A novel low-profile external skeletal fixator for type IIIB open tibial fractures: A biomechanical and clinical pilot study

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Abstract

Background: Although external fixator is standard for managing staged treatment of open tibial fracture, the main disadvantage of this device is too bulky to be tolerated by most patients for longtime use. The purposes of this pilot study were to compare the biomechanical properties of a novel low-profile external fixator (LP-ESF) with a traditional ESF and also to evaluate its performance in patients with Gustilo type IIIb tibial open fractures.

Methods: A prospective clinical pilot study started from January 2015 to December 2017, and 18 patients with Gustilo type IIIb open tibial fractures underwent the fixation with a novel LP-ESF system. The biomechanical properties of the LP-ESF were compared with the Synthes External Fixation System according to the standard ASTM F1541-02. These patients were divided into two groups according to the size of bony defect. The postoperative clinical outcomes were subsequently collected.

Results: The biomechanical properties of the LP-ESF were comparable with those of Synthes External Fixation System and had an improved the axial/torsional stiffness and ultimate strength. In the clinical study, all patients with LP-ESF had fracture union. The duration of application of LP-ESF was 3.5 to 18 months until fracture union. In 10 of 18 patients, their fractures were immobilized with the LP-ESF until bone union, and no pin tract infection and no chronic osteomyelitis were recorded. The 36-Item Short Form Health Survey life quality and health survey were good to excellent in these patients. Notably, the LP-ESF allowed a patient with severe bone and soft-tissue defects to preserve the leg and joints function.

Conclusion: In this study, we found that the novel LP-ESFs had improved clinical outcomes. The long-term LP-ESF application seems to be tolerable in our patients. This novel approach permits better controls in deep infection and faster healing of fractures, and thus may provide a viable alternative treatment for Gustilo type IIIb open tibial fractures.

Keywords: Bone union; Gustilo open type IIIb; Low-profile external skeletal fixator; Tibial fractures.

1. INTRODUCTION

Open fractures of the tibia are the most common open long bone fractures.[1] The severe injuries and damage seen in Gustilo type IIIb open tibial fractures may be a veritable challenge. These fractures comprise multifragmented fractures, the contamination of the fracture site, and the devitalization of the soft-tissue envelope,[2] which significantly increase the risks of nonunion and deep infection and may result in traumatic amputations.[3–5] The management of these fractures commonly includes initial debridement, antimicrobial cover, adequate fixation, and early coverage of soft-tissue defect.[6]

In managing the type IIIb open tibial fractures, the external skeletal fixators (ESF) is routinely accepted with the successful outcome in achieving temporary fixation, allowing soft-tissue treatment and convenient removal.[7,8] However, a spanning ESF must be placed across the knee or ankle joint when proximal or distal metaphyseal fractures are present, which may lead to joint stiffness.[9,10] Due to the bulky traditional ESF constructs, they often interfere with patients' daily activities or cause the loss of reduction at the fracture site.[11,12] In addition, complications, such as pin track infection or loosening, and loss reduction, are frequently seen in ESFs.[13] To avoid these complications, the early change to internal fixation (plate or nail) is following the removal of ESF.[13] However, the secondary infection remains a problem when converting an ESF to internal fixation.[14,15]

Some orthopedic surgeons use a locking plate as an external fixator to immobilize open tibial fractures, with good to excellent results reported in recent years.[12,16,17] Most locking plates are considered as an off-label use without supports from the standard biomechanical analyses,[18] so locking plates could not be considered as a standard procedure.[11] We designed a new low-profile ESF (LP-ESF) for patients with type IIIb open fractures of the tibia may offer a low-profile alternative posing less obstructive and inconvenient for definitive fixation and limit the
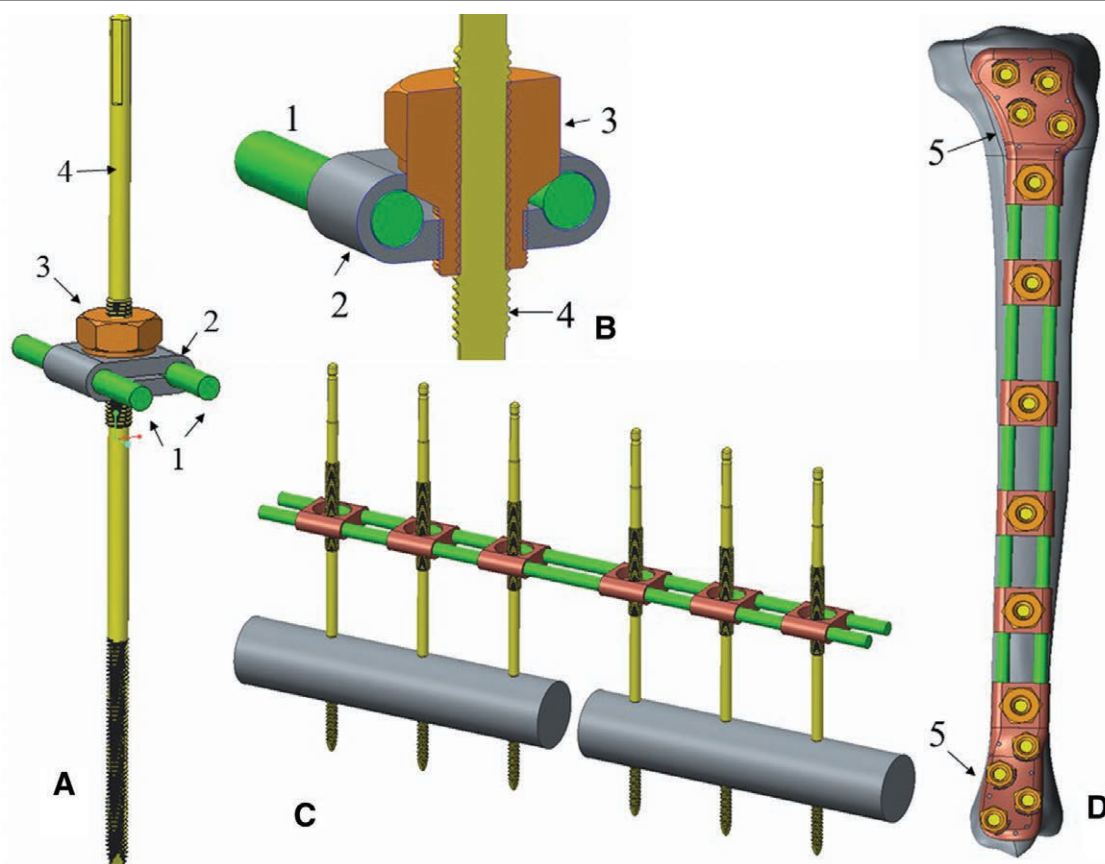
Fig. 1 The computational design of the low-profile external fixator (LP-ESF) system. A, The elements include (1) two rods (250 mm, φ6 mm), (2) the square connector, (3) the cross-cutting cannulated nut, and (4) double-threaded half pins (180 mm, φ5 mm). The square connector links two rods and double-threaded half pins; these are locked by the cross-cutting cannulated nut, which has internal and external threads. B, A left-right parallel of two rods. C, The tips of the double-threaded half pins are designed to insert into the bone with the other threads linked by the two rods. D, Two proximal (element 5) and four double-threaded half pins distal locked in the anatomic external blocks.

