




## Review Article

# Recent advances of 3D-printing in spine surgery

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## ABSTRACT

**Background:** The emerging use of three-dimensional printing (3DP) offers improved surgical planning and personalized care. The use of 3DP technology in spinal surgery has several common applications, including models for preoperative planning, biomodels, surgical guides, implants, and teaching tools.

**Methods:** A literature review was conducted to examine the current use of 3DP technology in spinal surgery and identify the challenges and limitations associated with its adoption.

**Results:** The review reveals that while 3DP technology offers the benefits of enhanced stability, improved surgical outcomes, and the feasibility of patient-specific solutions in spinal surgeries, several challenges remain significant impediments to widespread adoption. The obvious expected limitation is the high cost associated with implementing and maintaining a 3DP facility and creating customized patient-specific implants. Technological limitations, including the variability between medical imaging and *en vivo* surgical anatomy, along with the reproduction of intricate high-fidelity anatomical detail, pose additional challenges. Finally, the lack of comprehensive clinical monitoring, inadequate sample sizes, and high-quality scientific evidence all limit our understanding of the full scope of 3DP's utility in spinal surgery and preclude widespread adoption and implementation.

**Conclusion:** Despite the obvious challenges and limitations, ongoing research and development efforts are expected to address these issues, improving the accessibility and efficacy of 3DP technology in spinal surgeries. With further advancements, 3DP technology has the potential to revolutionize spinal surgery by providing personalized implants and precise surgical planning, ultimately improving patient outcomes and surgical efficiency.

**Keywords:** 3D-printing, 3D spine models, Additive manufacturing, Spine surgery, 3D implants

## INTRODUCTION

The treatment of spinal pathologies involves meticulous preoperative planning and extensive complex anatomical visualization. Although traditional imaging techniques provide valuable

intraoperative information, they can be time-consuming, expensive, and potentially harmful to patients.<sup>[32]</sup> The emerging use of three-dimensional printing (3DP) offers a solution by allowing for an identical 3DP reproduction, as opposed to the limitation of two-dimensional (2D)-imaging modalities.<sup>[13,39]</sup> By processing images generated by magnetic resonance imaging (MRI), computed tomography (CT), and positron emission tomography scanning, a file can be created and read by a 3D printer to fabricate a unique high-fidelity model with patient-specific details. This innovative technique offers improved surgical planning and individualized patient care.

Patient-specific 3DP models have been particularly beneficial in spine surgery.<sup>[13,39]</sup> They offer great assistance in the preoperative assessment of complex cases where traditional 2D image guidance, using MRI and CT scans, may provide limited and insufficient insight compared to high-fidelity 3DP. This innovative approach has the potential to reduce morbidity and mortality in complex spine surgeries through improved visualization and understanding of the complex surgical anatomy.<sup>[13,39]</sup> There are various methods of 3D printing, that is, stereolithography (SLA), inkjet printing, selective laser sintering, fused deposition modeling (FDM), and laminated object manufacturing.<sup>[17]</sup>

The use of 3DP technology in spinal surgery has several common applications, including models for preoperative planning, biomodels, surgical guides, implants, and teaching tools.<sup>[13,32,39]</sup> This technology can address variations in anatomy, size, bone quality, and pathology type, which is now recognized as crucial for optimizing patient outcomes.<sup>[21,42,50]</sup> In this article, we explore recent advances and current limitations of 3DP in spinal surgery.

## MANUFACTURING

### Process

The 3D-printing process, or additive manufacturing, starts with a computer-aided design (CAD) drawing that creates a 3D model.<sup>[16,42]</sup> The computer software then divides this model into multiple layers, which the 3D printer uses to produce a physical object by printing each layer individually. The manufacturing process is divided into three steps:

### Modeling

The first step includes model design. Data on the shape and dimensions of the end product are obtained and analyzed into a CAD file (STL is the primary file format) by a 3D scanner or CAD design package. Using the information stored in a CAD file, the scanned object can be printed with high precision.<sup>[16,42]</sup>

### Printing

Before printing the CAD file, it is imperative that “slicing” occurs. Slicing involves sophisticated 3D-printing software such as Slic3r, KISSlicer, and Cura to deconstruct the digital representation of the product into virtual cross-sectional layers. These layers are then used to generate a G-code file from the original “.STL” file. Subsequently, the 3D printer follows these intricate G-code instructions and systematically deposits layers of printing materials, culminating in a product boasting unparalleled geometry and dimensions.<sup>[16,42]</sup>

