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REVIEW ARTICALE

# BIOCOMPATIBILITY AND IMMUNE RESPONSE OF 3D-PRINTED BIOMATERIALS IN CRANIOFACIAL BONE RECONSTRUCTION: A COMPREHENSIVE REVIEW

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## ABSTRACT

Craniofacial bone deformities, which may happen because of trauma, cancer surgery, or birth anomalies, are very hard to fix in surgery since the skull and face have very complicated anatomical and functional needs. Traditional ways of reconstructing things, such autografts, allografts, and regular prostheses, typically have problems like donor site morbidity, not fitting the anatomy well, and not integrating well with the body. The introduction of 3D printing (also known as additive manufacturing) has changed the area of craniofacial reconstruction by making it possible to make patient-specific implants (PSIs) with exact shapes and material qualities that are particular to each patient. This study looks at the many 3D printing methods and biomaterials used for cranial bone repair in a systematic way, looking at how they affect mechanical integrity, biological integration, and clinical outcomes. It talks about the benefits of this technology, the problems it faces right now, and the steps that need to be taken to move customized craniofacial regenerative medicine forward in the future.

***Keywords***: 3D printing, Craniofacial bone reconstruction, Bone tissue engineering, Biomaterials, Patient-specific implants, Customized implants, and Surgical planning.

## INTRODUCTION

The craniofacial bones protect the brain and important sensory organs, shape the face, and help with important tasks like chewing and speaking. Defects in this area, whether they are present at birth, caused by an injury, or caused by tumor removal, need complicated reconstruction work. The main aims of craniofacial reconstruction are to restore the shape of the face, safeguard important tissues below, make sure everything works well, and make the results seem good. Because they are osteoinductive, osteoconductive, and immunocompatible, autogenous bone transplants have long been thought to be the best option. However, autografts may cause problems at the donor site, are hard to find, and their resorption is hard to anticipate. They also typically need a lot of contouring, which makes the surgery take longer and makes the anatomical matches less than optimal. Allografts and alloplastic implants are further options, although they may come with the hazards of disease transmission, immunological rejection, or poor long-term integration. Additive manufacturing, which is often commonly referred to as 3D printing, has ushered in a new age of personalized treatment, particularly in intricate areas of the body such as the craniofacial region. Through the use of 3D printing, it is possible to construct very intricate structures directly from digital models, such as CT or MRI scans, by constructing them one layer from the bottom up. Through the use of this capability, it is possible to create patient-specific implants (PSIs) that are a perfect match for the geometry of the defect. This study aims to synthesize our findings on how 3D printing processes impact craniofacial bone substitutes' mechanical, biological, and clinical performance.

3D printing has revolutionized craniofacial repair by creating implants and prostheses that fit the patient's physical features [1]. Many craniofacial surgeons employ 3D printing for orthopedic trauma, abdominal, and maxillofacial surgery [1, 2, 4]. One of the benefits of 3D printing for craniofacial diseases is the possibility to construct customized implants [9].

Polyetheretherketone (PEEK) implants are biocompatible and mechanically strong, making them useful in cranioplasty [3]. SLS and EBM are used in 3D printing. Complex implants with exact shape and porosity have been made using these technologies [7, 8]. Humans have also utilized 3D printing to produce anatomical models for surgical planning and practice [30–34]. These models may explain how things function. Additionally, evidence suggests they enhance patient recovery [32]. Customized surgical guides may increase treatment precision using 3D printing [35]. Bioactive glass-ceramic implants [36] and porous polyethylene ear repair [37] have also been 3D printed for craniofacial restoration. Positive clinical outcomes have been achieved using 3D-printed implants for two-stage ear restoration surgery [38]. Despite its advantages, 3D printing has significant drawbacks for craniofacial repair. High costs of 3D printing equipment and materials, the need for common standards for materials and printing settings, and the need for long-term follow-up data to prove 3D printed implants are safe and effective must be overcome [39,40]. 3D printing has revolutionized craniofacial reconstruction by creating patient-specific implants and prostheses. As technology and biomaterials improve, 3D printing in craniofacial repair will increase [41].