risk of secondary infections. The objectives of this study are to introduce a novel LP-ESF, to assess its biomechanical properties, and to evaluate its clinical outcome and the satisfaction of patients with type IIIb open tibial fractures.

2. METHODS

We designed the novel LP-ESF system (Aplus Biotechnology Company, New Taipei city, Taiwan) in this study. The main frame was made by aluminum alloy 6061 and the fixator pins was by ASTM F138 steel. The LP-ESF includes two rods (250 mm, φ6 mm), a square connector, a cross-cutting cannulated nut, and double-threaded half pins (180 mm, φ5 mm) (Fig. 1A). Because the two rods of the LP-ESF are in a left-right parallel manner (Fig. 1B) instead of an up-and-down, the LP-ESF is able to lie closely to the skin. The tips of the double-threaded half pins are inserted into the bone with the other threads linked by the two rods (Fig. 1C). Four double-threaded half pins were locked in the proximal or/and distal anatomic external blocks and allow the fixation of the metaphyseal fractures, but enable the active joint motion without joint stiffness (Fig. 1D).

2.1. Biomechanical properties evaluation

To evaluate the strength of the LP-ESF system for the clinical use, the biomechanical properties of this system and a commercialized external fixator, the Synthes ESF System, were compared. Both fixators were exanimated in the bone analog models with

a simulated fracture gap using a static axial load test, a multi-cycle axial load test, and a static torsional test, according to the American Society for Testing and Materials (ASTM) Standard 2.1.1. Specification and Test Methods for External Skeletal Fixation Devices F1541-02.

2.1.1. ASTM standard test setup

All test specimens were fixed at bone analogs simulating the tibia with 4 pins, 2 pins at both proximal and the distal bone analogs (Fig. 2A). The bone analog was a solid cylinder (30 mm in diameter and 130 mm in length) made by Nylacast polyacetal (POMO-C, Nylacast, Leicester, UK). The fixator-bone construct was clamped into the testing system (HT-2402 Computer Servo Control Testing Machine, Taiwan) The fixator-bone construct parameters were designated according to *ASTM F1541-02 standard* for lower limb fractures: 50-mm frame offset (F_0), 20-mm gap size (G), 90-mm pin span (PS), 20-mm pin offset (P_0), and tightening torque 10 Newton meters (Nm) (Fig. 2A).

