Review Article

Systematic review of 3D printing in spinal surgery: the current state of play

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Abstract: Three-dimensional printing (3DP), also known as "Additive Manufacturing", is a rapidly growing industry, particularly in the area of spinal surgery. Given the complex anatomy of the spine and delicate nature of surrounding structures, 3DP has the potential to aid surgical planning and procedural accuracy. We perform a systematic review of current literature on the applications of 3DP in spinal surgery. Six electronic databases were searched for original published studies reporting cases or outcomes for 3DP surgical models, guides or implants for spinal surgery. The findings of these studies were synthesized and summarized. These searches returned a combined 2,411 articles. Of these, 54 were included in this review. 3DP is currently used for surgical planning, intra-operative surgical guides, customised prostheses as well as "Off-the-Shelf" implants. The technology has the potential for enhanced implant properties, as well as decreased surgical time and better patient outcomes. The majority of the data thus far is from low-quality studies with inherent biases linked with the excitement of a new field. As the body of literature continues to expand, larger scale studies to evaluate advantages and disadvantages, and longer-term follow up will enhance our knowledge of the effect 3DP has in spinal surgery. In addition, issues such as financial impact, time to design and print, materials selection and bio-printing will evolve as this rapidly expanding field matures.

Keywords: Three-dimensional printing; 3D; patient-specific implant; spinal surgery; spine; lumbar; off-the-shelf; additive manufacturing

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Introduction

Three-dimensional printing (3DP) is a rapidly growing industry. A variety of techniques can be used to print physical models from three-dimensional renderings based on CAD software, and STL design files. Whilst the use of this technology in medicine is still in its infancy, 3DP offers the possibility of revolutionising healthcare with its ability to rapidly create customized shapes from a wide range of materials (1-6).

One sector of medicine where 3DP offers great potential benefits is in neurosurgery, and in particular spinal surgery. Due to the complex anatomy of the spine, as well as the delicate nature of the surrounding structures, any technique that may aid surgical planning and procedural accuracy offers the ability to improve patient outcomes (5). This systematic review will cover the current applications of 3DP in spinal surgery, including its role in surgical planning, surgical guides, customised implants and "Off-the-Shelf" implants. It will conclude with a brief overview of future directions of 3DP in this field.

Methods

Purpose

The objective of this review is to summarize the literature regarding the use of 3D printing technologies for the planning or production of patient-specific implants (PSIs) for spinal surgery. A comprehensive search of the Medline and EMBASE databases was conducted in line with the PRISMA guidelines (7-9) (Supplementary).

Search strategy

A comprehensive search of published reports was performed via six electronic databases; namely, Ovid Medline, PubMed, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, American College of Physicians Journal Club and Database of Abstracts of Review of Effectiveness from their date of inception to March 2017. To maximise the sensitivity of the search strategy, the terms; “three-dimensional”, “3D”, “patient-specific”, “spinal surgery”, “fusion”, were combined as either key words or MeSH terms. The reference lists of all retrieved articles were reviewed to identify additional potentially relevant studies.

The population to be studied included any patient presenting for spinal surgery. Exclusion criteria included a non-surgical focus, non-spinal focus, animal studies and 3D imaging focus. No limits were set on time or level of evidence, as 3DP in spinal surgery is recent and evidence is mainly limited to low-power studies.

Results

These searches returned a combined 2,411 articles, of which 453 duplicates were removed, before the remaining 1,958 articles were screened by title and abstract for relevancy, leaving 75 articles for full text review. Of these, 54 were included in this review. A flow-chart of this process is shown in *Figure 1* (9).

A summary of 3DP of pre-operative models is given in *Table 1*. A summary of 3DP surgical guides is given in *Table 2*. *Table 3* summarizes the current literature on the use of customised 3DP implants for spine surgical procedures.

Discussion

Surgical planning

3DP is most frequently utilised in spinal surgery in the pre-operative planning stage. A full-scale, stereoscopic understanding of the pathology allows for more detailed planning and simulation of the procedure (10-18,20-30,50-52). Assessing complex pathologies on a model overcomes many of the issues associated with traditional 3D imaging, such as the lack of realistic anatomical representation and the associated complexity of computer-related skills and techniques (10,12). Sugimoto *et al.* (25) reported that the usefulness of 3DP increases with the complexity of the pathology, with the surgeon’s ability to manoeuvre a model being useful to appreciate patient’s anatomy without having to mentally reconstruct multiple 2D images (*Table 1*).

