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Development of Risk-Management Approach in Additive Manufacturing of Orthopedic Implants

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Extended Abstract

The emerging interest in use of customized implants developed through additive manufacturing (AM or 3D printing) increases the complexity of the choice of test materials and the applicability of pre-clinic tests, since a single piece is developed for the specific patient needs [1,2]. Currently, literature lacks on standardization of this type of assessment [3] and there is still no consensus on whether starting materials, after going through additive manufacturing are still biocompatible or that their performance and material properties was not affected by post-processing steps of AM [4]. In this context, this study aimed to develop a risk-based approach, in accordance with applicable standards, in order to ensure the safety and effectiveness in the use of customized orthopaedic implants made of titanium. The implants are obtained by additive manufacturing using Electron Beam Melting (EBM) technology, by Iconacy Orthopedic Implants Ind. e Com. de Prod. Médico Hosp. Ltda, a Brazilian company. The risk assessment considered the processing steps: additive manufacturing, machining, dust removal, cleaning, sanitization, drying, engraving, packaging and terminal sterilization by gamma-ray. Based on ICH Q9 [5] and ISO1497 [6], our multidisciplinary research team used FMEA (Failure Mode and Effect Analysis) to determine the risks related to materials and manufacturing processes. Considering potential sources of failure and their severity of harm to patients, we calculated risks based on the implemented controls, which determined the probability of occurrence and detection. The risk assessment results showed that the greatest risks to patient safety relates to microbiological and chemical pre-sterilization contamination during cleaning; changes in biocompatibility after AM processing; and low biocompatibility of the product due to its composition. Based on risk, the team designed and built testing samples that are representative of those customized implants surfaces and their tri-dimensional structures. The samples were submitted to all the processing steps simulating final products. We conducted complementary tests for product biocompatibility and cleaning validation, as part of risk assessment outcomes, which results were satisfactory. Then, the identified risk categories were all reduced to “low” or “medium”. Medium category was restricted to those risks which severity of damage was classified as “5 (severe)”, due to the inherent high risk of this type of medical devices, therefore, considered acceptable, given the strict controls implemented. Therefore, our research group determined, based on the risk assessment developed that product safety benefit-risk balance is positive, being the studied customized implants safe for use in clinical practice. This study also contributed to scientific research with technical bases in the field of evaluation of customized implants, increasing the safety of their use, and accelerating the delivery of these products to patients awaiting this therapy in the hope of improving quality of life.

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