2.1.2. Axial load tests

The alignment of the fixator-bone construct was collinear with the loading axis of the machine before testing. For the static load tests, the load was applied under force control until contact between the proximal and distal bone analogs occurred (Fig. 2B). Construct stiffness and yielding strength were calculated from the load-displacement data. For dynamic tests, cyclic loads were applied under force control with a sinusoidal
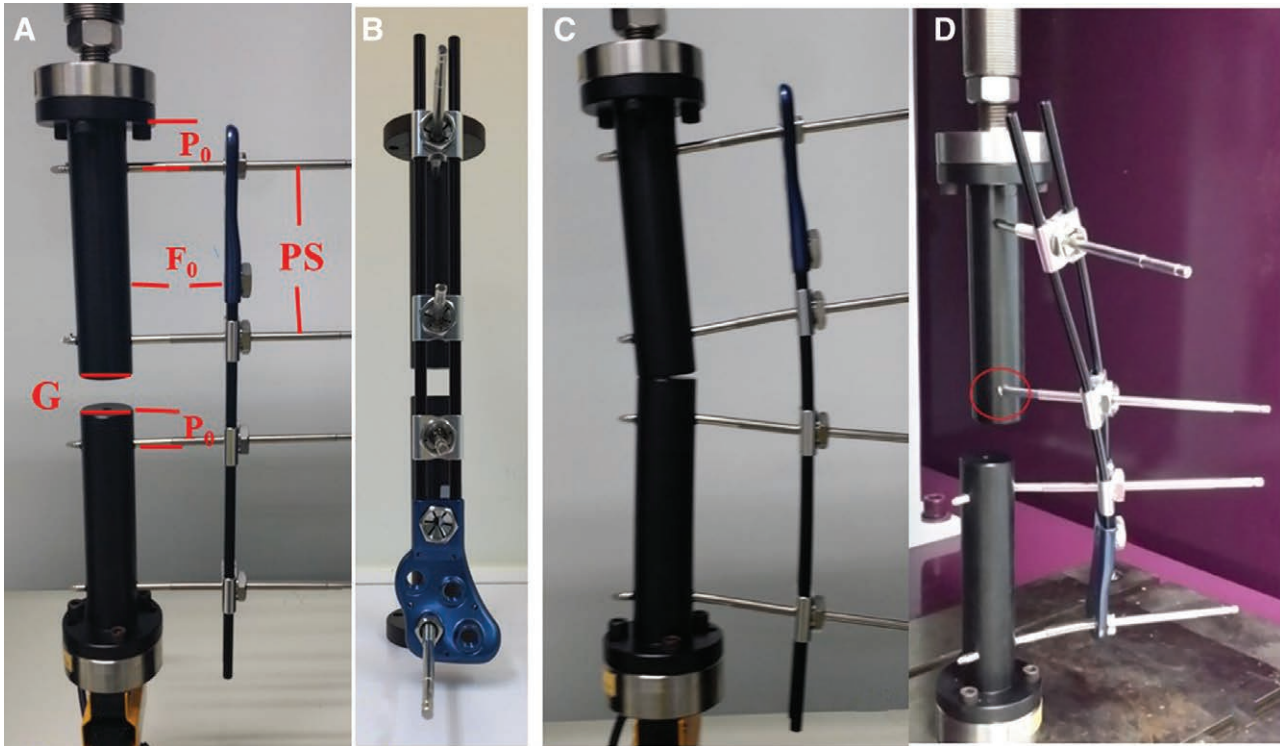
Fig. 2 The biomechanical test and design. A, The fixator-bone construct setup, the anteroposterior view; (B) the lateral view. F_0 (fixed outlet) = 50 mm; G (gap) = 20 mm; PS (pin span) = 90 mm; P_0 (pin offset) = 20 mm. C, A specimen for the static axial loading test or multicycle axial loading test. D, A specimen for the fixator failure at the static torsional test.

loading between −200 N and 200 N at 1 Hz (Fig. 2C). Tests were run for at least 50,000 cycles to ensure the qualification of the specimens.

2.1.3. Static torsional tests

During the torsion test, the specimens were loaded at a rate of 0.15° per minute (Fig. 2D). The test was stopped when any part of the fixator failed, or the plastic behavior appeared. The torsional stiffness was calculated from the slope of the linear portion of the torque-angle curve.

2.2. Clinical application

From January 2015 to December 2017, 18 patients (10 M/8 F), who had type IIIb open tibial fractures with poor soft-tissue coverage or severe wound contamination and underwent surgery with LF-ESF, were included in this prospective study. This study was approved by the Institutional Review Board of Kaohsiung Veterans General Hospital, and informed consents were obtained from all patients.

The fracture sites of all patients were initially immobilized with a traditional ESF. They had received wound debridement and antibiotic treatment for 2 to 3 weeks. Patients who are not suitable for free flap or local flap to cover the soft-tissue defect because of multiple comorbidity were enrolled in our study. The other patients who had repeated infection and debridement would have a great risk during the implantation of plate are also enrolled in our study. All these patients need long duration of application of ESF for stabilizing bone and also have segmental bone defect after series treatment. They were divided into two groups.

Group 1 consisted of six patients (Fig. 3) with bone defects (<2 cm) and more than 1/2 of the cortical bone contact. After the use of the vacuum-assisted closure (VAC) system for 2 to 3 weeks (Fig. 3C), the granulation tissue formation indicating

the poor condition of the wounds was found in these patients. LP-ESF was chosen for this group of patients because of poor envelope of tibial soft-tissue condition; LP-ESF was then used to replace the traditional ESF (Fig. 4A, B) after adequate reduction and minimal fixation and cancellous bone graft over the fracture site (Fig. 4C).

Group 2 consisted of 12 patients with large bone defects (2-5 cm) (Fig. 5A), a poor soft-tissue envelope, and less than 1/2 of the cortical bone contact. The LP-ESF was applied after the soft-tissue reconstruction, and we used ipsilateral nonvascularized free fibular as a bone graft (Fig. 5C, E). The intramedullary fibular bone graft could provide more rigid fixation and help rapid bone union because of large bony defect.[19]

After discharge from the hospital, routine follow-up was scheduled at the first and sixth week after surgery, then the third, fourth, sixth, ninth, and twelfth month, and follow-up time was up to 24 months postoperatively, including clinical and radiographic examinations. During the visit, the wound healing and the function of the knee and ankle joint were recorded.

