Clinical Study of a New Design Multifunction Dynamic External Fixator System for Bone Reconstructions

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Background: *Fractures with related problems including intercalary bone defect, shortening, and malunion are still major problems in orthopedic practice. The Ilizalov's circular external fixator device has several advantages for bone reconstruction but also has certain drawbacks such as its bulkiness and complicated mounting. To maintain the advantages of Ilizalov's original concept and combine with the simplicity of monolateral frame, a new design multifunction dynamic external fixator system was developed to overcome the drawbacks.*
Objective: *To evaluate the clinical results and complications of a new design multifunction dynamic external fixator system for bone reconstructions.*
Material and Method: *Twenty patients requiring reconstructions between 2006 and 2009 participated in this study. The new design multifunction dynamic external fixators were used in 11 tibial and two femoral intercalary defects for bone transportation, three tibial and one femoral lengthening, and three tibial malunion correction (45,60 and 75 degrees).*
Results: *In bone transportation, new bone formation and union at the docking site were achieved in all patients. The mean new bone formation was 5.8 cm (range 3.5-14) in tibia and 4.3 cm (range 3.5-5) in femur. The mean healing index was 46.3 days/cm (range 42-60) in tibia and 93.9 days/cm (range 85.7-102) in femur. In bone lengthening, new bone formation and union were achieved in all patients. The mean amount of elongation was 3.5 cm (range 3-4) in tibia and 5 cm in femur. The mean healing index was 71.1 days/cm (range 68.6-76) in tibia and 73 days/cm in femur. In malunion correction, the mean correction time was 65 days (range 35-84) and the mean healing time was 187.3 days (range 154-212).*
Conclusion: *The new design multifunction dynamic external fixator system was successfully used for bone transportation, bone lengthening, and malunion correction with good results and low complications. It is simple, safe, and easy to use.*

Keywords: *External fixators, Bone transport, Bone lengthening, Bone malalignment*

J Med Assoc Thai 2011; 94 (10): 1224-9
Full text. e-Journal: *http://www.mat.or.th/journal*

Fractures with related problems including intercalary bone defect, shortening and malunion are still major problems in orthopedic practice. In the treatment of related problems, many instruments and surgical intervention are required. The Ilizalov's circular external fixator device has several advantages for bone reconstruction but also has certain drawbacks such as its bulkiness and complicated mounting. To minimize these drawbacks while still maintaining the advantages of Ilizalov's original concept(1-3) and combine with the simplicity of monolateral frame, a new design multifunction dynamic external fixator system was developed to overcome these problems.

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Objective

The primary objective was to evaluate the clinical results of a new design multifunction dynamic external fixator system for bone transportation, bone lengthening, and malunion correction. The secondary objective was to evaluate the complications from the use of this external fixator.

Design

A new design dynamic external fixator system was a monolateral frame made from stainless steel, consisting of an inner rod that had axial motion in the outer tube for dynamization to enhance bone healing. There were clamps for rod and tube, which

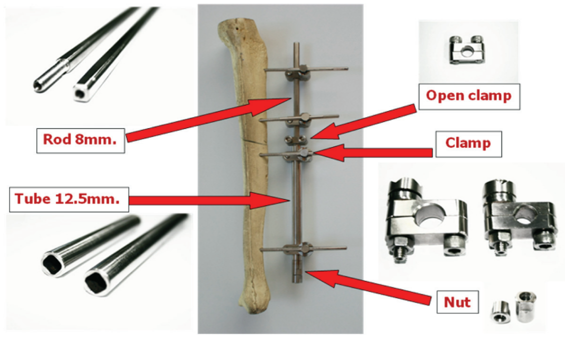

Fig. 1 Design of a new multifunction dynamic external fixator system

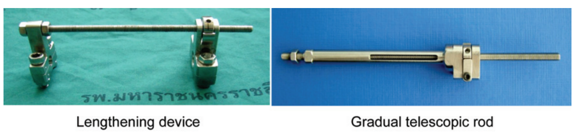

Fig. 2 Two accessories for multifunction applications

had six-degrees of freedom. An open clamp was designed for limit tube movement. There were distal nuts to bone gap closure function (Fig. 1). The other two accessories were a lengthening device for bone transportation and lengthening and gradual telescopic rod for malunion correction (Fig. 2).

