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A Novel Instant 3-Dimensional Printing System for Postoperative Fracture Patients: A Comparative Cohort Study

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Background: Traditional plaster (TP) is a widely used auxiliary fixation (AF) approach for postoperative fracture patients. However, patient discomfort and inconvenience to clinicians has limited its application. We introduce a novel instant 3-dimensional printing appliance system (3D-AS) to address such issues.

Material/Methods: Twenty-seven postoperative fracture patients were divided randomly between a TP group and a 3D-AS group, and analyzed retrospectively. Radiographic images during follow-up were evaluated for fracture healing and fracture reduction quality. The range of motion (ROM) was recorded to assess motor performance. Patient pain was assessed using the Visual Analogue Scale (VAS). Complications were also compared between the 2 groups.

Results: The patients comprised 17 men and 10 women with ages ranging from 21 to 69 years (mean age: 47.35). All patients completed a follow-up visit (range: 14–19 months, mean: 13.59 months). Although no significant difference was found between general characteristics ($P>0.05$) and the time of fracture union ($P>0.05$), significant differences between groups were seen in complications ($P<0.05$), VAS ($P<0.01$), patient satisfaction ($P<0.05$), and ROM for the upper joints ($P<0.05$).

Conclusions: Our study suggests that 3D-AS provides better upper-limb ROM and more comfortable healing for postoperative fracture patients, indicating that it can be recommended for use in such patients.

MeSH Keywords: **Auxiliary Fixation • Fracture Healing • Imaging, Three-Dimensional**

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Background

Recently, traumatic bone fracture incidence has increased with developments in transportation [1]. Patients with fractures often suffer serious pain due to the displacement of the fracture end, and serious secondary injury, including nerve injury, blood vessel injury, and osteofascial compartment syndrome, which may occur should the fracture end not be fixed appropriately [2]. In addition to temporary preoperative fixation, postoperative auxiliary fixation (AF) is also important for fracture patients. To the best of our knowledge, the use of traditional plaster (TP) is amongst the most widely used approaches to AF [3]. However, the disadvantages of TP should not be dismissed. First, TP is bulky, increasing the burden and discomfort of patients [4]. Secondly, TP is formed from a material that is not breathable, and consequently often gives rise to bedsores [5]. Thirdly, artifacts may be created with TP; therefore, TP must be removed before any X-ray examination. This increases both the workload of medical staff and patient burden [6]. Fourthly, plaster solidification is protracted, requiring technicians to handle fixation [7]. Finally, plaster removal is inconvenient, and TP cannot be reused [8].

Given such disadvantages, attention has turned to other approaches better able to address these issues [9]. Recently, 3-dimensional (3D) printing has been introduced, and found to be useful in many areas of medicine [10]. For example, Zhou et al. reported the application of a 3D-printed template to assist sacroiliac screw placement, improving the operation's safety profile [11]. Moreover, a 3D-printed brace was recently used for adolescent idiopathic scoliosis patients [12]. However, an important bottleneck to the wider application of 3D printing in medicine is the availability of a human-suitable, safe, and environmentally friendly 3D printing material. Additionally, as the extrusion speed of a current 3D printer is approximately 60 grams per hour, there can be a very long wait for each 3D-printed product [13]. For example, a wrist joint weighs over 300 grams, so patients can wait 5 or more hours before fixation. Three-dimensional printing materials are typically also very expensive, and production costs are high [14]. To address such issues, we introduced a novel instant 3D printing splint system (3D-AS) for postoperative fracture patients. In the current study, 3D-AS was undertaken using an instant 3D printer (BiYing-3D instant printer, Wuhan Biying Biotechnology Co., Ltd). A biodegradable corn starch-based material was designed and used as the printing material; the cost of this material is similar to that of TP. Using the 3D-AS approach, a 3D-printed splint can be constructed in 5-10 minutes.

Material and Methods

Patient eligibility

Between August 2018 and May 2019, 27 postoperative fracture patients with AF were included in the study. Ethics approval and informed consent to participate were obtained from each patient. Inclusion criteria were: (1) closed fracture patients; (2) postoperative fracture patients with TP or 3D-AS for AF; (3) aged over 18 years; (4) full mental competence; (5) American Society of Anesthesiology (ASA) score <level 3. Exclusion criteria were: (1) open fracture patients with external fixation; (2) fracture patients receiving non-surgical treatment; (3) postoperative fracture patients without AF; (4) ASA score >level 3; (5) under 18 years.

