Customized Three-Dimensional-Printed Orthopedic Close Contact Casts for the Treatment of Stable Ankle Fractures: Finite Element Analysis and a Pilot Study

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ABSTRACT: Ankle fracture is one of the most common traumatic fractures among the elderly population. The majority of ankle fractures are stable types with the typically conservative strategy of close contact casting treatment. The continuous use of unventilated standard cast immobilization severely affects patient’s satisfaction and compliance and markedly increases the rates of various complications. Three-dimensional (3D) printing for casts has advantages of lightweight, ventilated, proper-fit, and esthetic improvements. In this work, this novel 3D-printed cast has been applied to individuals with stable ankle fractures, and its effectiveness can be successfully validated with finite element analysis and a pilot study. A 30% reduction of the volume was chosen as the optimal result in topology optimization. Both 3D-printed casts and conventional casts showed significant ankle function improvement after immobilization for 6 weeks (p = 0.000). The 3D-printed casts were superior to the traditional casts in Olerud–Molander Ankle Scores (OMAS), with the mean difference of 8.3 ± 8.57 OMAS points (95% CI −10.8 to 27.5; p = 0.354) for 6 weeks, implying that the 3D-printed casts possibly maintain the equal clinical efficacy as the traditional casts. The statistically significant difference between groups from the 3D-printed cast and the traditional one observed in C-QUEST 2.0 was 11.3 ± 1.5 points (95% CI 8.0−14.6; p = 0.000), indicating that the 3D-printed cast possesses outperforming satisfaction and compliance and has great potential in practical applications. There were no severe complications in the 3D-printed casts, but more moderate complications were observed in the traditional casts.

1. INTRODUCTION

Ankle fractures are one of the most commonly encountered fractures in the emergency trauma department, with an annual incidence of up to 179 cases per 100 000 population.1 It is estimated that more than 5 million people in the US alone have sought medical care for ankle fractures.2 Although accurate statistical data are lacking on the prevalence and incidence of ankle fractures in China, there will be much more considerable data because they occur annually in a much greater population. This rate may further increase due to the growth of the aging population and participation in sports.3 Depending on the mechanism of injury, the vast majority of ankle fractures are lateral malleolus, and the most common type is the Weber B type fibula fracture with 65.8%. Based on the Arbeitsgemeinschaft für Osteosynthesefragen Foundation/Orthopedic Trauma Association (AO/OTA) classification, the Weber B type fibula fractures without syndesmotic injury are generally considered as stable fractures.4 Abundant evidence demonstrated that conservative methods could treat stable...
fibular fractures with excellent functional outcome and no increased risk of arthritis up to 30 years in the follow-up study.4−7

An orthopedic cast is the most commonly used nonoperative circumferential immobilizer method, which is inexpensive and easy to obtain in the emergency room. The utilization of an orthopedic cast is intended to control the fracture site by redistributing the axial load and then cause sufficient fracture healing (bone union).8 A close contact cast (CCC) was usually employed as a first-line treatment9,10 to apply plaster or fiberglass into the area from the knee to the foot to withhold the ankle in the functional position. Many studies demonstrated that the CCC exhibited equivalent functional results and lower complications for 6 months compared to the open surgical reduction in elderly patients.11−13 Although there was unquestionable clinical efficacy of the traditional CCC, its inadequate ventilation and improper fit still severely reduce the satisfaction and compliance of the patients. Meanwhile, the continuous use of unventilated cast immobilization leads to various complications that seriously hinder rehabilitation approaches and early-stage activities.10

