Review

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Review

3D Printing in Surgery and Beyond

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Abstract

3D printing plays ever increasing role in healthcare. It allows doctors to personalize patients treatment at lower cost. Due to this outstanding feature, 3D printing is revolutionizing healthcare, in particular surgery, manufacturing implants and prostheses, modelling of diseases, especially cancer, *etc*. In some areas, like Virtual Surgery Planning and manufacturing of implants and prostheses, 3D printing has reached massive applications. Examples are: overtaking in 98% 3D printed hearing aids and hip prostheses, 100 000 of which were implanted until 2018. In other domains, like drug delivery methods on the basis of 3D printing and human organ 3D printing, considerable efforts are indispensable. In addition, higher precision of 3D printers, development of novel materials, and legal regulations are a must. Together with robotics, Artificial Intelligence and Augmented Reality 3D printing is going to transform healthcare.

Keywords: 3D printing; healthcare; surgery; virtual surgery planning; prostheses; drug delivery systems; disease modelling

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1. Introduction

Robotics, Artificial intelligence, AI, and Augmented Reality, AR, 3D printing, 3DP, are going to revolutionize medicine [1]. The idea of 3DP came from an old inkjet printer in the 1980ties, or even earlier. Its onset, together with the digitalization of manufacturing processes, is considered the basis of the third, or perhaps fourth, industrial revolution [2]. The beginning of the first one was marked by the introduction of weaving machines in Great Britain at the end of XVIII century. Either the invention of steam engine or the introduction of the moving assembly line by Henry Ford is considered as a beginning of The Second Industrial Revolution. The Third Industrial Revolution was initiated in the middle of XX century. According to World Economic Forum 3DP together with genetics, artificial Intelligence, robotics and some other domains herald the beginning of The Fourth Industrial Revolution [3].

The term 3D printing was coined by Prof. Ely Sachs from MIT in 1995.

In this review, after short introduction, 3DP as a method of manufacturing will be briefly presented first. Presentation of applications of 3DP in surgery encompassing among other the applications of virtual surgery planning, those in customized nonbiological medical devices, the application of 3DP at the Point-of-Care and new drug delivery systems on the basis of 3DP will follow. A presentation of the future prospects of 3DP in surgery will conclude this review.

Introduction of 3DP into healthcare system is not always a smooth process. Manufacturing of hearing aids [4] and hip prostheses [5] exemplify the successful action. However, in numerous other medical domains implementation of 3DP is rather slowly. To invigorate introduction of 3DP into healthcare system, Deutsche Bahn (yes, yes, German Railways) established MGA Medical to connect 3DP industry with medical world and its stakeholders [6]. With this purpose in mind, MGA Medical has started cooperation with several companies active in the healthcare domain on the one hand. On the other, it has chosen six topics to investigate deeper into emerging challenges and opportunities to be studied. Among them pharmaceuticals, materials, and hospitals are included covering among other introduction of Point-of-Care units in them. This may create a great boost for introduction of 3DP units inside hospitals, thus, among other, speeding up and considerably lowering cost of 3DP of

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organ models, on the one hand, and contributing to teaching medical professionals this technology on the other.

2. 3D Printing as a Relatively Novel Manufacturing Method

The idea of 3D printing originated from old-fashioned inkjet printers. 3DP or additive manufacturing consists in the construction of a three-dimensional object either from a computer-added design, CAD, or a digital 3D model by sequentially adding material layer by layer with their subsequent fusion together. Let us specify that today the term „additive manufacturing", AM, is applied mainly for industrial applications of 3DP. On the other hand, 3DP is used either for other applications of this method of manufacturing, such as those in art, education or healthcare or it denotes the whole area encompassing also AM. It should be stressed that at the beginning 3DP was a very slow and expensive process. Today, due to its significantly higher speed and lower cost, it has found numerous applications in industry and in other countless areas.

This method of manufacturing has several advantages since it allows one among other

1. to create very complicated shapes at no additional costs, in particular, to personalize 3D printed objects.
2. To build objects with holes inside or parts moving with respect to each other.
3. To limit waste considerably. Sustainability of 3DP is its great advantage.
4. To eliminate tools or molds.
5. To design objects that, due to the holes inside, are lighter and use less materials than those manufactured in the traditional way. It is a great advantage *e.g.* in aviation industry where expensive metals are used.
6. To control precision of the 3DP.
7. In healthcare (and otherwise), in accordance with the Toffler idea of the product personalization [7], 3DP allows for inexpensive customization, for instance by creating implants or prostheses for a specific patient [8] on the basis of Computer Tomography, CT, [9] or Magnetic Resonance Imaging, MRI, [10] examination. A 3D printed titanium ribcage and sternum implanted after surgery at CSIRO in Australia has been reported as early as in 2015 [11].

In addition of the almost total overtaking of manufacturing of hearing aids [12], 3DP plays an important role in dentistry [13], surgery [14,15], drug design and drug administration [16], and numerous other areas of medicine [17], e.g., for 3D printed prostheses, the original data required are gathered from CT or MRI. They are later transformed using specialized 3D Computer-Aided Design software into 3D printable files.

