

Clinical Application of Six Axis External Fixator Based on Digital Reduction Technology in the Treatment of Genu Varus in HTO

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Abstract: The number of patients with osteomyelitis, bone defects and lower limb deformities caused by open fractures of lower extremities has increased significantly, which makes the application of Ilizarov ring external fixator gradually increase. This paper discusses the application of six-axis digital orthopedic external fixator based on CT data in the correction of complex knee deformity. This study retrospectively analyzed 22 genu varus patients who underwent surgery in our department from January 2021 to December 2022. Valgus deformity of distal femur was fixed by medial closed osteotomy TomoFix plate, and varus deformity of tibia was corrected by QSF slow traction. CT scan of lower extremity was performed after osteotomy. Then obtain the adjustment prescription according to the software calculation. Deformities were corrected slowly as prescribed. The self-developed QSF was used for orthosis and fixation. The length of the six connecting rods of the external fixator was adjusted according to the "digital external fixator prescription" at 1 week after operation, and the lower limb force line was slowly corrected. The external fixator was removed after bone healing at the osteotomy site. The postoperative effect was evaluated by analyzing the correction of lower limb alignment, the healing time of osteotomy, the range of motion (Joint association (AKS) score, visual analogue scale (VAS) and Tegner score. It was found that bone union was achieved at the osteotomy site 13 weeks after operation, and the deformity did not recur. The range of motion of the joint was slightly limited during the strap period, and the ROM of the joint was restored to the preoperative level after 4 weeks of removal and fixation. Preoperative knee pain and discomfort, 3 months after surgery, AKS score and Tegner score were significantly improved, the difference was statistically significant ($P < 0.05$). The six-axis external fixator has been widely used in the treatment of lower limb nonunion, bone defects, horseshoe foot and joint deformities, and the incidence of postoperative complications is significantly lower than that of the Ilizarov ring external fixator.

1. Introduction

In 1937, Blount first summarized and reported a series of diseases characterized by posterior medial varus and pronation deformity of the proximal tibia, which involved the epiphyseal and metaphysis, and proposed the concept of "tibial varus". Since then, the literature reporting the disease has referred to this deformity as Blount's disease. The pathogenesis of Blount's disease is not fully understood. The time of initial discovery is often used as the basis for the classification of Blount's disease, which can be divided into infantile (early onset) and adolescent (late onset) forms. The proximal tibia deformity is more serious in children with early onset, mostly involving both sides. In children with delayed onset, distal femoral epiphysis malformation often precedes other malformations and is generally limited to one side [1]. Many of these patients cannot be treated with internal fixation and can only be treated with external fixators, but conventional external fixators cannot correct the deformity after surgery. In addition, there are a large number of patients with various types of limb deformities in China, and many of these patients cannot be treated with internal fixation or ordinary external fixators, which makes the application of Ilizarov ring external fixators gradually increase. Due to the increasing demand of patients for the effect and convenience of treatment, the Ilizarov ring external fixator can no longer meet the corresponding demand. Due to the long learning curve of Ilizarov annular external fixator, the application of this type of external fixator is limited by the high requirements of user experience and technology.

The six-axis external fixator developed based on computer navigation technology has gradually entered clinical practice. It has continued the advantages of the annular external fixator and has made many improvements to the defects of the Ilizarov annular external fixator and achieved good therapeutic effects. However, due to the high requirements and high price, the six-axis external fixator has not been widely used in China at present [2]. At present, the number of literatures related to six-axis external fixators in China is small, and most of them are clinical studies of single-type external fixators. Based on the above situation, this paper proposes a six-axis digital orthopedic external fixator (QSF) based on CT data, whose structure is similar to Taylor's frame. It is composed of two distal and proximal rings and six connecting rods. By adjusting the length of the six connecting rods, the deformity is corrected in three-dimensional and six degrees. Its supporting software is based on CT data and optimized by the structure of the connecting rod. In terms of reduction accuracy, fixation effect, learning curve, intraoperative operation, and postoperative complexity, it is significantly better than Taylor frame. From January 2021 to December 2022, 22 patients with complex knee deformity were treated with QSF in the orthopedic department of Integrated Traditional Chinese and Western Medicine, and all of them achieved good results. The report is as follows.

