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Original Article

Application of 3D Printing Navigation Template Technology in Severe Hallux Valgus Surgery

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Abstract

Objectives: To explore the application of 3D printed navigation template technology in severe Hallux valgus surgery. **Methods**: Forty-eight patients with severe Hallux valgus were selected. There were 24 cases in the control group underwent hallux valgus osteotomy using traditional methods and fixed with fully threaded hollow screws during the surgery. There were 24 cases in the 3D group who underwent personalized osteotomy using 3D printing navigation template technology. Patients were followed up regularly for six months after surgery. **Results**: The surgery time of the 3D group was shorter than that of the control group, and the intraoperative bleeding was reduced ($P<0.05$). Compared with the preoperative data, the HVA and IMA significantly reduced immediately and 1, 3, and 6 months after surgery ($P<0.05$). The VAS scores decreased significantly, while the AOFAS and SF-36 scores increased ($P<0.05$). At three months and six months after surgery, the VAS score of the 3D group was lower than that of the control group, while the SF-36 score was higher ($P<0.05$). During the follow-up period, both groups had no recurrent cases or complications. **Conclusions**: The 3D printing navigation template technology improves patients' prognosis, functional recovery, and quality of life.

Keywords: 3D Printing Navigation Template Technology, Osteotomy Surgery, Precision Therapy, Severe Hallux Valgus

Introduction

Hallux valgus is a common foot disease and a deformity in which the Hallux valgus skews outward with a Hallux valgus angle (HVA) more prominent than a normal physiological angle and is common in women (incidence 12%). With the change in social life, acquired Hallux valgus is increasing and seriously affects human life and work[1]. The pathological mechanism and surgical therapy of Hallux valgus have been in-depth studied since the 18th century, and more than 150 surgeries for Hallux valgus deformity of varying degrees exist. Surgical treatments increase the orthopaedic ability of Hallux valgus deformity. However, postoperative complications influence efficacy, especially the postoperative complications of severe Hallux valgus. This is mainly associated with incorrect selection of surgeries and intraoperative procedures. The current surgical protocol relies on the surgeon's clinical experience and preference rather than individualization and standardization, consisting of a common reason for the postoperative complications of Hallux valgus surgery.

Gradual maturation of 3D printing navigation template technology provides individualized, precise treatment for Hallux valgus patients, including preoperative diagnosis, preoperative simulated surgery, intraoperative assistant surgery, and individualized implants[2]. Before the osteotomy, the 3D model of the affected foot is printed based on data acquired by a CT scan, and the surgical navigation template and the corrective osteotomy protocol are designed according to the model of the affected foot. Based on this, a computer software is set to determine the position of the navigation plate in the metatarsal bone surface, the spatial location of

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the drilling and pendulum saw osteotomy, the position and the axis of the positioning hole of the individualized surgical navigation template, the rotation angle, the extension length, and the internal displacement of the bone reposition after osteotomy. By calculating all the data as mentioned earlier, the fixation protocol is determined[3].

3D printing navigation template technology transforms the virtual design of surgical protocol into the procedure of realistic surgery. It provides a practical pathway from virtual to reality[4]. However, the application of 3D printing navigation template technology in Hallux valgus is less studied. Partial study and clinical application have been conducted before the present study, i.e. 3D printing navigation template technology has been applied in patients with mild Hallux valgus. Compared with conventional surgery, the clinical application of 3D printing navigation template technology in treating Hallux valgus is disruptive. It is simple and can shorten the surgical time, increase the surgery's success, reduce both short- and long-term postoperative complications, shorten the learning curve of surgeons, have reproducibility and is suitable for clinical application. The present study aims to further explore the efficacy of individualized and precise 3D printing systems and navigation template systems in treating severe Hallux valgus to establish and evaluate the safety of applying the 3D printing navigation template technology in Hallux valgus. In summary, it provides new ideas, methods, and standards for treating Hallux valgus.

