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An Original Single-Body Synthetic Heart Valve: Feasibility Study And Prototype Realization

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Objectives:

The research for durable, non-thrombogenic heart valve prostheses able to overcome the limits of biological and mechanical ones, promoted the development of synthetic valves. Their success has been hampered by lack of durability, due to calcification and thromboembolic complications. The aim of this work was to develop a prototype of a new elastomeric biocompatible valve, durable and free from calcification.

Method:

A PEtU-PDMS material was sinthetized and processed by a "phase inversion" technique spraying it directly on a mould mounted as a rotating mandrel on a "spray-machine". The mould reproduces the morphology of a commercially available biological aortic valve. Varying chemical composition and fabrication parameters it was possible to obtain valves with different properties of biocompatibility, biostability and mechanical behaviors. The material was subjected to *in vitro* biostability, biocompatibility, calcification and flexural fatigue tests.

Results:

The obtained valve was composed by a single-body incorporating a stent, without suture or gluing agent, reproducing the morphology of the reference valves. The material deposition was regular guaranteeing a uniform distribution of thickness along the leaflets. *In vitro* tests demonstrated low propension to calcification, good biostability and biocompatibility and good flexural resistance during opening and closing phases, of the synthetic valve prototype.

Conclusions:

The PEtU-PDMS materials demonstrated to have the potentiality to be used for the realisation of synthetic valves able to substitute the biological and mechanical ones avoiding calcification and thromboembolic complications. The spraying procedure allowed to reduce the stress concentration on the leaflet commissures and to guarantee high long term performance and durability.