3D Printing in Orthopaedic Preoperative Planning Improves Intraoperative Metrics: A Systematic Review

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Abstract

Purpose of study: 3D printing has seen increasing interest in Surgery, where it improves visualisation of difficult anatomy in complex cases. This literature review investigates the benefits and limitations of 3D printed models in preoperative planning in the field of Orthopaedic Surgery.

Methods: A literature search was performed using the Ovid platform on the EMBASE and MEDLINE databases using the terms: “3D printing”, “Orthopaedics” and “Surgical Planning”.

Studies using 3D printed models as a part of preoperative planning were included. All others were excluded. Data regarding the metrics used to assess the benefit of the use of 3D models, surgical outcome, and surgeon or patient opinion on the technology were extracted.

Results: 41 studies resulted. Eight (19.5%) were case control studies, the remainder were case reports or case series. Assessment of benefit was mostly subjective, although the case control studies included objective metrics such as operation time, intraoperative blood loss and intraoperative fluoroscopy time. The use of 3D printing technology showed subjective benefit for both patient and surgeon as well as indicating clinically significant improvements in intraoperative metrics.

Conclusion: Despite the current absence of large scale trials, 3D printing has clear benefits in preoperative planning, particularly when utilised in complex cases. A streamlined workflow for case selection, in-house model creation and pre-operative rehearsals is still required to be developed before the process is ready for routine use. Evidence supports an improvement in intraoperative metrics and patient engagement but data to support improved clinical outcome is lacking.

Keywords: three-dimensional printing, orthopedics, orthopedic procedures, computer aided design, stereolithography

Introduction:

The introduction of three-dimensional (3D) modelling and printing to medicine has seen a proliferation of new and exciting uses. Surgical applications have seen the most growth, ranging from education of patients and trainee surgeons to custom implantable devices⁽¹⁾.

Of the specialties adopting this technology, Orthopaedics and Maxillofacial Surgery have made the greatest strides into researching its utility⁽²⁾. The accessibility of open source segmentation software as well as the simplicity with which bone can be separated from its surrounding tissues due to disparate Hounsfield Units has facilitated the application of 3D printing within these specialties.

Various modes of 3D printing technology have seen use in the surgical field. Printing technologies such as Fused Deposition Modelling (FDM), Stereolithography (SLA) and Selective Laser Sintering (SLS) are well described⁽³⁾ with the chosen technology based on considerations such as: cost of the printer, cost of printing material, printing time, print resolution and the option of sterilisation for inclusion into the surgical field⁽²⁾.

Current preoperative planning in Orthopaedic Surgery relies on the use of plain radiographs or CT images to convey topographic information of the pathology to the surgeon⁽⁴⁾. The value of this relies heavily on surgeon expertise, especially in more complex cases such as complex fractures where there is significant bone loss or distortion of normal anatomy, and spinal cases⁽⁵⁾. Novel methods have been investigated with the aim of improving this process. Surgical planning using 3D printed models has been an early application of the technology⁽¹⁾. Its use in preoperative analysis of relevant surgical anatomy and relations as well as its utility in the creation of patient specific instrumentation for on-table use has been documented⁽¹⁾.

Further applications include virtual simulation or rehearsal of the surgery with patient-specific 3D virtual models, creation of patient-specific instruments from virtual models and creation of implantable prostheses but these will not be explored in this review.

Methods:

To capture all relevant articles relating to the use of 3D printed models for the purpose of Orthopaedic Surgical planning, a comprehensive search was conducted using a combination of subject headings and free text. The search was conducted on the EMBASE and MEDLINE databases using the Ovid platform with the final results including all papers published until the end of 2018.

The search strategy captured references to “3D printing”, “3D modelling” and “3D technology” in combination with the Orthopaedic key terms “Orthopaedic”, “bone” and “joint”. The search was restricted to consider only surgical planning articles by using the terms “surgical”, “surgery”, “preoperative”, “preop” and “plan”. Articles relating to the field of cranial and maxillofacial surgery were excluded by removing the keywords “jaw”, “maxillofacial”, “craniofacial”, “orthognathic” and “mandibular”.

Papers which satisfied the inclusion criteria of full text, original articles in English regarding the direct use of 3D printed models in Orthopaedic preoperative planning for human patients were considered. Articles regarding virtual 3D simulations were excluded along with papers investigating applications in fields other than Orthopaedics. The information extracted from these papers included the metrics used to measure surgical outcomes, surgical outcome and surgeon or patient opinion

regarding the use of the 3D printed models. A PRISMA diagram of the search strategy is provided in Figure 1.

