# The efficacy of 3D printing-assisted surgery for traumatic fracture: a meta-analysis

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## ABSTRACT

**Background** Recent years have witnessed a rapid development of three-dimensional (3D) printing technology applied in orthopaedic surgery. To be assisted by 3D printing is a potent method to realise accurate and individualised operation. The objective of this meta-analysis was to assess the efficacy of 3D printing technology in the management of trauma fractures.

**Methods** PubMed, Embase and the Cochrane Library were systematically searched up until January 2019 to identify relevant studies. All clinical studies comparing conventional surgery and 3D printing-assisted surgery in the management of orthopaedic trauma were obtained. The meta-analysis was performed with RevMan V.5.3 software.

**Results** Four randomised controlled trials, four retrospective comparative studies and two prospective comparative studies involving 521 patients were included. Compared with conventional surgery, 3D printing-assisted surgery leads to shorter operation duration (mean difference (MD) −16.59 (95% CI −18.60 to −14.58), p<0.001), less intraoperative blood loss (standardised mean difference (SMD) −1.02 (95% CI −1.25 to −0.79), p<0.001) and fewer intraoperative fluroscopies (SMD −2.20 (95% CI −2.50 to −1.90), p<0.001). However, 3D printing-assisted surgery leads to longer hospital stay (MD 2.51 (95% CI 0.31 to −4.72), p=0.03). No significant results were found regarding fracture healing time, the rate of excellent and good outcomes, anatomical reduction and complications.

**Conclusions** These results suggest that 3D printing-assisted surgery outperforms conventional surgery in the management of orthopaedic trauma fractures with shorter operation duration, less intraoperative blood loss and fewer intraoperative fluoroscopies.

## INTRODUCTION

As one of the leading causes of global mortality and disability, traumatic fracture places a tremendous burden on healthcare systems around the world.[1] It is usually caused by accidents and fierce dynamic forces. Furthermore, complex injury mechanisms lead to various types of fractures of different bones, making the management complicated. The aims of traumatic fracture treatment are anatomical reduction and rigid fixation,[2] whereby conservative treatment can be considered in many fractures, while a large number of fractures require operative treatment.[3]

Conventional surgery has some drawbacks. Surgeons, making preoperative planning based on X-ray, CT and MRI radiographs, only have vague insight into the shape of the fracture due to the two-dimensional (2D) nature of images. Complete exposure of the surgical site and contouring of fixation plates intraoperatively after reducing fracture are unavoidable. This increases the invasiveness of surgery, which inevitably leads to unnecessary tissue damage, and increased haemorrhage and operation time.[4] In consequence, the outcome of those treatments is still far from satisfaction, and excellent outcomes always rely on senior surgeons' experience, which cannot be acquired before going through a long learning curve.

To present direct and interactive display of fracture characteristics to surgeons, three-dimensional (3D) printing technology based on CT postprocessing has become one of the main advanced methods of preoperative planning.[5 6] A 3D printed model enables accurate remodelling of detailed fractures based on imaging data, making it possible to perform virtual procedures in vitro, such as fracture reduction, and is conducive to setting up a complete preoperative plan.[7] 3D printing is a potent method in terms of realising accurate and individualised surgery, and recent years have witnessed a growing number of attempts in this field. However, it is not clear whether patients with traumatic fracture can benefit from 3D printing-assisted surgery compared with traditional surgery in several key outcome domains, such as success of operation, risk of complications and financial burdens of hospital stay. Therefore, it is essential to perform a systematic review and meta-analysis for clarification.

## METHODS

This study was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines,[8] as well as the Cochrane Handbook for Systematic Reviews of Interventions (V.5.0.2).