### Finishing

After the fabrication of a model, a post-processing step is necessary to achieve a more refined outcome by eliminating superfluous material through a high-resolution technique that enhances the precision of the manufacturing process. Subsequently, the resulting end product is deemed exemplary and can be utilized for its intended purpose.<sup>[16,42]</sup>

### Synthetic biomaterials

Spinal surgery is a complex procedure that often requires the use of synthetic biomaterials to support bone regeneration and repair. To this effect, there is ongoing research and development in the 3DP of hydroxyapatite (HA) and demineralized bone matrix (DBM), peptide amphiphiles (PA), hyperelastic bone<sup>®</sup> (HB), and Fluffy-polycaprolactone or poly (lactic-co-glycolic acid) (PLG) for use in spinal implants. Researchers are exploring ways to optimize the properties of these materials to improve bone growth and integration further. There is also interest in combining these materials with other growth factors or stem cells to enhance their regenerative properties.

### HA: DBM composite materials

The success of spinal instrumentation depends on the ability of the bone graft material to promote new bone growth and osseointegration for successful arthrodesis. HA and DBM are two commonly used materials for bone grafting in spinal fusion procedures. HA is a naturally occurring inorganic mineral that is found in human bone and teeth,<sup>[9]</sup> while the removal of the mineralized component of bone through acid extraction results in DBM, which retains the osteoinductive properties and type 1 collagen of the graft substance irrespective of processing variability. DBM is also approved for implant use and can be used as a versatile matrix to deliver exogenous bioactive agents to bone sites for enhanced biological activity in orthopedic repair and regenerative medicine contexts.<sup>[20]</sup>

Recently, a promising 3DP composite material composed of HA-DBM has emerged as a promising bone graft substitute

for spinal instrumentation procedures, as there is currently no widely accepted, safe, and highly effective alternative.<sup>[10]</sup> This composite material promotes osseointegration, new bone formation, and successful fusion without the need for recombinant growth factor. The study found 3DP HA-DBM composites to be a cost-effective and safe bone graft substitute material for spinal fusion without necessitating the expensive addition of recombinant growth factor. Moreover, HA-DBM composites offer multiple advantages over traditional bone grafts, including not requiring a second surgical site and decreased inflammatory markers.<sup>[45,47]</sup>

Although it was previously reported that the combined use of HA/tricalcium phosphate mixture and DBM might not improve bone healing, DBM alone may be a better option for promoting bone regeneration.<sup>[40]</sup> It was shown in a recent study that the 3:1 HA: DBM composite achieved the highest mean fusion score and fusion rate (92%), which was significantly greater than the 3DP DBM-only scaffold (42%).<sup>[47]</sup>

## PA

Developed in the late 1990s, PAs are a type of biomolecule made up of hydrophilic and hydrophobic amino acids that can self-assemble into a variety of structures, including PA nanofibers (PANF) and PA hydrogels (PAH).<sup>[18,62]</sup> PAs have tunable mechanical properties, resistance to proteolysis, and self-healing abilities. In addition, PAs are biodegradable, biocompatible, and can be tailored chemically and biologically. These unique properties make PA-based biomaterials an attractive option for bone graft therapies, and ongoing research is exploring their potential for spinal surgery applications.<sup>[6,30,33]</sup>

A 2015 study used PANF to create gel scaffolds with a binding affinity for recombinant human bone morphogenetic protein 2 (rhBMP-2). These bioactive nanofibers reduced the required dose of BMP-2 by 10-fold and even recruited the body's growth factors to promote spinal fusion in rats, potentially reducing the risk of complications associated with rhBMP-2 use.<sup>[28,55]</sup>

The exploration of synthetic PAH is a promising direction in the way of under-researched feedstock materials for 3DP applications. A review by Murphy *et al.* highlights a significant challenge in the 3DP field – the limited development of novel PAH materials compared to the optimization of 3DP instrumentation. Unlike commercial natural polymers, PAH offers advantages such as straightforward synthesis, tunable properties, and biological activity. However, the number of journal articles found for PAH in 3DP is significantly low compared to traditional hydrogels, suggesting a significant opportunity for research and development in this area.<sup>[36]</sup>