Material and Method

The present study was approved by the Ethics Committee of Maharat Nakhon Ratchasima Hospital. Patients with complications from fractures that required reconstructions between December 2006 and 2009 were included in the present study. According to deformities, patients were divided into three study groups.

1. Bone transportation group: Old implants removal, debridement, and fixation with this external fixator and lengthening device were performed in all patients (Fig. 3). Two screws were inserted in the transport fragment. Serial debridements were needed in almost all the patients. Corticotomy was performed later when infection had subsided. Bone transportation process was begun one week after corticotomy in the rate of 1 mm/day (0.25 mm every 6 hr) according to Ilizalov's technique. Iliac bone grafting was performed at the docking site when it was considered necessary for enhance bone union. The following parameters were evaluated, new bone formation, transportation time, healing time, healing index, and complications during treatment.

2. Bone lengthening group: Corticotomy and fixation with this external fixator and lengthening device were performed in all patients. Lengthening process was begun one week after corticotomy at the rate of 1 mm/day (0.25 mm every 6 hr) according to Ilizalov's technique until limb length discrepancy was corrected (Fig. 4). The following parameters were evaluated, amount of elongation, lengthening time, healing time, healing index, and complications during treatment.

3. Malunion correction group: All patients had corticotomy performed and rotational malalignment corrected before applying this external fixator with gradual telescopic rod. Malunion correction process was begun in the first postoperative day at the rate of 1 mm/day (0.25 mm every 6 hr) according to Ilizalov's technique until good alignment was achieved (Fig. 5). Patella bearing cast was applied for four weeks after external fixator was removed before tibial nailing was performed to created union. The following parameters were evaluated, correction time, healing time and complications during treatment.

Pin site care was performed daily using Betadine solution and covered with gauze. Rehabilitation program consisting of passive and active movement of knees and ankles was started on the first postoperative day. Progressive weight bearing was allowed in all groups until bony union. Follow-up examinations were done at two weeks after discharge and then every four weeks until bony union. After bony union, there was continued followed-up every two months. Descriptive statistics in term of frequency mean and range were applied.

Results

Twenty patients were included in three study groups according to deformities to be corrected. The mean follow-up time was 26.5 months (range 13-48).

1. Bone transportation group: Thirteen patients were included (11 tibias and 2 femurs). Patients ranged in age from 14 to 53 years. Eleven patients were chronic osteomyelitis and the other two were open tibial fractures with severe bone loss (Table 1).

A new bone formation and union at the docking site were achieved in all patients. The mean new bone formation was 5.8 cm (range 3.5-14) in tibia and 4.3 cm (range 3.5-5) in femur. The mean transportation time was 78.6 days (range 44-160) in tibia and 53 days (range 40-66) in femur. The mean healing time was 257 days (range 150-486) in tibia and 405 days (range 300-510) in femur. The mean healing index was 46.3 days/cm (range 42-60) in tibia and

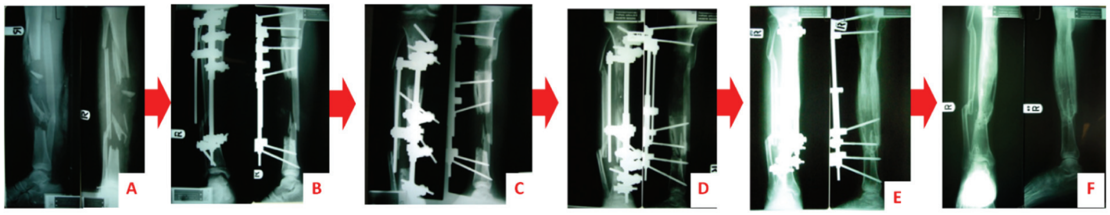

Fig. 3 The radiographic of a patient with open tibial fracture type IIIA with bone loss 14 cm
A: before surgery, B: Radical debridement and applied new design dynamic external fixator with lengthening device, C & D: during transportation process, E: radiograph showing bony union, F: external fixator was removed