The improved visualization and preparation afforded by the use of individualized models has clinical benefits, with reduced operation time and perioperative blood loss being most commonly reported (11,13,14,21-23,26-28,30). Reduction in operation time of 15–20% has been reported in multiple studies (11,14,23) across various surgical procedures. The main reasons given for reduced operation time included a more evolved understanding of the pathology, such as location and surgical approach, and the facilitation of pre-operative instrumentation decisions (14,16,18-21,24,27,28,50). Other clinical benefits such as improved diagnosis, reduction in fluoroscopy time, better communication within the surgical team and lower rates of screw misplacement have been reported when compared with the use of conventional imaging in pre-operative planning (11,14,20,26,30). Izatt *et al.* (14) found that the use of a 3DP biomodel improved surgical outcomes in 78% of cases, though this is contradicted by Li *et al.* (23) who reported no change in complication rates or clinical outcomes. As many of the studies performed are small scale with no controls, it is likely there is not enough evidence to properly elicit benefits of 3DP models in surgical preparation on these parameters. Larger scale studies with the power to detect differences more accurately are required.

Some barriers exist for the translation of 3DP models for surgical planning in small scale studies to general clinical practice. In the studies reviewed, time taken to create the models ranged from 5 hours to 2 days, with extra costs anywhere between $300 and >$1,000 (10,11,13,18,20,22,26,27). Izatt *et al.* (14) stated that these additional costs were offset in 59% of cases by the more

