Aleksandar Rajić [10]
Technical College of Applied Sciences in Zrenjanin, Zrenjanin/Serbia
Ljubica Lazić Vulićević [11]
Technical College of Applied Sciences in Zrenjanin, Zrenjanin/Serbia
Dušan Malić [12]
Technical College of Applied Sciences in Zrenjanin, Zrenjanin/Serbia

INDUSTRY 5.0 IN BIOMEDICAL ENGINEERING: DEVELOPMENT OF PERSONALISED IMPLANTS USING ADDITIVE MANUFACTURING AND 3D SCANNING

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Abstract:
This paper examines additive manufacturing technologies in the context of personalised implants within Industry 5.0, with a focus on biomedical engineering. Additive manufacturing enables the production of complex, patient-specific implants directly from digital models. A key component is reverse engineering using 3D scanning, which provides accurate anatomical data for implant design. Industry 5.0 emphasises human–machine collaboration, personalisation, and sustainability, while additive technologies support flexible and efficient production of biocompatible implants. The paper outlines the main advantages, challenges, and future prospects of these technologies in medical applications. It concludes that the integration of additive manufacturing, reverse engineering, biomedical engineering, and Industry 5.0 principles has strong potential to enhance healthcare through innovation and personalised solutions.

Keywords: *Additive manufacturing, 3D Scanning, Industry 5.0, Biomedical engineering, Personalised implants*

Introduction

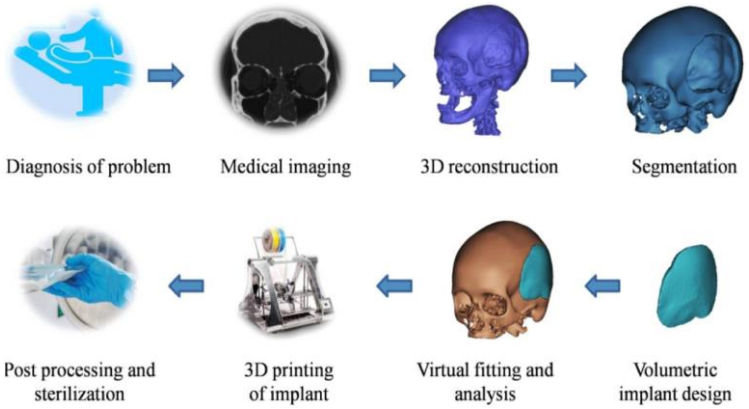
Industry 5.0 represents a paradigm shift in industrial development, evolving beyond the digitalization focus of Industry 4.0 to emphasize human-centric approaches in technological advancement. While Industry 4.0 concentrated on interconnected systems and automation, Industry 5.0 seeks to create a symbiotic relationship between humans and machines, leveraging cutting-edge technologies to enhance human potential rather than replace it. This evolution is particularly significant in healthcare, where the integration of advanced technologies must be carefully balanced with patient needs, comfort, and outcomes. Within healthcare applications, prosthetics development stands as a prime example of Industry 5.0's human-centric approach. Modern prosthetics require the integration of multiple advanced technologies to meet individual patient needs while ensuring functionality, comfort, and biocompatibility [1]. Key

[10] aleksandar.rajic@vts-zr.edu.rs, ORCiD: 0000-0003-3921-1502
[11] lazic.ljubica@yahoo.com, ORCiD: 0009-0002-1975-3961
[12] dusan.malic@outlook.com, ORCiD: 0009-0002-1846-4228

technologies driving this transformation include additive manufacturing (AM), machine learning (ML), digital twins, and tissue engineering. Additive manufacturing enables the creation of highly customized prosthetic geometries with unprecedented precision and speed, particularly through techniques such as fusion deposition modelling (FDM) and extrusion-based methods. Machine learning approaches enhance production processes by enabling precise fitting based on individual patient data, while digital twins provide virtual representations that integrate physical and digital information throughout the product lifecycle. Tissue engineering, through bio printing technology, offers promising approaches for creating complex, personalized tissue structures that enhance prosthetic integration with the human body [1,2].

