

Quality of life and complications at the different stages of bone transport for treatment infected nonunion of the tibia

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Abstract

The aim of this study was to assess Physical Component Summary (PCS), Mental Component Summary (MCS) of the Mos 36-item Short Form Health Survey (SF-36) score, and the virtual Analogue Scale (VAS) of pain during the treatment period and the complication rate associated with infected nonunion of the tibia managed surgically by bone transport.

This is a retrospective analysis of prospectively collected data in a consecutive patient cohort. Patients suffering from infected nonunion of the tibia were treated by bone transport from 2012 to 2014. Follow-up was for at least 2 years after complete osseous consolidation. Standardized treatment included bacterial eradication by segmental resection, bone transport using Ilizarov apparatus, and docking maneuver. The main outcome measurements consisted of the quality of life (PCS and MCS scores) and the VAS of pain during the different stages of therapy. In addition, all complications were documented.

Our series comprised 12 men and 3 women with an average age of 36.9 years (range: 20–55 years). All patients previously undergone an average of 2.9 operations (range: 1–6 operations). In all patients, bone defects were present with a mean size of 7.5 cm (range: 3–12 cm), and all patients were suffering from soft tissue defects (range: 5–17 cm²). The mean external fixator time (EFT) was 48 weeks (range: 30–62 weeks) and the mean external fixation index was 43.1 days/cm (range: 33–62 days/cm). All patients achieved bone union, and no recurrence of infection was observed. According to the Paley classification, patients suffered 15 minor and 13 major complications. The average complication rate per patient comprised of 1.0 minor and 0.9 major complications. Bone grafting was required in 6 cases at the docking site. One patient suffered from equinus deformity, and refused any further surgical procedures. We performed 28 operations in 15 patients (average 1.9 operations per patient). After the period of bone transport, PCS and MCS scores increased continuously. After completed consolidation, the average MCS score was comparable to a normal collective, and the average VAS score was 1.87 (range: 0–3).

Bone transport is a safe option for the treatment of infected nonunion of the tibia despite the high complication rate. The arduous and demanding nature of this treatment subjects patient to considerable the pain, mental, and physical stress. The average VAS scores, PCS, and MCS scores significantly improve at final follow-up. It is essential to communicate this fact to the patients and their relatives before the application of the frame in order to increase their compliance with the long and emotionally draining treatment.

Abbreviations: EFT = external fixator time, MCS = mental component summary, PCS = physical component summary, SF-36 = the Mos 36-item Short Form Health Survey, VAS = visual analogue scale.

Keywords: bone transport, infected nonunion, SF-36, tibia

Editor: Johannes Mayr.

Each author certifies that he has no commercial associations that might pose a conflict of interest with the submitted article.

This material has not been read or exhibited at a meeting before submission to Xing Wu.

The study was approved by the institutional review board of HongHui Hospital, Xi'an Jiaotong University.

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Medicine (2017) 96:45(e8569)

Received: 17 March 2017 / Received in final form: 13 October 2017 / Accepted: 18 October 2017

<http://dx.doi.org/10.1097/MD.0000000000008569>

1. Introduction

Infected nonunion of the tibia is usually associated with deformity, bone loss, persistent infection at the fracture site, and severe adverse effects on health-related quality of life.^[1] This is a challenge for orthopedic surgeons and patients. Several surgical treatment options have been proposed. The Ilizarov method can overcome all associated problems simultaneously; therefore, it has evolved to become the main treatment for infected nonunion. Although lots of studies showed high rates of successful with surgical treatment of infected nonunion of the tibia by bone transport,^[2–15] but the pain, long treatment process, and prolonged external fixation are considered to be the main and unavoidable shortcomings^[2,3,6–8,11–15]; this results in a significant physical and mental burden for the patient. The previous studies^[2–15] mainly evaluated the physiological outcomes at final follow-up, whereas psychological burdens and pain did not receive enough investigation at final follow-up and during the long treatment process.

