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ORIGINAL STUDY

A comparison of external fixation alone or combined with intramedullary nailing in the treatment of segmental tibial defects

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The purpose of this study was to compare the results of external fixation alone versus external fixation combined with intramedullary nailing in the reconstruction of segmental defects of the tibia resulting from chronic osteomyelitis.

Thirty-two patients were treated with external fixation alone and 17 patients with the combined technique. Surgical reconstruction utilised distraction osteogenesis by focal segment transport after infection was eradicated.

In the external fixation group, the mean size of the defect was 7.24 cm, external fixation index was 56.32 days/cm and consolidation index was 40.09 day/cm. In the combined technique group, the mean size of the defect was 8.89 cm, external fixation index was 16.31 days/cm and consolidation index was 25.7 days/cm.

There was no difference in non-union, deformity, limb length discrepancy (LLD), bone and functional results. However, there was a higher rate of reinfection in the combined group when tibial lengthening exceeded 9.25 cm and lengthening ratio was more than 24.8%.

Keywords : segment transport ; combined technique ; nonunion ; tibial defect ; osteomyelitis.

INTRODUCTION

Treatment of infected tibial pseudoarthrosis can be extremely difficult. These patients usually have coexisting problems, such as deformity, bone loss, suboptimal local vascularity, soft tissue coverage problems, systemic disease and other comorbidities, such as smoking (*17*). Even after prolonged treatment, patients may have complications that result in amputation (*18*). Returning patients to their previous functional status remains a challenging goal in these cases. Treatment of infected tibial pseudoarthrosis requires the eradication of infection and the restoration of bone defects during its course. Many different methods of dealing with such problems have been described in the literature (*2*).

The treatment for infected tibial pseudoarthroses is usually initiated with a series of radical debridements that may result in bone defects. External fixators are usually applied for stabilisation. After

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the infection has been cleared, bone defects and shortening are addressed. With smaller defects, acute shortening can be achieved. For larger defects, segment transport based on the principle of distraction osteogenesis may be required (*21*).

Distraction osteogenesis relies on gradual lengthening with the use of external fixation to form new bone where bone defects and gaps exist (*4*). The prolonged use of the external fixator is the most difficult aspect of segment transport or limb lengthening for patients to tolerate. When the full extent of the lengthening has been achieved, patients must wait for consolidation (*3*). During the consolidation phase, patients become eager to have the external fixator removed. Premature removal, however, may lead to regenerate fractures, resulting in deformity, shortening or nonunion. Because of these complications in distraction osteogenesis with external fixation alone, a combined method using an intramedullary nail was devised (*16*). With this method, both the external fixator time and the complications related to the external fixator are decreased. Patients are more comfortable with this method, but the combined method also has risks, such as implant failure and infection (*5*).

The results of the different methods for segment transport in the infected tibia have been described in the literature (*1-15*). To our knowledge, this is the first study to compare the results of treatment of bone defects encountered during treatment of infected tibial pseudoarthrosis using an external fixator alone or using a combined method.

MATERIALS AND METHODS

Between 1998 and 2009, 49 patients were treated for infected tibial pseudoarthroses.The initial step of treatment in all patients was eradication of infection, which was achieved by radical debridement and pathogen-specific antibiotic therapy. Five patients received debridement elsewhere prior to attending our clinic. Different methods of external fixation were applied following the initial management of infection ; these methods included unilateral external fixator (monorail, orthofix), circular external fixator (Ilizarov, hexapod) and external fixator with the intramedullary nail (combined technique). Based on these techniques, we divided the patients into two groups. The external fixation group consisted of patients who underwent external fixation alone (Fig. 1 & 2), whereas patients who were treated with the combined technique represented the combined group (Fig. 3 & 4). In the combined group, we used a locked intramedullary

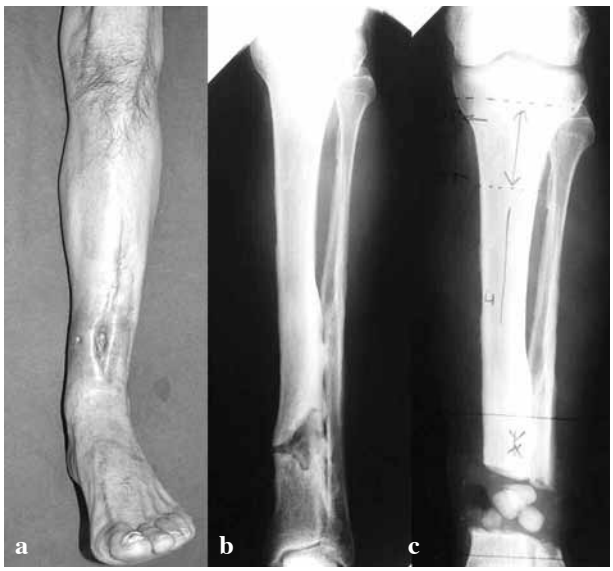

Fig. 1. — External fixator group Patient 9. a) Preoperative clinical photograph. b) AP radiograph of the patient. c) The planning of segment transport after resection of the infected segment.