### Literature search

To obtain relevant literature for this meta-analysis, we systematically searched the electronic databases of PubMed, Embase and the Cochrane Library through January 2019. We performed a literature search using both text word and Medical Subject Headings strategies with the terms '3-dimensional or 3D or computer-aided or rapid prototyping', 'printing or printer', 'traumatic', 'fracture', 'management or treatment' and 'fixation or plate'. In the retrieval process, a manual search was conducted to identify additional studies. Requests were emailed to the authors when supplementary information and essential data were needed.



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**Table 1** Characteristics of all the studies included in this meta-analysis

| Study | Year | Country | Study design | Patients (n) | Gender (M/F) | Length of follow-up (month, mean) | Site of fracture | Length of operation (min, mean) | Blood loss (mL, mean) |
|---|---|---|---|---|---|---|---|---|---|
| Hung *et al*[16] | 2018 | China | RCs | 16 (G1)<br>14 (G2) | 18/12 | 24.3 | Anterior pelvic ring fracture | 206.13 (G1)<br>276.21 (G2) | 275.00 (G1)<br>549.29 (G2) |
| Shuang *et al*[18] | 2016 | China | RCT | 6 (G1)<br>7 (G2) | 10/3 | 10.6 | Intercondylar humeral fractures | 70.6 (G1)<br>92.3 (G2) | NA |
| Maini *et al*[17] | 2017 | India | RCT | 12 (G1)<br>13 (G2) | 23/2 | NA | Acetabulum fracture | 111 (G1)<br>119 (G2) | 467 (G1)<br>525 (G2) |
| Yang *et al*[20] | 2017 | China | RCT | 20 (G1)<br>20 (G2) | 28/12 | 10.6 | Elbow fracture | 61 (G1)<br>82 (G2) | 47 (G1)<br>69 (G2) |
| Cai *et al*[13] | 2018 | China | RCs | 65 (G1)<br>72 (G2) | 82/55 | 9 | Unstable pelvic fracture | 58.63 (G1)<br>72.38 (G2) | NA |
| Wang *et al*[19] | 2018 | China | RCs | 21 (G1)<br>25 (G2) | 14/32 | 17.8 | Humeral shaft fracture | 42.62 (G1)<br>60.36 (G2) | 105.19 (G1)<br>120.80 (G2) |
| Giannetti *et al*[15] | 2016 | Italy | PCs | 16 (G1)<br>24 (G2) | 22/18 | 13.3 | Tibial plateau fractures | 148.2 (G1)<br>174.5 (G2) | NA |
| Zheng *et al*[22] | 2017 | China | PCs | 19 (G1)<br>20 (G2) | 22/17 | 6 | Intertrochanteric fracture | 46.27 (G1)<br>60.58 (G2) | 98.35 (G1)<br>162.57 (G2) |
| You *et al*[21] | 2016 | China | RCT | 34 (G1)<br>32 (G2) | 27/39 | 22.3 | Proximal humeral fracture | 77.65 (G1)<br>92.03 (G2) | 235.29 (G1)<br>281.25 (G2) |
| Chen *et al*[14] | 2018 | China | RCs | 32 (G1)<br>53 (G2) | 22/63 | 26.4 | Proximal end of the humerus fracture | 61.5 (G1)<br>80.4 (G2) | 83.1 (G1)<br>100.5 (G2) |

G1, 3D printing group; G2, conventional treatment group; M/F, male/female; NA, not available; PCs, prospective comparative study; RCT, randomised controlled trial;RCs, retrospective comparative study.

## Inclusion and exclusion criteria

After duplicates were removed, the titles and abstracts of all records retrieved by the search were assessed independently by two authors (LX and ZC). Any disagreements were resolved by discussion and arbitration by a senior author (HL). After initial screening of these abstracts, two authors (LX and ZC) assessed the remaining full-text articles for inclusion in the study. This study considered inclusion of randomised controlled trials (RCTs), prospective comparative studies (PCs) and retrospective comparative studies (RCs) to compare the efficacy of 3D printing-assisted surgery and conventional surgery in the management of traumatic fractures. The outcomes used in this study to measure the efficacy were operation duration, intraoperative blood loss, number of fluoroscopies, fracture union time, the rate of anatomical reduction and excellent outcomes, complication rate and length of hospital stay. Inclusion criteria were studies in humans with the aim of comparing 3D printing-assisted and conventional surgery in the management of traumatic fractures. Exclusion criteria used in this study were (1) case reports, technical reports, animal studies, in vitro studies, reviews and commentaries; (2) studies of other types of fractures; (3) studies providing insufficient data and (4) articles not in English.

