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3D Printing in Spine Care: A Review of Current Applications

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Running title: 3D Printing in Spine Surgery: A Review

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ABSTRACT

3D printing (3DP) has been brought to medical use since the early part of this century- but it has been widely researched on and publicized only in the last few years. Amongst patients with spinal disorders, 3DP has been utilized in various facets of patient care. These include pre-operative aspects - such as patient education, resident training, pre-operative planning and simulations, intra-operative assistance in the form of customized jigs for pedicle screw insertion, patient specific interbody cages and vertebral body substitutes in complex malignancies and spinal infections. It has also been utilized in deformity surgeries and has opened new avenues in minimally invasive spine care. Guidelines have now been drafted by various organizations including the FDA with a prime focus on quality control measures applicable to this new technology. There has been a recent surge in publications supporting the use of 3DP in spinal disorders, reporting an improvement in various aspects of patient care. As the technology spreads out its wings further, more innovations and applications are expected to unfold in the coming years. Considering the rapid advances that 3DP has made, having a basic understanding of this technology is imperative for all spine surgeons. Despite promising preliminary results, there still exist a few pitfalls of the technology which have hindered the universal application of 3DP. Most importantly, there is a dearth of data related to long term outcomes supporting its clinical use. The prohibitive cost of 3D models, the specialized manpower it necessitates and the need for specific instrumentation are major deterrents to widespread use of this technology, particularly in small-scale healthcare setups. With further advancements in technology, the goal must be to make it more accurate and affordable to hospitals and patients so that the benefits of the technology can reach a wider patient population.
Keywords: Additive Manufacturing, Rapid Prototyping, Spine, Technology, 3D printing, 3D models
INTRODUCTION

Three-dimensional printing (3DP) has been used for the last three decades after it was first developed by Charles Hull. It is also referred to as Stereolithography (SLA), Solid free-form technology (SFF), Rapid prototyping (RP) or additive manufacturing (AM).\textsuperscript{1,2} The foray of 3DP in healthcare and surgery has been more recent – with a surge of interest being noticeable only in the past few years. It is currently considered to be one of the latest and most advanced tools in the armamentarium of orthopaedic surgeons. 3DP has been widely propagated and utilized in various subdisciplines of orthopaedic surgery with the intent of improving the precision and reproducibility of the surgical technique. This has been possible due to parallel advances made both in medical imaging and bioengineering. With newer advances coming to the fore on a day-to-day basis, demand for the technology is only going to rise further.\textsuperscript{3} It has been most widely used in complex regions such as in spine and pelvic surgeries which is evident by the increasing literature available over the last few years.\textsuperscript{4} Éltes et al have shown in a survey of AO Spine members that there is avid interest amongst spine surgeons towards incorporation of 3DP technology in spine care.\textsuperscript{5} Amongst patients with spinal disorders, 3DP has been utilized in various aspects of patient care. These include pre-operative applications such as patient education, pre-operative planning in the form of better assessment of imaging and development of surgical plan. Intra-operative aid is provided by the creation of patient specific jigs and implants. Customized jigs act as guide and help in perfect positioning of pedicle screws and cages especially in patients with complex anatomy as in severe spinal deformities. 3DP has opened new avenues in managing patients with extensive involvement of the spine, as in the cases of malignancies and infections. A large amount of focus has also been given to resident training and hands-on experience which has shown to improve patient care outcomes. Minimally invasive surgeries and drug delivery systems have
also been explored by numerous researchers. Post-operative care in the form of patient specific brace therapy has also been studied.

Despite advances in the field over the past decade, the literature pertaining to 3DP in spine care is mostly based on case reports and case series. 3DP technology is costly, time consuming and needs specialized personnel and equipment. This along with the strict regulations surrounding the technology still limit its use to tertiary centres of care. The purpose of this review is to provide the readers with a brief understanding of the technology and summarize the current evidence supporting various clinical applications in spine care. The limitations of 3DP technology and the challenges for its further expansion have also been discussed.

