ADDITIVE MANUFACTURING OF MEDICAL IMPLANTS WITH BIOCOMPATIBLE MATERIALS, A CHALLENGING APPROACH IN INDIVIDUALIZED PRODUCTION IN MEDICAL ENGINEERING

MSc. Ali Abdolahi [1], Prof. Dr. Britta Nestler [1,2], Prof. Dr.-Ing. Rüdiger Haas [1]

Institute of Materials and Processes (IMP), Hochschule Karlsruhe – Technik und Wirtschaft, Karlsruhe, Germany[1]

Institute for Applied Materials - Computational Materials Science IAM-CMS, Karlsruhe Institute of Technology (KIT), Karlsruhe, Germany[2]

ali.abdolahi@hs-karlsruhe.de, britta.nestler@kit.edu, ruediger.haas@hs-karlsruhe.de

Abstract: *In this paper, the capacity of additive manufacturing in the medical engineering will be considered in order the fourth industrial revolution, industry 4.0. The benefits of additive manufacturing, particularly individualization and sustainability, will be discussed and the particular demands of medical engineering are mentioned in relating to the manufacturing technology. Also, the challenges and technical lacks of the technology, mechanical properties, will be analyzed due to the scientific experiments and technical reports. The solutions for the problems are considered briefly and the alternative systems or processes will be obtained regarding the medical application. This research presenting the starting steps of the new project which is planned for next years, in the Institute of Materials and Processes, IMP, at Karlsruhe University of Applied Sciences.*

Keywords: ADDITIVE MANUFACTURING, MEDICAL IMPLANTS, BIOCOMPATIBLE MATERIALS, NUMERICAL SIMULATION

1. Introduction

Nowadays, Additive manufacturing, A.M, is rapidly developed for production of complex shapes and forms. One benefit of A.M. is the possibility of production of the entire form of a product without using different technologies of conventional or unconventional manufacturing processes [1]. Also, A.M. is highly sustainable technology, which has the close-to-zero waste materials, due to less usage of subtractive manufacturing technologies [2]. In other hand, customization of products is the new trend in production engineering which is one of potential of cyber-physical system and cloud computation in the fourth industrial revolution, Industry 4.0 [3, 4]. Combination of these three concepts lead us to the individualized production system, which can produce wide range of products according to the customers' order. Additive manufacturing, which is known as 3D printing, is the unique manufacturing process which has the potential of individualized production in fast procedure of soft tissue and artificial organs for body, medical implants, and biomedical ergonomic devices. [5] Regarding the research, 3D printing is a valuable technique for production of medical implants, [6, 7] which has to be prepared based on patients requirement, in a particular dimension and in few numbers, mostly it is requested to make an implant in desired dimensions once [8].

Particularly, the novel 3D computer models of the structure and shape combined with simulations, e.g. of the mechanical characteristics, support the future design of optimized individual implants. The mechanical properties of the material and the structure will be improved toward the implant development with accepted performance. Thus, additive manufacturing is the fascinating technology that increase the effectiveness of medical companies in the modern market. Briefly, additive manufacturing of the live tissue, similar characteristics as cells, skin, and bone, is the leading edge of the science to improve the medical treatments of patients [7, 9, 10, and 11] and societies' health level.

2. Individualization processes

In the modern trend of manufacturing systems, Industry 4.0 utilizes cyber-physical systems to develop the traditional systems to smart factories. This involves cloud systems to collect the data from different manufacturing units [12, 13], and to make the production system adopted to the market's demand. Development of manufacturing systems in the recent decades was aimed to make it more adoptive and responsive to the market demand. Flexible Manufacturing System FMS and Reconfigurable Manufacturing System RMS are two examples to adjust the manufacturing systems for variable products production as requested by clients [14, 15]. The next level was customized production which is using the cloud systems to collect the desired options for a product from clients. Thus, industry 4.0 prepares the platform for collecting the customers' orders, analyzing them to obtain the new product. In this direction, additive manufacturing will be the unique technology, to use the analyzed data to produce the customized product. In this category, the product can be produce exactly regarding the customer's order [12, 15]. This is the concept of individualized production utilizing 3D printing.