## Data extraction

Two authors (LX and XL) independently extracted data from each included study. Any discrepancies were resolved by a third author (ZC). The following information was extracted from each study: the first author's name, year of publication, country, study design, sample size, gender, length of follow-up result of operation time, intraoperative blood loss, number of fluroscopies, fracture union time, the rate of excellent outcomes, the rate of anatomical reduction, complication rate and the duration of hospital stay.

## Quality assessment

Three investigators (LX, HL and XL) independently assessed the methodological quality of RCTs on the Risk of Bias Tool recommended by the Cochrane Collaboration.[9] The methodological quality of PCs and RCs are assessed on the Newcastle-Ottawa Scale.[10] Any disagreements were discussed with the corresponding author (TX) to reach consensus. The PCs and RCs with scores of >6 are regarded as high quality.

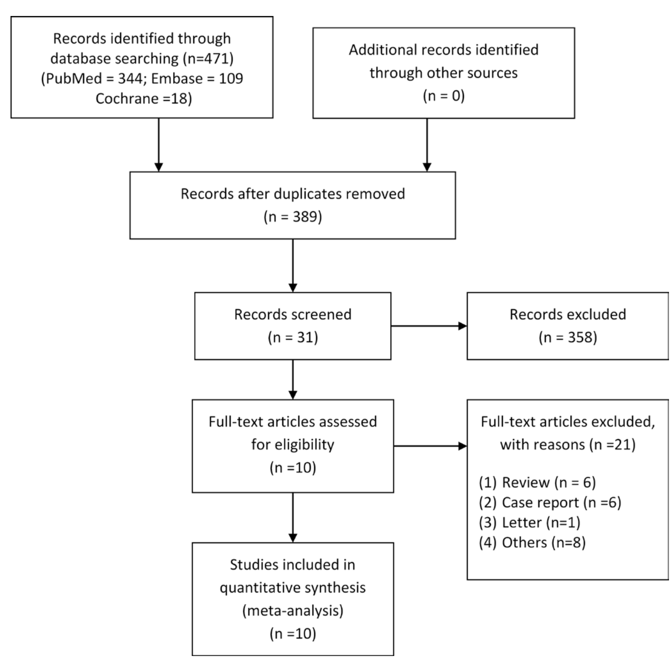


**Figure 1** A Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart of study selection.



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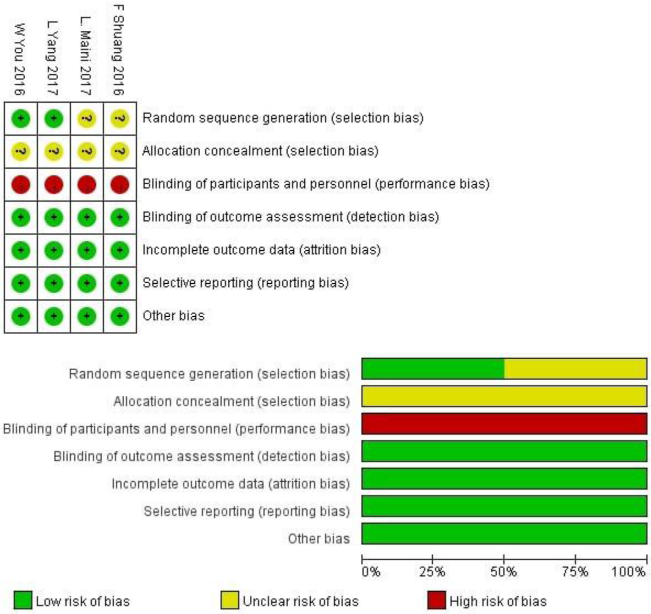