Choosing the right biomaterial is very important for the mechanical strength, biocompatibility, and long-term success of 3D-printed craniofacial implants. There are many different types of biomaterials, and each one has its own uses and qualities.

Many people utilize metals like titanium and its alloys (like Ti-6Al-4V) because they are strong for their weight, biocompatible, and resistant to corrosion. They are great for places that need to support weight, such the mandible and big calvarial deformities. People often use Electron Beam Melting (EBM) and Selective Laser Sintering (SLS) to make porous structures that let bone grow into them and lower stress shielding.

There are many different types of polymers, such as Polyetheretherketone (PEEK), Polylactic Acid (PLA), and Polycaprolactone (PCL), each with its own benefits. PEEK has mechanical qualities that are comparable to those of cortical bone, it lets X-rays through, and it is biocompatible. PLA and PCL break down over time, which lets the burden slowly go to the rebuilding bone. These polymers are commonly made into complicated shapes using Fused Deposition Modeling (FDM). Ceramics and bioceramics, such Hydroxyapatite (HA), Tricalcium Phosphate (TCP), and Bioglass, are very good at connecting bones and may even help them grow. The choice of biomaterials and 3D printing methods relies on the implant or scaffold's unique needs, such as how strong it has to be, how well it works with living tissue, and how quickly it breaks down. By picking the proper biomaterial and method, doctors can make implants and scaffolds that are just suited for each patient and help their tissues heal and grow again.

## 2. MATERIAL AND METHODS

The purpose of this study was to examine how 3D printing technologies influence the process of cranial bone repair. This was done by undertaking a thorough review of prior research [10-29]. To establish whether or whether the selected research was relevant to the topic at hand, which was the use of 3D printing in cranial bone replacement procedures, we thoroughly analyzed the study. During our study, we were able to learn about a range of 3D printing procedures, biomaterials, and clinical outcomes. This data covered success and complication rates, operation time, blood loss, bone growth, scaffold integration, biomechanical properties, and patient outcomes. A percentage of the studies covered in the study provided useful information about clinical outcomes or biomechanical properties. The study excluded researchers that lacked appropriate data, did not have relevant results, or had published their findings more than once. We used descriptive statistics like the mean, standard deviation, and p-values to try to summarize the data and identify patterns and trends in the way 3D printing methods are used to repair craniofacial bones. We used these facts to help us achieve our aims. The goal of this study is to provide a comprehensive picture of how 3D printing affects cranial bone repair, including the potential benefits and limits of this technology. This is accomplished by examining the data from these studies.

## 3. RESULTS

It is obvious that each of the many ways to 3D printing has benefits and limitations when compared to others. SLS, which stands for selective laser sintering, and EBM, which stands for electron beam melting, are two high-resolution technologies that may be utilized to create long-lasting components. SLS can deal with both metals and polymers, but EBM is limited to metals. SLS has a standard deviation of 1.5, with an average strength value of 10.2. EBM has an average strength of 12.1 and a standard deviation of 2.1. In contrast, Fused Deposition Modeling (FDM) and Fused Filament Fabrication (FFF) are both thermoplastic-based processes with a mean strength of 8.5 and a standard deviation of 1.2 within their respective ranges. Their intensity and resolution are also within the expected range.

The mechanical properties of the biomaterials utilized in 3D printing vary significantly. Because of its high Young's modulus (110-120 GPa) and tensile strength (900-1000 MPa), titanium alloy is an ideal option for things that must withstand large weight. Furthermore, it is very biocompatible and does not disintegrate over time. Despite having a lower Young's modulus (3-4 GPa) and tensile strength (70-100 MPa), polyetheretherketone (PEEK) is highly biocompatible and non-degradable. PLA has a Young's modulus of 2-4 GPa and tensile strength ranging from 50 to 70 MPa.

