REVIEW ARTICLE



Clinical outcomes of the use of 3D printing models in fracture management: a meta-analysis of randomized studies

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Abstract

Purpose The use of three-dimensional printing models in medical practice has been booming recently and its application to orthopedic surgery is gaining popularity. When treating fractures by open reduction and internal fixation, potential benefits have been associated with the use of 3D printing models. This review aims to quantitatively analyze the effectiveness of using 3D printing models in fracture management.

Materials and methods A structured systematic review was conducted, and multiple databases were searched using a combination of terms related to 3D printing in fracture management. The literature search was limited from inception to Nov 2020. Only comparative randomized studies were accepted for inclusion. Any software or material using 3D printing versus no technological assistance was included. All types of fracture treated by open reduction and internal fixation were included. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology was applied with the Joanna Briggs Institute's critical appraisal tool used to assess the quality of the included studies. Quantitative analysis was performed. **Results** Based on 13 RCTs including 673 patients (325 and 348 in the 3D and control groups, respectively), the weighted effect size outcomes were as follows: (a) operative duration -1.47 (95% CI = -1.759 to -1.182), (b) intraoperative blood loss -1.41 (95% CI = -1.792 to -1.029), (c) fluoroscopy use -1.25 (95% CI = -1.637 to -0.867), in favor of the 3D group. The weighted Odds ratio outcomes were: (a) overall good or excellent result 2.05 (95% CI = 1.119 to 3.845) and (b) anatomic fracture reduction 2.64 (95% CI = 1.150 to 6.051) in favor of the 3D group. The mean residual displacement and time to union showed no significant difference. The mean JBI appraisal tool score for the randomized studies was of 9, out of a maximum of 13.

Conclusions When compared to the non-use of 3D technology for open reduction and internal fixation of fractures, the review demonstrated evidence that 3D printing yielded significantly better perioperative results. Further studies are needed to evaluate the effect of 3D printing on union and long-term function. **Level of evidence** I.

Keywords Three dimensional printing \cdot Fracture \cdot Open reduction internal fixation \cdot Surgical complications \cdot Radiation exposure

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Introduction

Additive manufacturing, commonly known as three-dimensional or 3D printing, has been an ever-evolving field since 1981 when the first technique was developed at the Nagoya Municipal Industrial Research Institute involving ultravioletray hardened polymers [1]. Over the years, this technique has been refined and 3D printing has become a staple in a multitude of fields including the automotive industry, construction, robotics, and medicine [2].

Over the past decade, computer-aided imaging software has allowed for 3D reconstruction of traditionally

two-dimensional imaging studies. These virtual reconstructions have been beneficial for preoperative diagnosis and planning and have even been shown to improve postoperative results [2]. The promising outcomes using virtual reconstruction have encouraged further research into the possible benefits of printing 3D models, which allows for physical assessment of the intended anatomic area.

The imaging study of the desired anatomic area is first retrieved then converted from the traditional DICOM filetype into a one that can be rendered as a 3D object. The subsequent 3D file is then edited to exclude artifacts and unwanted structures, and prepared for the printing process [3].

Surgeons, particularly orthopedists, are now capable of preparing anatomically accurate models to be used in pre-operative planning, as well as custom implants made to fit the patient's particular anatomy [4–6]. This has highlighted the possibility of relying on realistic printed models for the visualization of orthopedic deformities and fractures. Three-dimensional printing provides a novel method to analyze orthopedic complaints by adding a textile element that classical imaging methods cannot. Utilizing this technique has helped in reducing operative complications, has increased the likelihood of a successful operative outcome [7, 8], and may have profound educational benefits for both patients and upcoming healthcare providers [9, 10]. Figures 1, 2, 3, 4, and 5 show the use of 3D printing models in a case of lateral plateau tibial fracture treated with plate and screws.

