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Research Article
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# 3D-printed models improve surgical planning for correction of severe postburn ankle contracture with an external fixator

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**Abstract:** Gradual distraction with an external fixator is a widely used treatment for severe postburn ankle contracture (SPAC). However, application of external fixators is complex, and conventional two-dimensional (2D) imaging-based surgical planning is not particularly helpful due to a lack of spatial geometry. The purpose of this study was to evaluate the surgical planning process for this procedure with patient-specific three-dimension-printed models (3DPMs). In this study, patients coming from two centers were divided into two cohorts (3DPM group vs. control group) depending on whether a 3DPM was used for preoperative surgical planning. Operation duration, improvement in metatarsal-tibial angle (MTA), range of motion (ROM), the American Orthopedic Foot and Ankle Society (AOFAS) scores, complications, and patient-reported satisfaction were compared between two groups. The 3DPM group had significantly shorter operation duration than the control group ((2.0±0.3) h vs. (3.2±0.3) h, $P<0.01$). MTA, ROM, and AOFAS scores between the two groups showed no significant differences pre-operation, after the removal of the external fixator, or at follow-up. Plantigrade feet were achieved and gait was substantially improved in all patients at the final follow-up. Pin-tract infections occurred in two patients (one in each group) during distraction and were treated with wound care and oral antibiotics. Patients in the 3DPM group reported higher satisfaction than those in the control group, owing to better patient-surgeon communication. Surgical planning using patient-specific 3DPMs significantly reduced operation duration and increased patient satisfaction, while providing similar improvements in ankle movement and function compared to traditional surgical planning for the correction of SPAC with external fixators.

**Key words:** Ankle contracture; Ilizarov; Postburn contracture; 3D printing; Surgical planning

## 1 Introduction

Severe postburn ankle contracture (SPAC) is a disabling deformity characterized by excessive hypertrophic scarring and limited range of motion (ROM); thus, it significantly impairs the patient's daily activity and quality of life (Pehde et al., 2020). SPAC is often associated with substantial shortening of tendons, ligaments, and neurovascular bundles (Carmichael et al., 2005). Acute, complete correction of SPAC is unfeasible because it may overstretch these contracted tissues or increase the risk of neurovascular injury, ischemia, and even amputation (Tan et al., 2019). Gradual distraction with an external fixator is therefore required to lengthen the contracted tissues and achieve plantigrade, painless, and stable foot and ankle (van Roermund et al., 1998).

Since Ilizarov (1988) first introduced the Ilizarov frame, external fixators (e.g., hexapod frames and unilateral, bilateral, and combined-type external fixators) have been widely used in the treatment of ankle deformities caused by trauma, burn injury, infection, congenital malformation, and neuromuscular pathology (Paley et al., 2006). Of all types of external fixators,

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the Ilizarov frame is the most commonly used device for the treatment of SPAC due to its stability, accessibility, and capacity for multiplanar correction (Huang, 1996; Goldstein et al., 2013; Jordan et al., 2013). For example, Khodzhakulov et al. (1991) reported improvement of weight-bearing function in 81% of 82 SPAC patients treated with the Ilizarov technique. van Roermund et al. (1998) observed improvement of joint function in three patients with ankle joint stiffness. Similarly, Saghieh et al. (2011) described their successful experience in treating SPAC with the Ilizarov technique in three patients.

However, the installation of an external fixator is complex and challenging, and requires familiarity with the anatomical structure as well as a great deal of experience (Calhoun et al., 1992). Even in trained hands, attempts at K-wire insertion and frame adjustment may be required intraoperatively, leading to prolonged surgical time and increased risk of complications (Ferreira and Costa, 2009). These could be minimized via more accurate preoperative planning. However, traditional surgical planning mainly depends on two-dimensional (2D) images, such as X-rays and computed tomography (CT). Although these are helpful to identify the area and severity of the deformity, they are unable to accurately reflect the complex three-dimensional (3D) structure, reproduce the actual spatial geometry, or offer tactile feedback (Ploch et al., 2016; Pfeil et al., 2018). Surgical planning is thus compromised, and preoperative surgical rehearsal is impossible based on conventional 2D imaging (Ganguli et al., 2018).

