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3D Printing Applications in the Biomedical Industry

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Anahtar Kelimeler

3B Baskı
Biyomedikal Uygulamalar
Hızlı Üretim
Biyomalzemeler
Biyomürekkepler

Graphical/Tabular Abstract (Grafik/Tablolu Özet)

Table: *Summary of 3D Printing Applications in the Biomedical Industry /* ***Tablo:*** *Biyomedikal Endüstride 3B Baskı Uygulamalarının Özeti.*

Aspect (Kapsam)	**Details (Detaylar)**
Methods (Yöntemler)	*SLA, SLS, FDM, DIW, SLM.*
Materials (Malzemeler)	*Polymers, Hydrogels, Metal Alloys, Bio-Inks. / Polimerler, Hidrojeller, Metal Alaşımlar, Biyomürekkepler.*
Applications (Uygulamalar)	*Prosthetics, Implants, Tissue Engineering, Drug Delivery, Surgery. / Protezler, İmplantlar, Doku Mühendisliği, İlaç Taşıma, Cerrahi.*
Advantages (Avantajlar)	*Customization, Fast Prototyping, Cost-Effective, Less Waste. / Kişiselleştirme, Hızlı Prototipleme, Maliyet Etkinliği, Daha Az Atık)*
Challenges (Zorluklar)	*Limited Materials, Biocompatibility, Regulations, High Cost. / Sınırlı Malzeme, Biyouyumluluk, Mevzuat, Yüksek Maliyet.*
Future Prospects (Gelecek Öngörüleri)	*AI Integration, Advanced Biomaterials, Standardized Regulations, Enhanced. / Yapay Zeka Entegrasyonu, Gelişmiş Biyomalzemeler, Standartlaştırılmış Düzenlemeler.*

Highlights (Önemli noktalar)

- *3D printing enables the production of personalized biomedical devices such as prosthetics, implants, and tissues. / 3B baskı, protezler, implantlar ve dokular gibi kişiselleştirilmiş biyomedikal cihazların üretimini sağlamaktadır.*
- *Key 3D printing methods are evaluated in terms of advantages and limitations. / Temel 3B baskı yöntemlerinin avantajları ve sınırlamaları açısından değerlendirilmiştir.*
- *Material selection, regulatory challenges, and advancements in AI and biomaterials will enhance 3D printing applications in healthcare. / Malzeme seçimi, düzenleyici engeller ve yapay zeka ile biyomalzeme alanındaki gelişmeler, 3B baskının sağlık sektöründeki uygulamalarını ileriye taşıyacaktır.*

Aim (Amaç): *This study aims to evaluate the role of 3D printing in biomedical applications, focusing on key printing methods, material selection, and regulatory challenges while highlighting future prospects for healthcare advancements. /Bu çalışma, 3B baskının biyomedikal uygulamalardaki rolünü değerlendirerek temel baskı yöntemlerine, malzeme seçimine ve düzenleyici engellere odaklanmakta ve sağlık sektöründeki gelecekteki gelişmelere ışık tutmayı amaçlamaktadır.*

Originality (Özgünlük): *This study provides a comprehensive evaluation of 3D printing technologies in biomedical applications by analyzing key printing methods, material selection, and regulatory challenges, offering a unique perspective on future advancements in the healthcare sector. / Bu çalışma, 3B baskı teknolojilerinin biyomedikal uygulamalardaki rolünü kapsamlı bir şekilde değerlendirerek temel baskı yöntemleri, malzeme seçimi ve düzenleyici engelleri analiz etmekte ve sağlık sektöründeki gelecekteki gelişmelere dair özgün bir bakış açısı sunmaktadır.*

Results (Bulgular): *The study highlights 3D printing's transformative role in biomedical applications by enabling personalized medical solutions, improving efficiency, and expanding material options. However, challenges in biocompatibility, regulations, and scalability must be addressed for broader clinical use. / Çalışma, 3B baskının biyomedikal uygulamalarda kişiselleştirilmiş tıbbi çözümler sunarak verimliliği artırdığını ve malzeme seçeneklerini genişlettiğini vurgulamaktadır. Ancak, biyouyumluluk, mevzuat ve ölçeklenebilirlik sorunlarının daha geniş klinik kullanım için çözülmesi gerekmektedir.*

Conclusion (Sonuç): *3D printing is a breakthrough technology in biomedical applications, enabling personalized medicine, tissue engineering, and medical device production. However, challenges in material selection, regulations, and scalability persist. Addressing these issues through technological advancements and standardized regulations will enhance its impact in healthcare and enable broader clinical use. / 3B baskı, kişiselleştirilmiş tıp, doku mühendisliği ve tıbbi cihaz üretiminde çığır açan bir teknolojidir. Ancak, malzeme seçimi, mevzuat ve ölçeklenebilirlik sorunları devam etmektedir. Bu sorunların teknolojik ilerlemeler ve standartlaştırılmış düzenlemelerle ele alınması, 3B baskının sağlık sektöründeki etkisini artıracak ve daha geniş klinik kullanımı mümkün kılacaktır.*

