Clinical Study of a New Design Multifunction Dynamic External Fixator System for Open Tibial Fracture

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Background: *The tibial shaft is one of the most common sites of open fracture. External fixators emerged as the treatment of choice for high energy open tibial fractures because they were easy to apply, allow sufficient access for wound care and provide sufficient mechanical fixation for patient mobilization and bone healing. Based on the advantages of dynamization in increased union rate and the simplicity of monolateral frame, a new design dynamic external fixator system was developed for definite treatment in open tibial fracture.*
Objective: *To evaluate the clinical results of open tibial fractures treated with a new design dynamic external fixator system until healing.*
Material and Method: *The case series of 60 patients with open tibial fracture treated with the new design dynamic external fixator system for acute and definitive-treatment frame between 2005 and 2009. According to the system of Gustilo and Anderson, 14 fractures were classified as type II, 43 as type IIIA, and three as type IIIB. Partial weight bearing with crutches was instructed when tolerable for dynamization. When there were evidences of fracture healing in both clinical and radiographic, external fixator was removed.*
Results: *All fractures united. The median union time was 12 weeks (range, 10-15) in type II, 16 weeks (range, 10-24) in type IIIA, and 20 weeks (range, 20-21) in type IIIB. Iliac bone grafting was performed in six cases at a mean time of 3.8 weeks to enhance bone union. Seven cases (12%) developed pintract infections. No deep infection was found in the present study. Ninety-five percent of fractures united with less than 10 degrees angulation in any plane. No instrument failure was found. The external fixator frame could be reused.*
Conclusion: *The new design dynamic external fixator system successfully treated open tibial fractures with a good result and low complication rate. It is simple, safe, and easy to use.*

Keywords: *External fixators, Fractures, Open, Tibia*

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Open fractures and related problems including intercalary bone defect, shortening, infected nonunion and malunion are still major problems in orthopedic practice. The tibial shaft is one of the most common sites of open fracture. The objectives of open fractures treatment are to prevent infection, promote fracture healing, and restore function[1]. External fixators emerged as the treatment of choice for high energy open tibial fractures because they were easy to apply, allow sufficient access for wound care, and provide sufficient mechanical fixation for patient mobilization and bone healing. The major problems of static external fixator frame are delayed union and pintract infection because of prolonged use of the frame. Dynamization has a benefit in increase union rate and decreased the time spent in external fixation frame, thereby, decrease rate of pintract infection[2]. Based on the advantages of dynamization and the simplicity of monolateral frame, a new design dynamic external fixator system was developed for definitive-treatment frame in open tibial fracture.

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Objective

The primary objective was to evaluate the union time of open tibial fractures treated with a new design dynamic external fixator system until

healing. The secondary objective was to evaluate the complications from the use of this external fixator such as pintract infection, deep infection, and malunion.

Design

A new design dynamic external fixator system was a monolateral frame made from stainless steel. It consisted of an inner rod with axial motion in the outer tube for dynamization to enhance bone healing. There were clamps for rod and tube with six-degrees of freedom. An open clamp was designed for limit tube movement. There were distal nuts for bone gap closure function (Fig. 1).

Materials and Method

The present study was approved by the Ethics Committee of Maharat Nakhon Ratchasima Hospital. Patients with open tibial fractures between April 2005 and 2009 without associated lower extremity fracture, could ambulate with crutches postoperatively and could come to follow-up were included in the present study.

All fractures were treated according to a basic principle for open fractures: assessment of the patient, classification of the injury, antibiotic therapy, debridement and wound management, fracture stabilization, early bone grafting, and supplemental procedures to achieve healing[3]. External fixators were applied immediately by the first author or the last-year resident orthopedic surgeons for definitive-treatment frames (Fig. 2). Wound coverage and closure was assessed intraoperatively. Intravenous cefazolin was given in all cases and gentamycin was added in type IIIA and IIIB until forty-eight hours after the wound was closed then antibiotic was changed to oral form and continued for two weeks. When it was considered necessary, iliac bone grafting was performed as local and systemic conditions allowed. Pin site care was performed daily using Betadine solution and a cover with gauze. Rehabilitation protocol consisting of passive and active movement of knees and ankles and straight-leg raising was started on the first postoperative day. Ambulation with crutches was introduced as soon as associated injuries allowed in each patient. Partial weight bearing was instructed when tolerable for dynamization in the first four weeks[4]. Progressive weight bearing was allowed until fracture healing. Follow-up examinations were done at two weeks after discharge and then every four weeks until fracture healing. When there were evidences of