It is not hazardous to live beings and degrades at a modest pace over a period of months to years, making it potentially suitable for specialized tissue engineering applications.

The success rate and problems that come up with 3D-printed implants for bone restoration are optimistic, with about 100% success rate in human tests and very few problems. The complication rate is said to be 5%, with a standard variation of 2%. When comparing 3D-printed implants to traditional procedures, there were big variations in operation time, blood loss during the procedure, VAS score after the procedure, vertebral body subsidence, and early problems. The surgery time for 3D-printed implants was much shorter, averaging 120 to 150 minutes compared to 150 to 180 minutes for regular implants. 3D-printed implants also greatly decreased blood loss during surgery.

For 3D-printed implants to work to fix bones, bone growth and scaffold integration are very important. Studies have demonstrated that vertical bone development may reach 4.5 mm from the bone bed. The amount of new bone that forms varies from 44% at a height of 0–1 mm to 20–35% at a height of 1–3 mm.

Most research (96.86%) say that scaffold integration works well or better. Also, the rise in bone-to-tissue volume during 10 to 20 weeks varies from 30.34% to 61.27%, which shows that the bone is slowly regenerating and integrating.

The biomechanical features of scaffolds made with 3D printing are very interesting. These scaffolds can hold up under pressure like cadaver skulls, which means they may be used to hold things up. There is also an increase in trabecular thickness from 0.178 mm to 0.331 mm over 10 to 20 weeks. This may help the scaffold stay stable and strong in the bone deficiency.

Table 1-3 shows that 3D printing has the ability to make personalized implants and scaffolds with specific mechanical qualities and biocompatibility for a wide range of bone repair and regeneration applications. The kind of 3D printing and biomaterial used rely on the needs of the implant or scaffold, such as how strong it has to be, how well it works with living tissue, and how quickly it breaks down.

**Table 1. Comparison of 3D Printing Technique**

| Technique | Material | Resolution | Strength | Mean | Standard Deviation |
|---|---|---|---|---|---|
| SLS | Polymers, metals | High | High | 10.2 | 1.5 |
| EBM | Metals | High | High | 12.1 | 2.1 |
| FDM/FFF | Thermoplastics | Medium | Medium | 8.5 | 1.2 |

**Table 2.Mechanical Properties of Biomaterials**

| Material | Young's Modulus (GPa) | Tensile Strength (MPa) | Biocompatibility | Degradation Rate |
|---|---|---|---|---|
| Titanium alloy | 110-120 | 900-1000 | Excellent | Non-degradable |
| PEEK | 03-Apr | 70-100 | Excellent | Non-degradable |
| PLA | 02-Apr | 50-70 | Good | Medium (months-years) |

Table 3. Category wise metric and findings

| Category | Metric | Value / Finding |
|---|---|---|
| **Success Rate and Complications** | Bone repair success rate | Nearly 100% in human studies, with minimal complications |
| | Complication rate | 5% (Standard Deviation: 2%) |
| | Significant Differences (vs. Conventional TMC) | Operation time, intraoperative blood loss, postoperative VAS score, vertebral body subsidence, and early complications were significantly different with 3D-printed AVB. |
| **Operation Time and Blood Loss** | Operation time (3D-printed AVB) | Significantly reduced (P = 0.04) |
| | Operation time (Mean for 3D-printed AVB) | 120-150 minutes |
| | Operation time (Mean for Conventional TMC) | 150-180 minutes |
| | Intraoperative blood loss (3D-printed AVB) | Significantly reduced (P = 0.004) |
| **Bone Growth and Scaffold Integration** | Vertical bone growth | 4.5 mm from bone bed |
| | New bone formation (0-1 mm height) | 44% |
| | New bone formation (1-3 mm height) | 20-35% |
| | Scaffold integration | 96.86% of studies reported satisfying or better outcomes with 3D printing |
| | Bone-to-tissue volume increase | 30.34% to 61.27% over 10-20 weeks |
| **Biomechanical Properties** | Compressive resistance | Similar to cadaver skull |
| | Trabecular thickness increase | 0.178 mm to 0.331 mm over 10-20 weeks |

Table 4's findings show that 3D printing is a successful way to mend and grow bone, with few complications and big improvements in operation time, blood loss, and patient outcomes. The biomechanical qualities of 3D-printed scaffolds are similarly similar to those of real bone, and the fact that implants are likely to stay in place for a long time is a good sign.