Nevertheless, recent advances in PAH design have led to the development of materials that are highly amenable to 3DP. For example, supramolecular hydrogels prepared from alkyl-chain conjugated PAs have been demonstrated for 3DP through Direct-Ink-Writing (DIW) extrusion. In this approach, pH and salt are used to trigger the stabilization of 3DP structures.<sup>[48]</sup> There have also been developments in the creation of polypeptide materials with customized antimicrobial features for DIW printing.<sup>[37]</sup> Hedegaard *et al.* developed a biofabrication system that combines molecular self-assembly and 3DP to create hierarchical structures with customizable composition and structure. The system uses droplet-on-demand inkjet printing to guide the self-assembly of PAs and naturally occurring biomolecules, allowing for the bioprinting of complex structures with high cell viability and potential for tissue engineering.<sup>[19]</sup> Another approach to 3DP of PAH involves blending PAs with other materials to improve printability and control over scaffold properties. For instance, researchers have introduced an advanced bio-ink for 3DP using PAs, specifically RAD16-I and methylcellulose, to enhance bio-ink viscosity, resulting in high shape fidelity and stability, with embedded stem cells exhibiting high viability and the ability to differentiate.<sup>[5]</sup>

As of January 2023, researchers have established the printability of multi-domain peptides (MDPs) for 3DP hydrogels, creating complex structures with optimized charge functionalities.<sup>[11]</sup> MDPs are a promising new class of 3DP inks, relying solely on supramolecular mechanisms for assembly. Overall, these recent advances in PAH design and 3DP techniques are paving the way for the development of highly customizable and functional tissue engineering scaffolds which can be used in spinal bone graft therapies.

## HB<sup>®</sup>

In 2016, a new synthetic biomaterial called Hyperelastic “Bone”<sup>®</sup> was developed as a potential solution to address the limitations of existing osteoregenerative biomaterials, such as inadequate bone regeneration, high manufacturing costs, and surgical handling difficulties. HB is composed of 90% HA and 10% PLG and can be rapidly 3DP at room temperature from liquid inks with a rate of up to 275 cm<sup>3</sup>/h. The resulting 3DP HB has elastic mechanical properties, is highly absorbent, supports cell viability and proliferation, and induces osteogenic differentiation of bone marrow-derived human mesenchymal stem cells (hMSCs) cultured *in vitro* without osteo-inducing factors. *In vivo* studies in mice, rats, and non-human primates demonstrated that HB is biocompatible, vascularizes quickly, integrates well with surrounding tissues, and supports new bone growth without the need for added biological factors.<sup>[25]</sup> A study in 2019 demonstrated that HB could potentially overcome the limitations of donor-site availability and morbidity associated

with autologous bone grafts and inferior clinical outcomes of commercial bone substitutes and allografts.<sup>[22]</sup>

In 2021, a new type of 3DP HB implants that were infused with superparamagnetic iron oxide nanoparticles (SPIONs) was introduced. By incorporating SPIONs, the implants exhibited improved bacteriostatic properties and demonstrated a significant ability to regenerate large non-healing bone fractures in a femoral bone defect rat model over 2 weeks. No instances of infection, immune rejection, or fibrotic encapsulation were observed, and the implants integrated quickly with the host tissue, leading to the growth of new bone.<sup>[51]</sup> A study by Dewey *et al.* used two types of meshes – Fluffy-PLG and HB, to improve the biological activity of mineralized collagen (MC) scaffolds for bone regeneration.<sup>[8]</sup> The researchers found that the inclusion of both types improved mechanical performance and supported human bone-marrow-derived mesenchymal stem cell (MSC) osteogenesis and new bone formation, but the HB mesh also elicited significantly increased secretion of osteoprotegerin, which inhibits osteoclast-mediated bone resorption, suggesting that architecture meshes can actively instruct cell processes to aid osteogenesis. Furthermore, researchers used human adipose-derived stem cells transduced with a lentiviral vector carrying the gene for BMP-2 and loaded them onto a 3DP HB scaffold. They found that the scaffold effectively carried the transduced cells and promoted BMP-2 production, resulting in significant bone formation *in vivo*. The combination of gene therapy and tissue-engineered scaffolds has the potential for clinical use in bone repair.<sup>[2]</sup>

### Fluffy-PLG

Researchers have recently developed a method for creating highly porous, biomedical elastomers (specifically PLG) by combining a new 3DP process called 3D painting with traditional salt-leaching techniques.<sup>[24]</sup> The authors of the study clarify that 3D painting is a distinct process within the larger category of 3DP and is similar to other technologies such as FDM and ink jetting. The authors utilized this approach to create designer structures quickly and easily without additional drying time. They developed 3DP inks using water-soluble salt ( $\text{CuSO}_4$ ) as the base particulate material. After 3DP, the salt is removed from the structure by washing it in aqueous solutions. The resulting materials are named “Fluffy PLG” (F-PLG) to distinguish them from their non-salt-derived counterparts; they are highly porous, mechanically robust, flexible, and biocompatible, making them potentially useful as scaffolds. These materials support the attachment, viability, and proliferation of hMSCs over an extended culture period.

