Clinical assessment of three-dimensional printing assisted osteotomy guide plates in precise osteotomy of adult talipes equinovarus

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Research article

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Abstract

Objectives: This current research is aimed to assess clinical efficacy and prognosis of three-dimensional (3D) printing assisted osteotomy guide plate in precise osteotomy of adult talipes equinovarus (ATE).

Materials and Methods: We included a total of 27 patients of ATE malformation (including 12 males and 15 females) from January 2014 to June 2018 in current research. The patients were divided into the routine group (n=12) and 3D printing group (n=15) based on different operative methods. The parameters, including the operative time, intraoperative blood loss, complications, time to obtain bony fusion, functional outcomes based on American Orthopedic Foot and Ankle Society (AOFAS) and International Congenital Clubfoot Study group (ICFSG) scoring systems between the two groups were observed and recorded regularly.

Results: The 3D printing group exhibits superiorities in shorter operative time, less intraoperative blood loss, higher rate of excellent and good outcomes presented by ICFSG score at last follow-up ($P < 0.001$, $P < 0.001$, $P = 0.019$) than the routine group. However, there was no significant difference exhibited in AOFAS score at last follow-up and total rate of complications between the two groups ($P = 0.136$, $P = 0.291$).

Conclusions: Operation assisted by 3D printing osteotomy guide plates for correcting the ATE malformation is novel and feasible, which might be an effective method to polish up the precise osteotomy of ATE malformation and enhance the clinical efficacy.

Introduction

Talipes equinovarus (TE) is a kind of complicated ankle deformity, which is mainly manifested as the plantar flexion and posterior talipes varus deformities, and in severe cases, it is often combined with anterior talipes adduction and arch elevation [1, 2]. ATE malformation is mainly caused by factors such as the congenital talipes equinovarus (CTE) without treatment or recurred after the treatment, polio sequelae, trauma and so on [3]. The pathological changes of ATE malformation mainly include severe soft tissue contractures and bone and joint deformities. The older the patients are, the more severe the bone and joint deformities are, and the more difficult the treatment is [4, 5]. Currently, there is no unified standard for the treatment strategy of ATE malformation, and the routine surgical methods mainly include Achilles tendon lengthening, balance the muscle force of internal and external inversion, and the triple arthrodesis (TA) [6].

Since the TA was first proposed and applied in 1923 [7], it has gradually become the most important surgical method for the correction of ATE malformation. However, due to the complicated deformity of ATE malformation, the difficulty of osteotomy in TA is so great that it is difficult for partial patients to obtain the ideal outcomes, and it is also easy to leave the deformities or cause deformities recurrence [8, 9]. Thus, in order to further evaluate the clinical efficacy of 3D printing osteotomy guide plate in accurate osteotomy of ATE malformation, this current research compared the routine TA with operation assisted by 3D printing osteotomy guide plate, and evaluated the prognosis.

Materials And Methods

Patients

This retrospective research included a total of 27 patients (12 males and 15 females) of ATE malformation who admitted to Jiangxi Provincial People's Hospital Affiliated to Nanchang University from January 2014 to June 2018. After admission, according to the random number table method, 12 patients were enrolled into routine group and 15 patients were enrolled into 3D printing group, and treated with different operative methods. The patients included in this research were all resulted in the CTE without treatment. All patients included in research have signed the informed consents, and the research was approved by Jiangxi Provincial People's Hospital Affiliated to Nanchang University.