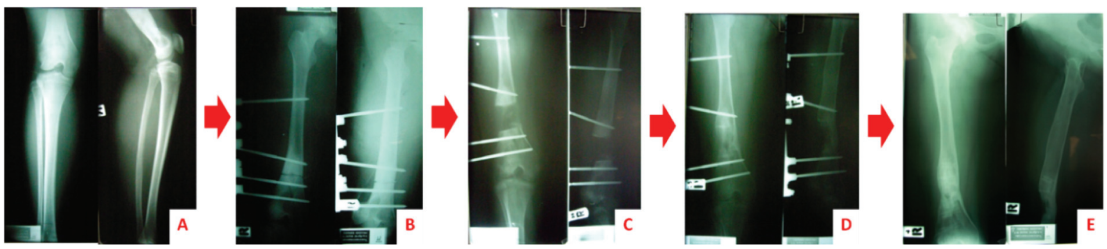

Fig. 4 The radiographic of a patient with 5 cm. femoral shortening from old epiphyseal plate injury
A: before surgery, B: corticotomy and applied new design dynamic external fixator with lengthening device, C & D: during lengthening process, E: radiograph showing bony union and external fixator was removed

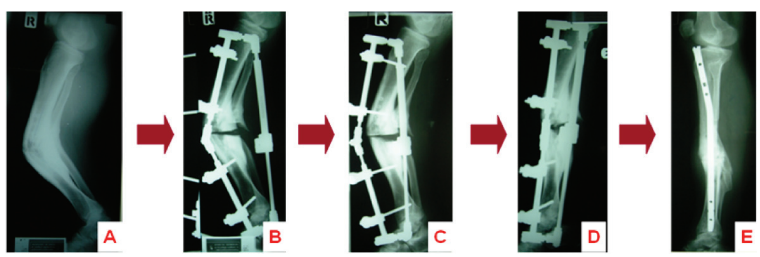

Fig. 5 The radiographic of a patient with 3 years tibial malunion 45 degrees
A: before surgery, B: corticotomy and correct rotational malalignment then applied new design dynamic external fixator with gradual telescopic rod, C & D: during correction until good alignment was achieved, E: created bony union by tibial nail

93.9 days/cm (range 85.7-102) in femur. Iliac bone grafting was performed in seven cases of tibia and one case of femur at the docking site to enhance bone union. After removal of external fixator, patella bearing cast was applied for 4 to 6 weeks to prevent stress fracture in eight cases of tibial transportation. Pintract infection was found in two cases of tibia and one case of femur but good response to local pin care and oral antibiotics (Table 1).

2. Bone lengthening group: Three patients with tibial shortening from old fracture and one patient with femoral shortening from old epiphyseal plate injury were included. Patients ranged in age from 13 to 42 years.

A new bone formation and union were achieved in all patients. The mean amount of elongation was 3.5 cm (range 3-4) in tibia and 5 cm in femur. The mean lengthening time was 55.3 days (range 50-60) in tibia and 120 days in femur. The mean healing time was 251 days (range 210-304) in tibia and 365 days in femur. The mean healing index was 71.1 days/cm (range 68.6-76) in tibia and 73 days/cm in femur. There was one pintract infection in tibia but good response to local pin care and oral antibiotics (Table 2). Good aesthetic and functional results were obtained. Patients had no leg discrepancy compared to their normal limb.