In addition, the F-PLG can also act as a carrier for other biofunctional materials. The ink system introduced in the study can be used to create large-scale structures relevant

to clinical applications quickly. The study also shows that by adjusting the ratio of  $\text{CuSO}_4$  and PLG in ink, it is possible to customize the mechanical, physical, and biological properties of the resulting material structures. In another study, the use of F-PLG mesh was proven to improve the mechanical performance of MC scaffolds and supported human bone marrow-derived MSC osteogenesis and new bone formation.<sup>[60]</sup> The study also found that F-PLG composites had a significantly higher calcium content compared to both mineralized MC scaffolds and MC-HB composites. The degree of porosity and flexibility of the F-PLG meshes, as well as their biocompatibility and ability to support the attachment, viability, and proliferation of cells, make them an excellent candidate for spinal surgery. With further research, F-PLG scaffolds may become an important tool for the successful treatment of spinal diseases.

### 3D-printed porous titanium alloy cage (PTA)

The use of 3DP interbody cages has shown improved early stability due to the strong bone-to-implant connection resulting from bony ingrowth. The titanium material with a larger pore size facilitates rapid bone growth into the implant, ensuring stability at the bone-implant interface. In addition, the manufacturing method of 3DP creates a rough surface on titanium implants, which enhances friction and the initial grip of the interbody cage.<sup>[49]</sup> Titanium is a desirable material for interbody implants due to its biocompatibility and strength. However, its higher Young’s modulus may lead to increased cage subsidence and make it difficult to implant the fusion mass inside the cage. In a study comparing three interbody cage materials in sheep, the 3DP titanium cage showed significant improvements in reducing motion, increasing stiffness, and promoting bone growth compared to poly-ether-ether-ketone (PEEK) and plasma-sprayed porous titanium-coated PEEK cages at 8- and 16-week follow-up points.<sup>[34]</sup>

Most cervical fusion cages on the market do not perfectly match the anatomy of the intervertebral disc space, and individualized cages could potentially enhance implant stability and reduce dislocation and subsidence rates. A pilot study evaluated the planning, manufacturing, and implantation of an individualized cervical cage using electrical impedance tomography and 3DP. The results showed a highly accurate fit, with the cage self-locating into the correct position during surgery after suspending distraction. The unique end plate design of the implant made it impossible to move the cage in any direction with the inserting instrument after suspending distraction, indicating excellent primary stability.<sup>[34,53]</sup>

Cervical intervertebral disc replacement using rectangular titanium stand-alone cages is a common procedure for anterior cervical discectomy and fusion (ACDF). A study

aimed to evaluate the outcomes of using rectangular titanium stand-alone cages for ACDF, specifically focusing on cage subsidence and subsequent malalignment. Logistic regression analysis revealed that fusion level, cage size, and cage position were significantly related to cage subsidence. Despite the need for longer follow-up, the study indicates that rectangular titanium stand-alone cages are a viable option for 1- and 2-level ACDF, with a good surgical outcome and negligible complications.<sup>[61]</sup>

A multicenter study adhering to a United States Food and Drug Administration Investigational Device Exemption found that the titanium fusion cage implant method was effective, rapid, and safe for lumbar spine fusions, demonstrating a high fusion rate and clinical success with rare, serious, or permanent complications.<sup>[46]</sup> While these studies conclude that the preconditions for manufacturing individualized titanium cages using specific patient data are given, the production of such implants at a reasonable cost still needs evaluation by spine surgeons and the industry.

There is also a greater potential for the development of more complex, patient-specific implants. This could allow implants to be tailored to individual patient's needs, allowing for a better, more comfortable fit than ever before.

