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Efficacy comparison of double-level and single-level bone transport with Orthofix fixator for treatment of tibia fracture with massive bone defects

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Abstract

Purpose The aim of this study was to evaluate the clinical and functional outcomes of patients with large post-traumatic tibial bone defects managed by double-level bone transport using the Ilizarov technique and compare it with one-level bone transport technique.

Methods A retrospective cohort study was conducted on 26 patients with open tibial fracture from January 2010 to January 2017. All cases were Gustilo III. Depending on the site of osteotomy, the patients were divided into single-level ($n = 13$) and double-level groups ($n = 13$). The bone transport time, consolidation time of the distraction gap, docking site healing time, external fixation time, external fixation index, soft tissue defect area, soft tissue growth index, operating time, and surgical bleeding volume were recorded and compared between the two groups. Bone and functional results were evaluated according to the Association for the Study and Application of the Method of Ilizarov (ASAMI) criteria.

Results The mean duration of follow-up was 28.5 ± 5.8 months (range 13–38 months) since the Orthofix fixator was removed, all patients achieved complete union in the docking site and consolidation in the regenerate bone; moreover, the wound was closed The mean bone defect length after debridement was 7.2 cm (range 5.8–9.0 cm) in single-level group vs. 10.7 cm (range 7.5–15.0 cm) in the double-level group ($P < 0.05$). The mean docking site healing time was 10.85 ± 1.52 months in the single-level group vs. 8.93 ± 2.29 months in the double-level group ($P < 0.05$); external frame time was 18.06 months (range 15–20 months) in single-level group vs. 12.71 months (range 9.5–16.0 months) in the double-level group ($P < 0.05$); external fixation index was 2.52 months/cm (range 2.15–2.94 months/cm) versus 1.22 months/cm (range 0.96–1.67 months/cm) in double-level group ($P < 0.01$); and soft tissue growth index was 0.29 months/cm^2 (range 0.21–0.45 months/cm^2) in the single-level group versus 0.62 months/cm^2 (range 0.47–0.86 months/cm^2) in the double-level group ($P < 0.01$). According to the ASAMI classification, the clinical and functional results in the double-level group were better than in the single-level group.

Conclusion The Ilizarov technique of double-level bone transport with Orthofix external fixator can be used successfully to repair and reconstruct the tibial bone loss and accompanying soft tissue defect.

Keywords Tibial fracture · Bone transport technique · Large bone defects · External fixator

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Introduction

The incidence of open fractures (especially of the tibia) caused by injuries such as traffic accidents, falling from height, and serious crush injuries has increased year by year. Open fractures cause large bone defects, seriously affecting quality of life. Ilizarov bone transport has become a gold standard for the treatment of massive tibial bone defects, eradicating infection and solving bone and soft tissue defects at the same time [1, 2]. However, with most surgeons using the single-level bone transport technique to heal bone defects > 6 cm, the treatment period is long. Additionally, the failure rate of extension area consolidating, pin-tract infection, and other complications is higher [3]. In order to shorten treatment time and reduce the corresponding complications, this study compared the efficacy of double-level bone transport technique and single-level bone transport technique in the case of large bone defect strains and assessed the effect of double-level bone transport technique with Orthofix external fixation on large bone defects of open fractures of the tibia.

Materials and methods

Patients' data

We retrospectively reviewed a consecutive series of 26 patients who were managed with the Ilizarov technique of bone transport in the tibia between January 2010 and January 2017 at our institution. The study population included 20 males and six females with a mean age of 40.4 years (range 22–56 years). The causes of injury included motor-vehicle accidents ($n = 17$), crush-related injury ($n = 3$), and fall from height ($n = 6$). All patients had open fractures classified as type III of the Gustilo and Anderson classification [4]. The patients were divided into two groups depending on the site of osteotomy. Half underwent osteotomy and unilateral bone lengthening with Orthofix external fixation, while the other half underwent osteotomy and bidirectional bone lengthening with Orthofix external fixation. Exclusion criteria were major diseases and critical organ damage, chronic osteomyelitis, and congenital deformity or pre-injury dysfunction. The study was approved by The Affiliated Hospital Of Southwest Medical University in Luzhou, China.

Treatments

Damage control and wound treatment

All patients underwent debridement and unilateral external fixation within two to 12 hours after injury to limit damage. Patient care included daily change of wound dressing, improved nutritional status, assessment of the incision site, and blood monitoring of WBC, CRP, ESR, and other inflammatory indicators. Combined antibiotic treatments were used for patients with signs of infection according to the bacterial drug sensitivity.