3D-AS protocol

3D-AS was performed using an instant 3D printer (BiYing-3D instant printer, Wuhan Biying Biotechnology Co., Ltd, Wuhan, China). A biodegradable corn starch-based material was designed and used as the 3D-AS printing material. The 3D-printed splint was able to be constructed rapidly; in 5–10 minutes. The whole 3D-AS procedure comprised 4 steps: 3D scanning, slicing administration, 3D printing, and wearing. First, for 3D scanning, stereolithography (STL) file format was used by both the designing software and the printing device. The STL file uses triangular faces to approximate an object's surface. The smaller the triangular face, the greater the surface resolution. The Python Lex-Yacc (PLY) scanner reads 3-dimensional data from a file and produces a VRML- or WRL-format file, often used as input for full-color printing (**Figure 1A**). Secondly, for slicing, the printer reads cross-sections from the file, printing it layer-by-layer from a liquid, powder, or flake, and then stitches these sections together to create a single final entity. The technology is characterized by its ability to make objects of almost any shape (**Figure 1B**). Thirdly, for 3D printing, the 3D printer's resolution is adequate for most tasks, although curved surfaces can be rough. Higher resolution structures can be obtained by printing a slightly larger object, and then grinding surfaces smooth (**Figure 1C–1E**). Finally, clinicians provide the instant 3D-printed AF to the patient, assisting him or her to wear the AF with optimal tightness (**Figure 1F**). As 3D-printed splints are constructed based on the individual characteristics of each patient, the fit of 3D-AS is better than that of TP. Furthermore, the splint is printed immediately before handling the affected limb. Hence, patients just need help to put on their appliances, rather than needing to go through the shaping and maintaining procedures required with TP. An example of a 3D-AS is shown in **Figure 2**.

