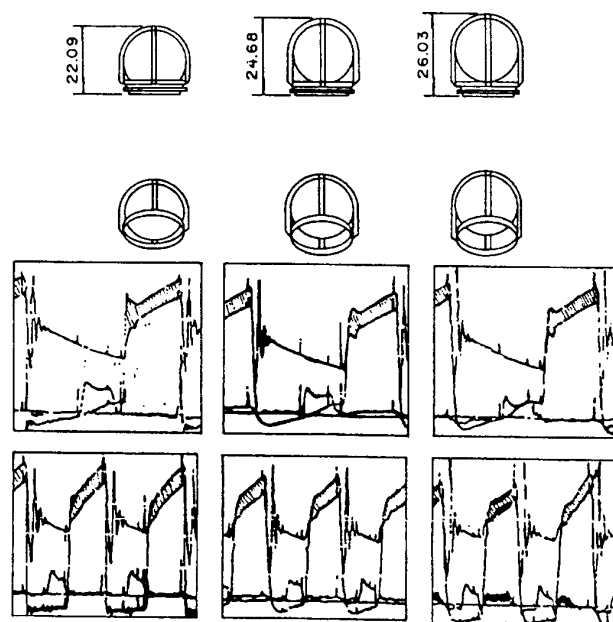
## Testing equipment

Following rigorous quality control tests, the valves are subjected to hydrodynamic tests in a cardiac duplicator in which the "cardiac" output may be regulated to 3.0, 4.5, 6.0 and 8.0 L/min. Results are recorded with a serial number for each valve.

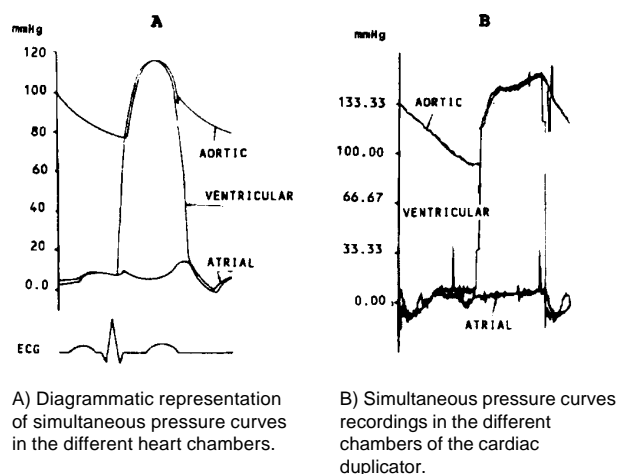
The equipment consists of a pump whose movements are equivalent to ventricular systole in the human heart (Figure 6). The fluid contained in the system is emptied into a closed air-filled chamber and is precalibrated by modifying the number of small channels which constitute a first set of resistances. This compressible chamber stores energy throughout systole, which is then released during diastole as in the large arteries of the human circulatory system (Figure 7).

A series of small channels of predetermined caliber and length constitute a second set of non-compressible resistances that can be calibrated manually, making it possible to vary their magnitude. The reciprocal adjustment of its components permits to increase or decrease the number of channels, which in turn increases or decreases re-

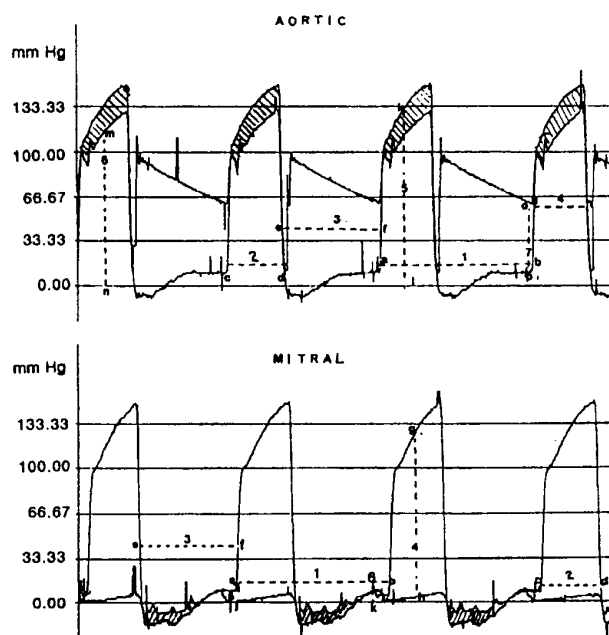
## Mechanical BIOMED Caged-ball Prosthetic Valve Hydrodynamic Study



**Figure 8.** The upper part of the figure depicts different heights of the caged-ball prosthetic valves. The lower figure illustrates the "ventricular" pressure curves for each valve height.