3. Malunion correction group: Three patients with tibial malunion (45, 60, and 75 degrees) for average

Table 1. Results of bone transportation by new design multifunction dynamic external fixator system

	No.	New bone formation (cm)	Transportation time (days)	Healing time (days)	Healing index (days/cm)	Iliac bone grafting (case)	Pintract infection (case)
Tibia	11	5.8 (3-14)	78.6 (44-160)	257 (150-486)	46.3 (34.7-60)	7	2
Femur	2	4.3 (3.5-5)	53 (40-66)	405 (300-510)	93.9 (85.7-102)	1	1

Data were presented as mean and range

Table 2. Results of bone lengthening by new design multifunction dynamic external fixator system

	No.	Amount of elongation (cm)	Lengthening time (days)	Healing time (days)	Healing index (days/cm)	Iliac bone grafting (case)	Pintract infection (case)
Tibia	3	3.5 (3-4)	55.3 (50-60)	251 (210-304)	71.1 (68.6-76)	-	1
Femur	1	5	120	365	73	-	-

Data were presented as mean and range

Table 3. Results of tibial malunion correction by new design multifunction dynamic external fixator system

	No.	Malunion time (yr)	Degree of malunion	Correction time (days)	Healing time (days)	Pintract infection (case)
Tibia	3	6 (3-10)	60 (45-75)	65 (35-84)	187.3 (154-212)	1

Data was mean and range

six years (range 3-10) were included. The mean correction time was 65 days (range 35-84). The mean healing time was 187.3 days (range 154-212). There was one pintract infection but good response to local pin care and oral antibiotics (Table 3).

Discussion

Intercalary bone defects have been treated by various procedures, including cancellous bone grafting[4,5], vascularizied fibular grafting[6-9] and internal bone transport with an external fixator[10-13]. Problems associated with autogenous bone grafting including resorbtion of the graft, delayed consolidation and nonunion. An alternative treatment, single vascularized fibular grafting, has been successful for treatment of large bone defects in upper limb. However, this procedure has disadvantages of stress fractures and pseudoarthroses when used in lower limb.

The internal bone transport using the Ilizalov's method has several advantages compared with other techniques. Good bone consolidation is usually obtained without the need of bone grafting or internal fixation method. Early weight bearing is possible and recurrence of infection can be avoided because of increased blood flow to bone and soft tissue during distraction process[14]. Despite these advantages, Ilizalov's circular external fixation device also has certain drawbacks, such as its bulkiness, complicated mounting and difficulties in post-operative management. To minimize these drawbacks while still maintaining the advantages of Ilizalov's original concept, monolateral frames were used for bone transportation and bone lengthening. There were easier to mount and manage postoperatively.

Base on Ilizalov's concept, this new design multifunction dynamic external fixator system is a monolateral frame which can be used for bone transportation, bone lengthening and malunion correction with good results and low complication. In bone transportation group, the mean healing time was 257 days (range 150-486) in tibia and 405 days (range 300-510) in femur. The mean healing index was 46.3 days/cm (range 42-60) in tibia and 93.9 days/cm (range 85.7-102) in femur. These results were similar to the previous literatures[15-17], which used monolateral frames for bone transportation.

In cases of 14 cm bone transportation, the major concern was related to how the skin, muscles, and other soft tissues would tolerate the longitudinal migration of the pair of screws inserted in bone fragment to be transported. With progressive distraction, the screws were cutting the skin producing the longitudinal wound that healed proximally as the screws passed. There was neither skin tension at the zone of distraction nor redundant skin or folds at the compression site.

In bone lengthening group, the mean healing time was 251 days (range 210-304) in tibia and 365 days in femur. The mean healing index was 71.1 days/cm (range 68.6-76) in tibia and 73 days/cm in femur. These results were similar to the previous literature[18,19] that used monolateral frames for bone lengthening.

In malunion correction group, the mean correction time was 65 days (range 35-84). The mean healing time was 187.3 days (range 154-212). The important technique was the rotational malalignment must be corrected before applied external fixator because it is a monolateral that can correct malalignment in only one plane. It used the slow correction principle of the Ilizalov system but it simplified the process of fixation and easier to manage postoperatively. To authors' knowledge, there has been no study that used monolateral frame for correction of tibial diaphyseal malunion. The more popular devices are Ilizalov frame and Taylor Spatial Frame (TSF)[20] but more technical demands are required and complicated mounting.