The treatment strategy of distraction osteogenesis consists of 4 distinctive phases of treatment, including bacterial eradication, bone transport following construction of the Ilizarov apparatus and corticotomy, docking maneuver with osseous consolidation, and patients' rehabilitation after removal of the construct. This study reviewed outcomes of 15 patients who underwent bone transport for infected nonunion of the tibia. We evaluated external fixation time, external fixation index, and complications from chart review. In addition, it was our goal to assess Physical Component Summary (PCS), Mental Component Summary (MCS) of SF-36 score, and the Visual Analogue Scale (VAS) of for pain measurement during the different treatment periods. We also analyzed the complication rate associated with this technique.

2. Patients and methods

2.1. Patients

We performed a retrospective analysis of data in a consecutive patient series with infected nonunion of the tibia. All patients underwent bone transport from 2012 to 2014. The inclusion criterion for this study was a patient with infected nonunion of the tibia. Other inclusion criteria comprised at least one positive microbiological culture from an intraoperative tissue specimen, requirement to perform bone transport with bone defects of at least 3 cm, angiography without signs of peripheral arterial occlusive disease, normal sensory and motor function, and the absence of nicotine abuse. Patients suffering from intraarticular fractures and fractures with vascular compromise, age > 65 years, pathological fractures, and any medical or skeletal illness affecting bone healing were excluded. Demographic data, hospitalization, and procedure details were recorded (Table 1), and follow-up was for at least 2 years after complete osseous consolidation.

Bone loss was located in the middle third of the diaphysis (7 cases) and at the distal diaphyseal-metaphyseal level (8 of 15 cases). Eight patients (53%) suffered an open fracture classified according to Gustilo et al,^[16] including 6 Type II cases and 2 Type III cases. A total of 3 fractures were initially stabilized using external fixation, 8 using plate osteosynthesis and 4 by intramedullary nailing.

2.2. Surgical technique

In cases of infected nonunion, the devitalized bone was transversely resected at the limit of apparently healthy bleeding bone. The infected scarred soft tissues and sinus tracts were debrided adequately. In order to ascertain the vitality of the residual bone, we drilled several holes into the bone ends and observed bleeding with the tourniquet deflated. The bone transport segment end was cut till coverage of skin was possible so that bone transport segment was covered by soft tissue and skin during distraction. In all cases, 3 swab samples were taken for culture during surgery. Bacterial species grown in culture are summarized in Table 1. All patients received a course of antibiotics for at least 4 to 6 weeks postoperatively according to sensitivity tests.

After debridement, we conducted bone transport with the circular external fixator. The assembly comprised of 6 rings: 2 proximal rings, 1 for transport, 2 distal, and 1 ring at the foot for preventing foot drop. Two Kirschner wires were inserted and tensioned for each of the rings. The site of the corticotomy was made at the proximal metaphysis. The osteotomy was performed with a Gigli saw after the fixator was applied. For coverage of the soft-tissue defects, we applied the vacuum-assisted closure device.

After reaching the docking site, moving the ring continued for 3 or 4 days to compress the bone at this site. If progress to union was not observed 3 months after docking or if malalignment was evident at the docking site, the treatment was changed to radical surgical debridement. If small residual gaps were seen between the 2 bone ends, we removed cancellous bone from the ipsilateral iliac crest and grafted the docking site. In 3 cases, due to lack of consolidation and ossification of the regenerate column, we replaced the fixator with an intramedullary nail.

The frame was dynamized before removal in order to assess the mechanical stability of the regenerated bone. When radiographs showed solid docking-site union and the regenerate area had a minimum of 3 complete cortices, the Ilizarov external fixator was removed. After frame removal, a functional brace (patellar tendon bearing) was applied for at least 4 weeks, and we encouraged full weight bearing to protect the bone.

In the postoperative period, joint motion and partial weight bearing mobilization with crutches or walker was encouraged

Table 1

Clinical data from 15 patients.

