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Original Article

A novel external fixator to facilitate accurate and efficient fracture treatment

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Abstract: Background: With the rapid popularization and application of the technology of external skeletal fixation, using an external fixator is becoming an effective method for treating various complex fractures. However, due to the instability, assembly complexity and poor controllability, designing a new external fixator to facilitate accurate and effective treatment of fractures has become an interesting challenge to peruse. Methods: We designed a new type of external fixator suitable for the treatment of clinically complex fractures. Then, a prospective study (trial number: 201636) was conducted on patients with various complex fractures from September 2017 to September 2019 in Jiangxi Provincial People's Hospital. During this period, 24 patients were treated using a kind of universal joint external fixator and its therapeutic effects were evaluated. In addition, we adopted universal joint external fixators (UJEF) and assembly external fixators (AEF) to fix adult cadaveric femoral fractures, and subsequently their mechanical stability was assessed by a biomechanical testing machine. Results: This device design not only fits the repair site but can also be conveniently installed and implanted. Lastly, all patients treated with the universal joint fracture external fixators achieved good fixation and healing. With *in vitro* biomechanical testing, the constructed models were loaded under axial compression, lateral compression and torsion respectively. As a result, there was no significant difference in the total axial stiffness between the two groups. Besides, the lateral stiffness was 1.554 ± 0.017 mm for the UJEF group and 1.342 ± 0.020 mm for the AEF group ($P<0.001$) under a 600 N load, while the torsional stiffness was 15.727 ± 0.141° for the UJEF group and 14.472 ± 0.292° for the AEF group under a 40 Nm load. Conclusion: In this relatively small and preliminary study, the universal joint external fixator which achieved a stable mechanical structure was strengthened, as an effective and comprehensive therapy tool for fractures. If these findings can be confirmed in a larger study, this external fixator may be widely used in certain situations where traditional external fixators are not a convenient choice.

Keywords: External fixator, fracture, cadaver femur fracture, biomechanics

Introduction

Contemporarily, external fixation systems are widely used for treating fractures. There are many commonly recognized indications for the application of an external fixator, such as open fractures that require continuous debridement, soft tissue coverage and eventual stable internal fixation [1]. Although there are many types of external fixators applied in the process of fracture healing, they have numerous shortcomings including potential nail infection, instability, assembly complexity and poor controllability [2, 3]. At disaster sites, because of the high number of casualties with complicated situations, it is an emergency to quickly fix fractures to reduce the secondary injury caused by the displacement of the fracture ends, and effectively reduce bleeding so as to create conditions for further treatment. The unilateral Bastiani external fixator is widely used but it has been criticized for having complex operations, and for the dependence on auxiliary imaging equipment and instability [4]. Hence, it is not suitable to be applied in emergencies, such as large-scale disasters. For open fractures with extensive soft tissue injury, it is hard to apply the "reduction-first" type of external