With the development of 3D printing technology, 3D-printed models (3DPMs) have gained global popularity owing to their individualization, visualization, and tangibility with actual dimensions and spatial geometry (Cutroneo et al., 2016; Fitzhugh et al., 2016; Gu et al., 2016; Rashaan et al., 2016; Schepers et al., 2016; Qiu et al., 2017; Zhang WX et al., 2017; Peng et al., 2019; Zhang B et al., 2019). Previous studies have shown that use of 3DPMs is associated with decreased surgical time and increased operative accuracy and safety in the treatment of ankle deformities compared to traditional imaging (Pfeffer et al., 2018; Sobrón et al., 2019). For example, Duan et al. (2019) found that preoperative planning with 3DPMs facilitated accurate drilling of K-wires into the appropriate position and reduced the operation time and intraoperative radiation in 29 patients who underwent subtalar joint arthrodesis. A randomized controlled trial by Zheng et al. (2018) showed that 3DPM-assisted surgical planning led to shorter operation duration, less blood loss, and less X-ray exposure, as well as better anatomic reduction and clinical outcomes than conventional planning, in 100 patients with Pilon fractures. However, few studies have explored 3DPMs in combination with external fixators for the treatment of lower extremity deformity (Burzyńska et al., 2016; Corona et al., 2018; Morasiewicz et al., 2018). To the best of our knowledge, no study has reported the application of 3DPMs in the correction of SPAC with external fixators.

The purpose of this retrospective study was to evaluate the effect of surgical planning with patient-specific 3DPMs on the treatment of SPAC with external fixators. We hypothesized that 3DPM-assisted surgical planning would reduce the operation duration compared to traditional planning with 2D imaging. The specific aims were to compare 3DPM-assisted and traditional surgical planning with regard to operation duration, ROM, the American Orthopedic Foot and Ankle Society (AOFAS) scores, complications, and patient-reported satisfaction.

## 2 Patients and methods

### 2.1 Study design

After approval by the Institutional Ethics Committees of Chinese PLA General Hospital (Approval ID: S2021-241-01), we implemented a two-center retrospective cohort study involving consecutive patients who underwent external fixation for the treatment of SPAC at the Department of Plastic and Reconstructive Surgery, Chinese PLA General Hospital, Beijing, China or the Department of Plastic Surgery and Department of Orthopedic Surgery, Xijing Hospital, Xi'an, China, between January 1, 2008 and June 1, 2018.

### 2.2 Participants

Inclusion criteria were: (1) postburn ankle contracture; (2) use of an external fixator (e.g., Ilizarov frame, hexapod frame, or combined external fixator) to correct the deformity; (3) availability of complete medical records including medical history, physical examination, operation notes, imaging, and a minimum of two years of follow-up. Exclusion criteria were: (1) contractures caused by other etiologies, such as trauma, congenital malformation, syndromes, neuropathy, or haemophilia; (2) other joint contractures, such as knee, shoulder, elbow, wrist, or hand; (3) incomplete information. Participants were divided into two cohorts (3DPM group vs. control group) according to whether a 3DPM was used for preoperative surgical planning.

### 2.3 Production of 3DPMs

Thin-layer CT scanning of the ankle and foot was routinely performed, with 0.6-mm slice thickness (SOMATOM Definition, Siemens, Germany). We processed the Digital Imaging and Communications in Medicine (DICOM) data using Materialise Interactive Medical Image Control System (MIMICS) (Materialise, Leuven, Belgium) to create a 3D model. The dataset was saved in Standard Tereolithography Language (STL) format and imported into a 3D printer (iSLA880; ZRapid Tech, Beijing, China). The model was printed with photosensitive resin as the raw material, using Stereolithography Apparatus technology, with a shell thickness between 0.80 mm and 2.00 mm and a layer height of 0.05 mm.