Osteotomy guide plate fabrication and simulation operation

All of the patients were routinely examined by computed tomography (CT) scan and anterolateral X-rays of malformed ankle joint at the time of admission. The CT scanning data of 15 patients in 3D printing group were gathered by dual-source 64-slice spiral CT system (Siemens, Munich, Germany). The exact scanning parameters of CT system included the voltage of 120 KV and the pitch of 0.625 mm. Then, the data were further imported into Mimics 19.0 software (Materialise, Leuven, Belgium) in Digital Imaging and Communications in Medicine (DICOM) format, so as to reconstruct the 3D model of the malformed ankle joint. Furthermore, in order to correct the deformities of talipes varus and arch elevation caused by ATE malformation, the osteotomy planes were defined at calcaneocuboid, talonavicular and talocalcaneal joint surfaces respectively, and the consistent shape of guide plates were established individually. Meanwhile, the data of Kirschner wire guide holes on each guide plate were also improved respectively. Then the further simulated osteotomy was carried out, and the osteotomy surfaces of each joint were aligned to make the foot correct to the neutral position. After Boolean operation, the boundaries of guide plates were further trimmed and all guide holes were penetrated through, thereby completing design and production of guide plates. Finally, the obtained data were saved in STereoLithography (STL) format and further imported to the 3D printer (Waston Med, Inc., Changzhou, Jiangsu, China) to print out the target models and osteotomy guide plates (Fig. 1).

Surgical procedures

Senior surgeons in the same treatment group completed the surgical procedures of all patients in this research. Under the general anesthesia or epidural, the patient was placed in the supine position, and the blood circulation of proximal thigh was blocked by the pneumatic tourniquet. Then, an arc-shaped incision was made from the dorsolateral side of the foot to about 2 cm below the lateral malleolus, and the flap was further freed to expose the calcaneocuboid, talonavicular and talocalcaneal joints. As for the 3D printing group, the determination of osteotomy lines and the placement of osteotomy guide plate were directly according to outcomes of previous simulation. Subsequently, two 2.0 mm Kirschner wires were then drilled into the model along with guide plate hole to set each guide plate. After ensuring that osteotomy guide plates were matched and firmly fixed, the pendulum saw was used to carry out the

precise osteotomy along the osteotomy guide plate (Fig. 2). However, in routine group, the determination of osteotomy lines was determined only according to the preoperative planning and the intraoperative attempts. After confirming that orthopedic osteotomy was satisfactory, the talocalcaneal and calcaneocuboid joints were fixed with hollow screws, and the talonavicular joint was fixed with door-shaped screw. Ultimately, the reconstruction plates (Dongya Med, Inc., Shenyang, Liaoning, China) were selectively used for the shaping and fixation according to the specific degree of deformities.

Postoperative managements

There was no significant difference in postoperative managements between the two groups. After operation, the ankle joint of the affected side was fixed in 90 ° metatarsal flexion with lower leg plaster, and the affected limb was raised to observe the peripheral blood supply and skin sensation. Furthermore, the postoperative anterior and lateral X-rays and CT of the affected ankle joint were reexamined regularly. Until the bony fusion was confirmed by imaging examination, the plaster was demolished and the patients were instructed to begin partial rehabilitation training. During follow-ups, the incision, skin healing, range of ankle joint motion, complications and the time to obtain bony fusion were regularly observed and recorded.

Parameters assessment

The parameters, including operative time, intraoperative blood loss and the time to obtain bony fusion were observed and recorded regularly. At the last follow-up, the functional outcomes of ATE malformation were evaluated by AOFAS [10] and ICFSG scoring systems [11]. In ICFSG scoring system with a total score of 60, 0 is regarded as normal, 0–5 is regarded as excellent, 6–15 is regarded as good, 16–30 is regarded as fair, and > 30 is regarded as poor.

Statistical analysis

Data presented in this current research were statistically analyzed by the SPSS 24.0 software (SPSS, Inc., Chicago, USA) and exhibited as mean $\pm$ standard deviation (SD) or count (percentage). The statistical methods of Chi-squared test, Fisher exact test and Student's t test were applied in this research. The independent t test was used to assess the continuous variables, and the chi-square test or Fisher exact test was used to assess the categorical variables of different parameters collected between the two groups. P value < 0.05 was represented as statistically significant.

Results

Demographic data and ATE malformation characteristics

Table 1 presents the demographic data and ATE malformation characteristics of the two groups in this research. However, there was no significant difference between the two groups in age, gender, ATE malformation side and causes of ATE malformation (P > 0.05 for all).

