BIOMATERIALS IN MEDICAL APPLICATION: ARE WE TESTING CORRECTLY?

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Testing of biomaterials and its precursor polymers prior to their final clinical application is a condition- sine-qua-non. Once, such materials are incorporated into medical devices, testing should not only involve their physical performance but also assess the material's biocompatibility. Special problems arise, when materials are dedicated for longterm use, as e.g. in chronic diseases. In this context, biomaterial testing should also be performed under the aspects of longterm stability, i.e. biostability and thus, consider the specific conditions of an exposure to body liquids under the special situation of a physiological stress-environment. This implies an extended exposition of biomaterials to body liquids, such as blood or serum or e.g. to a highly acidic environment in order to simulate stomach conditions.

Testing biomaterials or medical devices should always be considered under the premises of a "Systems Approach", taking into account the specific situation of the final application. This implies that testing should not exclusively be done with healthy blood as a testing solution. As an example, diabetic patients show disturbances of the blood coagulation cascade and an impaired platelet behaviour, dialysis patients exhibit electrolyte imbalances such as high serum phosphate levels or a certain serum toxicity with impact on white blood cell behaviour. Donor blood for biomaterial testing should simulate this situation as close as possible in order to receive reliable data for material selection. Further, bystander effects may also contribute to these complicated figures. 1. Immunological conditions may vary during the time course of the day. A circadien rhythm can be found for T-cell activity, which is highest during night times as compared during the time course of the day. 2. Nutritional conditions, such as a high fat or NaCl intake may influence device performance in terms of clotting or blood pressure behaviour.

Technical properties of medical devices, such as artificial organs, may depend on the final clinical procedure applied. Biomaterial testing should be done by simulating all possible procedures and consider surface area in contact with blood, blood flow, blood pressure and time scale of application during in vitro testing. In other words, miniaturized devices should be tested with performance features which had been reduced accordingly. Testing polymers and biomaterials for their application in medical devices should always be performed as a systems approach, taking into account a series of side effects. The development of a score model, which summarises several impact factors at a time, may be a solution.