Materials and Methods

General information

A total of 48 patients with severe Hallux valgus admitted to Shenzhen Pingle Orthopedic Hospital from October 2017 to October 2020 were selected and randomly assigned into two groups based on a random number table. The control group included 24 patients and 26 feet, i.e. three males (3 feet) and 21 females (23 feet); the mean age was 42.14 years±6.85 years (range: 32-50); 9 left feet, 15 right feet and bilateral feet (n=1); the duration of the disease was reported to range from 3 to12 years (6.65 years±2.39 years). The 3D group included 24 patients and 26 feet, i.e. two males (2 feet) and 22 females (24 feet); the mean age was 42.54 years±6.59 years (range: 34-50); 8 left feet, 16 right feet and bilateral feet (n=1); duration of the disease fluctuated from 4 to 10 years (6.45 years±2.54 years). Basic information was comparable and not significantly different between the two groups, $p>0.05$.

The diagnostic criteria used are referred to Campbell's Operative Orthopaedics[5]. **Inclusion criteria**: Severe Hallux valgus, HVA>40°, IMA>20°; age 20~50; simple congenital Hallux valgus and acquired Hallux valgus; persistent functional pain with deformity was not improved after conservative treatment, and the deformity aggravated progressively; no history of Hallux valgus surgery. **Exclusion criteria**: complicated with other foot diseases; osteoarthritis of the first metatarsophalangeal joint; severe osteoporosis; rheumatoid arthritis; severe internal medicine disorders affecting anaesthesia and surgical safety; active infection; poor compliance and failure to cooperate with the study.

Methodology

The surgical process was performed by the same senior orthopedic surgeon with clinical work experience using 3D printed navigation template technology and traditional methods for the Ludloff osteotomy of hallux valgus for two groups of patients.

3D group: The same experienced surgeon performed the surgery guided by the preoperative plan with 3D printing navigation template technology. Before the surgery, AP, lateral and oblique X-rays and a 3D CT scan of the affected foot were performed. CT data were collected and analyzed with Imageware 13.0 software, and a 3D model of the forefoot and midfoot was constructed and printed.

Surgical preparation: 1) Determination of the positioning hole of the individualized surgical navigation template: design of the positioning hole of the navigation template of metatarsal bone: The 3D coordinate system was built with Imageware 13.0 software with the 3D CT data of the foot, the distance between the fixation hole and the osteotomy groove in the metatarsal distal osteotomy module was used as the standard to determine the plate of the navigation positioning hole of metatarsal distal osteotomy, then the position and direction were determined. The design of the positioning hole of the individualized navigation template of the proximal metatarsal bone was similar to that of the metatarsal bone. The 3D coordinate system was built with Imageware 13.0 software, the plate where the navigation positioning hole of metatarsal osteotomy was localized and the direction and position of internal fixation of K-wire were determined according to the reference point of metatarsal osteotomy in Geomagic 11.0 and the distance between the metatarsal osteotomy groove and the fixation hole. Multiple-angle observation and measurement of the model after osteotomy was performed in the 3D window. HVA and IMA were realigned and repositioned, and the talus, navicular bone, medial cuneiform bone and the 1st metatarsal bone were maintained in one axis. 2) Making of the navigation template: Based on the above navigation positioning hole, the positioning hole of the navigation template was established in the software with the position coordinates of the positioning hole of the navigation template. The template was stored in the "STL" format, and the physical template was printed in the 3D printer.

Surgical procedures: The patient was supine and underwent continuous epidural block anaesthesia. The surgical field was disinfected. An internal incision was made at the distal end of the 1st metatarsal bone, and the joint capsule was opened with an inverted L-shaped cut to expose the 1st metatarsal bone and metatarsophalangeal joint. The positioning hole was found by referring to the mould, the 3D printing navigation template was placed and adhered to the navigation template, and after positioning the