**Figure 9.** The left diagram illustrates the aortic, ventricular and atrial pressures as well as an electrocardiogram in one human cardiac cycle. The right diagram is the actual recording of the "aortic", "ventricular" and "atrial" pressure curves obtained in the cardiac duplicator which are quite similar to the human cardiac cycle.



**Figure 10.** The upper curves represent the aortic and ventricular curves obtained with a caged-ball prosthetic valve implanted in the "aortic" root. The shaded area represents the transvalvular "gradient" which is not significant. The lower curves represent the left ventricular and left atrial pressures when the caged-ball valve is implanted in the "mitral" position. Again, the shaded area represents the transvalvular "gradient" which is minimal.

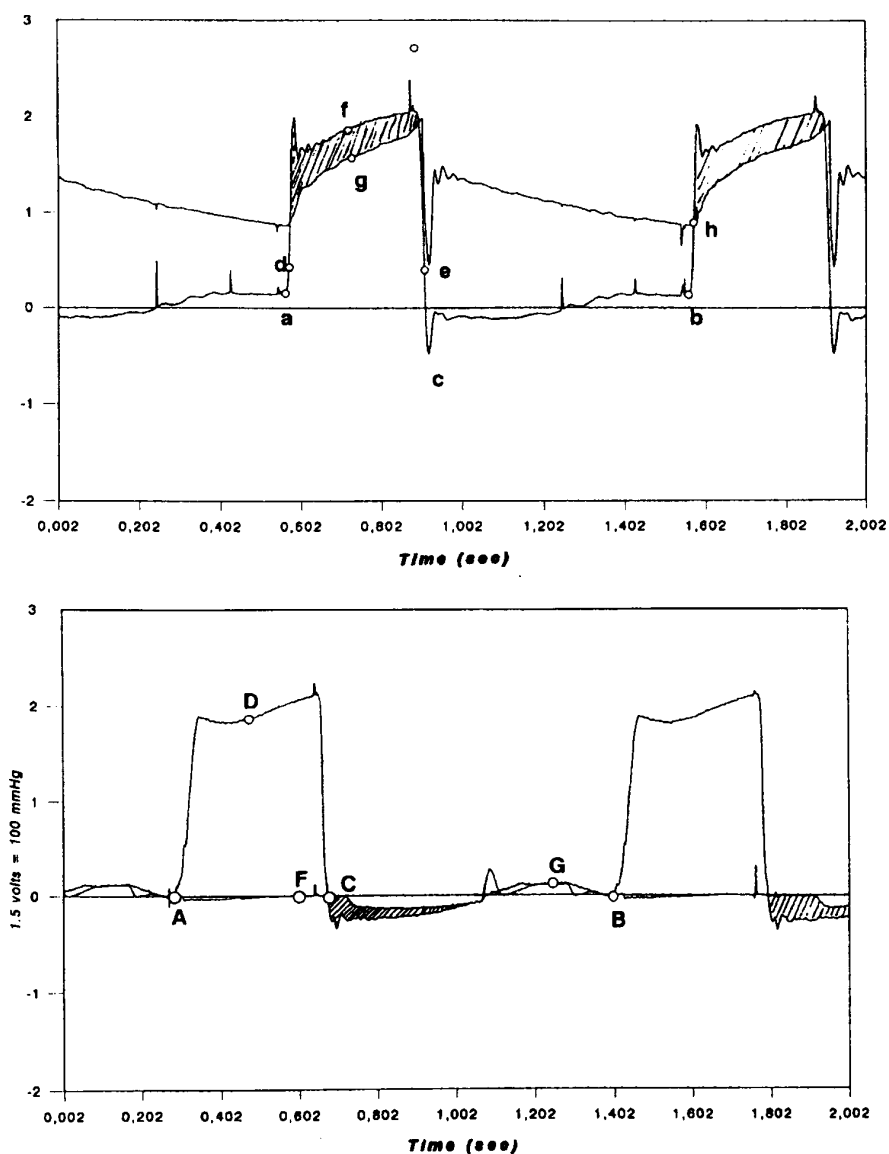
sistances, as a function of output and pressure. This line of resistances is comparable to the muscular action of arteriolar walls in humans. These can be regulated to reproduce hypertension, normotension or hypotension during the hydraulic tests for each valve.

Following the ejection period, when the fluid has circulated through the entire system, it returns and gradually fills a chamber representing the atrium; subsequently it receives pneumatic pressure simulating atrial systole at the end of ventricular diastole.