1. Biomedical application of additive manufacturing and 3D scanning

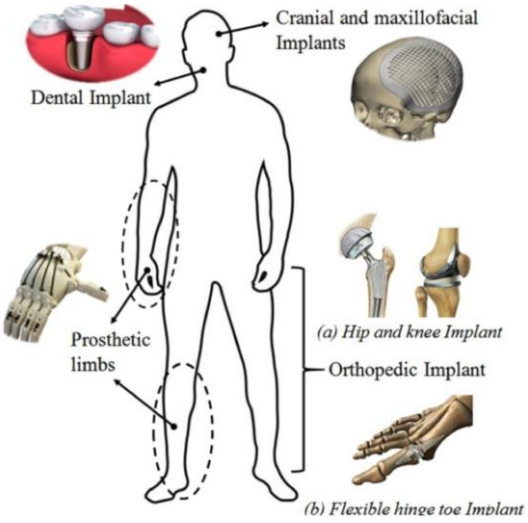
The development of CAD/CAM technologies, and later additive manufacturing (AM) technology, enabled the production of orthopaedic implants of highly complex structures and shapes. Along with them, different approaches to the design of orthopaedic implants have emerged as well as new possibilities for their manufacturing [2]. Finding the right design and procedures for making orthopaedic implants is one of the priorities of current research in the field of AM technologies application in medicine, picture 1. Increasing quality, productivity, profitability and conformity to ecological criteria require further rationalization and optimization of conventional technologies for the production of orthopaedic implants through the development and application of new technologies [3].



Picture 1. *Additive manufacturing representation of the biomedical product manufacturing process [2]*

Custom-made devices produced by 3D printing include orthopaedic, mandibular, maxillofacial, and craniofacial implants. Additional medical applications are scaffolds for tissue engineering, mechanical bone replicas, forensic models, surgical planning models, medical-device design, and bespoke implant design.

Picture 2 illustrates additively manufactured customized implants and prostheses - cranial and maxillofacial implants for skull reconstruction, dental implants for tooth replacement, and orthopaedic implants such as hip and knee replacements.



Picture 2. *Additively manufactured customized implants and prostheses [2]*

This also applies to investment casting foundries which have the ambition to produce demanding, complex and high quality castings for the use in medicine. Their development requires appropriate innovations, application of the latest technological knowledge and information technology [3,4].

The term Rapid Investment Casting (RIC) represents the employment of AM technologies in investment casting. The designing costs as well as the metal tools manufacturing costs for the development of master patterns can be overcome by applying AM technologies. The employment of AM technologies also results in shorter casting time while providing the same quality. AM has been particularly effective in prototyping, as well as in single and small scale productions. A large number of cost-effective solutions for investment casting of orthopaedic implants employing additive technologies have been reported in the literature so far.

Harrysson et al. [5] proposed a computer-aided methodology for customized knee implants manufacturing. The process involves the integration of technologies such as Computed Tomography (CT), image processing, Stereolitography (SLA) process, Room Temperature Vulcanizing (RTV) and investment casting, in the design and manufacturing of a near optimal fit between the patient's bone and the implant component.

Horacek et al. [6] describe the application of AM technologies and the investment casting process in the production of knee prostheses. The ABS master pattern of the knee implant was manufactured using the FDM process. After the manufacturing of the master pattern, the technology of vacuum casting in a silicone rubber (RTV) mould was applied, which produced a wax pattern of the knee implant. The obtained wax pattern was later applied in the investment casting process. The authors conclude that using the approach which integrates processes such as FDM, RTV and investment casting, it is possible to produce knee prostheses, whose mechanical characteristics and material properties, can compete with those of the conventional knee prostheses.