Given the shortage of abovementioned traditional casts, there is growing interest in the three-dimensional printing (3D printing) technology in the orthotics field recently. Benefited from its digital manufacturing system, physicians could fabricate the 3D-printed cast with freeform, comfortable, lightweight, ventilated, user-fit, and esthetic improvements,11 even create new functionalities and applications combining with the physical modalities. A previous study proposed a standard 3D printing streamline to produce a customized forearm cast of favorable quality with an appropriate fit and a ventilated structure, exhibiting the 3D-printed forearm casts as having potential and better benefits in clinical applications.12 Compared to the traditional standard methods susceptible to technical differences, the 3D printing process could serve as a useful alternative to improve reproducibility and design standardization.13,14 Various 3D printing casts or orthoses have been studied,12,15−17 some of which even have been approved by the FDA and covered by most US insurance providers, such as ActivArmor. A review confirmed that the 3D-printed technology could be a replicable process to support professionals in designing appropriate assistive equipment.13 A foot orthosis made from the 3D printing method presented superior effects on biomechanical parameters and favored clinical efficacy.15 The same observation in a preliminary study of 3D-printed wrist orthosis for wrist pain17 exhibited significant pain relief as the conventional cock-up orthosis.

For integrating the advantages of the CCC and 3D printing technique, this study proposed a novel customized 3D-printed orthopedic CCC that could provide practical immobilization for patients with stable ankle fractures. After engineering assessment using finite element analysis (FEA), the novel cast stress distribution under the different loading conditions showed that this cast enables to adequately protect the fracture site. According to the abovementioned analysis with the stress distribution and displacement contour, the whole cast structure was optimized to minimize structural compliance and simultaneously maintain the cast’s required stiffness. As a pilot study, we are mainly concerned about the differences in the clinical efficacy and complication between 3D-printed casts and standard conventional casts, demonstrating that a 3D-printed cast is superior to or comparable to the traditional one. It is anticipated that the as-fabricated cast can pave the way to the new designs of multifunctional CCC for high-performance devices in stable ankle fractures.

2. RESULTS

2.1. Finite Element Analysis. 2.1.1. Stress Distribution. As we all know, the fibula does not carry any significant loads of body weight. Nevertheless, the accidental collision at the fracture area frequently happens in daily activities. This FEA was used to evaluate the fracture protection of the 3D-fabricated cast under accidental collision at the fracture site. After imposing restrictions on the plantar surfaces of the low extremity model without casts, 200 N force was delivered directly at the lateral malleolus. The von Mises contour of the low extremity model showed the stress distribution mainly at the fracture site with 14.81 MPa (Figure 1a). After applying the 3D-printed cast onto the low extremity model, the stress at the fracture site decreased to 8.85 MPa, while the remaining...
stress was distributed to the soft tissue and cast (5.45 MPa was distributed to the cast) (Figure 1b,c). No overconcentrated stress was found in von Mises contour at the fracture site, indicating that the novel cast could effectively protect the cast from secondary injury (Figure 1b).

2.1.2. Optimization Analysis. The displacement analysis contour showed that the maximum distortion area was located at the proximal of the low extremity (Figure 1d). Based on the contour of stress distribution and displacement, both the proximal and the terminal regions were excluded from optimization analysis (Figure 2a). The optimizations of both structural compliance and volume reached a convergence. Figure 2b–e depicts structural compliance and the progression of element density distribution during the optimization process. The topology optimization regions had a reasonable manufactural distribution for the cast design. To ensure that the cast has a minimized structure compliance and satisfying stiffness, a 30% reduction of the volume was applied as the optimal result. The optimizations only required 15 iterations to reach convergence and compliance. Based on the topology optimization and FEA analysis results, the cavities and openings of the cast were created on the cast for lightweight and ventilation design (Figure 3).

2.2. Clinical Evaluation. All of the demographic and clinical characteristics of the recruited patients can be seen in Table 1, with all of the baseline characteristics well matched between groups. The average age of participants is 67 years. All of the patients completed the 6 week follow up and clinical treatment on time. Once the study was completed, all of the clinical performances of the two casts were analyzed by the same physician.

| Metric                                   | 3D printing cast | traditional cast | p value |
|------------------------------------------|------------------|------------------|---------|
| age (years)                              | 68.3 ± 12.1      | 66.0 ± 11.7      | 0.740   |
| gender                                   | 3 F + 3 M        | 4 F + 2 M        | 0.558   |
| weight (kg)                              | 76.7 ± 7.3       | 76.5 ± 8.8       | 0.584   |
| affected side (R, %)                     | 57%              | 43%              | 0.558   |
| OMAS                                     | 16.7 ± 10.3      | 18.3 ± 9.8       | 0.781   |
| VAS at weight-bearing                    | 5.0 ± 0.9        | 5.5 ± 0.5        | 0.448   |
| inversion, compared with uninjury ankle (%) | 71.6 ± 5.8   | 64.5 ± 4.8       | 0.397   |
| inversion, compared with uninjury ankle (%) | 59.9 ± 5.7   | 57.4 ± 3.9       | 0.064   |

