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New expandable polyurethane stent valve for transcatheter implantation in children with 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.

Materials & 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 follow-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 15th 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.

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