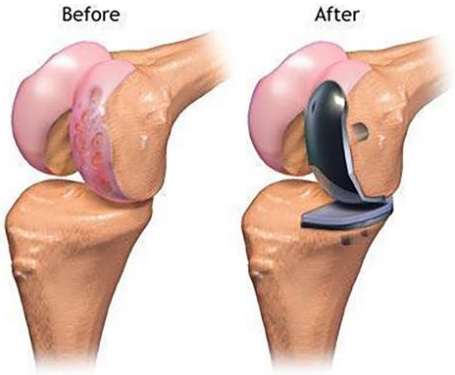
Ramos et al. [7] showed the development of technical procedure for hip prototype implant manufacturing. The authors reported that the vacuum casting technique combined with RTV procedure was suitable for master patterns manufacturing for investment casting of some prototypes. They concluded that the tested technical procedure was acceptable for manufacturing of many cheap metal prototypes with excellent characteristics and functionality.

Maji et al. [8] reported the possibility to use RIC technology to obtain craniofacial implants manufactured from bio-compatible materials. The research was conducted using the following process series: 3D CAD – Rapid Prototyping - Rapid Tooling - Investment casting. Aluminium craniofacial implants were manufactured and since aluminium is not a bio-compatible material, further researches will include application of this kind of materials.

2. Design procedure for patient-specific implants using AM

During 1972, the unicondylar knee prosthesis appeared (picture 3), but the main drawback of the construction was the technical solution for correct positioning of the prosthesis, especially in cases of degenerative changes on the medial and lateral sides. The unicondylar knee prosthesis is intended for the surgical treatment of arthrosis of only one side of the knee (in most cases, the medial compartment). During the implantation of a unicondylar knee prosthesis, about 75% less bone and cartilage is removed than during the implantation of a total knee endoprosthesis. This makes it an ideal

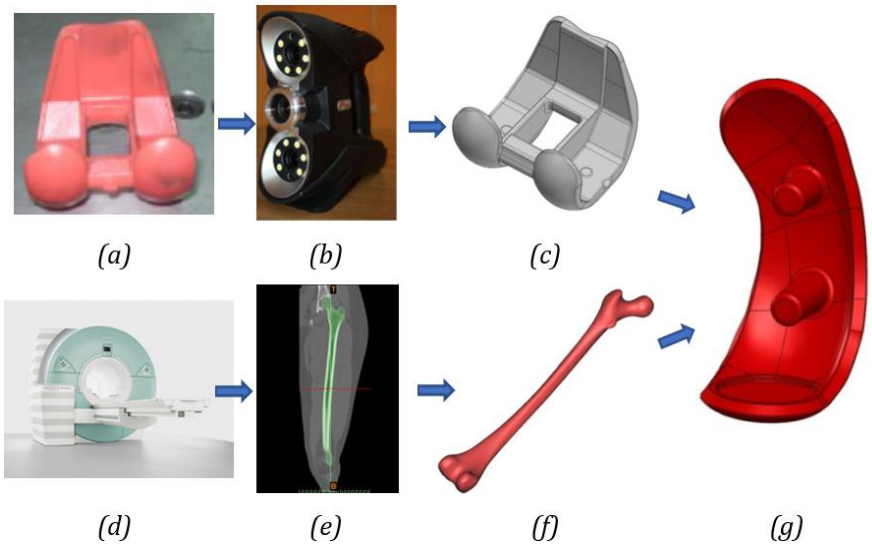
treatment for patients with unicompartmental osteoarthritis of the knee, in whom there is a possibility of the need for later revision surgery.



Picture 3. *Unicondylar knee replacement*

In the first phase of the research the selected sample of the knee implant (picture 4-a) was scanned by the optical 3D scanner OptiNum, Noomeo, France (picture 4-b) and saved in ASCII format using Numisoft software. The digitalization of the knee implant physical model involved the use of modern equipment with output databases suitable for converting into databases compatible with the SolidWorks software used for adjusting the scanned models. Due to a small differences generated by the scanner while recognizing the geometry, the obtained scanned model shown in was not an entirely true copy of the original, so the output databases were imported in the SolidWorks software package for modelling. Picture 4-c shows the knee implant CAD solid model obtained using the optical scanner Noomeo OptiNum.