*R’ = right, OMAS = Olerud–Molander Ankle Score, and VAS = Visual Analogue Scale.
Both groups showed significant improvement in OMAS after immobilization for 6 weeks (p = 0.000). However, the comparison between the two groups showed no difference in OMAS, with a total score of 72.5 ± 14.1 for group A and 80.8 ± 15.6 for group B (p = 0.971). Moreover, the mean difference between 3D printing cast vs traditional one was 8.3 ± 8.57 OMAS points (95% CI −10.8 to 27.5; p = 0.971). These results indicated that the 3D-printed cast had a favorable performance compared to the traditional cast (Table 2 and Figure 4a). The 3D-printed cast was proven to be more effective in dealing with joint stiffness for each item. The eversion and inversion ROM of the ankles in two groups showed statistical difference with group A 76.2 ± 3.3 vs group B 82.2 ± 8.2 (p = 0.042) and group A 75.7 ± 3.7 vs group B 87.1 ± 8.8 (p = 0.016) (Figure 4c,d), implying that the 3D-printed casts were beneficial to decrease the rates of joint stiffness, which generally happens in traditional casts. However, there were no significant improvements in functional activities, such as stairs, supports, and sporting activities. No difference was observed between groups on the VAS pain scale (p = 0.583).

No patients experienced severe complications in the 6 week follow ups, such as venous thromboembolism, secondary reduction, skin breakage, structural compliance with suitable stiffness, and complex regional pain syndrome. Two patients in the traditional group complained about the cast with overweight, discomfort, skin itchiness, and joint stiffness during the follow-up period. However, no such grumble happened in the 3D-printed group. The 3D-printed cast is remarkably superior to the traditional one as the total score of C-QUEST 2.0 is 11.3 ± 1.5 points (95% CI 8.0–14.6; p = 0.000) collected from the participants’ feedback (Figure 4b). Most subjects were satisfied with the effectiveness, safety, and durability between the two groups, confirming that the 3D-printed cast has tremendous potential in treating stable ankle fractures.

### 3. DISCUSSION

It is recognized that orthopedic CCC is generally used to treat stable ankle fractures for 6 weeks. Several pieces of evidence have shown that this nonoperative cast had a successful fracture union.4,5,18,19 However, various complications have been reported due to improper fit, the wet cast of an unventilated structure, and unbalanced pressure.12 A retrospective care record audit in Sweden showed that 25% of the patients experienced complications.20 To overcome these obstacles, we proposed a novel close contact casting fabricated using a 3D printing technique that held the fractured ankle in a proper position and successfully decreased the rate of complications.

According to clinical observation, the leading causes of fracture displacement were uncontrolled ankle movement and shear forces. A 200 N force directly loaded to the low extremity model was simulated at the fracture site, showing that the stress concentrated upon the fracture site in the von Mises contour. After uniting the cast on the low extremity model, FEA results demonstrated that the fracture area stress was successfully transferred to the cast with no stress concentration, indicating that this novel cast could protect the fractured site efficiently during the accidental collision. According to the stress distribution and displacement contour, the structural optimization was performed to minimize structural compliance with suitable stiffness. A new shape of CCC was made to reduce the former volume by 30% with sufficient immobilization strength. The new optimized 3D printing cast was created with the least weight and proper functionality.

