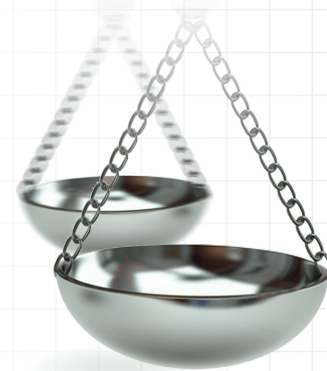




The efficacy of 3D printing-assisted surgery in treating distal radius fractures: systematic review and meta-analysis

Journal of **Comparative Effectiveness Research**

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Aim: To compare the efficacy of 3D printing-assisted surgery with routine surgery in the treatment of distal radius fractures to evaluate whether 3D printing technology has more advantages. **Materials & methods:** To retrieve all published studies that compared the efficacy of 3D printing-assisted surgery with routine surgery for distal radius fractures. Operation time, frequency of intraoperative fluoroscopy, blood loss and other outcomes were assessed. **Results:** The results suggested that 3D printing-assisted surgery was better than routine surgery in the fields of operation time, frequency of intraoperative fluoroscopy, and blood loss. **Conclusion:** In the treatment of distal radius fractures, 3D printing-assisted surgery may be superior to routine surgery.

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Keywords: 3D printing • blood loss • distal radius fractures • intraoperative fluoroscopy • meta-analysis • operation time • surgery • systematic review

Distal radius fracture is one of the most common upper limb fractures, accounting for approximately 1.5% of emergency department cases [1–3]. Distal radius fractures occur more frequently in older and younger adults [4]. Osteoporosis is the main cause of distal radius fractures in the elderly, and the prognosis is good after routine treatment [5]. High-energy collisions are a common cause of such fractures in young patients [6]. Because of this, such fractures require surgical treatment to heal young patients. High-energy collisions lead to significant displacement of fractures, and surgical treatment is more effective in anatomical reduction and fixation [7]. In rare cases, conservative treatment may result in malunion, leading to a poor prognosis [8–10].

Conventional surgical treatment of distal radius fractures sometimes causes complications such as extensor and flexor tendon irritation, carpal tunnel syndrome and complex regional pain syndrome [11]. A small number of patients may also have complications such as poor alignment, nonunion and malunion [12–14]. As 3D printing technology has become more and more mature, it has been widely used in orthopedics [15]. This technology is based on the imaging data of patients, and the original fracture model is established with a 3D digital model [16]. Surgeons can use the model to simulate the surgical procedure and identify problems that may occur during surgery, thus improving surgical plans and reducing the incidence of postoperative complications [17]. Currently, there is a lack of meta-analyses comparing the efficacy of 3D printing-assisted surgery and routine surgery in the treatment of distal radius fractures. Therefore, this research analyzed the data to obtain clearer and more realistic results to guide clinical treatment.

Materials & methods

Search strategy

A detailed search for clinical studies was conducted in the major electronic databases, including PubMed, EMBASE, Web of Science, the Cochrane Library, Wan Fang data, CBM and CNKI, up to March 2020. There were no language restrictions. In addition, we searched the references contained in the relevant articles for potential studies. The keywords we used in the database searches included 'radius fractures', 'three-dimensional' and '3D printing'. These were combined using Boolean operators.

Inclusion & exclusion criteria

Studies were incorporated if they met the following criteria: patients were diagnosed with distal radius fracture; the study compared the efficacy of 3D printing-assisted surgery with that of routine surgery; studies were randomized controlled trials (RCTs), prospective comparative studies or retrospective comparative studies; the included Chinese studies had to have English titles and abstracts; the study included the following results: operation time, frequency of intraoperative fluoroscopy, blood loss, postoperative visual analogue scores (VAS), Gartland–Werley scores, excellent and good rate of wrist function, range of motion (ROM) and radiological outcomes. We excluded the following types of studies: other types of fractures; related data in study is incomplete; animal experiments; systematic reviews, meta-analyses, case reports, conference papers and studies which only had an abstract.

Data extraction

Two reviewers examined the included studies and extracted the main data including: name of the first author, publication year, recruitment year, country, groups, study design, sample size (males/females), patient age, distal radius fracture classifications, follow-up time and time from injury to surgery. The reviewers extracted the data independently and discussed any differences to reach a consensus.

Quality assessment

We used the Cochrane risk assessment scale to assess the quality of the RCTs, including random sequence generation, allocation concealment, blinding, selective outcome reporting, incomplete outcome data and other bias. The Methodological Index for Non-Randomized Studies (MINORS) was used to assess non-RCTs. Two reviewers evaluated the articles independently.

Statistical analysis

We performed statistical analysis using the RevMan 5.3 software (Cochrane Collaboration, Oxford, UK). Weighted mean difference (WMD) was used to pool continuous results and risk ratio was used to pool dichotomous result. We used 95% CI to estimate interval. $P \leq 0.05$ was considered statistically significant. We estimated the interval using 95% CI. I^2 statistics were used to assess statistical heterogeneity. $I^2 > 50\%$ indicated significant heterogeneity, used the random-effects model for the analysis, or else, used the fixed-effect model. In addition, sensitivity analysis was performed to identify the source of heterogeneity.

