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Analysis of functional outcomes and complications of tibial bone defects treated with Ilizarov bone transport technique

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Abstract

Background Trifocal bone transport (TF) rather than bifocal bone transport (BF) can shorten the treatment time when treating of large bone defect in tibia. However, few studies have reported efficacy and complications among different bone transport.

Aim To evaluate the effectiveness and complications of bone transport technique for the treatment of large bone defect in tibia.

Methods The retrospective study including 48 patients who underwent bone transport for the treatment of large bone defect in tibia from May 2015 to September 2019. A total of 30 were treated by bifocal bone transport (BF group) and 18 by trifocal bone transport (TF group). Patient demographic data, intraoperative outcomes, postoperative variables, complications and clinical outcomes of the two groups were recorded and compared at a minimum follow-up of 24 months. Postoperative complications were also evaluated according to Paley classification. Based on the Association for the Study and Application of Methods of Ilizarov (ASAMI) standard, the bone and functional results were evaluated at the last clinical follow-up.

Results All patients with an average follow-up of 27.5 months. All patients achieved complete union in the docking site and consolidation in the regenerate bone. Compared to the BF group, the TF group had a longer bone defect length($9.08 \pm 1.74 > 6.33 \pm 3.15$, $P < 0.01$) but a shorter external fixation index ($42.22 \pm 2.41 < 65.82 \pm 6.98$, $P < 0.001$). The mean number of complications per patient was 1.6 and 1.7 for BF and TF patients ($P > 0.05$). At the postoperative follow-up, there were no significant differences between the 2 groups in the bone and functional results ($P > 0.05$).

Conclusion For tibial bone defects, both bifocal and trifocal bone transport can achieve good clinical results. Compared to the bifocal bone transport, The trifocal bone transport can significantly shorten the external fixation index without increasing the incidence of associated complications.

Keywords Bone transport, External fixation, Ilizarov, Complication, Tibia, Segmental bone loss

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Background

Large tibial bone defects are encountered commonly by trauma surgeons. Such injuries may be caused by high-energy trauma, infection, tumours, and bone nonunion. Managing such injuries has been a challenge for orthopedic surgeons [1]. In recent years, techniques such as plate osteosynthesis with cancellous bone grafting, bone grafting with autogenous or allogenic bone grafts, bone shortening and lengthening technique, tibialization of the fibula, vascularized fibular grafts, the Masquelet induced membrane technique have achieved certain clinical results for the bone defects. However, the shortcomings and problems of these methods still remain the issues which restrict their overall use [2–5].With the development of microsurgical techniques and the improvement of external fixation devices. At present, Ilizarov bone transport techniques based on the concept of "distraction osteogenesis" have played an irreplaceable role in the treatment of bone defects because of their simplicity and effectiveness and ability to maximize the preservation of the biomechanical environment required for fracture healing [6]. 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 [7]. Bone transport may be bifocal or trifocal [8]. The regeneration of a long defect by distraction of one osteotomy site in the bifocal technique takes a long time in the frame, which may increases the incidence of complications such as pin tract infection, delayed union, joint stiffness and axial deviation, which often require further surgical and bring great psychological and economic burden to patients [9]. Trifocal technique has been shown to reduce wear time [10]. However, the trifocal technique needs a more complex assembly of the frame as well as the additional osteotomy, which may lead to the generation of related complications [11].

The purpose of this study was to analyze 48 cases of tibial bone defects treated with Ilizarov bone transport technique and to investigate the differences in efficacy and complications between trifocal anf bifocal bone transport.

Methods

The institutional review board (IRB) approval was gotten from the ethics committee of our institution. All methods were performed according to relevant guidelines and regulations.

Patients

There are 48 patients with tibial bone defects treated by the Ilizarov bone transport technique from March 2015 to May 2019 in our study. The inclusion criteria were as follows: (1) Patients over 18 years; (2) Patients with tibial bone defects ≥ 3 cm; (3) follow-up time after frame removal ≥ 24months. The exclusion criteria were as follows: (1) Combined with systemic metabolic diseases affecting bone healing; (2) Bone defect caused by pathological fracture; and (3) Poor compliance, can not cooperate with the treatment and follow-up.

A total of 53 patients with tibial bone loss who underwent Ilizarov bone transport technique treatment were initially screened, and 48 patients who met the inclusion and exclusion criteria for this study were included.