3. RESULTS

In the LP-ESF, the axial stiffness was 75.05 ± 6.95 Nm, the yield strength was 262.51 ± 29.87 N, and the ultimate strength was 888.53 ± 95.02 N. In the Synthes ESF, the axial stiffness was 55.18 ± 3.98 Nm, the yield strength as 266.01 ± 18.69 N, and the ultimate strength was 806.19 ± 91.23 N. Data from the multicyclic axial load test showed that both fixators withstand 50 000 cycles without damage or loss of stiffness. In the static torsional test, the irrecoverable deformation and breakage of one fixation pin were found in the LP-ESF, while the breakage of two fixation pins was discovered in the Synthes ESF. The torsional stiffness was 0.41 ± 0.02 Nm/degree, the torsional
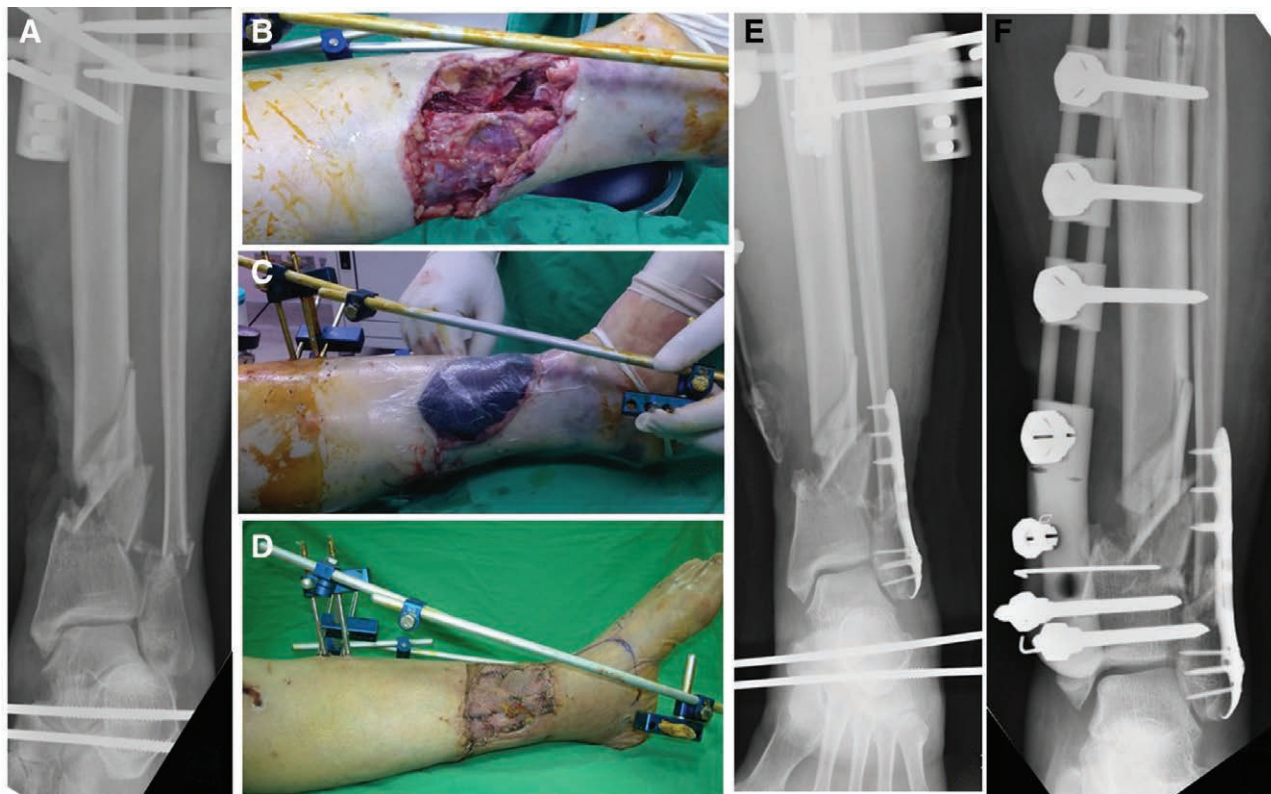
Fig. 3 A 71-year-old woman with a Gustilo type IIIb open tibial fracture (A) anteroposterior (AP) view of x-ray of lower leg (B) bone exposure and a large soft tissue defect was shown in the trauma area. C, After applying a period of vacuum-assisted closure system, good granulation tissue formation was present. D, The skin graft was performed and simultaneous open reduction and internal fixation with locking plate fixation over lateral malleolar fracture was done. E, Postoperative AP view of x-ray. F, As the soft tissue was feasible, low-profile external fixator was then applied after the autologous cancellous bone graft implantation and the skin grafting.
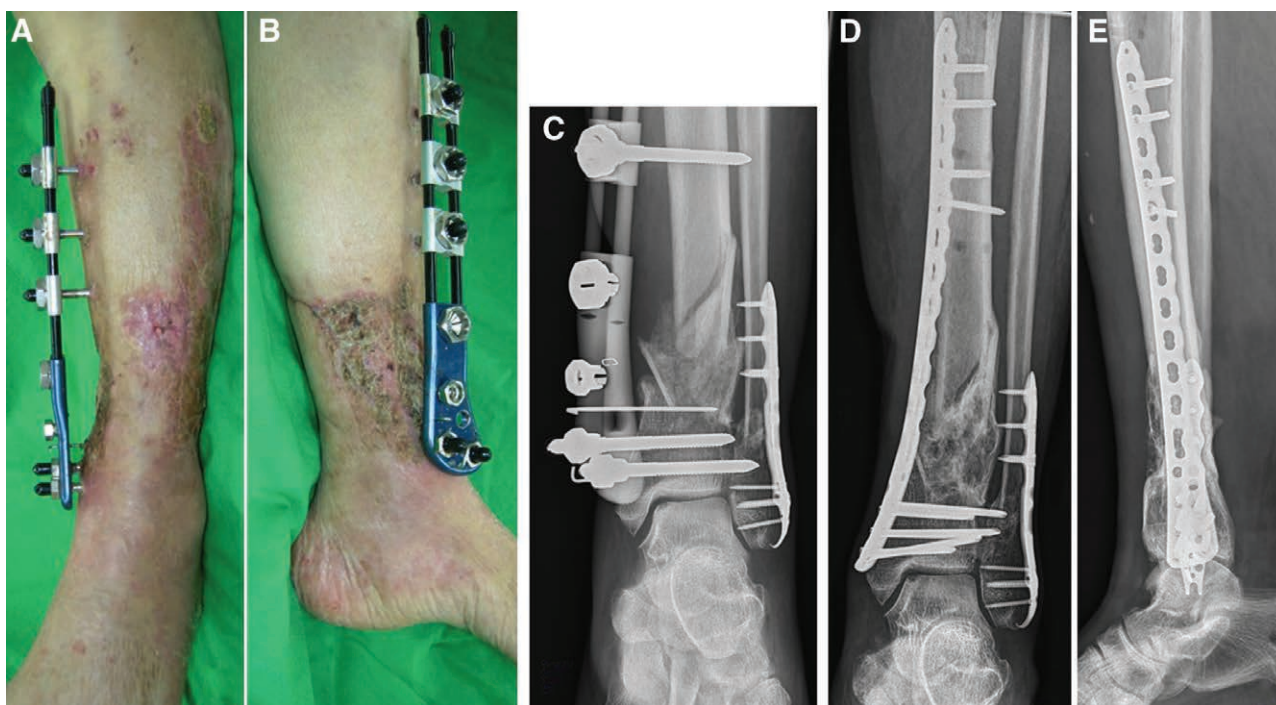
Fig. 4 The images of the same patient as Fig. 3. A and B, The postoperative photo of the low-profile external fixator (LP-ESF) with a distal anatomic external block fixation on the patient's lower leg and (C) the callus formation was found over fracture site for postoperative 3.5 mo. D and E, The LP-ESF was removed and open reduction and internal fixation with locking plate fixation via minimally invasive plate osteosynthesis technique after soft tissue condition stable.