2. Data and Methods

2.1. General Information

From January 2021 to December 2022, 22 patients with severe horseshoe foot treated with posterior foot osteotomy plus Taylor space external fixation stent in our research group were collected. There were 8 males and 14 females. The age ranges from 13 to 52. The causes were trauma and burn sequelae in 5 cases, congenital sequelae in 4 cases, poliomyelitis sequelae in 6 cases, spina bifida and tethered cord in 4 cases, and other 3 cases. The main manifestations were horseshoe deformity > 40 °13 feet, anterior and middle feet combined with obvious adduction, and varus > 20 °10 feet. Severe stiffness in 8 feet, moderate stiffness in 12 feet, and moderate stiffness in 2 feet. Seven

foot deformities were combined with tibial rotation and shortening the deformity, 11 limbs were corrected at the same time, and 4 limbs were corrected later. Five foot deformities were combined with knee deformities, and the two limbs needed to be corrected.

2.2. Surgical Methods

2.2.1 Fibula Osteotomy

A 1cm length of the fibula was cut off from the middle and lower third of the fibula, and a longitudinal incision was made on the lateral side of the middle of the fibula. After the fibula was exposed, the fibula was cut under the periosteal with a swing saw, and the incision was sutured [3].

2.2.2 Tibial Osteotomy

Transverse osteotomy was performed 1cm below the tibial tuberosity, but it was not completely truncated to facilitate the installation of external fixators [4].

2.3. Force Analysis of Six-Axis Space Support

The six-axis space support system is composed of a fixed ring, a steel needle, a nut column, a retractable threaded rod, and the upper and lower ends of the tibia. Its structure is shown in Figure 1.

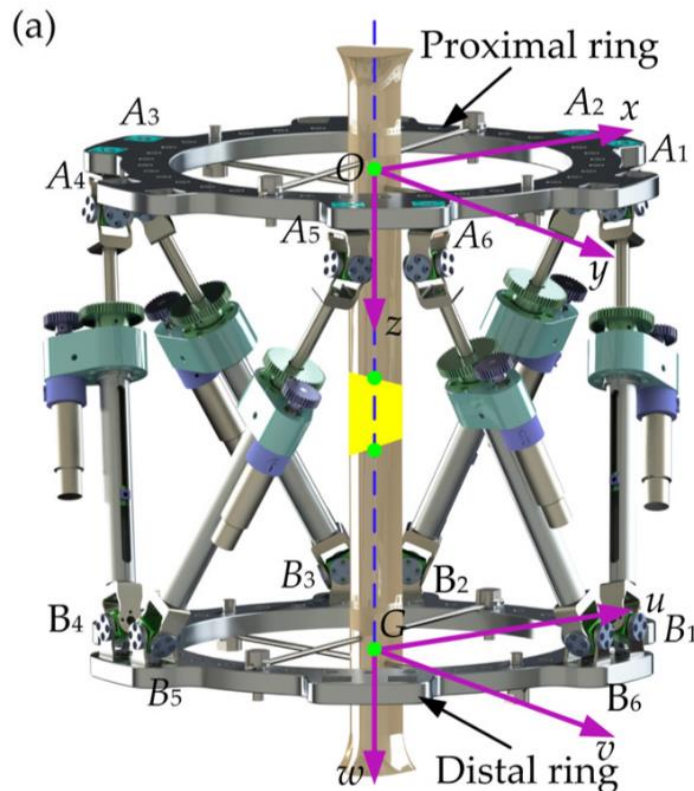


Figure 1: Schematic diagram of six-axis space support structure and force

Patients can start rehabilitation training after surgery to install a six-axis space stent. Let the tip of the tibia experience F_{up} vertical downward pressure. There is a support force $F_i (i=0,1,\dots,6)$ on the upper fixed ring for each of the 6 connecting rods. The supporting force of the fracture end F_{mid} , the

upper fixation ring, and the upper tibia are regarded as a whole, and the calculation formula of F_{mid} can be obtained according to the statics theorem:

$$F_{mid} = -F_{up} - \sum_{i=0}^6 F_i \quad (1)$$

The sizes of F_{up} and F_i can be obtained by installing sensors on the external fixator and the patient's foot or force point, and the key is to obtain the direction of the force on the connecting rod [5]. The six-axis space support can be regarded as a parallel Stewart platform, or the connecting rod can be regarded as a two-force rod, and the direction of the force on the connecting rod is the direction of the connecting rod. In the actual rehabilitation evaluation process of patients, it is difficult to obtain the direction of the connecting rod relative to the global coordinate system in real time, and the length of the connecting rod can be directly read out. Therefore, the correct solution of the position of the six-axis spatial scaffold mechanism is the most important step in the research.