Results:

The literature searched revealed 55 suitable articles. The majority of the papers were case reports or case series (44 out of 55) with a further 11 case-control studies. Across the studies, a total of 948 patients were involved. There is a clear trend of increasing interest in 3D printing technology in Orthopaedic surgery, as shown in Figure 2.

The case-control studies⁽⁶⁻¹⁶⁾ focused on objective measures of benefit when using 3D printed models during the preoperative phase of the procedures. The workflow to create the model was very similar in all studies, with the patient's medical image data processed in segmentation software prior to printing on a 3D printer. The models were then used to simulate the surgery⁽⁶⁻¹³⁾ with further steps such as pre-bending of implants⁽¹¹⁾ and planning screw placements^(6, 12) being undertaken in three studies.

Anatomical accuracy of the 3D printed models were validated in four studies with the most common method being evaluation via questionnaire by senior surgeons^(6, 10, 11). Karlin et al⁽⁸⁾ compared the anatomical accuracy of models and the resultant diagnostic findings to patient CT scans and intraoperative findings.

The utility of the models has been evaluated both objectively and subjectively. Operating time, intraoperative blood loss and intraoperative fluoroscopy time were measured in most case studies to evaluate the impact of the models on the surgical procedure. Clinical measures were employed to

assess for improvements in surgical outcome, such as the number of complications postoperatively. Three studies also employed a survey of both patients and surgeons to determine their respective perceived benefit of the models^(6, 10, 11). A summary of these results is provided in Table 1.

Across the board, the case-control studies showed that using 3D printed models as a part of the perioperative plan showed consistent improvements in intraoperative metrics but did not significantly affect the surgical outcome. All studies which measured operating time showed a clinically significant if not statistically significant reduction in operating time compared to the control cohorts^(6, 7, 9-13). In the studies which measured blood loss volume and fluoroscopy time⁽⁶⁻¹³⁾, the results were similar, with most finding statistically significant reductions in these metrics (two studies showed similar levels of intraoperative blood loss^(7, 8)).

The measures of surgical outcome, however, were similar between model and control groups in most studies. Two studies found a slight improvement in postoperative results^(8, 10) but neither was statistically significant. Length of hospital stay was investigated in two studies^(12, 13) which found no significant difference between groups, although Zheng et al⁽¹³⁾ found a statistically significant reduction in time to ambulation of 2 days in the group using 3D printed models for preoperative planning.

Survey results showed that the 3D printed models were perceived as extremely beneficial by patients^(6, 10, 11). Patients felt that they had much better understanding of their injury and the planned operation when compared to the control groups. Surgeons also felt that they were able to communicate these details more effectively to patients via the models. One study found that surgeons found the technology less useful for simple cases⁽⁶⁾. Surgeons were surveyed on the usefulness of the

models for preoperative planning, similarity to patient anatomy and overall satisfaction. The patient survey assessed the understanding of their condition and overall satisfaction with their interaction with their surgeon. A total of 177 patients and 12 surgeons were surveyed.

Case series⁽¹⁷⁻³⁶⁾ focused on subjective measures. Clinical outcomes in all cases were satisfactory, with some of that success attributed to the use of 3D models. The surgeons were able to better understand the patient's anatomy, with the models resulting in an altered surgical plan or approach in some cases^(19, 21, 26, 37). Simulated surgery aided in instrument selection resulting in less need for adjustment intraoperatively as well as providing a better understanding of landmarks such as resection margins and screw placements⁽¹⁷⁻²⁸⁾. Surgeons commented that they felt the models were less useful for simple pathologies but could greatly improve understanding of more complex fractures and deformities⁽¹⁸⁾.

Case reports described similar results⁽³⁷⁻⁶⁰⁾. The cases chosen were all complex, with the 3D printed model used to gain a more detailed appreciation of the relevant anatomy, planning the surgical approach and selecting instruments in advance. Surgical approaches were better anticipated, which reduced the need to improvise intraoperatively^(39, 40, 49, 50, 54-57). In one case, the surgical plan was altered upon visualisation of the 3D model, reducing the need for future revisions⁽³⁷⁾. Simulated surgery was also performed in eight cases⁽⁵⁰⁻⁵⁷⁾, allowing surgeons to perform necessary adjustments, such as planning graft sites and contouring implants preoperatively and focus solely on the surgical process during the operation.

Discussion:

The role of 3D printing

The role of 3D printing in surgery has yet to be fully determined. Many fields are exploring the ways in which the technology can be employed⁽⁶¹⁾. With regards to Orthopaedic surgical planning, it is evident that the technology offers advantages⁽⁴⁾.