Sustainability of 3DP is a very broad topic. On the one hand, it allowed users for its massive applications in many areas. On the other, it contributed to the transition of this method of fabrication from low- and medium scale to the production of long series. Madelaine P. [18] presented 10 features characterizing eco-friendliness of this method of manufacturing encompassing: reduction of waste and materials, local and on-demand production, service life extension through repair (*e.g.* 3DP of parts for cars or machines not produced anymore), recycling and upcycling, using eco-friendly materials (*e.g.*, biodegradable PLA plastic), energy-saving production (*e.g.*, by making lighter jet parts with holes inside), making use of optimized design through software, environmental protection projects (such as 3D printed constructs enabling reef salvation [19]), and the impact on research and innovation taking advantage of a very low threshold for prototype development and experimentation. The last point contributes to the ease of start-up formation and founding new businesses.

3DP has also disadvantages:

1. Material limitations and their costs. The creation of novel materials with exciting versatile properties is the important aim of both typical 3DP companies and traditional ones, like the chemical giant BASF [20], that together with other recently has entered the field.
2. Restricted size of objects to be 3D printed is sometimes a limitation for the construction industry but usually not for the medical applications.

3. Until recently, post processing, *i.e.* a special treatment of 3D printed object before its usage, represented an important limitation of 3DP. Several methods speeding up and/or simplifying post processing have been developed [21,22]. However, it remains a serious hindrance in some 3DP application.

4. In addition to other technical limitations to 3DP, legal problems associated with this technology, especially those in healthcare, are a considerable problem. They consist among other in preserving intellectual property rights [23,24] and liability [25–27].

Materials applied in 3DP constitute an important issue, especially as concerns those used in healthcare [28] which must succumb to several limitations. They depend on the application and specific 3DP method of execution but for most of them biocompatibility is a must. For some of the applications, biodegradability is desirable. The materials applied in healthcare include mainly metals, polymers, ceramics, and hydrogels [29]. Some of the advantages and disadvantages of materials for 3D printing has been discussed by Boskurt and Karayel [30].

An exciting possibility presents 4D printing, 4DP, *i.e.* 3D printing of objects that, due to special properties of the applied materials, undergo preprogramed changes in their geometry or other properties after being 3D printed [31–33].

For instance, 4D printed objects can change their shape under the influence of external stimuli (*e. g.* light, heat, electricity, magnetic field), that can play diverse role in medical technology. In particular, 4DP offers applications making use of customized smart orthopedics implants, applied in spinal deformities, fracture fixation, joint and knee replacement. The breast implants, resorbable after being 3D printed and implanted, can be considered as an exciting example of medical applications of 4D printing [34].

The smart materials applied in 4D printing for biomedical applications must meet three crucial criteria: a) biocompatibility, to ensure physiological safety, b) functional responsiveness under physiological conditions, such as body temperature or pH level, and c) mechanical robustness during and after shape transformation [35,36].

In this review, in general no technical details will be discussed. In particular, a fascinating problem of printing materials for medical applications will usually not be presented. Only applications of 3DP in healthcare will be shown.

3. A Brief Overview of the 3DP Applications in Healthcare [14–17,29]

It should be stressed that, in addition to the applications of 3DP in automotive and aviation industry, the applications in healthcare play one of the most important roles in this domain. Tsoulfas *et al.* [14] and Suri *et al.* [15] published first two volumes of the series on 3DP applications in medicine and surgery. Numerous articles cover, among other, the role of 3D printing in creating 3D models used in preoperative surgical planning, VSP, in general surgery and in the wide range of distinctive areas of surgery such as liver transplantation, cardiac, vascular, orthopaedic, ENT, pancreatic, hepatobiliary, gynaecological and obstetric, and neurosurgery, but they also present novel approaches extending 3DP applications in surgery encompassing Artificial Intelligence, AI, in medical imaging, Augmented Reality, AR, in surgical guidance, and nanotechnology as well as 3D bioprinting in medical surgery.

Meister *et al.* [37] recently published on line a very valuable meta-analysis of medical 3D printing presenting results of 134 systematic reviews and meta-analyses published until 2023 concentrating themselves on the applications in orthopaedics, oral and maxillofacial surgery, dentistry, cardiology and neurosurgery as well as on creation of patient-specific models, implants and to a lesser extent prostheses, and materials used in the medical 3DP. However, they left aside such important areas as most 3D printed devices, in particular those in anti-tumour drug development, drug dosage forms, the application of 3D bioprinting in healthcare, involving tumour models, and some other. Meister *et al.* covered the following areas of the applications of 3DP in the following medical domains: anaesthesia, cardiology, dentistry and orthodontics, various areas of surgery and paediatrics, cranioplasty, gynecology, urology, brachotherapy, orthopaedics, otolaryngology, *etc*. Some of the reviews presented by Meister *et al.* cover oncology. The authors singled out devices as non-invasive (encompassing anatomical models), on-body (prostheses), invasive and non-permanent (surgical guides), and invasive and permanent (implants). They also covered articles dealing with 3D printed prostheses and teaching of medical personnel, students, and patients of the 3DP applications with a general conclusion of meta-analysis that the medical 3DP applications are continuously increasing, mainly in preoperative surgical planning, patient counselling and education. Moreover, by producing patient-specific models, prostheses, surgical guides, and implants 3DP contributes to a success of personalized medicine. As concerns the applications in surgery, they stress reduced operating time and blood loss, minimized fluoroscopy time, and improved surgical outcome. On the other hand, Meister *et al.* claim that the existing data on time and cost of medical 3DP are inconsistent.