Age	OTA	Gustilo	Size	Index	Pathogen	Docking strategy
20	43A3	II	6	33	MRSA	—
25	42C3	III a	12	34	PA	External fixation pressure and bone graft
28	42C2	Close	12	40	SA	Correct malalignment, debridement, and bone graft
35	42B2	Close	5	62	EF	Correct malalignment, debridement, and bone graft
32	43A3	Close	4	45	SE	—
45	43A3	III a	10	38	MRSA	Correct malalignment, debridement, and bone graft
50	43A3	Close	7	49	MRSA	Correct malalignment, debridement, and bone graft
45	43A3	Close	6	53	MRSA	Correct malalignment and debridement
50	42C2	II	10	38	SA	Intramedullary nail
40	42C3	II	8	44	SE	Intramedullary nail
38	42C2	III a	10	38	SE	Intramedullary nail
42	43C3	II	5	38	SE	—
55	43C3	Close	3	54	EF	—
28	42C2	II	8	46	EF	Correct malalignment, debridement, and bone graft
20	43A3	Close	6	35	SA	—
36.9	—	—	7.5	43.1	—	—

Size = Defect size (cm), Index = Heal index (days/cm).

EF = Enterococcus faecalis, MRSA = methicillin-resistant *Staphylococcus aureus*, PA = *Pseudomonas aeruginosa*, SA = *Staphylococcus aureus*, SE = *Staphylococcus epidermidis*.

depending on patient's compliance and status of pain. Bone transport was commenced 5 days after osteotomy at an average rate of 1/4 mm every 6 hours. Radiologic assessment of the alignment was undertaken to ensure adequate docking. If necessary, the frame was adjusted under anesthesia to correct malalignment. Patients were kept hospitalized in the first week postoperative to facilitate training about wound and frame care and to learn how to make gradual lengthening of the distraction rod in the Ilizarov frame.

2.3. Data collection

Radiographs were obtained every 2 weeks during the distraction period and monthly during the consolidation period. External fixation time, external fixation index, and the number of operations were all recorded. The external fixation index was calculated as the number of days the fixator was in situ divided by the distance of bone transported in centimeters.

All complications that occurred between the application of the frame and the final follow-up were registered. According to the Paley^[17] classification, complications were grouped as minor, major without residual sequelae, and major with residual sequelae. Minor complications generally required nonoperative treatment or a minor operative procedure that did not have an impact on the final result. Major complication without residual sequelae generally involved a more complex operative procedure that corrected the problem.

We divided the treatment process into 4 stages: stage I (preoperative phase), stage II (bone transport until the gap disappeared), stage III (docking maneuver until removal of external fixation), and stage IV (follow-up until 2 years after removal of external fixation). Functional results were evaluated according to PCS, MCS of SF-36 score, and the VAS for pain was obtained.

2.4. Statistical analysis

Statistical analysis was performed with the SPSS 17.0 software (SPSS Inc, Chicago, IL). Descriptive statistics were conducted for all variables. Continuous variables were expressed as the mean and standard deviation. Friedman test was used to examine mean differences in PCS, MCS, and the VAS scores of pain during the different stages of therapy. Statistically significant difference was defined as *P* value of < .05.

3. Results

Our series comprised 12 men and 3 women with an average age of 36.9 years (range: 20–55 years). Patients had previously undergone an average of 2.9 operations (range: 1–6 operations). Bone defect was present in all patients. The mean distance of the bone defect after resection measured 7.5 cm (range: 3–12 cm), and all patients suffered from soft tissue defects (range: 5–17 cm²). The mean EFT was 48 weeks (range: 30–62 weeks) and the mean external fixation index was 43.1 days/cm (range: 33–62 days/cm). All patients achieved bone union, and we observed neither a neurovascular complication nor a recurrence of infection.

According to the Paley classification, patients suffered 15 minor and 13 major complications (Table 2). The average complication rate per patient consisted of 1.0 minor and 0.9 major complications. One patient with sequela suffered from equinus deformity, and refused any further surgical procedures. Pin tract infection and loosening of pins were the most commonly observed complications. Pin tract infections occurred in 6 patients and were successfully treated by local care and administration of oral antibiotics.

Docking site united primarily (Fig. 1) in 5 cases (33%) and the most frequently encountered complication was failure of the tibial docking site to consolidate (10 cases). Bone grafting was required in 6 cases at the docking site and external fixation pressure in 1 case. We noted lack of maturation of the bone of the regenerate column in 3 patients, and we replaced the fixator with an intramedullary nail.