In the smart factories production processes are running under the cyber-physical network which the data are storing in it continuously. The data is transferred within the cloud system, for processing and real-time decision making actions [3]. Thus, smart factory prepares the interactive field for dynamic response to demands, toward manufacturing the individualized products. Although, the response time of the factory depends on the facilities and flexibility of the production system [4, 13].

3. 3D printing of biocompatible materials

Biocompatibility is a characteristic of materials, which are non-toxic, and has not harmful progress on body. Also, the biocompatible materials are corrosion resistant [16]. Generally, National Institute of Health determines biomaterials as "any substance (other than a drug) or combination of substances synthetic or natural in origin, which can be used for any period of time, as a whole or part of a system which treats, augments, or replaces tissue, organ, or function of the body." Biocompatibility is the key parameter of the implanted materials which is defined as surface properties. This covers how the body reacts in the interaction with the implant on the surface [17]. Chemical reaction on the implant's surface means instability of the material and unpredicted effects during the time. The physical diffusion of the soft tissue in the porous structure of the implant is accepted if there is not any chemical reaction or mechanical instability.

There are known categories of biocompatible materials, which are used in medical implants and some medical devices. Titanium is widely used for bone and dental implants and their accessories for example screws or bolts. Titanium alloy grade 5 (ASTM F136) is an alloy with 6% Aluminum and 4% Vanadium [12], and titanium grades 4, 3, 2, and 1 [ASTM F67] are unalloyed. Titanium grade 1 has the highest purity and lowest mechanical strength, and respectively, Titanium grade 5 has less purity and highest mechanical strength [16]. On the other hand, there are biocompatible ceramics and polymers, which are used for production of medical implants, artificial vessels and skins, artificial heart and heart valves, biocompatible coating and drug delivery [17]. The leading research on synthesis of the new biocompatible materials is concentrated on polymer- or ceramic-based materials [18, 19], which are adjusted for different mechanical characteristics, for wide variety of applications with different properties and characteristics. Ultra-high-molecular-weight polyethylene (UHMWPE), Polyether ether ketone (PEEK), and photopolymer are three groups of the polymers, additionally Alumina, bio-ceramics and bio-glasses are the biocompatible ceramics, which are used for medical implants [17]. Referring the goal of the research, the mechanical characteristics of the biocompatible materials are investigated and developed. The numerical simulation of the implant's structure will guide the mechanical characteristics as required criteria for the aimed application.

4. Microstructure modeling

The medical implants are mechanical structures which are involved with cells and organs of an alive body. The implant is used in a patient's body, which is named "host". The implant is installed on the body, which has to have the mechanical and biological behavior as the normal organ or tissue. However, the mechanical behavior of the bone implants will be developed in the 3D numerical simulation. The numerical modeling will be performed in PACE3D, which is developed during years for microstructure simulation. Due to the goal of the research, the porous structure and network of microscale strings of the implants is simulated mechanically, to realize the optimum design for the structure and to improve the material properties and characteristics.

Also, the mechanical structure has to have the adoptive interaction with host's organs, which means the healthy application of the implant. There are two factors effective on healthy application of an implant, the biocompatibility which is described before, and the ergonomic bio-design, due to interaction of host's cells and the surface of implant microstructure. The medical implants cause two different responses during the time which is used in host's body. The initial response, due to mechanical forces, protein adsorption or cell adhesion [18], will be damped with medicaments and post-threating. Although, the determinative parameter is referred to the progression of the host response. Negative factors, e.g. calcification or inflammation [18] are followed and the interaction of the implant is simulated to find out the reasons. The feedback will lead researchers to develop the implants as similar as the body elements, with the adoptive healthy performance. The numerical modeling in the porous is a developed numerical simulation of vector-valued multiphase-field model [20, 21], to simulate the mechanical characteristics and surface interaction of the medical implant. Also, the mechanical strain will be analyzed regarding the elasto-plastic behavior of the structure, with using the multiphase-field model [22]. The evaluated strain in 3D model will improve the initial design of the structure for production.