Our research verified the effectiveness by virtual computer simulation analysis and provided a pilot compared study to observe the clinical performance and efficacy of a 3D-printed cast. The 3D-printed casts and traditional casts showed significant results after 6 weeks of immobilization with the improvement of OMAS and VAS scores. Furthermore, the ankles’ eversion and inversion demonstrated in the 3D-printed group were superior to traditional for 6 weeks, as proved by other 3D-printed cast studies.12 Although the 3D-printed casts

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Table 2. Primary and Secondary Outcomes at 6 Weeks

|                          | 3D printing cast | traditional cast | p value |
|--------------------------|------------------|------------------|---------|
| OMAS                     | 80.8 ± 15.6      | 72.5 ± 14.1      | 0.971   |
| QUEST 2.0                | 39.2 ± 2.6       | 27.8 ± 2.6       | 0.000   |
| eversion, compared with uninjury ankle (%) | 88.2 ± 8.2 | 76.2 ± 3.3 | 0.042  |
| inversion, compared with uninjury ankle (%) | 87.1 ± 8.8 | 75.7 ± 3.7 | 0.016  |
| VAS at weight-bearing    | 1.2 ± 1.0        | 1.5 ± 1.0        | 0.583   |
| rate of complications (%)| 0%               | 33.3%            | 0.121   |

OMAS = Olerud–Molander Ankle Score, QUEST 2.0 = Quebec Auxiliary Technology User Satisfaction Assessment Scale, and VAS = Visual Analogue Scale.

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acquired equal clinical efficacy, participants in the 3D-printed group with the removable structure could receive early rehabilitation treatment, such as PRICE protocols, electrical stimulus, and ultrasound. Sufficient research confirmed that early rehabilitation approaches could eliminate edema and improve the healing process of soft tissue and bone injury.\(^{21,22}\) Clinical assessment in OMAS showed no difference between the two groups, but the fracture line in the 3D-printed group healed faster than the traditional group at a visit after 6 weeks. This finding is consistent with the evidence from biomechanical studies, suggesting that early mechanical stimuli can efficiently enhance fracture healing. Hastie et al.\(^{23}\) and the NICE guideline\(^{24}\) also encouraged that bracing and early tolerated rehabilitation had a low risk of complications and good clinical results.

Although the risk of compartment syndrome and venous thromboembolism has been reported in other pieces of the literature,\(^{20}\) there were no severe complications identified in our two groups. However, some minor problems were easily induced in the conventional casts with the unventilated cyclic structure, such as improper fitting of the cast, joint stiffness, pink skin, and itchiness. Although there is a lack of 3D-printed research in the low extremity cast, abundant studies have demonstrated other types of casts or orthoses with the 3D printing technology with lower rates of complications. Newly designed 3D-printed forearm casts in our previous study showed the same conclusion that the skin problems, such as pink skin, were more common in conventional casts compared to the 3D-printed casts with proper fitting and early functional exercise.\(^{12}\) Besides, Graham et al.\(^{25}\) reported that 3D-printed wrist orthosis with waterproof, lightweight, and breathable features was suitable to the skin as a better candidate for wrist orthoses without adverse effects on the skin. Moreover, Yoo et al.\(^{26}\) demonstrated that no side effects were found in the newly developed hand orthosis combining the 3D printing and electromyography (EMG)-based control strategy.

QUEST 2.0 is a measurement test to allow researchers to evaluate participants’ satisfaction and compliance in various aspects, which is essential in a device study. QUEST 2.0 was used worldwide in different versions with sufficient reliability and validity, including the Chinese edition.\(^{27}\) The adopted Chinese-edition QUEST 2.0 showed that the wear characteristics have a clear advantage in the 3D-cast group from the patient’s perspective, such as comfort, weight, and ease of use. Based on the results of the Chinese-edition QUEST 2.0 in this study, the most important factor for hindering the patients’ adherence to plaster casts is the comfort of the patients. Most patients who wore the conventional casts complained about skin itchiness and unventilation, and some patients who encountered psychological consequences were afraid of the removal of the plaster casts operated by a dangerous saw later. Due to the advantages of the 3D printing technology, the casts are rationally designed to be ventilated, detachable, and washable. All of these features can largely decrease the rates of skin-related problems and improve the patients’ satisfaction and compliance. Compared with the conventional cast, this innovative cast had several advantages, such as lighter weight, ventilation, detachable design, the precision of fit, and no later removal with a dangerous saw. Previous studies have demonstrated that the common factor in posing adults to wear casts is the heavyweight.\(^{28}\) The heavier casts increase the energy expenditure in the daily activities and undoubtedly influence weight-bearing training. However, it is noted that the weight of 3D-printed casts is much lighter than that of the plaster ones in this study. The ventilation structure and the waterproof feature of the 3D-printed cast could significantly improve skincare hygiene to decrease skin breakage or ulcer.\(^{29}\) Besides, the 3D-printed casts with the cavities and openings allow patients and physicians for frequent skin checks to efficiently reduce the possibility of the compartment syndrome, which can also be discovered early to avoid severe consequences.\(^{25,30}\) A total novel manufacturing streamline can be successfully formed to decrease the rates of iatrogenic problems. As some previous results had reported, the complication risks may be due to the application by inexperienced practitioners, which could also be avoided by a skilled physician to a great extent.\(^{25}\) Even when fabricated by a professional physician, it is difficult for the traditional cast to precisely fit at the sites of bone prominences. With the digital design and 3D printing technique, the new process could achieve a more accurate manufacturing method with tunable parameters and a standardized streamline.

