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INTRODUCTION OF A THREE-DIMENSIONAL COMPLETE UNILAYER FLEXIBLE POLYMERIC VALVULAR RING : A NEW CONCEPT FOR TRICUSPID VALVE REPAIR IN CARDIAC SURGERY.

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Only incomplete techniques of tricuspid valve repair annuloplasty are used to avoid conduction tissues and complications. The tricuspid rings available are incomplete demonstrating limits in valve repair particularly in rheumatic patients. We propose a new concept of valve reconstruction thanks to a new three-dimensional complete unilayer flexible polymeric ring. The new ring is described and in vivo results are reported. Methods : The 3D Complete Polymeric Tricuspid Ring (3DCPTR) is a remodeling ring with a three-dimensional complete design. This ring is entirely made of polytetrafluoroethylene. The thickness of the ring is modulated to allow a modulated flexibility. The holder is integrated to the ring for stabilization during the surgical insertion. This insertion is facilitated by the presence of multiple holes (for the stitches). Refined technology and chip removal machining are used in the manufacturing process of the ring. To confirm the safety of the 3DCPTR we have implanted it in a canine animal model. Four dogs received the tricuspid annulus and histopathology findings were recorded once the rings were explanted (after 12 weeks). Results : The new design of the 3DCPTR combined with its polymeric composition provides a three-dimensional remodeling shape and size of the tricuspid valve annulus particularly useful in rheumatic heart valve disease. The modulated flexibility of the 3DCPTR accommodates to the tricuspid annulus and right heart dynamics when inserted. A fast surgical insertion technique is possible. The biomaterial characteristic provides a fast endothelialization of the ring reducing thromboembolic events. The unilayer composition permits easy and low cost manufacturing. Histopathologic findings in animal testing showed good tolerance and biocompatibility of the polymeric ring. Conclusion : The new 3DCPTR is a new tool for cardiac surgery and a new concept of complete tricuspid valve repair ensuring safety of use in animal testing.