ORIGINAL RESEARCH

Use of Foot Correction Exerciser for Rehabilitation Following External Fixation in High-Energy Pilon Fracture

Na Lu, MM; Xiaolong Mei, MM; Tao Zhang, MM; Xiaolong Mei, MM

ABSTRACT

Objective • Our aim was to study the clinical effect of a foot correction exerciser used for postoperative rehabilitation in external fixation in high-energy Pilon fracture.

Methods • From March 2017 to November 2019, 43 patients with AO/OTA type C closed Pilon fractures treated with external fixation were retrospectively analyzed. A total of 23 patients were rehabilitated by foot correction exerciser (1 patient fell off the study), and 20 patients were treated by conventional rehabilitation (2 patients fell off the study). During postoperative hospitalization and regular follow-up after discharge, various indicators were recorded for statistical comparison and evaluation through angle measurement, imaging and questionnaire surveys.

Results • There was no significant difference in postoperative complications in the 2 groups ($P > .05$). The fracture healing time and stent wearing time in the study group were shorter than in the control group, and the comfort score and functional exercise compliance were higher in the study group than in the control group. The ankle joint mobility was higher in the study group than in the control group at all time points in the first 6 months, and the excellent and good rate of ankle joint function was higher than in the control group, with statistical significance ($P < .05$).

Conclusion • Use of the orthopedic exerciser in the high-energy Pilon fracture external fixation postoperative rehabilitation process and the early introduction of resistance training can reduce pain and soft tissue edema and improve the degree of patient comfort and exercise compliance, accurately measure the force load of the limbs, contribute to the dataization and standardization of rehabilitation exercise programs, accelerate the recovery of joint mobility and improve long-term limb function. (*Altern Ther Health Med.* [E-pub ahead of print.])

Na Lu, MM; **Xiaolong Mei**, MM; **Tao Zhang**, MM; **Xiaolong Mei**, MM, Department of Traumatic Orthopedics; Tianjin Hospital; Tianjin; China.

Corresponding author: Xiaolong Mei, MM
E-mail: nksod1979@163.com

INTRODUCTION

A Pilon fracture is an unstable fracture in which the tibiotalar articular surface collapses due to an axial compressive load acting on the distal third of the tibia,[1] causing injury. Most of the causes are high-energy impact and 50% to 70% are accompanied by local soft tissue damage.[2] The purpose of clinical treatment is to achieve good reduction and reliable fixation of fractures while protecting the blood supply of local soft tissues, so as to maximize the recovery of ankle joint function.[3]

With the innovations in medical concepts and technologies, the concept of biological osteosynthesis (BO) has been widely recognized in recent years,[2,3] and has gradually become the development trend. An external fixator device combined with a minimally invasive internal fixation technique is considered a feasible and effective method for treatment of high-energy injury Pilon fracture.[4,5] In recent years, our department has adopted Taylor space external fixation brackets, combined with limited internal fixation such as hollow nails, to achieve minimally invasive reduction and fixation of Pilon fractures. Local pressure or stretch micro-movement is used to achieve elastic fixation of the fracture,[6] and has achieved good results.

Changes in the biomechanical environment after a fracture have an important impact on the function of the ankle joint. Choosing an effective rehabilitation strategy is of great significance for the recovery of limb weight-bearing and activity function.[7] A large number of studies in recent years have proved that the early implementation of systematic and effective self-rehabilitation training strategies after surgery is of great importance for the recovery of long-term ankle joint mobility and the prevention of joint stiffness and foot drop.[1,8] However, clinical feedback shows that patients often have low rates of cooperation and poor compliance

with early self-exercise exercises due to factors such as limb swelling, pain and unclear quantification standards for functional training, which in turn affects the postoperative rehabilitation effect.

This study summarized the use of the foot correction exerciser developed by our department (invention patent number: ZL201620192237.9) in patients with high-energy OA/OTAC-type Pilon fractures, and the postoperative rehabilitation training results.