As early as in 2016, Martelli and coworkers [38] analysed 158 studies in which 3DP was used to produce anatomic models, surgical guides and templates, implants and moulds primarily in maxillofacial and orthopaedic operations. The main advantages reported were the possibilities for VSP, the accuracy of the process used, and the time saved in the operating room. However in 2016, 34 studies stressed that the accuracy was not satisfactory. The authors concluded that at that time the additional cost and the time needed to produce devices by current 3D technology still limited its widespread use in hospitals.

Importantly, recently Calvo-Haro and coworkers [39] stated that 3DP in orthopaedic surgery and traumatology (and not only in these domains, HD) was widely used and underwent a conceptual evolution from DIY to Point-of-Care modes of actions (see Sect. 3.3).

Shaylor *et al.* [40] reviewed the program of 3D modelling to assist in preoperative anaesthesia planning. The authors found that 3DP or VR reconstruction are feasible in clinical anaesthesia and their routine use for patients with challenging airway anatomy correlated well with the final clinical outcome in most cases. However, high-quality imaging is essential for the success of the application.

The 3DP applications in healthcare can be discussed in frame of several broad categories, including VSP, *i.e.* virtual or presurgical surgery planning [41–43], anatomical models [44], creation of customized prosthetics [45,46], implants [47–50], , tissue engineering [51] and organ fabrication [52–54], manufacturing of specialty patient specific surgical instruments [55] and diverse medical devices [56], pharmaceutical research aiming at drug discovery, fabrication, and dosage forms, as well as modes of drug delivery [57] and several other.

3DP applications in medicine include the customization and/or personalization of medical products, drugs, and equipment [58]. They lead to lower costs and improved patients well-being, thus his/her faster recovery, increased productivity, the democratization of design and manufacturing, as well as enhanced collaboration. Serrano *et al.* presented the applications of 3DP in personalized medicine and nanomedicines, as well as in biopharmaceuticals stressing that this method of manufacturing enables medicine customization adapted to patients' needs. Of special interest are biopharmaceuticals and nanotechnology-based drugs manufactured by nanoprinting that can be obtained using 3D printed microfluidic chips.

3DP applications are very versatile and include among other

1. hearing aids almost fully overtaken by 3DP [4].

2. The applications in dentistry involving 3D printing of tooth implants and prostheses, bridges, aligners and drilling guides [59,60]. 3DP is also of importance in the complicated craniofacial regeneration [61].

3. Patient-specific models manufactured on the basis of Computer Tomography and/or Nuclear Magnetic Imaging that allow surgeons to carry out virtual preoperative planning of the surgery mentioned above [41,62,63], contribute to the patient education [64], teaching and training [65,66] as well as to communication with the patient and his/her family [67–69].

To conclude, the usage of 3D printed models allows doctors to shorten the operative time and speed up the patient recovery, thus lowering medical costs and enhancing the patients well-being. It should be noted that Stratasys company developed a special printer, enabling creation of biomechanically accurate and functional anatomical models [70].

4. 3D printed medical devices covering numerous applications in healthcare are regulated among other by American Food and Drug Administration, FDA, [71]. They include, not only patient-specific surgical tools [55] or even robotic systems [1,72] including Virtual and Augmented Reality [1,73,74], but also specific 3D printed devices for posterior atlantoaxial transarticular fixation surgery [75], diagnostic 3D printed models [76,77], and the devices that can dispense therapeutic drugs [57,58], implantable medical devices (vascular stents, heart valves and joint prostheses including biodegradable stents) [78], inexpensive stethoscopes for doctors and hospitals not only in poor countries [79]. Drug delivery devices such as inhalers [80,81] and injectors [82] as well as patient-specific radiation shields [83,84] and boluses [85], a model to safeguard the life of an unborn child [86] or those of normal and abnormal fetal hearts [87], 3D bioprinted 'cardiac patch' [88], 3DP suturing device for minimally invasive surgery [89], and textiles for medical drainage around wounds [90] have to be added to the listing.

5. Implants and prostheses [91–93] (sometimes considered as medical devices) other than teeth prostheses today are manufactured mainly from titanium or titanium alloys, but an application of ceramics in this field is increasing [94]. The prostheses include among other jaw [95,96], sternum and rib cage [11], biodegradable breast replacements after cancer involving 4D printing [97,98], ear bones (to treat conductive hearing loss) [99,100] and oral-maxillofacial and cranial implants [48,101], as well as implants and prostheses of hands and feet [102], hip and pelvis [103,104], spine [105–107]. Some of them are applied on a massive scale [5,107].