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3D Printing Applıcatıons in the Biomedical Industry

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Abstract

Technological developments have triggered a transformation in industry, giving rise to the concept of the Fourth Industrial Revolution (Industry 4.0). This transformation has brought concepts such as rapid production, innovation, sustainability, digitalisation, personalisation and smart manufacturing to the forefront of many sectors around the world. 3D printing technologies are now a staple in various industries, including biomedical, due to their unparalleled personalised design options, production flexibility and faster product commercialisation using a wide range of materials. This technology has clearly surpassed traditional methods in biomedical applications. It has made it possible to produce complex objects such as implants, prostheses, tissues and organs that are difficult or impossible to produce traditionally. In addition, it has become possible to produce precise microstructures in this field in a cost-effective and personalised manner. This study presents research into 3D printing technologies that are expected to be indispensable in the future for tissue regeneration, therapeutic applications, medical device manufacturing and surgical planning in both research and clinical settings. The focus is on materials that have been and are being developed for biomedical applications, highlighting 3D printing processes that address challenging and limiting conditions and the improvements needed to address these conditions.

Biyomedikal Endüstride 3 Boyutlu Baskı Uygulamaları

Makale Bilgisi

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Öz

Teknolojik gelişmeler, sanayide dönüşümü tetikleyerek Dördüncü Sanayi Devrimi (Endüstri 4.0) kavramını ortaya çıkarmıştır. Bu dönüşüm, hızlı üretim, inovasyon, sürdürülebilirlik, dijitalleşme, kişiselleştirme ve akıllı üretim gibi kavramları birçok sektörde ön plana çıkarmıştır. 3B baskı teknolojileri, kişiye özel tasarım olanakları, üretim esnekliği ve geniş malzeme yelpazesiyle daha hızlı ürün ticarileştirme imkânı sunarak biyomedikal sektör de dahil olmak üzere çeşitli endüstrilerde vazgeçilmez hale gelmiştir. Bu teknoloji, biyomedikal uygulamalarda geleneksel yöntemleri geride bırakarak, implantlar, protezler, dokular ve organlar gibi karmaşık nesnelerin üretimini mümkün kılmıştır. Geleneksel yöntemlerle üretilmesi zor veya imkânsız olan bu yapılar, 3B baskı sayesinde daha hassas, maliyet-etkin ve kişiye özel olarak üretilebilmektedir. Ayrıca, bu teknoloji sayesinde biyomedikal alanda hassas mikro yapılar da ekonomik ve özelleştirilmiş bir şekilde üretilebilmektedir. Bu çalışma, doku rejenerasyonu, terapötik uygulamalar, tıbbi cihaz üretimi ve cerrahi planlama gibi alanlarda hem araştırma hem de klinik uygulamalarda gelecekte vazgeçilmez olması beklenen 3B baskı teknolojilerine yönelik araştırmaları sunmaktadır. Çalışmada, biyomedikal uygulamalar için geliştirilen ve geliştirilmekte olan malzemeler ele alınarak, 3B baskı süreçlerinin mevcut zorlukları nasıl ele aldığı ve bu zorlukların aşılması için gerekli iyileştirmeler vurgulanmaktadır.

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1. INTRODUCTION (GİRİŞ)

3D printers, widely regarded as a leading technology in recent years, have had a significant impact on manufacturing processes by quickly converting digital designs created with computer-aided design (CAD) software into tangible products. This capability has been established as an essential component of modern production [1]. Furthermore, as market-driven products prioritize design, prototyping, and manufacturing, industries have paid close attention to this trend. As a result, sectors have actively adopted and integrated this technology [2-3]. In addition to their manufacturing capabilities, 3D printing technologies offer substantial economic and environmental benefits.

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Traditional production methods, which often result in significant material waste owing to subtractive processes, are contrasted with 3D printing, which employs additive techniques that utilize only the necessary material, thus significantly reducing waste.

In addition, many materials used in 3D printing, such as polylactic acid (PLA), are recyclable or biodegradable, aligning them with sustainable production goals. These attributes not only reduce production costs but also mitigate environmental impacts, making 3D printing an attractive choice for industries that prioritize sustainability. By promoting resource-efficient manufacturing, this technology facilitates the transition to a circular economy, while fostering innovation in material science. These features underscore the potential of 3D printing to simultaneously drive economic growth and environmental responsibility across a range of applications [4-5].

As manufacturing technologies continue to evolve, many share core principles with 3D printing. However, 3D printing is notable because of its extensive material compatibility, reduced waste generation, and cost-effectiveness. Fundamentally, 3D printing is a process that constructs three-dimensional objects by depositing materials layer-by-layer. Thermoplastic polymers, which are typically amorphous in nature, are commonly used for this purpose. These polymers have a specific melting point, softening as the temperature increases and viscosity decreases. When subjected to pressure during extrusion, they are deposited in layers and quickly solidify, retaining their properties. As the model or prototype walls are aligned side by side or as layers are stacked upon one another, strong adhesion and effective bonding are achieved (Figure 1.) [6-7].