MATERIALS AND METHODS

General Information

Tianjin Hospital in China is a large-scale comprehensive hospital with a focus on orthopedics, featuring trauma emergency treatment and diagnosis and treatment of difficult and severe orthopedic conditions. It is one of the most famous orthopedic centers in China. Our study participants were inpatients with OA/OTA type C closed Pilon fractures who were treated in our department from March 2017 to November 2019. A total of 43 patients received external fixation with brackets, and they were divided into the study group and the control group. There were 23 patients in the study group; 1 patient dropped out during the study, and 22 patients were finally enrolled.

The study group comprised 16 men and 6 women, age 21 to 65 years, with an average age of 43.45±12.57 years; cause of injury: 7 patients with high-altitude falls, 11 with traffic accidents and 4 with other injuries; average injury to surgery time 4.80 ± 0.89 days.

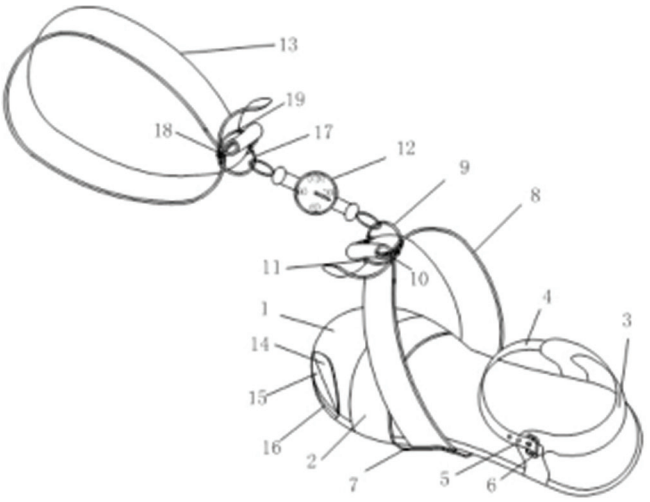
There were 20 patients in the control group; 2 dropped out during the study, and 18 were finally enrolled, including 13 men and 5 women, age 19 to 64 years, with an average age of 39.70±14.17 years; cause of injury: 6 patients with high altitude falls; 9 with traffic accidents, and 3 with other injuries; average time from fracture to surgery 4.65±0.93 days.

There was no significant difference in baseline data such as age, gender or time from injury to surgery in the 2 groups ($P > .05$) (see Table 1).

Table 1. Comparison of General Information

Group	n	Age (yrs)	Gender		Time from injury to surgery (days)
			male	female	
Observation	22	43.45 ±12.57	16	6	4.80±0.89
Control	18	39.70±14.17	13	5	4.65±0.93
t/χ^2	—	0.885	0.111		0.519
P value	—	> .05	> .05		> .05

Figure 1. Structural diagram of foot correction exerciser.



Note: 1. Support plate; 2. Foot front fixing belt; 3. Rear heel fixing belt; 4. Ankle fixing belt; 5. Round hole; 6. Buckle assembly; 7. Fixing belt; 8. First elastic belt; 9. First buckle; 10. Second buckle; 11. Third buckle; 12. Force measuring device; 13. Second elastic band; 14. Covering layer; 15. Collodion layer; 16. Base plate; 17. Fourth buckle; 18. Fifth buckle; 19. sixth buckle.

Selection criteria

Inclusion criteria. Patients (1) had unilateral Pilon fracture with OA/OTA type C type; (2) were age 18 ≤ to ≤ 65 years; (3) had fresh closed fracture caused by trauma ≤ 21 days; (4) had normal communication skills; (5) whose surgical plan was Taylor space external fixation device combined with limited internal fixation.

Exclusion criteria. Patients had (1) pathological fractures caused by tumors, etc.; (2) had fractures combined with serious medical diseases; were unsuitable for surgical treatment; (3) had open fractures, soft tissue defects, infections or blood vessel and nerve injuries, etc., who could not perform early functional exercises after surgery; (4) had severe organ injuries or multiple traumas; (5) had ankle joint deformity or dysfunction before the injury; (6) had mental or cognitive impairments and could not cooperate with treatment; had follow-up interruption or poor compliance; (7) in whom deep vein thrombosis occurred during treatment without surgical intervention; (8) had other serious complications after surgery; (9) had other factors that affected the study progress.