Surgical technique of bone transport

The patient was placed in the supine position on a radiolucent table under general anaesthesia. The wound was completely cleaned with removal of infected soft tissue, and the original external fixation. Necrotic bone was resected, the medullary cavity was opened, and debridement was performed until the wound edge and the bone end have fresh blood oozing out (Paprika sign [5]). The mean bone defect length after debridement was 8.94 ± 2.45 cm (range 5.8–15 cm) and the mean area of soft tissue defect after debridement was 6.94 cm × 4.29 cm (range 4.0 cm × 3.0 cm to 16.0 cm × 10.0 cm), both measured intra-operatively. On the medial tibia, two or three Schanz screws were implanted at the far and near ends, respectively, and implanted two Schanz screws in the transported sections of the bone. The Orthofix frame bracket (Orthofix Medical Inc., Shanghai CIIC Instrument Co., Ltd) was placed to adjust the tibia force line through the clamps. Percutaneous osteotomy of the tibia was made at the proximal tibia metaphysis and distal metaphysis (single-level group selects only one osteotomy) in order to obtain a good blood supply. Percutaneous corticotomy was done in a minimally invasive fashion utilizing the multiple drill holes and osteotome technique to keep endosteum intact. All cases were followed by bone transport and lengthening to restructure bone defect and restore limb length. The amount of wound surface for stitching was reduced as much as possible, and for incisions that could not be stitched or closed, synchronous or second-stage skin grafts are selected according to soft tissue.

Post-operative treatment

The bone transport technique can treat large-area soft tissue defects simultaneously. Bone transport started after a latent period of two weeks. The fragment at the proximal end was transported at a rate of 0.25 mm four times a day and the fragment at the distal was transported at a rate of 0.25 mm two times a day, the two fragments converging. Thus, the distraction rate at proximal site of osteotomy was 1 mm/day, the distraction rate at distal site of osteotomy was 0.5 mm/day, and the bone defect shortened 1.5 mm/day. X-ray films were reviewed monthly to monitor the progress of bone transport and quality of the regeneration during transport, observing the growth of osteotylus and healing of the docking site. The patients' pain symptoms were closely monitored during the bone extension period and the pin-tract was kept clean.

Patients were encouraged to exercise early without weight load, such as isometric contraction training of limb muscles, with active knee, ankles, and foot range of motion. When radiographs showed that complete cortices had formed in the regenerated bone and union in the docking site of the bone was achieved, the frame was removed and the patients began to walk with the help of a brace.

Statistical methods

The bone transport time, consolidation time of the distraction gap, docking site healing time, external fixation time, external fixation index, soft tissue defect area, soft tissue growth index, occurrence of complications, operating time, and surgical bleeding volume were recorded and compared between the two groups. Bone and functional results were evaluated according to the Association for the Study and Application of the Method of Ilizarov (ASAMI) criteria [3, 6, 7]. This study used the SPSS 20.0 software package to perform statistical analysis on the collected data.

T tests were used for metering data, and chi-square test was used for counting data. When $P < 0.05$, the difference was considered to be statistically significant.

Results

The mean duration of follow-up was 28.5 ± 5.8 months (range 13–38 months) since the Orthofix fixator was removed, all patients achieved complete union in the docking site and consolidation in the regenerate bone. Compared between the two groups of patients, the difference in soft tissue defect area, soft tissue healing time, bone transport time, consolidation time of the distraction gap, and surgical bleeding were not statistically significantly different (*P* 0.05). As shown in Table 1, there were several significant differences between the single-level and double-level groups in the mean bone defect length after debridement was greater in the double-level group (mean 7.2 vs 10.7 cm, $P < 0.05$), the mean docking site healing time was greater in the double-level group (mean 10.85 vs 8.93 months, $P < 0.05$); external frame time was higher in the single-level group (mean 18.06 vs 12.71 months, $P < 0.05$), external fixation index was higher in the single-level group (mean 2.52 months/cm vs. 1.22 months/cm; $P < 0.01$); and soft tissue growth index was lower in the single-level group (mean 0.29 months/cm^2 vs. 0.62 months/cm^2, $P < 0.01$). Obviously, the distraction rate was faster in the double-level group (mean 1.5 mm/day vs 1 mm/day).