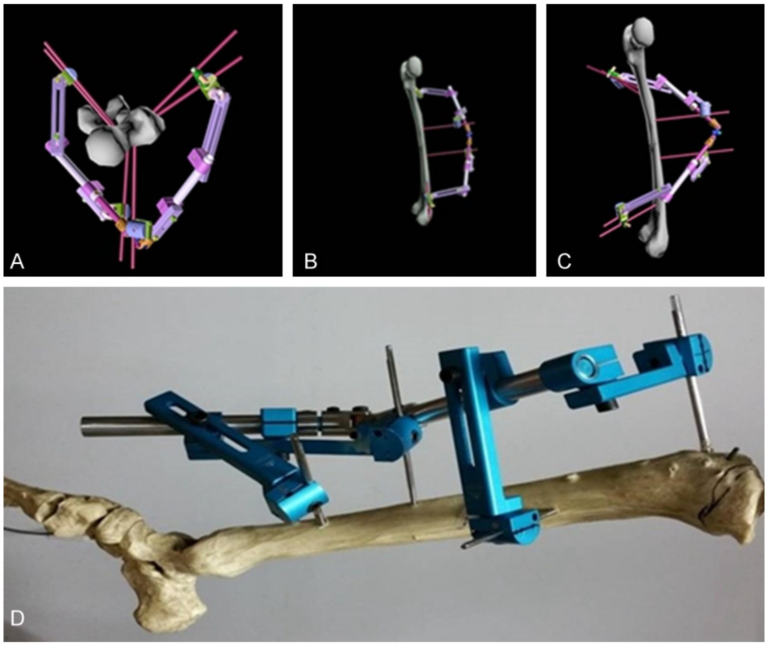

Figure 1. A schematic diagram of external fixator designs. A-C. Computer aided designs of the external fixator model. D. Application of the external fixator in a tibial specimen.

fixator due to the lack of safe nail pathways [5]. Meanwhile, the existing "nail-priority" external fixator has a complicated combination structure and requires loads of components that need to be connected to achieve a stable structure. Besides, there are no specific rules for the combination and consumption of the parts [6, 7]. Thus, this has great demands on the surgeon's skill levels. Conventional external fixators are difficult to apply at the initial injury site, as well in patient transfers and also in the absence of imaging assistance.

Accordingly, designing a targeted external fixator is a critical issue. For patients with fractures from severe trauma, adopting an external fixator treats the fractures with simple, convenient and fast temporary fixation on the spot, and it not only allows patients to be transferred fast, but it also reduces the secondary fracture injury. Thereby, it creates opportunities for rescue of life-threatening vital organ injuries and partly restoring the function of impaired limbs, so that surgeons can arrange an appropriate date to perform well-planned operations to treat non-fatal wounds. In this study, we designed a novel external fixator that is applicable in various kinds of environments in order to facilitate the treatment of fractures, such as in simple, convenient and fast temporary fixation for severe trauma fractures and field trauma. Through assessing the clinical efficacy of healing in patients with fracture, we also show the mechanical stability and practical flexibility of our universal joint external fixator.

Materials and methods

External fixator designs

Application: To overcome the shortcomings of existing external fixators, such as not being well adapted for good controlled fixation of the accident victims' injury at the scene of the injury; therefore, we invented a novel external fixator. This external fixator can conveniently perform damage-controlled fixation of various complex fractures in various places, and clinicians can also apply the original external fixator in the secondary restoration, therefore achieving non-invasive correction and re-fixation without changing the nail path when the patients' general condition and medical conditions permit.

Technical scheme: a) This external fixator is designed as a single-arm external fixator with few components, which is convenient for distribution, sterilization and transportation. b) This fixation method is designed to be a multiplanar fixation that prioritizes screwing in the nail to increase the fixation strength. c) Between both ends of the fracture, a connection which can produce large transformation in all directions is designed, making it more flexible for the nail penetration and non-invasive secondary reduction and fixation.

Instrument structure: We used Mimics 19.0 software to design a universal joint fracture external fixator based on a three-dimensional model and nailing scheme (**Figure 1**). This novel device is composed of brackets, nail lockers and fixed nails. Among them the brackets are composed of a distal bracket, a proximal bracket and a coupler. The distal and the proximal brackets are the main frames of the external fixator and they are used as the distal and proximal nails and attachment brackets for the locked nails. The coupler is a universal fastening bonder, connecting the distal and proximal brackets together. Should the coupler become loose, the distal and proximal brackets can be closed relatively, displaced, tilted or twisted. Once the coupler is tight, the device will become a rigid fixator.

Patient inclusion criteria

After receiving approval from Jiangxi Provincial People's Hospital Affiliated to Nanchang University, we carried out a prospective trial from September 2017 to September 2019 in our hospital, and the research subjects were patients who suffered from various traumas complicated with fracture. Based on the willingness of the patients and their guardians to be treated with universal joint external fixators (UJEF), 24 patients were included in this study. Afterwards, we evaluated the clinical efficacy of the universal joint external fixators in terms of the practicality and related complications. The radiographs were analysed before fixation, after fixation and at the final follow-up.