Study Methods

Design and production of the foot correction exerciser (**Figure 1**). The design of the foot correction exerciser was completed and the national utility model patent number ZL201620192237.9 was obtained before the start of the study.

Preparation stage

A rehabilitation training treatment team was established before surgery that included a professional rehabilitation therapist, an attending physician and a responsible nurse who has been engaged in trauma orthopedic nursing for longer than 10 years. The team members jointly drew up a rehabilitation exercise plan, the responsible nurse explained the use of the foot correction exerciser to assist the doctor in completing the follow-up visits, demonstrated the functional exercise steps to the patient with the help of computer simulation technology, and the rehabilitation coach was responsible for the specific exercise plan. After surgery, the attending physician conducted follow-up visits and performed the evaluations.

Clinical implementation

The affected limb(s) of the patients were elevated after surgery to reduce swelling and prevent and control infection;

pain management was implemented and multi-mode preemptive analgesia was administered so that patients experienced slight or no pain. Early rehabilitation exercises were performed in a comfortable setting. The study group wore a foot correction exercise device for early rehabilitation exercises after surgery, and the control group performed routine rehabilitation exercises.

Study group treatment plan

Week 1: Beginning 1 day after surgery, patients wore a foot correction exercise device to maintain the functional position of the ankle, and performed early rehabilitation exercises with the assistance of the device (see Figure 2).

Specific operation. The rehabilitation therapist assisted the patient with flexion and extension of the toes, active plantar flexion and back extension of the ankle joint, twice a day, for 20 minutes each session. The range of motion was within the range that the patient could tolerate.[10] Each movement was kept at the tolerance limit for 5 seconds. At the same time, the patient performed active flexion and extension exercises of the hips and knee joints and isometric contraction exercises of related muscle groups.[9]

Week 2: The elastic band on the device was adjusted to an appropriate level, and the patient continued to perform voluntary plantar flexion and dorsiflexion of the ankle joint, gradually increasing the flexion and extension angle, 3 times a day for 20 minutes per session.

Week 3: The patient continued the functional exercises, added isometric resistance training,[8,10] and tightened the elastic band in combination with the tolerance belt in order to increase exercise resistance and improve training intensity. The patient held the elastic band or fixed it to the external fixation device, maintained the tension of the band and overcame the resistance of the plantar support pedal in order to complete plantar flexion and dorsiflexion. The maximum angle was maintained for 5 seconds, for 20 minutes per session, and the upper limit reached was recorded on the dynamometer. The resistance value at the angle was limited to no more than 10 kg, and the resistance force was gradually increased. The patient was required to move slowly and at a uniform speed, and at the same time exert force on the ankle joint and calf muscles. After exercise completion, ice compresses were applied for 10 minutes to reduce swelling and increase comfort. The tension of the elastic band was adjusted, and the foot kept in the neutral position.

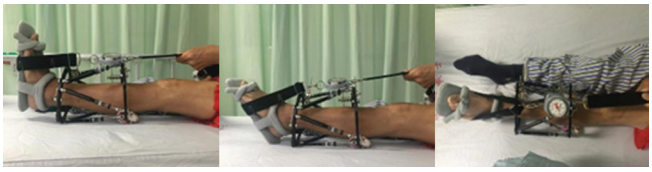
Weeks 4 to 6: The attending physician evaluated the growth of the patient's callus via X-ray films, removed the brace under the guidance of the rehabilitation coach, and gradually carried out touch-to-ground weight-bearing training.[11]

Weeks 6 to 8: Patients were instructed to use walking aids to carry out partial weight-bearing walking training, and gradually transition to full weight-bearing.[12]

Control group treatment plan

The control group patients did not wear foot correction exercise equipment, and carried out routine rehabilitation exercises under the guidance of rehabilitation coaches.

Figure 2. Photographs of the clinical application of the foot correction exerciser.



Weeks 1 and 2: One day after surgery, after spontaneous movement of the limbs had recovered, flexion and extension of the toe joints was begun, and 72 hours after surgery, ankle plantar flexion and back extension exercises were performed. The range of motion of the ankle joint was increased, in conjunction with range of motion exercises of the hip and knee joints and lower limb muscle strength training.