**Figure 2** Risk of bias assessment of the randomised controlled trials.

## Statistical analysis

OR was used as summary statistics for dichotomous variables. ORs were reported with 95% CIs, and statistical significance was set to $p<0.05$. For continuous data, mean difference (MD) was calculated with the 95% CI as a summary statistic. Standardised mean difference (SMD) was used when variables were not reported on the same scale of measurement or the SD of included studies varied over 10 times. Mantel-Haenszel method was used for dichotomous outcome variables. Inverse variance method was used for continuous outcome variables. Zero cell counts would be automatically checked and a 0.5 added to all cells in RevMan when inverse variance method was used. For the Mantel-Haenszel method, zero-cell corrections would be used only if the same cell was zero in all the included studies. Statistical heterogeneity between included studies was evaluated by $I^2$ and $\chi^2$ tests with significance set at $p<0.10$. $I^2$ values of 25%, 50% and 75% were considered low, medium and high heterogeneities, respectively.[11] Random-effects or fixed-effects model was used, depending on the heterogeneity of the study. Egger's linear regression test[12] was used to assess the possibility of publication bias. To validate the credibility of outcomes in this meta-analysis, sensitivity analysis was performed by omitting every included study at a time to reflect the impact of individual data sets on the results. Subgroup analysis was also performed based on the type of fractures (limbs fractures vs trunk fractures to identify potential differences between 3D printing-assisted and conventional surgery across trials). Data analysis was performed with Review Manager V.5.3 (The Cochrane Collaboration, London, UK).

## RESULTS

### Literature search

In total, 679 candidate publications were identified, and then 386 were excluded due to duplications. Following that, further 275 publications meeting exclusion criteria were excluded. After assessing the 18 potentially relevant articles, 10 studies[13–22] were enrolled in this meta-analysis. The reasons for excluding the relevant eight studies were (1) four[23–26] came from the same study group as Cai *et al*'s study,[13] (2) one study[27] came from the same study group as Yang *et al*'s study,[20] (3) one study[28] was from the same study group as Maini *et al*'s study,[17] (4) one study[29] was in unavailability of original usable data and (5) one study[30] provided abnormal data in their results.

### Study characteristics and methodological quality

The characteristics of all 10 included studies are summarised and shown in table 1. Four out of 10 studies are RCTs,[17 18 20 21] 2 are PCs[15 22] and 4 are RCs.[13 14 16 19] Fractures investigated in these 10 studies include pelvic fracture, intercondylar humeral fracture, elbow fracture, proximal humeral fracture, humeral shaft fracture, intertrochanteric fracture and tibial plateau fracture. All the included trials studied operation duration, seven trials compared blood loss in the operation, three trials assessed intraoperation fluoroscopies, three trials evaluated the fracture healing time, two trials evaluated the rate of excellent outcomes, two trials evaluated the rate of anatomical reduction, five trials studied complications and two trials evaluated the duration of hospital stay. The details of study selection are presented in figure 1, all of which were published between 2016 and 2018. Five hundred twenty-one patients were enrolled in this meta-analysis. Risk of bias assessment of RCTs is presented in figure 2. Two studies that explicitly used random sequence generation were considered of high quality, and the other two studies were of moderate quality. When using the Newcastle-Ottawa Scale to assess the risk of bias of the PCs and RCs, the final scores were all higher than 6, indicating low risks of bias (online supplementry tables S1 and S2).