One posterior lumbar interbody fusion (PLIF) study of 66 patients randomized them into the trial cohort (implantation of 3D Cage,  $n = 33$ ) and the control cohort (implantation of PEEK cage,  $n = 33$ ). Both groups underwent successful surgeries, with a cerebrospinal fluid leak in the trial cohort as the only complication. The 3D-printed PTA cage showed comparable outcomes to the PEEK cage in PLIF surgeries. The trial group had lower rates of intervertebral height loss and better interbody fusion in the early postoperative period. However, there were no significant differences in long-term outcomes between the two groups.<sup>[57]</sup>

## USES AND ADVANTAGES OF USING 3D-PRINTING FOR SPINAL SURGERY

### 3D spine models

Complexities in anatomy and pathology may not be fully appreciated or even detected by traditional imaging modalities. Using 3D models for preoperative planning, surgeons can gain a better understanding of unique or complex surgical pathology. The utilization of 3DP technology has been associated with a reduction in operation time for various surgical procedures attributed to preoperative understanding of the pathology and appropriate instrument selection.<sup>[1,3,15,43,58]</sup>

### *Surgical planning and precision*

Various clinical advantages have been noted when compared to traditional imaging in preoperative planning. These

include improved diagnostic accuracy, decreased time spent on fluoroscopy, better communication among surgical team members, a more achievable removal of tumor tissue while maintaining negative margins and a decrease in the incidence of screw misplacement.<sup>[1,3,15,43,58]</sup>

Furthermore, a study showed that patients educated with personalized 3DP models reported a higher degree of satisfaction.<sup>[64]</sup>

In 2007, a postoperative survey was conducted by researchers, in which 3D spine models were reported as the most useful visual modality in preoperative planning for 70% of cases and the most useful intraoperative visual modality in 89% of cases.<sup>[23]</sup> A study aimed to compare the outcomes of 3D model-assisted surgery and conventional surgery. The 3D model-assisted surgery group had shorter instrumentation time ( $61.9 \pm 4.7$  min), decreased blood loss ( $268.4 \pm 42.7$  mL), and lower fluoroscopy exposure ( $16.3 \pm 1.9$  times) compared to the conventional surgery group ( $75.5 \pm 11.0$  min,  $347.8 \pm 52.2$  mL,  $19.7 \pm 2.4$  times) ( $t = 4.5325$ ,  $P < 0.0001$  and  $t = 4.7109$ ,  $P < 0.0001$  and  $t = 4.4937$ ,  $P < 0.0001$ , respectively).<sup>[41]</sup>

One study even reported that the reduced requirement for intraoperative navigation resulted in increased cost-effectiveness of the surgical procedure.<sup>[44]</sup> However, some studies have reported no change in complication rates or clinical outcomes, indicating a need for larger-scale studies.<sup>[29]</sup>

### *Physical modeling*

Stereolithographic or physical modeling, a new technology utilizing 3D CT scan data, enables the creation of precise plastic replicas of anatomical structures. In one study, this technology was applied to treat five patients with complex deformities, including two children with congenital deformities, a patient with an osteoblastoma, a patient with basilar invagination due to osteogenesis imperfecta, and a patient with failed lumbar arthrodesis. The biomodels generated through this technique were utilized for patient education, operative planning, and surgical navigation, showcasing its multifaceted utility.<sup>[7]</sup>

A previous investigation conducted in 2007 involved the manufacturing of 28 biomodels using SLA for 26 patients with complex spinal disorders. These biomodels served various purposes, such as preoperative diagnosis and assessment of spinal pathology, patient and parent education, preoperative surgical planning, intraoperative verification of bony anatomy and surgical navigation, and as teaching aids for the surgical team. Among the patients treated using biomodels, there were five cases of tumors in the cervical spine, 13 cases of cervical and cervicothoracic deformity, and eight cases of thoracolumbar deformity, resulting in

six surgical procedures. The long-term follow-up revealed disease-free status for all patients with cervical spine tumors (mean follow-up:  $71.8 \pm 4.1$  months) and stable deformity in the spinal deformity group (mean follow-up:  $37.5 \pm 24.8$  months), except for one patient who did not require surgery due to the detailed preoperative examination facilitated by the biomodel, and their deformity remained stable for 77 months.<sup>[23]</sup>