Results

Results of literature retrieval

The reviewers identified 204 published articles that were potentially relevant to our study. A total of 92 duplicate articles were excluded. By conducting preliminary screening of the titles and abstracts of the articles, 100 studies were excluded. After perusing the full text, six studies were excluded because they focused on osteotomy for malunion of distal radius fractures [18–23]. Finally, six studies were included in the meta-analysis [24–29]. The characteristics of the final included studies are shown in [Table 1](#). The literature retrieval process is shown in [Figure 1](#).

Study characteristics

Baseline characteristics of the selected studies were extracted, and are listed in [Table 1](#). The six studies involved a sample size of 15–55 patients and were published between 2017 and 2020. These studies were all performed in China.

Assessing the quality of the studies

We included five RCTs, all of which showed clear inclusion and exclusion criteria. Randomization methods were clearly described in all the RCTs included [24–28]. In one RCT, the researchers used opaque sealed envelopes to

Table 1. Characteristics of the included studies.

Study	Year	Recruitment	Country	Design	Groups	Sample size(M/F)	Age $\pm$ mean (years)	AO classification of fractures	Follow-up (month)	Time from injury to surgery (day)	Ref.
Chen <i>et al.</i>	2017	2013–2015	China	RCT	3D R	52(30/22) 55(35/20)	27.69 $\pm$ 6.64 29.15 $\pm$ 6.86	52 B1 55 B1	13.08 $\pm$ 0.78 13.07 $\pm$ 0.79	3.19 $\pm$ 1.70 3.15 $\pm$ 1.55	[24]
Tan <i>et al.</i>	2017	2015–2016	China	RCT	3D R	26(9/17) 29(16/13)	38.27 45.47	15 C1, 6 C2, 5 C3 13 C1, 9 C2, 7 C3	9~18	NR	[28]
Luo <i>et al.</i>	2018	2015–2017	China	RCT	3D R	15(9/6) 15(8/7)	41.80 $\pm$ 11.86 41.87 $\pm$ 9.52	10 C2, 5 C3 9 C2, 6 C3	6	NR	[27]
Xu <i>et al.</i>	2018	2015–2016	China	nonRCT	3D R	25(11/14) 25(13/12)	42.7 $\pm$ 1.9 43.6 $\pm$ 1.8	8 A, 8 B, 9 C 6 A, 13 B, 6 C	15~24	6.72 $\pm$ 0.27 4.88 $\pm$ 1.59	[29]
Chen <i>et al.</i>	2019	2014–2015	China	RCT	3D R	23(14/9) 25(17/8)	38.7 $\pm$ 13.6 40.7 $\pm$ 11.4	10 C1, 9 C2, 4 C3 11 C1, 11 C2, 3 C3	13.0 $\pm$ 0.7 13.1 $\pm$ 0.7	3.3 $\pm$ 1.8 3.7 $\pm$ 1.6	[25]
Kong <i>et al.</i>	2020	2017–2018	China	RCT	3D R	16(10/6) 16(9/7)	41.1 $\pm$ 6.4 42.8 $\pm$ 5.1	4 B, 12 C 5 B, 12 C	6	7	[26]
3D: Print-assisted surgery; F: Female; M: Male; R: Routine surgery; RCT: Randomized controlled trial; NR: Not reported.											

