**A Systematic Review of the Uses and Benefits of 3-D Printing in Orthopaedic Surgery**

**(Can be shortened to “A Systematic Review of 3-D Printing in Orthopaedic Surgery”)**

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**Abstract**

**Introduction:** The objective of this systematic review was to analyse 3-D printing in orthopaedic surgery, focussing on pre-operative planning, patient specific implants, instruments, and orthoses.

**Method:** The PRISMA methodology was followed and literature searches were conducted on Medline, Embase and the Cochrane library. MeSH search terms and Boolean operators included ‘3-D printing’, ‘orthopaedic’, ‘pre-operative plan’, ‘implants’, ‘patient specific instruments’ AND ‘orthosis’.

**Results:** Searches resulted in 36 studies included in the review. The increasing interest in 3-D printing in orthopaedics is reflected in the rise in publications between 2015 and 2020. The most common application, reported by 75% of the studies was the use of 3-D printed anatomical models to aid in pre-operative planning. The models were also utilized for surgical simulation (31%), intraoperative navigation (8%), and patient/family and surgical education (8%). The use of 3-D printing to manufacture patient specific orthoses, implants and instruments was reported in 14%, 11% and 8% of the studies respectively. The advantage of 3-D printing reported most (56%) was the educational and training opportunities the models provided for junior surgeons. Doctor-patient communication and improved consenting was a reported benefit in 28% of the studies. Objective benefits of 3-D printing included reduced operating time (42%), instrumentation time (11%), fluoroscopy time (31%) and intraoperative blood loss (33%).

**Conclusion:** The literature shows 3-D printing has improved pre-operative planning, allowed for surgical simulation, training and education. These benefits have led to improved operating metrics. There are currently no studies which demonstrate these reported benefits led to improved patient outcomes.

**Introduction**

Three-dimensional (3-D) printing was developed by Charles Hull in 1986 [1]. Since its introduction, 3-D printing has renovated the manufacturing industry. The first application of 3-D printing in medicine was documented by Mankovich *et al.* [2] in 1990, when the group used the technique to produce a model of cranial bone anatomy. Since then, the utilisation of 3-D printing in medicine and surgery has increased over the last decade. In 2014, the medical 3-D printing industry was worth $11 million dollars and was projected to become a $1.9 billion industry by 2024 [3].

In healthcare, 3-D printers can use magnetic resonance imaging (MRI) or computerised tomography (CT) scan images to provide the instructions for the printhead to build a 3-D construct one layer at a time. The process of generating a 3-D printed anatomical model is complex and is comprised of several phases [4]. Firstly, image acquisition and denoising is conducted where the CT scan or MRI Digital Imaging and Communication in Medicine (DICOM) data is acquired, and image artefacts are removed. Secondly, segmentation of the image takes place where the anatomical area of interest is labelled and separated from the rest of the image. This segmented image is then used to generate the computer aided design (CAD) model, which is the blueprint for the 3-D printer to produce the final 3-D model (***Figure 1***).

Figure 1: Flowchart for generating a 3-D printed anatomical model.

Traditionally, surgeons would rely solely on the CT scan and MRI images to formulate a surgical plan preoperatively. In recent years, as radiological imaging software has improved, 3-D projections and reconstructions on the two-dimensional computer screen were made possible to assist the surgeon. The ability to produce 3-D printed models of the patient’s anatomy has added new dimensions to surgical planning, multi-team discussions and even allowed for surgical rehearsal to be conducted [5].

In Orthopaedic surgery, the use of 3-D printing has expanded to areas such as surgeon and patient education, construction of patient specific implants, instrumentation, and orthoses [6].

The objective of this systematic review was to analyse the uses and benefits of 3-D printing specifically in orthopaedic surgery, focusing on the areas of surgical pre-operative planning, surgeon and patient education, manufacture of patient specific implants and instruments, and orthoses. As the field of medical 3-D printing has advanced rapidly only references from 2015 to 2020 were analysed in this review to ensure the most up-to-date applications of 3-D printing were recorded.

**Method**

The ‘Preferred Reporting Items for Systematic Reviews and Meta-Analyses’ (PRISMA) methodology was used to conduct the systematic review [7]. The eligibility criteria for the review included papers that only discussed the use of 3-D printing in orthopaedic surgery. The literature searches were carried out on 28th December 2020 on Medline, Embase and the Cochrane library to ensure a thorough search was conducted. The MeSH search terms and Boolean operators used were “orthopaedic” OR “orthopedic”, AND “three-dimensional printing” OR “3D printing” OR “stereolithography”. To maintain focus on the areas of interest separate searches were also conducted which included the terms, “pre-operative plan”, “implants”, “patient specific instruments” and “orthosis”. All the results were grouped together before going through the stages of screening and ensuring they were eligible to be included in the systematic review (***Figure 2***). The exclusion criteria apart from studies that were noth related to 3-D printing in orthopaedics included studies that were veterinary medicine related, studies that were not in the English language and conference abstracts that no extended papers could be identified.