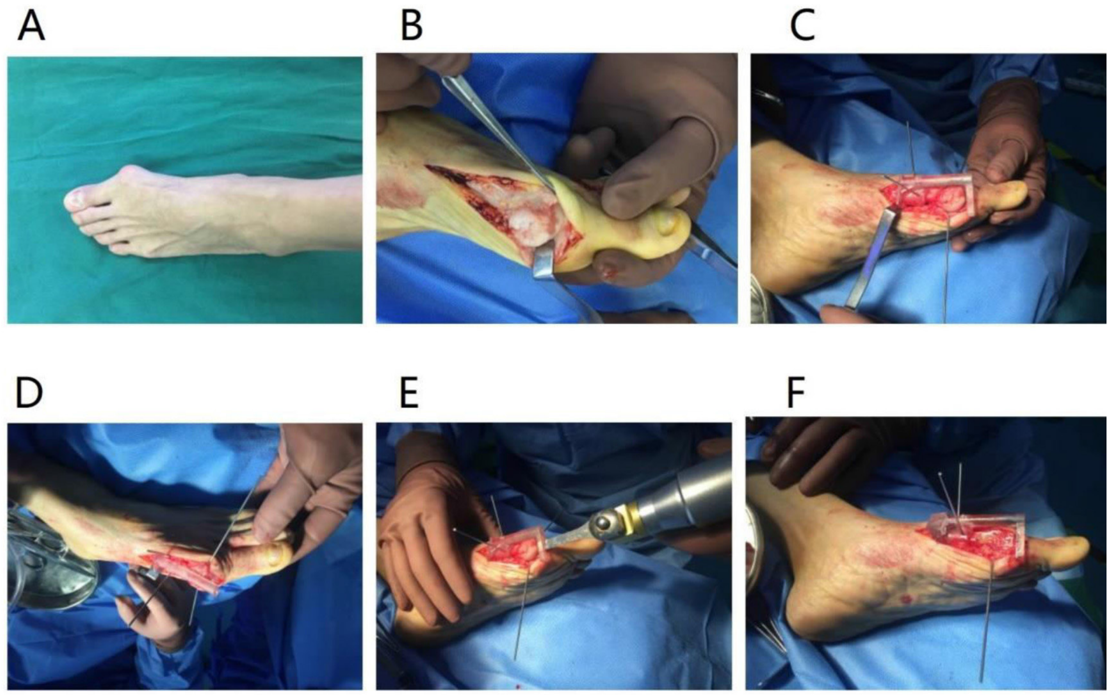

Figure 1. Intraoperative operations of case 1. A: A severe hallux valgus foot, gross examination of the toe shows hallux valgus, metatarsal adduction, and formation of hallucitis. B: Through the medial longitudinal approach, the first metatarsophalangeal joint was fully exposed, and proliferation can be seen in the distal medial osteophyte of the first metatarsal bone, with partial destruction of joint cartilage, and the first metatarsophalangeal joint was in a dislocation state. C: The periosteum was peeled off, the bony protrusions was fully exposed, and a navigation template designed and printed before surgery based on the bony marker device was used, then reinforced with Kirschner wire for stabilization (medial view). D: Lateral view of the device navigation template. E: A micro pendulum saw was used to design a osteotomy route based on the navigation template before surgery and then osteotomy was performed. F: Medial view after osteotomy.

osteotomy line, a V-shaped osteotomy was performed. When 3/4 osteotomy was completed, a K-wire was placed at the proximal end of the dorsal part of the bone. The distal bone was cut off completely, and the distal metatarsal bone was pushed to make the K-wire rotate outward to the external rotation correction angle designed before the surgery. Then the second K-wire was placed. After removing the navigation template, two Herbert screws (3.2 mm) were screwed to fix the osteotomy plane. After the osteotomy, the lateral soft tissue was released according to intraoperative condition and repositioning and fixation were performed with the navigation system. The medial joint capsule was sutured, and the incision was closed.

Control group: AP, lateral and oblique X-rays of the affected foot were taken to measure HVA and IMA before the surgery. An experienced surgeon determined and performed the osteotomy based on the preoperative X-ray, according to the method described in Campbell's Operative Orthopaedics[5]. The surgical method is the same as the 3D group, and there is no 3D printed model as a reference for preoperative and intraoperative use. Full-threaded cannulate screws were used for fixation.

