Meetings International
SciTechnol

Miguel Angel Maluf et al., Int J Cardiovasc Res 2018, Volume: 7
DOI: 10.4172/2324-8602-C2-008

INTERNATIONAL HEART CONFERENCE

August 13-14, 2018 | Singapore City, Singapore

Expandable polyurethane stent valve for transcatheter implantation in children suffering from heart valve disease; results of physical, hydrodynamic and experimental tests

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Introduction: Transcatheter valves manufactured using biological tissue, as the essential structural component, can be induced to: mechanical degradation after crimping and early calcification in pediatric patients.

Objectives: Manufacture and successful tests of one expandable polyurethane stent valve, may reduce the repeated operations of valve replacement, during the growing children.

Material / Methods: I)Physical testing: Prostheses were submitted to universal testing in machine EMIC and a computer with Tesc software, able to generate graphs of force versus deformation (stretching). II)Hydrodynamic testing: Prostheses with diameters from 12 to 22 mm, were submitted to pulsatile physiological flow and stress conditions. III)Experimental implants in sheep: Ten sheep was submitted to prosthesis implant, by trans catheter technique in pulmonary position. In Group A: Four sheep w/ <20 kg, the stent was expanded up to 18mm and in Group B: Six sheep w/ > 20 kg, expanded up to 22mm.

Results: Physical and Hydrodynamic testing of Polyurethane strip removal of stent valve, before and after undergoing to 30 minutes crimping, showed preservation of properties of resistance and elasticity elongation. In vitro durability was proven for >15 years. Eight sheep, were submited to 3D echo study, performed in the 6th month of f.-up, showed: there was no significant transvalvular gradients and trivial regurgitation in 3 cases. Histologic, radiologic and electron microscopic study of the first prosthesis shows: integrity of structure and free of calcification. Seven survival sheep are well, after 24th months of follow-up.

Conclusion: Expandable polyurethane stent valve, with special design for implant and expansion in growing children, has experimental satisfactory hemodynamic performance and durability in vitro and in vivo tests. Calcification and structural changes were not observed. In the next step, clinical studies are be planned.

Biography

Miguel Angel Maluf has graduated from Universidade Nacional de Córdoba, Argentina and become a medical doctor in 1973. Dr. Maluf did specalization in Cardiovascular Surgery at Instituto do Coracao (INCOR) – São Paulo, Brazil. His Surgical Fellowship training was finished by defending the Master's, Doctoral and Postdoctoral thesis, in the Cardiovascular Division at Universidade Federal de São Paulo, Brazil. His research includes development of several models of biological cardiac prosthetic to remodeling of the right ventricle outlet tract, in congential heart disease. Dr. Maluf has more than 25 internattional plus 40 national publications, as well as 80 international and 250 national presentations and more then 11 book chapters related to his research areas. Currently he works as Associate Professor of the Cardiovascular Division at São Paulo Federal University.

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