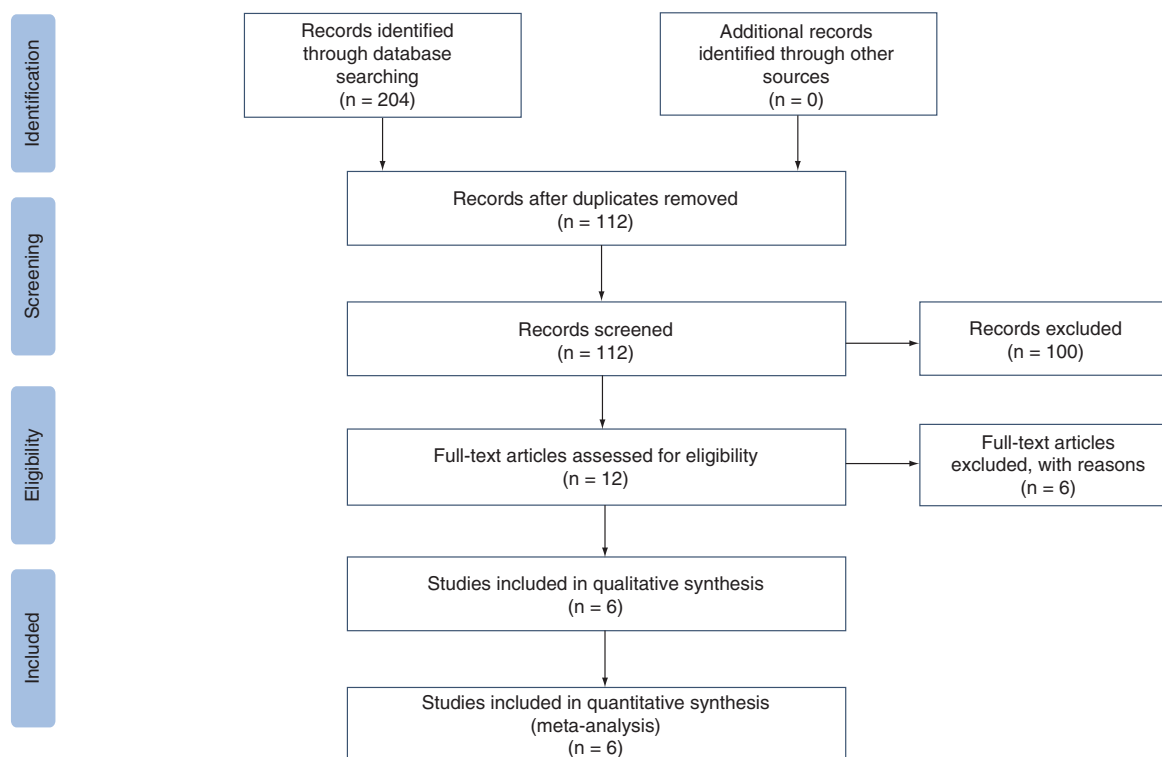


Figure 1. Flow chart of study selection.

Table 2. Quality assessment of the nonrandomized trial.

Quality assessment of the nonrandomized trials.	Xu <i>et al.</i> (2018)
A clearly stated aim	2
Inclusion of consecutive patients	2
Prospective data collection	2
End points appropriate to the aim of the study	2
Unbiased assessment of the study end point	2
A follow-up period appropriate to the aims of study	2
Less than 5% loss to follow-up	2
Prospective calculation of the sample size	0
An adequate control group	2
Contemporary groups	2
Baseline equivalence of groups	2
Adequate statistical analyses	2
Total score	22

perform the allocation concealment [26]. Three RCTs described details in blinding of participants and personnel [24–26]. Complete outcome indicators were reported in all RCTs. Detailed information of the study quality is shown in Figure 2. We used the MINORS scale to assess the quality of the non-RCT study, the detailed information of which is shown in Table 2.

Operation time

All studies reported on operation time [24–29], and as the heterogeneity among these studies was high ($I^2 = 97\%$), we performed a meta-analysis using a random-effects model. The results showed that the operation time of the 3D printing-assisted surgery group was significantly shorter (WMD = -14.52; 95% CI: -21.79 to -7.24; $p < 0.0001$) (Figure 3).