### 2.4 Preoperative surgical planning

In the control group, we performed traditional surgical planning by viewing CT scans (Fig. 1). In the 3DPM group, we performed surgical planning and rehearsal on the 3DPMs, including assembly and configuration of the external fixators, ring placement, and determination of the drilling location and direction of pins and wires (Fig. 2). Once prepared, the fixator was sterilized for intraoperative use.

### 2.5 Surgery and postoperative distraction

Patients were in a supine position and received epidural or general anesthesia. Scars were excised. The surgeon performed conservative correction of the articular position, avoiding exposure or overstretch of the tendon, ligament, and neurovascular bundle. The subsequent defect caused by scar resection was then covered by skin grafting. The preconstructed external fixator was applied and K-wires were inserted as preoperatively planned (Fig. 3).

Gradual distraction was started after a 10-d latency for grafted skin healing. Distraction was performed over four weeks by manually rotating the nuts to lengthen the distraction rods at a rate of 1.0–4.0 mm/d, which corresponded to 0.5–1.0 mm/d at the level of the

**Fig. 1 Traditional surgical planning based on computed tomography (CT) scans.**

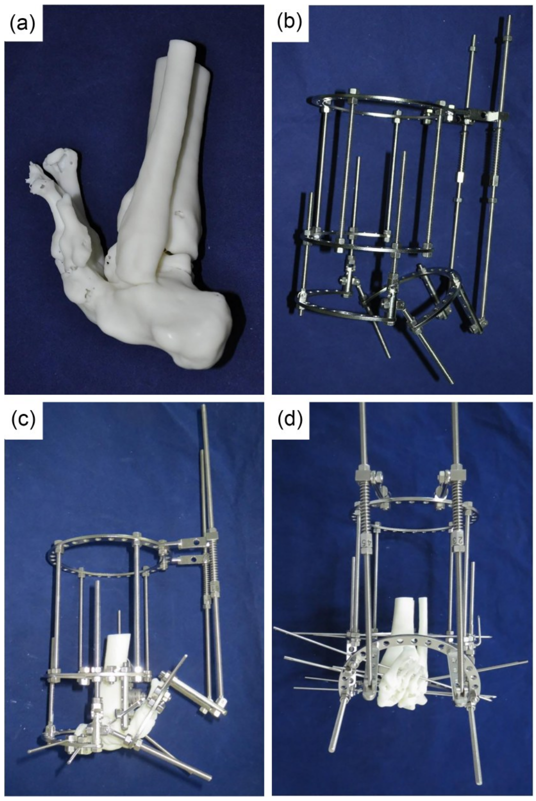

**Fig. 2 Surgical planning and rehearsal were performed on the 3DPMs, including assembly and configuration of the external fixators, ring placement, and determination of the drilling location and direction of pins and wires. (a) Lateral view of a 3DPM. (b) Preconstructed Ilizarov frame. Lateral view (c) and anterior view (d) after the frame was applied on the 3DPM in surgery rehearsal. 3DPMs: three-dimension-printed models.**

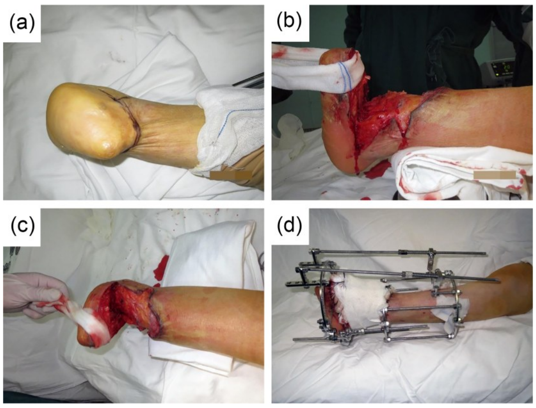


**Fig. 3 Surgical correction of the ankle contracture and installation of the external fixator. (a) Design of fish-bone incision for contracture release. Lateral view (b) and anterior view (c) of conservative correction of the articular position, avoiding exposure or overstretch of the neurovascular bundle. (d) The defect was covered by skin grafting. The preconstructed external fixator was applied and K-wires were inserted as preoperatively planned.**