Surgical technique

Standard anteroposterior and lateral radiographs of the affected limb were taken for detailed preoperative planning. Perfect relevant examinations, after excluding surgical contraindications, thorough debridement was performed under general anesthesia or epidural anesthesia. Bacterial culture and drug sensitivity test were performed for surface secretions and deep tissue scrapings were retained of infected individuals to guide subsequent anti-infective treatment. All local necrosis, infection, and inflammatory granulation tissue were removed, and sequestrum, nonunion site, or sclerotic bone were completely removed to keep the broken end flat until cortical bleeding at the bone end, described by the so-called "paprika sign [12]", was accepted as an indication of vital osseous tissue. A large amount of iodophor, normal saline, and hydrogen peroxide were alternately irrigated to the surgical area. External fixators were installed according to preoperative planning, and antibiotic-impregnated spacers were placed in the infected bone defect site to improve stability. The rail fixator was installed according to the location of bone defect and soft tissue conditions during operation. Close the wound adequately in tension free manner by direct closure or use of free/local fap if necessary. For bone defects larger than 8 cm or exceeding 40% of the original bone length, a trifocal bone transport procedure was performed.

Postoperative management and follow-up

Sensitive antibiotics for 6 weeks according to the results of bacterial culture and drug sensitivity test, until the ESR and CRP level returned to normal. Encourage patients to perform early muscle isometric contraction exercises and active movement of adjacent joints. Distraction osteogenesis was started 7 days after operation. For cases with bifocal bone transport, the rate and rhythm was 1 mm/day, which was completed 4 times. In cases of trifocal bone transport, if bone transport in the same direction, the fragment near the bone defect was transported at a rate of 0.5 mm f and 4 times/day, and the other fragment far from the defect was transported 0.25 mm and 4 times/day. For converged bone transport, each fragment on both end of the bone defect was transported at a rate of 0.25 mm four times per day. The rate and rhythm of

Table 1 Patient demographics at baseline and intraoperative parameter between BF and TF group

Date	BF	TF	t	*P*
Sex(male / female)	6/24	3/15	0.011	0.916
Age(years)	37.00 ± 12.83	38.50 ± 12.69	0.394	0.696
Smoking(yes/no)	13/17	11/7	1.422	0.233
Injured side(left/right)	13/17	9/9	0.201	0.654
The etiology of bone defect(high-energy trauma / fall injury /other)	11/5/2	11/7/6	0.660	0.719
Primary fixation (internal/external)	14/16	7/11	0.277	0.599
Previous operation time(s)	3.30 ± 1.80	3.61 ± 2.15	0.539	0.593
Interval duration before bone transport(months)	31.60 ± 47.03	61.02 ± 103.80	1.135	0.269

BF, bifocal bone transport; TF, Trifocal bone transport

Table 2 Comparision of postoperative date between the BF and TF group

	BF	TF	t	*P*
Size of bone defect(cm)	6.33 ± 3.15	9.08 ± 1.74	3.889	0.000
DT(d)	91.10 ± 44.41	76.44 ± 27.94	1.403	0.165
CT(d)	255.87 ± 112.45	237.56 ± 53.56	0.760	0.451
EFT(d)	402.18 ± 172.54	379.65 ± 68.77	0.636	0.528
EFI(d/cm)	65.82 ± 6.98	42.22 ± 2.41	16.922	0.000

BF, bifocal bone transport; TF, Trifocal bone transport; DS, defect size; DT, docking time; CT, consolidation time; EFT external fixation time; EFI, external fixation index

distraction were adjusted according to patient tolerance and radiographic evaluation of the distracted region. When the transported bone segment reached the docking site, revision of the docking site was then performed to excise interposed soft-tissues, the bone end was fresh, and any malalignment was corrected, and bone graft was applied if necessary. The Ilizarov fixator was removed after an X-ray taken in two planes showed corticalization of four cortices [13]. Additionally, all patients was protected in a long-leg cast or brace for 4 weeks to protect against refracture. Docking time (DT), external fixation time (EFT), external fixation index (EFI), duration of regenerate consolidation time (CT) and complications during treatment were recorded. Complications were classified with the Paley criteria [14]. ASAMI [15](Association for the Study and Application of the Method of Ilizarov) criteria were used to assess the bony and functional outcomes at follow-up.

Statistical analysis

Data analysis was performed using SPSS version 22.0 (IBM Corp, United States) to analyse all data; all variables were examined for normal distribution. The measurement data are expressed as the mean ± standard deviation (SD). The enumeration data are expressed as percentages. Continuous variables were compared by using t tests, and Pearson's chi-square test or Fisher's exact test was used to compare categorical variables. and results with $p < 0.05$ were considered significant.