Biomechanical testing

After receiving approval from Jiangxi Provincial People's Hospital Affiliated to Nanchang University, we made 10 approximate models of adult cadaveric femoral fracture (**Figure 2**). Femoral middle oblique fracture specimens were used for biomechanical experiments, because this type of fracture model is usually used to simulate the comminuted fracture in the middle of the femur. If the strength of the external fixator is adequate to meet clinical needs in this fracture model, then it is obvious that the fixation strength of other fracture sites can also be satisfied. Therefore, we selected this model with the highest fixed strength requirement to do the biomechanical loading experiment. These femur fracture models were divided into two groups according to external fixators: the UJEF group (n=5) and the assembly external fixators (AEF) group (n=5). The two groups were then tested non-destructively by using a CTM2200 microcomputer-controlled electronic universal testing machine, a Zwick (B22.5/TSIS, Germany) material testing machine and a 100 Nm microcomputer-controlled torsion testing machine to determine the axial, lateral and torsional stiffness (**Figure 3**). For axial and lateral compression, a maximum load of 600 N was applied at respective loading speeds of 20 N/s and 50 N/s with a preload of 200 N, and then we measured the displacement of the specimens. For torsion, a maximum load of 40 Nm was applied at a rotational speed of 0.3°/s, and then we measured the rotation angle.

Statistical analysis

The results were presented as a mean ± standard deviation (SD). The unpaired t-test was used for comparisons between these groups in continuous variables when the collected data were normally distributed and with homogeneity of variance. If not, the Kruskal-Wallis rank sum-test was applied. All tests were two sided with a statistical significance limit set at $P<0.05$. Statistical analyses were performed using SPSS v.21.0.

Results

Advantages of the UJEF external fixator

First, the universal joint external fixator is a versatile device that prioritizes nail penetration and is capable of single-arm multi-dimensional fixation (**Figure 1A**). Meanwhile, it does not touch the wound surface and it connects the bone nails in multiple dimensions to form a strong multi-planar fixation. A single-arm fixator can fix nails whose diameters are approximately 2/3 of that of the bone. Second, it is noninvasive and corrects reduction by utilizing UJEF (**Figure 1B** and **1C**). Furthermore, the number of components did not increase nor did the position of the nails change when we needed to correct fracture reductions. Thirdly, the UJEF consist of only a few components, which are easier to carry and assemble than traditional ones, so they are of higher efficiency. Since they can be flexibly adjusted, the UJEF can be applied in pelvic fractures, limb fractures, ankle fractures, etc.

Clinical application

As the biomechanical loading experiments have confirmed, the fixation strength of the external fixator for oblique fractures of the middle femur meets the clinical needs, and the