Seven patients across the two groups had symptoms of pin-tract infection, including one in the double-level group and six in the single-level group. Where one patient in the single-level group (Dah1 classification [8] III) infection was controlled through debridement, the remaining six patients (Dah1 classification II) the infection was controlled by daily local care and oral empirical broad spectrum antibiotics. Six patients across the two groups showed failed healing of docking site, two in the double-level group and four in the single-level group; after docking point bone implantation surgery, the docking point finally healed. In 18 of the 26 patients, there was foot-radiating pain during the transport process, which was alleviated by slowing the transport rate and symptomatic treatment. According to the ASAMI classification, the bone results in double-level group were graded as excellent in 11 and poor in two patients. The functional results were graded as excellent in 12 and good in one patient. The two results were both better than in the single-level group. Double-level bidirectional bone transport significantly shortened the external frame retention time, thereby reducing the complications caused by the external fixing stent. The comparison of the main indicators of the two groups is listed in Table 1 and Fig. 1.The typical cases are illustrated in Fig. 2.

Discussion

Treatment of large bone defects in the tibia

The treatment of large bone defects of the tibia caused by various causes such as trauma, infection, and necrosis is a

Table 1 Comparison of the main indicators of the two groups

	Single-level group	Double-level group	*Z* or *t* value	*P* value
Age (years)	41.23 ± 8.66 (30–56)	39.62 ± 7.92 (22–54)	$t = 0.477$	$P = 0.6377$
Sex (male/female)	10M, 3F	10M, 3F	$z = 0.001$	$P > 0.05$
Bone defect (cm)	7.223 ± 0.889 (5.8–9)	10.65 ± 2.32 (7.5–15)	$t = 3.887$	$P < 0.0001$
Soft tissue defect (cm^2)	21.42 ± 8.621	42.54 ± 37.94	$t = 1.957$	$P = 0.0621$
Bone transport time (days)	79.85 ± 12.73 (60–100)	73.31 ± 15.60 (55–100)	$t = 1.171$	$P = 0.2530$
Consolidation time of the distraction gap (months)	12.94 ± 1.437 (10–15)	12.31 ± 2.386 (9–18)	$t = 0.8217$	$P = 0.4194$
Docking site healing time (months)	10.85 ± 1.519 (8.5–14)	8.931 ± 2.289 (6–15)	$t = 2.514$	$P = 0.019$
Time in frame (months)	18.06 ± 1.49 (15–20)	12.71 ± 1.921 (9.5–16)	$t = 7.937$	$P < 0.0001$
External fixation index (months/cm)	2.524 ± 0.262 (2.15–2.94)	1.223 ± 0.201 (0.96–1.67)	$t = 14.18$	$P < 0.0001$
Soft tissue growth index (days/cm^2)	0.29 ± 0.06 (0.21–0.45)	0.62 ± 0.14 (0.47–0.86)	$t = 7.698$	$P < 0.0001$
Operating time (minute)	139.2 ± 5.9 (130–150)	164.6 ± 13.5 (150–200)	$t = 6.241$	$P < 0.0001$
Surgical bleeding volume (ml)	246.90 ± 34.97 (200–300)	270.80 ± 39.89 (200–350)	$t = 1.621$	$P = 0.1181$
Pin-tract infection	Infected 6	Infected 1	$z = -2.168$	$P = 0.03$
ASAMI[1] bone results	Excellent 9 Poor 4	Excellent 11 Poor 2	$z = -0.913$	$P = 0.361$
ASAMI functional results	Excellent 10 Good 3	Excellent 12 Good 1	$z = -1.066$	$P = 0.286$