5. Conclusion

In this research, the capacity of additive manufacturing technology in medical engineering is reviewed and examined, also the challenges in the manufacturing techniques and the material production are analyzed as it will be simulated in 3D novel model. The numerical model will be developed particularly for the medical application, based on the PACE3D code on Linux machines. Finally, the benefits of product individualization in medical field is presented, as a comparative advantage of cyber-physical systems in Industry 4.0. The manufacturing process of the product, considering the above factors, is the next step of the project, which will be conducted beside the research.

References

1. Gibson I, Rosen D, Stucker B. Additive Manufacturing Technologies, Springer 2015
2. Muthu S. Handbook of sustainability in additive manufacturing, Volume 1, Springer 2016
3. Brecher C. Integrative production technology for high-wage countries, Springer 2011
4. Prinz A, Bauernhansl T. Optimization of global production network structures, 15.Internationales Stuttgarter Symposium. Proceedings. Wiesbaden, Springer Fachmedien Wiesbaden 2015
5. Ventola CL. Medical Applications for 3D printing: current and projected uses, Pharmacy and Therapeutics, Vol. 39, No. 10, 2004
6. Huang SH, Liu P, Mokasdar A, Hou L. Additive manufacturing and its societal impact: a literature review, Int. J. of Advanced manufacturing Technology 67, 2013
7. Melchels FPW, Domingos MAN, Klein TJ, Malda J, Bartolo PJ, Hutmacher DW. Additive manufacturing of tissue and organs, Progress in Polymer Science 37, 2012
8. Bose, S., Vahabzadeh S, Bandyopadhyay A. Bone Tissue Engineering using 3D printing, Materials Today, Vol. 16, No. 12, 2013
9. Arabnejad S, Johnston RB, Pura JA, Singh B, Tanzer M, Pasini D. High-strength porous biomaterials for bone replacement: A strategy to assess the interplay between cell morphology, mechanical properties, bone ingrowth and manufacturing constraints, Acta Biomaterialia 30, 2016
10. Marga F, Jakab K, Khatiwala C, Shepherd B, Dorfman S, Hubbard B, Colbert S, Forgacs G, Toward engineering functional organ modules by additive manufacturing, Biofabrication 4, 2012
11. Mota C, Puppi D, Chiellini F, Chiellini E. Additive manufacturing techniques for the production of tissue engineering constructs, Journal of Tissue Engineering and regenerative medicine, No. 9, 2015
12. Bauernhansl T, Hompel Mt, Vogel-Heuser B. Industrie 4.0 in Produktion, Automatisierung und Logistik, Spronger Vieweg
13. Jeschke S, Isenhardt I, Hees F, Henning K, Automation, Communication and Cybernetics in Science and Engineering 2011/2012, Spronger-Verlag 2013
14. Joergensen SN, Nielsen K, Joergensen KA. Reconfigurable Manufacturing Systems as an application of mass customization, Int. J. of Industrial Engineering and Management, IJIEM, Vol. 1. No. 3. 2010
15. Brecher C. Advances in Production Technology, Springer 2015
16. Elias CN, Lima JHC, Valiev R, Meyers MA. Biomedical applications of Titanium and its alloys, Journal of Biological Materials Sciences, March 2008
17. Binyamin G, Shafi BM, Mery CM. Biomaterials: A primer for surgeons, Seminars in Pediatric Surgery 15, 2006
18. Williams DF. There is no such thing as a biocompatible material, Journal of Biomaterials, No. 35, 2014
19. Williams DF. On the mechanisms of biocompatibility, Journal of Biomaterials, No. 28 (2008)
20. Said MB, Selzer M, Nestler B, Braun D, Greiner C, Garcke H. A Phase-field approach for wetting phenomena of multiphase droplets on solid surfaces, Langmuir No. 30, 2014
21. Steinmetz P, Yabansu YC, Hötzer J, Jainta M, Nestler B, Kalidindi S. Analytics for microstructure datasets produced by phase-field simulations, Acta Materialia 103, 2016
22. Scheider D, Schmid S, Selzer M, Böhlke T, Nestler B. Small strain elasto-plastic multiphase-field model, J. Computational Mechanics, Vol. 55, 2015