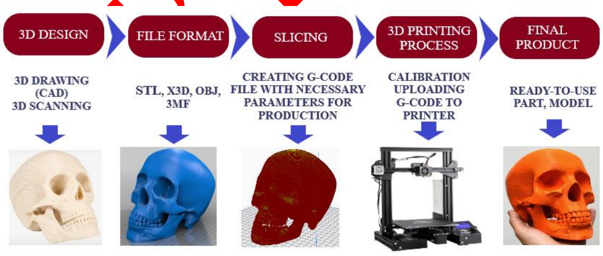

Figure 1. Schematic representation of the 3D printing process (3B baskı sürecinin şematik gösterimi)

This meticulous layering technique enables a high-resolution production and facilitates the creation of intricate geometries. Advancements in material science have continued to expand the functionality and mechanical performance of printed structures. Such progress in 3D printing has enhanced manufacturing efficiency while significantly reducing material waste.

The continuous expansion of the material diversity in 3D printing technology has enabled a broad range of applications. Various materials, including starch, protein- and fiber-rich foods [8], reduced graphene oxide (GO) [9], graphene-based polybutylene terephthalate (PBT) [10], mixtures with iron oxide powders [11], plasticized starch [12], and mashed potatoes [13], among other solid, liquid, and gaseous substances, can be used in 3D printing. This variety of materials has amplified the importance of 3D printing, which has found applications in sectors such as textiles [14], aerospace [15], automotive [16], medicine [17-18], construction [19], and pharmaceuticals [20].

Owing to its wide applicability, 3D printing has significantly facilitated the production of artificial organs, implants, drugs, bones, and prosthetics, and has also become increasingly widespread in the biomedical field. Traditional manufacturing methods involve many restrictive and costly steps, such as molding for shaping and various machines (e.g., CNC and lathe) for extrusion processes, which are generally not suitable for the complex geometries required in biomedical applications [21]. By contrast, 3D printing offers a highly cost-effective solution for producing geometrically complex objects that are difficult to produce using traditional methods [22-23]. Consequently, this transformative technology is being increasingly adopted in the healthcare, medical, and biomedical sectors [24-27].

3D printers have gained importance, particularly in therapeutic applications [28], surgical planning [29], implant design [30], and tissue engineering. A unique and rapidly advancing application of 3D printing is bioprinting, which allows layer-by-layer deposition of living cells. Method has attracted considerable attention [31]. This method has enabled the production of in vitro models for drug testing and disease research, and the bioproduction of implantable tissues such as skin [32], cartilage [33] and bone [34]. In this study, 3D printing technologies commonly used in the biomedical field were investigated, and the biomaterials commonly used in these applications were examined to create a general perspective in this field. For this purpose, databases such as Elsevier, Springer, Wiley, Elsevier Specialized Journals, Materials Today, Taylor & Francis, SAGE, MDPI, Nature Publishing Group, ASME, and IEEE have been used, and studies on biomaterials and bioprinting applications have been conducted.

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2. 3D PRINTING METHODS IN BIOMEDICAL APPLICATIONS
(BİYOMEDİKAL UYGULAMALARDA 3B BASKI YÖNTEMLERİ)

Owing to technological advancements in the field of 3D printing, significant progress has been made in the biomedical sector, and 3D printing technology is now considered as an alternative to current clinical treatments. These advancements have made it possible to produce a wide range of products, from life-saving implants and soft tissues to hard prostheses, as well as artificial organs made using living human cells, all tailored to the individual. Furthermore, this technology not only addresses the shortage of artificial organs or tissues but also enables the design and production of complex and precise microstructures using bioinks, which are preferred in 3D printing for biomedical applications [35]. Additionally, the ability to customize each product to match the patient's unique biological needs further enhances the potential for personalized medicine. Commonly used printing methods include thermal and piezoelectric inkjet printing, extrusion, and laser methods (Figure 2).

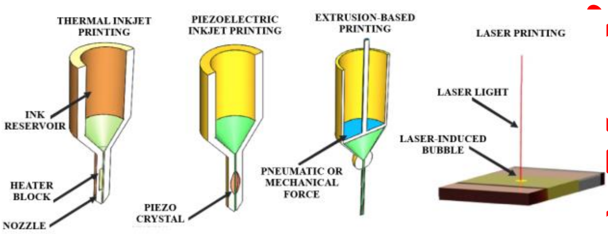

Figure 2. 3D printing technologies preferred in biomaterial production [39] (Biyomalzeme üretiminde tercih edilen 3B baskı teknolojileri)

The potential of using thermal and piezoelectric inkjet printing methods for rapid prototyping and personalized manufacturing provides a more attractive alternative to traditional manufacturing methods [36]. Owing to advantages such as high printing speed and excellent accuracy during the printing process, these methods have become a focal point in many studies. Inkjet printing allows for high-precision printing by adjusting the range of printing parameters required for the production process and controlling the size and spraying rate of the ink droplets used in the printing process. Although these methods hold promising potential for applications such as bone regeneration, wearable technology, and localized drug delivery for injuries, the use of hydrogel materials with inkjet printing technologies requires further technological advancements and material optimization [37-38].