When analysing the subjective data regarding the benefits of 3D models, there is a consistent trend that surgeons found 3D models useful when dealing with complicated anatomy^(8, 17-19, 21, 25, 26, 37, 40, 42, 50, 53-56). 3D printed 1:1 scale models allowed surgeons to appreciate the structure and relations of the relevant anatomy much better than the visualisation provided by 2D CT images conventionally used today. Inspection of these models also revealed structural abnormalities not appreciated on CT which altered the surgical approach in a significant number of cases^(19, 21, 28, 37, 54).

These models can also be sterilised and taken into the surgical field to provide the surgeons with a template to review intraoperatively^(1, 10, 18, 20). Even common, inexpensive printing materials such as Polylactic Acid (PLA) can withstand high pressure steam without deforming^(10, 20), but there has been limited work in validating the sterility of such models. As such, a standardised protocol for each of the 3D printing technology has yet to be established. Reviewed papers came to similar conclusions that, whilst not beneficial for simple pathologies in which traditional methods of preoperative planning can be reliably used, 3D printing can offer more accurate evaluation of relevant surgical structures in complex cases such as spinal deformities and acetabular fractures^(6, 18).

Apart from the subjective benefits, 3D printed models also offer objective benefits in surgery. The case-control studies consistently showed that 3D model cohorts had shorter surgery times, lower

volumes of blood loss intraoperatively and shorter fluoroscopy times⁽⁶⁻¹³⁾. The ability to use the models to simulate the surgery allowed for planned placement of implants and selection of instrumentation, thus reducing the number of adjustments and the need to contour implants intraoperatively.

Models were also used to evaluate the structural integrity of landmarks to which the implants are fixated. For example Mizutani⁽²¹⁾ et al showed that models demonstrated structural instability with initial surgeon selected screw placements which were then adjusted accordingly. Planning of osteotomies is another benefit of the models, allowing analysis of complex anatomy in 3D, providing improved precision and accuracy compared to 2D modalities^(28, 40, 50, 52, 53, 57). While the difference in the rate of complications is reported as statistically insignificant in all cases, it is important to note these small scale studies are not adequately powered, reinforcing the need for further large scale trials to be performed. Two papers showed an observable difference in complication rate^(7, 12).

Patients surveyed in the literature responded with enthusiasm regarding the use of 3D printed models. All patients felt that they better understood their injury and their upcoming surgery. Surgeons also felt that 3D printed models were a valuable communication tool when counselling patients. They felt having a tangible structure to show the patient the procedure they were about to perform was superior to all currently available media^(6, 10, 11). The surveys only assessed the quality of the surgeon-patient interaction, and as such evaluation of patient satisfaction in regard to their surgical outcome is lacking. Exploration of patient experience in future questionnaires is merited given the positive responses in the literature.

Limitations

Despite the discussed benefits of 3D printing, there are several limitations that must be addressed before the process becomes routine.

The sample sizes of these studies were insufficient to provide statistical significance to some of their results⁽⁶⁻¹³⁾. While the papers managed to demonstrate that the intraoperative benefits were significant, the surgical outcomes were insufficiently powered to demonstrate any surgical improvement or decrease in complication rate^(7-9, 12). In particular when evaluating rates of serious complications, larger cohorts are necessary to arrive at a statistically significant conclusion^(7, 12). Furthermore, two papers stated that the surgeons employed in the studies were senior surgeons used to dealing with complex cases^(7, 9). Further studies investigating the utility of preoperative simulation in trainees where a larger variation in skill and experience exists may yield a clearer picture of the advantages of 3D printing in Orthopaedic preoperative planning. One study did employ the use of a questionnaire to assess the usefulness of the models to trainees⁽²⁴⁾. Another two used the models for surgical education^(17, 18) which yielded positive feedback. The applications of 3D printing in education has been well cited in the literature⁽¹⁾, as the models allow trainees exposure to complex pathologies and the ability to focus on complex techniques in a controlled environment.

The variability of the complex cases presented in the studies makes comparison difficult. While the dominant opinion is that 3D printed models offer the most benefit in complex cases, recruiting a cohort of patients with homogenous complex pathology is challenging. Aside from inter-study variation in pathology, intra-study variations in pathology must be considered. For example, Karlin et al⁽⁸⁾ stated in their study of 3D printing in myelomeningocele repair that despite the cohort having a common diagnosis, true comparison of the pathologies would not be appropriate. All patients

presented unique challenges when deciding on an appropriate surgical plan with the more complex patients being placed in the 3D modelling group as routine methods were deemed insufficient. This highlights the difficulty which arises when aiming to perform a comprehensive assessment of clinical benefit from 3D printed models across a range of diagnoses. As such, developing a unified protocol with which to assess the clinical benefit may prove difficult, as each case may provide advantages in disparate aspects of patient care.