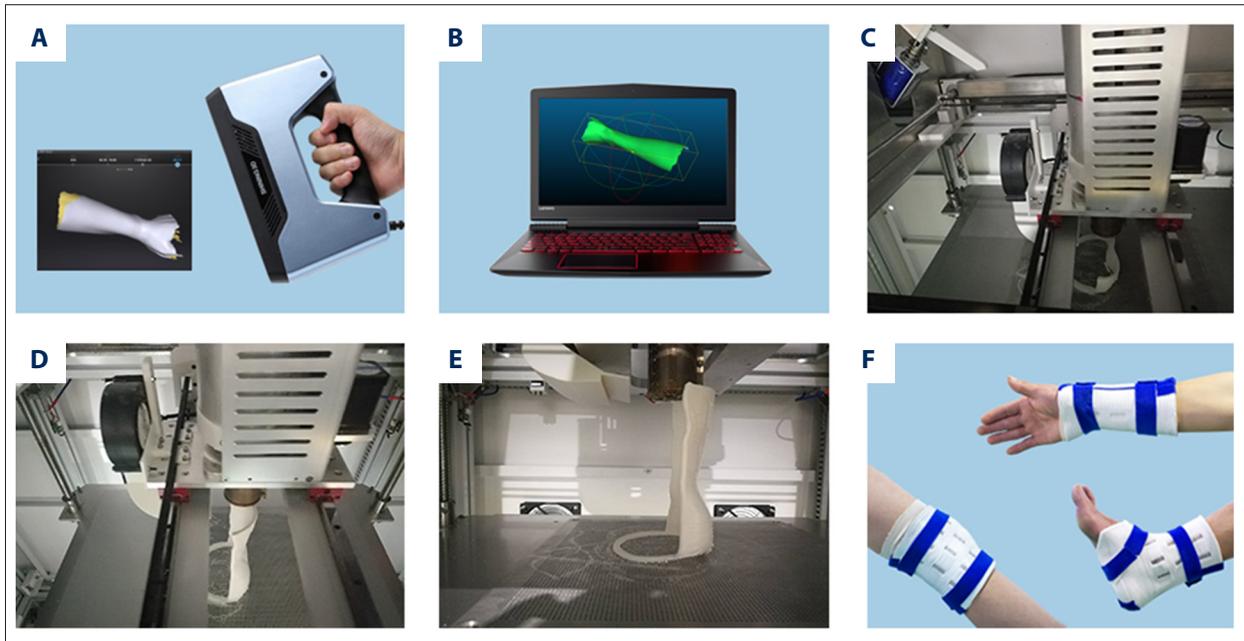


Figure 1. (A) An input file is produced by a scanner for further full-color printing. (B) The printer reads the cross-section in the file and then creates a single entity. (C–E) The printing process of the 3-dimensional printing appliance system. (F) Application of the 3-dimensional printing appliance system.

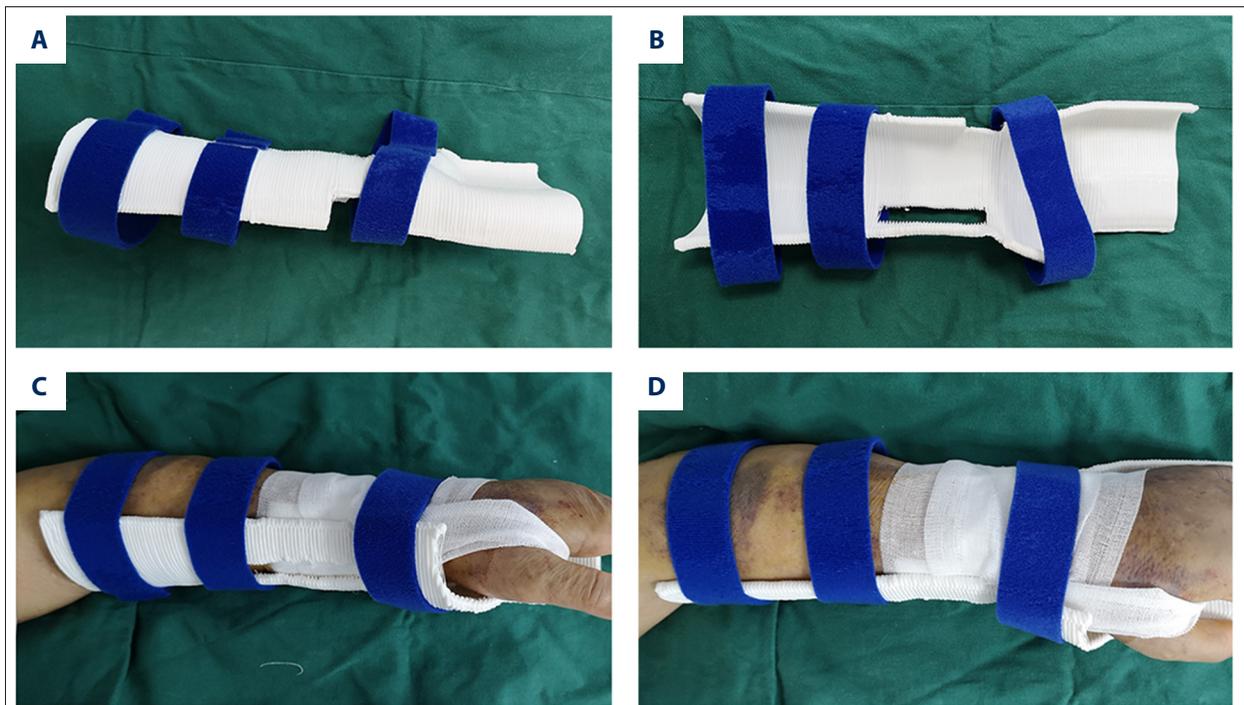


Figure 2. (A–D) Application of the 3-dimensional printing appliance system for distal radius fracture.

Table 1. Patient satisfaction survey.