Results

Demographic and clinical characteristics

All patients in the two groups completed the surgery successfully without neurological or vascular injuries. All patients finished the follow up with 24 to 40 months, with an average of 27.5 months. There were no significant differences between the two groups in terms of age, gender, smoking, affected side, causes of injury and previous treatment($P > 0.05$), as detailed in Table 1.

Postoperative outcomes

In terms of surgical outcomes, in the BF group, the size of bone defect was 6.33 ± 3.15 cm, the DT was 91.10 ± 44.41 days, the CT was 255.87 ± 112.45 days, the EFT was 402.18 ± 172.54 days and the EFI was 65.82 ± 6.98 d/cm. In the TF group, the size of bone defect was 9.08 ± 1.74 cm, the DT was 76.44 ± 27.94 days, the CT was 237.56 ± 53.56 days, the EFT was 379.65 ± 68.77 days and the EFI was 42.22 ± 2.41 d/cm. the TF group exhibited a longer average defect size. Similarly, the EFI was significantly lower in the TF group. But not in the DT, the CT and the EFT($P > 0.05$), as shown in Table 2.

Bone and functional outcomes

The bone result was excellent, good, fair and poor in 16, 11, 2 and 1 in group BF; and 15, 10, 4, and 1 in group TF, respectively. The functional results were excellent, good, fair, poor and failure in 11, 4, 3, 0 and 0 in group BF; and 10, 5, 2, 2 and 0 in group TF, respectively. With respect to bone and function results, there was no significant differences between the two groups($p = 0.508$ and $p = 0.958$, respectively), as shown in Table 3.

Complications

Complications were classified according to Paley classification. No case encountered joint luxation, vascular or nerve compromise in both groups and the results are shown in Table 4.

For BF group, there are twenty-nine problems, thirteen obstacles, and seven complications. In TF group, seventeen problems occurred. Eight obstacles happened, and five cases suffered from complications. The mean number of complications per patient was 1.6 for BF patients and 1.7 for TF patients, and the difference was no significant ($p > 0.05$).

Complications were treated similarly in both groups. Among them, thirty-two patients had a pin tract infection, which was cured in most patients with daily pin site care and oral antibiotics. One patients suffered from a

Table 3 Comparision of the evaluation of ASAMI bone and functional grade between the BF and TF group

Grade	bony		functional	
	BF	**TF**	**BF**	**TF**
Excellent	16	11	15	10
Good	11	4	10	5
Fair	2	3	4	2
Poor	1	0	1	1
Failure	/	/	0	0
	P = 0.508		*P* = 0.958	

BF, bifocal bone transport; TF, Trifocal bone transport

Bone results

Excellent: Union, no infection, deformity < 7°, limb length discrepancy (LLD) < 2.5 cm Good: Union plus any two of the following: absence of infection, deformity < 7°, LLD < 2.5 cm

Fair: Union plus any one of the following: absence of infection, deformity < 7°, LLD < 2.5 cm

Poor: Nonunion/refracture/union plus infection plus deformity > 7° plus LLD > 2.5 cm Functional results

Excellent: Active, no limp, minimum stiffness (loss of < 15°knee extension/< 15°ankle dorsiflexion) no reflex sympathetic dystrophy (RSD), insignificant pain

Good: Active, with one or two of the following: limb, stiffness, RSD, significant pain

Fair: Active, with three or all of the following: limb, stiffness, RSD, significant pain Poor: Inactive (unemployment or inability to return to daily activities because of injury)

Failure: Amputation

deep pin tract infection, which was successfully treated by pin replacement and intravenous antibiotics. Fifteen patients developed delayed union which were successfully managed by intensive physiotherapy or extending apparatus across the stiffed joint and mobilizing the joint prior to its removal. Muscle contraction was encountered in nine cases were instructed to participate in functional exercises or manual release. Eigth patients had axial deviation were managed by adjusting the transport frame. Seven patients developed delayed union, which were successfully treated by the accordion technique. There were two cases of nonunion at the docking site, which were treated by autocancellous bone graft from iliac crest. One patient developed soft tissue incarceration and underwent soft tissue resection and the iliac bone graft was introduced, and all eventually healed. One case refracture achieved bony union by wearing a protective brace.