Immediately after surgery, AP, lateral and oblique X-rays were taken to record HVA and IMA. Gauze and elastic bandages were used for pressure dressing after surgery. Lower limbs were elevated for three days. Pressure relief shoes were worn to protect walking after removing the sutures for 2-3 weeks later. The bandages were removed according to bone union eight weeks after surgery. The patient began weight-bearing exercises gradually. Hallux valgus brace was advised to protect the foot and maintain efficacy. Follow-up observations were carried out 1, 3 and 6 months after surgery. When the bone at the osteotomy site healed, the internal fixation was removed or maintained if no particular discomfort occurred. The operation procedures are shown in Figure 1 (Case 1) and Figure 2 (Case 2).

Observation

Surgical time, hospital stay and intraoperative bleeding volume were recorded.

AP, lateral and oblique X-rays were taken before surgery, immediately after surgery, and 1 month, 3 months and 6

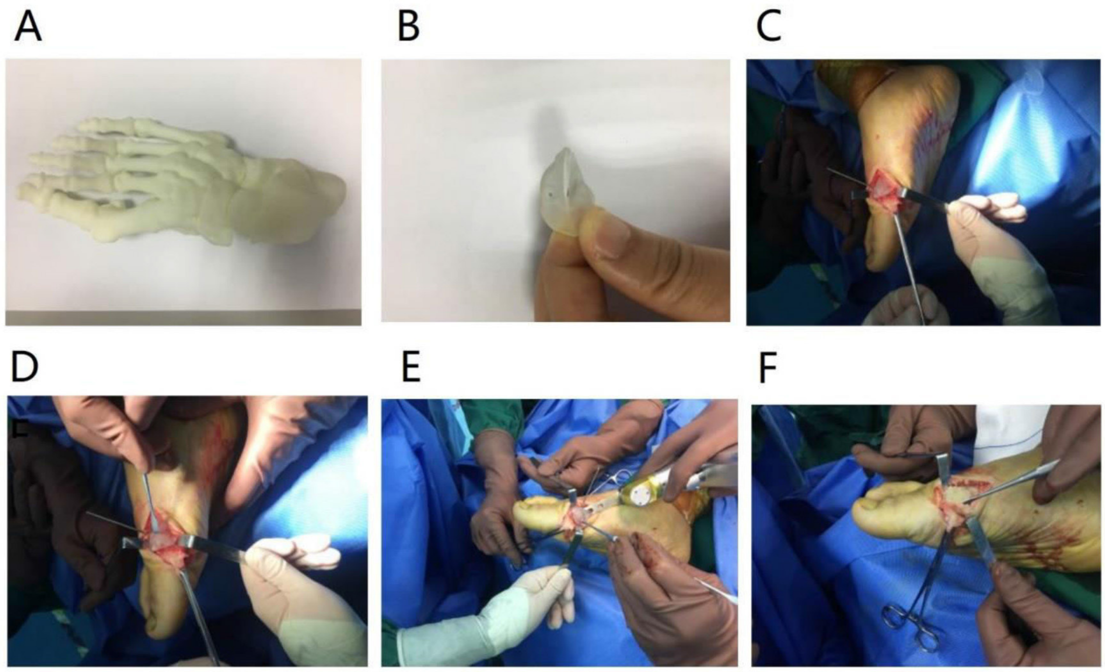

Figure 2. Intraoperative operations of case 2. A: Based on foot CT data before surgery, Geomagic 11.0 was used for editing and printing a 3D model of the foot. B: Before surgery, a navigation template was designed based on the 3D model of the foot and the osteotomy angle, and then printed. C: The bony protrusions was fully exposed. D: the navigation template designed and printed before surgery based on the bony marker device was used, then reinforced with Kirschner wire for stabilization. E: A micro pendulum saw was used to design a osteotomy route based on the navigation template before surgery and then osteotomy was performed. F: Medial view after osteotomy.

months after surgery to record HVA and IMA.

The AOFAS[6], VAS[7] and SF-36[8] were evaluated before surgery, immediately after surgery, and 1 month, 3 months and 6 months after surgery. AOFAS is a 100-point scale, including pain (40), joint function (50) and line of force (10). The higher the score, the better the foot function. VAS is a 10-point scale. The higher the score, the more severe the pain. SF-36 is a 100-point scale including eight dimensions. A higher score means a higher quality of life.