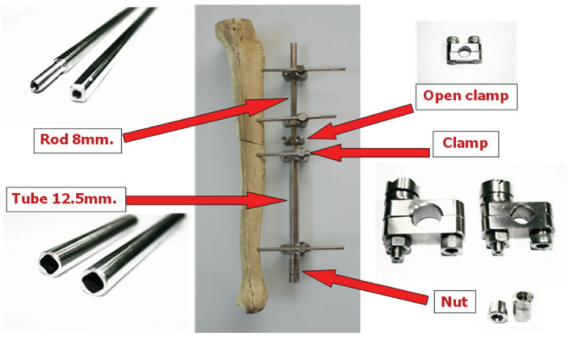

Fig. 1 Design of a new dynamic external fixator

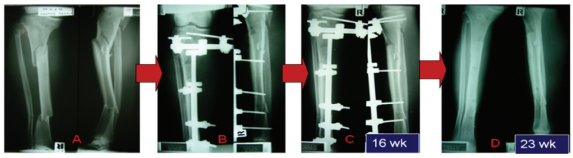

Fig. 2 The radiographic of a patient with type IIIA A: before surgery B: Radical debridement and applied new design dynamic external fixator immediately C: radiograph at 16 weeks post-operatively D: radiograph at 23 weeks post-operatively showing bony union and external fixator was removed

fractures healing in both clinical and radiographic, external fixator was removed. The patients were instructed to continue partial weight bearing with crutches for one month and continued follow-up every two months for two years. The demographic data, the union time, deep infection, incidence of bone grafting and pintract infection were all recorded.

Statistic analysis

The union time of type II, IIIA and IIIB were compared using Kruskal-Wallis nonparametric test. A p-value of less than 0.05 was considered statistical significant difference.

Results

Sixty patients with open tibial fractures were included in the present study. Patients ranged in age from 15 to 53 years. There were 48 men (80%) and 12 women (20%) in the study group. The majority (52) of fractures were caused by motorcycle accidents, the remaining injuries resulted from car accidents[6], and pedestrian accidents[2]. According to the system of Gustilo and Anderson[5,6], 14 fractures (23%) were classified as type II, 43 (72%) as type IIIA, and three

(5%) as type IIIB. The mean duration of follow-up was 1.5 years (range, 1.1-2.4).

All fractures united. The median union time was 12 weeks (range, 10-15) in type II, 16 weeks (range, 10-24) in type IIIA and 20 weeks (range, 20-21) in type IIIB (Table 1). The result showed that the median union time of type II was shorter than type IIIA and IIIB significantly (p-value < 0.001). There was no difference between type IIIA and IIIB. Two cases of type IIIA developed compartmental syndrome post-operatively which needed fasciotomy and delayed split thickness skin grafts. Three cases of type IIIA needed serial debridements and delayed split thickness skin grafts. The gastrocnemius flap and split thickness skin graft were performed in all three cases of type IIIB. Iliac bone grafting was performed in six cases (5 in type IIIA and one in IIIB) at a mean time of 3.8 weeks (range, 2-5) to enhance bone union because of cortical bone loss greater than 50% circumference. There were seven cases (6 in type IIIA and one in IIIB) of pintract infections (12%), five cases had good response to local pin care and oral antibiotic and the other two (3%) needed to change from external fixators to patella-bearing casts until healing because of pin loosening. No deep infection was found in the present study. Ninety-five percent of fractures united with less than 10 degrees angulation in any plane. There were two cases of 15 degree and one case of 20-degree malunion but patients denied further corrective osteotomy. No instrument failure was found.

Discussion

External fixator is a minimally invasive technique for management of fractures and other complicated musculoskeletal conditions. Currently, external fixators have two common treatment configurations: the damage-control orthopedic frame, which was designed to be a temporary device, and the definitive-treatment frame, which was designed to be used for definitive management of fractures and for posttraumatic reconstructions[7].

Dynamization of the external fixator frame has a beneficial effect on union rate. This new design dynamic external fixator system was developed based on the advantages of dynamization in increased union rate and the simplicity of monolateral frame. In the present study, 97% of open tibial fractures were successfully treated with the new design dynamic external fixators until healing with a median union time of 12 weeks in type II, 16 weeks in type IIIA, and 20 weeks in type IIIB. The union time was shorter than static external fixator frame [8-10] in the previous literature (Table 2). This result was similar to a previous comparative study of dynamic and static external fixator by Barquet A et al[11]. They demonstrated that the dynamic group gave a higher rate of union (97% vs. 87%), a shorter healing time (19 weeks vs. 29 weeks) and a decreased need for bone grafting (21% vs. 84%). The incidence of pintract infection was also decreased in the dynamic group. Kenwright et al[12] also demonstrated more rapid achievement of clinical