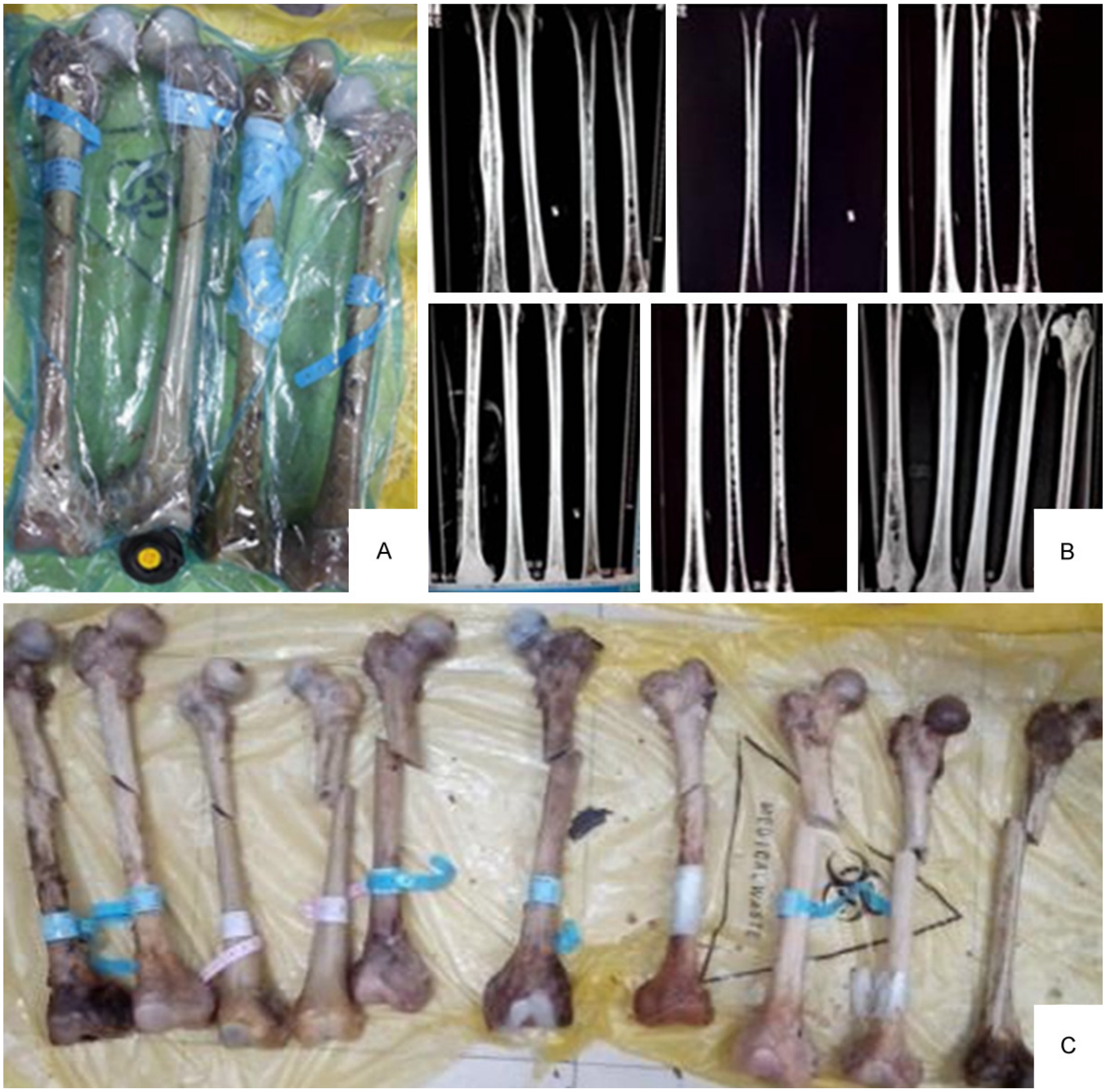

Figure 2. Demonstration of adult adaver femur fracture models. A and B. Adult adaver femur specimens and radiography. C. Adult adaver femur fracture models.

focus of the clinical trials was to prove the extensiveness of indications and application environments, with simplicity of the installation procedure, non-invasiveness of correcting the reductions, and convenience in operations to retain joint motion while fixing fractures. Thus, our study included twenty-four patients treated by the inventor with different types of fractures. All the included patients were suitable for external fixator treatment and had signed the informed consent for clinical trials in advance. After discharge, all the patients were followed up for an average of 23.7 months (21-36 months). Among them there were 17 males and 7 females, and the ages ranged from 7 to 60 years old. Patients who were treated in both trauma scenes and the hospital were assessed in terms of the damage-controlled fixation, fracture fixation and complications after the UJEF were installed. Moreover, through radiographic observation, we assessed the patients' fracture fixation as well as the fracture healing. In the course of medical treatment, the UJEF were fixed firmly without nail loosening and displacement. The fracture patients healed well during the follow-up, and there were no intraoperative or postoperative complications like infection, delayed union or breakage of UJEF.