Scientific studies in the biomedical field (Figure 3) have made significant advancements with 3D printing technology playing a critical role. This technology not only provides personalized preoperative consultation for patients, but also offers various advantages in diagnostic processes during surgical resections. 3D printing enables surgeons to make more precise and informed decisions, particularly regarding visualization of complex anatomical structures and preoperative planning.

By developing appropriate extruder mechanisms, biological materials can be used in 3D printers, contributing to a wide range of applications in bioprinters. Bioprinting is achieved by layer-by-layer deposition of biological materials and live cells, allowing the production of 3D tissue structures such as skin, cartilage, tendons, cardiac muscle, and bone. For example, simpler structures such as the skin are easier to produce, whereas complex structures requiring features such as vascularization, such as cardiac muscle and bone tissue, require more advanced printing techniques and inks.

The process begins with careful selection of cells suitable for the target tissue structure [40]. The selected cells were then combined with an appropriate bioink to prepare the printing material. The biocompatibility and mechanical durability of bioinks directly impact the functionality of the final structure; therefore, the compatibility of the cell type and bioink is crucial. In the final step, the prepared material was printed with the required dimensions using a suitable printer to achieve specific biomechanical properties. After printing, the produced tissues are cultured and biologically mature to achieve full functionality [41].

Furthermore, the use of 3D-printed models extends beyond tissue engineering and offers significant improvements in prosthetic and surgical implant planning. For instance, highly personalized 3D models of patient-specific anatomical features can be created to optimize the fit of implants, thereby ensuring a higher success rate in surgery. Additionally, the ability to fabricate functional bioprinted tissues for testing and drug development accelerates preclinical trials, reducing reliance on animal models. Despite promising applications, challenges remain, including the complexity of printing vascular networks for large-tissue structures and ensuring the long-term functionality of printed tissues in vivo. However, ongoing research continues to address these hurdles, holding great potential for the future of regenerative medicine and personalized healthcare (Table 1) [42].

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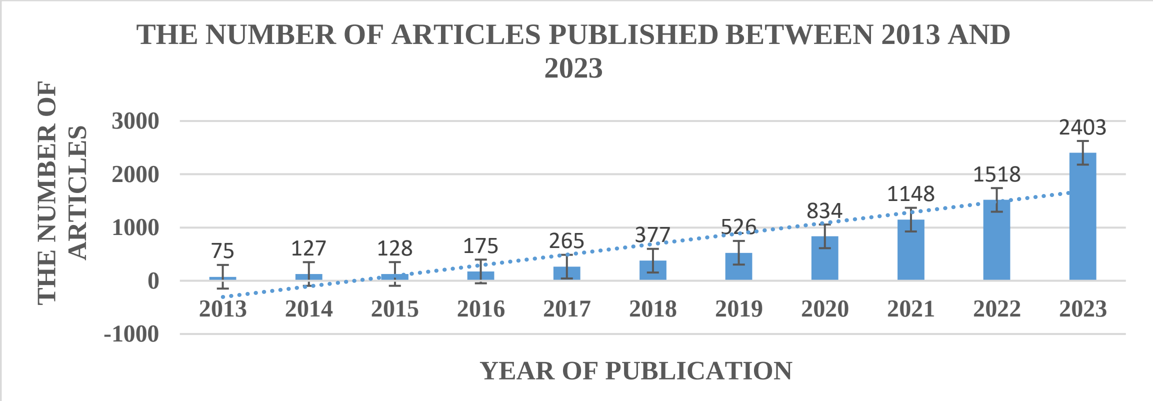

Figure 3. Statistical data on studies conducted in the biomedical field over the last eleven years based on 3D printing technology. The dataset was obtained from the number of articles found in Science Direct between the selected years using the search terms "3D printing" and "biomedical applications" (Şekil 3. Son on bir yılda 3B baskı teknolojisine dayalı olarak biyomedikal alanında gerçekleştirilen çalışmalara ait istatistiksel veriler. Veri seti, belirlenen yıllar arasında Science Direct'te "3D printing" ve "biomedical applications" arama terimleri kullanılarak bulunan makale sayılarından elde edilmiştir.)

Unlike many traditional 3D printing methods, the selection of 3D bioprinting materials in the biomedical field is a more complex process in terms of growth differentiation factors in cell types and the sensitivity of living cell structures. The 3D bioprinting process (Figure 4) can be categorized into three main stages: preparation, printing, and post-processing.