**Understanding the 3D printing technology**

Various researchers have in detail explained the types of 3D printing available for medical use.\(^{2,4}\) 3 major methods of 3DP for medical applications include-

1. **Fused deposition modelling (FDM)**: deposition of a thermoplastic polymer via an extrusion based technique. This is the most economical method but is not a viable option for intra-operative use as it can be done only by materials with a low melting point, which makes sterilization difficult.\(^{5}\)

2. **Selective laser sintering (SLS) / Electron beam melting (EBM)**: using a laser or electron beam energy source which acts on a powder based material. This powder can include various materials like titanium, nylon, ceramics and stainless steel. This method has high accuracy and can print objects as small as 0.5 ± 0.2 mm. The drawback of this method is need of extensive processing after printing to obtain a smooth surface if laser is used.\(^{4}\)

3. **Stereolithography (SLA)**: based on photocurable liquid resin curing. It involves serial solidification of layers of liquid on top of each other as the 3D model grows to reach its
final form. This produces material with a good finishing, but the resin is relatively expensive.6

In all these processes CT scans or MRI scans are utilized to obtain DICOM images of the proposed site. This is followed by creation of a computer based 3D CAD model (.stl file) of the vertebral column, which can then be utilized to create further models of jigs and implants. (Figure 1). This model is then printed by fusing or depositing materials like metals, plastics, powders, ceramics, liquids or living cells in successive 2D layers.1 The most basic 3D models are directly printed from this CAD file which help understand the anatomy of a complex spinal deformity or to better assess the extent of a malignancy. (Figure 2A)

There has been extensive research to analyze the best materials to be utilized to create these 3D models which best mimic the densities of human vertebrae and thus provide the best tactile feedback. A study by Hao et al showed a combination of 15% gypsum mixed with 100% clear resin and 10% castable resin mixed with 90% clear resin had the best internal structure fit to form a vertebra.7 In a feasibility study by Clifton et al, it was noted that dual material print made of polylactic acid [PLA] and polyvinyl alcohol [PVA] represents the sensation of in vivo instrumentation during pedicle probing, pedicle tapping, and screw placement.8

Intra-operative model preparations which act as a guide to instrumentation have been described for complex cases. These involve creation of a 3D model which templates over the 3D scan of the vertebra, taking cues from specific tactile points. The guides can be placed in a similar orientation intra-operatively and have been shown to have better outcomes as compared to free hand screw placement in cervical, thoracic and lumbar spine. They have also been used in complex cases, such as patients with deformity or as compression screws in spondylolysis.9–14 A more recent development is the shift to utilization of patient specific implants which includes development of interbody fusion cages, 3D printed vertebral body in patients with malignancies
and lately even implantable intervertebral disc.\textsuperscript{15–19} Now focus has also shifted to usage of more biological material coated around the implants which can decrease failures especially in the form of pseudarthrosis and subsidence.\textsuperscript{20} There has also been development of materials with drug eluting properties and nanocomposites which aid in bone regeneration.\textsuperscript{21} With the rise in usage of these devices it is also important to develop and follow guidelines for these materials which are to be used intra-operatively. Guidelines have now been placed by various organizations including the FDA and a prime focus of these is on the quality control measures which need to be borne in mind at each step of the production of 3D implants.\textsuperscript{22}

**APPLICATIONS IN SPINE CARE**

One of the first papers which described the use of 3DP in spine was by D’Urso et al, in which they developed a biomodel which helped plan and understand cases better.\textsuperscript{23} Following this over the next 15 years these biomodels were the only primary use of 3DP in spine care. It was only after 2015 that the true potential of 3DP in spine care came to the fore with development of models for resident and patient education, intra-operative assisting guides and patient specific implants. Currently 3DP has been inculcated in almost all the major pathologies of the spine to a variable extent, which includes spine trauma, degenerative pathologies, malignancies and complex kyphotic and scoliotic deformities. It has also developed a role in minimally invasive spine surgery. 3DP has led to better understanding, enhanced research and management of all spinal pathologies.