Statistics of relapse and complications: Complications include hallux varus, metastatic metatarsal pain, necrosis of the first metatarsal head, delayed union or non-union of bone

Statistical analysis

SPSS 19.0 software was used to analyze data. Measurement data were represented by $\bar{x}\pm s$, and Student's t-test analyzed the intergroup difference. Repeated measurement analysis of variance was used to analyze intragroup at different time points. Enumeration data were represented by n (%) and analyzed by the chi-square test. P<0.05 indicated a statistically significant difference.

Results

Perioperative indicators

Stage I healing of the surgical incisions was achieved in all patients without early complications. As shown in Table 1, the surgical time was significantly shorter, and the intraoperative bleeding volume was significantly less in the 3D group, p<0.05. Yet, the hospital stay was not significantly different between the two groups, p>0.05.

HVA and IMA

As shown in Table 2, the HVA and IMA immediately and 1 month, 3 months and 6 months after surgery were significantly lower than before, p<0.05. The HVA and IMA in the 3D group at all time points after surgery were slightly lower than those in the control group, yet the differences were not significant, p>0.05.

Score change

As shown in Table 3, the VAS score was significantly lower, and the AOFAS score and SF-36 score were significantly higher immediately and 1 month, 3 months and 6 months after surgery than those before surgery, p<0.05. Three

Table 1. Perioperative indicators [n (%)].

Group	n	Surgical time	Hospital stay	Intraoperative bleeding volume
Control group	24	52.13±10.52	6.78±2.62	34.52±3.09
3D group	24	40.36±9.45	6.59±2.45	23.65±2.54
χ^2		4.078	0.259	13.313
P		0.000	0.796	0.000

Table 2. HVA (°) and IMA ($\bar{x}$±*s*).

Group	n	HVA				
		Before surgery	Immediately after surgery	1 month	3 months	6 months
Control group	26	48.23±6.52	14.12±2.19a	14.16±3.21a	14.51±2.68a	14.85±3.06a
3D group	26	47.52±5.98	13.63±2.45a	13.82±3.15a	13.88±3.42a	14.05±2.96a
χ^2		0.409	0.760	0.385	0.739	0.958
P		0.684	0.451	0.702	0.463	0.343
Group	n	IMA				
		Before surgery	Immediately after surgery	1 month	3 months	6 months
Control group	26	22.12±1.05	7.15±1.32[a]	7.22±1.15[a]	7.53±1.36[a]	7.96±1.79[a]
3D group	26	22.36±1.21	6.79±1.52[a]	6.82±1.26[a]	6.96±1.45[a]	7.02±1.66[a]
χ^2		0.764	0.912	1.196	1.462	1.963
P		0.449	0.366	0.237	0.150	0.055
In comparison with before surgery, [a]P<0.05.						

Table 3. Score change ($\bar{x}$±*s*).

Group	n	AOFAS scores				
		Before surgery	Immediately after surgery	1 month	3 months	6 months
Control group	24	50.23±6.96	79.68±5.35[a]	80.63±5.96[a]	83.63±7.52[a]	84.52±6.45[a]
3D group	24	51.45±7.25	80.23±4.52[a]	83.26±6.98[a]	85.12±7.26[a]	89.46±5.79[a]
χ^2		0.595	0.385	1.404	0.698	2.792
P		0.555	0.702	0.167	0.488	0.008
Group	n	VAS scores				
		Before surgery	Immediately after surgery	1 month	3 months	6 months
Control group	24	5.32±1.26	4.16±2.05a	2.45±0.72a	2.56±0.45a	1.98±0.26a
3D group	24	5.36±1.52	4.22±2.16a	2.15±0.69a	2.22±0.36a	1.63±0.21a
χ^2		0.099	0.099	1.474	2.890	5.130
P		0.921	0.922	0.147	0.006	0.000
Group	n	SF-36 scores				
		Before surgery	Immediately after surgery	1 month	3 months	6 months
Control group	24	56.35±12.15	57.52±7.45[a]	63.25±4.29[a]	70.63±5.18[a]	86.25±4.15[a]
3D group	24	55.36±10.52	58.36±5.36[a]	65.36±6.48[a]	75.63±5.69[a]	90.52±3.16[a]
χ^2		0.302	0.448	1.330	3.183	4.010
P		0.764	0.656	0.190	0.003	0.000
In comparison with before surgery, [a]P<0.05.						