The equipment has strategically placed transducers (Statham P-23) to register pressure variations. The electrical signal from the transducer is sent to

the amplifiers and to a digital oscilloscope; it is then sent to a computer and a laser printer. This permits an accurate assessment of the function of the valves.

The optimal height of the valve cages was determined for each size (diameter). The curves of the different heights depict pressure/time variations and transvalvular (gradient) pressure loss expressed in millimeters of mercury. Cycle rate, duration of systole and diastole, systolic and diastolic ventricular pressure, aortic pressure, atrial pressure and "cardiac" output are thus measured. Once the pressure curves are recorded, the corresponding variables are measured according to previous calibration<sup>31</sup> (Figures 8-11).



**Figure 11.**

*Another set of pressure curves after implanting the caged-ball valve prosthesis in the aortic position (upper curve) and in the mitral position (lower curve).*



The first Mexican mechanical valve prostheses were implanted in children in 1986 at the Instituto Mexicano de Asistencia a la Niñez (presently the Instituto Nacional de Pediatría).<sup>32</sup> One of the first valves was implanted in an 8 year old boy. It was substituted by a larger valve when the patient was 17 years of age and the prosthesis had become too small. The recovered valve was in excellent condition after nine years (*Figure 12*). That same year,



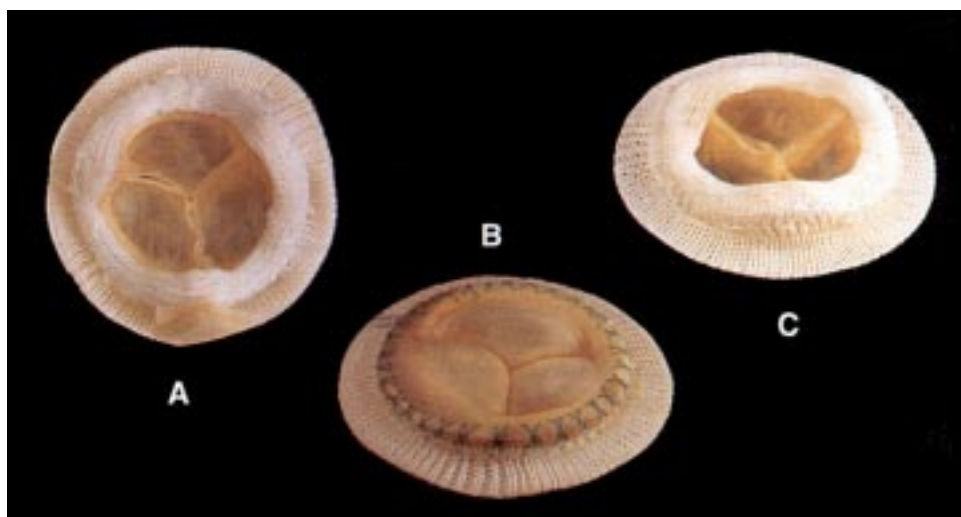
**Figure 12.** A caged-ball valve made in Mexico. This valve was recovered from a 17 year old patient who had it implanted at the age of 8 years. A new larger valve was implanted. Notice the excellent condition of this valve.



**Figure 13.** Upper and lower aspects of two models of finished caged-ball prosthetic valves made in Mexico.

several Biomed valves were successfully implanted in patients at the Hospital 1º de Octubre (ISSSTE) in Mexico City (*Figure 13*).

These valves were also implanted in patients at the Centro Médico of San Luis Potosí and at the Hospital Morones Prieto by Rosillo-Izquierdo et al., whose first report includes 25 implants in 23 patients operated between 1985 and 1986.<sup>33</sup> Only one death occurred. The mean follow-up period was five months. There were no late deaths nor complica-



**Figure 14.**

Porcine valvular prosthesis.  
This photograph depicts the upper (A), lower (B) and lateral (C) aspects of the Mexican made valve.

tions related to the valve. The actuarial survival curve at 10 months was 98%. The patients improved substantially after surgery.

In 1997 Rosillo-Izquierdo et al.<sup>34</sup> reported 120 prosthetic valves implanted in 105 patients over a period of eight years. Most patients were in heart failure preoperatively (Class III of the NYHA); they improved to Class I or II. A few patients remained in Class III. Actuarial survival rate at six years was  $88 \pm 6\%$ . Several more valves were implanted in patients at the Hospital General SSA in Mexico City. By 1994, 150 more valves had been implanted in other hospitals in Mexico. From 1993 to date, 500 valves have been implanted in India and Pakistan.