The lack of soft tissue structures in some 3D printed models is a disadvantage mentioned by surgeons^(6, 11). While the models provide a good representation of the bony anatomy, the associated soft tissues and vital structures such as blood vessels or nerves are often not included^(6, 20). This reduces the usefulness of the model in cases such as complex tumour resection near vital structures. It is important to note that the inclusion of such structures is technically feasible, but increases the processing time and can subject the patient to additional risks such as via CT angiography to highlight vascular structures. Critical structures can be marked onto the 3D model or correlated with medical imaging data as demonstrated by Yamazaki et al^(50, 54-56), but proper visualisation would require manual segmentation of the structure from medical images which can be labour intensive and often impractical.

A comprehensive cost-benefit analysis of 3D printing in Orthopaedic Surgery is yet to be established, and will vary between intended application, health systems and countries. The workflow from medical image to completed model can take upward of 50 hours depending on the size of the model and 3D printing technology utilised^(6, 13, 19, 37, 62). The time required for the current workflow also makes the technology unsuitable for emergency procedures requiring urgent intervention⁽²⁾. 3D printing technology can also be unreliable, with desktop FDM printing in particular. The dimensional accuracy

and resolution of the final 3D model is also reliant on the quality and resolution of the original image data⁽¹⁾. High resolution imaging is required to be able to fully assess the 3D anatomy. The cost of this process itself is also a factor as either the surgeons would be required to acquire the technical skills to process the imaging data or a technician would be required. All of these factors need to be compared to the potential cost savings of decreased operating time, decreased morbidity and bed days, and rationalisation of surgical trays and tools.

There are further time costs and overhead costs (the simulation of a surgical procedure also requires time, with one paper stating that each simulated surgery took 2.5 hours⁽⁶⁾. The cost of the printers and models themselves also needs to be considered.) While the models range from \$2-3⁽¹⁰⁾ to \$1500⁽¹⁹⁾ per model, the printers and software can represent a large initial investment. Whilst cheaper printers may only cost a few thousand dollars⁽⁷⁾, reliable industrial printers can cost a minimum of \$60,000⁽⁶²⁾ and up to \$500,000. These factors require the establishment of a consistent protocol for the use of 3D printing technology with regards to case selection, image processing, 3D printing and the surgical simulation in order to streamline the process⁽⁶²⁾. A mixture of in-house and commercial outsourcing was seen in the literature. In-house printers offer the advantage of increased control over the workflow and decreased turn-around time. However running, maintenance and labour costs must be considered⁽⁶²⁾. Building on the generalised 3D printing workflow previously described by our group⁽³⁾, Figure 3 demonstrates the costs to consider in an in-hospital 3D printed anatomical model workflow, after the acquisition of imaging through regular means.

Future directions

While the current literature demonstrates that there are objective benefits to 3D printing in the field of Orthopaedic Surgery, further studies are required to examine what aspects of the technology contribute to this. The literature asserts that the ability to simulate surgery reduces the number of

adjustments required intraoperatively⁽⁷⁾, which merits further exploration. In addition, most studies involved the use of a single anatomical model. There is potential in select cases for multiple models to be used to allow the surgeon to simulate multiple approaches and select the optimal plan with more certainty⁽⁷⁾.

Published direct comparison of conventional 2D modalities compared to 3D models for preoperative planning are lacking⁽⁸⁾. Metrics such as time taken, cost effectiveness, accuracy, impact on surgical plan, training proficiency time and surgeon confidence should all be explored. This would allow studies approaching the topic to report using more objective metrics to ascertain the benefits of the technology.

The inclusion of soft tissue structures within anatomical models is another aspect with limited evidence. While such models are more technically challenging to produce, they allow for an enhanced understanding of neurovascular relationships when preparing for difficult cases and merits further investigation.

Ultimately, we highlight the need for the field to develop a streamlined protocol for the use of 3D printed models in Orthopaedic Surgery. This protocol should address issues surrounding the workflow such as case selection, the minimum image quality required to produce a model that is both safe and of clinical use, material properties of the 3D printed model, the surgical steps that should be rehearsed, and the detail required in the anatomical models.

Conclusion:

The current literature regarding the use of 3D printed models for the purpose of enhancing preoperative planning in Orthopaedic Surgery suggests that there is a tangible benefit to its implementation. Surgeons and patients alike reported great benefit in its use as an educational tool. The technology also offers objective improvements to the surgical procedure itself. While these reported benefits may be sufficient for centres to trial the technology, further investigation into the development of a validated protocol is required before the technology becomes a routine part of planning complex Orthopaedic procedures.