Table 1

Comparisons of demographic data and ATE malformation characteristics between two groups

Characteristics	Routine group (n = 12)	3D printing group (n = 15)	P value
Mean age (range), years	54.7 ± 12.3 (45–68)	56.1 ± 13.2 (43–69)	0.579
Gender, n (%)			0.743
Male	5 (41.7)	7 (46.7)	
Female	7 (58.3)	8 (53.3)	
ATE malformation side, n (%)			0.285
Left	8 (66.7)	9 (60.0)	
Right	4 (33.3)	6 (40.0)	
Causes of ATE malformation, n (%)			0.641
Neglected treatment of CTE	12 (100)	15 (100)	
Recurrence of CTE after treatment	0	0	
Sequelae of polio	0	0	
Trauma	0	0	

Clinical data and functional outcomes

Clinical data and functional outcomes of the two groups are summarized in Table 2. In terms of operative time, (96.3 ± 14.2 min) in 3D printing group was significantly less than (122.9 ± 18.3 min) in the routine group ($P < 0.001$). In terms of intraoperative blood loss, the difference between 3D printing group (98.6 ± 18.7 ml) and routine group (126.5 ± 23.2 ml) was statistically significant ($P < 0.001$). However, there was no significant difference in follow-up time, time to obtain bony fusion, range of ankle joint motion and AOFAS score at last follow-up ($P > 0.05$). As for the ICFSG score at last follow-up, 5 patients were evaluated as excellent, 9 patients were good and 1 patient was fair in 3D printing group. In routine group, 3 patients were evaluated as excellent, 6 patients were good and 3 patients were fair. The rate of excellent and good outcomes of 3D printing group was 93.3%, which was higher than that of routine group (75%, $P = 0.019$).

Table 2

Comparison of clinical data and functional outcomes between two groups of ATE malformation

	Routine group (n = 12)	3D printing group (n = 15)	P value
Operative time, min	122.9 ± 18.3	96.3 ± 14.2	0.001
Intraoperative blood loss, ml	126.5 ± 23.2	98.6 ± 18.7	0.001
Follow-up time, month	26.1 ± 7.6	25.3 ± 6.9	0.352
Time to obtain bony fusion, week	13.3 ± 3.1	12.6 ± 2.7	0.243
Range of ankle joint motion at last follow-up, °			
Dorsal expansion	23.6 ± 3.4	24.2 ± 3.8	0.371
Plantarflexion	26.8 ± 3.7	27.4 ± 2.9	0.253
Inversion	24.3 ± 3.1	25.5 ± 3.5	0.162
Eversion	27.3 ± 3.4	28.1 ± 3.2	0.527
AOFAS score at last follow-up, point	77.8 ± 9.1	78.5 ± 8.5	0.136
ICFSG score at last follow-up, n (%)			
Excellent	3 (25.0)	5 (33.3)	0.257
Good	6 (50.0)	9 (60.0)	0.632
Fair	3 (25.0)	1 (6.7)	0.876 ^a
Poor	0	0	—
Rate of excellent and good outcomes, %	75.0	93.3	0.019
^a P value for continuity-corrected chi-squared test;			
ICFSG, International Congenital Clubfoot Study Group; AOFAS, American Orthopedic Foot and Ankle Society			

Complications

As shown in Table 3, 1 patient in routine group developed a deep infection after surgery, while 1 patient in 3D printing group developed a superficial infection, and the symptoms disappeared after treatment of intravenous antibiotics and regular dressing intervention. Moreover, 1 patient in 3D printing group and 1 patient in routine group have existed temporary anklebone stiffness, but they have recovered to normal after removing the plaster and undergoing gradual rehabilitation exercise. In addition, no other complications were observed in two groups, such as skin necrosis, vascular and nerve injuries, and

osteotomy nonunion. Thus, the total rate of complications of 3D printing group and routine group were 13.3% (2/15) and 16.7% (2/12), respectively, and there was no significant difference ($P = 0.291$).