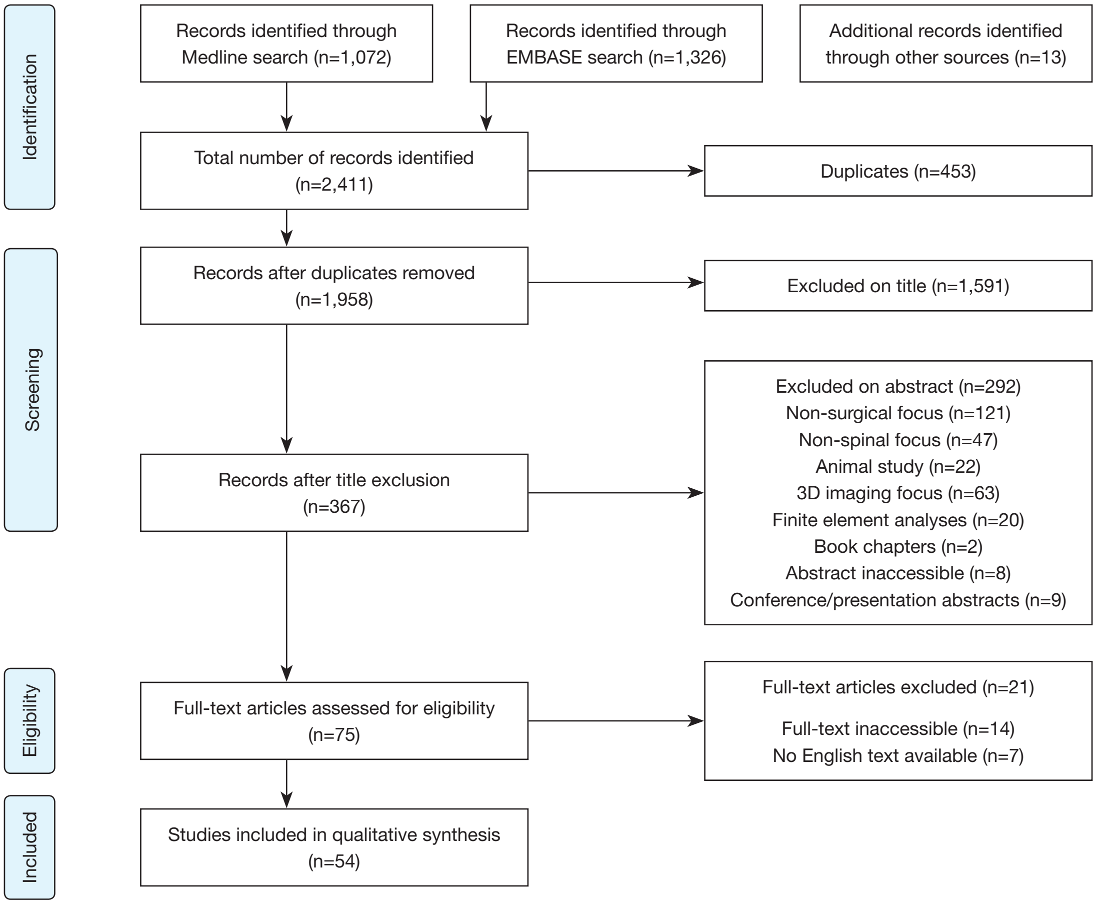

Figure 1 Flow chart of literature search performed using PRISMA methodology (9).

efficient operative technique and planning afforded by the models, as well as fewer intra-operative complications and greater accuracy associated with their use. This was supported by Wang *et al.* (28), who found that the decreased need for intra-operative navigation made the procedure more economical. However, time and cost are still likely to limit the use of this technology in the immediate future. Other limitations include a lack of surgically useful information, such as joint instability, and an absence of real-time information like those provided by imaging (18). Guarino *et al.* (13) also found that access issues were not only due to cost, but also a paucity of providers with the equipment and expertise to make the widespread use of this technology commercially viable. The learning curve for the required familiarity with the software has also been reported as a barrier (23,30). As time taken to create the models and the associated costs continue to decline, there should be an increase in the use of this technology in clinical practice.

Another well reported benefit of 3DP models is improved patient education (11,13,17,19,53). A physical model is much easier for a patient to understand than complex MRI and CT scans. D'Urso *et al.* (11) reported a statistically significant improvement in informed consent from the patient's perspective, confirmed by 25% higher patient informed consent scores using a biomodel demonstration when compared to pre-operative image demonstration. In one study (17), anxiety-related pain was found only to be relieved after a patient understood her condition with the aid of a biomodel, suggesting using models in patient education may improve clinical outcomes.

Surgical guides

Spinal surgery is inherently dangerous due to the delicate nature of the surrounding anatomy. Intra-operative guides, created with patient-specific data, may have the ability to

Table 1 Summary of 3DP in spinal surgery planning

Year	Author	Pathology	Material	3DP technology	Cost	Time
1999	D'Urso *et al.* (10)	Osteogenesis imperfecta, cervicothoracic deformity, lumbar spinal fusion, cervical osteoblastoma	Polymer	Stereolithography	$1,000 US	2 days
1999	D'Urso *et al.* (11)	Craniofacial, maxillofacial and skull base cervical spine pathologies	Polymer	Stereolithography	–	–
2005	D'Urso *et al.* (12)	Complex spinal disorders	Acrylate	Stereolithography	–	–
2007	Guarino *et al.* (13)	Multiplane spinal and pelvic deformities	Polymer	Stereolithography, fused deposition modelling	$600–$2,500	–
2007	Izatt *et al.* (14)	Deformities, spinal tumours	Polymer	Stereolithography	$900–$1,500	12–16 hrs
2007	Paiva *et al.* (15)	Cervical Ewing Sarcoma	Polymer	Stereolithography	–	–
2008	Mizutani *et al.* (16)	Rheumatoid cervical spine	Polyurethane, plaster	Stereolithography	–	–
2009	Madrazo *et al.* (17)	Degenerative cervical disease, instrumental failure	Polymer	Stereolithography	–	–
2010	Mao *et al.* (18)	Kyphoscoliosis, congenital malformations, neuromuscular disease	Polystyrene	Selective laser sintering (SLS)	2,000 RMB	5–16 hrs
2010	Yang *et al.* (19)	Kyphoscoliosis	Polymer	SLS	–	–
2011	Wu *et al.* (20)	Severe congenital scoliosis	–	Fused deposition modelling	$300	–
2013	Toyoda *et al.* (21)	Atlantoaxial subluxation	–	–	–	–
2014	Yang *et al.* (22)	Atlantoaxial instability	Polymer	SLS	$330 US	–
2015	Li *et al.* (23)	Revision lumbar discectomy	Polystyrene	SLS	–	–
2015	Kim *et al.* (24)	Thoracic tumours	Polylactic acid	Stereolithography	–	–
2015	Sugimoto *et al.* (25)	Congenital kyphosis	–	Rapid prototyping	–	–
2015	Yang *et al.* (26)	Adolescent idiopathic scoliosis	Polystyrene	SLS	–	–
2016	Goel *et al.* (27)	Craniovertebral junction anomalies	–	Colourjet printing	$350 US	5 hrs
2016	Wang *et al.* (28)	Congenital scoliosis, atlas neoplasm, atlantoaxial dislocation	Polymer	Stereolithography	2,000–3,000 RMB	9–27 hrs
2016	Xiao *et al.* (29)	Cervical bone tumours	Polylactic acid	–	–	–
2017	Guo *et al.* (30)	Cervical spine diseases	Polylactic acid	Stereolithography	–	–