ankle. We adjusted the distraction rate according to the patient's pain tolerance and skin reaction (numbness, swelling, temperature, and color). The external fixator was maintained in situ for another 4–6 weeks. We performed X-rays to confirm satisfactory correction before removal of the external fixator (Fig. 4). The external fixator was then removed, and a short-leg walking splint was applied for six weeks, followed by an ankle-foot orthosis for three months. First partial and then full weight bearing was encouraged. We recommended physiotherapy to prevent recurrence and regain maximum function. Patients received follow-up annually (Fig. 5).

## 2.6 Data collection

The following data were collected from the electronic medical records. (1) Demographics: gender, age, and type of ankle deformity (e.g., plantarflexion, dorsiflexion, plus varus and/or valgus). (2) Type of external fixator used. (3) Operation duration, blood loss, and length of hospital stay. (4) Metatarsal-tibial angle (MTA), ROM, and AOFAS ankle and hindfoot scores pre-operation, after removal of the frame, and at a ⩾2-year follow-up. MTA was measured as the angle between the diaphysis of the tibia and the diaphysis of the first metatarsal, using a lateral goniometer according to the established protocol (Richtr et al., 1992). ROM was calculated as the MTA at the maximum plantar-flexion position minus the MTA at the maximum dorsiflexion position.

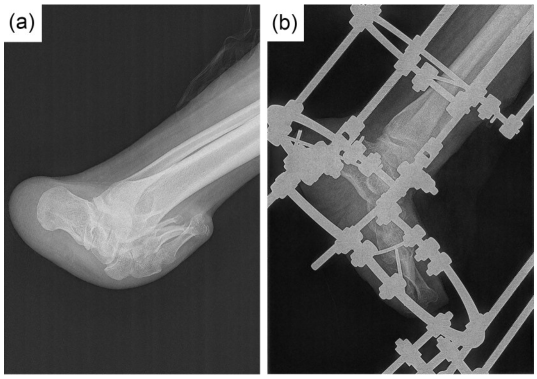


**Fig. 4 Preoperative and postoperative X-rays. (a) Preoperative lateral X-ray. (b) X-ray was performed to confirm satisfactory correction before removal of the frame.**


**Fig. 5 Images before and after removal of the frame, and at follow-up. Lateral view (a) and anterior view (b) before removal of the circular frame. Lateral view (c) and anterior view (d) after removal of the frame. Lateral view (e) and anterior view (f) of the ankle at 2.5-year follow-up.**

The AOFAS scale has a total of 100 points, including 40 points for pain, 50 points for function (i.e., 10 points for activity limitation and support requirement, 5 points for maximum walking distance, 5 points for walking surfaces, 8 points for gait abnormality, 8 points for sagittal motion, 6 points for hindfoot motion, and 8 points for ankle stability), and 10 points for alignment (Kitaoka et al., 1994). (5) Complications: pin-tract infection, fixation failure, neurosensory disturbance, and re-contracture. (6) Patient-reported satisfaction measured using a three-question survey (Table 1). The primary predictor variable was whether a 3DPM was used for preoperative surgical planning (3DPM group vs. control

**Table 1 Patient satisfaction scale**

| Questions | Patient satisfaction scale | | |
|---|---|---|---|
| | 1 | 2 | 3 |
| 1. How would you rate your communication with surgeons? | Poor | Fair | Good |
| 2. Is it easy to understand the surgical procedures? | Difficult | Neutral | Easy |
| 3. How would you rate your overall satisfaction with the hospital experience? | Dissatisfied | Neutral | Satisfied |

group). The primary outcome variable was the operation duration. Other outcome variables included improvement in MTA, ROM, AOFAS scores, complications, and patient-reported satisfaction.