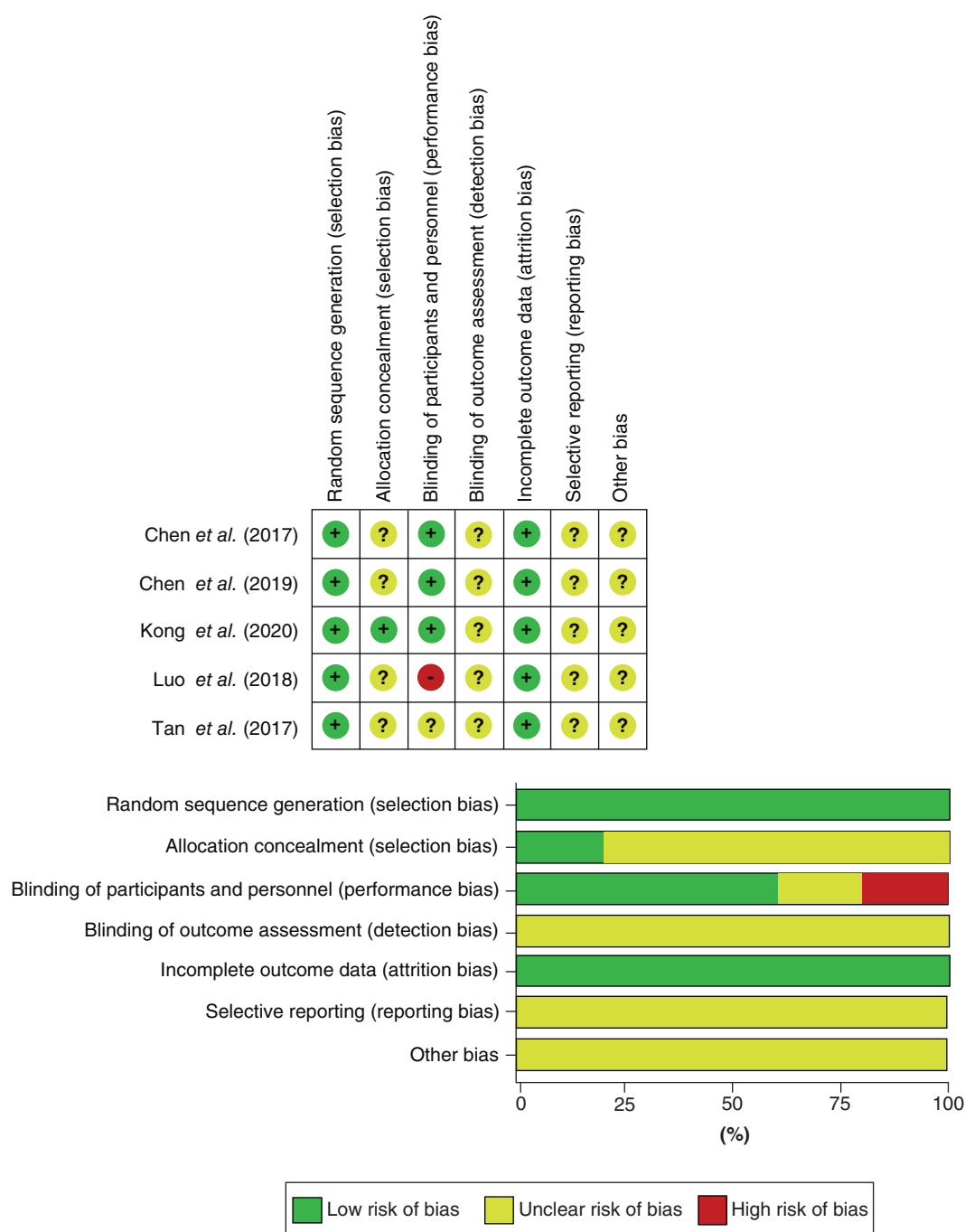


Figure 2. Quality assessment of the randomized controlled trials.

Frequency of intraoperative fluoroscopy

Five studies reported on frequency of intraoperative fluoroscopy [24–28], and the results showed that the frequency of intraoperative fluoroscopy for the 3D printing-assisted surgery group was significantly less (WMD = -2.14; 95% CI: -3.43 to -0.85; $p = 0.001$), and the heterogeneity among these studies was high ($I^2 = 95\%$; Figure 4).

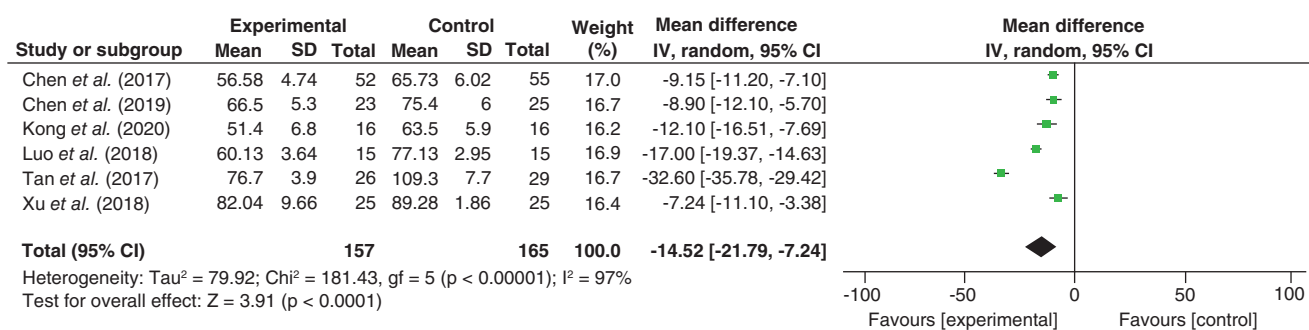


Figure 3. Comparison of operation time. Forest plot comparing operation time between the 3D printing-assisted surgery group and the routine surgery group.

SD: Standard deviation.

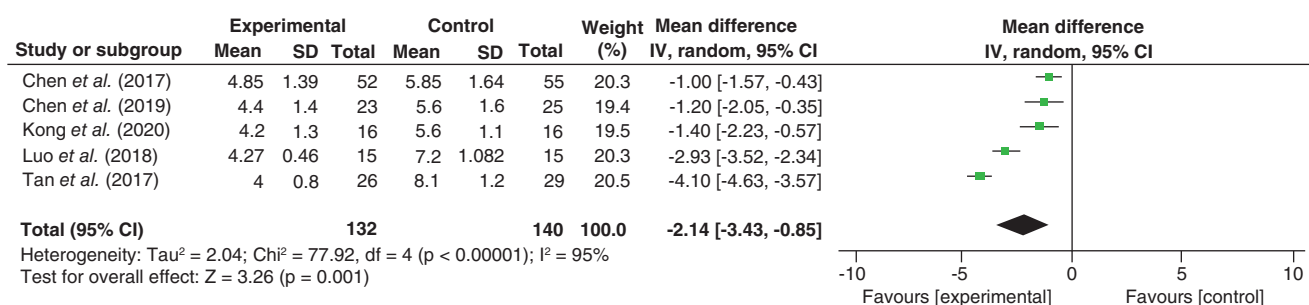


Figure 4. Comparison of frequency of intraoperative fluoroscopy. Forest plot comparing frequency of intraoperative fluoroscopy between the 3D printing-assisted surgery group and the routine surgery group.

SD: Standard deviation.

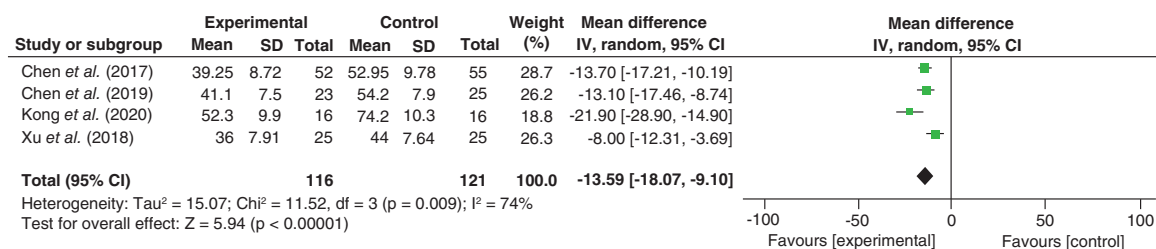


Figure 5. Comparison of blood loss. Forest plot comparing blood loss between the 3D printing-assisted surgery group and the routine surgery group.