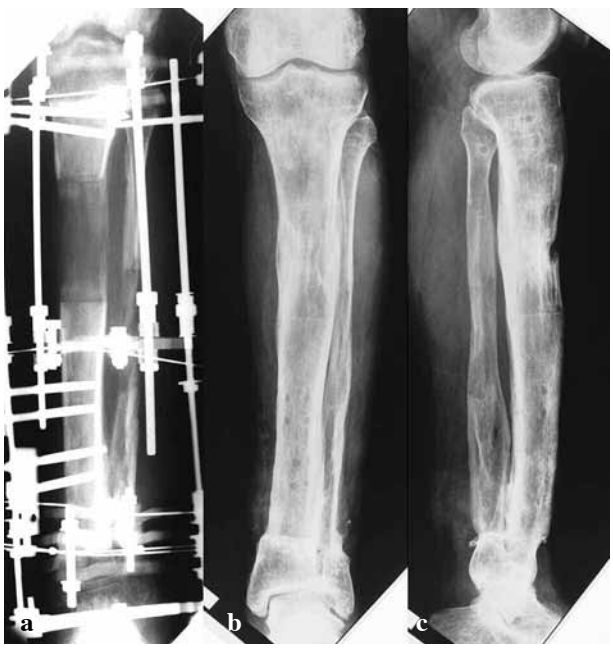

Fig. 2. — External fixator group Patient 9. a) AP view of the segment transport with external fixator alone. b-c) AP and lateral radiographs at the last follow-up visit.

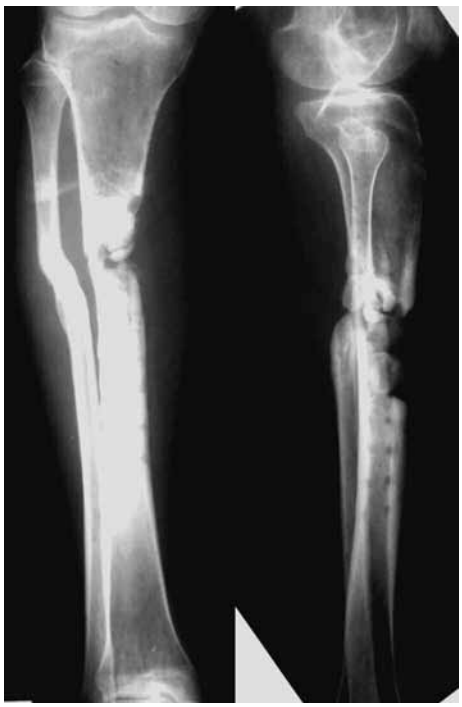

Fig. 3. — Combined group Patient 9. Preoperative AP and lateral radiographs.

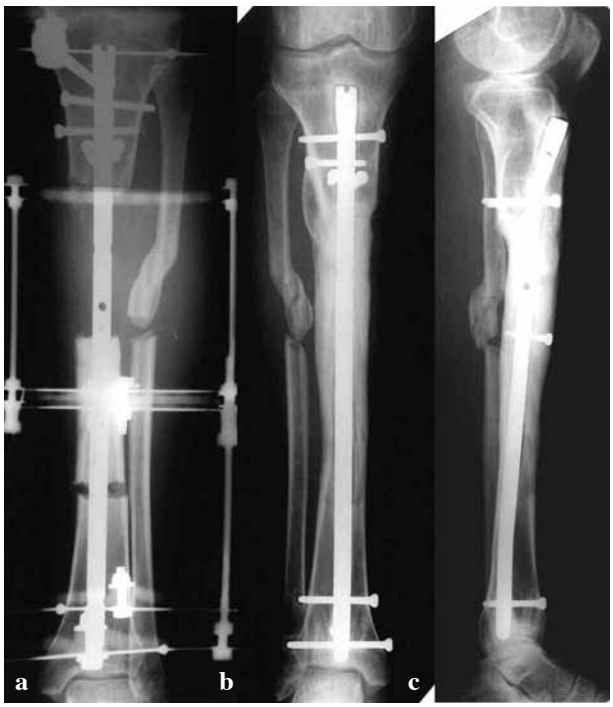

Fig. 4. — Combined group Patient 9. a) AP view of the segment transport with the combined method. b-c) AP and lateral radiographs at the last follow-up visit.

tibial nail (Orthopro Tibia Nail 4G, Orthopro Orthopaedics, İzmir, Turkey). Reaming of the medullary canal exceeded the size of the intramedullary nail by 1.5 mm to prevent possible resistance during distraction. After reaming, corticotomy was done with drills and osteotome. The nail was then inserted. In all patients the fibula was osteotomized and proximally and distally fixed to the tibia with Kirschner wires.