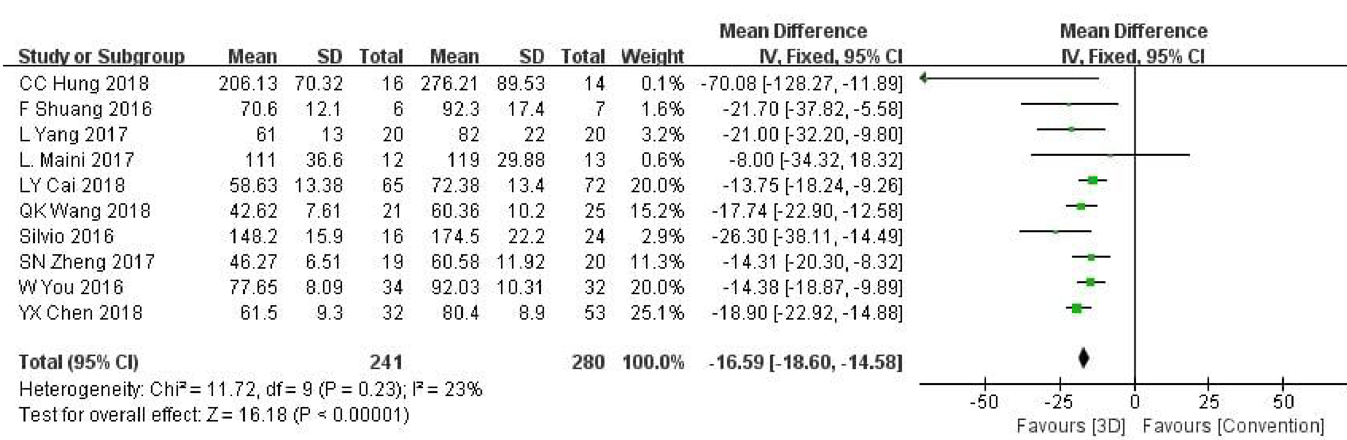


**Figure 3** Forest plot of analysis for operation time. 3D, three dimensional; IV, Inverse Variance.



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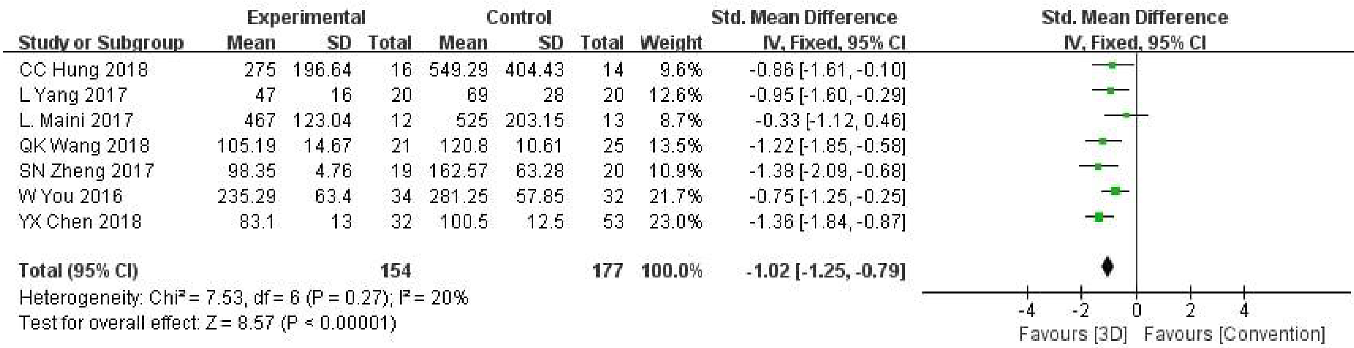


