

## Implant of polyurethane prosthesis, in pulmonary position: An experimental study in sheep

Miguel A Maluf

Sao Paulo Federal University, Brazil

**Introduction:** The cardiac stents on the market today: mechanical or biological, are durable and functional, but still not the ideal valve replacement. In search of material biostable, biocompatible, wear resistant and low incidence of calcification, thromboembolism and infection Segmented Polyurethane (SPU), is a viable alternative.

**Objectives:** SPCU prosthesis it was developed to be implanted in pulmonary position in sheep for the purpose of analyzing the results of hemodynamic and histological changes of the prosthetic tissue after 24 weeks of implantation.

**Material and Methods:** Manufacturing: The prototype of the prosthesis SPU was designed in 3D, followed by preparation of the matrix. Through the injection of liquid PCU was filled and shaped by the PCU in the matrix technique esterolitografia. Thus builds a prosthesis comprising: a flexible ring with 3 stems (20 mm) and three movable booklet (thickness: 0.3 mm) in a block. A knitted fabric flap was sutured on the prosthetic ring.

**In vitro tests:** The materials used in the manufacture of prostheses were approved in biocompatibility testing according to ISO 10993-Biological evaluation of medical devices. The dentures will undergo physical tests, hydrodynamic and durability according to ISO 5840-Cardiovascular Implants-Prosthetic heart valves.

**Experiment:** Implantation of the prosthesis in the pulmonary ring of 15 sheep, 6-8 months of age and weight 30-40 kg, will be performed with the aid of cardiopulmonary bypass. Following, will be carried out analysis of hemodynamic performance of the prosthesis with Doppler echocardiography and Computed Tomography Angiography and finally histological study of the prosthetic tissue after explant the prosthesis, in the sixth month.

**Results:** It will be observed the macroscopic and microscopic optical and electronic scanning and imaging studies. The data will be sorted by making emphasis on the degree of calcification, presence of thrombi, infection and integrity of the prosthesis SPU.

**Discussion:** Experimental studies published showed good hemodynamic performance of the polyurethane prostheses, implanted on the right side of the heart: the absence of significant pressure gradients 1 year after implantation. The objective of this research is to reproduce these results and further studies, carried out to better understand the properties of the SPU and level of reliability with a view on release, compared to health authorities for clinical application, thus becoming one more option among the prostheses on the market today.

### Biography

Miguel A. Maluf is graduated in medicine from Cordoba National University, Argentina (1972) he has done his residency in general surgery from Cordoba hospital, Argentina in the year 1973-1974 and thoracic surgery residency from Cordoba hospital, Argentina (1974-1976). And his specialization course in cardiovascular surgery at University of São Paulo-Brazil (1977-1985), as Assistant Professor. E. J. Zerbini. And his Masters during 1986-1987, Ph.D. (1988-1991) and Became a Full Professor (1988) at São Paulo Federal University. Visiting Professor to the service of Prof. De Leval, at Great Ormond Street Hospital, London (1987), sharing the experience with technique of cavopulmonary shunt (bidirectional Glenn and tunnel VCI-APD), instead of atriopulmonary (Fontan operation), for the treatment of univentricular heart; Introducing this technique at UNIFESP, since 1990, being the first center in Brazil using routine technique Bidirectional Glenn and Tunnel VCI-APD; subsequently adopted by the Pediatric Heart Surgery services by all over the world, with significant reduction in mortality. Right Ventricle remodeling technique using four own models of porcine pulmonary prosthesis for surgical correction of Congenital Heart Disease with obstruction of the pulmonary outlet tract. Implementation of the modified technique of ultra filtration after CPB and in Pediatric Intensive Care Unit, developed by Prof.. M. Elliott, at Great Ormond Street Hospital, London (1995).

[miguelmaluf@gmail.com](mailto:miguelmaluf@gmail.com)