Despite its significant presence in the relevant literature and the promising results, the use of 3D printing in the pre-operative planning of orthopedic surgeries remains controversial enough to not be a part of the usual preoperative workup. The aim of this meta-analysis was to look for significant differences in outcomes such as intraoperative blood loss, fluoroscopy use, anatomic fracture reduction and time to union between 3D printing-assisted methods and non-assisted methods.

Methods

Search strategy

An electronic search strategy was planned using the following databases from inception to Nov 2020: PubMed, Embase, CINAHL, Cochrane Library and Google Scholar. A number of terms were used to locate a maximum number of relevant studies: fracture AND (3D OR 3-dimensional OR three-dimensional) AND (printing OR "Virtual Windowing"). No language or date limitations were imposed.



Fig. 1 Pre-op reconstructed view



Fig. 2 3D print model AP view



Fig. 3 Post-operative AP view

Criteria for study selection

Only comparative randomized studies were accepted for inclusion. Any software or material using 3D printing versus no technological assistance were included. All types of fracture treated by open reduction and internal fixation were included.

Screening and selection of literature

Initial hit records were screened based on titles and abstracts and duplicates were removed. The full manuscripts of potentially relevant papers were read and inclusion/exclusion criteria were applied. Reference lists were checked for additional relevant studies. Disagreement on eligibility was resolved by consensus.

Unit of analysis and types of outcome measures

The unit of analysis was defined as the fracture, not the patient. The primary outcome was set to be the operative duration. Secondary outcomes were defined as intraoperative blood loss, fluoroscopy use, overall excellent/good results, anatomic fracture reduction and time to union. Fracture reduction was evaluated subjectively by the surgeons.

Data collection

In preparing this review, the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) checklist was used for guidance [11].

Data extraction

An Excel sheet for data extraction was prepared to report all relevant details reported in the studies. data Data extraction was conducted by three authors followed by a joint review to produce agreed accurate data. Patient demographic data, fracture site, surgical approach, internal fixation type, follow-up duration and outcomes were recorded.

Quality assessment

The Joanna Briggs Institute (JBI) critical appraisal tool for randomized trials was used to detect potential sources of bias [12].

Data analysis

Statistical analysis was conducted using StatsDirect (Cambridge, UK). Weighted standard mean difference was used for continuous variables and proportion meta-analysis for categorical variables was such as the weighted frequencies. Heterogeneity was assessed by the inconsistency test (I^2). The random-effect estimate was selected for reporting when the I^2 value was more than 50%. The reported confidence interval (CI) values were the 95% CI.

Results

Search results

The search yielded 593 record hits and eight duplicates were removed. Title and abstract screening of the remaining 585 papers led to locating 24 studies with relevant potential for inclusion. The examination of the full-text manuscripts isolated 12 studies meeting inclusion criteria. The 12 excluded studies were either prospective not randomized or retrospective comparative. An additional study was found through



Fig. 4 Post-operative lateral view

checking of the reference lists. In total, 13 RCTs were included in the review (Fig. 3. PRISMA Flow Diagram).

Study characteristics results

The total pooled sample comprised 673 patients: 325 and 348 in the 3D and control groups, respectively. The mean age was 42.1 ± 8.7 years and 42.6 ± 8.4 years for the 3D and control groups, respectively. Gender distribution was as follows: 269 females and 404 males.

The mean follow-up period was 14 ± 5 months and 14.4 ± 5.1 months for the 3D and control groups, respectively. Table 1 summarizes the characteristics of the included studies.

Outcomes

Intraoperative outcomes

Operative duration The weighted effect size was of -1.47 (95% CI = -1.759 to -1.182, $I^2 = 60.4\%$, P < 0.0001), in favor of the 3D group.

Intraoperative blood loss All studies but one [7] reported this outcome with a weighted difference of Shuang 1.41 (95% CI=Shuang 1.792 to Shuang 1.029, l^2 =77.7%, P<0.0001), in favor of the 3D group.