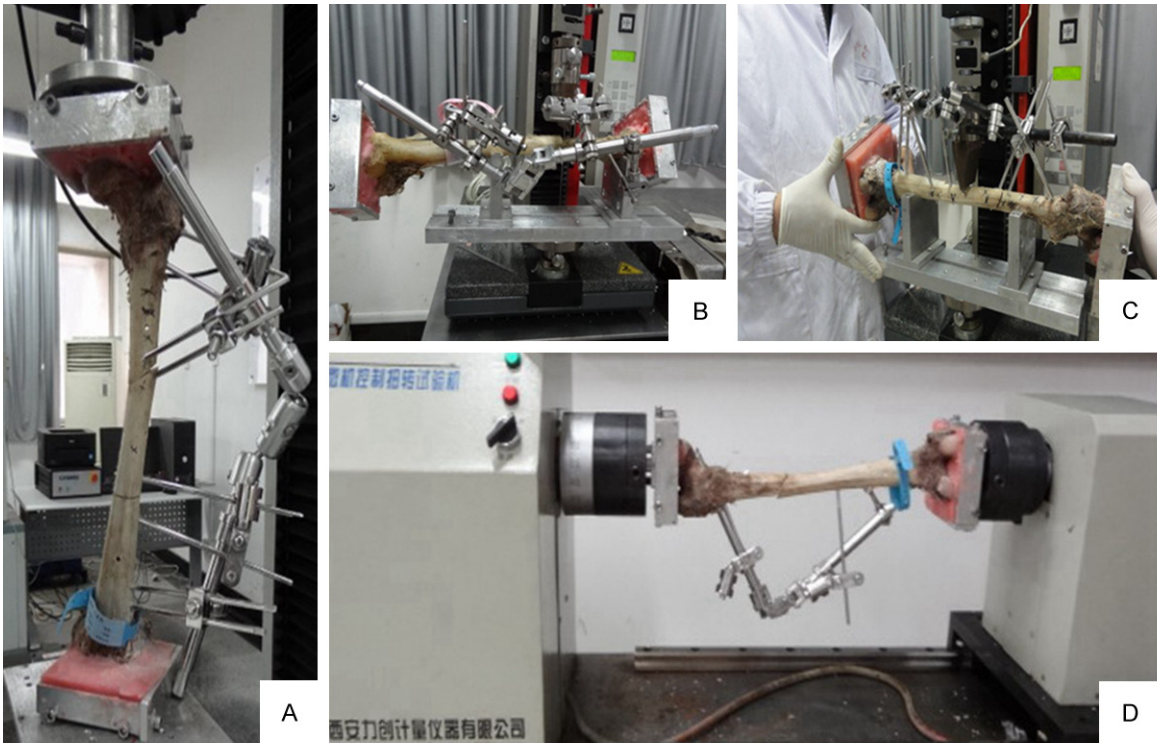

Figure 3. The mechanical stability of universal joint external fixation device and assembly fracture external fixation device. A. The axial loading displacement experiment. B and C. The lateral loading displacement experiment. D. The torsional loading experiment.

A typical case treated with the UJEF is described hereafter. A 60-year-old male suffered multiple open and comminuted fractures of the right upper limb and open injuries of the elbow and wrist, for 4 hours which were caused by an automobile accident. Systemic treatment and anti-infection treatment were carried out with debridement and suturing, and a Kirschner wire and plaster external fixation were performed in this emergency. There were wide and scattered wounds which involved the affected limb, with many fracture segments. Traditional combined external fixation was used to fix the limb, there were at least 2 nails needed on each bone segment, and many parts were assembled, which resulted in difficult dressing changes. Plaster was used for external fixation after surgery, and the plaster was removed every day after dressing for re-fixation. Therefore, when the patient saw the doctor again at 38 days after the injury, the right forearm had been shortened into angular malformation with abnormal movement, and the X-ray film showed no signs of bone union. Dilated debridement was implemented at 40 days after the injury, and then only a pair of UJEF was used to fix the fracture of three ulna fragments and two radius fragments. The goal was that releasing the universal coupling and exercising the flexion and extension function of the elbow twice a day after surgery would allow healing. Thus, the range of motion of flexion and extension of the elbow reached 80°-165° after removal of the super elbow and super wrist fixed parts, three months after surgery (**Figure 4**).