Name: _____ Hospitalization Number: _____ Department: _____ Date: _____

No.	Item	Quite satisfied		Satisfied		Acceptable		Dissatisfied		Quite dissatisfied		Reason and advice
		10	9	8	7	6	5	4	3	2	1	
1	Hospital environment											
2	Hospital service facilities											
3	Diagnosis and technique of doctors											
4	Service and technique of nurses											
5	Is preoperative and postoperative check in time?											
6	Are problems solved in time during hospitalization?											
7	Postoperative rehabilitation instruction											
8	Respect and care for patients											
9	Hospitalization charge											
10	Other											
Total score:												
Any complaint or advice to XX:												
Signature: _____												

Evaluation index

The general characteristics of the included patients and their postoperative outcomes were compared. Radiographic images, taken during follow-up, were used to evaluate fracture healing and fracture reduction quality. The range of motion (ROM) in both upper-limb joints (elbow and wrist) and both lower-limb joints (knee and ankle) was used to assess patient motor performance at their final follow-up visit. Patient satisfaction was evaluated using an investigator-designed questionnaire (see **Table 1**). Patient pain in both groups was assessed after surgery using the Visual Analogue Scale (VAS). Complications including incision infection, non-union, and fragment displacement were compared between groups.

Statistical analysis

Fisher’s exact test was used to compare categorical variables between the TP group and the 3D-AS group, as data were limited. A Kolmogorov-Smirnov test was performed to test whether continuous variables complied with normal distribution. An independent group *t* test was applied to normally distributed

continuous variables; otherwise, the Mann-Whitney U test was used. *P*<0.05 indicated statistical significance. Statistical Product and Service Solutions (SPSS) software (version 23, IBM Corp, Armonk, NY) was used for all statistical analyses.

Results

The 27 patients in the study were treated using TP or 3D-AS. The 2 cohorts had similar characteristics (see **Table 2**): average age (46.46±11.33 years vs. 51.57±9.81 years, *P*=0.221), gender distribution (male: female ratios, 8: 5 and 9: 5, *P*=1.000), and body mass index (BMI, 29.31±3.04 kg/m² and 29.86±2.82 kg/m², *P*=0.630). No differences were found in the costs of the intervention or treatment in the primary health care sector or secondary health care sector between the TP group and the 3D-AS group (**Table 3**).

Similarly, no statistically significant difference was seen in the time to fracture union (18.08±3.00 weeks vs. 18.96±2.80 weeks, *P*=0.434). However, statistically significant differences were seen in observed complications (see **Table 4**):

Table 2. General characteristics of the included patients.

Patient number	Age (years)	Gender (M/F)	Injury classification	BMI (kg/m ²)	Affected joint	TF approach	ASA score
1	44	M	Traffic	31	Ankle	TP	Level 2
2	21	F	Traffic	26	Wrist	TP	Level 1
3	41	F	Traffic	32	Ankle	3D-AS	Level 2
4	42	M	Traffic	29	Ankle	TP	Level 1
5	39	M	Traffic	31	Elbow	3D-AS	Level 1
6	56	M	Fall	35	Ankle	TP	Level 2
7	42	F	Fall	28	Ankle	TP	Level 1
8	51	M	Traffic	27	Knee	TP	Level 1
9	52	M	Fall	32	Ankle	3D-AS	Level 1
10	32	F	Traffic	24	Wrist	TP	Level 1
11	44	F	Traffic	31	Elbow	3D-AS	Level 1
12	52	M	Traffic	32	Ankle	3D-AS	Level 1
13	65	F	Traffic	29	Elbow	3D-AS	Level 2
14	42	M	Traffic	33	Elbow	3D-AS	Level 1
15	49	M	Fall	34	Knee	TP	Level 1
16	52	F	Fall	31	Wrist	TP	Level 1
17	51	M	Traffic	32	Knee	3D-AS	Level 1
18	62	F	Fall	30	Knee	TP	Level 2
19	44	M	Traffic	28	Elbow	TP	Level 2
20	42	F	Fall	31	Wrist	3D-AS	Level 1
21	64	M	Fall	30	Wrist	3D-AS	Level 2
22	46	M	Trauma	23	Knee	3D-AS	Level 1
23	58	F	Fall	29	Wrist	3D-AS	Level 2
24	57	M	Traffic	26	Wrist	3D-AS	Level 1
25	62	M	Trauma	30	Elbow	TP	Level 1
26	47	M	Traffic	28	Elbow	TP	Level 2
27	69	M	Fall	27	Knee	3D-AS	Level 2