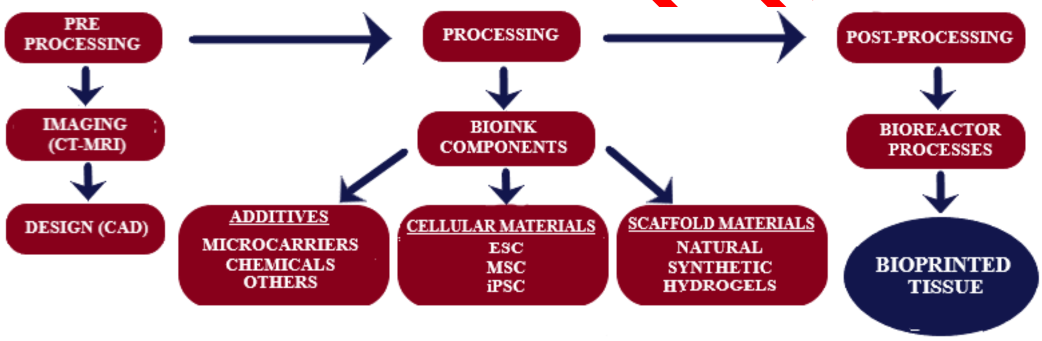

Figure 4. Schematic representation of bioprinting processes (CT: Computed Tomography, MRI: Magnetic Resonance Imaging, ESC: Embryonic Stem Cell, MSC: Mesenchymal Stem Cell, iPSC: Induced Pluripotent Stem Cell) (Biyobaskı süreçlerinin şematik gösterimi (CT: Bilgisayarlı Tomografi, MRI: Manyetik Rezonans Görüntüleme, ESC: Embriyonik Kök Hücre, MSC: Mezenkimal Kök Hücre, iPSC: İndüklenmiş Pluripotent Kök Hücre))

The preparation stage involves converting the images obtained from a bioimaging system (such as MRI) into a suitable format, which is then transformed into an STL file for printing. This step ensured that the digital model accurately represented the anatomy of the patient, allowing precise customization of the printed structure. The printing stage encompasses the actual printing process using bioprinters equipped with electronic components, such as ink reservoirs, video cameras, fiber optic light sources, temperature sensors, and piezoelectric humidifiers, with the print head tailored to the desired form.

The use of bioinks, which consist of living cells or biomaterials, is crucial to ensure that the printed structure closely mimics the properties of natural tissues. Additionally, the selection of bioinks plays a key role in determining the functionality and biocompatibility of the final construct. Finally, the postprocessing stage includes the necessary procedures to convert the printed structure into an organ suitable for surgical implantation [43-44]. Table 1 highlights various printing methods utilized in biomedical applications, offering significant potential to revolutionize organ transplantation and regenerative medicine.

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Table 1. Some printing methods used in biomedical applications (Biyomedikal uygulamalarda kullanılan bazı baskı yöntemleri)

Printing Method	Material	Print Sensitivity	Biomedical Applications
Directed Energy Deposition (DED)	Metal Wires, Nylon	0,1-5 mm	Limited use in medical applications but utilized in situations requiring high strength [45].
Spray Deposition	Metal Powder, Sand	0,05-4 mm	Used in the production of hard, mineralized tissues and iron-based implants [46].
Fused Deposition Modeling (FDM)	Thermoplastics, Hydrogels, Ceramics, Bio-Ink	0,1-0,2 mm	Used in surgical planning for creating hard and soft anatomical models (tissues, organs, etc.) [47].
Powder Bed Fusion Systems (DMLS, SLM, EBM)	Thermoplastics, Metal Powders, Ceramics	0,02-0,2 mm	Used in the production of temporary and fracture-resistant implants for head, neck, and facial regions (e.g., dental implants) [48].
Sheet Lamination	Paper, Ceramics, Metal	~0,5-1 mm	Used in the production of macroscopic anatomical models [49].
Spheroid Assembly	Bio-Ink, Organoids	0,1-0,2 mm	Used for free-form production of biologically active models (soft tissue, organs) [50].
Stereolithography (DLP, SLA)	Photopolymer, Bio-Resin	0,001-0,2 mm	Used for bio-printing scaffold structures for cell culture, tissue, and organ development. Applicable for both soft and hard tissues [51].

FDM: fused deposition Modelling; DMLS: direct metal laser sintering; SLM: selective laser melting; EBM, electron beam melting; DLP: digital light processing; SLA: stereolithography.

Computed tomography (CT) and magnetic resonance imaging (MRI) are among the most commonly used methods in presurgical planning. However, these methods often lead to oversight of critical information, preventing the achievement of more accurate pathological diagnoses and disregarding physiological and anatomical differences between patients. By utilizing innovative technologies, such as 3D printing technology, in presurgical planning, patient-specific organ models can be created, enabling the visualization of differences between patients. This approach enhances the success rate of surgeries and reduces complications such as blood loss and even patient mortality [52].