The follow-up rate was 100% until 2 years after external fixator removal. The combined physical and mental component scores were 13.8 ± 4.0 and 37.5 ± 4.5 , respectively, during the distraction period. After the period of bone transport, PCS and MCS scores increased continuously. When consolidation was completed, the MCS of the SF-36 at final follow-up was 72.5 ± 5.5 and therefore higher than during the distraction period ($T=24.145$, $P=.000$) (Table 3). We observed a mean PCS of 13.8 ± 4.0 during the distraction period and mean PCS increased to 44.1 ± 5.3 at the final examination ($T=20.247$, $P=.000$). All the patients had a feeling of pain during the distraction period, and the average VAS scores was 6.1 (range: 5–8), but they were able to tolerate pain with the administration of oral analgesics. This significantly improved to 1.9 (range: 0–3) at the final follow-up ($T=11.039$, $P=.000$).

Table 2
Complications and sequela.

Complications	Therapy	Number	Rate (%)
Minor complications			
Pins tract infected and loose	Oral antibiotics	6	40%
Pin loosening	—	2	13%
Malalignment of callus distraction zone	—	3	20%
Delayed union at docking site	Compression by external fixator	1	7%
Delayed ossification of callus distraction zone	Prolonged external fixation	1	7%
Equinovarus	Correction by external fixation	2	13%
Total		15	100%
Major complications			
Delayed union at docking site	Intramedullary nail	3	20%
Docking site malalignment	Correction of malalignment and bone graft	6	40%
Hammer toe deformity	Severing the flexor tendon	3	20%
Equinovarus	Correction by external fixation	1	7%
total		13	87%
Sequela			
Equinovarus	Patient refused further treatment	1	7%



Figure 1. (A, B) X-rays show this patient with infected nonunion after treatment by monorail external fixator. (C, D) After reaching docking site and ossification of the regenerate column, and the clinical view of the circular external fixator. (E, F) At the final follow-up, docking site union and correct alignment of the tibia. (G) The clinical view of the lower extremity at 2 years after external fixator removal.

Table 3
MCS, PCS, and VAS scores.

	PCS	MCS	VAS
Stage I	20.6±4.3	45.3±5.1	4.8±1.1
Stage II	13.8±4.0	37.5±4.5	6.1±1.0
Stage III	14.1±3.7	38.3±4.6	6.1±1.3
Stage IV	44.1±5.3	72.5±5.5	1.9±0.9

PCS, MCS, and VAS scores during the different stages of therapy. The results that there are significant differences in PCS, MCS, and VAS scores between stages II and IV ($T=20.247$, $P=.000$; $T=24.145$, $P=.000$; $T=11.039$, $P=.000$, respectively).

MCS=Mental Component Summary, PCS=Physical Component Summary, VAS=Visual Analogue Scale.

4. Discussion

The treatment of infected nonunion of the tibia is challenging. Bone transport is an alternative option^[2-15]; it has the following advantages: this is a minimally invasive surgical technique that can correct deformities and shortening at the same process, even with poor soft tissue coverage. There are many published papers describing outcomes and complications of bone transport treatment for long bone defects,^[2,3,6-8,11-15] but the pain, long treatment process, and prolonged external fixation are considered to be the main and unavoidable shortcomings^[2,3,6-8,11-15],

this results in a significant physical and mental burden for the patient. The previous studies^[2–15] mainly evaluated the physiological outcomes at final follow-up, whereas psychological burdens and pain did not receive enough investigation at final follow-up and during the long treatment process. The purpose of this work was to assess PCS, MCS of SF-36 score, and the VAS of pain during the different treatment period and the complication rate associated with this technique.

The majority of patients had suffered from complications during the long treatment period. The average complication rate per patient consisted of 1.0 minor and 0.9 major complications. Yu et al^[18] conducted a systematic review of tibia bone defect treated by Ilizarov method between January 1995 and April 2013; their results showed that the mean number of complications per patient was 1.47, the mean external fixation index was 1.46 months/cm, and the mean size of bone defect was 6.01 cm. In our study, the mean external fixation index was 1.43 months/cm, and the complications was 1.9 per patient; this was quite similar with the results by Paley and Maar^[19]; their study consisted of 19 patients, the result showed 22 minor and 19 major complications, and the complications were 2.2 per patient. Our results showed an obviously higher complication rate when compared with previous literature,^[4,5,8,9,19] whereas all of patients in this study suffered tibial infected nonunion, experienced with multiple previous treatment failures, even in the presence of poor soft tissue coverage; this was an obvious difference from aforementioned studies. Pin-track infection was the most frequently observed complication in the course of bone transport in previous reports,^[4,5,8,9,19] and this complication was also noted frequently in our study without a negative impact on the final outcome.