In addition to 3D printed surgical devices and models applied in oral and maxillofacial surgery, Ye and Guo *et al.* [108] discussed also in detail 3DP materials used and maxillofacial prostheses. They concluded that introduction of 3DP has significantly transformed oral and maxillofacial surgery by enabling customization and personalization through the creation of 3D-printed surgical devices including PSIs, surgical guides, splints and 3D models. In addition, the convergence between 3D printing and virtual surgical planning has revolutionized surgical workflows, leading to improved accuracy, reduced surgical time, and decreased costs greatly benefiting bone reconstruction, orthognathic surgery, and temporomandibular joint treatment, while also improving communication with patient and education. The authors call for addressing cost and regulatory considerations which limit further advancements that will lead to improved patient outcomes, and enhanced overall experiences in oral and maxillofacial surgery.

Zoabi *et al.* [109] not only reviewed the use of 3DP and VSP but also applications of VR and AR in oral and maxillofacial surgery with additional emphasizes on Point-of-Care, PoC, units in hospitals.

Interestingly, foundations, such as e-NABLE [110] and NotImpossible [111] produce implants and prostheses for people in need. They collect money for design and manufacturing the prostheses showing social responsibility in the 3DP community.

6. 3D bioprinting in tissue engineering will allow doctors for tissue repair and organ transplantation in future. According to Ramadan and Zourob, "3D bioprinting is the process of integrating living cells with biomaterials that allows controlled layer-by-layer deposition of cells/bioink, which is characterized by hierarchical structural properties, with maintained cellular viability in 3D space to create complex, multifaceted tissues. 3D bioprinting benefited from several technologies such as tissue engineering, synthetic biology, micro/nanofabrication, and bioprocessing biomaterial production" [112,113]. It was used to create organ-level structures including liver [114], bone [115], cornea [116], skin [117,118], heart and heart patches [119,120].

Wang *et al.* [121] applied *in situ* 3D bioprinting of living photosynthetic scaffolds for autotrophic wound healing.

3D printed skin grafts are used for healing burn and accident wounds. Actually, 3DP of skin is the only area where the skin mimics have achieved the level enabling the transplantation [122,123].

7. 3D bioprinting for drug testing and discovery and disease modelling [112,113]. In particular, 3D bioprinting of cancer models enables testing of anticancer drugs [124]. It also improves cancer treatment [125] and revolutionizes personal cancer therapy [126].

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8. An emerging tissue engineering approach, *in vivo* direct 3D printing [127–129] allows for the direct deposition of bioink into the defect sites inside the patient's body enabling the rapid on-site management of tissue injuries.

The above list of the various domains of application of 3DP in healthcare is not exhaustive since today it is not possible even to mention all of them. One of them, somewhat untypical, is 3DP of food encompassing producing food for people with dysphagia (*i.e.* swallowing problems) [130] or 3DP of personalized diet food [131].

An involvement of 3DP community in the fight against coronavirus [132] have to be mentioned here since it played an important role at the early stage of the pandemic and made 3DP more visible.

3.1. Virtual Surgical Planning, VSP, and Training [41,63,133–135]

A removal of cancerous tissue is a prerequisite of the most successful cancer treatments and virtual surgical planning on the basis of 3DP plays an important role in planning surgical operations, education and training on human anatomical models. It also allows doctors for intraoperative assessment of complex surgical operations, postoperative evaluation, and patient counselling [63,135].

While 3D printed models in surgeries were initially limited to use as visual aids in preoperative planning for complex pathology, 3DP has more recently been applied to create patient-specific instruments (*i.e.* intraoperative patient-specific screw guides and templates) as well as implants and prostheses and is increasingly being used in surgical education and training.

As presented above, patient-specific 3D printed models are used in VSP revolutionizing medicine in four domains:

Personalized medicine

1. Computer Tomography or Magnetic Resonance Imaging images are used to create patient-specific, life-size 3D printed models.

2. A physical model shows the location of tumours along with neighbouring bones, internal organs, nerves and blood vessels.

3. The model is used by medical professionals to plan surgery, *i.e.* to carry out VSP, to map out challenges and discuss several possible treatments.

Benefitting patient care

1. By less need for exploratory surgery, thus smaller incisions.

2. By faster surgeries since surgeons could work out each step in advance.

3. By faster recoveries due to less invasive and extensive surgery.

4. By precise reconstruction, *e.g.* by using 3D printed patient-specific cutting guides for bone and tissue reconstruction or custom 3D printed titanium implants.

Education

1. Examination of 3D printed models of tumour and its environment helps surgeons understand their options and make better informed decisions about treatments.

2. The models can be used to train future doctors.

Research

1. More accurate modelling in research labs.

2. Tumour tissue 3D printed with the patient tumour cells which can be used to test treatments.

3. A support system can be 3D printed to allow the patient's stem cells to attach and grow new bone or cartilage.

Materialise was the first company to receive FDA clearance for diagnostic 3D printed anatomical models [77], while Stratasys recently inaugurated a multi-colour, multi-material patient-specific J5 Digital Anatomy 3D printer enabling the creation of biomechanically accurate, highly realistic anatomical models [70]. The models of the operation site are developed mostly on the basis of computer tomography or Magnetic Resonance Imaging or less frequently other techniques, and then 3D printed [136]. They can also help by fetal surgeries [137].