### 2.7 Data analysis

Continuous variables were expressed as mean± standard deviation (SD) or median (range), depending on their distributions. Categorical variables were expressed as percentage and proportion. We performed the *t*-test and Fisher's exact test to compare the normally distributed continuous variables and categorical variables, respectively. $P<0.05$ was considered statistically significant. Statistical analysis was performed using Stata v15.1 (StataCorp, College Station, Texas, USA). This study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (von Elm et al., 2014).

## 3 Results

Between January 2008 and June 2018, ten patients (five males and five females, with an average age of (23.8±14.1) years) with SPAC (five dorsiflexion deformities, three plantarflexion deformities, one plantarflexion with varus, and one dorsiflexion with varus) were treated with external fixators at the two centers (five patients at each center). Ilizarov frames were used in six patients and combined-type external fixators in four patients. 3DPMs were used for surgical planning in five patients. The 3DPM group had significantly shorter operation duration than the control group ((2.0±0.3) h vs. (3.2±0.3) h, $P<0.01$). We did not observe a significant difference in blood loss or length of hospital stay between the two groups. Patients in the 3DPM group reported higher satisfaction than those in the control group, owing to better patient-surgeon communication (Table 2).

MTA, ROM, and AOFAS scores between the 3DPM and control groups showed no significant

**Table 2 Comparison between the 3DPM and control groups**

| Characteristics | Total (*n*=10) | 3DPM (*n*=5) | Control (*n*=5) | *P* value |
|---|---|---|---|---|
| Age (years) | 23.8±14.1 | 30.8±14.2 | 16.8±11.1 | 0.12 |
| Gender | | | | 1.00 |
| Female | 5 | 2 | 3 | |
| Male | 5 | 3 | 2 | |
| Site | | | | 1.00 |
| Beijing | 5 | 3 | 2 | |
| Xi'an | 5 | 2 | 3 | |
| Type of deformity | | | | 1.00 |
| Plantarflexion | 3 | 1 | 2 | |
| Dorsiflexion | 5 | 3 | 2 | |
| Plantar with varus or valgus | 1 | 1 | 0 | |
| Dorsal with varus or valgus | 1 | 0 | 1 | |
| External fixator | | | | 1.00 |
| Ilizarov | 6 | 3 | 3 | |
| Combined-type | 4 | 2 | 2 | |
| Operation duration (h) | 2.6±0.7 | 2.0±0.3 | 3.2±0.3 | <0.01 |
| Blood loss (mL) | 51.0±20.3 | 44.0±11.4 | 58.0±25.9 | 0.30 |
| Hospital stay (weeks) | 9.9±1.3 | 9.7±1.6 | 10.1±1.1 | 0.67 |
| Patient satisfaction scores | 7.5±1.4 | 8.6±0.6 | 6.4±1.1 | <0.01 |
| Follow-up (years) | 7.6±4.0 | 7.0±4.2 | 8.0±4.3 | 0.70 |

3DPM: three-dimension-printed model. Data are expressed as number of patients or mean±standard deviation.