Week 3: The rehabilitation practitioner instructed the patient to perform flexion and extension exercises by stepping on the palm placed by the rehabilitation practitioner on the sole of the foot to complete the resistance training.

Weeks 4 to 8: X-ray films were checked, and partial weight bearing was started according to the state of the fracture healing, and walking aids were used to gradually transition to full weight-bearing.

Outcome Indicators

During postoperative hospitalization and regular follow-up after discharge, the following indicators were recorded for comparison and evaluation via angle measurement, imaging and questionnaires.

(1) **Fracture healing time, stent wearing time and postoperative complications**.

(2) **Comfort score**: The comfort level of patients in the 2 groups was compared 1 day before surgery, 24 hours after surgery and 1 day before discharge with an open questionnaire. The simplified Koloaba Comfort Scale (GCQ)[13] was used to evaluate a total of 28 items from the 4 dimensions of physiology, psychology, society and environment, using a 1 to 4 point Likert Scale scoring method, with a total score of 114 points. The higher the score, the more comfortable a patient was.

(3) **Functional exercise compliance**:[14,15] the patient's compliance with functional exercise-related measures at 1 and 3 weeks after surgery was evaluated and categorized as one of four grades: excellent, good, fair and poor.

Excellent. The patient voluntarily completed the established functional exercise tasks according to the standards required by the doctor.

Good. Under external supervision, the prescribed rehabilitation exercise can be completed as required or 2/3 of the task can be completed.

Fair. patients are able to complete 1/2 to 2/3 of the established rehabilitation exercise content.

Poor. Under the supervision and urging of the physician, the patient could not correctly carry out the rehabilitation exercises ordered by the doctor or completed less than 1/2 of the exercise tasks.

(4) **Ankle range of motion**: Active dorsiflexion and plantar flexion were measured with the neutral-zero method:[10] The patient lay on their back, legs naturally straightened, the neutral position of the ankle joint was set at zero degrees, and active dorsiflexion and plantar extension were measured. The ankle is bent at the maximum angle, measured 3 times and the average value calculated.

(5) **Ankle joint function**: In accordance with the Mazur Ankle Evaluation and Grading System,[12] at 6 and 12 months after surgery, the pain, daily activities and range of motion of the ankle joint were determined to comprehensively evaluate the function of the ankle joint on the affected side. The maximum score was 100 points, which were divided into 4 grades: excellent, good, fair, and poor.

Statistical Methods

IBM SPSS 22.0 (IBM, Armonk, New York USA) statistical software was used for data analysis. The measurement data conformed to the normal distribution, and the data were expressed as mean ± standard deviation. The fracture healing time and stent wearing time were compared in the 2 groups by independent sample *t* test. Ankle joint mobility and comfort scores in the 2 groups at each time point after surgery were compared using repeated measures analysis of variance. Point comparisons were corrected using the Bonferroni method. Enumeration data were expressed in rate, functional exercise compliance, complications, and excellent and good ankle joint function were compared in the 2 groups by χ^2 test. The inspection level was α=0.05.

RESULTS

Of the 23 patients in the study group, 1 patient dropped out due to postoperative loss to follow-up, and 22 patients were finally enrolled in the group, Of the 20 patients in the control group, 1 patient dropped out due to lower extremity deep vein thrombosis, and 1 patient dropped out due to postoperative loss to follow-up; 18 patients were finally enrolled. All enrolled patients were followed up regularly; the follow-up time was 12 to 24 months.

Fracture healing time, stent wearing time and postoperative complications (Table 2).

The fracture healing time and stent wearing time in the study group were shorter than in the control group, and the difference between the 2 groups was statistically significant ($P < .05$). In the study group, there were 3 patients with needle tract infection and 1 patient with needle tract skin incision; in the control group, 1 patient had poor healing of the surgical incision and 2 patients had needle tract infection. All patients were cured after changing the dressing, and there was no statistical difference between the 2 groups ($P > .05$).

Comfort score (Table 3)

There was no significant difference between the 2 groups in the Kolcaba Comfort Scale score 1 day before surgery ($P > .05$). The Kolcaba Comfort scale score 24 hours after surgery and 1 day before discharge was higher in the study group than in the control group, and the difference was statistically significant ($P < .05$).