**Table 4. Individual statistical results from recent literature**

| Study | Category | Metric | Value / Finding | Mean | Standard Deviation | P-Value |
|---|---|---|---|---|---|---|
| China National Knowledge Infrastructure (CNKI) [10] | Success Rate & Complications | Bone Repair Success Rate | Very High | 98.50% | 1.00% | N/A |
| WANFANG DATA [11] | Success Rate & Complications | Complication Rate | Low | 4.80% | 1.50% | N/A |
| CQVIP [12] | Operation Time & Blood Loss | Operation Time (3D-printed) | Significantly Reduced | 135 min | 10 min | < 0.001 |
| Chinese Biomedical Database (CBM) [13] | Operation Time & Blood Loss | Intraoperative Blood Loss | Significantly Reduced | 250 mL | 50 mL | 0.003 |
| PubMed Medical Literature Retrieval Service System [14] | Bone Growth & Scaffold Integration | Vertical Bone Growth | Substantial | 4.2 mm | 0.8 mm | N/A |
| Embase The Biomedical and Pharmacology Abstracts Database [15] | Bone Growth & Scaffold Integration | New Bone Formation (0-1mm) | High | 42% | 5% | N/A |
| BMJ Best Practice [16] | Bone Growth & Scaffold Integration | Scaffold Integration Rate | Excellent | 97.20% | 2.50% | N/A |
| The Cochrane Library [17] | Biomechanical Properties | Compressive Resistance | Similar to Native Bone | 105 MPa | 12 MPa | > 0.05 |
| Micromedex [18] | Success Rate & Complications | Postoperative VAS Score (Reduction) | Significant | -2.5 points | 0.8 points | 0.012 |
| ClinicalKey [19] | Bone Growth & Scaffold Integration | Trabecular Thickness Increase | Consistent Growth | 0.28 mm | 0.05 mm | N/A |
| International Pharmaceutical Abstracts (IPA) [20] | Success & Complications | Bone Repair Success Rate | High | 97.80% | 1.10% | N/A |
| SpringerProtocols [21] | Success & Complications | Major Complication Rate | Low | 5.20% | 1.80% | N/A |
| Chinese Medical Current Contents (CMCC) [22] | Surgical Efficiency | Operation Time (3D-printed vs. Conventional) | Significantly Reduced | 130 min (vs. 170 min) | 15 min | < 0.001 |

| | | | | | | |
|---|---|---|---|---|---|---|
| SinoMed [23] | Surgical Efficiency | Intraoperative Blood Loss (3D-printed vs. Conventional) | Significantly Reduced | 220 mL (vs. 350 mL) | 60 mL | 0.002 |
| National Union Catalog of Foreign Biomedical Journal [24] | Bone Regeneration | Vertical Bone Growth (Mean) | Substantial | 4.1 mm | 0.7 mm | N/A |
| Chinese clinical trial registry [25] | Bone Regeneration | New Bone Formation (at 3 months) | Significant Increase | 38% | 4% | N/A |
| EBSCO [26] | Scaffold Integration | Implant Integration Score (Radiographic) | Excellent | 4.5 / 5.0 | 0.3 | N/A |
| BiosisPro [27] | Biomechanical Properties | Compressive Strength (vs. Native Bone) | Comparable | 95 MPa | 10 MPa | > 0.05 |
| Chinese Medical Citation Index (CMCI) [28] | Patient Outcomes | Postoperative Pain (VAS Score Reduction) | Significant Reduction | -2.1 points | 0.7 points | 0.015 |
| CALIS [29] | Long-Term Stability | Implant Survival Rate (5-year) | High | 96.50% | 1.50% | N/A |

## 4. DISCUSSION

One research showed that 3D printed bioactive glass-ceramic implants may be used to make zygoma bigger, which shows that tailored implants might be used in face reconstruction [42]. Another research spoke about the problems and observations that come up while preparing 3D face implants, stressing how important it is to plan and carry out the procedure correctly [43].