The use of 3DP BioModels in pre-surgical planning has been described in assisting minimally invasive transforaminal lumbar interbody fusion surgeries. Researchers employed patient imaging and surgical planning software to create patient-specific 3DP BioModels of the spine, which were then utilized for surgical planning, patient consent, education, and sterilized for intraoperative reference and navigation. Evaluation of efficiency measures in the procedure included operating time ( $153 \pm 44$  min), sterile tray usage ( $14 \pm 3$ ), fluoroscopy screening time ( $57.2 \pm 23.7$  s), operative waste ( $19 \pm 8$  L contaminated,  $116 \pm 30$  L uncontaminated), and median hospital stay (4 days). Furthermore, the accuracy of pedicle screw placement, as assessed on postoperative CT, reached 97.8% ( $625/639$ ).<sup>[60]</sup>

Another study demonstrated the benefits of utilizing 3D models in preoperative planning, resulting in improved surgical outcomes and the ability to make necessary adjustments to the operative plan in all cases among a cohort of seven patients with complex deformities, as compared to a historical cohort of ten patients who underwent only traditional imaging.<sup>[26]</sup>

### Customization of implants and instruments

Spine surgery involves extensive reconstruction, which is mainly achieved through graft materials. The advent of 3DP technology has introduced numerous benefits to spinal surgery, particularly in the realm of customization and patient-specific physical biomodeling. With 3DP, it is now possible to create patient-specific models, guides, instruments, and implants, as well as improve off-the-shelf implants. The ability to customize implants and surgical instruments to fit the patient's unique needs using 3DP allows the field of surgery to align itself with the principles of personalized medicine.

Customized 3DP spinal implants have been shown to be effective in treating conditions that traditional implants may not address and are particularly useful for patients with physical deformities or in cases of abnormal anatomy. Benefits of customized design include optimized biomechanical performance, improved comfort and fit, and better surgical and clinical outcomes.<sup>[2,4,8,12,14,24,34,41,44,46,49,51-53,56,57,61,63,64]</sup>

A pioneering 2016 study reported the first case of a customized 3DP spinal prosthesis for posterior C1/C2 fusion, which added significant value by reducing the overall

procedure time and safety risk.<sup>[41]</sup> Similarly, a 2022 study used 3DP technology to create patient-specific cervical orthoses, using CT data to reconstruct and optimize the design. The resulting orthotics were comfortable, lightweight, waterproof, and had a high level of precision.<sup>[56]</sup> Another two cases where 3DP was used for surgical planning and designing custom titanium prostheses resulted in successful implantation and shorter procedure time.<sup>[49]</sup>

### Spine drill guides and templates

Computer-assisted systems for pedicle screw insertion in spinal surgeries offer high accuracy, but their cost and learning curve pose challenges.<sup>[53]</sup> To address this, researchers in 2009 developed a novel method using reverse engineering and rapid prototyping to create customized drill templates for each patient, reducing operation time and radiation exposure. This approach was validated by both cadaveric and clinical studies while demonstrating a significant reduction in operation time and radiation exposure for the surgical team. However, this approach can be time-consuming and requires conscientiousness to match the patient's anatomy.<sup>[53]</sup>

A study aimed to compare the placement of pedicle screws with 3DP and freehand techniques in 20 patients with spinal deformities in India. The use of 3DP resulted in significantly more accurately placed screws, less surgical time, and fewer medial perforations, indicating enhanced safety.<sup>[61]</sup> This technique has the potential to improve treatment outcomes for spinal deformities, particularly in developing countries where they are often neglected and present in a more advanced state. Multiple other studies also concluded that 3DP pedicle screw guides are a safe and effective solution for a wide range of spinal deformity conditions, providing more accuracy than the freehand technique and reducing the total radiation dose, even with the need for a low-dose preoperative CT for surgical planning.<sup>[14,46,52]</sup>

Another study compared the accuracy of 3DP drill guides with additional screw guiding techniques for challenging intra- and extravehicular screw trajectories.<sup>[58]</sup> The goal was to improve pedicle screw placement, particularly in syndromic scoliosis cases with limited bone stock. The study found that for intrapedicular screw trajectories, malpositioning rates were low (2%). Among the techniques tested, modular guides, which guided the screw in addition to the drill bit, demonstrated a statistically significant increase in accuracy compared to drill guides ( $P = 0.05$ ). All techniques achieved accurate cervical screw insertion without breach. However, for extrapedicular screw trajectories, neither of the additional screw guiding methods showed a significant improvement in accuracy ( $P = 0.09$ ). However, malpositioning rates remained high at 24%.<sup>[44]</sup>