Firstly, the equivalent coordinate system top view of the six-axis space support platform is established. As shown in Figure 2, the center point O of the platform is set as the origin of the equivalent coordinate system. The thick solid line represents the lower platform of the six-axis space support platform, and the thin solid line represents the upper platform of the six-axis space support platform. The connecting rod between the upper and lower hinges is represented by the dashed line. The lower platform of the six-axis space bracket is taken as the static platform, and the upper platform is taken as the moving platform.

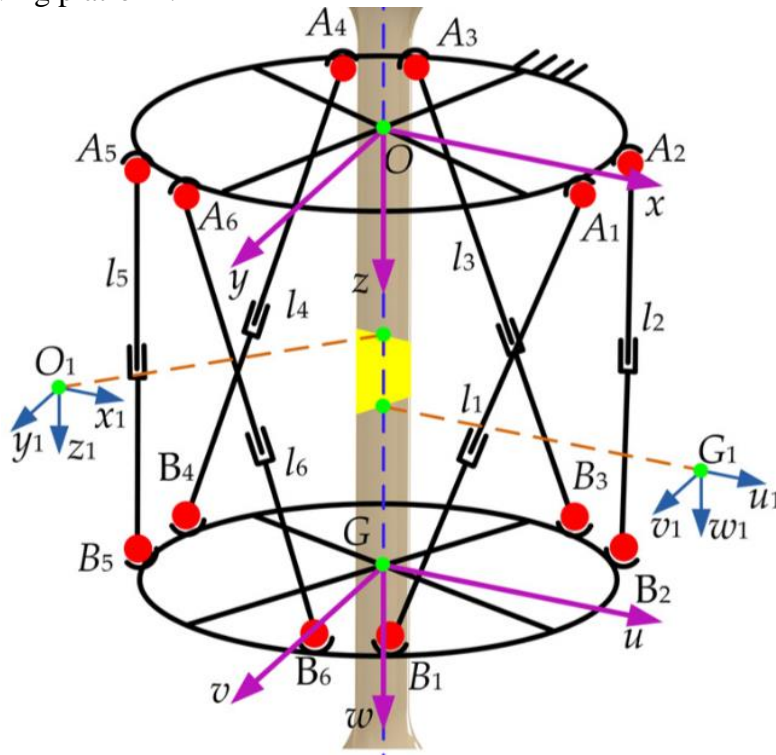


Figure 2: Top view of the equivalent coordinate system of the six-axis space support platform

$A_i (i = 1, 2, \dots, 6)$ represents the 6 universal joint hinge points of the upper platform, and the vector in the coordinate system of the upper platform is $A_i = [A_{ix} \ A_{iy} \ A_{iz}]^T$. $B_i (i = 1, 2, \dots, 6)$ represents the 6 universal joint hinge points of the lower platform, and the vector in the coordinate system of the lower platform is $B_i = [B_{ix} \ B_{iy} \ B_{iz}]^T$. The pose K of the upper platform is denoted as

$$K = [\delta^T | P_0^T] T = [\omega \ \theta \ \varphi | x_0 \ y_0 \ z_0] \quad (2)$$

Where P_0 is the position vector of the center point of the upper platform relative to the coordinate system of the lower platform. δ is the Euler Angle vector of the upper platform coordinate system around the x, y, and z axes. The rotation matrix of the upper platform coordinate system relative to the lower platform coordinate system is

$$R = \begin{pmatrix} c\beta c\gamma & -c\beta s\gamma & \\ sas\beta c\gamma + cas\gamma & -sas\beta s\gamma + cac\gamma & -sac\beta \\ -cas\beta c\gamma + sas\gamma & -cas\beta s\gamma + sac\gamma & cas\beta \end{pmatrix} \quad (3)$$

The vector of the upper hinge point in the upper platform coordinate system can be transformed into the vector of the points in the lower platform coordinate system. The length l_i ($i=1,2,\dots,6$) of each link can be obtained from Equation (3).

$$l_i = \sqrt{\|RA_i + P_0 - B_i\|^2} = f(K)_i \quad (4)$$

The idea of forward kinematics is to set the initial pose of the platform and solve the length of the six links through the reverse kinematics. Through Newton iteration method, the pose of the upper platform is continuously modified until the maximum value $\max|\Delta l_i(6)|$ of the difference between the length of the connecting rod and the actual measured length of the connecting rod is solved, and the calculation stops when it is less than the allowable deviation. The algorithm flow chart is shown in Figure 3.