Table 3
Comparison of complications between two groups of ATE malformation

Complications	Routine group (n = 12)	3D printing group (n = 15)	P value
Superficial infection	0	1 (6.7)	1.000 ^a
Deep infection	1 (8.3)	0	1.000 ^a
Skin necrosis	0	0	—
Nerve injury	0	0	—
Vascular injury	0	0	—
Osteotomy nonunion	0	0	—
Anklebone stiffness	1 (8.3)	1 (6.7)	1.000 ^a
Total	2 (16.7)	2 (13.3)	0.291
Values are expressed as, n (%); ^a P value for Fisher's exact test			

Typical case

Female, 57 years old, who has suffered from CTE in right side for 50 years. The patient has not paid enough attention to it and walked on the back of foot for 20 years. Later, the patient was admitted to our hospital for more than half a year due to the right foot pain and limited activity (Fig. 3). Physical examination revealed that the right ankle joint was stiff, the subtalar joint had no range of motion, and the knee tendon reflex was hyperactive. After the TA assisted by 3D printing osteotomy guide plates, postoperative imaging examination indicated that the osteotomy end was well aligned and the fixation effect was reliable. At 12 weeks postoperatively, the osteotomy end obtained the bony fusion (Fig. 4). At the last follow-up, her AOFAS score was evaluated as 81 points, and the ICFSG score was 12 points, which was evaluated as good.

Discussion

In recent years, with the in-depth understanding of ATE malformation, more and more scholars believe that the ATE malformation is a kind of three-dimensional and multi-directional anatomical relationship disorder [12, 13]. However, the pathogenic factors of ATE malformation are complicated, and the degree of deformities is not uniform. Moreover, the best treatment strategy for ATE malformation has not yet reached a consensus currently, which has presented a great challenge for surgeons to a certain extent [14]. During the operation, it is hard for operators to accurately adjust the osteotomy direction and angle of each dimension, so it is often need to repeatedly adjust or determine the correction strategy only based

on subjective assumptions, which eventually leads to a huge deviation from the preoperative planning, and the prognosis will be unoptimistic. Hence, it is vital to develop an appropriate and personalized treatment plan for different etiology, deformity location and degree of ATE malformation for the excellent functional reconstruction [15, 16].

In this research, we retrospectively compared the clinical efficacy and prognosis of routine TA and the operation assisted by 3D printing osteotomy guide plates for ATE malformation patients. In 3D printing group, the personalized osteotomy guide plate fabricated by 3D printing can be closely fitted to each joint surface. In all 15 patients, the osteotomy was performed successfully in one time, avoiding the repeated adjustments and tests during operation, which contributes to a more standardized and simpler operation. Meanwhile, it also reasonably explained that the parameters of operative time and intraoperative blood loss in the 3D printing group were less than that in routine group ($P < 0.001$). In addition, the osteotomy guide plate can be fixed with the preset Kirschner wire guide holes on the binding surfaces, which can effectively prevent the pendulum saw from slipping during the operation and producing deviation. Hence, after the rigorous design and standardized operative process, the accurate osteotomy of ATE malformation can be realized, and the clinical efficacy was equivalent to the preoperative planning. Meanwhile, the 3D printing group also presented a higher rate of excellent and good outcomes than routine group in ICFSG score at last follow-up (93.3% versus 75.0%, $P = 0.019$).

Although 3D printing assisted guide plates have been diffusely applied in clinical correction researches of cubitus varus deformity, developmental dysplasia of the hip, spinal scoliosis, hallux valgus and other deformities [17–20], while the application in ATE malformation correction has been rarely reported. Previously, Windisch et al. [21] applied 3D printing technology to fabricate a physical model of ATE malformation with a magnification of 4 times for surgeons to accurately analyze all bone and joint deformities, and perform preoperative planning, but this application only played the most basic role of 3D printing. Moreover, Gozar et al. [15] and Barker et al. [22] applied computer modeling analysis technology to the correction of TE malformation, and obtained the satisfactory short-term outcomes, but still lacked a long-term prognostic comparison with routine group. In this research, there was no significant difference between the two groups in total rate of complications (13.3% vs 16.7%, $P = 0.291$). This outcome was consistent with the research results of Zhang et al. [23] who used the 3D printing for the patients with complicated ankle fractures, indicating that 3D printing presents no apparent superiorities in avoiding complications. Furthermore, at the last follow-up, there was no significant difference in range of ankle joint motion, including the dorsal expansion, plantarflexion, inversion and eversion, between the two groups ($P > 0.05$). This may be attributed to the similar time of obtaining bony fusion, and taking the similar programs of rehabilitation training between the two groups, and both groups presented the relatively excellent postoperative functional outcomes.

