Reg. No: 2023/49/B/ST11/03301; Principal Investigator: dr hab. in . Marcin Łukasz Basiaga

Atrial septal defect (ASD) is one of the most common congenital abnormalities in children and the most common congenital abnormality found in adults. It accounts for 5.9% to 22% of all congenital heart defects. The atrial septal defect causes left-right blood leaks and increased pulmonary flow. According to the ESC 2020 guidelines for the treatment of adults with congenital heart disease, it is recommended to close the defect percutaneously (minimally invasive method). Several types of ASD closure kits are currently available. One of the most frequently used is the self-expanding Amplatzer Septal Occluder set. The design of these implants is based on NiTi alloy. Despite the good biocompatibility of NiTi alloys, comparable to the biocompatibility of pure titanium, the use of these materials for long-term implants raises doubts due to the high content of nickel and the risk of its ions being released as a result of corrosion in the body environment. Percutaneous closure of ASD is associated with a complication risk of 7.2% compared with a postoperative complication risk of 24%. Complications include allergic reactions and thromboembolic complications. There are two ways to improve the hemocompatibility of NiTi alloys. The first is the replacement of nickel in the alloy with less toxic elements such as Pt, Pd, Zr, Hf, or Nb, however, alloying additives significantly change the characteristic temperatures of martensitic transformation, thus excluding the possibility of using these alloys in medicine. Another way to improve the hemocompatibility of NiTi alloys is realized by the modification of their surface. From the analysis of a study, most of the work on the use of NiTi alloys shows that the effectiveness of their use is determined by the physicochemical properties of the their surface. Therefore, in current studies, the greatest attention is focused on the development of the production of coatings on the surface of NiTi alloys significantly reducing the blood coagulation process and ensuring their good biotolerance in the cardio-vascular environment. Despite the involvement of many scientific centers in the world, the issue of NiTi alloys for medical applications is based on partial research. There are no studies synthesizing comprehensive issues of corrosion and biocompatibility in relation to specific forms of medical devices intended for long-term use. There is no data on the structure of the surface layers produced, their deformability, adhesion, and surface topography, as well as the behavior of surface layers during phase transformations, conditioning the use of a given shape memory phenomenon. Against this background, a comprehensive assessment of the results obtained by individual authors is difficult to generalize. Therefore, the proposed project will develop conditions for the production of surface layers with physicochemical properties adequate to the specificity of the cardiovascular system. Thus, the main goal of the research will be to determine the correlation between the structure and physicochemical properties of the layers (shaped by the technological conditions of the process) applied to the substrates of NiTi alloy intended for contact with blood, and their hemocompatibility. The first stage of the project implementation will involve the development of conditions for the deposition of surface layers SiO₂ and Ta₂O₅ using the ALD (Atomic Layer Deposition) and EPD (electrophoretic deposition) methods. The use of this type of surface treatment is dictated by the need to ensure invariable geometric, structural, and mechanical properties of the metal substrate subjected to surface treatment processes. Comprehensive tests for their corrosion resistance will be carried out for the surface layers produced under conditions simulating the circulatory system environment. Next, for selected variants of surface treatment, also tests of the chemical and phase structure of the produced layers, their mechanical properties, surface topography, and physical properties will be carried out. Their effect will be to determine the correlation between the microstructure, mechanical properties of the metal biomaterial, and the morphological structure and physicochemical properties of their surface. This will enable us to identify a more favorable variant of this process. In the final stage, for the samples prepared in this way, in vitro biological tests, based on the ISO 10993 standard, are divided into the general assessment of biocompatibility and the hemocompatibility test under the conditions of potential, post-project use. The scope of the research will allow a comprehensive analysis of the impact of the structure and physicochemical properties of surface layers on the processes occurring on the surface of implants after their introduction into the blood system. The planned research is innovative and the obtained results will have a great impact on the development of the scientific discipline.