In vitro testing

Because of the experimental variability, there was no between-group difference associated with nail distances or nail insertion angles in the sagittal, coronal and horizontal planes (**Tables 1-4**). In axial compression testing, no significant difference was detected between the two groups for loads of 100 N, 200 N, 400 N and 600 N as **Table 5** shows. For lateral compression, **Table 6** depicts that there was no significant difference for loads of 100 N, 200 N and 400 N. However, the UJEF group exhibited less stiffness with a load of 600 N (equivalent to the weight of an average adult) than the AEF

Figure 4. A 60-year-old male suffered multiple open and comminuted fractures of the right upper limb and open injuries of elbow and wrist due to a car accident. Then he received debridement and suture, Kirschner wire and plaster external fixation in the emergency ward. After the surgery, the dressing was changed every day. Extended

debridement and open reduction combined with universal joint external fixation was performed 40 days after injury. A. Plain radiographs showed fractures of the right condylus medialis humeri, olecranon of ulna, the shaft of ulna, as well as distal Middle Segment Comminuted Fractures. B. One month postoperatively, radiographs indicated that the right ulna and radius had shortening displacements, and the broken ends showed a backward and radial angular displacement deformity. Beside, no callus shadow was observed between the broken ends. Fractures of the right condylus medialis humeri and olecranon of ulna were well reduced, which were fixed with 4 Kirschner wires. The right wrist was fixed in the functional position with crossed Kirschner wires. C, D. Gross photograph 38 days after injury showed an angular deformity of the right forearm. There were still superficial wounds on the dorsal and ulnar sides of the upper segment of forearm as well as the ulnar side of the lower segment of upper arm. E, F. For ulnar and radial shaft fractures, an extended debridement and a limited open reduction combined with universal joint external fixation were performed 40 days after the initial debridement. One universal joint external fixator was able to fix fractures of the right ulnar and radius in 3 places, and simultaneously achieve the hyperarticular fixation of both elbow and wrist joints. G. X-rays 5 days after the external fixation operation showed that several fractures of the right ulnar, radius and above-mentioned joints were fixed firmly. H, I. This patient could do some functional exercise of the right elbow through loosing the universal coupling twice a day after the surgery. When he began the postoperative exercise, the range of flexion-extension motion of the right elbow joint was 85°-110°. J, K. The fixing components of the right elbow and wrist joints were removed 3 months postoperatively, and the range of the flexion-extension motion reached 80°-165° at that time. L. 7-month follow-up frontal and lateral X-ray images depicted that the right ulnar and radius were well aligned. In addition, a large number of continuous calluses were formed in the site of three fractures.

Table 1. The Nails distance of two groups

Nail Distance	UJEF group Mean ± SD	AEF group Mean ± SD	*p* value
A	7.5 ± 0.30 mm	7.5 ± 0.16 mm	0.344
B	7.0 ± 0.02 mm	7.0 ± 0.02 mm	0.782
C	7.9 ± 0.02 mm	7.9 ± 0.03 mm	0.112
D	6.3 ± 0.02 mm	6.3 ± 0.02 mm	0.924
E	6.7 ± 0.01 mm	6.7 ± 0.01 mm	0.962

UJEF, Universal joint external fixators; AEF, Assembly external fixators.