3. BIOPRINTING-COMPATIBLE 3D PRINTING MATERIALS (BİYOBASKI UYUMLU 3B BASKI MALZEMELERİ)

In bioprinting applications using 3D printer technology, there is a clear distinction between the direct printing of a cell-seeded material, referred to as bio-ink (Figure 5), and the printing of a scaffold that can later be seeded with biomaterial ink [53]. When selecting the ink, both the final function of the part and the printing technique must be considered. Biomaterial inks are typically employed to create rigid structural scaffolds that provide permanent or slow-degrading structural stabilization. These inks often require processing under cytotoxic conditions such as extreme temperatures or solvent use. Additionally, they can be used with therapeutic molecules that can withstand these processing conditions. The choice of the ink directly affects the mechanical properties, degradation rate, and biocompatibility of the final product. Furthermore, the development of new bioinks that can better mimic the properties of human tissues is a key area of research. With advances in technology, these inks are expected to become more specialized for complex tissue regeneration applications.

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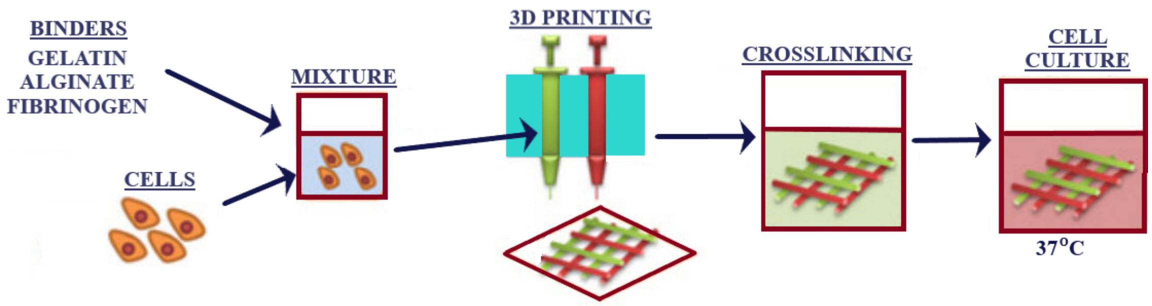

Figure 5. Schematic representation of the process for creating a 3D model using bio-inks (Biyomürekkepler kullanılarak 3B model oluşturma sürecinin şematik gösterimi)

Unlike biomaterials, bioinks are used to produce softer structural scaffolds that can be rapidly replaced by a new extracellular matrix, which is deposited by the embedded cell population [54]. In the production of bioinks, many bioinks have been developed from hydrogels, which are well-known materials with excellent biological compatibility and are suitable for 3D cell cultures (Table 2) [55].

Hydrogels are generally suitable for extrusion-based bioprinting. The best hydrogels for creating cell culture scaffolds typically have low viscosities before crosslinking, and are suitable for extrusion-based bioprinting [56]. Owing to these advantages, recent studies have focused on the development of new bioinks and techniques for cell-seeded biofabrication applications [57].

Table 2. Commonly used compatible materials in bio-ınks and their corresponding cell and tissue types (Biyomürekkeplerde yaygın olarak kullanılan uyumlu malzemeler ve ilgili hücre ve doku türleri)

Bio-Printing Compatible Materials	Commonly Used Cells and Tissue Types
Gelatins	Used with Umbilical Vein Endothelial cells and Mesenchymal Stem Cells (bone, cartilage) [58].
Fibrinogen	Used with plant-derived medicinal product cells in skeletal muscle [59].
Collagen	Used with Hepatocytes (intestinal) and liver cells [60].
Agarose	Used with Chondrocyte cells that produce cartilage matrix and Mesenchymal Stem Cells [61].
Alginate	Used with Chondrocyte cells that produce cartilage matrix [62].
Gellan Gum	Used with Osteoblast cells that promote bone formation and Chondrocytes that produce cartilage matrix [63].
Hyaluronic Acid	Used with Fibroblast cells that are crucial for connective tissue structure and skin integrity [64].
Polyethylene Glycol	Used with Chondrocyte cells, Human Mesenchymal Stem Cells, and Fibroblast cells [65].
Tissue-Derived Extracellular Matrix	Used with Apical Papilla Stem Cells (dental bone, kidney) [66].

In addition to the materials listed in Table 2, thermoplastics that are commonly used in bioprinting applications are preferred in many 3D printing applications. Their primary advantages in biological printing are their processability and their ability to undergo multiple thermal cycles [67]. Thermoplastics such as Polycaprolactone (PCL), Polyvinyl Alcohol (PVA), and Polylactic Acid (PLA) are frequently used as support materials for hydrogels that require mechanical reinforcement and are directly used in implant applications [68].