The most common complication of the present study was pintract infection (25%) but all cases had good response to local pin care and oral antibiotics. No deep infection was found. There was no serious complication and no instrumentation failure in the present study.

The present study was subject to limitation, especially the small sample size (20 patients). Further work is required for a larger study.

Conclusion

Based on the advantages of Ilizalov's concept combined with the simplicity of monolateral frame, this new design multifunction dynamic external fixator system was successfully used for bone transportation, bone lengthening and malunion correction with good results and low complications. It is one of the treatment options for posttraumatic reconstructions.

Potential conflicts of interest

This research was financially supported by the Medical Education Center, Maharat Nakhon Ratchasima Hospital.

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การรักษาภาวะแทรกซ้อนจากกระดูกหักโดยใช้โครงยึดตรึงกระดูกนอกกายอเนกประสงค์แบบใหม่

ยิ่งยง สุขเสถียร, รัชวรรณ สุขเสถียร

ภูมิหลัง*: ภาวะกระดูกขาดหายไป ขาสั้นและกระดูกติดผิดรูปยังคงเป็นปัญหาสำคัญ คณะผู้นิพนธ์ได้ประดิษฐ์โครงยึดตรึงกระดูกนอกกายอเนกประสงค์แบบใหม่เพื่อใช้รักษาภาวะดังกล่าว*

วัตถุประสงค์*: เพื่อประเมินผลการใช้โครงยึดตรึงกระดูกนอกกายอเนกประสงค์แบบใหม่ในการรักษาภาวะกระดูกขาดหายไป ขาสั้น และกระดูกติดผิดรูป*

วัสดุและวิธีการ*: ศึกษาในผู้ป่วยย้ายกระดูกหน้าแข้ง 11 ราย ย้ายกระดูกต้นขา 2 ราย ยืดกระดูกหน้าแข้งสั้น 3 ราย ยืดกระดูกต้นขาสั้น 1 ราย และแก้มุมกระดูกหน้าแข้งติดผิดรูป 3 ราย*

ผลการศึกษา*: ในกลุ่มย้ายกระดูก พบว่ามีกระดูกงอกใหม่และติดทุกรายโดยกระดูกงอกใหม่เฉลี่ย 5.8 ซม. ในกระดูกหน้าแข้ง และ 4.3 ซม. ในกระดูกต้นขาโดยมีอัตราการงอกของกระดูกใหม่เฉลี่ย 46.3 วัน/ซม. ในกระดูกหน้าแข้ง และ 93.9 วันต่อซม. ในกระดูกต้นขา ในกลุ่มยืดกระดูก พบว่ามีกระดูกงอกใหม่และติดทุกราย โดยกระดูกถูกยืดออกโดยเฉลี่ย 3.5 ซม. ในกระดูกหน้าแข้ง และ 5 ซม. ในกระดูกต้นขาโดยมีอัตราการงอกของกระดูกใหม่เฉลี่ย 71.1 วันต่อซม. ในกระดูกหน้าแข้ง และ 73 วันต่อซม. ในกระดูกต้นขา ในกลุ่มแก้มุมกระดูกหน้าแข้งติดผิดรูป ระยะเวลาแก้มุมโดยเฉลี่ย 65 วัน และระยะกระดูกติดเฉลี่ย 187.3 วัน ไม่พบภาวะแทรกซ้อนที่รุนแรงใด ๆ*

สรุป*: โครงยึดตรึงกระดูกนอกกายอเนกประสงค์แบบใหม่ใช้ย้ายกระดูก ยืดกระดูก และแก้มุมกระดูกติดผิดรูปได้ผลการรักษาที่ดีและพบภาวะแทรกซ้อนน้อย*