Table 1. Results of new design dynamic external fixator system in open tibial fractures

Open grade	No. of patients	Median union time (wk) (range)	Deep infection (%)	Bone graft (%)	Pin tract infection (%)
II	14	12 (10-15)	0	0	0
IIIA	43	16 (10-24)*	0	5 (12)	6 (14)
IIIB	3	20 (20-21)*	0	1 (33)	1 (33)

* p-value < 0.001

Table 2. Results of static external fixators in open tibial fractures

Study	No. of Patients	Open grade	Unions (week)	Deep infection (%)	Bone graft (%)	Pin tract infection (%)
Edwards[8]	202	3	36	15	28	29
Court-Brown[9]	51	3	37	18	70	35
Behrens[10]	26	2, 3	26	0	45	25

and radiographic union in the dynamic group in a randomized-prospective study comparing dynamic external fixator versus static external fixator.

In the present study, pintract infection was found in only seven cases (12%) because dynamization has a benefit in increased union rate and decreased time spent in external fixation frame, thereby, decrease rate of pintract infection. Pintract infection was usually found in cases with prolonged use of the external fixator frame.

This external fixator system could provide sufficient stabilization for patient early mobilization, rehabilitation, and maintained alignments until bony union occurred without instrumentation failure. Furthermore, it could be reused. When applied with other three accessories, lengthening device, adjustable ring connector, and gradual telescopic rod, this system can be used versatility such as bone transportation, lengthening, infected nonunion treatment, and malunion correction, which will be demonstrate in another study.

Conclusion

A new design dynamic external fixator system was successfully used on open tibial fractures with good results and a low complication rate. They were easy to use, safe and provided a stable construct in which the mechanical parameter (rigidity and alignment) could be modulated as needed throughout treatment. With partial weight bearing, the system could allow micromotion to enhance bone healing.

Potential conflicts of interest

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การรักษากระดูกหน้าแข้งหักแบบมีแผลเปิดโดยใช้โครงยึดตรึงกระดูกนอกกายอเนกประสงค์แบบใหม่

ยิ่งยง สุขเสถียร, รัชวรรณ สุขเสถียร

***ภูมิหลัง**: ภาวะกระดูกหน้าแข้งหักแบบมีแผลเปิดเป็นภาวะที่พบได้บ่อย การรักษาด้วยโครงยึดตรึงกระดูกนอกกายเป็นการรักษาที่ได้ผลดี คณะผู้นิพนธ์ได้ประดิษฐ์โครงยึดตรึงกระดูกนอกกายอเนกประสงค์แบบใหม่เพื่อใช้รักษาภาวะกระดูกหน้าแข้งหักแบบมีแผลเปิดจนกระทั่งกระดูกติด*

***วัตถุประสงค์**: เพื่อประเมินผลการใช้โครงยึดตรึงกระดูกนอกกายอเนกประสงค์แบบใหม่ในการรักษาภาวะกระดูกหน้าแข้งหักแบบมีแผลเปิด*

***วัสดุและวิธีการ**: ศึกษาในผู้ป่วยกระดูกหน้าแข้งหักแบบมีแผลเปิด 60 ราย โดยแบ่งเป็นชนิด II 14 ราย ชนิด IIIA 43 ราย และชนิด IIIB 3 ราย ใส่โครงยึดตรึงกระดูกนอกกายอเนกประสงค์แบบใหม่แล้วให้ผู้ป่วยเดินลงน้ำหนักบางส่วนจนกระทั่งกระดูกติด*

***ผลการศึกษา**: ผู้ป่วยกระดูกติดทั้ง 60 ราย โดยในชนิด II มีระยะกระดูกติดเฉลี่ย 12 สัปดาห์ ชนิด IIIA 16 สัปดาห์ และชนิด IIIB 20 สัปดาห์ ทำการปลูกกระดูกเพิ่ม 6 ราย พบการติดเชื้อรอบรูเข็มที่เจาะ 7 ราย (12%) ไม่พบกระดูกติดเชื้อ 95% ของผู้ป่วยกระดูกติดที่มุมผิดรูปน้อยกว่า 10 องศา*

***สรุป**: การรักษาภาวะกระดูกหน้าแข้งหักแบบมีแผลเปิดโดยใช้โครงยึดตรึงกระดูกนอกกายอเนกประสงค์แบบใหม่ได้ผลการรักษาที่ดีและพบภาวะแทรกซ้อนน้อย โดยพบว่าโครงยึดตรึงกระดูกนอกกายอเนกประสงค์แบบใหม่ใส่ง่าย ปลอดภัยและแข็งแรง*