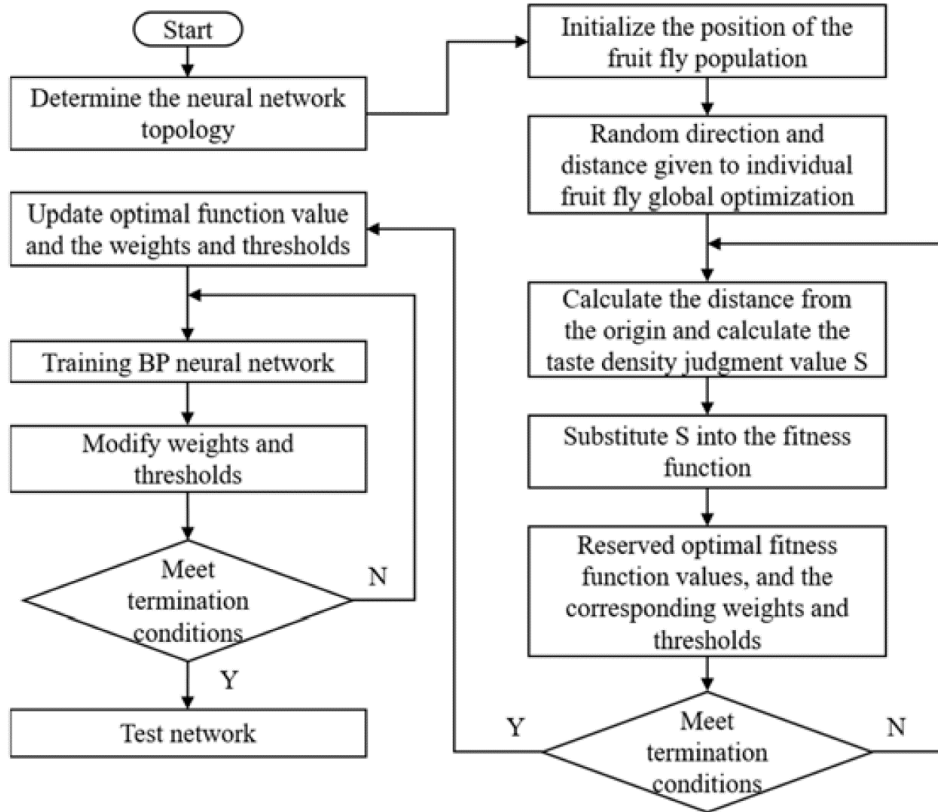


Figure 3: Flow chart of forward kinematics algorithm of six-axis space support

$$F_i = |F_i| \frac{RA_i + P_0 - B_i}{l_i} \quad i = 1, 2, \dots, 6 \quad (5)$$

Where $|F_i|$ is the force on the connecting rod, which can be directly read by the sensor on the connecting rod, and the direction of the force is a function of K , which can be obtained from Equation (2). When the magnitude and direction of the force on the six links were known, the force on the fracture end was obtained by substituting it into Equation (1).

2.4. Postoperative Review and Evaluation

Functional exercise with the help of a continuous passive knee exercise machine was started on the second day after surgery [6]. The patient walked with crutches and the affected limb could bear partial weight until the imaging examination confirmed the fracture healing at the review. Reexamination was performed once a month. Anteroposterior and lateral radiographs of the bilateral knee joints and full-length anteroposterior and lateral radiographs of both lower limbs were taken until the osteotomy site healed and complete weight bearing began. After every 6 months, reexamination 1 time; Paley function score was used to evaluate the function once a year after 1 year. The Paley Function score is divided into the following 4 categories:

LDFA, MAD, and range of motion (ROM) of the knee were measured before and after operation. If the postoperative MAD is between 15mm medial to 10mm lateral to the center of the knee joint, the force line of the affected limb is considered satisfactorily corrected. If the postoperative LDFA was within the normal range (84° to 90°), the patient's LDFA was considered satisfactorily corrected.