The identification stage involved conducting the searches on the named databases. Screening involved removing the duplicates, filtering for date of publication (2015-2020). A search of the ‘grey literature’ was conducted by reviewing the titles and abstracts of each article referenced within the publication list to determine if the article met the criteria of being related to 3-D printing in orthopaedic surgery in human subjects. From the list of references that met these criteria, the full text was reviewed to ensure it could be included in the systematic review. The final list of references that were included in this review were the clinical case reports, case series, clinical trials that have been published discussing the direct application of 3-D printing in orthopaedic surgery. Articles that the full text could not be accessed or obtained through the Athens portal or other web searches were excluded from the final list. The application of 3-D printing in orthopaedic surgery, and the benefits its use provided to the orthopaedic procedure were recorded from the articles that were included in the systematic review and analysed. There was no funding sourced or required for this systematic review.

Exclusions:

Literature review (n = 34)

Conference abstracts (n = 27)

No full text available (n = 15)

Outside focus areas (n = 27)

Exclusions:

Not orthopaedic related (n = 76)

Not 3D printing related (n =66)

Not in English language (n = 15)

Veterinary medicine related (n = 12)

Exclusions:

Duplications (n = 266)

Publications pre 2015 (n =15)

Screening

Included

Eligibility

Identification

Figure 2: PRISMA flow chart of included studies.

**Results**

The literature searches uncovered 36 references for inclusion in this systematic review [4, 8-42]. ***Table 1*** shows that most of the references were comparison studies (12 randomised control studies and nine case-control studies) which separated their patients into ‘3-D printing used’ groups and control groups (no 3-D printing used). The remaining references included were either case reports or case series detailing their experiences using 3-D printing in orthopaedics.

Table 1: Distribution of types of studies in the systematic review.

|  |  |  |
| --- | --- | --- |
| **Type of Study** | **References included (n = 36)** | **(%)** |
| Randomised control | 12 | 33.3 |
| Case-control | 9 | 25.0 |
| Case report | 8 | 22.2 |
| Case series | 7 | 19.4 |

The popularity of 3-D printing in orthopaedics appears to be increasing based on the rising number of publications between 2015 (n = 1) and 2019 (n = 12), and only decreasing slightly in 2020 (n =11) (***Figure 3***).

Figure 3: Number of publication of references in the systematic review between 2015 and 2020.

The applications of 3-D printing in orthopaedic surgery outlined in the studies included in the systematic review were varied (***Figure 4***).

The use of 3-D printing to create patient anatomical models to aid pre-operative planning was the most common application and was highlighted in 27 (75 %) of the references. Eleven articles (31 %) mentioned using the 3-D printed patient models to undertake surgical simulations. Three articles (8 %) referenced using the 3-D printed patient models to aid intra-operative navigation and referencing. The application of 3-D printing for education refers to junior surgeon, patient and/or family education to assist in explaining the orthopaedic condition and assisting in gaining consent. There were three articles (8 %) that highlighted education as one of the uses of 3-D printing.

Another application of 3-D printing in orthopaedics was in manufacturing patient specific orthoses (five articles, 14 %). These included three articles referencing wrist/ankle orthoses, one article references 3-D printed insoles and one article detailing a 3-D printed cervical orthosis.

There were four articles (11 %) that described the use of 3-D printing to manufacture patient specific implants. Luenam et al [8] reported the use of a 3-D printed implant to reconstruct the lateral column of a patient’s distal humerus following a traumatic injury. Han et al [21] and Wong et al [30] both specified the use of 3-D printing to produce patient specific pelvic implants to reconstruct a pelvis following tumour resection. So et al [26] also referenced using 3-D printed patient specific implants to reconstruct large osseous defects in the foot and ankle.

Three articles detailed the use of 3-D printing to create patient specific instrumentation such as guide plates for core decompression and rod placement for treatment of femoral head osteonecrosis.

Figure 4: Number of references detailing applications of 3-D printing in orthopaedic surgery in the systematic review.

The benefits provided by 3-D printing that were reported in were wide-ranging so were therefore grouped into subjective benefits and objective benefits (***Figure 5***).