In the study by Paley and Maar,^[19] cases of tibial nonunion were treated with Ilizarov fixators, which resulted in that persistent infection in 3 cases (10.7%). Spiegl et al^[20] investigated the complication rate associated with distraction osteogenesis in the treatment of chronic tibial osteitis. Their results showed that infectious recurrences were detected in 7 cases (28%). In our study, all patients achieved bone union, and no recurrence of infection was observed. All required excision of a segment of bone with a mean length of 7.5 cm, which was then regrown from regions of good vascularity. It is possible that such radical treatment excised some bone unnecessarily, but we had no failures and consider that the risk was justified.

There is a controversial view on regular bone grafting at the docking site.^[21–24] Most authors currently recommend routine staged docking site revisions during bone transport.^[21,22] We applied bone grafting at the docking site in 9 of 15 patients. This is similar to the results published by Tetsworth et al.^[15] The patient group of Paley and Maar^[19] consisted of 19 patients, and docking site union was achieved without open resection of scar tissue and osteosynthesis in the majority of patients. In addition, data by Krappinger et al^[6] showed that patients with multiple surgical interventions showed a significant lower satisfaction. It is therefore crucial to perform a thorough debridement of the bone to decrease the number of staged surgical docking site procedures. We perform routine docking site revision with bone grafting only when axial deviations occurred. In order to provide the greatest opportunity for the most reliable and rapid union at docking site, attention should be paid to the following points: Ilizarov external fixator should be assembled under fluoroscopy monitoring before resection of infected bone. X-ray films should be reviewed every 2 weeks during the bone transport period in order to detect malalignment early and to correct immediately.

A further focus of this study was to analyze the MCS, PCS, and VAS of pain during the different treatment periods. Treatment by bone transport reduced physical and mental well-being, and patients suffered from severe pain for long periods of time. At the final follow-up, the scores of physical functioning and pain were still significantly lower when compared with the normal population, and MCS scores were slightly lower comparable to the general population. Although with a long treatment process and the severe pain, the final clinical outcomes have improved significantly. Nevertheless, the final outcomes of this group are still not equal to the normal population, which may be due to muscle atrophy, ankle joint stiffness, and these had a difficult recovery within a short time. There is a selection bias. In general, young patients are more likely to choose reconstruction of lower extremity, while older patients are more likely to choose amputation. Our series comprised 12 men and 3 women with an average age of 36.9 years (range: 20–55 years), and these patients are extremely motivated and cooperative. This may explain that the MCS scores are equivalent compared with the general population.

The majority of complications had been resolved without a negative impact on the final outcome. Our results showed that despite patients suffered the severe pain, significant low MCS and PCS scores in the course of treatment, the final outcome was significantly improved, and even MCS was close to normal. Our study provides more information for patients and surgeons in treatment of infected nonunion of the tibia by bone transport; this will be contribute to decrease in the patients' fear, increase their compliance with the long treatment period, and improve confidence both for surgeons and patients.

There are lots of limitations for this study. One of the main limitations of the present study is the small sample size. This is due to the low incidence of patients with infected nonunion of the tibia in whom treatment by bone transport is required. This study is unique in regard to assessment of quality of life at different stages of the treatment.

5. Conclusion

Bone transport is a safe option for the treatment of infected nonunion of the tibia despite the high complication rate. The arduous and demanding nature of the clinical course subjects the patient to severe pain, mental, and physical stress. Thankfully, the average VAS scores, PCS, and MCS scores significantly improve within 2 years after the end of treatment. It is essential to explain this to the patients and their relatives before the application of the frame to increase their compliance with the long and emotionally draining treatment.

Acknowledgment

We extend our thanks to the following individuals for their participation in the study: Yang-Jun Zhu, MD, Zhong Li, MD.

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