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Figure Legend

Figure 1. A PRISMA diagram detailing our search strategy.

Figure 2. Number of Orthopaedic publications per year in the field.

Figure 3. Approximate workflow detailing steps and cost involved

Summary: Case control studies (Table 1)

		Objective measures (3D group vs control group)								
Paper	Author/year	Operating time		Blood loss		Fluoroscopy time		Surgical outcome measures	Patient opinion	Surgical opinion
Treatment of Die-Punch Fractures with 3D Printing Technology	Chen et al 2017	56.57±4.74 min	65.73±6.02 min	39.25±8.72 ml	52.95±9.78 ml	4.85±1.39 times	5.85±1.64 times	Degree of wrist motion and radiological condition. No significant difference between groups	Increased knowledge of fracture and surgical plan	Useful to communicate with patients, accurate but not very useful for preoperative plan
Patient specific 3D print models improve deformity correction after proximal femoral osteotomy for slipped capital femoral epiphysis	Cherkasskiy et al 2016	125.8±25.4 min	170.4±76.4 min	962.6±276.1ml	979.8±316.2 ml	0.6±0.4 min	0.3±0.3 min	Radiographical analysis. No significant difference between groups, may be due to surgery itself		Useful for practicing osteotomy. Less complications but not statistically significant
The surgical treatment of spinal deformity in children with myelomeningocele: The role of personalized three-dimensional printed models	Karlin et al. 2017			442 ml /24% blood volume	960ml /26% blood volume	0.2 min	0.42 min	Percentage correction based on radiographic evidence. 12% better correction in 3D group		Useful aid for surgery. Discovered additional anatomy. Group A had more complex patients
Application of the polystyrene model made by 3-D printing	Li et al 2015	106.53±11.9 1 min	131.92±10. 81min	341.67±49. 45ml	466.77±71.46 ml			Complications, disability and pain scores. Similar		All surgeons were experienced in complex cases. 3D printing useful

rapid prototyping technology for operation planning in revision lumbar discectomy								between both groups		for reducing intraoperative metrics
Application of 3D rapid prototyping technology in posterior corrective surgery for Lenke 1 adolescent idiopathic scoliosis patients	Yang et al 2015	184.32±4.65 min	212.32±8.1 7 min	846.68±26. 11ml	1029.65±72.1 8ml			Degree of correction, complications, length of hospital stay. Statistically insignificant differences between groups		Observable but not statistically significant reduction in screw misplacement and complications.
Application of 3D Printing in the Surgical Planning of Trimalleolar Fracture and Doctor-Patient Communication	Yang et al 2016	71±21 min	98±20 min	65±26 min	90±38 min			Postoperative X ray shows good reduction and fixation	Better understanding of injury and surgical procedure. Use of model improved patient doctor communication	No adjustments of entry point and placement were needed. Survey showed surgeons were impressed with usefulness of model
Three dimensional printing technology and materials for treatment of elbow fractures	Yang et al 2017	61±13 min	82±22 min	47±16 min	69±28 min			Anatomic reduction, complications, Mayo elbow performance score. Observable improvement in 3D group but not statistically significant	Improvements in patient doctor communication regarding nature of injury, surgical plan	Allowed better visualisation and understanding of fracture pattern. Reduced need to adjust implants intraoperatively.

Application of 3D printing rapid prototyping-assisted percutaneous fixation in the treatment of intertrochanteric fracture	Zheng et al 2017	46.27±6.51 min	60.58±11.9 2min	98.35±4.67 ml	162.57±11.92 ml			Similar clinical outcome, 3D group had shorter time to ambulation. Similar length of hospital stay		The models were useful for simulating surgery and allowing preselection of the correct instrumentation
Computer-assisted virtual surgical technology versus three-dimensional printing technology in preoperative planning for displaced three and four-part fractures of the proximal end of the humerus	Chen et al 2018	61.5±9.3 min	80.4±8.9mi n	83.1±13ml	100.5±12.5ml	5.7±1.1 times	8.3±1.4 times	There was improved surgical planning in both the virtual and 3D model groups along with improved intraoperative metrics		
More accurate correction can be obtained using a three-dimensional printed model in open-wedge high tibial osteotomy	Kim et al 2018							More satisfactory correction of deformity was possible when utilising a 3D model for high tibial osteotomies		

Preliminary results using patient-specific 3d printed models to improve preoperative planning for correction of post-traumatic tibial deformities with circular frames	Corona et al 2018	172.4min	329min					Surgical time was significantly longer in the conventional group. The circular frames also required many adjustments intraoperatively in this group, compared with minimal in the 3D group.		
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