**Figure 4** Forest plot of analysis for intraoperative blood loss. 3D, three dimensional; IV, Inverse Variance.

## Operation duration

All of the included studies[13–22] involving a maximum of 521 patients reported results for length of operation. The fixed-effects model was used for low heterogeneity ($I^2$=23%, p=0.23) . The result showed a significantly shorter operation duration in 3D printing-assisted surgery than in conventional surgery, with the pooled MD being −16.59 (95% CI −18.60 to −14.58, p<0.001; figure 3). No substantial asymmetry was identified in the funnel plot (online supplementry figure S3). Meanwhile, the pooled MD was −17.29 (95% CI −19.55 to −15.03, p<0.001) in limb fractures[14 15 18–22] without significant heterogeneity($I^2$=3%, p=0.41) and was −13.91 (95% CI −18.33 to −9.50, p<0.001) in pelvic fractures[13 16 17] with mild heterogeneity ($I^2$=47%, p=0.15). Data from RCTs included four studies, with a corresponding MD being −15.52 (95% CI −19.51 to −11.53, p<0.001) with no heterogeneity ($I^2$=0%, p=0.56). Data from six non-RCT studies showed an MD of −16.96 (95% CI −19.28 to −14.63, p<0.001) with mild heterogeneity ($I^2$=46%, p=0.10).

## Blood loss

Seven studies[14 16 17 19–22] provided available data on operation blood loss, and the pooled results demonstrated that the 3D printing-assisted surgery group had significantly less blood loss than the conventional surgery group (SMD=−1.02, 95%CI −1.25 to −0.79, p<0.001; $I^2$=20%, p value for heterogeneity=0.27; figure 4). In RCTs, data were presented from three studies, showing an SMD of −0.72 (95% CI −1.08 to −0.37, p<0.001; $I^2$=0%, p=0.50). In non-RCTs, data from four studies showed an SMD of −1.25 (95% CI −1.55 to −0.94, p<0.001; $I^2$=0%, p=0.71).

## Number of fluoroscopies

Three studies[13 14 21] provided available data on the number of fluoroscopies during surgery, and the pooled outcomes demonstrated that the 3D printing-assisted surgery group had fewer fluoroscopies than the conventional surgery group (SMD=−2.20, 95%CI −2.50 to −1.90, p<0.001; $I^2$=0%, p=0.64; figure 5). Data from two non-RCTs showed an SMD of −2.16 (95% CI −2.50 to −1.83, p<0.001; $I^2$=0%, p=0.41).

## Fracture union time

Three studies[13 19 21] provided available data concerning fracture union time, and the pooled outcomes demonstrated that there was no significant difference between the groups (SMD=0.09, 95%CI −0.29 to 0.47, p=0.63; $I^2$=51%, p=0.13; online supplementry figure S4A). Two non-RCT studies showed an SMD of 0.18 (95% CI −0.32 to 0.96, p=0.48; $I^2$=57%, p=0.13).

## The rate of excellent outcomes

Two studies[13 18] provided available data, and the pooled results demonstrated that there was no significant difference between the two groups (OR=1.17, 95%CI 0.59 to 2.33, p=0.65; $I^2$=0%, p=0.50; online supplementry figure S4B).

## The rate of anatomical reduction

Two studies[17 20] provided available data, and the pooled results demonstrated that there was no significant difference between the groups (OR=2.29, 95%CI 0.55 to 9.45, p=0.25; $I^2$=0%, p=0.94; online supplementry figure S4C).

## Complication rate

Five studies[14–16 18 20] provided available data concerning complication rate, and the pooled results demonstrated that there was no significant difference between the groups (OR=0.59, 95%CI 0.24 to 1.45, p=0.25; $I^2$=0%, p=0.67; online supplementry figure S4D). Two RCTs showed an OR of 0.41 (95% CI 0.08 to 2.06, p=0.28). Data from three non-RCTs showed an OR of 0.70 (95% CI 0.24 to 2.05, p=0.52).

## Length of hospital stay

Two studies[14 22] compared the length of hospital stay between 3D printing-assisted surgery and conventional surgery.

