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Expandable polyurethane stent valve, as an option for pediatric patients with valve diseases: Result of physical, hydrodynamic and experimental studies

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Background: A Expandable Polyurethane Stent Valve®, (EPSV), with a special design for pediatric patients, may be an option for biological prostheses, whose calcification or mismatch, in child's development, shorten their durability.

Methods: An expandable chrome - cobalt stent, was applied polyurethane, for the formation of three cusps, without sewing, it was submitted to: 1- In vitro tests: I- Physical test. Universal tests of samples of PU crimped and non-crimped was performed: A- Strength versus deformation (stretching). B- Scanner for surface for mechanical properties. II- Hydrodynamic test. Using a pulsatile flow, to register: valvular area, pressure gradient and valve regurgitation. 2- In vivo test: III- Experimental: Ten sheep were submitted to implantation of expandable polyurethane stent valve by catheter, in pulmonary position, using right ventricle approach. Expansion diameter: Group A: 22mm (7 cases) and Group B: 18mm (3 cases).

Results: I - In vitro tests: PU showed to be a thermoplastic structure with high deformation, resistant to crimping and elongation. The hydrodynamic test showed low gradients and absent or trivial regurgitation of the prosthesis. 2- In vivo tests: After 5th months of follow-up, a 3D echocardiographic study, was performed in eight survival sheep and showed: satisfactory hemodynamic performance, with no significant transvalvular gradient ($M = 6.60$ mmHg), absent or trivial valvular regurgitation, absent leak and free of calcification. Five survival implanted sheep are well after 24 months of follow up

Conclusions: Monitoring of favorable results, confirms that the expandable PU stent valve, can be implanted in pulmonar position in growing children, below 7 years, during conventional surgery and above 7 years, by peripheral vessels.

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