When looking at the subjective benefits, the most common advantage of using 3-D printing was for the surgeon’s education and training and was described in 20 articles (56 %). This included the surgeons using the 3-D models to fully conceptualise and understand the patients’ orthopaedic conditions as well as, using the models for the junior surgeons to undertake as surgical simulations, providing training opportunities. There were 10 articles (28 %) that highlighted the use of 3-D printed models aiding the doctor-patient/family communication and assisting in the consenting process. The applications of 3-D printing in orthoses and manufacturing of the device designed to prevent excessive drilling [33] reported cost effectiveness (n = 3, 8 %) and the ability to easily reproduce the 3-D printed item if it is lost (n = 5, 14 %) as advantages provided by the technology. Four of the orthosis studies (11%) reported that the 3-D printed orthosis provided the patients with increased comfort when compared to traditional orthosis.

All the objective benefits of 3-D printing in orthopaedics surgery analysed were detailed in references that used the technology for pre-operative planning and measured comparable outcomes such as operation time, intraoperative blood loss, fluoroscopy time and instrumentation time. Fifteen articles (42 %) stated using 3-D printed led to reduced operation time. Twelve papers (33 %) showed that the patients that were assigned to the 3-D printed groups had a significant reduction in intraoperative blood loss. Eleven references (31 %) reported 3-D printing reduced fluoroscopy time. Four articles (11 %) highlighted 3-D printing reduced operative instrumentation time.

Figure 5: Number of studies detailing subjective (grey) and objective (black) benefits of 3-D printing in orthopaedic in the systematic review.

The quality of the studies reporting the objective outcomes was measured based on study type, sample size and the National Institute of Health study quality assessment tools [43] (***Table 2***). Of the randomised control trials (RCTs), Chen et al (2019) [36] had the highest quality paper as the study scored 12.5 of 14 marks (89.3%). The case-control studies by Li et al [18, 32] were ranked lower in quality than the RCTs as both assorted the patients into the respective groups according to the decision of the chief surgeons, thus increasing the risk of selection bias in the papers. There were four case series studies that claimed a reduction in operation time as a benefit of utilising 3-D printing but were ranked lowest as they did not have a control group to compare against to verify the claims.

Table 2: Quality ranking of references reporting objective benefits of 3-D printing.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Quality Ranking** | **Quality Assessment (%)** | **Reference** | **Type of Study** | **Sample Size**  **(3-D printed group = 3DPG, Control Group = CG)** |
| 1 | 89.3 | Chen et al (2019) | Randomised control | 48  (3DGP = 23, CG = 25) |
| 2 | 85.7 | Chen et al (2018) | Randomised control | 107  (3DGP = 52, CG = 55) |
| 3 | 82.1 | Kong et al (2020) | Randomised control | 32  (3DGP = 16, CG = 16) |
| 4 | 78.6 | Huang et al (2020) | Randomised control | 40  (3DGP = 20, CG = 20) |
| 5 | 78.6 | Ozturk et al (2020) | Randomised control | 37  (3DGP = 18, CG = 19) |
| 6 | 71.4 | Zheng et al (2017) | Randomised control | 75  (3DGP = 35, CG = 40) |
| 7 | 71.4 | Yang et al (2017) | Randomised control | 40  (3DGP = 20, CG = 20) |
| 8 | 64.3 | Wan et al (2019) | Randomised control | 96  (3DGP = 48, CG = 48) |
| 9 | 64.3 | Zheng et al (2018) | Randomised control | 91  (3DGP = 43, CG = 48) |
| 10 | 64.3 | You et al (2016) | Randomised control | 66  (3DGP = 34, CG = 32) |
| 11 | 57.1 | Yang et al (2016) | Randomised control | 30  (3DGP = 15, CG = 15) |
| 12 | 58.3 | Li et al (2019) | Case control | 16  (3DGP = 7, CG = 9) |
| 13 | 50 | Li et al (2018) | Case-control | 40  (3DGP = 20, CG = 20) |
| 14 | 100 | Samaila et al (2019) | Case series | 52 |
| 15 | 100 | Wong et al (2018) | Case series | 10 |
| 16 | 77.8 | Mishra et al (2019) | Case series | 91 |
| 17 | 77.8 | Bagaria and Chaudhary (2017) | Case series | 50 |

**Discussion**

**Three-dimensional printed models:**

The technology of 3-D printing to create the anatomical models from the patient’s radiological images has been especially useful in orthopaedics, traumatology as well as other specialities such as maxillofacial surgery [44]. The anatomical models have proven to aid pre-operative planning, allow for surgical simulation, and assist in the education of both surgeons and patients.

Pre-operative planning was the most common application of 3-D printing in orthopaedic surgery in this review. Complex fracture patterns and revision arthroplasty surgeries are areas of orthopaedics that have found the application of 3-D printed models to be particularly useful.