Table 2. The sagittal nails insertion angle of two groups

Nail Insertion Angle	UJEF group Mean ± SD	AEF group Mean ± SD	*p* value
A	15.1 ± 0.16°	15.1 ± 0.11°	0.632
B	15.5 ± 0.10°	15.9 ± 0.12°	0.877
C	18.9 ± 0.12°	19.2 ± 0.09°	0.783
D	20.7 ± 0.14°	20.5 ± 0.39°	0.762
E	19.3 ± 0.11°	19.2 ± 0.10°	0.814

UJEF, Universal joint external fixators; AEF, Assembly external fixators.

Table 3. The coronal nails insertion angle of two groups

Nail Insertion Angle	UJEF group Mean ± SD	AEF group Mean ± SD	*p* value
A	30.8 ± 0.34°	30.9 ± 0.27°	0.863
B	33.8 ± 0.29°	33.8 ± 0.30°	0.735
C	70.6 ± 0.35°	70.6 ± 0.29°	0.983
D	50.3 ± 0.43°	50.4 ± 0.39°	0.699
E	41.8 ± 0.20°	41.7 ± 0.23°	0.831

UJEF, Universal joint external fixators; AEF, Assembly external fixators.

group ($P<0.001$). With regard to the torsion, **Table 7** demonstrates that the UJEF was more likely to twist when the load exceeded 40 Nm.

Discussion

The external skeletal fixation technique is a minimally invasive operation in which nails are percutaneously implanted and connected with external frames. The stress transmitted between nails stimulates the regeneration and reconstruction of the bone tissue [8]. Previous studies have justified the benefits of an external fixator in the treatment of fractures, as it can (1) maintain fracture stability by resisting rotation, shearing and various-valgus forces [9, 10]; it also (2) alleviates articular surface pressure in articular fractures, thereby protecting the articular surface [11]; and it (3) provides a suitable environment for the recovery of soft tissue and muscles [12]. At present, external fixators are rarely used in trauma scenes, especially in field medical treatment. Although hybrid external fixators have relatively broad functions, a large number of components must be maintained to meet the needs of different types of

Table 4. The horizontal nails insertion angle of two groups

Nail Insertion Angle	UJEF group Mean ± SD	AEF group Mean ± SD	*p* value
A	30.8 ± 0.34°	30.9 ± 0.27°	0.863
B	33.8 ± 0.29°	33.8 ± 0.30°	0.735
C	70.6 ± 0.35°	70.6 ± 0.29°	0.983
D	50.3 ± 0.43°	50.4 ± 0.39°	0.699
E	41.8 ± 0.20°	41.7 ± 0.23°	0.831

UJEF, Universal joint external fixators; AEF, Assembly external fixators.

Table 5. The Axial Loading Displacement Experiment

Load	UJEF group Mean ± SD	AEF group Mean ± SD	*p* value
100 N	0.126 ± 0.020 mm	0.120 ± 0.022 mm	0.408
200 N	0.294 ± 0.154 mm	0.297 ± 0.204 mm	0.585
400 N	0.563 ± 0.202 mm	0.549 ± 0.265 mm	0.198
600 N	0.919 ± 0.038 mm	0.957 ± 0.043 mm	0.785

UJEF, Universal joint external fixators; AEF, Assembly external fixators.

Table 6. The lateral loading displacement experiment

Load	UJEF group Mean ± SD	AEF group Mean ± SD	*p* value
100 N	0.327 ± 0.021 mm	0.333 ± 0.015 mm	0.331
200 N	0.661 ± 0.016 mm	0.607 ± 0.019 mm	0.305
400 N	0.995 ± 0.017 mm	0.994 ± 0.021 mm	0.931
600 N	0.995 ± 0.017 mm	1.342 ± 0.020 mm	<0.001

UJEF, Universal joint external fixators; AEF, Assembly external fixators.