Nevertheless, the 3D-printed CCC will be further improved in future. The computer FEA analysis would be applied with a detailed biomechanical parameter profile to gain optimal ankle fracture treatment. Considering all of the related costs, including the materials, machine maintenance, skilled labor, and other additional running, the approach requires an accurate cost-effective analysis against conventional casting practices. As for a pilot study, only a small number of patients are required to explore the clinical feasibility for applying the 3D-printed cast in practical applications. Future clinical research is also necessary to improve the creditability of this 3D printing method in a larger sample size with a multicenter, random, open-control design.

4. CONCLUSIONS
In summary, we proposed a novel 3D printing CCC with lightweight and ventilation. It was demonstrated that the 3D printing cast was capable of immobilizing the fractured site with the FEA and clinical evaluation. Simultaneously, compared to the conventional cast, the new-edition cast received more positive feedback on patient adherence and satisfaction in the short 6 weeks and the 3D printing cast was comparable to the traditional cast in the functional outcomes of the Olerud–Molander Ankle Score. Furthermore, this study developed a light, new cast without losing its original function by rational design and topology optimization. This pilot study is only early-stage research with limited samples, and further studies are underway to in-depth understand the structure–property relationship. These data show that 3D-printed casts could be utilized as an alternative to a traditional cast in remote regions during the coronavirus pandemic, and pave the way to new designs for 3D-printed multifunctional devices to meet the growing demands.

5. MATERIALS AND METHODS

5.1. Finite Element Analysis. 5.1.1. Finite Element Modeling. A healthy male volunteer (56 year old, 170 cm in height, and 60 kg in weight) was recruited with written informed consent with no history of ankle trauma, tumor, or anatomical abnormalities. Computed tomography images (CT; Philips Brilliance 64-slice spiral CT) were recorded with a slice thickness of 0.67 mm in the low right extremities, ranging from the tibia to the whole foot. The volunteer’s ankle remained in a
neutral position during the CT scan. Subsequently, the DICOM-formatted CT data were reconstructed in 3D models after being imported into Mimics 10.01 software (Materialise, Belgium).

5.2. Digital CCC Design. 5.2.1. Geometric Model of the Low Extremity and Cast. The 3D models of soft tissue and bone were obtained separately using Boolean operation in Mimics and then exported as STL geometric files (Figure 5). The 3D bone geometric model was created and smoothed using Geomagic Studio software (version 12, Raindrop Geomagic, NC), and a stable Weber-B1 fibular fracture was stimulated as a 4 mm transverse fracture gap above the lateral malleolus with the surface cutting function (Figure 6).

Considering the manufacturing guideline instructions\textsuperscript{32} and cooperation with orthopedic surgeons, the curve command in the software was used to draw the trimming line on the geometric soft tissue model.