Table 2. Fracture Healing Time, Stent Wearing Time and Postoperative Complications

Group	n	Fracture healing time (months)	Stent wearing time (months)	Postoperative complications
Study	22	6.12±0.85	7.50±0.91	4
Control	18	7.39±0.78	8.72±0.89	3
t/χ^2value	–	−4.632	−4.25	0.229
P value	–	<.05	<.05	>.05

Table 3. Kolcaba Comfort Scale Score

Group	n	1 day before surgery	24 hours after surgery	1 day before discharge
Study	22	67.23±3.90	54.92±3.84	88.23±5.67
Control	18	61.68±3.94	45.23±3.36	72.59±4.58
F value	–	2.328	11.208	16.206
P value	–	>.05	<.05	<.05

Table 4. Functional Exercise Compliance

		1 Week After Surgery				3 Weeks After Surgery			
Group	n	Excellent	Good	Can	Difference	Excellent	Good	Can	Difference
Study	22	9	7	4	2	12	8	2	0
Control	18	4	4	7	3	8	4	4	2
χ^2value	–	2.788				5.334			
P value		< .05				< .05			

Table 5. Ankle Dorsiflexion Range of Motion (°)

Group	Week 1	Week 2	Week 3	Week 6	March	June	December
Observation	9.23±0.22	13.5±0.32	16.36±0.41	18.23±0.47	20.23±0.52	22.36±0.58	24.27±0.67
Control	5.89±0.25	8.94±0.36	11.5±0.45	14.06±0.52	16.78±0.58	19.72±0.64	22.00±0.74
F value	100.69	90.32	63.75	35.05	19.72	9.35	5.22
P value	< .05	< .05	< .05	< .05	< .05	< .05	> .05

Table 6. Ankle Plantar Flexion Range of Motion (°)

Group	Week 1	Week 2	Week 3	Week 6	March	June	December
Observation	23.96±4.61	31.91±4.43	39.23±4.17	45.95±4.01	49.18±3.53	50.86±3.45	54.77±3.38
Control	16.94±3.78	23.89±3.85	33.33±3.88	38.78±3.90	43.67±3.56	48.67±3.01	50.50±12.49
F value	26.797	36.466	21.015	32.507	23.975	25.113	2.376
P value	< .05	< .05	< .05	< .05	< .05	< .05	> .05

Functional exercise compliance (Table 4)

The excellent and good rates in the study group at 1 week after surgery was 72.7%, and the excellent and good rate in the control group was 44.4%; the excellent and good rate in the study group at 3 weeks after surgery was 90.9%, the excellent and good rate in the control group was 66.7%; the study group rate was higher than the control group at each time point, and the difference was statistically significant ($P < .05$).

Ankle joint range of motion (Table 5, Table 6)

Patient's ankle joint plantar flexion and dorsiflexion range of motion on the first day after operation, the difference between the 2 groups was not statistically significant ($P > .05$). At 1, 2, 3 and 6 weeks and 3 and 6 months, patient ankle joint plantar flexion and dorsiflexion gradually increased; they were higher in the study group than in the control group at each time point, and the difference was statistically significant ($P < .05$). At 12 months after surgery, the range of motion of the ankle joints in each group continued to improve, but there was no significant difference between the 2 groups ($P > .05$).

Excellent and good ankle joint function (**Table 7**).

Mazur Ankle Evaluation and Grading System score 6 months after surgery was excellent and good rate was 59.1% in the study group and 38.9% in the control group. At 12 months after surgery, the excellent and good rate in the study group was 72.8% and 61.1% in the control group. At each time point, the study group had a higher rate than the control group, and the difference was statistically significant ($P < .05$).