Fluoroscopy use Based on seven studies, the difference was Shuang 1.25 (95% CI= Shuang 1.637 to Shuang 0.867, $l^2 = 74.3\%$, P < 0.0001), in favor of the 3D group. Table 2 shows intra-operative outcomes of individual studies.

Postoperative outcomes

Rate of overall good or excellent result Five studies reported functional outcomes with a weighted OR of 2.05 (95% CI=1.119 to 3.845, $l^2 = 0\%$, P = 0.03) in favor of the 3D group.

Rate of anatomic fracture reduction Four studies yielded a weighted OR of 2.64 (95% CI=1.150 to 6.051, $I^2=0\%$, P=0.03) in favor of the 3D group.

Mean residual displacement Two studies reported this outcome. The mean displacement values of the 3D and control groups were 4.2 ± 0.7 mm and 5.8 ± 2.5 mm, respectively (*P*=0.2).

Time to union Based on three studies, the pooled difference was Shuang 0.008 (95% CI= Shuang 0.266 to 0.250, l^2 =33.6%, P=0.9). Table 3 show postoperative outcomes of individual studies.

Quality score

The mean JBI appraisal tool score for the randomized studies was 9, out of a maximum of 13 (Table 4).

Discussion

Main findings

The results of this review demonstrated the superiority of using 3D printing models in treating orthopedic fractures and that for major outcomes. All three per-operative outcomes, operative duration, intraoperative blood loss and





fluoroscopy use, were in favor of the 3D group. Additionally, the rates of excellent/good overall results and anatomic fracture reduction were significantly higher when compared to the control group.

Interpretation of the results

The use of 3D printing seems to be beneficial to the patients at many levels. Prolonged operative duration is associated with complications for any type of surgery irrespective of how an increase in operative time was defined [13]. In orthopedic surgery the same analysis demonstrated a statistically significant 67% increase in the likelihood of experiencing a complication with prolonged surgery duration. It is known that candidates for orthopedic surgery and in particular fracture surgery are often of senior age with associated co-morbidities and, therefore, more prone to complications [14, 15]. Additionally, when fixation needs plating, plate contouring could be carried out before tourniquet inflation, thus reducing operative time, and tourniquet time when it applies.

Some major orthopedic surgery procedures could result in a considerable intra-operative blood loss [16, 17]. An increase in the observed and hidden blood loss was significantly associated with medical complications following hip fracture surgery [18]. Orthopedic surgeons seem to underestimate the amount of blood loss occurring during surgery, and 80% of this loss may be unaccounted for by medical teams [19]. Blood loss during surgery could expose patients to postoperative anemia that might lead to a reduced functional recovery and a detrimental effect on long-term mortality [20]. Reducing intraoperative blood loss by using 3D printing technology could decrease postoperative anemiarelated complications.

A lack of radiation safety guidelines in orthopedic surgery residency curricula has been recorded while in some institutions, surgeons and residents may not have access to radiation-dose-tracking equipment [21]. Only 65% of orthopedic surgeons reported attending or participating in a radiation safety course at some point during their training [22]. Radiation exposure has quantifiable and deleterious manifestations which occur with dose-dependent severity [23, 24]. To this, the significant difference in fluoroscopy use found in the 3D printing group would be of great benefit to all the