SD: Standard deviation.

Blood loss

Four studies reported on blood loss [24–26,29], and the results showed that blood loss during the 3D printing-assisted surgery group was significantly less (WMD = -13.59; 95% CI: -18.07 to -9.10; $p < 0.00001$), and the heterogeneity among these studies was high ($I^2 = 74\%$; Figure 5).

Postoperative VAS

Postoperative VAS was reported on in two studies [26,29], and the results showed the two groups had no statistical differences (WMD = -0.55; 95% CI: -1.72 to 0.62; $p = 0.36$), and the heterogeneity between the studies was high ($I^2 = 91\%$; Figure 6).

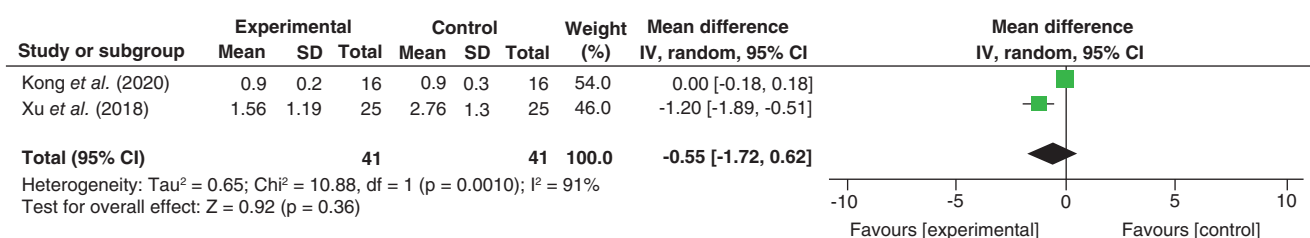


Figure 6. Comparison of postoperative visual analogue score. Forest plot comparing postoperative visual analogue score between the 3D printing-assisted surgery group and the routine surgery group.
 SD: Standard deviation.

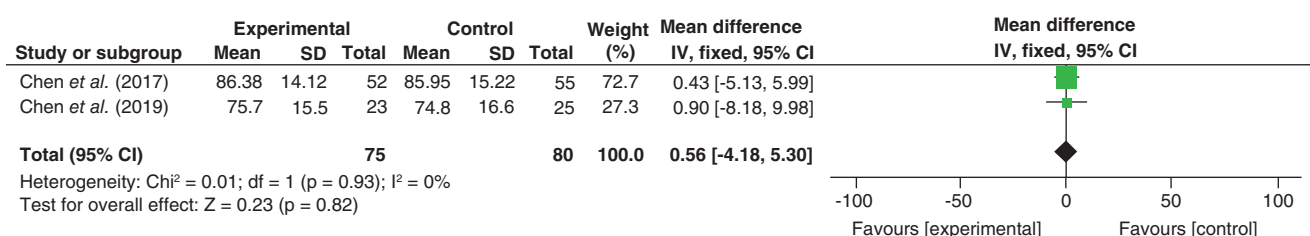


Figure 7. Comparison of Gartland–Werley scores. Forest plot comparing Gartland–Werley scores between the 3D printing-assisted surgery group and the routine surgery group.
 SD: Standard deviation.

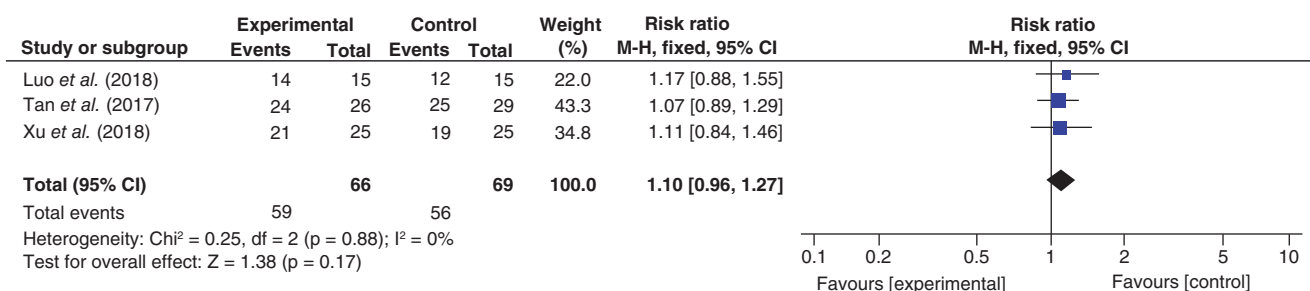


Figure 8. Comparison of excellent and good rate of wrist function. Forest plot comparing excellent and good rate of wrist function between the 3D printing-assisted surgery group and the routine surgery group.
 SD: Standard deviation.

Gartland–Werley scores

Gartland–Werley scores were reported in two studies [24,25], and the results showed the two groups had no statistical differences (WMD = 0.56; 95% CI: -4.18 to 5.30; $p = 0.82$), and the heterogeneity between the studies was low ($I^2 = 0\%$; Figure 7).