**Patient and resident education**

A lot of focus in the recent years has been placed on the provision of hands-on experience to residents and trainees, without using cadavers which are both costly and difficult to obtain. Research has been undertaken to create models which are able to provide tactile feedback along with being stereographically sound. Education right from the undergraduate level has been shown to have improved with the help of 3D models as compared to radiographic images.\textsuperscript{24}
Various reports have shown the corroboration of resident training with their performance on a 3D model which shows the improvements that can be achieved by practicing on these models.\textsuperscript{25} 3D models have been shown to improve surgical training in both minimally invasive procedures such as in degenerative diseases and open posterior procedures.\textsuperscript{25,26} 3D models not only provide improved understanding of the anatomy of the spine but also help understand physiology and pathology better as was shown by Clifton et al in their cervical spine model.\textsuperscript{27} Burkhart et al. in their study have found haptically and biomechanically realistic simulation of posterior spinal procedures with 3D printed models which have outperformed sawbones. These can eventually also be used for preoperative simulations especially in complex cases.\textsuperscript{28}

Patient education leads to better disbursement of information and a more meaningful consent for the procedures due to a better understanding of the pathology and the procedure that is planned. It has also been shown to improve subjective satisfaction of patients in the post-operative period.\textsuperscript{29}

**Pre-operative planning**

In taking cue from the resident training, pre-operative planning in the form of simulations on radiation-free biomodels are being used as a handy tool especially in cases with complex anatomy and in cases where revision procedures are being planned.\textsuperscript{30,31} The models are compatible with X-Ray imaging and thus sizing and geometries of screw placement can be studied easily. We have now shifted to models which include translucent and coloured models that aid in better delineating the extent and margins of diseased tissue such as bone tumours. Models which can be disassembled to simulate surgical resection of the pathology and then subsequently reconstructed are now available. Pre-operative planning with the help of biomodels decreases operative time. They reduce the risk of surgery by reducing the chances of encountering unexpected anatomy or relative positioning of structures and/or devices. Parr
et al have shown that reduction of operative time by 14 minutes can potentially reduce cost to health care providers. These benefits of shorter operative time, reduced blood loss and radiation exposure have been reiterated in a Level I study by Öztürk et al. by their model used in AO type-C thoracolumbar fractures planned for posterior long-segment fixation. In another case report by Liawrungrueang et al, they undertook pre-operative planning with the help of a 3D model in a rare case of bilateral pure facet joint dislocation in thoracolumbar junction (T11–T12) without facet fracture in order to help with emergency early open reduction and instrumentation with fusion.

In some patients Galvez et al noted a change in surgical strategy due to pre-operative planning. This led to a reduction in the number of surgeries as well as the aggressiveness of surgery. Pre-operative analysis of 3D models in deformity surgeries has shown to have improved outcomes with surgeons developing confidence in undertaking higher grade osteotomies keeping safety in check.

**Patient specific instrumentation**

Patient specific instrumentation is being utilized in a range of pathologies of the spine including infection, degenerative diseases, malignancies and deformities. It is also being utilized at all levels from cervical spine to sacrum and helps orthopaedic surgeons combat complex problems by providing tools and implants which fulfil functions that ‘off-the-shelf’ implants would not be able to.

**Interbody cage**

With increasing understanding of biomechanics and bone biology, spinal implants have undergone changes over the last 50 years. Wallace et al and Fogel et al have shown how 3DP has allowed us to develop customized interbody cages with features which include windows for bone growth, surface porosity, endplate matching, body lattice and microporous endplates which allow for integral fixation and decrease stress shielding thus preventing subsidence and
pseudoarthrosis.\textsuperscript{16,17} The benefits of these 3D printed patient specific implants have been further corroborated in prospective and retrospective studies.\textsuperscript{18,19}

**Vertebral body substitutes**

A very large number of case reports and case series are available on custom made implants for stabilization of the anterior column of the spine after resection of a large malignancy or following infectious spondylodiskitis. These studies have shown a novel method which has been developed to combat these pathologies at all levels of the spinal cord, from cervical spine to the sacrum, with otherwise poor prognosis.\textsuperscript{36–39}