2.5. Statistical Methods

SPSS 18.0 software was used for statistical analysis. Measurement data were expressed as $(\bar{x} \pm s)$. Paired t-test was used to compare preoperative and postoperative measurement indicators, and $P < 0.05$ was considered statistically significant.

3. Results

The tibial deformity was slowly corrected with QSF exoskeleton in all 11 patients, and in 7 of them, femoral closure osteotomy was performed in 4 lower extremities at the same time, and the osteotomy site was fixed with TomoFix plate. Among them, a 42-year-old woman with early-onset Blount's disease in the left lower limb had a preoperative MAD value of 112.1mm, FTA of 42.9° , MPTA of 59° , and FCTSA of 62° . The preoperative surgical plan was one-stage tibial QSF osteotomy and the second-stage closed femoral osteotomy. After the tibial osteotomy healed, the knee joint pain was significantly improved, and the second-stage surgical treatment was refused. The other patient had bilateral Blount disease, and only right surgery was performed. The mean follow-up time was (21.7 ± 10.4) months (range, 11-38 months). The mean MAD of the patients was corrected from (62.0 ± 28.7) mm preoperatively to (8.9 ± 14.8) mm at last follow-up. Before FTA, it was $(17.3 \pm 1.6)^\circ$, and at last follow-up, it was $(-2.8 \pm 4.9)^\circ$. The preoperative MPTA was $(65.7 \pm 8.7)^\circ$, and the last follow-up was $(85.6 \pm 2.4)^\circ$. The preoperative FCTSA was $(62.2 \pm 10.7)^\circ$, and the last follow-up was $(84.5 \pm 2.6)^\circ$. The average healing time of osteotomy was (13.8 ± 1.7) weeks. The LLD was (16.5 ± 9.8) mm before operation and (2.4 ± 1.4) mm at last follow-up. The values of all measured indexes after operation were significantly improved compared with those before operation ($P < 0.05$, Table 1).

Table 1: Preoperative and last follow-up X-ray measurements

In patients with		BT	LF	LQ	ZY	YS(right)	YS(left)	ZG	ZX
Types of bone cutting		double	single	double	single	double	double	double	single
MAD(mm)	preoperative	27.71	72.29	55.42	116.77	88.75	75.10	30.63	50.21
	postoperative	-6.35	14.17	7.92	44.69	6.04	0.00	3.54	4.69
FTA(°)	preoperative	7.29	17.71	11.46	36.46	34.38	22.92	4.17	10.42
	postoperative	-9.38	-3.13	-3.13	8.33	-2.08	-2.08	-6.25	-5.21
MPTA(°)	preoperative	76.04	68.75	72.92	61.46	52.08	62.50	77.08	77.08
	postoperative	85.42	87.50	89.58	88.54	88.54	93.75	88.54	91.67
LDFA(°)	preoperative	81.25	92.71	87.50	86.46	81.25	86.46	87.50	90.63
	postoperative	87.50	92.71	91.67	86.46	90.63	92.71	92.71	90.63
FCTSA(°)	preoperative	72.92	64.58	67.71	64.58	45.83	51.04	78.13	73.96
	postoperative	84.38	86.46	85.42	86.46	91.67	90.63	88.54	90.63
LLD(mm)	preoperative	11.46	-6.25	-15.63	37.50	-13.54	17.71	9.38	-15.63
	postoperative	2.08	19.79	4.17	3.13	17.71	0.52	1.04	4.17
Osteotomy healing time (weeks)		12.50	13.54	15.63	16.67	15.63	11.46	14.58	15.63

All wounds were healed and sutured within 2 weeks. There were no complications such as nonunion, neurovascular injury, needle tract infection, and osteomyelitis. A typical case was a 42-year-old female patient with late-onset Blount disease, who was treated with a right femur and tibia osteotomy in the first stage, and the QSF was removed by osteotomy and healed at 21 weeks after operation. The left lower limb surgery was performed 6 months later, and the femur and tibia were treated with osteotomy and healing at 17 weeks after operation. The tibial side was corrected slowly with QSF, and the femoral side was fixed with TomoFix plate, and the QSF data were adjusted slowly for 45d (Figures 4 to 7).