Fig. 5 A 21-year-old man sustained a Gustilo type IIIb open tibial fracture (A) bone exposure and a large soft-tissue defect was shown. B, Due to the application of the vacuum-assisted closure system, the bone is viable and good granulation tissue was present. C, The ipsilateral non- vascularized free fibula grafting was transferred into the large bone defect of the proximal tibia, and (D) the bone was covered with the media gastrocnemius muscle flap. E, The low-profile external fixator was then applied after the closure of wounds and (F) the skin grafting was completed.

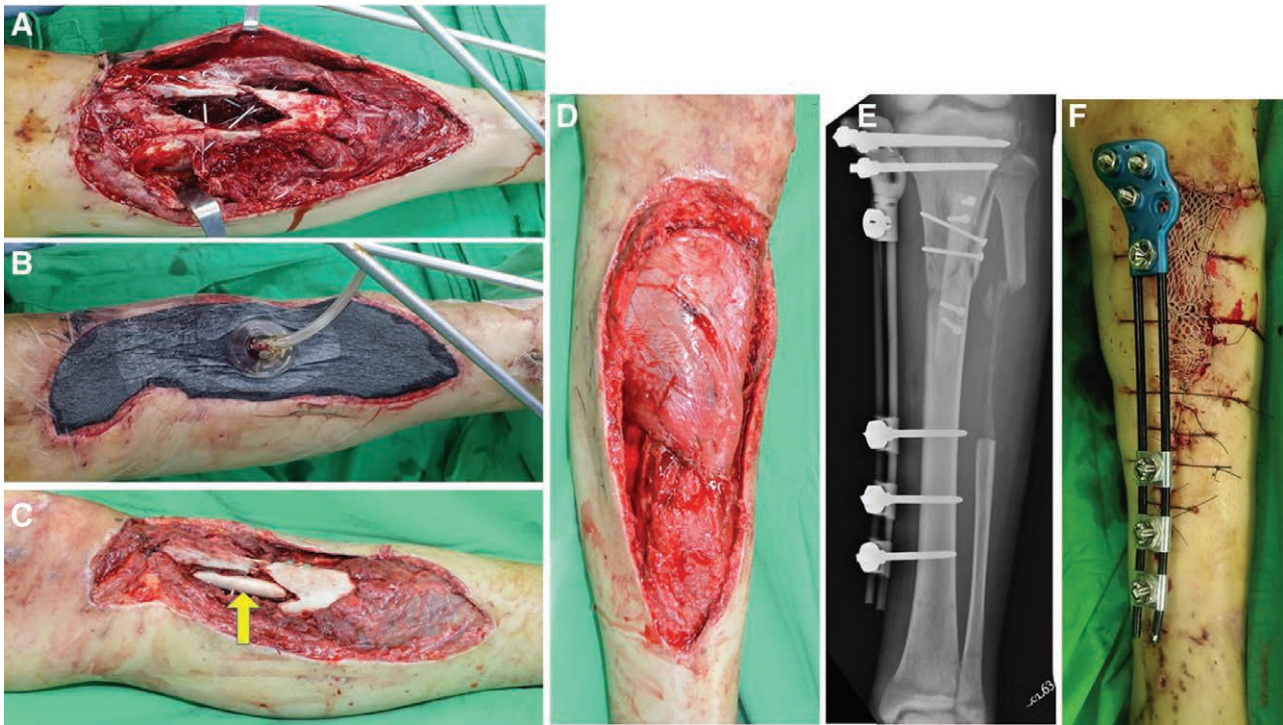yield strength was 14.69 ± 2.62 Nm, and the ultimate torsional strength was 43.8 ± 3.39 Nm in the LP-ESF. The torsional stiffness was 0.21 ± 0.03 Nm/degree, the torsional yield strength was 15.05 ± 3.78 Nm, and the ultimate torsional strength was 33.25 ± 2.13 Nm for the Synthes ESF. Overall, LP-ESF is comparable with Synthes ESF.