Discussion

The theoretical basis of Ilizarov's technology is the tensionstress 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 [16]. Currently, it has emerged as the gold standard for the treatment of massive tibial bone defects, eradicating infection and solving bone and soft tissue defects at the same time. Bone transport tecnique include distraction and consolidation period. The distraction period is generally 7 to 10 days after osteotomy, the bone segment is transported at a rate of 1 mm/d to reach the expected extended length and then enters the consolidation period, and the external fixator is removed after the newly formed bone is completely consolidation [17]. As a result, large bone defects tend to require longer EFT and increases the frame-related complications such as pin-tract infection, pin loosening, joint stiffness and psychological symptoms [2].

Several authors [18] have addressed different treatment options in order to shorten treatment period and reduce the incidence of complications. Apivatthakakul [19] successfully cured 2 cases of distal femoral bone defects using MIPO technique combined with external fixator, and although the alignment of the docking end was maintained, it has also been found that the built-in

Table 4 Comparision of complications between the BF and TF group

Parameter	BF			TF			Total
	problem	**obstacle**	**complication**	**problem**	**obstacle**	**complication**	
Pin-site infection	18	2	0	10	1	1	32
Delayed union	3	1	0	2	1	0	7
Muscle contractures	3	2	0	2	2	0	9
Axial deviation	0	5	1	0	2	0	8
Nonuion	0	0	1	0	0	1	2
Soft tissue incarceration	0	0	1	0	0	0	1
Joint stiffness	5	3	1	3	2	1	15
Limb shortening	0	0	3	0	0	1	4
Refracture	0	0	0	0	0	1	1
Total	29	13	7	17	8	5	79
			x^2=0.090 *P*=0.956				

BF, bifocal bone transport; TF, Trifocal bone transport. Complications were classified according to Paley classification. Problem: a potential expected difficulty that arises during the distraction or fixation period that is fully resolved by the end of the treatment period by nonoperative means. Obstacle: a potential expected difficulty that arises during the distraction or fixation period that is fully resolved by the end of the treatment period by operative means. Complications include any local or systemic intraoperative or perioperative complication, a difficulty during distraction or fixation that remains unresolved at the end of the treatment period, and any early or late posttreatment difficulty plate affects the generation of callus at the bone end [20]. Liodakis [21] found that external fixation combined with intramedullary nail technique not only shortens the EFT. Moreover, combined external and internal fixation was found to have a greater risk of infection recurrence in the treatment of infected tibial nonunion and chronic osteomyelitis. Some more options of a combined technique have been reported, such as a lengthening nail for transport and a locking plate for docking and a carbon-fiber IMN [22]. However, besides its high cost, it was found clinically that the nail performs poorly in long-bone surgery and cannot be added to external fixation instead of a titanium nail even for combination.

Because accelerated lengthening at one osteotomy site is not possible due to biological and neurovascular considerations, the solution was to add one osteotomy while lengthening, ideally doubles the rate of lengthening effectively. Borzunov [23] first used double-level bone transport using the Ilizarov technique to treat large tibial bone defects, with a 2.5 times shorter docking time and a 1.3–1.9 times lower EFT compared with the single-level bone transport. Similarly Paley and Maar et al. [24] recommended double-level bone transport for bone defects greater than 10 cm in order to shorten the EFT. It has also been suggested that trifocal bone transport should be considered when the defect length is over 6 cm [25]. However, the above studies did not describe complications, and bone or functional outcomes in the two groups.

We also compared the above two methods in this study, the mean bone defect length was greater in the TF group than in the BF group ($P<0.05$). Although there were no statistically significant differences in DT, CT, and EFT between the two bone transport modes, the means of these data were smaller in the TF group than in the BF group, and the mean EFI was shorter in the TF group ($P<0.05$). This finding suggests that despite the increased complexity of the TF group, it may provide a rapid recovery pathway.

Trifocal bone transport equates to faster docking contacts, which leads to early docking healing [26]. we anticipated that the addition of an osteotomy to the TFT would increase complications associated with the wires and distraction sites. In the study, the complication rate was 1.6 per patient in BF group and 1.7 per patient in TF group, the results showed no statistically significant complication rate between the two groups ($P=0.956$). Possibly due to the relatively early frame removal in the two-level group. Therefore, we believe that the occurrence of complications may is associated with longer EFT. According to our experience and study, we recommend trifocal bone transport was performed when if the bone defect is more than 8.0 cm.