Table 2 Summary of 3DP used in spinal surgical guides

Year	Author	Location	Material	Technique	Cost	Manufacture time	Patients/ specimens	Total no. of pedicle screws	Accuracy–Experimental	Accuracy–Control
2007	Owen *et al.* (31)	Cervical	Acrylonitrile butadiene styrene	Fused deposition modelling	\$30–\$50	–	1	2	100%	–
2009	Lu *et al.* (32)	Lumbar	Acrylate resin	Stereolithography	\$20	16 hours	12	58	100%	–
2009	Lu *et al.* (33)	Cervical	Acrylate resin	Stereolithography	\$20	16 hours	9	19	100%	–
2011	Lu *et al.* (34)	Cervical	Acrylate resin	Stereolithography	\$20	1 day	6	84	97.6%	–
2015	Chen *et al.* (35)	Lumbar	Polyamide	SLS	–	–	43	240	100%	98.4%
2016	Chen *et al.* (36)	Thoracic	Photo-sensitive resin	Stereolithography	–	–	3	50	100%	–
2016	Deng *et al.* (37)	Cervical	Photo-sensitive resin	Stereolithography	–	–	10	48	97.9%	–
2016	Huang *et al.* (38)	Cervical	–	Rapid prototyping	–	–	1	2	100%	–
2016	Liu *et al.* (39)	Thoracic	Photo-sensitive resin	Stereolithography	\$290	1–2 days	10	152	93.8%	78.8% (freehand)
2016	Lu *et al.* (40)	Cervical	–	–	\$20–\$400	1–7 days	–	–	–	–
2016	Otsuki *et al.* (41)	Cervical Lumbar	Titanium	Selective laser-melting (SLM)	–	–	3	5	100%	–
2016	Takemoto *et al.* (42)	Thoracic	Titanium	SLM	\$100	1 day	40	466	98.7%	–
2017	Guo *et al.* (30)	Cervical	Polylactic acid	Stereolithography	–	–	13	74	94.6%	70.27% (fluoroscopy)
2017	Sugawara *et al.* (43)	Cervical	Acrylate	Polyjet printing	\$100	4–6 days	12	48	100%	–

SLS, selective laser sintering.

Table 3 Summary of customised 3DP implants

Year	Author	Pathology	Material	3DP implant	Outcomes
2016	Phan *et al.* (44)	Facet joint arthropathy	Titanium	C1/2 posterior fixation device	Nil complications; pain reduction; satisfactory imaging 6 m post-op
2016	Wei *et al.* (45)	Sacral chordoma	Titanium	Sacrum replacement prosthesis	Asymptomatic instrumental failure at 8 m; in-growth at bone-prosthesis interface
2016	Xu *et al.* (46)	C2 Ewing sarcoma	Titanium	Axial vertebral body device	Nil complications; no evidence of tumour and satisfactory imaging at 12 m
2017	Kim *et al.* (47)	Sacral osteosarcoma	Titanium	Hemisacrum	Nil complications. Improved symptoms and satisfactory imaging at 12 m
2017	Mobbs *et al.* (48)	C1/2 chordoma & congenital L5 hemivertebra	Titanium	Occipito-cervical fixation device and hemivertebra prosthesis	Case 1 had complications associated with prolonged operation time; satisfactory imaging at 9 and 12 m respectively
2017	Choy *et al.* (49)	T9 primary bone tumour	Titanium	Axial vertebral body device with inbuilt fixation holes	Nil complications; no evidence of tumour and satisfactory imaging at 6 m

mitigate the risks associated with these procedures (4,54).