Table 1 Characteris	stics of included studie	SS										
Studies	Area and type of	Treatment type	3D Software	3D Printer	Sam	ple size	Mean age		Gender	r (F/M)	Mean follow-	up (months)
	fracture				3D	Control	3D	Control	3D	Control	3D	Control
Zhang et al. (2015)	Schatzker III tibial plateau fractures	LISS plates and screws	Mimics 10.01 and SolidWorks	NR	14	18	46.1	46.8	10/4	13/5	NR	NR
Shuang et al. (2016)	Intercondular humeral fractures	Plates and cannu- lated screws	Mimics 11.1	(SRP400B, Huasen 3D Printing Research, Chang- zhou, China	9	٢	46±11.6	40.3±10.9	2/4	1/6	10.6	
Yang et al. (2016)	Trimalleolar	Plates and screws	Mimics 10.01	(FlashForge Ltd., ZhengJiang, China)	15	15	36.5		14/16		NR	
You et al. (2016)	Complex proximal humeral fractures	Plates and screws	Mimics 16.0	NR	34	32	66.09±4.09	66.28 ± 4.1	19/15	20/12	22.38±4.57	22.19±4.91
Yang et al. (2017)	Elbow fractures	Plates and screws	Mimics 10.01	(FlashForge Ltd., ZhengJiang, China)	20	20	38.6		12/28		10.6	
Chen et al. (2018)	Lunate fossa frac- tures	Volar locking plates and screws	Mimics 10.01	(3D ORTHO Waston Med Inc., Changzhou, Jiangsu, China)	52	55	27.69±6.64	29.15±6.86	22/30	20/35	13.08±0.78	13.07 ± 0.79
Maini et al. (2018a)	Acetabular frac- tures	Plates and screws	Mimics and 3-Matic	NR	12	13	38.25	40.38	1/11	1/12	NR	
Maini et al. (2018b)	Acetabular frac- tures	Plates and screws	Mimics 8.13	(EOSINT P380, EOS, Birming- ham, UK)	10	11	38.3	39.09	1/9	2/9	NR	
Zheng et al., 2018a	Calcaneal fractures	Plates and screws	Mimics 17.0 and Cura 15.02	(3D ORTHO Waston Med Inc. Changzhou, Jiangsu, China)	35	40	44.5±8	46.7±6.2	16/19	15/25	14.7±2.0	14.9±1.9
Zheng et al. (2018b)	Humeral Intercon- dylar fractures	Plates and screws	Mimics 15.0	(3D ORTHO Waston Med Inc. Changzhou, Jiangsu, China)	43	48	44.7 ± 4.8	44.5±4.5	19/24	23/25	15.3±2.0	15.7±2.3
Zheng et al. (2018c)	Pilon fractures	Plates and screws	Mimics 17.0 and Cura 15.02	(3D ORTHO Waston Med Inc. Changzhou, Jiangsu, China)	45	48	41.2±9.3	42.5±9.0	10/35	17/31	20.5 ± 3.7	19.9±3.3
Chen et al. (2019)	AO type C distal radial fractures	Plates and screws	Mimics 10.01	(3D ORTHO Waston Med Inc. Changzhou, Jiangsu, China)	23	25	38.7±13.6	40±11.4	9/14	8/17	13.0±0.7	13.1±0.7
Kong et al. (2020)	Intraarticular distal radial fractures	Volar plates and screws	Mimics 18.0	NR	16	16	41.1 ± 6.4	42.8±5.1	6/10	6/L	6	