Demographic data, wound management, and outcomes are presented in the Table. In this series of 18 patients, their mean age was 49.9 years (range, 21-82 years) and patients were divided into two groups according to the involvement of bone defects. For patients in group 1 (patient nos 1-6), the LP-ESF were performed to replace the traditional ESF after treating with VAC for 2 to 3 weeks (Fig. 3C). Split-thickness skin graft (STSG) and cancellous bone graft were placed over the fracture sites. After about 3 to 4 months with the infection under control, the recovered soft tissue and callus formation were observed in these patients. Four of six patients chose to remove LP-ESF after 3.5 to 5 months due to loss of reduction, instability, or intolerance. The LP-ESF was replaced with a medial tibial plate using a minimally invasive plate osteosynthesis (MIPO) technique (Fig. 4D, E). The soft-tissue condition was relatively stable in the four patients after the replacement. The other two patients had LP-ESF until their fractures were healed. The two patients were full weight-bearing (with LP-ESF) without a walker after approximately 6 months.

For patients in group 2 (patient nos 7-18), the LP-ESF was applied after the soft tissue had reconstructed (Fig. 3B). All patients had received multiple surgeries, which had led to scarring, poor blood supply of the surrounding soft tissue, and excessive sequestra over the fracture site. After appropriate sequestrectomy and trimming of the scar tissue, local antibiotic-impregnated cement spacers were put into defect and the traditional ESF was applied (Fig. 5A). The bone defect was filled contralateral with vascularized free fibula grafting

(VFFG) or ipsilateral non-VFFG (Fig. 5C), which was inserted into the intramedullary canal to increase rigidity of the fracture sites[19] and the surrounding muscle was placed in direct contact with the graft (Fig. 5D). When healthy granulation tissue was proliferated, LP-ESF was used to replace the traditional ESF to provide more rigid immobilization and allow the surrounding muscle to provide an abundant blood supply to the free fibular graft. Among these patients, two (nos 7 and 8) had received non-VFFG, gastrocnemius rotational muscle flap, and STSG over the proximal tibia with LP-ESF (Figs. 5 and 6). Two (nos 9 and 10) had received contralateral VFFG because of severe crushing injury over tibial shaft without soft-tissue coverage. Eight (nos 11-18) had a very poor soft-tissue condition with a high-risk wound problem if plate fixation, so they had continued to use the VAC system and received non-VFFG with the LP-ESF fixation. One (no. 9) patient had a severely wound contamination with *Vibrio vulnificus* and >6 cm segmental bone loss. Because of the segmental bone loss and the extensive soft-tissue defect (Fig. 7B), we had to perform VFFG with muscle flap from the contralateral lower leg and STSG and combined LP-ESF for 18 months (Fig. 7E). The fracture and wound had healed after 4 months (Fig. 7C and D). Four of 12 patients had replaced LP-ESF fixation to plate fixation after 3 to 5 months due to intolerance. However, due to the concerns about repeated infections and surgeries, the others carried the LP-ESF for more than 1 year until bone union.

Overall, the LP-ESF was applied and carried for an average of 9.42 months (range, 3.5-18 months). There is no recurrence of infection in all cases with reducing the necessity of debridement because of limited implants in the fracture site. In 10 of the 18 patients, their fractures were immobilized with the LP-ESF until bone union, and no pin tract infection, life inconvenience, or discomfort were reported from these patients.

Demographic features, management, and outcomes of patients with type IIIB open tibial fractures.

No	Age	Sex	Management of trauma zone	Location	Time of LP-ESF, mo	Bone union	Change to plate
Group 1							
1	64	M	VAC + STSG + cancellous B.G.	Proximal tibia	14	Y	N
2	82	F	VAC + STSG + cancellous B.G.	Distal tibia	12	Y	N
3	59	F	VAC + STSG + cancellous B.G.	Distal tibia	5	Y	Y (loss reduction)
4	61	M	VAC + STSG + cancellous B.G.	Proximal tibia	4	Y	Y (instability)
5	71	F	VAC + STSG + cancellous B.G.	Distal tibia	3.5	Y	Y (patient cannot t tolerate)
6	46	F	VAC + STSG + cancellous B.G.	Distal tibia	4	Y	Y (patient cannot t tolerate)
Group 2							
7	21	M	Non-VFFG + gastrocnemius muscle flap + STSG	Proximal tibia	12	Y	N
8	62	M	Non-VFFG + gastrocnemius muscle flap + STSG	Proximal tibia	4	Y	Y (patient cannot tolerate)
9	61	F	VFFG with muscle flap + STSG	Tibial shaft	18	Y	N
10	56	M	VFFG with muscle flap + STSG	Tibial shaft	5	Y	Y (patient cannot tolerate)
11	36	M	VAC + STSG + non-VFFG	Tibial shaft	12	Y	N
12	52	M	VAC + STSG + non-VFFG	Distal tibia	18	Y	N
13	38	M	VAC + STSG + non-VFFG	Distal tibia	13	Y	N
14	36	M	VAC + STSG + non-VFFG	Tibial shaft	4.5	Y	Y (patient cannot tolerate)
15	21	F	VAC + secondary suture + Non-VFFG	Distal tibia	13	Y	N
16	58	M	VAC + STSG + non-VFFG	Tibial shaft	3.5	Y	Y (patient cannot tolerate)
17	27	M	Non-VFFG + free flap	Distal tibia	12	Y	N
18	48	F	VAC + secondary suture + non-VFFG	Distal tibia	12	Y	N

B.G. = bone graft; STSG = split-thickness skin graft; VAC = vacuum-assisted closure, VFFG = vascularized free fibular graft.