According to Müller and collaborators who discussed the preoperative planning in craniofacial modelling and neurosurgery [138] and Kalejs and von Segesser [139], who built a model of the human aortic root for *in vitro* training in valved stents deployment, the models offer a number of advantages, such as better tactile understanding of the anatomy, rehearsal of the exact surgical route, implant and prosthesis planning and tailoring, easy intraoperative access for surgical guidance, and better communication between surgeon and patient.

Meyer-Szary *et al.* [134] presented a detailed review of the role of 3DP in complex medical procedures and training of medical professionals covering divers areas of surgery such as cardiology, urology, obstetrics, gynaecology, oncology, radiotherapy, orthopaedics, trauma, otolaryngology, head and neck surgery, and mandible reconstruction. The authors attempt to point out how 3D printing has begun to reshape and improve treatments across various medical specialties and where it has the potential to make a significant impact.

In addition to reviewing the healthcare applications of 3DP and VSP in oral and maxillofacial surgery mentioned earlier, Zoabi *et al.* [109] also discussed applications of VR and AR with additional emphasis on Point-of-Care, PoC. After a detailed review they state that it has brought a marked improvement in clinical outcomes and considerable time savings. The latter are of special importance in oncological surgeries. Some limitations to the use of 3D printed implants, in particular the lack of legal regulations [140*],* still need to be tackled. Future development encompassing wider advancement from biocompatible metal implants toward bioactive, drug-releasing resorbable implants will mark one of the upcoming surgical revolutions.

Dzierżanowska *et al.* [141] reviewed the applications of 3DP in neurosurgery including several examples of the cancer treatment and training of residents and young surgeons. According to the authors, today's limitations of the 3DP technology consist in high cost, sometimes low print quality, long preparation time and insufficient quality of material available. Creation of novel materials imitating the physical properties of human tissue and organ fragments, printing with multiple materials, increasing resolution of CT and MRI techniques, as well as involvement and cooperation of IT specialists, radiologists, neurosurgeons, technicians within the hospital to introduce procedures that will allow rapid implementation of treatment based on 3DP is a must today. In a more distant perspective, an extension of the bioprinting applications in the field of implantology and *in situ* printing (that is executed using biopen even today [142]) are foreseen by Dzierżanowska *et al*.

Recently, Bulters and Katsamenis [143] carried a surgery removing a giant 7 cm *intracranial aneurysm* on the basis of a novel 3DP workflow involving VSP developed at the University of Southampton. Interestingly, after such a serious surgery the patient was discharged home just after two nights in the hospital.

Lan et al. [144] reported the application of 3D printed craniocerebral model in simulated surgery for complex intracranial lesions. Flaxman *et al.* presented a guide for creating patient specific 3D printed anatomical models from MRI for benign gynecologic surgery [145].

One of the most spectacular applications of VSP, was the separation of conjoint twins [146–148]. It should be stressed that in the case of craniopagus twins, that is the twins fused at the heads, most of them are stillborn, die either during labour or within 24 hours. A successful separation was carried out in case of two Pakistanian sisters born in 2017. The surgery involved VR, VSP and 3DP. The twins were separated at GOSH hospital in Great Britain over four months (from October 2018 to February 2019) with three procedures, involving a very large multi-specialty team including experts from specialties such as craniofacial, neurology and psychology, as well as nurses, radiologists, occupational therapists and physiotherapists. As mentioned before, another nontrivial application of VSP is using 3D printed models by surgeons to prepare for fetal surgeries [137].

An advantage of VSP was also shown by Chandak *et al.* [149]. To assess feasibility of pediatric kidneys transplantation, the authors 3D printed the models of kidneys of three patients presenting stage 5 chronic renal failure. The decision could not be taken on the basis of traditional imaging, whereas the 3D printed models successfully overcame this challenge. Moreover, the models were used to identify the optimal recipient vessel for anastomosis.

On the basis of literature search of 61 original articles published between 2014 and 2022, Portnoy et al. [135] concluded that 3DP "is currently the most advanced in terms of clinical use" providing "high-quality operative preparation" on the basis of better understanding of the patient's anatomy and the relevant pathological condition. The literature data allowed the authors to state that VSP lead to reduced operation time and less complications, as well as to shorter post-operative hospitalization [150,151]. Portnoy *et al.* [135] discussed not only the applications of VSP and patient-specific surgical instruments in bone surgeries but also those of novel three-dimensional technologies Augmented Reality and Virtual Reality. Contrary to VSP, today the applications of AR and VR in surgery are at the initial stage.

Using 3DP, Weinschenk and coworkers [152] developed models of normal human femoral diaphysis to create inexpensive, accessible, and reproducible specimens for flexural biomechanical studies. Their models with 20% infill density and six wall layers resulted in a flexural modulus of 18.54 ± 0.543 GPa emulating the biomechanical response of the normal human femur, as determined by historical target values derived from prior cadaveric and 3DP data.

3.2. 3DP of Medical Devices Including Implants and Prostheses [45,102]

At the very beginning it should be stressed that today, even in the case of traditionally manufactured medical devices, 3DP is used by their prototyping.

