Processes and devices for 3D printing of medical devices

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Abstract

Relevance of the research Three-dimensional printing processes represent a promising approach for fabricating intricately designed products through the layer-by-layer deposition of materials. Currently, a multitude of additive manufacturing technologies have been developed and implemented across various industries, including medicine, pharmaceuticals, and chemical manufacturing. Nevertheless, there is a need for the development of novel additive technologies and devices that facilitate the creation of personalized products with precisely defined properties. Among the diverse range of 3D printing technologies, those based on material extrusion are in high demand.

At present, the development of new devices and processes for additive technologies is an urgent task, as reflected in the decree of the Government of the Russian Federation on the "Development Strategy for Additive Technologies in the Russian Federation until 2030."

This dissertation is dedicated to the development of new 3D printing technologies and devices with the aim of producing personalized medical products. To achieve the formation of products, an approach to geometry design has been developed, universal methods for obtaining viscous "inks" for 3D printing processes have been devised, and principles for selecting material properties to create specific products have been established. Additionally, the dissertation introduces an approach to the process of supercritical fluid sterilization for highly porous products with intricate geometries, accompanied by the development of a mathematical model for the process.

The results obtained in this study can contribute to the efficient advancement of 3D printing processes in the fields of medicine and chemical industries, significantly expanding the applications of additive technologies.

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Analytical studies on the obtained aerogels and cryogels with intricate geometries were conducted using the shared equipment at the Center for Shared Use and the Department of Chemical and Pharmaceutical Engineering at Mendeleev University of Chemical Technology of Russia.

Mathematical modeling of the flow of non-Newtonian viscous fluid in a channel with complex geometry and the supercritical sterilization process was performed using the

computational resources of the Information Technology Department at Mendeleev University of Chemical Technology of Russia.

The aim of the study is to develop, experimentally and theoretically investigate the processes of producing medical devices with specified geometries using 3D printing technologies, various drying processes, and sterilization in a supercritical carbon dioxide environment.

Tasks:

1. Development of material compositions for implementing the 3D printing process using various additive manufacturing technologies (viscous "inks" formulations, heterophase system composition). Comprehensive investigation of the rheological characteristics of materials for implementing the 3D printing process.
2. Design of a printing setup for implementing the 3D printing process with viscous "inks". Study and optimization of process parameters for 3D printing using different technologies based on the geometry of the final product and the printing material.
3. Mathematical modeling of processes and design of complex geometries for personalized medical devices.
4. Investigation and comparison of supercritical and sublimation drying processes for intricately shaped products obtained through 3D printing processes.
5. Study of the supercritical fluid sterilization process for highly porous materials. Selection of parameters for the supercritical sterilization process. Development of a mathematical model based on continuum mechanics to investigate the supercritical sterilization process.

Scientific novelty. Various physicochemical and rheological properties of viscous "inks" based on sodium alginate, partially cross-linked sodium alginate, sodium alginate with incorporated nanomaterials (MWCNT, graphene), and a heterophase system based on gelatin were investigated. Based on the obtained experimental results, optimal compositions for implementing the 3D printing process were recommended.

The principles of implementing the 3D printing process using viscous "inks" of different compositions were defined for the formation of personalized products with a highly porous structure and functional properties. These principles guided the development of a 3D printing setup.

A mathematical model was developed to investigate the movement of non-Newtonian viscous fluid in channels with complex geometry under non-steady-state flow conditions.

The influence of incorporating nanomaterials (multi-walled carbon nanotubes (MWCNT), graphene) on the rheological characteristics of viscous "inks" was studied. Experimental investigations of products with complex geometry and incorporated nanomaterials revealed the impact of nanomaterial concentration and type on the characteristics of the products.

Mass exchange processes in a two-component system of carbon dioxide - hydrogen peroxide during supercritical sterilization were studied. A mathematical model was developed to determine the parameters for conducting the supercritical fluid sterilization process for highly porous biopolymer-based materials.

Practical significance. Developed laboratory techniques for the process of producing viscous "inks" with different compositions and a heterophase system based on gelatin for implementing the 3D printing process.

Proposed a design for a setup to implement the 3D printing process using "inks" based on biopolymers with varying viscosity. The design of the viscous "ink" extruder has been registered as proprietary know-how.

Introduced an algorithm for designing complex geometries of products based on the results of medical imaging studies (CT, MRI).

Developed processes for producing personalized medical devices using 3D printing, including hybrid bone tissue implants, vascular implants, and personalized conductive elements.

Proposed a method for supercritical fluid sterilization of highly porous biopolymer-based materials.

The main provisions for the defense.

– The results of experimental studies on the processes of obtaining materials for 3D printing are as follows: composition of sodium alginate-gelatin, viscous "inks" based on sodium alginate, partially cross-linked sodium alginate, sodium alginate with incorporated nanomaterials (MWCNT, graphene); heterophase system based on gelatin.

– The setup for implementing the 3D printing process using viscous "inks" based on biopolymers. The fundamental principles and parameters for conducting the 3D printing process using the developed material compositions.

– An algorithm for designing complex geometries of medical devices based on the results of medical imaging studies (CT, MRI). The results of calculating the mechanical properties of products with different internal geometry obtained through the 3D printing process.

– A mathematical model of the non-Newtonian viscous fluid flow in a channel with complex geometry under non-steady-state flow conditions, exemplified by the aorta.

– A method for supercritical fluid sterilization of highly porous biopolymer-based materials. A mathematical model of the process based on the principles of continuum mechanics.