months after surgery, the VAS score in the 3D group was significantly lower, and the SF-36 was significantly higher than that in the control group, $p<0.05$. Six months after surgery, the VAS score in the 3D group was significantly lower, and the AOFAS score and SF-36 score were significantly higher than that in the control group, $p<0.05$.

Relapse and complications

During follow-up, no relapse, hallux varus, metastatic metatarsal pain, necrosis of the first metatarsal head, loosening of internal fixation, delayed or non-union of bone occurred in neither group. Some patients had mild skin numbness symptoms that gradually disappeared without intervention. Two cases of metastatic metatarsal pain occurred in the control group, with an incidence of complications of 8.33%.

Discussion

The study advances in the treatment of Hallux valgus

Hallux valgus is a common hallux deformity manifested by valgus of the first Hallux and medial deviation of the first metatarsal bone. Hallux valgus has many subtypes and is classified into mild (HVA<30°, IMA<13°), moderate (30°<HVA<40°, 13°<IMA<20°) and severe (HVA>40°, IMA>20°) based on HVA and IMA in X-ray. In 1836, Gernet first reported the surgical treatment of Hallux valgus, and then the treatment was under exploration. Keller surgery was the main surgery early in the 20th century. With the development of surgeries of Hallux valgus (more than 150) and further study of foot biomechanics and the pathology of the first metatarsophalangeal joint, many procedures of Hallux valgus are abandoned because they resulted in more harm rather than good results. For the same reason, some classical techniques have been modified.

Osteotomy is the most used technique for correcting Hallux valgus deformity nowadays. It can be classified into the following types based on different osteotomy sites: proximal phalangeal osteotomy, the first metatarsal distal osteotomy, the first metatarsal osteotomy, the first metatarsal basal osteotomy, the first cuneiform bone osteotomy and arthroplasty of the metatarsophalangeal joint. As complications of varying degrees occur after any surgery, Dennis et al. adopted the complication of Reverdin osteotomy[9]: limited motion of the metatarsophalangeal joint, unguis aduncus, relapse of deformity, sesamoiditis, delayed union or non-union of the bone and avascular necrosis of metatarsal head. Alolayan et al. reported that the limitation of Mitchell osteotomy in the treatment of Hallux valgus was the shortening of the first metatarsal bone after surgery, which changed the partial weight-bearing function of metatarsophalangeal joint and caused pain in other metatarsal bones. Alolayan LI et al. used Mitchell osteotomy for the treatment of hallux valgus, which has the disadvantage of shortening the first metatarsal bone after surgery, altering the weight bearing function of the metatarsophalangeal part, leading to pain in other metatarsal and delaying the time for toe function exercise, all of which lead to a decrease in patient satisfaction[10]. Wanivenhaus et al. followed 135 hallux valgus patients (240 feet) who underwent Wilson osteotomy and found that the pain under the second metatarsal head was significantly related to the shortening of the first metatarsal bone[11]. Park et al. reported that 53 patients (62 feet) who underwent Chevron osteotomy still had complications, including relapse of deformity, hallux varus, infection, bone necrosis, stiffness, metastatic plantar pain, and degenerative arthritis[12]. Ludloff osteotomy for the treatment of severe Hallux valgus has poor stability, many postoperative complications, a long time of union and needs high operation technique. Thus it was not used extensively. Stith et al. treated Hallux valgus with Crescentic osteotomy and obtained some efficacy for postoperative deformity, yet many complications occurred, including varus overcorrection, under-correction, asymptomatic recurrence, metastatic metatarsal pain and malunion of dorsum flexion of foot[13]. Thus, although there were much clinical study and practice of osteotomy in the treatment of Hallux valgus, there is still lack of universal standards, which leads to complications.

