phenomenon, and a slightly greater pressure gradient across the valves than a mechanical valve (MV) [Bjork-Shiley monostrut valve]. The flow and pulsatile efficiency were adequate and similar to that of a VAD with MVs. In in vitro durability and hemolysis tests, a VAD with STV functioned well for 54 days and showed similar hemolytic profiles to a VAD with MVs. In an in vivo acute experiment using an adult sheep, our device was problem-free providing sufficient output as a left ventricular assist device (LVAD). Although it will be necessary to decrease the pressure gradient across this STV in the future, our device showed efficient performance as a practical land cost-effective VAD for short term use.

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Title

A newly developed porcine heart valve bioprosthesis fixed with an epoxy compound. An experimental evaluation.

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Abstract

Concerns with currently available bioprostheses are calcification, long-term durability, and functional and hemodynamic performance. It has been well known that these concerns are all more or less related to the fixatives, glutaraldehyde or formaldehyde, used in preserving bioprostheses. To address these concerns, we undertook the development of a porcine bioprosthesis fixed with an epoxy compound. It was discovered that the porcine leaflets fixed with the epoxy compound appeared more natural than those preserved with glutaraldehyde. The performance of this newly developed epoxy compound bioprosthesis (three samples) was evaluated in a juvenile sheep model. The results were compared to those of its glutaraldehyde counterpart (three samples). Two-dimensional echocardiographic inspection of the valvular leaflet motion indicated that the epoxy compound leaflets were more pliable than their glutaraldehyde counterparts. In addition, the epoxy compound valve appeared to open more widely than the glutaraldehyde valve. Color Doppler flow mapping demonstrated that the blood flow distal to the epoxy compound valve was slightly broader than that observed distal to the glutaraldehyde valve. Moreover, at retrieval, less calcium and pannus ingrowth were observed in the epoxy compound valve than its glutaraldehyde counterpart. The results of this preliminary evaluation indicated that the performance of this newly developed epoxy compound valve was at least equivalent to its glutaraldehyde counterpart, if not better.





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NORRED EXHIBIT 2215 - Page 1 Medtronic, Inc., Medtronic Vascular, Inc., & Medtronic Corevalve, LLC v. Troy R. Norred, M.D. Case IPR2014-00395