According to Food and Drug Administration [71], commercially available 3D printed medical devices include instrumentation (such as surgical guides [153]), FDA approved peripheral nerve repair device [154], implants (*e.g.* cranial plates [155]) or hip joints [156], splints [157], orthoses [158], surgical guides and other surgical instruments [55,159], devices enabling suture during surgical operations [160], laparoscopic forceps [161], and numerous other 3D printed devices. Taking into account the expected aging of world population and growing costs of healthcare, advantages of 3DP such as cost-effectiveness [162], design flexibility, reduced waste, rapid prototyping, enhanced functionality and customization offer a great help in management of the arising problems. For instance, rapid prototyping typical of 3DP speeds up the creation of 3D printed medical devices, that can be made specifically for the patient individual features enabling *e.g.* better surgery outcome in case of surgical guides [163–165], or other surgical instruments [166–168] leading to shorter surgery times and/or faster patient recovery.

Due to a large and growing patient population on the one hand and a rapid development of 3D printed medical devices on the other, 3D printing medical devices market is growing constantly. It was expected to reach USD 6.9 by 2028, growing at CAGR of 17.1% from 2022 to 2028 [169].

Spine implants were reviewed on the basis of literature reports by Burnard *et al.* [170] who compared the patient-specific and off-the-shelf spine implants. On the one hand, they found that 3DP spinal implants have been used safely, with positive surgeon- and patient-reported outcomes. On the other, short follow-up periods and small case series reported limit the conclusions. Burnard *et al.* also demanded more standardised reporting of clinical, radiographic and biomechanical outcomes.

As mentioned earlier, technical details, such as printing methods, printers applied, and materials, are not taken into account in this review. An exception here are three papers: the first one by Sidambe [171] in which biocompatible titanium implants, that are most frequently used, are reviewed. However, it should be stressed that at present there is a marked shift from the titanium to ceramic implants [172]. Another outstanding trend consists in replacing the standard implants by bioresorbable ones, especially in case of breast implants [173]. Yet another interesting development refers to the treatment of the 3D printed bone implant surface, namely, one does not use postprocessing to get a smooth surface but instead takes advantage of surface micropores promoting adherence of osteocytes, which further promote implant stability [174,175]. According to Y. Wu *et al.* [176], a proper surface treatment may enhance the adhesion and absorbance of the cells and proteins to form a better implant-tissues interface. Addition of growth factors [177], functional molecules, peptides or proteins [178–180] in the coatings can increase the osteogenesis, promote vessel formation within the implants, and inhibit bacterial proliferation [181]. Inclusion of 3D printed polymers or

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hydrogels with cells or growth factors as material-cell composites into the porous 3D printed implants may further improve their *in vitro* and *in vivo* performances [182–185]. The pores within the implants can be used for drug delivery [186], *e.g.* chemotherapy or antimicrobial drugs, thus 3D printed implants can contribute to the fighting of tumour recurrences [187] or infections [188]. Importantly, the 3D printed implants can be modified for functional reconstruction rather than for anatomical filling of the bone defect alone.

Recently, nTop portal summarized how this manufacturing method is changing the way how medical implants are designed and produced [189], while Carlota from 3Dnative portal [47] reviewed some of the most innovative 3D printed implants as of June 2024. They included among other the smallest bones in the human body involved in an ear implant, the Renishaw's rib cage replacing the bones resected in the tumour removing surgery, silicon heart valves, a carbon artificial retina, and the world's largest cranial implant.

3D printed medical devices encompass among other

1. Hearing aids that were the first medical domain practically fully taken over by 3DP [4].

2. Dentistry has been following the suit [190]. Custom-made dental appliances, such as orthodontic aligners, implant models and dentures, surgical guides, crowns and custom trays as well as customized dental implants, digital dentures and digital wax-ups can be manufactured by dentists, dental technicians and dental assistants fast and inexpensively. Today **chairside 3DP**, corresponding to 3DP at the Point-of-Care in hospitals, is a viable alternative in dental clinics to outsourcing work to dental lab allowing for the same-day production of dental restorations. This eliminates the need for multiple appointments and reduces patient wait times.

Recently, Dawa *et al.* [191] assessed AI-powered digital tools (including 3DP) in dentistry and their self-reported impact on dental practitioners' operation and its outcomes on the basis of a comprehensive questionnaire distributed to 126 dental professionals. The survey should provide data on assessment of their experiences and attitudes towards AI applications in diagnostics and treatment planning. It should also show how patients and dentists perceive the benefits and challenges associated with digital dentistry. The results showed that 1. Digital photographs and Cone Beam Computed Tomography, CBCT, have considerable advantages as compared in contrast with traditional intraoral scanners. 2. Barriers like high cost, specialty differences and lack of the appropriate training may hinder the applications of digital dentistry. 3. When used correctly, AI digital tools can significantly improve the quality of clinical practice and professional fulfilment. 4. On the other hand, the importance of tailored training programs and supportive infrastructures to facilitate the effective integration of digital technologies in dental practice is stressed.

