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Title: Is This a Good Study?

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Central Message:
Animal studies of new vascular prosthesis by independent researchers should be encouraged providing that the technique and methodology are rigorous. Heterogeneity of the findings suggests less than optimal technique. Strikingly different results than previously published need to be reproduced.

Central picture legend: Dr Christian Brizard

Long-term animal testing of tissues or valves is not an easy exercise. Numerous technical issues have to be mastered in order to produce reliable and reproducible results.
The recommendations for the conduct of animals models for the evaluation of safety and efficacy of cardiovascular prosthesis are clear and instructive[1]. Many studies involving animal implantation of CardioCel® in valvar and vascular position have been published. All are well designed, follow the recommendations and include a control group. The surgical technique is rigorous. In the study by Salameh et al "A one year study of bovine pericardial vascular patches (CardioCel®) in minipigs", many basic features necessary to judge the reliability of the results are missing and we have grave technical concerns as well.

First, there is no control group. This is a terrible deviation from recommendations.

Second, the lateral cross-clamping of the ascending aorta or the main pulmonary artery, *without* the assistance of cardiopulmonary bypass does not set for a satisfactory suture of a patch. We calculated that a side-biting clamp excluding a third of the aortic circumference in the 8mm aorta produces a fold of aortic wall barely 2 mm out of the jaws of the clamp.

Third: In the histological sections, the reader is stricken by the heterogeneous aspect from one animal to another. In some, it is hard to determine the exact location of the originally implanted tissue. In others, one sees enormous amount of newly formed tissue around the