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Comparative Assessment of Prosthetic Biomaterials for Cardiac Applications

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Extended Abstract

Heart valve dysfunctions are diagnosed annually in about 100 million patients. Consequently, new treatments are continuously developed in the attempt to enhance cardiac valve repairs and prosthesis manufacturing [1,2]. The treatment process of soft tissues for cardiac applications should preserve native tissue and guarantee good interaction with the host biological microenvironment. Commonly used biological prosthetic tissues are subjected to cross-linking treatments, aiming to improve their mechanical strength and durability; however, the associated alteration of the tissue natural texture could modify the interaction with the host environment. In the last decades, new generations of biomaterials are being developed to mimic native tissue structure-function [3]. In this study, a newly developed unfixed biomaterial, produced by ADEKA Corporation (Tokyo, Japan), is compared with other three clinically used biological tissues, two of them subjected to cross-linked processes (LeMaitre CardioCel®, CryoLife PhotoFix®) and one of them unfixed (CorMatrix CorPatch®).

The four tissues were used to manufacture four stented prosthetic aortic valves [4]. Hydrodynamic (through a pulse duplicator, ViVitro Superpump, SP3891, Canada) and durability (through a high cycle system, VDT-3600i, BDC Laboratories, CO, USA) assessment were performed according to ISO5840 [5], to investigate their performance and ability to withstand physiological operating conditions. In-vitro tests were performed to investigate their interaction with the complex biological neighbourhoods. The tissues were exposed to simulated body fluids [6,7] to evaluate calcification; and their aptitude to thrombus formation was investigated after tissues contact with fresh ovine blood. The calcification test results were analysed qualitatively via scanning electron microscopy (SEM) and energy dispersive X-ray spectroscopy (EDS) (Phenom Pro X, Thermo Fisher Scientific), and quantitatively by computed tomography with micro resolution (Micro-CT). The platelet test results were evaluated qualitatively via SEM and quantitatively via lactate dehydrogenase (LDH) test.

Although all tissues are able to provide ISO5840 compliant aortic valves, in vitro durability tests suggest that unfixed patches are inadequate to withstand the demanding operating conditions typical of left heart valves. The fixed patch PhotoFix failed after reaching a durability of one equivalent year. However, among the unfixed patches, Adeka product exhibits better mechanical properties over the CorPatch, and resulted in the lowest calcium and platelet deposition. Hence, the absence of crosslinked treatments, despite leading to a weaker tissue texture, helps in preserving a biological response more physiological.

References

[1] D. F. Williams, D. Bezuidenhout, J. de Villiers, P. Human, and P. Zilla, "Long-Term Stability and Biocompatibility of Pericardial Bioprosthetic Heart Valves," Front. Cardiovasc. Med., vol. 8, Sep. 2021, doi: 10.3389/FCVM.2021.728577.

[2] Zaidi, A. H., Nathan, M., Emani, S., Baird, C., del Nido, P. J., Gauvreau, K., ... & Padera, R. F. (2014). Preliminary experience with porcine intestinal submucosa (CorMatrix) for valve reconstruction in congenital

heart disease: histologic evaluation of explanted valves. The Journal of thoracic and cardiovascular surgery, 148(5), 2216-2225.
[3] Sharma, D., Ferguson, M., Kamp, T. J., & Zhao, F. (2019). Constructing biomimetic cardiac tissues: a review of scaffold materials for engineering cardiac patches. Emergent materials, 2, 181-191.
[4] Rahmani, B., McGregor, C., Byrne, G., & Burriesci, G. (2019). A durable porcine pericardial surgical bioprosthetic heart valve: a proof of concept. Journal of cardiovascular translational research, 12, 331-337.
[5] International Standard. ISO 5840-1:2015 (E): Cardiovascular implants: cardiac valve prostheses. Geneva: ISO Copyright Office; 2015.
[6] Implants for Surgery–In vitro Evaluation for Apatite-Forming Ability of Implant Materials; ISO 23317
[7] Kiesendahl, N., Schmitz, C., Menne, M., Schmitz-Rode, T., & Steinseifer, U. (2021). In Vitro Calcification of Bioprosthetic Heart Valves: Test Fluid Validation on Prosthetic Material Samples. Annals of Biomedical Engineering, 49, 885-899.