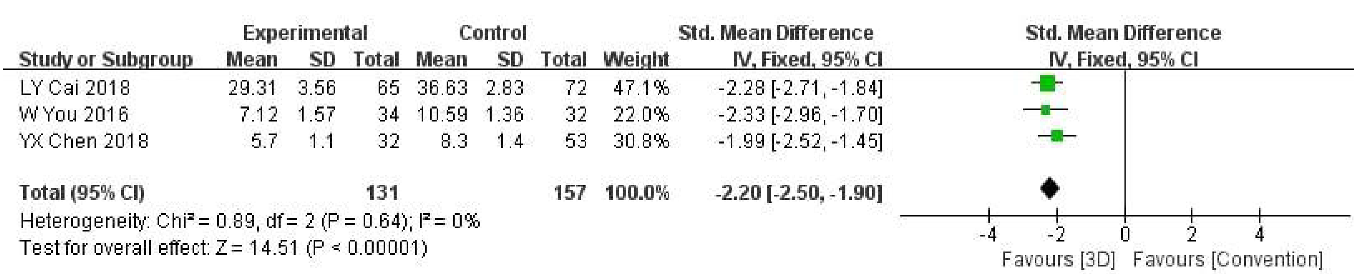


**Figure 5** Forest plot of analysis for number of fluoroscopies. 3D, three dimensional; IV, Inverse Variance.



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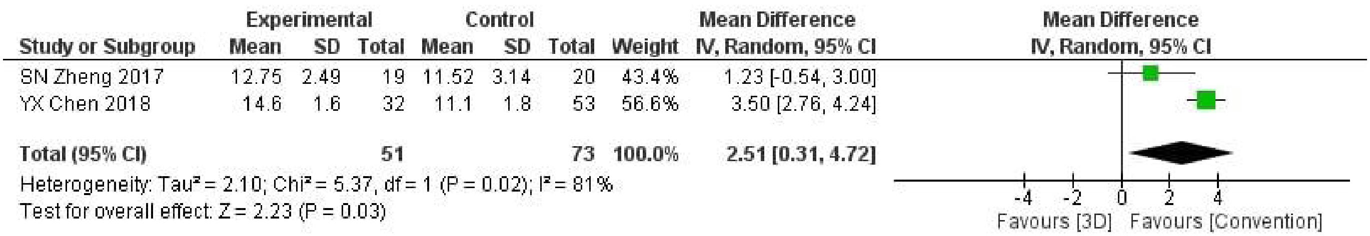


**Figure 6** Forest plot of analysis for the duration of hospital stay. 3D, three dimensional; IV, Inverse Variance.

Random-effects model was used for high heterogeneity ($I^2$=81%, p=0.02). The result showed that the length of hospital stay in the 3D printing-assisted surgery group is longer than that in the conventional surgery group, with the pooled MD being 2.51 (95% CI 0.31 to 4.72, p=0.03; figure 6).

## DISCUSSION

It is reported that traumatic fractures account for a major drain on healthcare resources.[31] Most traumatic fractures require surgery, and the main focus is to stabilise fractured bone and restore the length and alignment concurrently, allowing for weight bearing and functional exercise sooner.[3] In conventional surgery, orthopaedists come up with surgical plans mainly based on 2D radiograph. However, traumatic fractures, especially comminuted fractures, are always hard to display authentically on 2D images. Once the intraoperative finding is not consistent with preoperative imaging outcomes, orthopaedists have to change surgery plans based on their clinical experience, which can possibly lead to many unexpected outcomes, for instance, prolonged operation time, increasing blood loss, aggravating soft tissue injury and even the rising possibility of procedure failure. On the other hand, an authentic preoperative 3D printing model allows surgeons to rehearse procedures in vitro. They are able to predict the problems that may be encountered intraoperatively, which helps orthopaedists realise the goal of surgery of precision and individualisation.[32]