M – Male; F – Female; EF – external fixation; BMI – body mass index; ASA – American Society of Anesthesiology; TP – traditional plaster; 3D-AS – instant three-dimensional printing appliance system.

incision infection (4/13 vs. 0/14, $P=0.041$), fragment displacement (4/13 vs. 0/14, $P=0.041$), VAS after surgery (64.19 ± 5.72 vs. 52.75 ± 6.50 , $P<0.01$), patient satisfaction (87.31 ± 3.88 vs. 91.71 ± 5.02 , $P=0.018$), and upper-joint ROM (wrist degree of motion: 58.00 ± 6.76 vs. 63.21 ± 5.89 , $P=0.042$; elbow degree of motion: 99.31 ± 7.03 and 109.21 ± 11.74 , $P=0.014$).

Discussion

In postoperative fracture patients, AF helps prevent postoperative complications [15]. However, critical concerns about AF should not be ignored [16]. First, widely used AF approaches, including TP, plaster bandage, and splint, all have standardized production, so it is impossible to achieve a perfectly fitted

Table 3. Costs of the intervention; primary health care sector and secondary health care sector in the study (in United States dollars).

Item	TP group (n=13)	3D-AS group (n=14)	P value
Intervention			0.337
TP	33.61±12.58	/	
3D-AS	/	38.12±11.39	
Primary health care sector			
Rehabilitation physiotherapy	146.63 (51.32–344.57)	150.29 (104.11–241.94)	1.000
Transportation fees	29.33 (18.33–51.32)	27.86 (15.21–45.82)	0.650
Medicine	13.53±12.34	15.61±12.37	0.667
Other*	30.34±22.58	23.57±14.97	0.364
Subtotal	237.54 (146.63–406.89)	232.40 (152.13–311.22)	0.867
Secondary health care sector			
Outpatient**	161.57±52.11	162.13±54.58	0.979
Emergency	98.13±107.02	96.88±84.11	0.973
Surgery	347.51 (274.93–397.36)	313.05 (293.99–361.07)	1.000
Medicine	351.91 (326.98–396.63)	339.44 (306.45–419.35)	0.583
Examination fees	172.12±43.21	173.54±49.90	0.938
Other***	101.62±21.59	111.65±22.99	0.255
Subtotal	1247.52±243.62	1252.93±242.42	0.954
Total	1439.88 (1262.46–1671.55)	1426.69 (1249.27–1812.32)	0.981

Independent-Samples T Test or Mann-Whitney U test was selected to compare differences between TP group and 3D-AS group where appropriate. Values were presented as mean±SD or median (IQR) where appropriate. * Other, includes specialists or necessary examination; ** outpatient, includes postoperative re-examination fees; *** other, includes nursing care and bed charges.

Table 4. Clinical outcomes of the included patients.

Item	TP group (n=13)	3D-AS (n=14)	P value	
Fracture union time (weeks)	18.08±3.00	18.96±2.80	0.434	
Complications	Incision infection	4/13	0/14	0.041*
	None union	0/13	0/14	–
	Fragment displacement	4/13	0/14	0.041*
VAS post-surgery	64.19±5.72	52.75±6.50	0.000*	
Patients' satisfaction degree (%)	87.31±3.88	91.71±5.02	0.018*	
ROM (°)	Wrist	58.00±6.76	63.21±5.89	0.042*
	Elbow	99.31±7.03	109.21±11.74	0.014*
	Ankle (plantar flexion)	38.46±3.43	39.07±3.15	0.634
	Knee	115.23±4.51	114.86±5.97	0.857

* p<0.05; VAS – visual analogue scale; ROM – range of motion; TP – traditional plaster; 3D-AS – instant three-dimensional printing appliance system. Normal range of ROM (°): wrist: 0–80, elbow: 0–135/150, ankle (plantar flexion): 45, knee: 0–130.