In addition to thermoplastics, ceramics are preferred in biological printing for bone and dental applications owing to their osteoconductivity. Ceramics are inherently brittle; therefore, they are often mixed with binders in polymer form for use in printing [69]. The ceramics most commonly used in bioprinting include Tricalcium Phosphate (TCP), hydroxyapatite (HAP), Biphasic Calcium Phosphate (BCP), Polymethyl Methacrylate (PMMA), and biogass [70]. Moreover, metal implants traditionally manufactured by casting and forging methods using stainless steel, cobalt, chromium, molybdenum, and titanium alloys are widely used in orthopedic, dental, and craniofacial applications. Owing to advances in 3D printing technology, it has become possible to manufacture patient-specific implants, prostheses, and orthoses (Figure 6) using data from imaging systems, such as

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3D scanning, in contrast to traditional manufacturing methods.

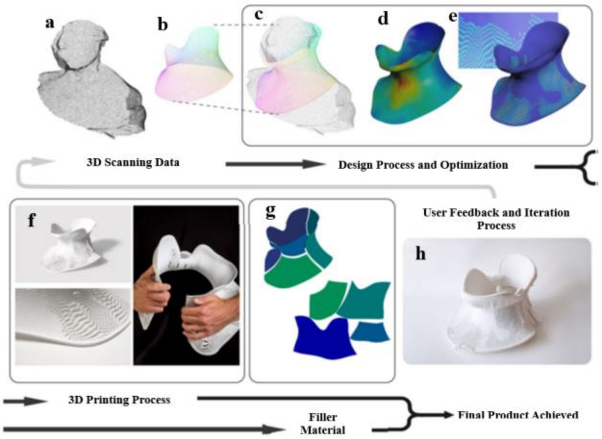

Figure 6. Manufacturing process of a custom-designed orthosis using 3D printing: a) 3D scanning, b) and c) designed orthosis, d) and e) design optimization, f) 3D-printed orthosis, g) orthosis infill trimming through variable surface cutting algorithm, h) final product obtained by assembling the printed components [71] (3B baskı kullanılarak özel tasarım bir ortezin üretim süreci: a) 3B tarama, b) ve c) tasarlanan ortez, d) ve e) tasarım optimizasyonu, f) 3B baskılı ortez, g) değişken yüzey kesme algoritması ile ortez dolgusunun düzeltilmesi, h) baskılı bileşenlerin birleştirilmesiyle elde edilen nihai ürün)

4. CHALLENGES OF 3D PRINTING APPLICATIONS IN THE BIOMEDICAL INDUSTRY (BİYOMEDİKAL ENDÜSTRİDE 3B BASKI UYGULAMALARININ ZORLUKLARI)

3D printing technology has brought significant advantages to the biomedical field; however, several limitations hinder its full potential and broad adoption. When these technologies first emerged, researchers envisioned them to be the driving force behind the new industrial revolution [72]. Although 3D printing has established a solid presence in areas such as research and product customization, its capability to replace traditional manufacturing methods in large-scale production has not yet been proven. This limitation arises primarily because of the low production volumes and extended time required for manufacturing products through 3D printing compared to conventional mass production methods.

Despite ongoing efforts to enhance the printing speed and efficiency, critical challenges, such as maintaining high precision and achieving acceptable surface quality, remain unresolved. Additionally, the limited selection of materials suitable for bioprinting and difficulties in ensuring the long-term structural stability of printed structures are major obstacles. Replicating the complex microenvironment of natural tissues, which is essential for functional and biocompatible biomedical applications, remains a major technical challenge. Furthermore, the high initial costs of 3D printing equipment and specialized materials continue to limit their accessibility and widespread use in clinical settings. Regulatory concerns and unanswered questions regarding the safety and long-term reliability of 3D-printed medical products further delay their integration into mainstream health care solutions.

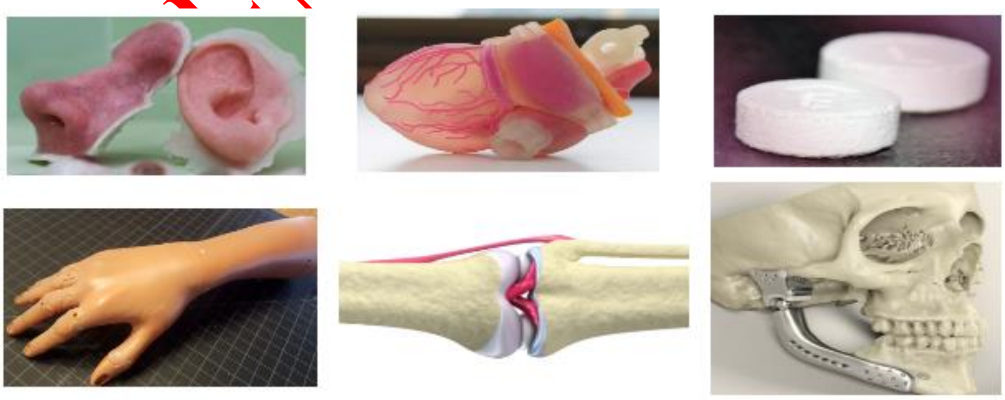

Figure 7. Visuals of some biomedical products developed using 3D printing methods (3B baskı yöntemleri kullanılarak geliştirilen bazı biyomedikal ürünlerin görselleri)

Initially, the range of printable materials and their applications in 3D printing were relatively narrow. However, continuous technological advancements have significantly expanded the variety of materials that can be used, thereby enabling the development of a growing number of innovative biomedical products (Figure 7). Despite this progress, the absence of universal regulations or standardized guidelines for 3D-printed medical devices remains a significant limitation [73]. The diversity of 3D printing techniques and wide range of biomaterials make it increasingly challenging to establish standardized guidelines applicable to all processes and materials [74].