Some authors found that hypoplastic bone formation may occur during defect filling when single-level distraction regeneration growth exceeds 5 cm or 40% of the original segment length [27]. Chaddha [28] applied trifocal bone transport to treat tibial bone defects and had a higher incidence of delayed consolidation, which was caused by the the more distal osteotom and there was a high incidence of trauma to the nutrient artery in trifocal bone transport. 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 [29]. No patient developed delayed consolidation in this study. This was done with both proximal-to-distal bone transport technique all cases in our study. In addition, the use of low-energy osteotomy techniques and adjustment of the lengthening rate may reduce the occurrence of such complications.

Although bone transport is widely used to treat large bone defects, some unavoidable complications have also been reported [30, 31]. In our study, pin tract infection is the most common complication in 32 patients (66.7%), including 12 case in the double level group and 20 cases in the single-level group. Dahl [32] classified pin tract infection into Grade V according to severity. According to the above classification, twenty-eight patients were Grade I, three patients were Grade III and 1 patients were Grade IV. Most pin tract infections are treatable with improved wound care and a short course of oral antibiotics. One patients(Grade IV) suffered from a deep pin tract infection, which was successfully treated by pin replacement and intravenous antibiotics.

Our experience is that frequency of needle track cleaning did not reduce the rate of pin track infection, but rather increased allergic reactions around the needle track. In addition, dry sterile gauze is wrapped around each pin site to maintain dryness around the pins sites significantly reduced the incidence of pin tract infection.

Relevant literature suggests that nonunion is the rate-limiting step in bone transport for the treatment of bone defects [33]. Most scholars suggest that early revision and bone grafting can significantly reduce the incidence of nonunion when the transported segment had reached the target site [34]. In this study, 9 patients showed delayed union or nonunion at the docking site, which healed completely after freshening of the fracture ends with removal of any interposed soft tissue at the docking end.

In this study, 15 patients developed joint stiffness, and the incidences of muscle contracture, axial deviation, soft tissue incarceration, limb shortening, and fracture were 31.3% (15/48), 3.6% (16.7/48), 2.1% (1/48), 8.3% (4/48) and 2.1% (1/48), respectively. but all of them were finally solved by various means. No serious complications such as nerve and blood vessel injury occurred.

Our present study showed that both bifocal and trifocal bone transport achieved satisfactory bone and functional results in the treatment of tibial bone defects, and there was no significant differences in the incidence of complications between the two groups. All patients achieved complete healing at the docking site and consolidation in the regenerate bone.

This study has several limitations. First, the small sample size and retrospective design. Further prospective studies are needed to address methodological limitations. In addition, there may be personal preferences in the choice of treatment options by the treating physician, which may lead to the risk of bias and confounding interference in this study (e.g., bifocal and trifocal bone transport distance), affect the objectivity of the efficacy evaluation, and be cautious when interpreting our bone and functional outcomes. Second, this study did not compare the operative time between different groups, and future studies need to expand the sample size, prolong the follow-up time, and use a prospective randomized controlled design to address methodological limitations. At the same time, the association analysis between complications and handling mode was further refined, and the effects of confounding factors such as physician experience and patient compliance were explored.

Both trifocal and bifocal bone transport can yield satisfactory results for treament of segmental tibial defects. Trifocal bone transport significantly reduced the decrease bone transport time, shorten frame time, and without increasing the associated complications. According to our experience, there are many factors that can influence the success of distraction osteogenesis, such as a comprehensive understanding of the application of external fixators, careful selection of patients, timely follow-up and early detection of predicted complications throughout the treatment. They are specialized surgical techniques that require significant expertise to master. Bone transport is a specialized technique with a long learning curve. No attempt should be made unless performed by an experienced Ilizarov surgeon.

Author contributions

All authors had full access to the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Y.X.Z. and D.W.F. Analysis and interpretation of the data: B.L.J, and J.D.W. Drafting of the manuscript: Y.X.Z. and J.D.W. Critical revision of the manuscript for important intellectual content: Z.W.L, and D.W.F. Obtained funding: D.W.F.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request; please contact the corresponding author, Dr. Feng.

Declarations

Ethics approval and consent to participate

This retrospective study was approved by the Ethics Committee of The First Affiliated Hospital of Hebei North University and carried out in accordance with the ethical standards set out in the Helsinki Declaration. Informed consent was received from all participating.

Consent for publication

Not applicable.

Clinical trial number

Not applicable.

Competing interests

The authors declare no competing interests.

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