Excellent & good rate of wrist function

Three studies reported excellent and good rate of wrist function in two groups [27–29]; the results showed the two groups had no statistical differences (risk ratio = 1.10; 95% CI: 0.96–1.27; $p = 0.17$) and the heterogeneity between the studies was low ($I^2 = 0\%$; Figure 8).

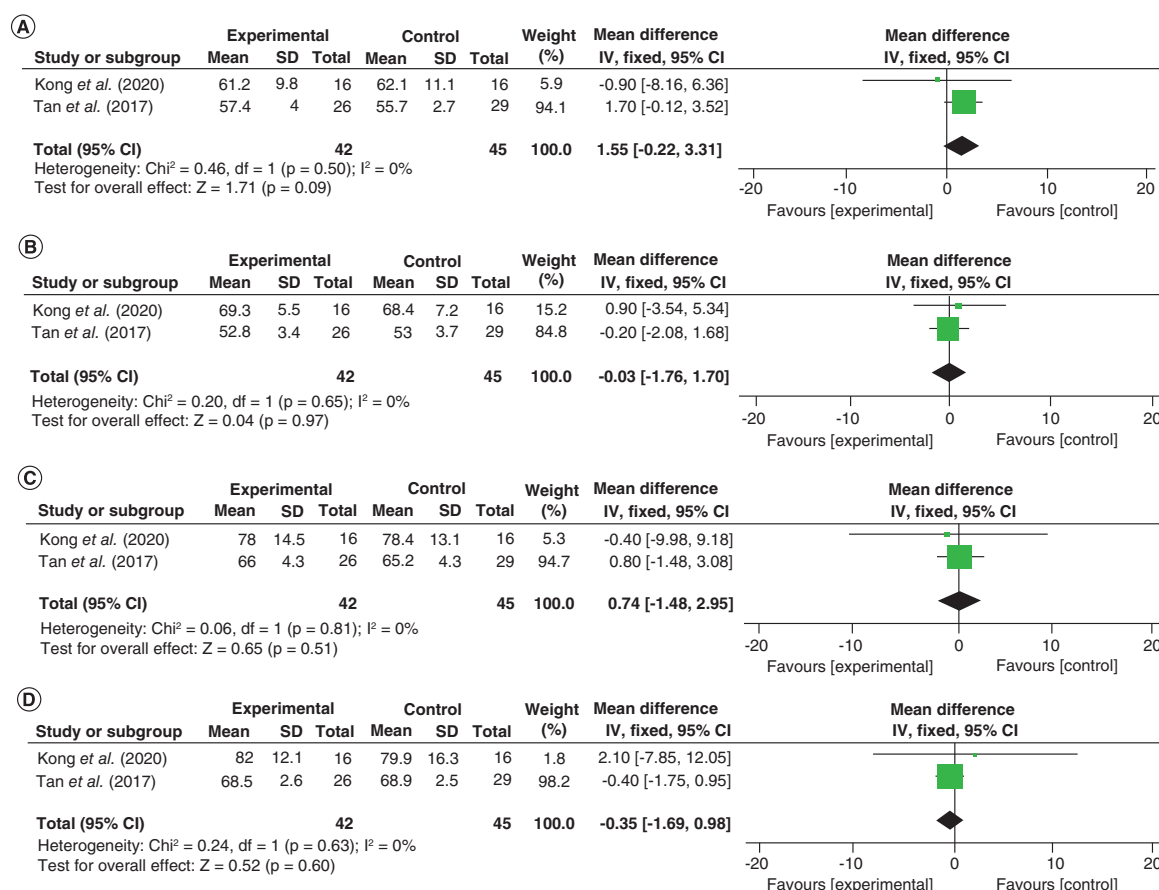


Figure 9. Comparison of range of motion. (A) Comparison of extension between the 3D printing-assisted surgery group and the routine surgery group. **(B)** Comparison of flexion between the 3D printing-assisted surgery group and the routine surgery group. **(C)** Comparison of pronation between the 3D printing-assisted surgery group and the routine surgery group. **(D)** Comparison of supination between the 3D printing-assisted surgery group and the routine surgery group. SD: Standard deviation.

Range of motion

Two studies reported on postoperative ROM of patients in two groups [26,28]. These studies evaluated four aspects of ROM, including extension, flexion, pronation and supination. Two studies reported postoperative ROM in two groups of patients.

Extension

In terms of extension, the results showed the two groups had no statistical differences (WMD = 1.55; 95% CI: -0.22 to 3.31; $p = 0.09$), and the heterogeneity between the studies was low ($I^2 = 0\%$; Figure 9A).

Flexion

In terms of flexion, the results showed the two groups had no statistical differences (WMD = -0.03; 95% CI: -1.76 to 1.70; $p = 0.97$), and the heterogeneity between the studies was low ($I^2 = 0\%$; Figure 9B).

Pronation

In terms of pronation, the results showed the heterogeneity between the studies was low ($I^2 = 0\%$), and the two groups had no statistical differences (WMD = 0.74; 95% CI: -1.48 to 2.95; $p = 0.51$; Figure 9C).