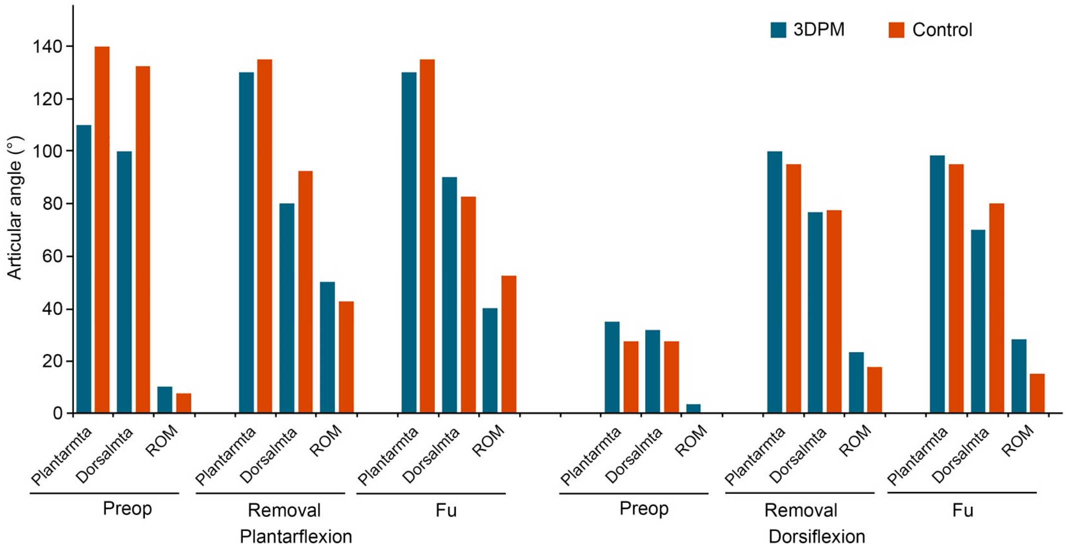


**Fig. 6 Changes of MTA and ROM in the 3DPM and control groups. MTA: metatarsal-tibial angle; ROM: range of motion; 3DPM: three-dimension-printed model; Plantamta: MTA at the maximum plantarflexion; Dorsalmta: MTA at the maximum dorsiflexion; Preop: preoperative; Removal: after removal of the external fixator; Fu: at the final follow-up.**

differences pre-operation, after removal of the external fixator, or at follow-up. ROM was substantially increased from pre-operation to the removal of the fixator in both groups (3DPM group: from 6.0°±5.5° to 32.0°±23.1°; control group: from 4.0°±4.2° to 31.0°±16.4°). The ROM was well maintained at 36.5°±19.7° over an average follow-up of (7.6±4.0) years (Fig. 6). In addition, the AOFAS scores significantly increased from 33.4±11.0 pre-operation to 64.4±4.7 after removal of the fixator, and further increased to 84.4±9.0 over the follow-up period (Fig. 7). A plantigrade foot was achieved and gait was substantially improved in all patients. Pin-tract infections occurred in two patients (one in each group) during distraction and were treated with wound care and oral antibiotics. No other complications occurred.

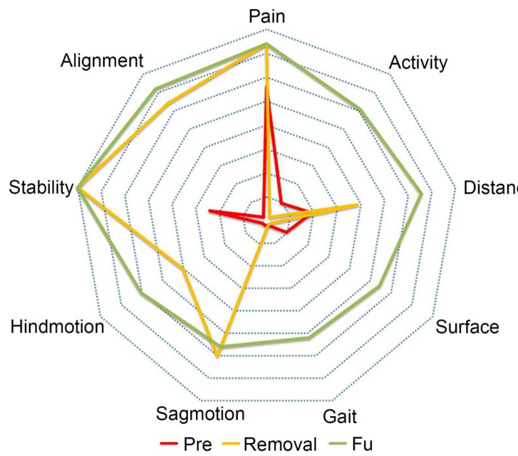


**Fig. 7 Changes in AOFAS scores. Activity: activity limitations and support requirement; Distance: maximum walking distance; Surface: walking surfaces; Gait: gait abnormality; Sagmotion: sagittal motion (flexion and extension); Hindmotion: hindfoot motion (inversion and eversion); Stability: ankle-hindfoot stability (anteroposterior, varus-valgus). AOFAS: American Orthopedic Foot and Ankle Society; Pre: preoperative; Removal: after removal of the external fixator; Fu: at the final follow-up.**

## 4 Discussion

### 4.1 Major findings

The results of this study showed that preoperative surgical planning using patient-specific 3DPMs significantly reduced the operation duration for correction of SPAC with external fixators, it improved patient satisfaction while providing similar improvements in ROM and AOFAS scores compared to traditional surgical planning.