AF for an affected limb, leading to potential chronic discomfort in patients. In our retrospective study, a statistically significant difference was found in VAS scores after surgery between the groups. When compared with 3D-AS, TP increased discomfort for fracture patients. Similarly, patient satisfaction in the 3D-AS group was greater than in the TP group, indicating a more comfortable experience in the 3D-AS group. Secondly, current AF approaches cover wounds and surgical incisions, severely hindering monitoring during healing. A statistically significant difference in the incidence of incision infection was seen between the groups, suggesting incision management was superior in the 3D-AS group. Thus, 3D-AS is the method of choice for surgical patients, based on our results. Existing AF approaches require complex handling by experienced healthcare professionals, particularly for TP and plaster bandage, which are time- and labor-intensive undertakings. As 3D-printed splints are constructed individually for each patient, their quality of fit is greater than that of TP, with the splint being printed essentially instantly prior to the handling of an affected limb. Hence, using 3D-AS, the only help patients need is help with putting on the splint, rather than requiring technicians to shape and maintain fixation, as with TP.

Another issue is fragment displacement that affects joint ROM. Four patients in the TP group had fragment displacement after surgery, all with upper-limb fractures (3 distal radius fractures and 1 olecranon fracture). Although displacement of the fracture fragment depends on the rigidity and choice of implants, other factors may also contribute to fragment displacement. First, the wrist and elbow are not weight-bearing joints, compared with the ankle and knee joints, and as such they are much more flexible. Thus, earlier joint exercise is needed in patients with these 2 affected joints, compared with lower-limb fracture patients, who are at greater risk of postoperative fragment displacement.

Patients wearing TP experience more discomfort than 3D-AS patients according to our study. This may reduce compliance in TP patients, due to discomfort, leading perhaps to earlier TP removal or inappropriate TP fixation. A statistically significant difference was also seen in ROM of the upper joints. The more comfortable, less painful experience of 3D-AS patients was crucial to a better clinical outcome; the 3D-AS patients were more active during joint function exercise in the affected limb, and exhibited better clinical compliance.

The manufacture of the 3D-AS was performed using an instant 3D printer (BiYing-3D instant printer, Wuhan Biying Biotechnology Co., Ltd, Wuhan, China). In previous cases, patients may have suffered secondary pain due to the use of inappropriate printing materials. Therefore, if material appropriate for the human body, which is safe and environmentally friendly, can be designed, it should become a key factor

in determining how 3D printing is applied in AF [17]. A corn starch-based biodegradable material was designed and used as the printing material for 3D-AS in our study. The cost of this material is close to that of TP while meeting the requirements above. The resulting printed product is non-stimulating, colorless, odorless, and waterproof, allowing it to be worn while bathing. The weight of the printed product is approximately 1/6 that of TP, and is 20 times as durable as TP. Moreover, the 3D printer was equipped with a more efficient materials inlet, which avoids silk blocking during the printing process. The printing speed is also a critical index, and 3D-AS is rapidly formed. After near-instant printing is completed, affected limbs can be fixed rapidly: the printing time of an ordinary wrist joint was completed within 10 minutes. Accurate printing can be achieved with 3D-AS, greatly reducing costs. Due to the porous design, more comfort was reported by patients. Owing to effective avoidance of wounds and incisions, 3D-AS improves the healing rate without altering management of dressing and wound treatment. Since the 3D-AS printing material was composed of corn starch-based material, there was no difference in the cost of intervention between the TP group and the 3D-AS group (Table 3, $P=0.337$). In addition, no statistically significant difference was found in the patients in the primary health care sector and those in the secondary health care sector. Therefore, 3D-AS should not increase the financial burden of patients.

Like all reported research, our study has some limitations. Firstly, outcomes from surgical treatment depend mainly on the fixation technique, the rigidity of fixation, and soft-tissue handling; our study focused only on the comparative efficacy of TP versus 3D-AS in postoperative fracture patients. Secondly, this is a retrospective study with a relatively small cohort. Finally, the follow-up period was relatively short, precluding a definitive conclusion.

Conclusions

Our study suggests that, compared with TP, 3D-AS provides better upper-limb ROM and a more comfortable experience for postoperative fracture patients, indicating that 3D-AS can be robustly recommended for such patients.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of Wuhan Union Hospital. Reference No. 2018–S209.

Conflict of interest

None.

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