The following principles that trim line of the cast are listed as below: (a) the cast starts under the tibial tuberosity at the front and 2 cm below the fibula head at the back, respectively; (b) the shell overlaps the anteroposterior midline by 1.5 cm; (c) at the ankle, the line is kept 1 cm anterior to the top of the malleoli; and (d) the cast ends at the first metatarsal head with all toe tips clearly visible (Figure 7). Two parts of the cast surface model were generated by clipping the contours of the soft tissue surface along the trim line separately. The whole cast surface model parallely moved outward 2 mm to keep a certain distance away from the skin surface. Meanwhile, to avoid skin pressure and wear comfort, the sites of internal and external malleolus prominences and flare edges of the cast model also required the 2 mm outward shift. An overlap area between the shell and the main part of the cast is easily adjusted using the surrounding Velcro straps to accommodate the initial inflammatory swelling phase. After finishing all of the following steps of exact surfacing, detecting contours, and constructing patches and temples in Geomagic Studio, the complete geometric model was then directly exported as an STP file.

5.2.2. Material Property. The whole geometric model, which contains bone, soft tissue, and the cast, was imported into FEA preprocessing software Hypermesh 13.0 (Altair) for meshing and set of loading constraints, contact conditions, and friction coefficient. The tetrahedral element was used to divide the mesh, and the unit size was 3 mm for bones, 1 mm for the soft tissue, and 1 mm for the cast. The total numbers of elements and nodes for the soft tissue were 332,094 and 66,072, respectively; for the bones were 188,392 and 38,208, respectively; for the casts were 528,447 and 122,363, respectively. According to the previous studies,\textsuperscript{12} we simplified the bone, soft tissue, and cast models as a homogeneous linear elastic material (Table 3). The self-contact set was applied to avoid penetrating interaction between the muscles and cast. The contact interfaces between the casts and skin were set as direct contact with a friction coefficient of 0.4.\textsuperscript{33}

5.2.3. Mechanical Loading Set. In this study, the FEA was carried out to figure out whether the cast could immobilize the fractured bone in different loading situations or not. Based on the AO/OTA classification and clinical features, the distal fibular model was cut approximately 2 cm above the lateral malleolus to simulate the typical fibula fracture. According to a former FEA study of distal fibula fractures, two different directional forces were simulated by applying a 600 N vertical
weight loading to the entire low extremity proximal surface with the cast and a force of 200 N directed toward the fracture site with or without the cast, respectively. All nodes on the distal surfaces of the foot and cast restrained the freedom in all directions to avoid rigid model movements during the analysis (Figure 8). The applied weight loading and outside force were much larger than that in the real-world situation.

5.2.4. Optimization Analysis and Design Optimization. After the topological optimization with the FEA code Optostruct (Radioss, Altair Hyperwork14, Altair Engineering, Inc.), the cast structure was optimized to reduce the volume while retaining its maximum stiffness at the same time, that is, it not only removes the unnecessary material to conduct topology optimization for minimizing structural compliance but also satisfies volume removal constraints under the different loading conditions. Considering that this topology analysis objective function was used to minimize structure compliance in accordance with reducing strain energy, the program’s decreased volume was set as 20, 30, 40, and 50% with 20 iterations. The convergence tolerance was set at 0.0001. When the optimization asymptotically reached a convergence, the retained elements presented an optimal material distribution as designed. According to the volume constraint of topology optimization, the cast’s corresponding design was employed to hollow the optimized regions with several plum blossom-shaped cavities. The models would increase ventilation, economize materials, and improve esthetics after optimization.

5.3. 3D Printing and Manufacturing Framework. We used a stereolithography-based 3D printer (Lite 600HD, Shanghai Union Technology Co., Ltd., China) to print each part of the cast with a C-UV 9400E printing material (Dongguan Aide Polymer Material Technology Co., Ltd., China), an ABS-like SL resin with flexible and high impact resistance. Stereolithography is one of the most widely used additive manufacturing techniques in 3D printing with salient advantages of rapid prototyping, precision fabrication, and low cost. After all of the computer-aided designs (CADs) were finished, a standard workflow of the novel cast fabrication was summarized without complex training, especially for medical staff. The following flow chart is shown in Figure 9.

5.4. Clinical Evaluation. The Medical Research Ethics Committee of our hospital reviewed and approved this prospective study (ID: 201603006). All of the procedures were performed in strict conformity with the Declaration of Helsinki. Before attending the study, each participant was provided with written informed consent regarding all of the details of the experiment.