### 4.2 Operation duration

Operation duration plays an essential role in surgical outcomes. Previous studies have demonstrated that surgical planning using 3DPMs reduces operation time for various ankle traumas and deformities (Liu et al., 2018). For example, Yang et al. (2016) found shorter operation time for 15 patients with 3DPM-assisted surgical planning than for 15 counterparts with conventional planning (71 min vs. 98 min) in the treatment of trimalleolar fractures. A randomized trial by Zheng et al. (2018) showed shorter operation time in a 3DPM-assisted group than in a conventional group (74 min vs. 90 min) in the treatment of Pilon fractures in 100 patients. Duan et al. (2019) noted shorter time for accurate drilling of a K-wire to the satisfactory position (2.1 min vs. 4.6 min) and fewer re-drills (two cases vs. eight cases) in 14 joints with 3DPM assistance than in 16 joints using the traditional method during subtalar joint arthrodesis. In addition, Corona et al. (2018) reported that the average surgical time for nine patients who underwent 3DPM-assisted surgical planning was approximately half the time required for ten patients with traditional planning (172 min vs. 329 min) in the treatment of post-traumatic tibial malunion or non-union using circular external fixation. Similarly, the study by Liu et al. (2020) demonstrated a shorter surgical time in 12 patients with preoperative surgical planning when using individualized 3DPMs of complex hypertrophic scars.

In accordance with these studies, we found significantly shorter operation time in the 3DPM group than in the control group. This was achieved via preoperative installation of the external fixators and surgical rehearsal on the 3DPMs. In the control group, frames were installed and K-wires were drilled intraoperatively based on surgeons' experience. Adjustment of fixator configuration and re-drilling may be required with this approach, leading to prolonged operative time. Using 3DPMs, surgeons are able to pre-assemble the external fixator, optimize its configuration, and simulate the placement, as well as determine the size, drilling location, and direction of K-wires prior to surgery. Therefore, intraoperative modification of the frame configuration and K-wire re-drills are minimized or avoided, which substantially reduces operation time.

### 4.3 MTA and ROM

Appropriate fixator construction and installation, as well as accurate insertion of wires and screws, are crucial for fixation stability and predictable outcome when treating ankle contracture using external fixators. According to the American Association for Orthopedics Surgeons, the normative values for ankle dorsiflexion and plantarflexion are 20°–30° and 40°–50° from the neutral position at 90° of MTA, respectively (Bava et al., 2010). Korp et al. (2015) defined functional ROM as follows: (1) dorsiflexion: 14°–20° mild contracture, 7°–13° moderate contracture, <6° severe contracture; (2) plantarflexion: 33°–49° mild contracture, 17°–32° moderate contracture, <16° severe contracture. We found significant increases in MTA and ROM in all patients, as shown in Fig. 6, though we did not detect significant differences in MTA or ROM between the 3DPM and control groups. This finding agrees with Zhang et al. (2018), indicating that 3DPM-assisted surgical planning offers similar effectiveness of correction compared to conventional surgical planning. This could be explained by the fact that most operations in this study were performed by a group of experienced surgeons. Since they were familiar with the anatomy and procedures, the benefits of 3DPM use might have been relatively limited. However, it is noteworthy that the use of 3DPMs is able to shorten the learning curve for junior surgeons (Yang et al., 2016; Liu et al., 2018, 2020). In our study, one surgery in each group was performed by a junior surgeon, who reported an easier learning process and more confidence when using the 3DPM due to the preconstructed frame and preoperative surgery simulation.