Pedicle screws are a fixation technique routinely used in spinal surgery, as they are the most effective way to stabilize vertebrae (4,37,43) and lower the risk of complications if inserted accurately (31). However, traditional techniques are associated with many problems and carry a high risk of breaching the pedicle, with the possibility of causing potentially fatal neurovascular injury (32). Thus, manual insertion based on surface anatomical landmarks, which is heavily dependent on the experience of the surgeon, is potentially undesirable. Computer assisted surgery can be used to monitor the placement of screws and increase the safety of these procedures. However this system is very expensive, complex to operate, cumbersome, has a long learning curve, often requires additional personnel and is associated with prolonged intra-operative time due to bone registration requirements (32,35,39). There are also issues with intra-operative changes in position, decreasing the accuracy of this technique (32). The use of intra-operative imaging increases harmful radiation exposure for both doctors and patients (30,34-36). 3DP guides may offer an alternative as a simple, convenient, low cost and complex-equipment free way to improve the accuracy of pedicle screw placement (30-37,39-43).

To create 3DP screw guides, a 3D CT scan must be taken of the target vertebrae. Next, a 3D model is generated by specialist software from which the optimal screw trajectory and size can be determined, often in consultation with the surgeon. Finally, a navigational template is designed and built with optimal screw trajectory, the surface of which is the inverse of the posterior vertebral surface to ensure a good fit and accuracy of screw insertion (30-43,55). Numerous studies demonstrated that the guides help to lower operation time, with Deng *et al.* (37) suggesting this may decrease complications related to operative time (e.g., infection) (30,35,37,43). Other benefits include decreased intra-operative radiation, simplicity of use, elimination of procedural subjectivity, enhanced pre-operative planning and moderate cost in comparison with other techniques (30,32-38,42,43).

It has been suggested that these guides may be particularly useful with more complex anatomy. In the cervical spine, asymmetry, vast inter-patient differences such as anomalous vertebral artery course, and the sensitive nature of surrounding tissues make procedural success more difficult to achieve, and hence able to benefit from individualised guides (30,31,33,34,37,38,40,43,56). Otsuki *et al.* (41) demonstrated that 3DP guides provide an extra benefit in revision surgery, where screw insertion is more difficult due to morphology changes caused by the first operation.

The most commonly reported issue with the use of these templates is the necessity for clean bone preparation. Soft tissue must be completely removed for the template to fix into the correct spot, which may increase operation time and intra-operative blood loss (34,37,40,43). Depending on the material of the template, debris may be produced intra-operatively. Takemoto *et al.* (42) utilised titanium templates with reduced contact area to minimise these problems, though the resulting templates were 5× the price of polymer based guides. Whilst cost is generally favourable in comparison to other techniques, the time taken to design and manufacture the guides was viewed as a negative. This limits the usefulness of this technology, for example it is not feasible in an emergency (30,37,40,42). Other concerns include deformation during the production, sterilisation or surgical procedure (37) as well as the long learning curve for software operation (30,40).

Whilst the use of 3DP surgical guides in spinal surgery is mainly limited to fixation screw placement, several other procedures have been found to benefit from the technology. Rong *et al.* (57) utilised 3DP to create guides for expansive open-door laminoplasty in cervical myelopathy. Trough preparation requires experience, and the authors reported positive results with high correlation of trough position to the ideal placement planned. Anchoring the drill template served to minimise any intra-operative movement, whilst depth control measures on the templates helped prevent iatrogenic injury to the spinal cord or nerve roots. Lin *et al.* (58) also prevented iatrogenic complications with a customized osteotomy tool guiding resection of a giant sacral schwannoma. As these tumours are clinically difficult to remove due to the extent of local invasion and the complexity of surrounding anatomy, complete removal without neurovascular complications or spinal instability is ideal, although difficult. In this case, more accurate intra-operative localization of the resection margin allowed total resection, with no complications at 2-year follow-up.