5.4.1. Participants. A total of 12 patients (five males and seven females) with stable ankle fractures were enrolled in the pilot study. They were recruited through Southern Medical University Hospital from October 2017 to April 2019 with the following inclusion criteria: (1) age above 16 years; (2) external rotation stress test negative and CT scan to confirm the stable ankle fracture, which met the diagnostic criteria (isolated fibular fracture, nondisplaced, and not associated with ligamentous rupture); and (3) participants expected to receive conservation treatment and adequately cooperated. The exclusion criteria were listed as below: (a) a medical history in the affected low limbs, such as fracture, metastases, metabolic disorders, or neuropathy; (b) current bilateral ankle fractures; and (c) unstable fracture or any skin break. All patients obtained a careful evaluation at baseline and 6 week follow up.

5.4.2. Randomization and Interventions. The experiment was designed to compare the CCC in different methods. Patients were randomly allocated to group A using a traditional approach or group B using a novel 3D printing approach (six numbers in each group). After provided with written informed consent, the participants were numbered by their first visit and

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Figure 8. Boundary condition and loading set. (a) Boundary condition; the (b) loading set at the fracture site; and the (c) overall view of the loading set.

Figure 9. Following flow chart of the 3D-printed cast.
assigned to the matching groups. All patients received CT scan and a standard below-the-knee CCC at first. Once the 3D-printed casts were prepared for 2 or 3 days, group B patients would replace the conventional casts with the 3D-printed casts immediately. All participants wore the casts for 6 weeks. Moreover, the 3D-printed group could receive rehabilitation treatment at the same time due to its removable design. If patients encountered uncomfortable ill-fitting or even pain, the same new cast was applied.

5.4.3. Outcome Measures. The primary results were recorded by the Olerud–Molander Ankle Score (OMAS) to evaluate clinical efficacy. This scoring system was designed to assess the ankle’s motor function and patients’ symptoms by the self-reported measurement. The scale of OMAS is 0–100, with lower scores indicating worse outcomes and more symptoms. The test consists of nine questions of pain, stiffness, swelling, stair climbing, running, jumping, squatting, use of supports, and work/activity level. Several clinical studies showed that OMAS was sensitive enough to assess minor changes before and after the interventions. Furthermore, it could be handled as a numerical continuum in the statistical analysis.

The secondary results were recorded by the Chinese Version of the Quebec Auxiliary Technology User Satisfaction Assessment Scale (C-QUEST 2.0). Visual Analogue Scale (VAS) for most severe pain during the treatment period, active eversion and inversion of the injured ankles compared to the uninjured sides, and the complication rate. C-QUEST 2.0 was used to evaluate the patient’s satisfaction with casts across 12 subscales from 1 to 5, with higher scores showing better satisfaction and compliance. We only surveyed concerning device dimension with eight items. VAS is the most common measurement instrument, ranging from 0 to 100, with a higher score indicating great pain intensity or dysfunction. The fibula injury mainly affected the eversion and inversion of the ankle movement. The proportion of eversion and inversion angles of injury sides was chosen to decrease the individual differences compared to uninjury sides. The related complications were carefully recorded during treatment periods, including pain, joint stiffness, muscle atrophy, skin itchiness, skin breakage/ulcer, deep vein thrombosis, complex regional pain syndrome, and nerve compression.

All primary and secondary measurements were assessed at baseline for 6 weeks by the same professional physician. Meanwhile, all participants received clinical examination and radiography of the injured ankle at the clinic visit. These data were only intended to demonstrate the treatment responses in different interventions.

5.4.4. Statistical Analysis. All of the statistical analyses were performed using Statistical Package for Social Sciences (SPSS) version 23.0 (IBM SPSS, Armonk, NY). Due to the relatively small sample size in this study, the continuous variable was not normal distribution or equal variance. All of the data were considered as nonparametric with Mann–Whitney tests to assess the statistical difference in OMAS, C-QUEST 2.0, VAS scores, and inversion and eversion angles between two groups. A p value of <0.05 was considered statistically significant for all tests.

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Notes

The authors declare no competing financial interest.

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