Two-dimensional imaging and 3-D radiologic reconstruction on the computer screen are normally used for these complex procedures, but Wei et al (2019) [10] were able to demonstrate how using 3-D printed models added to the pre-operative planning capabilities. Surgeons were able to use the models to plan for precise angle corrections, pre-bend plates, run a full simulation of the surgery to reduce the risk of any unanticipated complications as well as offering training opportunities for junior surgeons [13].

This extra dimension to the pre-operative planning process also translated to significant benefits to the patients as shown by Chen et al (2018) [24] and several other studies. In these studies, the patients in the 3-D printed groups had reduced operation times, fluoroscopy time and intraoperative blood loss when compared the patients that did not have 3-D printed model utilised. Reductions in these measures can also lead to reduced risks associated with anaesthetic time, radiation exposure, intraoperative infections, and other post-operative complications. Furthermore, the cumulative effect of these will also lead to reduced healthcare costs by reducing both the theatre costs and potentially post-operative hospital stay.

The quality of the papers that recorded the objective operative metrics (***Table 2***) was generally high. The three studies with sample sizes over 90 patients [24, 40, 37] all highlighted small sample size as a limitation of the study. Notable limitations in the randomised control studies included the use of a coin toss as the method of randomisation [36], and the inability to include blinding to the surgeon or the patients in the randomisation process might have influenced the results.

It must be stated that some studies have that shown that using 3-D printed models showed no significant difference in operation time, estimated blood loss, fluoroscopy time and over all post-operative outcomes [17] but this might be explained by the small sample size of 20 patients.

The 3-D printed models can also be utilised to assist in the doctor-patient communication where it is difficult for them to understand the associated complexities of their conditions. Downey et al [17], detailed the positive effect the 3-D printed models had on the communication which led to improved overall patient satisfaction. Bizzotto et al [45] were able to demonstrate the positive impact of 3-D printed models in the consenting process due to this improved doctor patient communication. The benefits of the 3-D printed models are not limited to pre-operative planning. The model can also be sterilised and used during the operation to aid in intra-operative referencing and navigation as shown by Bagaria and Chaudhary’s study [4].

Kong et al [42] highlighted that the time needed for the 3-D printer to create an anatomical model is hours and therefore was not a feasible option for the emergency patients that required immediate operation despite showing the clinical benefits its utility.

**Patient Specific Implants and Instrumentation:**

The use of 3-D printing to create non biologic patient specific implants has been widely reported and has benefited the treatment of orthopaedic tumours [21]. As well as being able to create complex anatomical structures particular to the patient’s needs following resections of their pelvic tumour, Wong et al [30] discussed the use of materials and porosity of the implant to promote osteointegration with the surrounding native bone following the reconstruction. Luenam et al [8] were also able to demonstrate the role of patient specific implants in treating patients following traumatic injury leading to considerable bone loss. In this article the surgeons were able to reconstruct the lateral column of the distal humerus with the 3-D printed implant leading to the restoration of full function of the elbow joint.

Patient specific 3-D printed instruments are also commonly used particularly as sterilisable surgical guides to assist with screwing and drilling in orthopaedic spinal surgery [46]. These guides have increased surgical accuracy when comparing to the use of expensive surgical navigation systems and therefore open potential healthcare cost savings opportunities without compromising on patient safety.

**Limitations of 3-D Printing:**

This review has focused on the benefits that 3-D printing provide to orthopaedic surgery, but the most common limiting factor for its routine use was the costs associated the technology. Heunis et al [19] highlights the costs of purchasing the printer itself and the ongoing costs of technicians to convert the CT imaging data as the major disadvantage.

Crawford [5] discussed two main reasons as to why 3-D printing still is not being used routinely despite all the benefits it provides. Firstly, getting access to the raw imaging data and finding out what the surgeon needs to be able to see in the final printed model has proven to be logistically quite challenging. Secondly, the process of segmentation of the raw data to extract the anatomical area of interest is massively time-consuming. The process of segmentation can take about four hours per case if conducted manually as it requires anatomical, medical physics and 3-D printing systems knowledge and is therefore not feasible for everyday routine use if done in individual hospitals.

The limitations regarding the scalability of 3-D printing have largely been solved by using artificial intelligence (AI) and machine learning algorithms to streamline the segmentation process. AI is used to extract the relevant data in minutes by using a database of 100,000s labelled data images created by experts to automatically identify the required anatomical structures [47]. By automating this process, AI could allow for point of care 3-D printing without the ongoing costs of staffing to manually convert images.

**Conclusion**

The literature shows that applications of 3-D printing have resulted in improved operating metrics due to enhanced pre-operative planning. The use of 3-D printing to provide patient specific implants remains limited to specific cases. The application of 3-D printing in biologics with advancement in tissue engineering opens exciting treatment options for orthopaedic conditions such as osteoarthritis and ligament repair.

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