Table 7. Ankle Function Score

Group	n	6 Months After Surgery				12 Months After Surgery			
		Excellent	Good	Can	Difference	Excellent	Good	Can	Difference
Observation	22	5	8	6	3	8	8	4	2
Control	18	3	4	9	4	5	6	5	3
χ^2value		5.368				1.284			
P value		< .05				< .05			

DISCUSSION

With the development of the transportation and construction engineering industries in modern society, Pilon fractures caused by high-energy injury are occurring more frequently, becoming a common clinical lower limb traumatic fracture. The traditional open reduction and internal fixation method has the disadvantages of aggravating soft tissue damage and destroying the blood supply around the fracture, which may increase the risk for complications such as postoperative soft tissue necrosis, infection and internal fixation exposure.[13]

In our study, we used a Taylor annular space external fixation bracket combined with small incision reduction and limited internal fixation to deal with high-energy injury Pilon fractures and achieved elastic fixation of the fracture ends via 6 adjustable support rods. Not only was the early fixation strong and reliable, but also it could be adjusted as needed and can form a fretting environment that is favorable to fracture healing.[16]

Early postoperative rehabilitation activities are helpful to maximize the recovery of long-term ankle joint function and muscle strength.[1,9] One of the contents of rehabilitation training is also the focus of orthopedic nursing.[17] The patient uses the foot correction exerciser to perform limb resistance training, which increases the intensity of the active contraction of the calf extensor and flexor muscles. The resulting dynamic axial stress stimulation and traction mechanical load on the bones[18] can promote the growth of callus and the formation and reconstruction of blood vessels at the fracture end, help prevent disuse porosis and promote fracture healing[19] (see Table 2).

Our data analysis showed that the study group was better off than the control group in terms of comfort 24 hours after surgery and 1 day before discharge (see Table 3). The reason is that the foot correction exerciser, through its shoe-shaped support and the associated elastic fixing belt structure, supports the foot and maintains a neutral angle, which meets the postural requirements of the limbs after external fixation. This puts the injured ankle joint in a tension-free healing state; relieves early postoperative pain, swelling, and muscle spasm; and satisfies the patient's physical and psychological needs, thereby improving overall subjective patient comfort.

The dynamometer in the foot correction exercise device can immediately provide the patient with accurate and intuitive feedback on strength measurement information during the lower limb resistance exercise process, which improves the safety, efficacy and fun of training. At the same time, exercising with the support and protection of the corrective exercise device effectively eliminates the patient's fear, enhances self-confidence and initiative, and thus improves the patient's compliance with exercise (see Table 4).

Our study shows that the range of motion of the ankle joint at the 1st, 2nd, 3rd and 6th week, and 3rd and 6th month after surgery, the dorsiflexion and plantar flexion angles in the study group were greater than in the control group (see Table 5, Table 6). At 6 months, the Mazur Ankle Evaluation and Grading System score in the study group was higher than in the control group (see Table 7). It shows that the foot correction exercise device assists postoperative functional exercise, which can accelerate the early recovery of ankle joint mobility and also help to improve the long-term function of the ankle joint (see Table 7). According to the investigators' analysis of the design, the adjustable elastic band of the foot correction exercise device introduces resistance training, increases strength training of the muscles around the calf and ankle joint and can prevent disuse atrophy of the affected limb muscles. The application of this device improves the correctness and effectiveness of exercise, can effectively inhibit the adhesion and calcification of soft tissue around the ankle joint and promotes tissue repair and recovery of ankle joint function.[20]

At 12 months after surgery, the dorsiflexion and plantar flexion angles in the study group were also greater than in the control group, but the difference was not statistically significant (Table 5 and Table 6), while the Mazur score in the study group remained higher than in the control group (see Table 7). The reason may be that after the removal of the external fixation bracket, there are individual differences in the patient's tolerance for active exercise, living conditions and other factors, resulting in variations in ankle joint mobility. The long-term result is generally the same, but early recovery of mobility can help improve the patient's self-perceived and functional scores.

CONCLUSION

In short, the application of high-energy injury Pilon fracture external fixation to the foot correction exercise device can assist the affected limb in maintaining the correct posture, relieve local muscle spasm, relieve pain and improve comfort. The design is light and portable, easy to wear and patients can operate it themselves, reducing their dependence on manual assistance, and can control the intensity and time of exercise themselves, which can improve the awareness of active participation and exercise compliance. Through early and effective resistance training, the strength of the muscle tissue around the fracture can be restored, which is conducive to improving the stability of the ankle joint, promoting the

recovery of ankle joint function, and improving patients' quality of life, which has good clinical application and promotion value.

CONFLICT OF INTEREST

None.

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