Expandable Polyurethane Stent Valve implanted by catheter in Pediatric patients

Miguel A Maluf and **Mariana G Massei**
São Paulo University, Brazil

Background: The shorten durability and high incidence of reoperations of biological prostheses, in child's development, due to mismatch and early calcification, justify further research.

Methods: An expandable chrome - cobalt stent, was applied polyurethane (PU), for the formation of three leaflets, without sewing, using the dip coated technique, it was submitted to: I- Physical test of samples of PU crimped and non-crimped was performed and scanner analysis, for surface for mechanical properties. II- Hydrodynamic test. Using a pulsatile flow, to register: valvular area, pressure gradient and valve regurgitation. III- Experimental: Ten sheep were submitted to implantation of this prosthesis by catheter, in pulmonary position. Expansion diameter: 22mm (7 cases) and 18mm (3 cases). Three sheep were submitted prosthesis expansion, using balloon catheter. Six prostheses were explanted with 6 to 21 months of follow-up.

Results: I- Physical tests: Structural analyzes of prosthesis showed: Surface scanning of pre and post crimp samples with equal characteristics. The analysis of 6 explanted prostheses with atomic microscopy did not detect the presence of calcium deposit, in any prosthesis. II- Hydrodynamic test showed that, using the same prosthesis under systemic pressure (120 mmHg) and variation of prosthesis diameters, (12, 16 and 22 mm) showed a pressure gradient oscillation between 5 mmHg and 20 mmHg. III- Experimental test: Eight (80%) surviving sheep were submitted to 3D echocardiographic study, showed: satisfactory hemodynamic performance, with low transvalvular gradient (M = 6.60 mmHg), Three sheep (18 mm valve stent), were submitted to expansion of the prosthesis to 22 mm, with success.

Conclusions: The results of the tests applied to the expandable Polyurethane stent valve showed: Resistance of material to wear, guarantee of stent valve expansion. There were no changes in the PU structure after the prosthesis crimped, absence of calcification of the PU leaflets and prosthesis thrombosis, during late follow up. The clinical trial is ongoing.