4. DISCUSSION

Type IIIb open tibia fractures often have extensive soft-tissue damage and bony comminution, and wound contaminated. We often spent much time in waiting soft-tissue reconstruction and infection control using ESF. Most patients would like to early change to internal fixation because the traditional ESFs are too bulky and inconvenient in daily activity. We often found the pin tract infection or loosening of ESF and joint stiffness due to longtime ESF fixation, or secondary deep infection, infective non-union and osteomyelitis because of early change to internal fixation without infection control.[20] We designed a novel LP-ESF for patients with type IIIb open fractures of the tibia to offer an alternative treatment permanent low-profile ESF rigid fixation without inconvenient until bone union. Data from our biomechanical analyses indicated that the LP-ESF is comparable to the traditional ESF in static and dynamic axial load tests (fatigue test) and a static torsional test. In this prospective clinical pilot study, patients in both groups had managed to tolerate the LP-ESF for an average of 9.42 months without any reported dissatisfaction. Even though the severity of the injury in group 2 was very high, they were successfully managed by the LP-ESF system.

In the LP-ESF, the rods are designed to run parallelly from left to right rather than up and down in the traditional ESF to fit more closely into the body and provide more rigid fixation for the fracture site. The traditional ESF always immobilized across
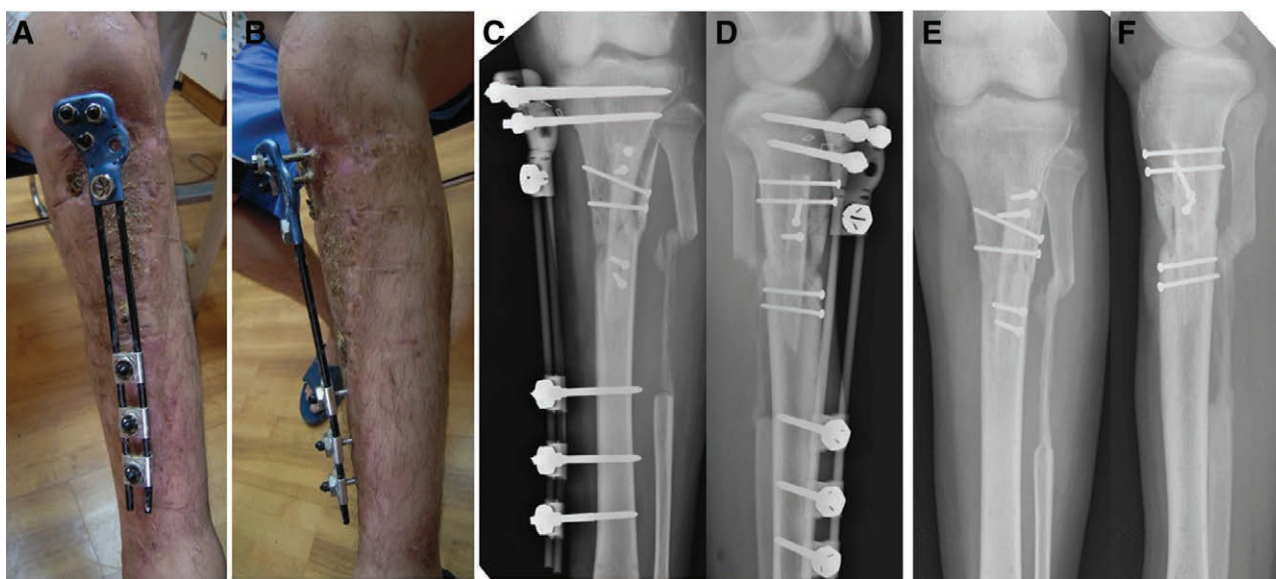

Fig. 6 Follow-up photos of patient of Fig. 5. A and B, The postoperative photo of the low-profile external fixator (LP-ESF) with a proximal anatomic external block fixation on the patient's lower leg and (C and D) the partial union was found over fracture site for postoperative 2.5 mo. Patient started partial weight-bearing ambulation at this status and complete weight-bearing was allowed at 4 mo. E and F, The LP-ESF was removed after complete bone union for 1 y.
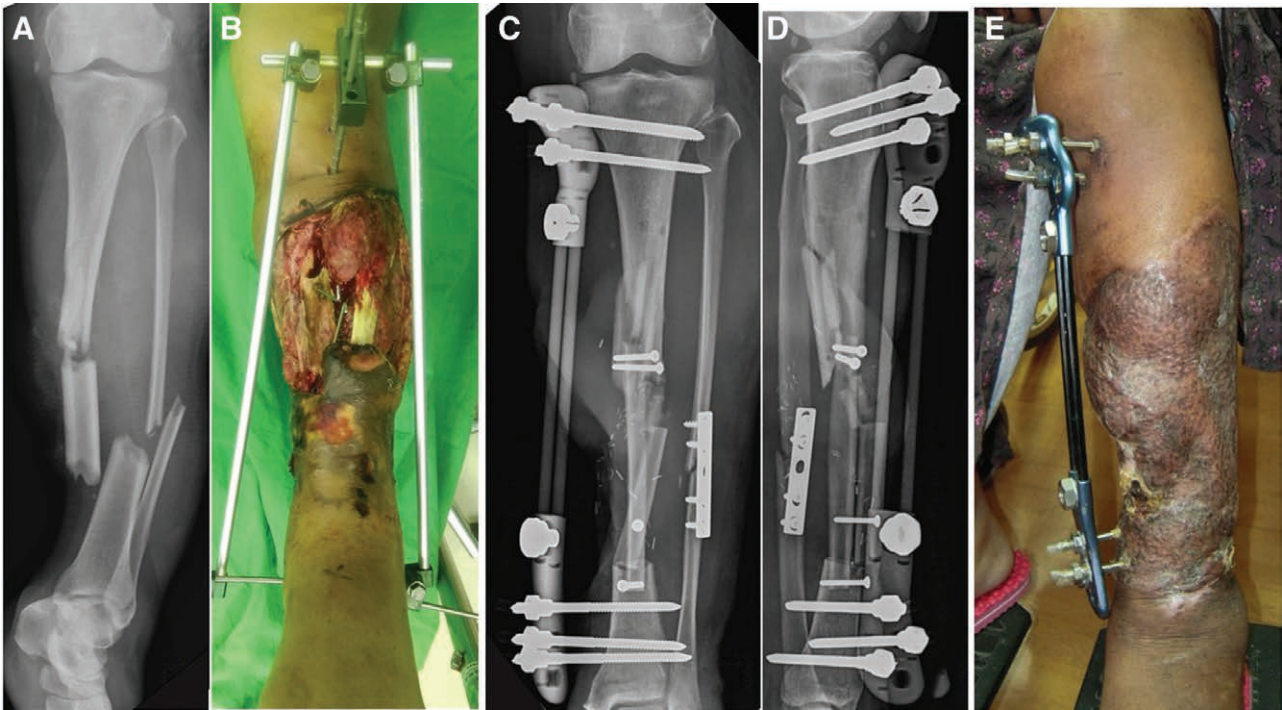
Fig. 7 A 61-year-old woman had a severe contaminated wound due to *Vibrio vulnificus* infection and segmental sequestrum in tibia. A, The x-ray image represented the fracture. B, The photo was before operation and (C and D) the x-ray image was the contralateral vascularized free fibula grafting to fill the bony defect and two proximal and distal external anatomical blocks were used simultaneously. E, The photo showed that the fourth month postoperative photo of the low-profile external fixator (LP-ESF) fixation on the patient's leg. Patient was partial weight-bearing ambulation at the fifth month and complete weight-bearing at the seventh month. Finally, the LP-ESF was removed after complete bone union for 18 mo.