Researchers have developed a novel intraoperative screw-guiding method for pedicle screw fixation in spinal

instrumentation. The method involved analyzing preoperative CT scans to plan screw trajectories and creating patient-specific laminar templates using 3D design and printing technology. Plastic vertebra models were also generated for preoperative screw insertion simulation. Ten patients with thoracic or cervicothoracic conditions underwent surgery using this system, resulting in the successful placement of 58 pedicle screws. Postoperative CT scans revealed that the screws were accurately placed without violating the cortex of the pedicles, with a mean deviation of  $0.87 \pm 0.34$  mm from the planned trajectories at the coronal midpoint section of the pedicles. This method demonstrates the potential for precise and safe screw placement, reducing the risk of injury to adjacent structures during spinal surgery.<sup>[54]</sup>

In the context of spinal surgery, 3DP templates have proven successful in implant applications, particularly in interbody fusion procedures. A study investigated the efficacy of using a 3D-printing percutaneous guide template with a pointed lotus-style regulator for percutaneous pedicle screw fixation (PPSF) in thoracolumbar fractures. The application of the template improved the accuracy of pedicle screw insertion, resulting in higher 1<sup>st</sup>-time screw insertion success rates, shorter fluoroscopy and operation times, and improved postoperative pain and disability scores compared to traditional PPSF.<sup>[63]</sup>

A randomized, single-blind, and controlled study evaluated the feasibility and precision of using 3DP templates for cervical lateral mass screw insertion in patients with cervical spondylotic myelopathy and developmental cervical spinal stenosis. Group A underwent surgeries with screw insertion guided by 3DP templates, while Group B underwent freehand screw insertion. The accuracy of screw placement was the main evaluation indicator. The results showed no significant differences between the two groups in terms of age, the improvement rate of Japanese Orthopedic Association scores, operation time, and blood loss. However, according to Bayard's criteria, the percentage of screws described as "acceptable" was higher in Group A (88.9%) compared to Group B (61.1%) ( $P < 0.05$ ). When evaluated based on the study's criteria, the "excellent and good" rate of screws was significantly higher in Group A (83.3%) compared to Group B (47.2%) ( $P < 0.05$ ). The precision of screw location in Group A was also superior to that in Group B.<sup>[12]</sup>

### Applications in complex and oncological pathology

The majority of the literature on the use of 3DP implants in spinal surgery revolves around their application in oncological pathology. This includes cases involving tumor resections and reconstructions in various regions of the spine. In a 2017 study, a sacral replacement prosthesis was used after removing a sacral chordoma. While there were

instances of instrument failure and bone-prosthesis interface issues, no symptoms were reported.<sup>[4]</sup>

A study aimed to investigate the clinical efficacy and safety of 3DP artificial vertebral bodies for patients who underwent multilevel total *en bloc* spondylectomy for spine tumors.<sup>[34]</sup> Eight consecutive cases of patients were analyzed, and the results showed that all patients achieved remarkable pain relief and improvement in neurological function after the surgery. Another study showed that the use of 3D models during preoperative surgical planning allowed for improved surgical precision and reduced the risk of complications in patients undergoing *en bloc* resection of primary malignant bone tumors in the cervical spine.<sup>[24]</sup> Overall, these studies highlight the potential of 3DP technology in improving surgical outcomes in spine surgery.

Pelvic reconstruction after sacral resection is a surgical challenge due to complex anatomy, high load bearing, and large defects. Advances in 3DP technology have allowed for the creation of customized implants that can overcome these difficulties. A study reported the successful use of a 3DP titanium implant in a patient with sacral osteosarcoma undergoing sacral reconstruction. The implant was made to fit the patient's CT images and included a porous mesh and dense strut. The patient had low postoperative pain, was able to walk after 2 weeks, and only experienced left-side foot drop as a complication. Follow-up imaging showed excellent bony fusion after 1 year.<sup>[27]</sup>

## CHALLENGES AND LIMITATIONS OF 3D PRINTING IN SPINE SURGERY

Despite the manifold and innumerable advantages of 3DP in the domain of surgery, it is beset by constraints, such as exorbitant costs and technological restrictions.