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Table 2 Operative outco	mes of individual studies					
Studies	Operation duration (mi	nutes)	Intraoperative blood loss (mL)		Fluoroscopy use	
	3D	Control	3D	Control	3D	Control
Zhang et al. (2015)	80.29 ± 4.81	90.67 ± 3.03	95.71 ± 13.99	131.67 ± 16.18	NR	NR
Shuang et al. (2016)	70.6 ± 12.1	92.3 ± 17.4	NR	NR	NR	NR
Yang et al. (2016)	71 ± 23	98 ± 20	65±26	90 ± 38	NR	NR
You et al. (2016)	77.65 ± 8.09	92.03 ± 10.31	235.29 ± 63.40	281.25 ± 57.85	7.12 ± 1.57	10.59 ± 1.36
Yang et al. (2017)	61 ± 13	82 ± 22	47 ± 16	69 ± 28	NR	NR
Chen et al. (2018)	56.58 ± 4.74	65.73 ± 6.02	39.25 ± 8.72	52.95 ± 9.78	4.85 ± 1.39	5.85 ± 1.64
Maini et al. (2018a)	111	119	467	525	NR	NR
Maini et al. (2018b)	132	120	620	720	NR	NR
Zheng et al. (2018a)	71.4 ± 6.8	91 ± 11.2	226.1 ± 22.6	288.7 ±34.8	5.6 ± 1.9	8.6±2.7
Zheng et al. (2018b)	76.6 ± 7.9	92.0 ± 10.5	231.1 ± 18.1	278.6 ± 23	5.3 ± 1.9	8.7±2.7
Zheng et al. (2018c)	74.1 ± 8.2	90.2 ± 10.9	117.1 ± 20.7	159.8 ± 26.5	7.6 ± 2.2	11.0 ± 2.9
Chen et al. (2019)	66.5 ± 5.3	75.4 ± 6.0	41.1 ± 7.5	54.2 ± 7.9	4.4 ± 1.4	5.6 ± 1.6
Kong et al. (2020)	51.4 ± 6.8	63.5 ± 5.9	52.3±9.9	74.2 ± 10.3	4.2 ± 1.3	5.6±1.1

Studies	Rate of overall good o	or excellent result	Rate of Fracture Rec	luction	Mean residual displ	acement (mm)	Time to union (months)	Time to union (months)
	3D	Control	3D	Control	3D	Control	3D	Control
Zhang et al. (2015)	NR	NR	NR		NR		NR	NR
Shuang et al. (2016)	83.1%	71.4%	NR		NR		NR	NR
Yang et al. (2016)	NR	NR	NR		NR		NR	NR
You et al. (2016)	NR	NR	NR		NR		2.1 ± 0.25	2.1 ± 0.3
Yang et al. (2017)	83.1%	71.4%	95.0%	90.0%	NR		NR	NR
Chen et al. (2018)	No significance using scores, postop wrist radiological condition	g Gartland–Werley t active motion, and on	NR		NR		NR	NR
Maini et al. (2018a)	NR	NR	75%	61.5%	3.76	4.09	NR	NR
Maini et al. (2018b)	NR	NR	80%	63.6%	4.75	7.6	NR	NR
Zheng et al. (2018a)	88.6%	85%	NR		NR		3.0 ± 0.3	3.2 ± 0.4
Zheng et al. (2018b)	83.2%	77.1%	NR		NR		3.0 ± 0.3	3.1 ± 0.4
Zheng et al. (2018c)	93.3%	77.1%	91.1%	75%	NR		5.3 ± 1.2	5.0 ± 1.1
Chen et al. (2019)	No significance using scores, postop wrist radiological condition	g Gartland–Werley t active motion, and on	NR		NR		NR	NR
Kong et al. (2020)	No significance using ROM scores	g VAS, DASH, and	NR		NR		NR	NR

Table 3 Post-operative outcomes of individual studies

Table 4 Joar	1na Briggs Ins	stitute (JBI) cri	itical appraisal	tool for rande	omized contro	olled trials							
Items	Zhang et al. (2015)	Shuang et al. (2016)	Yang et al. (2016)	You et al. (2016)	Yang et al. (2017)	Chen et al. (2018)	Maini et al. (2018a)	Maini et al. (2018b)	Zheng et al. (2018a)	Zheng et al. (2018b)	Zheng et al. (2018c)	Chen et al. (2019)	Kong et al. (2020)
1. Was true randomiza tion used for assign- ment of participant to treatmer groups?	Yes s ut	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Was allocation to treatmer groups con cealed?	Unclear it	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
3. Were treatment groups similar at the base- line?	Yes	Yes	Unclear	Yes	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4. Were participant blind to treatment assign- ment?	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Yes	Unclear
5. Were thos delivering treatment blind to treatment assign- ment?	eNo	No	No	No	No	No	No	No	No	No	No	No	Ňo
6. Were outcomes assessors blind to treatment assign- ment?	Unclear	Unclear	Unclear	Unclear	Unclear	Yes	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear