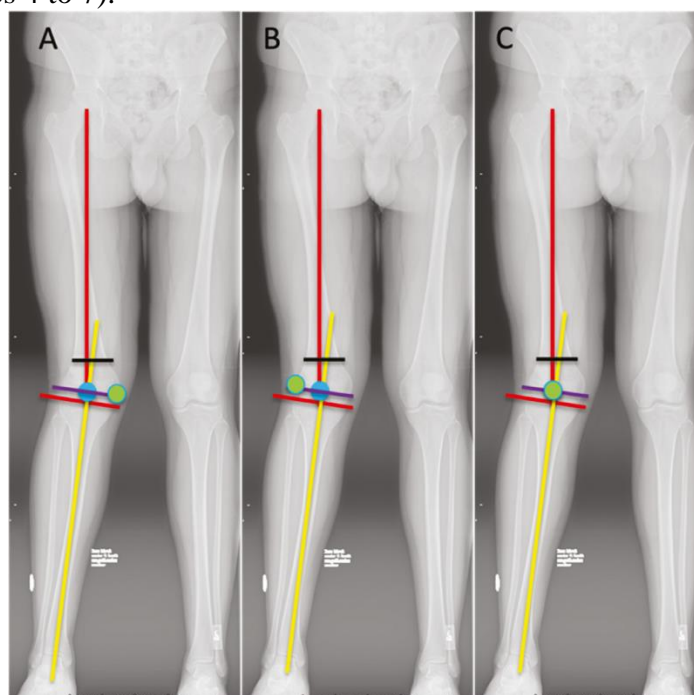


Figure 4: Injury to the epiphyseal plate of the lateral femoral condyle and valgus deformity of the knee caused by trauma

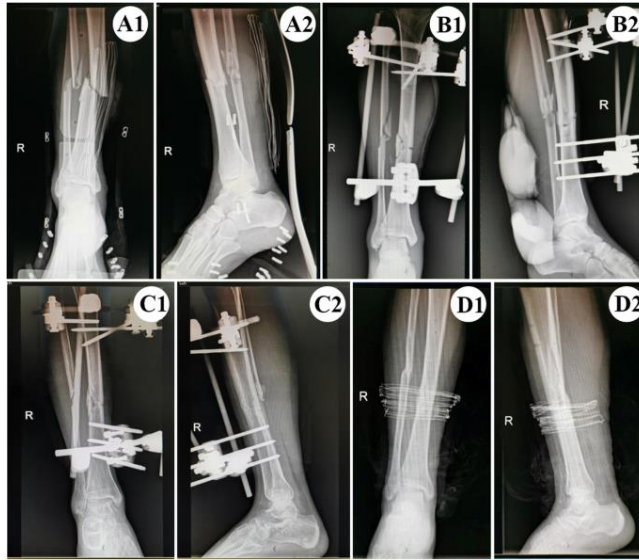


Figure 5: Intraoperative LRS reconstruction with the external fixator fixed to the lateral side of the femur



Figure 6: Postoperative full-length radiographs of both lower limbs showing restoration of lower limb alignment



Figure 7: Figure 4 Anterior and posterior view of the femur 6 months after surgery

4. Discussion

High tibial osteotomy is the most widely used orthopedic surgery, which is mainly due to the emergence of locking angle plate, which greatly improves the reliability of high tibial osteotomy. However, only using internal fixation to correct bone deformity is not enough for severe deformity or limb shortening. Soft tissue traction should also be taken into account. Some studies have shown that the posterior angle of the tibia changes significantly after high tibial osteotomy with internal fixation, which changes the biomechanics of the normal knee joint [7]. However, using external fixation to correct the knee deformity had little effect on tibial posterior inclination, which was also confirmed in this study. The treatment of the proximal lateral hemi-epiphyseal block of the tibia is a treatment method to correct the tibial varus by removing the lateral part of the epiphyseal plate, or placing the epiperiosteal endoplanta, non-locking plates and other fixed parts of the epiphyseal plate growing faster to limit the growth of the lateral epiphyseal plate, ensuring that the growth rate of the medial epiphyseal plate is greater than that of the lateral epiphyseal plate. 12 cases of infantile Blount disease were treated with "8" plates, and the success rate of correction was 89%. All children had spontaneous tibial rotation correction, but there was still residual rotation deformity. After 1 year of follow-up, 3 patients had varus recurrence of 5°. Some scholars used "8" plates to treat 17 patients with Blount disease, only 5 cases of juvenile type (all > 13 years old) had poor efficacy, and found that with the application of tension band plate and correction of varus angle, the tibial rotation deformity was also improved.