To date, this is the first meta-analysis to comprehensively evaluate the efficacy of 3D printing-assisted surgery in the treatment of traumatic fracture. Two meta-analyses have studied this problem only on site-specific fractures.[19 33] Our meta-analysis demonstrated that 3D printing-assisted surgery has great advantages over the conventional counterpart regarding the operation time, intraoperative blood loss and number of fluoroscopies. However, the 3D printing-assisted group had a longer duration of hospital stay than the conventional surgery group, which could result from longer preoperative preparation for 3D printing. However, the high heterogeneity could not be ignored, which might be attributed to the study design. No significant difference was detected between the two groups concerning fracture union time, the rate of anatomical reduction, excellent outcomes and complication. In the literature retrieval process, we found that some studies came from one research group in a similar time. Hence, we selected only their latest study in order to reduce an excessive influence from one institution, which may bias the combined result. We also excluded Lou's study, which was the major source of heterogeneity in some analyses. In Lou's study, the values of SD of operation time and intraoperative blood loss were abnormally small, which we thought was hard to achieve in practice. The result of Egger's linear regression test suggested that no publication bias existed in the analysis of operation time. Besides, the application of the trim-and-fill test did not change the average effect size, further suggesting that the result was not affected by publication bias.

There are some limitations in our study though. First, 6 out of 10 included studies were not RCT, which decreased the robustness of the conclusions. Although we did subgroup analyses based on study design, bias may still exist in the outcomes. Second, with no primary outcome reported, the incidence of both type I and type II errors was potentially enhanced. Third, there were several different types of fractures included in our study, which may have affected the reliability of our results. Fourth, some of our analyses enrolled only two or three studies since not all of them provided sufficient data on every outcome. Besides, due to the limited number of included studies, publication bias test was only conducted in the analysis of operation time. Additionally, due to insufficient number of included studies, we did not conduct metaregression to analyse the source of high heterogeneity of the length of hospital stay. As 3D printing technology is in rapid development, we will have more and better studies comparing the relative efficacy and convenience between 3D printing-assisted surgery and conventional surgery in the future, so as to provide a clearer guidance for clinicians to select a rational preoperative plan for traumatic fractures.

### Main messages

- ► 3D printing-assisted surgery outperforms conventional surgery in the management of traumatic fractures.
- ► 3D printing-assisted surgery leads to shorter operation duration, less intraoperative blood loss, and fewer intraoperative fluoroscopies compared with conventional surgery.

### Current research questions

- ► Does 3D printing-assisted surgery have strengths over conventional surgery in optimising clinical outcome of trauma fracture patients?
- ► Well-designed, large-volume randomised controlled trials with extensive follow-ups are required.
- ► Will 3D printing-assisted surgery prove to be cost-effective?

### What is already known on the subject

- ► 3D printing technology based on CT post-processing has become one of the main advanced methods of preoperative planning.
- ► 3D printing is a potent method in terms of realizing accurate and individualised surgery.



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Overall, our meta-analysis demonstrates that 3D printing-assisted surgery showed significant advantages in shortening the duration of operation, reducing the amount of intraoperative blood loss and the number of fluoroscopies, compared with conventional surgery in the management of traumatic fractures. Although 3D printing-assisted surgery had strengths over conventional practice concerning the rate of excellent outcomes, anatomical reduction and complication, there were no significant differences between the two groups. However, patients with traumatic fracture who had 3D printing-assisted surgery did have a significantly longer duration of hospital stay than those who had conventional surgery, which may add some financial burdens to certain patients.

## CONCLUSIONS

Our study suggests that 3D printing-assisted surgery outperforms conventional practices in the management of orthopaedic trauma fractures with shorter operation duration, less intraoperative blood loss and fewer intraoperative fluoroscopies.

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**Contributors** LX planned the study and wrote the manuscript. LX and XL conducted the statistical analysis and revised the manuscript. ZC performed statistical analysis. HL examined the data and included studies. TX supervised the study.

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**Competing interests** None declared.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** All data relevant to the study are included in the article or uploaded as supplementary information.

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