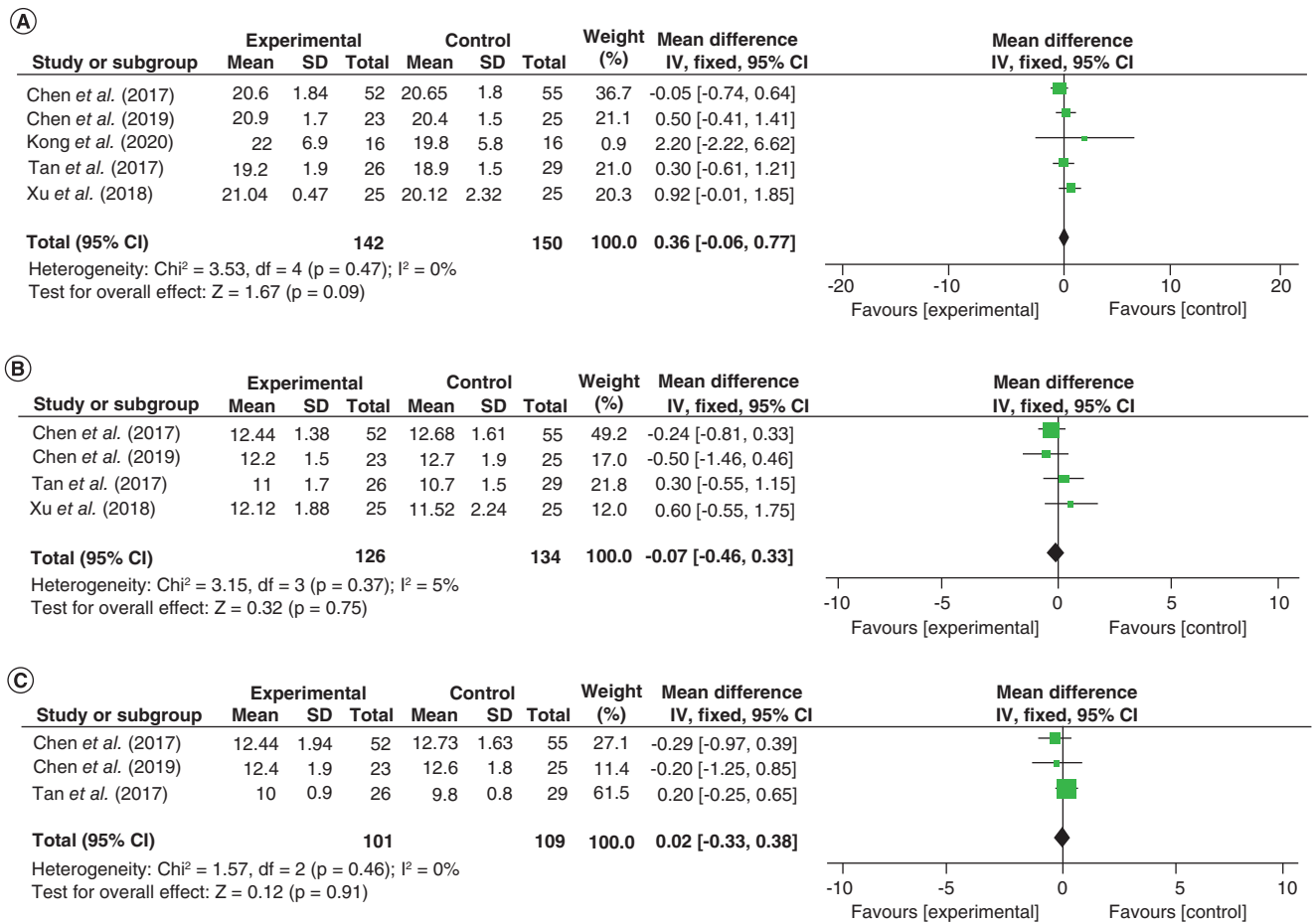


Figure 10. Comparison of radiological outcomes. (A) Comparison of ulnar deviation between the 3D printing-assisted surgery group and the routine surgery group. **(B)** Comparison of palmar tilt between the 3D printing-assisted surgery group and the routine surgery group. **(C)** Comparison of height of the radial styloid process between the 3D printing-assisted surgery group and the routine surgery group. SD: Standard deviation.

Supination

In terms of supination, the results showed the heterogeneity between the studies was low ($I^2 = 0\%$), and the two groups had no statistical differences (WMD = -0.35; 95% CI: -1.69 to 0.98; $p = 0.60$; Figure 9D).

Radiological outcomes

Ulnar deviation

Five studies reported on ulnar deviation [24–26,28,29], and the results showed the two groups had no statistical differences (WMD = 0.36; 95% CI: -0.06 to 0.77; $p = 0.09$), and the heterogeneity among these studies was low ($I^2 = 0\%$; Figure 10A).

Palmar tilt

Four studies reported on palmar tilt [24,25,28,29], the results showed the two groups had no statistical differences (WMD = -0.07; 95% CI: -0.46 to 0.33; $p = 0.75$), and the heterogeneity among these studies was low ($I^2 = 5\%$; Figure 10B).

