OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference on
Surgery and Anesthesia
September 16-18, 2013 Hampton Inn Tropicana, Las Vegas, NV, USA

New polyurethane prostheses for substitution of cardiac valve disease and remodeling of the right ventricle in congenital heart malformations

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Introduction: The biological cardiac prosthesis on the market today, are durable and functional, but still not the ideal valve replacement in children. In search of material biostable, biocompatible, wear resistant and low incidence of calcification, thromboembolism and infection, the segmented polyurethane (SPU), is a viable alternative.

Objectives: Develop three different models of polyurethane prostheses prototypes for substitution in cardiac valve disease and remodeling of the right ventricle, in patients with congenital heart disease.

Material and Methods: Manufacturing: Based on a computed tomography angiography of the aorta, we made a delrin ring, keeping the anatomical characteristics of the aortic annulus. A matrix we made from stainless steel with the shape of the three cusp aortic valve, followed by preparation of the injection of liquid polyurethane segmented (SPU), using an esterolitografia technique. Thus builds three models of prostheses comprising: Model 1 - *Trileaflets prosthesis:* Consist a flexible ring with three movable booklet stems (thickness: 0.3 mm) and a knitted fabric flap was sutured on the prosthetic ring. Model 2 - *Bicuspid prosthesis:* Consist of a ring with 2/3 of circumference containing two leaflets forming part of corrugated flap segment Model 3 - *Valved Conduit:* Consist a corrugated conduit containing a tri leaflet prosthetic into its middle stretch.

***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.

Results: The macroscopic appearance of these prototypes was approved by the group of Engineer, Biologist and Pediatric Cardiac Surgeon. 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. Experimental implants in growth sheep of these SPU models are in progress, which remain for six months. The explanted prosthesis will be followed by a detailed study with optical microscopy and electronic, will assess the presence or absence of calcification, thromboembolism or fatigue polyurethane.

Conclusion: It is possible 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.

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