### 4.4 AOFAS

The AOFAS ankle and hindfoot scale is a comprehensive, well-accepted method of evaluating ankle function. Duan et al. (2019) demonstrated comparable AOFAS scores between the 3DPM and control groups in the treatment of ankle deformities. In the study by Zhang et al. (2018), the AOFAS score was 87.4 in the 3DPM group and 84.7 in the conventional group. In agreement with these studies, we found no significant difference in AOFAS scores between the two groups. The AOFAS scores significantly increased after removal of the external fixator, and even slightly increased over follow-up. Although AOFAS scores improved, we would like to note that ankylotic ankles will still be stiff after correction into a plantigrade position. Therefore, it is crucial to discuss this expected outcome with patients preoperatively. Our study also showed that 3DPMs are helpful in doctor-patient communication due to the visualization and tactility provided, which improve patients' understanding of the surgical procedure and potential outcome, as well as their compliance with postoperative rehabilitation.

### 4.5 Complications

Complications associated with the use of external fixators for ankle contracture included intraoperative blood loss, fixation failure, pain, pin-tract infection, osteomyelitis, joint instability, neurovascular injury, and re-contracture. Of these, pin-tract infection is the most commonly reported complication in previous studies (Steinwender et al., 2001; Kocaoğlu et al., 2002; Saghieh et al., 2011; Refai et al., 2012). In the present study, pin-tract infections developed in two patients (one in each group). They were controlled with oral antibiotics and local dressings without any serious sequelae. Re-contracture is another common complication following correction of severe ankle contracture. To prevent recurrence, rigid ankle orthosis and physiotherapy were recommended after removal of the external fixator, until complete stabilization and remodeling were achieved.

### 4.6 Limitations

This study has several limitations. Although 3D printing has become more accessible and affordable over the past decade, the time (usually 24 h) and funds (more than 2000 RMB, approximately 300 USD) needed for manufacturing a 3DPM cannot be disregarded. In addition, all patients in our study were hospitalized until removal of the external fixators to facilitate adjustment of the distraction rate and minimize complications. This prolonged hospital stay inevitability increased the overall cost. Another major limitation is the small sample size. The number of patients with SPAC has dramatically decreased in Chinese hospitals due to a lower incidence of burns and higher rate of early intervention to prevent joint contracture. Despite these limitations, this is the first study to compare operation duration, ROM, and AOFAS scores between 3DPM-assisted and traditional surgical planning for the treatment of SPAC using external fixators. A future randomized controlled trial with adequate sample size will better elucidate the benefits of 3DPM-assisted surgical planning in the treatment of SPAC and other ankle deformities.

## 5 Conclusions

Preoperative surgical planning using patient-specific 3DPMs reduces operation duration and increases patient satisfaction while providing similar improvement in ankle movement and function compared to traditional 2D imaging-based surgical planning for the correction of SPAC with external fixators.

## Author contributions

Yan HAN, Youbai CHEN, and Zehao NIU drafted the manuscript and designed the study. Youbai CHEN, Zehao NIU, and Weiqian JIANG collected the data and performed the data analysis. Yan HAN, Yonghong LEI, Ran TAO, and Lingli GUO performed part of the surgeries. Wensen XIA, Baoqiang SONG, Luyu HUANG, Kexue ZHANG, and Qixu ZHANG measured MTA, ROM, AOFAS, and hindfoot scores. All authors have read and approved the final manuscript and, therefore, have full access to all the data in the study and take responsibility for the integrity and security of the data.

## Compliance with ethics guidelines

Youbai CHEN, Zehao NIU, Weiqian JIANG, Ran TAO, Yonghong LEI, Lingli GUO, Kexue ZHANG, Wensen XIA, Baoqiang SONG, Luyu HUANG, Qixu ZHANG, and Yan HAN declare that they have no conflict of interest.

All procedures followed were approval by the Institutional Ethics Committees of Chinese PLA General Hospital (Approval ID: S2021-241-01). All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). Informed consent was obtained from all patients for being included in the study.

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