The application of 3D printing navigation template technology in clinical diagnosis and treatment

3D printing is a manufacturing technology based on material stacking, which uses a reconstructed 3D digital model to divide the model into layers and then stack the model layer by layer into a solid model[14]. However, 3D printing navigation template technology is characterized by individualization and precision, which are the development direction of medicine in the 21st century. Jeong et al. made an individualized navigation template for total knee arthroplasty (TKA) by 3D printing[15]. This method simplified the placement of the prosthesis, reduced surgical time and complications, and increased surgical efficiency and precision. Du et al. designed a navigation template for precise osteotomy through 3D printing and used it to treat a case of tibial fracture deformity with satisfactory results[16]. Previous orthopaedic surgery relies on the accumulation of clinical experience, refers to a standard human anatomic structure, adheres to fixed surgical protocol, and ignores individual differences[17]. 3D printing navigation template technology helps to determine reproducible surgical procedures through preoperative simulated surgery. This method omits complicated preoperative imaging evaluation and technique selection, shortens the surgical time and reduces unnecessary surgical trauma, increasing the success rate and decreasing the complications[18].

In the present study, all patients had stage I healing of the surgical incision without early complications (infection). The surgical time was shorter, and intraoperative bleeding volume was less in the 3D group than in the control group. During follow-up, no relapse or severe complication occurred in either group; only 2 cases of metastatic metatarsal pain occurred in the control group with an incidence of

8.33%. Ludloff osteotomy, with the assistance of 3D printing navigation template technology, can achieve more precise control, rapid positioning and precise simulation of intraoperative osteotomy plane and angle before surgery, reducing manual operation error. Thus, surgical time is shorter, surgical precision is better, and safety is higher.

The HVA and IMA immediately and 1 month, 3 months and 6 months after surgery were significantly lower than those before surgery. The HVA and IMA in the 3D group at all time points after surgery were slightly lower than those in the control group, yet the differences were not significant. The VAS score was significantly lower, and the AOFAS score and SF-36 score were significantly higher immediately and 1 month, 3 months and 6 months after surgery were significantly lower than those before surgery; Three months after surgery, the VAS score in the 3D group was significantly lower, and the SF-36 was significantly higher than that in the control group; Six months after surgery, the VAS score in the 3D group was significantly lower, and the AOFAS score and SF-36 score were significantly higher than that in control group. These results indicated that 3D printing navigation template technology achieved good efficacy. However, the Ludloff osteotomy used in the present study could correct the Hallux varus and valgus of the 1st metatarsal bone, have stable internal fixation and satisfy the requirement of early weight-bearing exercise. Thus, HVA and IMA were not significantly different between the 3D and control groups. Yet, the long-term pain, functional recovery, and quality of life in the 3D group were superior to those in the control group. Precise preoperative evaluation of the deformity of Hallux varus is essential to successful osteotomy. In clinical practice, PA and lateral X-rays are used to measure HVA and IMA to indirectly calculate the osteotomy plane and angle. Corrective surgery of hallux varus needs not only precise osteotomy but also the clinical experience of surgeons, thus allowing better treatment of soft tissue and reducing complications.

In conclusion, 3D printing navigation template technology has a prominent efficacy in osteotomy of severe hallux varus, achieves precise individualized treatment, and increases the patient's prognosis, functional recovery, and quality of life with higher surgical safety. The present study analyzed the efficacy and feasibility of a 3D printing navigation template in Ludloff osteotomy. However, the feasibility of application in other correction surgeries of Hallux varus should be explored. In addition, if the design of the osteotomy protocol can simulate the distribution of plantar pressure after correction through CT data of a weight-bearing foot, we can understand the distribution of plantar pressure during daily walking and design and make the navigation template for osteotomy based on anatomy and biomechanics, it will be more reasonable.

Ethics approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of ShenZhen PingLe Orthopedic Hospital.

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Authors' contributions

TZ conceived and designed the study and drafted the manuscript. HC, BJ and YZ collected, analyzed and interpreted the experimental data. YW and YB revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

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