Implants and Prostheses [78,92–95,103,105,176,192–197]

Borthakur [193] analysed the role and future directions of 3DP in personalized prosthetic design stating that it revolutionized the prosthetics industry by improving accessibility, functionality, and customization and significantly reducing production time and costs. It has made prosthetics more affordable and accessible, especially for low-income patients. 3D printed highly functional personalized prostheses tailored precisely to individual needs, enhance patient satisfaction and quality of life extending the boundaries of this domain. The integration of novel advanced technologies, like artificial intelligence, smart sensors, and regenerative bioprinting, presents exciting possibilities although overcoming material constraints and regulatory hurdles will be critical for the development of 3DP applications in prosthetics. As these problems are addressed, 3DP will reshape prosthetic care and offer hope to millions worldwide.

Y. Wu *et al.* reviewed present and future perspective of 3D printed metal implants in orthopaedic applications [176] stressing their wide usage since 3D printed personalized implants with proper structural design (on the basis of CT, MRI, X-ray or ultrasonic scanning) can not only eliminate the stress shielding effect but also improve *in vivo* biocompatibility and functionality. However, the limitations concerning materials for printing and a lack of guidance from related regulations or laws may impede the development of 3D printed medical implants. Y. Wu et al. briefly discussed the data collection, design and manufacturing of prostheses as well as future directions in this domain. In particular they discussed maxillofacial, oral, shoulder, wrist, hip, knee joints, spine, pelvic applications. For hip prostheses, they state the difference between a raw, as printed, prosthesis and the postprocessed one with the smooth polished surface, that, as presented earlier, is not suitable for osseointegration [194]. The role of pore size and porosity in the 3D printed material is discussed. According to Y. Wu and coworkers, challenges of 3DP implants for orthopaedic applications consist in availability of materials for printing, printing efficiency, quality control, clinical trial, and regulatory concerns, while perspectives involve smart and bioactive implants. Although, challenges and barriers exist in the current state of the technology, the future of 3D printing in orthopaedic applications is still relatively bright and 3D printing is a promising technique that can help overcome some difficult clinical issues. As more and more professional researchers are active in the 3DP field, together with the continuous advances in hardware, software, imaging and regulations, it is likely that 3D printed implants will rapidly improve and eventually become widely commercially available on the market in the coming years. I (HD) believe this is an understatement: today several types of 3D printed implants like hip prostheses presented below or breast prostheses are commercially available.

3DP provides an opportunity for manufacturing patient-specific implants and prostheses [195,196] that accelerate the patient recovery after the surgery thus contributing to cost savings and the patient well-being. They include, among other, 3D printed hip prostheses that are massively implanted [5], hand, arm, and foot prostheses [197], spine [198,199], jaw [200], cranial implants [201], heart valves [202], pelvis [203], and numerous other. Even cornea [204] and retina [205] have been printed.

Few additional remarks:

1. Total Hip Arthroplasty involving 3DP is the most frequent application of additive manufacturing in the implants and prostheses domain [5,162,193]. Materials used for 3DP of hip prostheses has been reviewed by Sreejith *et al.* [206].

2. The creation of a prosthesis requires specific knowledge of the material properties involved as shown by Weinschenk and coworkers work briefly discussed earlier [152].

3. As concerns prostheses, it is interesting to note that children do not want to have prostheses mimicking their real hands [207]. They want them to be a gadget. As one girl put it: "Now they will not say: "Poor cripple". They will say with admiration: "What a gadget!".

4. The most sophisticated next-gen breast implants are bioabsorbable and customizable, i.e. they can be considered 4D printed breast replacements after cancer [34,97,98].

One cannot even mention all types of 3D printed medical devices, since they are limited by the doctors' creativity, *e.g.* patient-specific 3D printed catheters for premature newborns developed by researchers at Northeastern University [208].

3D printed medical devices in fight against Covid-19 pandemic [209,210] encompassed ventilators, personal protective equipment such as face masks and face shields, environmental solutions including door handles and devices detecting person-to-person distances to limit close contacts as well as equipment for disinfection and many more. They were manufactured often by volunteers from the socially-oriented 3D printing community and evoked renewed interest in 3DP.

3.3. The Application of 3DP at Point-of-Care, PoC [6,211–215]

As stated by Boelen [211], *"Point-of-Care (PoC) as a term may be misleading (in case of 3DP, HD); the term is normally used as "at the patient's bedside", but with respect to 3D (printing) technology, it means "at the Healthcare Facility". It has obvious advantages,* e.g. the establishment of a facility enabling 3D printing of prostheses in a hospital extends the possibility to apply 3DP at the Point-of-Care [212]. However, *there is a need for caution because*

a. hospitals have no manufacturing experience,

b. 3DP is not a mature technology, and

c. there is a practical lack of medical (ASTM/ISO) standards available.

As mentioned before, **Chairside 3DP** in dentistry corresponds to 3DP at the PoC.

As often happens in science, when people of different specializations begin a collaboration that will bring fruits later, the beginnings of introducing 3DP at PoC are painful and have to start with elaborating a common language among specialists in medicine and technical personnel. Only after a long cooperation this approach brings numerous advantages.

Bastawrous *et al.* [213] and Sheikh *et al.* [214] presented conditions for establishing PoC in hospital or clinic (focusing on radiology departments) stating that it has profound potential on the one hand, but must face sometimes unanticipated challenges. With their interest centred mainly on "hardware", the authors analysed infrastructure such as a dedicated space, trained personnel, and a clinical need. Facilities and building requirements, staffing needs, funding, training opportunities, and access to in-house subject from requesting departments are also important factors to assess.