[1] *ASAMI*, Association for the Study and Application of the Method of Ilizarov

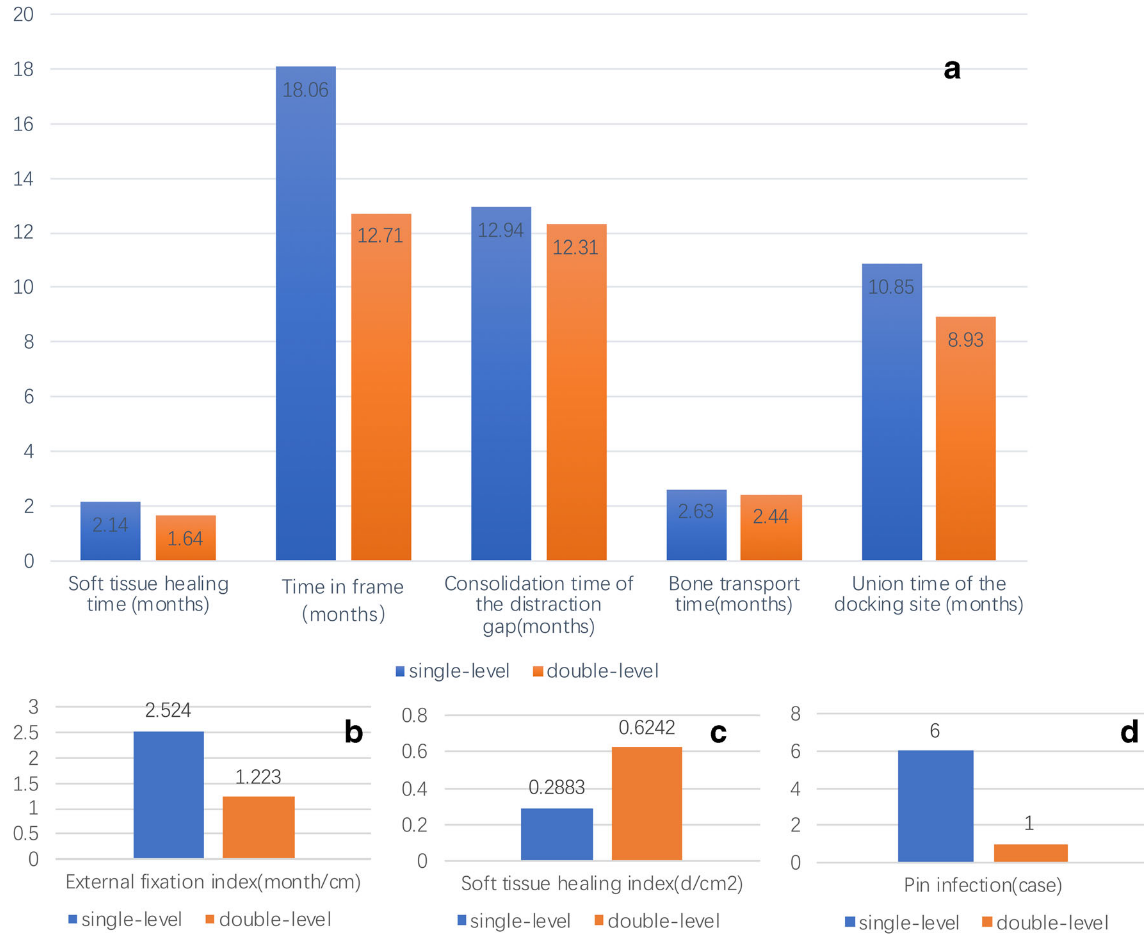

Fig. 1 Comparison of the main indicators of the two groups. **a** The soft tissue healing time, time in frame, consolidation time of the distraction gap, bone transport time, and the union time of the docking site were higher in the single-level group. **b** External fixation index was higher in the single-level group ($P < 0.01$). **c** Soft tissue healing index was higher in the double-level group ($P < 0.01$). **d** Infections between the two groups

common problem. The condition is complicated, the treatment time is long, the cost is expensive, and amputation is sometimes required. Previous and current treatments include the Masquelet technique, vascularized bone autografts [3], and the wrapped bone grafting technique [9].

However, the Masquelet technique, bone grafting, vascularized bone autografts have high infection recurrence rate, high risk of bone resorption, prone to stress fractures and nonunion [10–12]. Moreover, the wrapped bone grafting technique is not suitable for poor soft tissue conditions and in presence of infection [13, 14].

The theoretical basis of Ilizarov's technology is the tension-stress law, in which the living tissue is subjected to sustained, slow, and stable traction to produce tension that stimulates the regeneration and growth of the tissue, so that all the stretched bone and soft tissue produce regeneration and reconstruction. The commonly used bone transfer external fixators are mainly divided into Ilizarov circular fixator and monolateral fixators. Monolateral fixator for bone transport is simple in design and application, easy to carry out surgical procedure while maintaining it, and easy to remove, and its tapered and hydroxyapatite-coated pins decrease the risk of pin-tract infection spreading to bones [15], which is widely used for treatment of open fracture and osteomyelitis. To minimize errors, all cases selected in this study were treated with Orthofix monolateral external fixator.