#### DEVELOPMENT OF THE BIOMED PORCINE BIOPROSTHESIS

The initial steps in the development of biologic prosthetic valves presented with numerous obstacles and hesitations. Some of the first trials were based on the assumption that native valves could be imitated in order to reproduce their hemodynamic features. Various artificial materials were tried: Teflon, Dacron, Silicone, Polypropylene fabric and others. Valve leaflets and chordae tendinae were made with these materials and attached to the myocardium and to the free edge of the valve leaflets.<sup>34</sup> These attempts failed owing to rupture of the valves, thromboses, rigidity of the prosthetic elements, etc.<sup>35-37</sup>

A valuable contribution was the use of homografts with human cadaver valves initially implanted in the descending aorta<sup>38</sup> with excellent tolerance.<sup>39</sup> In the decade 1960-1970 another important contribution was the use of aortic homografts implanted in the normal position<sup>40,41</sup> after eliminating the diseased valves. The homografts were sterilized with ethylene oxide<sup>42</sup> or with beta propiolactone.<sup>43,44</sup> Viability of valvular tissues was preserved with glycerol or with sulfoxide dimethyl and freezing.<sup>45,46</sup> Fibroblasts remained viable for up to three months at a temperature of  $-195^{\circ}\text{C}$  in liquid nitrogen.

The hydrodynamic performance of these valves was excellent, but they eventually became incompetent (aortic incompetence) in about 2/5 of the patients.<sup>47</sup> In some instances the valves became calcified and ruptured.

One problem with implants of human homografts was their relative scarcity and the difficulty to obtain different size valves. Sterilization and storage were an added difficulty.

A spectacular breakthrough took place in 1975 when Binet et al.<sup>48</sup> implanted xenografts in patients with aortic valvular disease. Porcine xenografts were treated with 4% formaldehyde which served the purpose of tanning, sterilizing and dampening their antigenic properties. They were mounted in a flexible metal suture ring. Initially several failures occurred because the tissue disintegrated for lack of resistance as a result of immunologic rejection. Carpentier<sup>49</sup> obtained a perfect tanning and sterilization with glutaraldehyde and thus began the successful development of biological valves among which the Hancock valves gained universal acceptance.<sup>50</sup> Porcine xenografts were also implanted in the mitral position.<sup>51,52</sup> These valve xenografts had minimal thrombogenic properties, minimal hemolytic effect and a minimal transvalvular gradient. Homografts were then discontinued.

Senning<sup>53</sup> and Ionescu<sup>54,55</sup> suggested the use of fascia lata to construct valves. These trials failed because of frailty, and degeneration of the tissues as well as fusion of the commissures.

In 1977 Ionescu<sup>56</sup> resorted to the use of bovine pericardium, a tissue with excellent hemodynamic features and low thrombogenic properties. Unfortunately the valves implanted in the mitral position tended to rupture and to increase the transvalvular gradient.

Biomédica Mexicana decided to use porcine valves treated with glutaraldehyde at low concentrations, stabilized at a pH of 7.4 and free of monomers. This proved to be the best method for tanning the porcine valves. Resistance of the tissues was tested resorting to proteolytic digestion by an artificial "gastric juice" made of clorhydric acid and pepsin. Immersion of the valve for half an hour protected it against digestion; immersion during several hours in glutaraldehyde gave better results. This eliminated its antigenicity and the possibility of rejection. Furthermore they were compatible with the blood (*Figure 14*).

The use of glutaraldehyde requires constant monitoring of the content of polymers and their relation with active monomers. The solution is denaturalized with the formation of toxic polymers; these must be eliminated from the mixture with activated carbon which retains polymers and maintains monomers. Control is done by the technique of ultraviolet light deviation in a spectrophotometer at different light length waves. This makes it possible to determine the characteristic curve of a polymer-free monomeric glutaraldehyde solution. The

valves must be rinsed three times in sterile saline for two minutes each until the solutions contain one millionth part of glutaraldehyde, a concentration which the tissues tolerate.

The suture ring has a flexible solid polypropylene support smoothed with high speed tools. It is covered by Dacron fabric which permits its suture to the heart. Following the implants, a neoendothelium covers the suture.

## CONCLUSION

The manufacture of Mexican mechanical cardiac valve prostheses and porcine valve bioprotheses has been preceded by years of careful laboratory research which includes the selection of optimal materials and rigorous hemodynamic tests. Clinical successful experience with the implantation of hundreds of these valves attest to their high quality.

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