Some scholars used the "8" plate to treat 18 patients with adolescent Blount disease aged over 7 years, and 8 of them had a screw fractures, with a correction failure rate as high as 44%. For infantile Blount disease, the recommended surgical treatment is proximal tibial osteotomy. When the guardian refuses to undergo tibial osteotomy or the child is unable to cooperate with daily life and exercise after osteotomy, proximal lateral tibial hemi-epiphyseal block can be used as an alternative treatment for infantile Blount disease [8]. Type of teen Blount disease, because of the lateral half of epiphyseal block therapy is minimally invasive and reversible, operation difficulty, relatively few complications of lighter, smaller and does not affect the subsequent cut bone surgery, although the treatment effect may not be beautiful, there are still scholars suggest it as still has the growth potential of youth type Blount disease in treatment of children; In the case of poor efficacy, osteotomy can be used for any time.

Improve the uneven distribution of tibial plateau pressure, reduce the intraosseous pressure, and then relieve pain; maintain and improve knee function and natural joint life span [9]. The knee joint biological force line was adjusted to slightly exceed the neutral position, and the lower limb force line was changed from internal inversion to mild valgus. Increasing valgus by 1° to 3° is widely recommended. A meta-analysis of 1065 patients confirmed that lateral closed high tibial osteotomy can effectively reduce medial knee pain, slow down the progression of osteoarthritis, improve knee function, and avoid or delay joint replacement[10].

Fixture is varied, tubular cancellous screw, small steel plate, pressure support plate, tubular steel plate is internal fixation devices, which are frequently used in clinical advantage lies in the lower risk of infection, patients with convenient operation, nursing relatively simple and convenient, but there is also a need second operation to take out the internal fixation, intraoperative bone cutting Angle is difficult to accurately, shortcomings and so on postoperative fixed time is long. Some scholars have reported that Ilizarov external fixation has achieved good results. External fixation can continuously adjust the correction angle and restore the lower extremity line more accurately. Patients can have early functional exercise, which is conducive to maintaining stress stimulation and local blood circulation in the osteotomy area. However, the postoperative mobility of patients is not easy to cause nail tract infection and nerve injury. Previous literatures have reported that high tibial osteotomy

combined with Ilizarov external fixator or unilateral external fixator or plate fixation is used in the treatment of genu varus. Because the external fixator cannot be adjusted after operation, the operation of the osteotomy angle is high, and the length of the lower limbs needs to be shortened. Osteotomy itself can also lead to changes in the posterior inclination angle of the tibial plateau and the height of the patella. This research adopts the high tibia bone cutting, orthopaedic joint Taylor external fixator, fixed treatment of knee osteoarthritis and genu varus, Taylor external fixator has small trauma, postoperative adjustable, shorter operation time, blood loss, less elastic fixation for fracture healing, patients can early functional exercise and other advantages, has been widely used in clinical treatment of various fractures, complex deformity correction. It consists of two metal rings and 6 scalable link rods through the deformed parameter input parameters, installation and framework supporting software, computer automatic generation of electronic prescription, according to the electronic prescription link rod length to correct deformities, accurately adjust the lower limb mechanical shaft, completely retain the periosteal bone cutting end, in patients with intraoperative is easier to control the Angle of the bone cutting at the same time, It can reduce the difficulty of operation and effectively avoid the changes of lower limb length and vertical line caused by surgical osteotomy.

All 22 patients in this study successfully completed the operation, and the stitches were removed 14 days after the operation, including 2 cases of needle eye exudation and 1 case of incision fat liquefaction. No serious complications such as nerve injury, thrombosis, and patellar trajectory abnormalities occurred. The author thinks that the accuracy of needle threading should be improved and the second operation should be avoided.

5. Conclusion

The six-axis digital orthopedic external fixator based on CT data is composed of six telescopic rods with mutual angulation and two planar rings (or semi-rings) connected. The software was used to calculate the length of the 6 connecting rods to be adjusted, and then the prescription was given to complete the correction. Because the calculation software is based on CT data, the lower limb force line corrected by QSF is more accurate, and QSF can be adjusted several times until the correction is satisfactory. All patients in this study achieved good short-term clinical efficacy.

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