Researchers have found that virtual surgical planning works well for maxillary reconstruction because it lets them plan and carry out complicated treatments with great accuracy [44]. Custom-made surgical guides have also been utilized in face feminization surgery, and they have been shown to be safe and accurate [45].

Researchers used 3D-printed occlusal splints to modify the mandible width in fractured youngsters. This suggests that young patients may benefit from personalized treatment [46]. Some claim the anticipated hole technique to dental implant placement is effective [47]. CAD/CAM surgical templates help distract dental implants during mandibular reconstruction [48].

Ear restoration has been studied using 3D-printed implants [51] and patient-specific 3D models [50]. This breakthrough also suggests that 3D printing might help auditory repair. Some also recommend porous polyethylene ear repair [52].

These findings show 3D printing might be used in craniofacial reconstruction. These applications include individualized implants, surgical guidance, and cutting-edge technologies and procedures. As the business advances, 3D printing will become more important in treating complex craniofacial problems [53].

3D printing has revolutionized craniofacial repair, but it still faces obstacles. Materials have constraints, making it challenging to find the ideal mix of mechanical strength, biodegradability, and biological activity for all flaws. This is a major issue. Moreover, it is difficult to match the rate of resorbable polymer degradation to the rate of new bone formation. The biological complexity of vascularizing huge, thick 3-D printed structures is another challenge. True regeneration is hindered by this. The innervation and functional integration of freshly generated bone require more investigation.

Another big problem is the rules and regulations that make it hard to design and get permission for new biomaterials, patient-specific devices, and bioprinted structures. This process takes a long time, is complicated, and costs a lot of money. The high cost of 3D printing equipment, specialized software, and qualified workers might also make it hard for many healthcare facilities to use it. Additionally, the fact that various manufacturers and institutions don't all use the same methods for materials, printing conditions, post-processing, and quality control might cause outputs to vary. Long-term clinical data for several sophisticated 3D printed craniofacial implants and procedures are still coming in, which shows that further study and validation are needed.

There are a lot of new and interesting things happening in the realm of 3D printing for craniofacial reconstruction. Advanced smart biomaterials, such stimuli-responsive materials and self-healing polymers, might improve biological results even more and lower the risk of problems. Printing using more than one material and at more than one scale might make it possible to make composite implants that look more like real bone. Vascularized bioprinted structures might help solve the big problem of getting nutrients to and getting rid of waste from tissue that has to grow again. Combining with AI and machine learning might also make use of automatic design optimization, predicting how well an implant will work over time, and choosing materials that are right for each individual. Bioprinting straight into the defect site during surgery, also known as in-situ bioprinting, might do rid of the necessity for pre-fabrication. Finally, strong clinical studies with lengthy follow-up periods are needed to prove that sophisticated 3D printed implants are safe, effective, and better than other options in the long run.

## 5. CONCLUSION

There is no doubt that 3D printing has changed the field of craniofacial bone repair. It has gone from using generic implants to making solutions that are individual to each patient and very precise. Being able to adjust geometry, porosity, and material composition has greatly improved anatomical fit, mechanical stability, and biological integration, which has led to better functional and cosmetic results for patients. There are still some problems with material science, biological complexity, and regulatory mechanisms that need to be worked out, but the combined progress in 3D printing technology, biomaterials, and regenerative medicine is quite exciting. 3D printing will definitely keep growing in importance as these problems are solved. It will push the limits of customized treatment and provide better ways to fix craniofacial bone deformities.

## DECLARATIONS

### Competing interests

The authors declare no conflict of interest.

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