Indication of bidirectional bone transport technique with double-level bone amputation

When using the single-level bone transport technique to heal bone defects > 6 cm, the treatment period is long, the extension area consolidated poor, the nail infection rate is high, and there is a higher incidence of complications. Paley and Maar [3] suggested that double-level bone transport can be used when the bone defect is more than 10 cm. Rozbruch considered double-level bone transport if the defect is > 6 cm [16]. Chevardin et al. [17] thought that when a single-level distraction regeneration was grown to more than 5 cm or to the length that exceeded 40% of the original segment, hypoplastic bone formation could happen during defect filling. Thus, osteogenesis was delayed in 1.6–13.8% of the cases when fragment

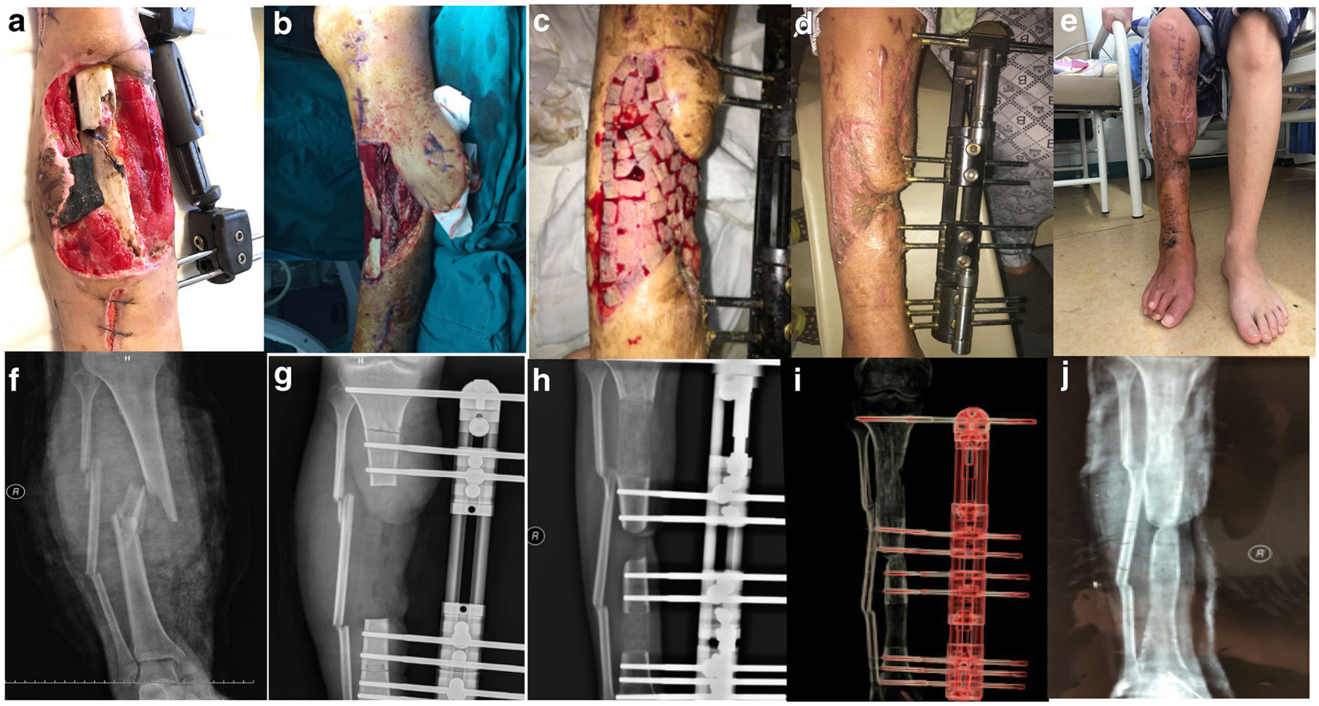

Fig. 2 Typical case. **a** After the surgery of debridement and external stenting, a large area of soft tissue defect with bone exposure. **b** Bone exposure after osteotomy, anterior transposition of gastrocnemius myocutaneous flap. **c** Soft tissue conditions improved after surgery, skin grafting was used to speed up wound repair. **d** Appearance after 6 months of operative. **e** The appearance after bone healing, removal of external fixation stent. **f** X-ray films before treatment, Gustilo IIIB. **g** After debridement, the bone defect reached 15 cm. The Orthofix stent was used to perform the distal and proximal biplane osteotomy. **h** The X-ray films at 80 days after surgery. The force line was available. **i** At 15 months, the butt joint healed. Regeneration zone growing well. **j** X-ray film after removing the external stent

lengthening was as high as 8–10 cm, and the regenerated bone tended to assume the shape of an hourglass. In our study, the mean length of the double-level group was 10.65 cm (7.5–15 cm). Double-level osteotomy transport means dividing the residual large segmental bone defect into two segments for two regions to stretch the osteogenesis, reducing the length of each extension zone and thereby reducing the occurrence of complications in the extension zone. According to our experience and study, we considered it is best to using double-level transport if the defect is ≥ 5.0 cm.