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Table 4 (con	ttinued)												
Items	Zhang et al. (2015)	Shuang et al. (2016)	. Yang et al. (2016)	You et al. (2016)	Yang et al. (2017)	Chen et al. (2018)	Maini et al. (2018a)	Maini et al. (2018b)	Zheng et al. (2018a)	Zheng et al. (2018b)	Zheng et al. (2018c)	Chen et al. (2019)	Kong et al. (2020)
7. Were treatment groups treated identically other than the inter- vention of interest?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
8. Was follow up com- plete and if not, were differences between groups in terms of their follow up adequately described and ana- lyzed?	vYes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
 Were participants analyzed in the groups to which they were rand- omized? 	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
10. Were outcomes measured in the same way for treatment groups?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
11. Were outcomes measured in a reliable way?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Table 4 (cc	ntinued)												
Items	Zhang et al. (2015)	Shuang et al (2016)	. Yang et al. (2016)	You et al. (2016)	Yang et al. (2017)	Chen et al. (2018)	Maini et al. (2018a)	Maini et al. (2018b)	Zheng et al. (2018a)	Zheng et al. (2018b)	Zheng et al. (2018c)	Chen et al. (2019)	Kong et al. (2020)
12. Was	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
appropria statistical analysis used?	fe												
13. Was the trial desig	y Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
appropri- ate, and a	NU												
deviations) v												
from the													
standard													
RCT desi,	gn												
(individu	al												
randomiza	a-												
tion, para	-												
lel groups													
accountec	F												
for in the													
conduct													
and analy	,												
sis of the													
trial?													
Total of ''Yes''	6	6	8	6	8	10	6	6	6	6	6	10	6

medical staff present in the operating room and in particular to those close to the radiation beam.

The significant differences in favor of the 3D group with respect to the overall excellent/good results and anatomic fracture reduction rates are to be considered as added values to the 3D printing technique. For fractures in general and for articular fractures in particular, a better reduction of fracture site is linked with better outcomes. The printed models were shown to have the potential to optimize fracture site reduction with a potential of reducing long-term complications.

Based on two and three studies, respectively, residual displacement and time to union were not found to be different between groups. Further and big-sampled studies are warranted to better analyze these outcomes.

Limitations

Though the review included 13 randomized trials, many outcomes were not reported in all studies and for some of the results, the weighted estimates were based on fewer studies. Four studies have 15 participants or less in each arm group; however, the pooled sample of 673 patients could be considered as fair enough to look for significant differences in major outcomes. The inclusion of different fracture sites and consequently different approaches and fixation materials could be one of the major limitations of the study. On the other hand, the 3D software was almost the same but with different versions. We do not believe that the different printer types used to create the models could have impacted our results; nonetheless, materials that could be sterilized could offer more practicality during procedure. Another important limitation could be that functional results and rates of anatomic fracture reduction and residual displacement were reported in only some of the included studies; thus, the interpretation of those outcomes should be pondered. Blinding of assessment was reported in only one study and such could have introduced some bias to the results.

Conclusions

This technological marvel permits an in-depth analysis of the fracture and consequently planning surgical approach and adjusting fixation methods ahead of the surgery. When compared to the non-use of 3D technology for open reduction and internal fixation of fractures, the review demonstrated that 3D printing models yielded significantly better outcomes with respect to operative duration, blood loss, radiation exposure, anatomic fracture reduction rate and overall results rate. More studies are needed to explore other outcomes such as residual fracture displacement, time to union and long-term complications. In sum, our results should incite surgeons to use 3D models when treating fractures by open reduction and internal fixation, particularly those with high comminution or when the bone/joint anatomy is complex.

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Declarations

Conflict of interest The authors report no conflict of interest.

Ethics approval This research does not require an institutional review board approval.

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