**Pedicle screw guides**

Despite being the workhorse of spinal instrumentation in modern times, pedicle screws have been known to be associated with complications resulting from screw malpositioning and pedicle perforation. Instrumentation of paediatric cervical and thoracic spine, cannulation of sclerotic or dysmorphic pedicles and neurofibromatosis with associated spinal deformity are examples of situations where higher rates of pedicle screw malpositioning may be expected. To ease out the process of screw application 3D printed patient specific guides have been created which help in drilling the best path. (Figure 2B, 3 and 4) In a study by Li et al, they found 3D printed navigation template provided a safer, more efficacious and accurate screw placement when compared to free hand surgery in odontoid fractures.\textsuperscript{12} A Level 1 systematic review of 13 studies which included 330 patients showed that the 3D-printed navigation template improves accuracy of pedicle screw placement in cervical spine surgeries and consequently improve outcomes.\textsuperscript{40} Recently in addition to 3D printed patient specific drill guides there has also been a development of screw guides in the form of modular devices or cannulated screws. Pijpker et al conducted a cadaveric study to compare these two techniques. They found that the accuracy of the 3D printed guides for drilling by themselves is very high.
and that there is thus no need of using cannulated screws or modular guides for the technically demanding extra pedicular screw technique as well as for intrapedicular screw insertion.\textsuperscript{41} Mobbs et al have shown that drill guides can also be used in narrow corridors for placement of compression screws across a pars defect in patients with spondylolysis.\textsuperscript{10}

**Deformity correction**

Adolescent idiopathic scoliosis is associated with various physical and mental health issues. Its management involves bracing in lesser degrees of curve and operative intervention for larger curves. Custom bracing using 3DP has been in use since 2015, though results are sketchy. Newer modifications in this field include patient specific custom braces which are also capable of detecting the pressures it applies on the human body, allowing fine-tuning of the brace and making the process of treatment more comfortable without compromising on the effectiveness of the brace. Also, now braces are available with a mesh like material, which make them more breathable and increases patient comfort. In a recent prospective RCT done by Lin et al it was noted that 3D printed patient specific orthoses lead to better outcomes with regards to mental health and self-health while showing similar decrease in curve progression.\textsuperscript{42} Pedicle screw guides have also been widely utilized in complex areas of spine deformity. Various studies have shown that use of intra-operative guides leads to decreased operative time and blood loss, along with placement of screws in the safe zone especially in the apex of a deformity avoiding any unforeseen complications. 3D printed guides also provide a cheaper alternative to those setups where access to high end technology like image-guided navigation and intra-operative CT scans is lacking.\textsuperscript{9,43,44}

**Minimally invasive surgeries**

Minimally invasive surgery is one of the latest aspects of spine surgery wherein 3DP has developed its role. Thayaparan et al have created a patient specific kit for undertaking a
minimally invasive transforaminal lumbar interbody fusion (MI-TLIF). They have shown that the placement accuracy was 97.8% on postoperative CT scans, with minimal complications in the 639 pedicle screws that they placed using 3D printed jigs.\textsuperscript{45} Ling et al have also utilized 3D printed implants to undertake a multilevel oblique lumbar interbody fusion procedure (OLIF) with good outcomes.\textsuperscript{46} Yang et al have utilized 3D printed endoscopic discectomy procedures, wherein using patient specific implants helped gain wider access without destruction of excess bone due to availability of an added portal.\textsuperscript{47}

Thus, patient specific instrumentation leads to an efficient surgical workflow which is because of the faster implant fit with minimal risk of complications.

**Newer applications**

In a field fuelled by growth in technology, there is no dearth of constant innovations. As 3DP has become more accessible it has taken centre stage in various research related activities. It has helped understand the biomechanics of forces acting on the spine. Karimi et al have shown that a combination of vertical and horizontal forces in a patient with scoliotic deformity provides better correction than vertical forces alone.\textsuperscript{48} 3DP is not only aiding in understanding these biomechanical forces but is also providing tools to conduct such studies. This was shown by Cornaz et al who have developed 3D printed clamps to aid in biomechanical analysis of the vertebrae.\textsuperscript{49} Various innovations aiding in ease of surgery are also being developed with the help of 3DP. Kolb et al have developed one such innovation for prone positioning of frail patients with advanced spinal deformity which matches patients curve contours thus decreasing forces acting on the skin.\textsuperscript{50} Another novel tool which leads to ease of TLIF is the low-cost 3D printed retractor developed by Ramirez and his associates. The retractor provided adequate visualization of the junction between the transverse process and superior articular process. It
anchors to the transverse process through a concave notch at its tip and its gutter shape helps stay within the ideal trajectory during screw insertion.\textsuperscript{51}

**DRAWBACKS**

Despite promising preliminary results there still exist a few pitfalls with regards to 3DP technology which have hindered its universal application. Most importantly there is a dearth of data related to long term outcomes largely due to the applications of the technology in spine care being relatively recent. Other major concerns which are inhibiting the widespread use of technology include:

*Time:* At least 24 hours are needed to plan, develop the CAD model and print the 3D models and instrumentation. This hinders its use in emergency and trauma settings. With newer advances this time duration should only decrease which will make its use more feasible. Often 3D printers lead to creation of a rough surface which may need more time for post-processing.\textsuperscript{6}

*Cost:* The costs incurred to create a single model are significant even for a tertiary care hospital setting. This is currently the single most important concern with regards to widespread use of the technology. Software costs, material costs, cost of a 3D printer and cost needed to support trained personnel together make 3DP a costly proposition for most healthcare facilities. Advances in bioengineering with increasing utilization of 3DP are together bringing down the cost incurred for setting up a 3DP machinery. A careful discussion prior to use with the hospital, patient, and insurance company regarding the financial burden of using customized implants is critical. Pijpker et al have noted that with the current status of 3DP using custom implants for isolated cases may not be feasible.\textsuperscript{11}

*Machinery:* 3DP needs a large setup. From advanced imaging tools to software for creation of computerized models and eventually 3D printers which in all can need investment in the range of tens of thousands of dollars.\textsuperscript{6}
Training: Specialized trained personnel are needed to help create 3D printed models. Collaboration between surgeons and engineers to help understand the exact nature of the model is a must. Thickness of 2D scan slices, threshold values for segmentation and method of printing all need prior training. Adequate material of use needs prior biomechanical analysis and there is often a chance of contamination especially if the model is planned for implantation.6

Government approvals: Currently, guidelines for use of 3DP technology only exist in USA, EU and China. In USA approval is given on a case-to-case basis by FDA which makes the whole process prone to legal issues. China has issued guidelines for the regulation and registration of 3DP medical devices. They have incorporated technical guidance for 3D printed artificial vertebrae and an acetabular cup. In India this is a lack of clarity on the applicability of legislations to 3D printed devices. This prevents standardization of 3D printed materials which can lead to complications if not addressed promptly.

Errors in any step of the process can result in a defective product. For technology in a nascent phase, errors are inevitable in the 3DP design and production process, such as possible errors in the 3D model reconstruction. Errors caused by the low accuracy of the printer can affect the accuracy of the model. In its current state there is the potential need to create multiple implants for a single case to impart a degree of modularity to the custom devices. These intraoperative alternatives will help the surgeon achieve the intended goals, which would not be possible by a single implant. As the technology grows, intermediate and long-term patient outcomes and studies comparing outcomes in patients receiving customized versus generic implants will be helpful in determining the limitations and broader application of this relatively new technology.

CONCLUSION
3DP technology has garnered a lot of interest from spine surgeons around the world. Even though the technology is in its primitive years of development, it has been utilized in almost all aspects of spine care. Patient counselling, resident education and pre-operative planning form the crux of spreading knowledge about our field. Customized implants provide ease of surgical workflow, decrease operative time, reduce blood loss and avoid unforeseen complications. Based on data from the short-term results, 3DP has shown to produce benefits in selected situations. With further advancements in technology the goal must be to make it more accurate and affordable to hospitals and patients so that efficient health care can be imparted at a reasonable cost.

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REFERENCES


FIGURE LEGENDS

Figure 1

1A) Pre-operative creation of a 3D CAD model of the spine of a scoliosis patient

1B) Creation of best pathway for pedicle screw placement in the software which helps in development of drill guide.

Figure 2

2A) 3D printed individual vertebrae of various thoracic levels along with drill guides

2B) 3D printed drill guide being assessed ex-vivo prior to surgery

Figure 3) Intraoperative photograph of 3D printed drill guide in use

Figure 4) Workflow diagram as a guide for creating drill guides
DICOM images from a CT scan uploaded onto CAD software (MIMICS, Materialize Inc, Belgium)

Creation of a 3D model of individual vertebra in MIMICS

Determining best entry point, screw trajectory and screw length in the software

Creation of a drill guide (jig) by reverse-engineering in 3-Matic (Materialise Inc, Belgium)

3D printing of the drill guide via 3D printer

Ex-vivo assessment of the template jig on the printed vertebra model

Sterilization of jig for intra-operative use