Customised implants

One of the most exciting applications of 3DP in spinal surgery is the ability to manufacture customised, patient-specific implants. Patients being subjected to complex surgery with difficult anatomy and deformity, have an increased risk of implant failure, especially if the “off-the-shelf” reconstructive option does not fit accurately into the reconstructive defect. Despite being a novel field of study, it is hoped that PSIs will prove to have better durability due to a more even load distribution and superior osseointegration. Currently, literature on PSIs in spinal surgery is limited to a select few case reports and case series, though this is predicted to expand rapidly over the next few years.

The cases performed thus far are limited to anatomically challenging, rare pathologies where an individualized solution to restore patient-specific anatomy is a key prognostic factor (44,46-48,59,60). These range from customised fixation in the upper cervical and lower lumbar spine (44,48,59) to insertion of a 3DP vertebra (46) and sacral reconstructions (45,47). A summary of PSIs used in spinal surgery in the literature is shown in *Table 3*. The lack of specialised implants for reconstruction after tumour resection is evidenced by the majority of cases being oncological in nature (45-48). The remaining cases utilised 3DP PSIs due to unique anatomy associated with degenerative change and a congenital anomaly (44,48). All customised prostheses were made from titanium alloy (TiV6Al4) due to its biocompatibility and ability to enhance bone healing by porosity optimisation to match trabecular bone structure.

All the implants were reported to fit well, indicating the accuracy of the 3DP process. This increases the stability of the implant whilst minimising complications such as stress shielding and subsidence (45-47). Xu *et al.* (46) created a prosthesis with zero profile anteriorly for this purpose, minimising the risk of dysphagia in their patient. This case also noted the minimisation of other morbidities, such as pain and limited function, associated with bone grafts. Another benefit of customised implants is a reduction in operation time (44,46-48), with Mobbs *et al.* (48) noting the ability to avoid bone harvesting with intra-operative fashioning to fit complex defects. Wei *et al.* (45) produced three different sized prostheses to fit the intra-operative bone defect. Kim *et al.* (47) described a process of multiple pre-operative modifications made to the implant to ensure anatomical accuracy. Both these measures shifted the time from intra-operative to the pre-operative planning phase, a positive for minimising complications such as infections. The sacrum produced by Wei *et al.* (45) had pre-designed holes and screw heads to simplify the reconstructive method. The PSI employed by Phan *et al.* (44) was found to reduce the risk of neurovascular complications due to screw holes with pre-calculated angulation and depth in-built.

Negatives are similar to those for other 3DP applications in spinal surgery, with extra time and cost required to design these highly specialised PSIs (44). The sophisticated software and machinery necessary for creation of the implants is also a barrier (48). Wei *et al.* (45) reported an instrumental failure, indicating more direct comparison with standard of care implants is required to demonstrate the efficacy of these prostheses. Comparative studies would also serve to remove the inherent subjectivity of case reports on a new technology, where results are often positively skewed (5). There is also a lack of long-term data on the performance of these prostheses (44). It should be noted that no regulatory framework exists for the use of PSIs in spinal surgery. A system for registration and approval for the production and implantation of these devices will be necessary in the future. Despite these factors, due to the positive patient outcomes and lack of serious complications shown thus far, it would appear that these techniques offer a viable future direction for spinal prostheses, particularly in complex cases.