There were 32 patients in the external fixator group (25 males and 7 females, with a mean age of 41 years, ranging from 11 to 79 years). The combined group consisted of 17 patients, 14 males and 3 females,with a mean age of 39 years (range 25-67 years).

Local skin condition, tibial shortening or deformity, distal neurovascular status and joint function were initially assessed in all patients. We measured the bone defect size of each patient at presentation. Following radical debridement, the defect size was increased in most of the patients. Therefore, the post-debridement defect sizes were measured and used as one of the treatment goals along with the achievement of union and reconstruction of limb length discrepancy. The mean initial defect size in the external fixator group was 1.02 cm (range : 0-11 cm), and the mean post-debridement defect was 7.24 cm (range : 1-21 cm) ; patients in this group had a mean of 3.6 (range : 1-13) previous surgical procedures. In this group, based on the Cierny-Mader *(12)* classification, 2 patients were Grade IIB, 3 patients were Grade IIIB, 5 patients were Grade IVA and 18 patients were grade IVB. In the combined group, the mean initial defect size was 4.25 cm (range : 0-16 cm), and the mean post- debridement defect size was 8.89 cm (range : 2.6-16 cm) ; patients in this group had a mean of 3.29 (range : 1-13) previous surgical procedures. In this group, based on the Cierny-Mader classification, 1 patient was Grade IIIA, 2 were Grade IVA, 10 were Grade IVB and 4 patients could not be graded because they were admitted to our clinic after receiving radical debridement elsewhere. When we compared each of these groups based on age, gender, initial and post-debridement defects, number of previous operations and the Cierny-Mader classification, no statistically significant differences were observed between these groups.

All data were collected by reviewing the patients' medical records ; the patient registry was maintained at our hospital, and all radiological and clinical images were stored in the patient archives. The data were stored and analyzed on SPSS statistical software (17.5 version),

Table I. — Overall results

N° Patients initial/final F.U.	External fixator group (n = 32/28)	Combined group (n = 17/15)
Mean age	41 (11-79) years	39 (25-69) years
Gender	25 Male, 7 Female	14 Male, 3 Female
Number of previous operations	3.6 (1-13)	3.29 (1-13)
Initial defect (cm)	1.02 (0-11)	4.25 (0-16)
Defect after resection (cm)	7.24 (1-21)	8.89 (2.60-16)
Lengthening (cm)	8.60 (4-21)	10.32 (4-16)
Months in external fixator	14.00 (6-24)	5.5 (3-8)
External fixator index (day/cm)	56.32 (20-127.5)	16.31 (10-24)
Consolidation time (months)	9.95 (4.5-16)	8.5 (4-12)
Consolidation index (day/cm)	40.09 (13.3-112.5)	25.67 (10-37.8)
Follow-up (months)	35.69 (9-113) 28 patients	28,59 (9-80) 15 patients
Lengthening ratio (%)	24.99 (10.67-65.62)	28.43 (11.76-44.44)
Union/Non-Union	23/5 (4 united after grafting and circular frame)	15 union
Grafting for delayed union	6 patients	1 patient
Regenerate	18 normal 9 narrow at docking 1 narrow at lengthening	11 normal 3 narrow at docking
Bone result Exc/Good/Fair/Poor	15/10/2/0	10/4/1/0
Function Exc/Good/Fair/Poor	19/5/1/3	10/5/0/0

and a p-value of less than or equal to 0.05 was accepted as statistically significant.

Mean values, standard deviation and frequency and percent values were analyzed. To compare frequency and percent values between groups, chi-square and Fisher's exact probability tests were used. To compare the mean values of the variables between the two groups, a t-test was used. The Receiver Operating Characteristic (ROC)curve analysis was used to determine the 'diagnostic performance', compare the effectiveness of the variables and determine the positivity threshold used in decision making.

Nearly all patients were followed up throughout the course of their treatment. Four patients in the external fixator group and 2 patients in the combined group were lost to follow-up. At the time of the last follow-up, functional and radiographic results were evaluated according to Paley *et al*'s criteria (*11*). The complications were also evaluated according to the criteria described by Paley *et al* (*12*).