Height of the radial styloid process

Three studies reported height of the radial styloid process [24,25,28], and the results showed the two groups had no statistical differences (WMD = 0.02; 95% CI: -0.33 to 0.38; $p = 0.91$), and the heterogeneity among these studies was low ($I^2 = 0\%$; Figure 10C).

Sensitivity analysis

Due to the low number of studies relating to some of the results, sensitivity analyses were performed only for operative time, frequency of intraoperative fluoroscopy and blood loss. After excluding a study each time, these results remained stable and the heterogeneity among the studies remained high.

Discussion**Main findings**

The results of our meta-analysis found that 3D printing-assisted surgery was better than routine surgery in terms of operation time, frequency of intraoperative fluoroscopy and blood loss. The advantages of 3D printing-assisted surgery included shorter operation time, less frequent intraoperative fluoroscopy and less blood loss.

Unlike long shaft fractures, distal radius fractures are usually more complex because they are often accompanied by comminuted fractures and intra-articular fractures [30,31]. Routine treatment often leads to malunion, so most distal radius fractures require surgery. Radial malunion usually results in difficulty in daily activities and requires corrective surgery [22]. Before using 3D printing technology, surgeons have relied on x-rays and other imaging data to analyze the details of distal radius fractures. These fractures are complex, so inadequate preoperative planning can lead to surgical failure [32]. Inadequate imaging data can lead to poor preoperative planning, which will prolong operation time and increase intraoperative blood loss [33] or even cause soft tissue necrosis and fracture repair failure [34].

3D printing technology allows the creation of a 1:1 fracture model, enabling orthopedic surgeons to simulate the entire surgical processes, fully assess key points to note during surgeries and design the best surgical methods and plans [25]. The surgeons can use the model to prebend the fixed steel plate, reducing operation time and improving the operation effect [35]. In addition, orthopedic surgeons can use 3D-printed models to communicate with the patients before the surgeries, so that the patients can understand the surgical procedures more intuitively, enhance their cognition and confidence in the operations and improve the satisfaction of the patients [36].

Although there is still room for improvement in 3D printing technology, it can promote the development of orthopedic surgery [37]. The increasing costs and expenses of surgery limit the spread and application of the technique [38]. At the same time, expensive 3D printing equipment and complex technical operations have also prevented many hospitals from performing 3D printing-assisted surgical treatment [32]. Many patients in trauma departments are in an emergency and require immediate treatment; however, 3D printing technology requires a certain amount of time to prepare for surgery, so can only be used for patients undergoing elective surgery. In more severe cases of fracture, it is not only necessary to treat the patients with fracture reduction and internal fixation, but also to repair the soft tissue around the fracture as well as nerves and blood vessels [31]. 3D printing cannot currently play a role in these aspects.

Due to the small number of studies involved, the impact of 3D printing on postoperative joint function recovery and reduction of complications has not been reflected. A large number of relevant clinical studies are needed to support a more accurate meta-analysis, depending on the further uptake of 3D printing technology.

Moreover, the clinical heterogeneity of the report is enumerated as follows: nonsurgical factors including 3D printing technology settings, postoperative measures and patient fracture classification; surgical factors including the differences in fracture fixation methods in different studies and the level of orthopedic surgeons.

Limitations

This study was based on five RCTs and one nonRCT to evaluate the efficacy of 3D printing-assisted surgery for distal radius fractures. We enumerate the limitations of the report: the small sample size in these included studies had an impact on obtaining accurate conclusions; in some RCTs, the methods used to generate, allocate, hide, blind and selectively report the results were not described, which may affect the accuracy of the results; we included one nonRCT, which may also influence the accuracy of the results.

Conclusion

This meta-analysis indicated that 3D printing-assisted surgery had shorter operation time, reduced frequency of intraoperative fluoroscopy and less blood loss. In terms of intraoperative results, 3D printing-assisted surgery was found to be better than routine surgery. A large number of more rational RCTs are needed to validate and update the conclusions of this meta-analysis. Increased uptake of 3D printing-assisted surgery may be the future trend of orthopedic surgery.

Future perspective

3D printing technology will become a routine orthopedic surgery auxiliary means in the next 5–10 years. At present, 3D printing technology is developing rapidly. It is believed that with the maturity of this technology, its application in orthopedic surgery will be more extensive.

Summary points

- A meta-analysis was conducted and the literature pooled to assess the clinical efficacy of 3D printing technology in surgery for distal radius fractures. Potential academic articles were identified from PubMed, EMBASE, Web of Science, Cochrane Library and other databases. RevMan 5.3 was used to analyze the merged data.
- The total participants in the 3D printing-assisted surgery group were 157, compared with 165 in the routine surgery group.
- This meta-analysis found that 3D printing-assisted surgery had shorter operation times, less frequent intraoperative fluoroscopy and less blood loss.
- However, no difference was found in postoperative visual analogue scores, Gartland–Werley scores, excellent and good rate of wrist function, range of motion and radiological outcomes.

Author contributions

LQ Yan conceived of the design of the study. DM Zhu, J Zhang and Z Zhang participated in the literature search, study selection, data extraction and quality assessment. DM Zhu, DY Chen, B Xie, YZ Shan and PR Liu performed the statistical analysis. DM Zhu finished the manuscript. All authors read and approved the final manuscript.

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