joint when the fracture site is near joint. It often lead to joint stiffness if longtime immobilization. To avoid joint stiffness, the anatomic external blocks were designed in the LP-ESF device (Figs. 4A, B, 6A, B, and 7E). The knee or ankle joints could be early active motion with LP-ESF, even if proximal or distal tibial extra-articular fracture. It has been indicated that when the fixators lie closely to the skin, they are more rigid and tend to reduce loss of reduction and the pin tract infection, and to facilitate earlier bone union. In the permanent LP-ESF fixation, there is no implant at the fracture site, which may reduce the administration of antibiotics. Whenever the plates or nails are implanted, we often worry about repeat infection and longtime antibiotics use. In addition, the faster fracture healing was noted because soft-tissue direct contacts to the fracture site without the obstruction from the implant. Additionally, muscle flaps with LP-ESF are more effective in bone blood supply to decrease the risk of infection and promote fracture healing.

Rigid fixation and efficient blood supply are main important factors for fracture healing, but usually difficult to achieve, especially in open type IIIb tibial fractures.[21] We found that the rigidity of bone defect <2 cm is enough to perform a cancellous bone graft and LP-ESF. However, patients with the bone defect >2 cm or less than 1/2 cortical bone contact, intramedullary fixation was advised by previous studies.[22] In our patients, the insertion of the non-VFFG into the intramedullary canal and fixation with two inter-fragmental screws with LP-ESF provides rigid fixation[19] (Fig. 6), which is comparable to internal plate fixation. In addition, it is possible to place cancellous bone grafts over the two ends of non-VFFG contact tibial canal site to improve fracture healing. The dilapidated soft tissue still provided efficient blood supply to the fracture site and bone graft without implants obstruction.

In our pilot study, eight patients had the LP-ESF replaced to locking plate via MIPO technique under partial union and complete infection control after 3 to 5 months. MIPO technique enables preserve previous soft-tissue coverage and provides the blood supply for fracture union.[23] Ten patients carried LP-ESF for 12 to 18 months until bone union because there was no space to place the plate on the bone and worry about repeat infection in these patients and they had acceptable discomfort in daily life. Finally, their LP-ESF was removed at our clinics without anesthesia. Our stage management with LP-ESF permitted these patients to preserve the renew soft-tissue, fracture union and infection control, and these patients may be required below-knee amputation in the past because of multiple complications.

The VAC is a negative pressure wound therapy system, which plays an important role in our initial approach. It provides lots of benefits, such as promoting local blood supply and reducing local edema, bacterial load,[24] and early development of granulation tissue by angiogenic stimulation.[25] We found skin graft was performed on the granulation tissue and lead to there is no subcutaneous tissue between skin and bone. In the past, these patients need free flap to cover the soft-tissue defect because it is difficult to replace implant on the bone. By using this strategy, we lower the reconstruction ladder thus reduce the necessity of using flap to cover the soft-tissue defect. However, sealing a negative pressure in the presence of a traditional ESF may be difficult, because Schanz screws preclude the vacuum. Fortunately, the VAC system is easy coverage without any air leakage in LP-ESF. In our series, it is seldom necessary a local or free flap in open type IIIb tibia fracture since combine VAC and LP-ESF, except one patient (no. 9) with severe soft-tissue loss (Fig. 7).

This study had some limitations, such as the small sample sizes and no control groups. Thus, studies with a larger sample size and comparisons with other techniques are needed. In conclusion, we have confirmed that LP-ESF can safely and effectively treat type IIIb open tibial fractures. However, it should

have a higher level of research evidence in more patients to confirm the clinical application of this technique.

ACKNOWLEDGMENTS

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