RESULTS

Table I presents the general results of the study. In the external fixator group, the mean follow-up period was 35.7 months (range : 9-113 months), and 4 patients were lost to follow-up. In the combined group, the mean follow-up period was 28.6 months (range : 9-80 months), and 2 patients were lost to follow-up. In the external fixator group, the mean lengthening was 8.60 cm (range : 4-21 cm), and in the combined group, the mean lengthening was 10.32 cm (range : 4-16 cm).

In the external fixator group, the mean fixator time was 14 months (range : 6-24 months), the mean external fixation index was 56 days/cm, the mean consolidation time was 10 months (range : 4.5-16 months) and the mean consolidation index was 40 days/cm. In the combined group, the mean external fixator time was 5.5 months (range : 3-

8 months), the mean external fixation index was 16.3 days/cm, the mean consolidation time was 8.5 months (range : 4-12 months) and the mean consolidation index was 25.7 day/cm.

The external fixator time and external fixator index in the combined group were significantly lower than those of the external fixator group ($p < 0.05$) ; however, we did not find any statistically significant differences in consolidation time and consolidation index between these two groups.

According to Paley's bone scoring system (*11*), 15 patients in the external fixator group had excellent scores, 10 had good scores, 2 had fair scores and 1 patient had poor bone results. With respect to functional status (*11*), 19 patients had excellent scores, 5 had good scores, 1 had a fair score and 3 had poor results. In the combined group, 10 patients had excellent bone scores, 4 had good scores and 1 patient had fair bone results. In the functional assessment of this group, 10 patients had excellent scores, and 5 patients had good results.

There were no statistically significant differences in bone and functional results between these two groups.

Union was achieved in 23 out of 28 patients in the external fixator group, and there were 5 nonunions in this group. Four of these patients were reoperated with an Ilizarov external fixator, and union was subsequently achieved. At the last follow-up, only one patient had non-union. In the combined group, union was achieved in all patients who were not lost prior to follow-up. Delayed grafting with autologous spongious graft from iliac crest because of delayed union was performed in 6 of the 32 patients of the external fixator group and in 1 of the 17 patients of the combined group . We didn't observe premature fusion.

Reinfection was observed in 2 patients in the external fixator group and in 3 patients in the combined group. There were no statistically significant differences in union and reinfection rates between these groups.

At the end of treatment in the external fixator group, 6 patients had residual deformity, and 5 patients had residual limb length discrepancy. In the combined group, 2 patients had residual deformity, and no patients had limb length discrepancy. In the external fixator group, 3 patients had equinus, and in the combined group, 4 patients had equinus.

There were no statistically significant differences between these two groups.

Complications were described using Paley's classification in which complications were classified as minor (complications that do not require surgical intervention), major without sequelae (complications that require surgery but do not impact the outcome) and major with sequelae (complications that require surgery and impact the outcome) (*14*). In the external fixator group, there were 8 minor complications, 5 major complications without sequelae and 5 major complications with sequelae. In the combined group, there were 2 minor complications, 3 major complications without sequelae and 2 major complications with sequelae (Table II). Upon analysis, there was no statistically significant difference between the two groups with respect to complications. We encountered four grade 3 pin tract infections in the external fixator group but none in the combined group. In the external fixator group, one patient had a broken K wire. In the combined group, one patient who had delayed union and a broken nail during the consolidation phase underwent exchange nailing and bone grafting ; as a result, union was achieved. We had two patients, one from each group, who had soft tissue problems during the lengthening period, which were managed by performing cross leg flaps. One patient, who had lengthening by the Ilizarov external fixator, developed reinfection, which resulted in amputation.

Complications were tabulated against lengthening amount and lengthening ratio in each group and in the whole study population ; however, no statistically significant differences were found between these groups.

With a ROC curve analysis on the combined group with respect to complications (reinfection, nonunion, limb length discrepancy, deformity, etc.), we found a cut-off point in non-union and reinfection. In patients with non-union, we discovered a cut-off point of a 23% lengthening ratio and a tibial lengthening of 8.25 cm. When all patients were analyzed according to this cut-off value, there was a statistically significantly greater incidence of non-union above this limit ($p < 0.05$) ; however, we

Table II. — Complications

Complications	Ext Fix Group	Combined Group
Nonunion	5	None
Reinfection	2	3
Equinus	3	4
Deformity (> 7 degrees)	6	2
Limb Length Discrepancy ≥ 3 cm	5	None
Grade 3 pin tract infection	4	None
Paley Classification	8 Minor 5 Major without sequelae 5 Major with sequelae	2 Minor 3 Major without sequelae 2 Major with sequelae

could not find any differences in group specific analyses.