The design procedure from computed tomography (CT) scan to final implant is described, below, with an example of a personalised partial knee implant. The purpose of acquiring a 3D CT scan is to produce a volumetric data set of the bone or part of the skeleton that needs an implant. Two different medical imaging techniques are magnetic resonance imaging (MRI) and CT. MRI provides better images for soft tissues and CT shows greater contrast between bones and soft tissue, and is therefore the method of choice in these applications. A CT is built up of a large series of 2D slices of data to represent the 3D geometry and each CT image is written as an individual file within a directory structure. The format of the images follows the medical industry standard, called DICOM (digital imaging and communications in medicine).



Picture 4. *Personalised partial knee implant virtual 3D modelling process: (a) knee implant wax master pattern, (b) 3D scanning, (c) implant CAD model, (d) Computed Tomography (CT), (e) medical modelling, (f) femur CAD model, (g) final CAD model*

The design procedure starts with removing the unwanted structures (skin, fat, muscles) from the CT data, using a threshold segmentation technique, where pixels are distinguished within an image by their grey-scale value. After bone segmentation, the femur is modelled into a 3D model, where the surface contours of the geometry are described by small, triangular surface elements. The full data set is known as a stereolitography (STL) file. This format is commonly used in AM, as it is easily transferrable between many software packages.

In order to create a personalized partial knee implant, the following global parameters of the femur were selected in this research: anatomical axis of the femur, mechanical axis of the femur, knee centre and tangent plane of the femoral condyle. After defining the global RGP femurs, further analysis of the polygonal model of the femur was undertaken in order to define the local geometric parameters, which will be applied to create the geometric model of the customized knee implant.

The pattern of the partial knee implant (picture 5) was made on the 3D Printing System Spectrum Z510 (3D Svet, Belgrade, Serbia) using the high quality powder composite ZP151 with the binder ZB60. The infiltration material was epoxy resin S5000. The thickness of the layer was 0.0889 mm, while the time required to produce the implant was 1.5 hours.



Picture 5. *Personalised partial knee implant additive manufacturing process: (a) partial knee implant STL format (31350 triangles), (b) 3DP Additive manufacturing system, (c) 3DP partial knee implant*

Two-component silicone rubber Hydrosil 1:1 SILADENT (Dr. Bohme & Schops GmbH, Germany) suitable for moulding ceramic, gypsum, wax, polyester and epoxy resin was used to make moulds for wax partial knee implant pattern. After the mould was made, a wax injection process followed using the injector nozzle with the following technical characteristics: vessel capacity - 2 litters, heater power - 500W / 220V, operating temperature - 75ºC (max. 100ºC). The wax used to make the model of partial knee implant was SRS 863 Pink Wax (SRS Limited, UK) with good general characteristics, a very low shrinkage percentage and a high elasticity. It is characterized by its extremely glossy surface. The injection temperature of this wax was 72ºC – 74ºC. Picture 6 shows a silicone rubber mould with a partial knee implant wax pattern made for research purposes. Applied master 3DP pattern is also shown.



(a) *(b)*

Picture 6. *3DP partial knee implant pattern (a) and silicone rubber mould with wax master pattern (b)*

3. Conclusions

The research has shown that AM and 3D scanning has great potential both in the manufacturing of knee customized implants. A contribution has been made to the development of a framework for the integration of Industry 5.0 technologies in the design and manufacturing of custom prostheses, demonstrating how human-centred approaches can be effectively applied in the field of biomedicine. The case study presented in the paper focuses on 3D scanning technology, medical imaging and high quality powder composite materials to create a master wax model of a custom knee implant based on silicone rubber mould making principles. The proposed approach represents a significant step towards realizing the full potential of Industry 5.0 in production for biomedical needs through the systematic integration of advanced technologies, additive manufacturing and 3D scanning, to provide personalized prosthetic solutions.

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