Intra-operative and post-operative treatment experience

For these operations, the Ilizarov technical principles should be followed, doing osteotomy at the metaphysis with percutaneous corticotomy done in a minimally invasive fashion utilizing the multiple drill hole and osteotome technique to keep intact for periosteum. Eralp believed that osteotomy technique respects the periosteum more than the drill hole corticotomy [18] and yields better healing indexes for tibial lengthening. The consolidation time of the distraction gap is also affected by blood supply, such that the closer the regeneration zone is to the metaphysis, the shorter the consolidation time. Pin-tract infection is a common complication in the transport process, the incidence of pin-tract infection being as high as 100% [19]. In our study, seven patients (26.9%) had different symptoms of pin-tract infection, including 1 case in the double-level group (7.7%) and six cases in the single-level group (46.2%). The rate of pin-tract infection was significantly ($P < 0.05$) higher in single-level group than in double-level group. It supported that double-level osteotomy transport could reduce the occurrence of complications.

As a result of the poor blood supply and poor contact of coapting surface, delayed union or nonunion of the docking site is also a common complication. Lovisetti and Sala's [20] study reported that the incidence of nonunion of the docking site up to 83%, and Iacobellis et al. [21] found 17 cases nonunion at the docking site out of 100 cases. In our study, six patients (23.07%) had nonunion of the docking site, four in single-level group (30.77%) and two in double-level group (15.38%). There was no significant difference between the two groups. One of them managed with intramedullary nailing and bone grafting, the remaining five proceeded with open bone grafting and achieved successful union. If a stress fracture occurs in the regeneration area, non-surgical treatment can be used. If refractures occurred at the docking site after it was healed, this can be managed with bone grafting or refixing such as intramedullary nailing.

Advantages of double-level bone transport compared with single level

The experimental findings and clinical outcomes of Borzunov [22] showed that as compared to traditional Ilizarov bone transport, double-level defect fragment lengthening could provide sufficient bone structure and reduction of the total osteosynthesis time in one stage. In 2006, Rozbruch [16] used Ilizarov frames to gradually close the bone and soft tissue defects simultaneously by using single-level bone or double-level bone transport. In the double-level bone transport group, the average bone defect was 8.2 cm, the distraction time was 15.3 weeks, average frame time was 34.3 weeks; in the single-level group, these data were 6.4 cm, 21.3 weeks, and 50.3 weeks, respectively. Sala et al. [1] also compared the above two methods, the average bone defect was 7.22 cm in single-level group, the mean external fixator index was 2.52 months/cm, while the data showed 10.65 cm and 1.22 months/cm in the double-level group. This was significantly less compared to the single-level group, indicating that the double-level group had shorter frame times and distraction times. In this study, the authors compared between the two groups, the patients in the double-level group had shorter frame time (12.71 ± 1.92 vs.18.06 ± 1.49 months), shorter union time of docking site (8.931 ± 2.289 vs.10.85 ± 1.519 months), smaller external fixator index (1.223 ± 0.2012 vs. 2.524 ± 0.2624 months/cm) and larger soft tissue healing index (0.6242 ± 0.1368 vs. 0.2883 ± 0.06422 days/cm^2). Several studies showed that because the double-level osteotomy bone transport external frame time was shorter, the pin-tract infection rate was also reduced. In our study, the incidence of pin-tract infection in double-level group was also less than single-level group. Unfortunately, this study has limitations including small sample size, retrospective study, and represents the experience of only one surgeon from our institution. There is thus a need for further studies to compare the efficacy of different bone transport treatment and different external fixation.

In conclusion, the Ilizarov technique of double-level bone transport with Orthofix external fixator can be used successfully to reconstruct the tibial bone loss and an accompanying soft tissue defect. It is especially noteworthy that it could significantly decrease bone transport time, shorten frame time, reduce complications, and reduce total treatment time.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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