In patients with re-infection, we found that re-infection occurred at values significantly higher than a cut-off point of a 24.8% lengthening ratio and a tibial lengthening of 9.25 cm ($p < 0.05$). When both groups of patients were analyzed according to this cut-off point, reinfection was statistically higher above this limit in the combined group (96% success rate). Therefore, if the tibial lengthening is greater than 9.25 cm and the lengthening ratio is greater than 24.8%, the external fixator method is safer than the combined method due to the greater reinfection risk in the combined method.

DISCUSSION

The integrity of the tibia regarding length and alignment plays a critical role in gait and in the function of the knee and ankle. As a result, tibial pseudoarthrosis causes considerable functional disability. As a result of repeated ineffective surgeries and soft tissue coverage problems, treatment of this condition becomes increasingly difficult. The problem of non-union is compounded by the presence of infection, bone loss, disuse osteoporosis, soft tissue atrophy and neurovascular damage. Even after prolonged treatment, complications may arise that may result in amputation. The return of the patient to his/her previous functional status remains a challenging goal in these cases (*9*).

Eradicating the infection with radical debridement is the first critical step of the treatment. Radical debridement must be conducted until living and bleeding bone is reached, as described by Cierny *et al* (*20*), and soft tissue problems must also be addressed. For a minimum 6-week period, pathogen-specific antibiotic therapy should be given, and erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) levels must be monitored. The resultant bone defect can be reconstructed by one of the previously described methods.

As a result of Ilizarov's pioneering work on callotasis and distraction osteogenesis, large defects of long bones can be successfully treated by gradually transporting bone segments using external fixators. This technique can be used to simultaneously treat bone defects, soft tissue loss, infection, deformity and leg length discrepancy (*13*).

A prolonged application of external fixation has its own problems and complications.

Because the time for consolidation at the distraction and docking sites is the longest phase of treatment, developing methods that decrease this time period may increase the acceptance of this method. To reduce the treatment time, methods such as double-level transport and lengthening over an intramedullary nail have been described. The use of combined techniques can aid in early removal of the fixator, and can remarkably decrease the external fixator time and index (*16,19*). In this study the external fixation time and external fixation index were indeed significantly lower in the combined technique group than in the fixator only group. There is support in the literature for the use of trifocal segment transport in defects larger than 10 cm because it significantly decreases the fixator

time and its related complications (*21*). Most of the complications that have been observed with the use of distraction osteogenesis are usually external fixator related, such as pin tract infection, and decrease with reduced external fixation time (*10*). We also observed this in the current study, though it was not a statistically significant effect.

Fracture or non-union (including delayed union) of the docking site are the most unique complications of the bone transport techniques (*8*). We observed 5 non-unions after segment transport. Four of these non-unions were reoperated using grafting and an Ilizarov ring external fixator, and union was subsequently achieved. One docking site was not united at the end of the treatment period. Grafting was used in 6 patients in the Ilizarov group and in 1 patient in the combined group because of delayed union. This patient in the combined group also had a nail breakage in the consolidation phase. Exchange intramedullary nailing and bone grafting subsequently lead to union. No patient experienced fractures. The fact that the docking site was protected by bracing after fixator removal in all patients and bone grafts were performed at the docking sites in indicated patients may be the reason for absence of refractures. Additionally, the retained intramedullary nail is supposed to successfully prevent such problems, even when the callus is too immature to remove the external fixator.

Some authors have suggested alternate solutions for the long external fixator time.

Oh *et al* have reported that minimally invasive plating of the consolidation or docking site can prevent collapse after external fixator removal (*12*).

In conclusion, infected tibial pseudoarthrosis and related bone defects can be effectively treated with both methods in experienced centers. The combined method provides comfort for patients with early removal of the external fixator and decreases external fixator related complications, such as pin tract infections. However, complications such as reinfection limit the use of this method in infected tibial pseudoarthrosis. Future studies investigating the appropriate patient for the combined method are required for the appropriate use of this treatment method.

In our study, there were no statistically significant differences in non-union, deformity, limb length discrepancy, bone results and functional results between these two methods.

However, ROC analyses revealed a cut-off value for non-union and reinfection. In all patients, non-union was statistically higher with a tibial lengthening greater than 8.25 cm and a lengthening ratio above 23%. However, there was no statistical difference in non-union between the groups at this value. Nonetheless, we found that re-infection was statistically higher in the combined group with a tibial lengthening of greater than 9.25 cm and a lengthening ratio above 24.8%. In patients who require tibial lengthening above these cut-off values, the external fixator method may be safer than the combined method.

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