Ultimately, it is essential to further point out and recognize the drawbacks of this research. For one thing, the mean follow-up time of this research was about 2 years. At last follow-up, the prognosis of some patients with ATE malformation (3 patients in routine group and 1 patient in 3D printing group) was evaluated as the fair, so it is essential to conduct further follow-up observation for a longer time in future.

For another thing, this current research is a retrospective research with a relatively small sample size. In order to further verify the clinical efficacy and prognosis of 3D printing assisted osteotomy guide plates for the correction of ATE malformation, multi-center prospective studies and larger sample size data are still needed.

Conclusion

Clinical application of 3D printing assisted osteotomy guide plates for correcting the ATE malformation is safe, precise and dependable. The 3D printing group exhibits the superiorities of shorter operative time, less intraoperative blood loss, higher rate of excellent and good outcomes presented by ICFSG score at last follow-up than routine group. Operation assisted by 3D printing osteotomy guide plate for correcting the ATE malformation is novel and feasible, which might be an effective method to polish up the precise osteotomy of ATE malformation and enhance the clinical efficacy.

Abbreviations

3D

Three-dimensional;

ATE

Adult talipes equinovarus;

AOFAS

American Orthopedic Foot and Ankle Society;

ICFSG

International Congenital Clubfoot Study group;

TE

Talipes equinovarus;

CTE

Congenital talipes equinovarus

TA

Triple arthrodesis;

CT

Computed tomography;

DICOM

Digital imaging and communications in medicine;

STL

STereoLithography.

Declarations

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Authors' contributions

YZ, LX, WG, SZ, WN and LD participated in the clinical data collection, data analysis and data interpretation. YZ, XX, WG, ZH and LD contributed to management of the clinical cases and interpretation of clinical data. YZ and LD wrote and edited the manuscript. LX, WN and LD contributed to the critical revision of the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The Ethics Committee of Jiangxi Provincial People's Hospital Affiliated to Nanchang University approved this study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Figures

Figure 1

Design and fabrication processes of the 3D printing models and guide plates. (A) According to the imported CT data, the deformed structure of the ankle joint was simulated in Mimics19.0 software. (B) 1:1 reference model printed based on simulation result. (C) In order to correct the deformity of arch elevation, the osteotomy planes were defined on the joint surfaces. (D) The simulated osteotomy for correcting the deformity of arch elevation was performed at the defined osteotomy planes and the reduction was performed after osteotomy (frontal view). (E) The result of reduction after the simulated osteotomy (lateral view). (F) In order to correct the deformity of talipes varus, the osteotomy planes were defined on the joint surfaces. (G) The simulated osteotomy for correcting the deformity of talipes varus was performed at defined osteotomy planes and the reduction was performed after osteotomy. (H) The osteotomy model and guide plates fabricated by the 3D printing.

Figure 2

Intraoperative photographs of TA assisted by 3D printing osteotomy guide plates. (A) The arc-shaped incision was made from the dorsolateral side of the foot to about 2 cm below the lateral malleolus. (B-C) The osteotomy guide plates were fixed with the preset Kirschner wire guide holes on the binding surfaces, and the precise osteotomy was performed under the guidance of guide plate. (D) The reconstruction plate was used for the shaping and fixation of ATE malformation.

Figure 3

Female, 57 years old, who has suffered from CTE in right side for 50 years. (A) The patient has not paid enough attention to the CTE and walked on the back of foot for 20 years. (B) Preoperative appearance, and the physical examination revealed that the right ankle joint was stiff, the subtalar joint had no range of motion, and the knee tendon reflex was hyperactive. (C-D) Preoperative X-ray and 3D reconstruction CT scanning of right ankle joint indicated the severe ATE malformation of the patient.

Figure 4

Postoperative imaging examinations and general appearance of right ankle joint. (A-B) Postoperative X-rays indicated that the osteotomy end was well aligned and the fixation effect was reliable. (C) At 12 weeks postoperatively, the osteotomy end obtained the bony fusion confirmed by CT scanning. (D) The general appearance of right ankle joint at the last follow-up.