Table 7. The torsional loading experiment

Load	UJEF group Mean ± SD	AEF group Mean ± SD	*p* value
10 Nm	2.027 ± 0.160°	2.094 ± 0.111°	0.632
20 Nm	5.483 ± 0.104°	5.550 ± 0.115°	0.077
30 Nm	9.200 ± 0.119°	9.177 ± 0.094°	0.583
40 Nm	15.727 ± 0.141°	14.472 ± 0.292°	<0.001

UJEF, Universal joint external fixators; AEF, Assembly external fixators.

fractures [6, 13]. In addition, when an external fixator is attached to a joint, it will adversely affect joint movement to some extent. Joint stiffness is also a common complication during the treatment with external fixators, even resulting in heterotopic ossification [13-16].

In this study, we designed a novel external fixator, aiming to overcome the shortcomings of existing external fixators since they cannot be well adapted for the damage-controlled fixation of the victim's injury at an accident site. Our new external fixator is not only convenient to perform the damage-controlled fixation of various complex fractures but it can also be flexibly adjusted. Additionally, the universal joint external fixator is an intensive device that has a number of superiorities compared with traditional external fixators. Some of its advantages are listed as follows.

(1) Convenient delivery. The new fixator is small and requires no extra components. (2) Easy to learn. The tools required are merely an electric drill and a wrench; even junior physicians can master it quickly. (3) Versatility. When applied to many kinds of fractures, the UJEF can continue the non-invasive controlled fixation until the final fixation. (4) No sterility requirement. External fixtures and tools can carry bacteria that need to be sterilized, which makes the new fixator suitable for reuse in battle fields and disaster areas.

In our study, fracture patients obtained good healing during follow-up according to radiographic observation. Because the UJEF can be adjusted flexibly, joint deformity and stiffness can be avoided, and cross-joint fixation does not require prenail implantation after fixation. Therefore, the dynamic external fixator is a reliable and effective device for treating fractures, allowing early postoperative functional rehabilitation and restoring joint function. During the treatment, the UJEF was fixed firmly without nail loosening and displacement. Moreover, there were no intraoperative or postoperative complications including infection, delayed union or breakage of the UJEF external fixators. Given that it supplied a suitable condition for fracture healing, the UJEF external fixator achieved an acceptable treatment result.

Previous studies have confirmed that fixator stiffness is closely related to stability and fracture healing [17-19]. The overall stiffness of the fracture fixation device directly impacts the axial, torsional, and shear interfragmentary movement at the fracture site [20-22]. In the axial and lateral biomechanical testing, we used a maximum load of 600 N, which is similar to the weight of an average adult, to estimate the mechanical performance of the UJEF. Our data suggests that the UJEF exhibited biomechanical stability similar to that of the AEF, which indicates that the UJEF conformed to clinical application standards. We found no significant difference in the stiffness of the rotational planes with a load below 40 Nm. This demonstrated that the UJEF had a normal anti-torsion effect. Therefore, the UJEF with its good biomechanical stability, will lead to axial interfragmentary movement and promote fracture healing.

Some limitations should not be ignored. First, because the UJEF external fixation technology was not officially listed, the patients and their guardians needed to fully understand the surgical purpose and the pros and cons of this technology as well as sign the consent before surgery, which required us to fully communicate this with them. Secondly, the relatively small sample size reduced the credibility of the conclusion, so a larger study is required to assess the mechanical stability of this novel external fixator.

Conclusions

In this small, preliminary study, we show that the universal joint external fixator prioritizes nail penetration and possesses a flexible spatial structure to provide an intensive and efficient treatment for patient fractures. Not only can it be noninvasively adjusted to ensure reduction of the fracture, but it can also improve the operation skills of surgeons. In addition, the universal joint external fixator has a stable mechanical structure. If these findings can be confirmed in a larger study, this external fixator may be widely used in certain situations where a traditional external fixator is not a convenient option.

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Disclosure of conflict of interest

None.

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