Another complication is the lack of global consistency in the regulatory frameworks governing 3D-printed biomedical devices. For instance, although the U.S. Food and Drug Administration (FDA) has introduced guidelines for 3D-printed medical devices, these guidelines are incomplete and fail to cover all material types or manufacturing methods. Similarly, the International Organization for Standardization (ISO) has issued general standards for additive manufacturing, such as ISO/ASTM 52900, which provides foundational guidelines, but lacks the level of detail required for biomedical applications. In the European Union, the Medical Device Regulation (MDR) addresses 3D-printed devices; however, inconsistencies in implementation among member states impede regulatory alignment [75]. These disparities in standards create challenges for the approval and development of 3D-printed biomedical products, increase production costs, and slow technological innovations.

However, the diversity of biomaterials significantly complicates the establishment of universal standards. Hydrogels, polymers, and metal alloys, each with their unique characteristics, require specialized testing protocols to meet clinical and regulatory standards. For instance, although polymers are commonly utilized for soft tissue engineering, metals are predominantly used for orthopedic implants, and both require distinct biocompatibility evaluations. This diversity hinders the development of a one-size-fits-all regulatory framework, delaying progress toward globally accepted guidelines [76].

To address these challenges, international collaboration is essential to harmonize regulatory processes. Establishing a global consortium involving organizations such as the FDA, ISO, and the European Commission could provide a unified framework for governing biomaterials, manufacturing processes, and clinical applications. Additionally, integrating innovative technologies, such as artificial intelligence-driven automated testing systems, can streamline regulatory approval processes, enhance product safety, and accelerate the adoption of 3D printing in the biomedical field [77]. Moreover, advancements in 3D printing have brought benefits such as improved material recyclability and waste reduction. However, these advantages remain underutilized in the absence of standardized regulations. Bridging these regulatory gaps would not only ensure sustainable and cost-effective production but also unlock the full transformative potential of 3D printing in biomedical applications [78-79].

5. CONCLUSIONS (SONUÇLAR)

This study investigates the use of 3D printing technology in biomedical systems. For this purpose, a general evaluation of 3D printers is used in biomedical systems and biomaterials used with these printers. Traditional manufacturing methods provide affordable costs, particularly for large-scale production. However, when new 3D printing techniques are considered, the costs are even more affordable because they do not require additional tools and offers the advantage of personalized production. Although the costs of printers and materials developed for the medical sector areis high, three-dimensional (3D) printing techniques are developing rapidly. This is expected to reduce costs and enable large-scale production in the future. It is believed that this promising technology will also contribute to the production of various formulations owing to its many features, such as changing drug concentrations and producing personalized drugs.

The flexibility and easy usability of 3D printing technology have and surgical planning in boths led to an increase in its use in hospitals, universities, schools, and even homes. This success will reach dimensions that will enable surgeries and medical treatments to be performed in the future, and will offer many opportunities for the health and medical sector. As it is known, 3D printing has managed to make revolutionary changes in the biomedical field for the production of implants, artificial and special tissues, organs and prostheses. Although this technology faces some limitations in the use of cell infiltration and vascularization in different fields, such as tissue engineering, owing to insufficient material or defective anatomy, it is promising in terms of overcoming these difficulties. As research in this field increases, the number of treatments that provide patients with a better lifestyle will increase. This technology will continue to be discovered in the near future and will have the potential to change the lives of many people by being launched on a larger scale, eventually overcoming other problems, such as cost and accuracy.

DECLARATION OF ETHICAL STANDARDS
(ETİK STANDARTLARIN BEYANI)

The author of this article declares that the materials and methods they use in their work do not require ethical committee approval and/or legal-specific permission.

Bu makalenin yazarı çalışmalarında kullandıkları materyal ve yöntemlerin etik kurul izni ve/veya yasal-özel bir izin gerektirmediğini beyan ederler.

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AUTHORS' CONTRIBUTIONS (YAZARLARIN KATKILARI)

Both authors have contributed equally to the manuscript.

Her iki yazar da makaleye eşit katkıda bulunmuştur.

CONFLICT OF INTEREST (ÇIKAR ÇATIŞMASI)

There is no conflict of interest in this study.

Bu çalışmada herhangi bir çıkar çatışması yoktur.

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