Recently, Ricoh established a new company Ricoh 3D for Healthcare [215] aiming at accelerating introduction of PoC units in hospitals. They will enable a faster and cheaper production of patient-specific 3D printed devices like 3D printed models for preoperative surgical planning patient-specific surgical instruments, and implants, *etc.* at the site.

The activities of MGA Medical [6] presented in the Introduction will also contribute to the introduction of the PoC units in hospitals.

3.4. 3D Bioprinting of Tissue and Organs

3D bioprinting of human organs is in the initial stage and the manufacturing of the full functioning organs in less than 10 years is not probable [216]. The situation is critical since, according to the Health Resources & Services Administration, in the USA every day 17 people die waiting for an organ transplant, to say nothing about the situation in other countries. The perspective to use the 3D printed transplant organs seems appealing, especially if one takes into account that in the USA one has to wait 5 years for a kidney, 11 months for liver, 4 month for lung and 2 years for pancreas transplant from living or deceased donors [217].

Some human tissues have been 3D printed including skin [218], brain-like structures [219,220], cartilage [221], heart valves [222] and patches [223]. However, it is not yet possible to print fully functional, transplantable human organs [52–54]. Vascularization, *i.e.* creation of blood vessels, of bioprinted tissue is one of the major challenges. The application of the 3D printed liver tissue for drugs screening was the first commercialization of a 3D printed tissue [224]. Chung *et al.* [225] discussed 3D printed scaffolds applied for regeneration of different types of organs (bone, cartilage, heart valve, trachea, blood vessel, liver, and skin). Ma *et al.* [123] discussed requirements for cell sources for organ fabrication. Jeon *et al.* [226] presented photocurable bioink supporting medium for 3DP generation of engineered tissue.

Biomedical devices *are often based on 3D printed scaffolds. The in situ* printing of the scaffolds is feasible and effective for promoting bulk tissue regeneration [227]. Similarly, 3DP of bones tissue directly into a patient's body has been mentioned [228]. Preparatory works are carried out to 3D print tubular human tissues or at least their scaffolds, like the trachea [229], intestine [230], bone [231], and blood vessels [232] that can be damaged by diseases and other traumas. Their fixing by autologous grafts is subjected to limitations. Nonstandard 3DP technique was applied by Rumanian and German researchers to manufacture such structures to be used in future in implantable grafts [233]. Another way to approach the problem of 3D printed tubular structures is to 3D print scaffold-free tubular tissue to be implanted with further remodelling [234]. Sophisticated ultra-complex 3D scaffolds were 3D printed in the Southwest Research Institute [235].

As stated before, 3D bioprinting of full organs will not be feasible in near future. However, 3D bioprinted heart patches were manufactured in one step involving built-in electronics [236] paving the way for their implantation. Recently, Rosselini *et al.* [237] reviewed the progress in 3D printed cardiac patches that involves an appropriate combination of cells, scaffold and signals. The authors stressed the importance of the development of a biomimetic scaffold with structural and compositional features mimicking the native tissue. They presented native cardiac extracellular matrix, ECM, 3DP methods, bioinks and strategies for functionalization of 3D printed structures, as well as the applications and future perspectives. As concerns the applications, several very promising *in vivo* studies of animal models are cited while *in vitro* cardiac tissue models are invaluable for deepening our understanding of cardiac physiology, studying the pathogenesis of heart diseases, and functioning as high-throughput platforms for drug screening. However, the authors conclude that despite significant progress of cardiac tissue engineering achieved in recent years, replicating the full complexity of the native myocardial microenvironment remains a continuing challenge in this field.

4. Future Prospects of Applications of 3DP in Surgery and Beyond

In spite of several obstacles slowing down the 3DP applications in healthcare, their use (also in the surgery) becomes more widespread. In some areas, like the implanted hip prostheses, it long ago exceeded 100 000 patients [5]. With more companies either adopting the technology or entering the field, more research on novel technologies and materials, the perspectives are bright. Initiatives such as MGA Medical established to connect 3DP industry with medical world and its stakeholders [6] aim at extending cooperation among 3DP industry and healthcare, on the one hand. On the other, it should boost investments in this domain.

One field in which definitely applications of 3DP in healthcare has become a vivid industry branch involves personalized 3D printed implants and prostheses. In particular, oncology prosthetic market was valued $450 Million in 2024 and is expected to grow to $1.2 Billion by 2033 [238]. Another domain rapidly developing at present are new remote care models in view of difficulties in serving patients living in rural or medical underserved areas on the one hand, and rising costs of healthcare, on the other. In this regard, applications of telemedicine combined with 3D printed wearable devices, boosted during Covid-19 epidemics, will help many patients and lower the cost of the treatment.

3D printed drug-loaded implantable devices and microfluidic devices represent domains that are also expected to grow rapidly and find numerous applications in coming years. However, we have to wait much longer for 3DP of organs for transplantation. 3D printed skin transplants will be, probably, the only exception, since they will find applications earlier.

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