3D printing of "Off-the Shelf" implants

Whilst customisation to patient-specific data is one of the biggest drawcards of 3DP, the technique itself offers advantages compared to traditional manufacturing processes. Spinal prosthetic manufacturers, such as Stryker and 4Web Medical, are beginning to utilise the technology to optimise the properties of devices to be implanted (61-64). 3DP allows the manufacturing of previously un-manufacturable geometries (61), including the ability to mimic the interconnected structure of cancellous bone. Through control of the porosity and surface roughness of implants, osseointegration can be optimized. When combined with an open architecture to allow maximum bone graft volume, implants can be created that make full use of the capabilities of 3DP, without all the planning associated with customisation. By offering a range of sizes of implants, including parameters such as widths, heights, lengths and angles, spinal instrumentation can be utilised in patients whilst minimising complications such as implant migration and stress-shielding (62-64). The use of 3DP in this setting is cost-effective and can produce the quantity of implants necessary to be competitive in the market place. In the future, it is predicted that more innovative features may be able to be incorporated, such as porous matrices where density, pore diameter and mechanical properties can differ in different regions of the implant (61).

Future directions

As 3DP technology continues to become cheaper, faster and more accurate, its use in the setting of spinal surgery is likely to become routine, and in a greater number of procedures (1-4,6,42,44,65). Lower cost desktop 3D printers for everyday use could soon be a reality, aiding real-time model and implant creation for more personalised surgical care (46,48). A greater range of materials is also expected to open new avenues, with improved biocompatibility, osseointegration, biodegradability and load-bearing properties just some of the expected benefits (3,4,48,65). However, the greatest step forward is anticipated to be bioprinting, where cells, growth factors and biomaterial are used to create living tissue. This could conceivably be used for direct tissue repair, and even the printing of complex organs in the foreseeable future (6).

Conclusions

3DP is rapidly becoming intimately integrated in both spinal surgical practice and the literature. It is currently used for surgical planning, intra-operative surgical guides, customised prostheses as well as "Off-the-Shelf" implants. The technology allows for enhanced implant properties, as well as decreased surgical time and improved patient outcomes. However, much of the data thus far is from low-quality studies with inherent biases linked with the excitement of a new field. As the body of literature continues to grow, larger scale studies and longer-term follow ups will enhance our knowledge of the effect 3DP has in spinal surgery.

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Footnote

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Supplementary

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Population	Intervention
((spin* or vertebr*) adj1 (surg* or operat* or procedure)).tw. (laminotom* or foraminectom* or disc replace* or fusion or spin* instrumentation).tw. exp foraminotomy/ or exp laminectomy/ or exp laminoplasty/ or exp spinal fusion/ or exp diskectomy/ exp spine/ or exp cervical vertebrae/ or exp thoracic vertebrae/ or exp lumbar vertebrae/ or exp sacrum/ OR/1-4	((3D* or three*dimension* or 3* dimension*) adj1 (print* or model* or reprod* or manufactur* or templat* or mould or prototyp* or framework or represent*)).tw. (additive* manufactur* or stereolithograph* or biomodel*).tw. (computer* aided manufacturing or CAM or computer* aided engineer* or CAE or computer* aided design or computer-assisted design or CAD).tw. (patient* adj1 (specific or adapt* or customi* or personali* or individuali*)).tw. (implant* or prosthe* or insert* or model* or guid*).tw. 9 adj1 10 (surg* adj1 (guid* or templ* or model*)).tw 6 OR 7 OR 8 OR 11 OR 12
5 AND 13 (1072 results)	

(Medline search as of 9/3/17)

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Population	Intervention
exp spine surgery/ exp disc prosthesis/ or exp spine fusion implant/ or exp intervertebral body fusion device/ or exp spine implant/ or exp spine non fusion implant/ or exp spine plate/ or exp spine fixation device/ exp spine/ exp spine disease/ OR/1-4	exp computer aided design/ ((3D* or three*dimension* or 3* dimension*) adj1 (print* or model* or reprod* or manufactur* or templat* or mould or prototyp* or framework or represent*)).tw. (additive* manufactur* or stereolithograph* or biomodel*).tw. (computer* aided manufacturing or CAM or computer* aided engineer* or CAE or computer* aided design or computer-assisted design or CAD).tw. (patient* adj1 (specific or adapt* or customi* or personali* or individuali*)).tw. (implant* or prosthe* or insert* or model* or guid*).tw. 10 adj1 11 (surg* adj1 (guid* or templ* or model*)).tw 6 OR 7 OR 8 OR 9 OR 12 OR 13
5 AND 14 (1326 results)	

(EMBASE search as of 9/3/17)