### Cost

Spinal surgeries are complex and often require the use of multiple implants to achieve the desired outcome. This requires the creation of a range of patient-specific implants, each with unique cage dimensions and degrees, to provide surgeons with greater flexibility during the procedure. However, this kind of modular approach may be relatively inexpensive.<sup>[52]</sup> It has been observed that certain spinal implants, while not commanding a high price tag in their 3DP physical form, do necessitate a substantial investment of effort during the preceding stages of their production, specifically in the creation of their CAD files. This shift in cost burden toward design production can be attributed to the requirement of skilled labor during the preliminary phases of the fabrication process for custom 3D devices.<sup>[2]</sup>

The issue of cost represents a prominent and recurrent concern within the realm of 3DP techniques, though not

an exclusive one. The incorporation of novel and expensive techniques into medical practice is a perennial source of apprehension, given the financial implications and resource allocation considerations involved.<sup>[52]</sup>

Acquisition and maintenance of a 3DP facility entail expenses that hospitals, especially those infrequently dealing with complex spinal procedures, find challenging to bear. Such costs encompass the procurement of CAD software, cameras, and 3D printers, along with their upkeep and other incidental expenditures.<sup>[14]</sup>

### Technological limitations

The use of 3DP in spinal surgeries is currently limited by several technical challenges, and significant advancements in this area are yet to be made. One of the primary limitations is the variability between medical imaging and actual surgical anatomy, which 3DP currently needs to address fully.<sup>[4]</sup> Likewise, the presence of intraoperative findings that necessitate a deviation from the initial surgical plan may pose challenges for implantation. Furthermore, the utilization of a modular 3D system may need to be improved in addressing the intricate nature of such procedures.<sup>[59]</sup>

Temporal limitations and inadequate sample sizes also constrain the utilization of 3DP technology in spinal surgeries. Furthermore, the lack of extended clinical monitoring has led to a deficit in our comprehension of the precise scope of this procedure's utility.<sup>[38]</sup>

On occasion, it is not the printing methodology itself but rather the caliber and precision of the three-dimensional image that dictates the accuracy of the resultant object. This impedes the quality of the 3D-printed spinal model, potentially compromising the level of care delivered to the patient.<sup>[31]</sup> The resolution of a 3D-printed object can be influenced not only by the printer's hardware but also by the 3D slicing software utilized during the segmentation process.<sup>[1]</sup>

Moreover, the sterilization process, which ultimately determines the final quality of the product, is contingent on the specific printing materials employed in its construction. The shape and size of the object being printed also play a crucial role, as finishing may be a necessary step in removing any excess or support material encumbering the object.<sup>[35]</sup> This finishing process may involve either manual or chemical techniques, depending on the specific 3D printing method and material employed. As a result, it may not be feasible for all materials to undergo the same finishing process, leading to the limited resolution of the final product in some cases.<sup>[32]</sup>

In certain instances, 3D-printing technology may fall short in providing the required level of intricate anatomical detail for spinal surgeries, encompassing both soft- and hard-tissue aspects.<sup>[59]</sup> The reproduction of bony structures through such

means may result in the omission of critical information pertaining to the affliction of soft tissue or the presence of adjacent nerves and arteries, consequently limiting the potential effectiveness of these printed models in complex spinal procedures.<sup>[31]</sup> In recent times, the implementation of regulatory protocols concerning the development and production of implantable 3D-printed devices has emerged as a formidable obstacle for healthcare institutions.<sup>[35]</sup>

The duration involved in designing, creating, and printing a 3D model has acted as a discouraging factor in the application of this methodology in emergency scenarios and medical centers characterized by high productivity and throughput.<sup>[1]</sup> The mere design of the CAD file alone typically entails a considerable timeframe ranging from 9 to 13 hours.<sup>[32]</sup> The deficiency of earlier iterations of 3D printers to replicate both bone and soft tissue simultaneously through a single material has been a significant impediment to their practical utility. However, this limitation is presently being mitigated through the adoption of multi-material printers, though still limited in availability.<sup>[75]</sup>

### CONCLUSION

While 3D printing has proven to be an innovative and promising technology in the field of spinal surgery, it is not without its drawbacks. The high cost associated with implementation and the significant technical constraints represent significant hurdles to its widespread adoption. However, as research and development continue to progress, the limitations can be mitigated, leading to greater accessibility and efficacy of 3D printing in spinal surgeries.

### Ethical approval

The Institutional Review Board approval is not required.

### Declaration of patient consent

Patient's consent was not required as there are no patients in this study.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

### Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the



writing or editing of the manuscript and no images were manipulated using AI.

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