Morbidity resulting from the treatment of tibial nonunion with the Ilizarov frame

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Objective: To determine the sources and magnitude of residual morbidity after successful treatment of tibial nonunion using the Ilizarov device and techniques. **Design:** A retrospective cohort study. **Setting:** A level 1 trauma centre. **Patients:** Sixteen patients with healed tibial nonunion. **Intervention:** Application of the Ilizarov device and techniques to obtain union of a previous ununited tibial fracture. **Main outcome measures:** Patient satisfaction and sources of morbidity through clinical review and a visual analogue scale. Two disease-specific outcome measurement scales were used to assess ankle dysfunction. Radiographs were examined to determine the presence of arthrosis. **Results:** Residual pain was present in over 90% of patients at a mean follow-up of 39 months: in 80% the worst pain was in the ankle, less than 10% felt the worst pain in the knee or at the fracture site. Mean ankle osteoarthritis scores were 3.4 for pain and 4.0 for disability, compared with 0.76 and 0.90 respectively for age-matched controls. Mean ankle–hindfoot scores were between 64 and 100. **Conclusion:** Ankle pain with disability is the major source of residual disability after successful use of the Ilizarov device for the treatment of tibial nonunion.

Objectif : Déterminer les sources et l'importance de la morbidité résiduelle après le traitement réussi de la non-consolidation d'une fracture du tibia à l'aide de l'appareil et des techniques d'Ilizarov. **Conception :** Étude de cohorte rétrospective. **Contexte :** Centre de traumatologie de niveau 1. **Patients :** Seize patients chez lesquels la non-consolidation d'une fracture du tibia a été traitée avec succès. **Intervention :** Utilisation de l'appareil et des techniques d'Ilizarov pour consolider une fracture du tibia sans ossification du cal. **Principales mesures de résultats :** Satisfaction du patient et sources de morbidité, selon un examen clinique et une échelle analogique visuelle. Deux échelles de mesure de résultats spécifiques à la maladie ont servi à l'évaluation du dysfonctionnement de la cheville. On a examiné des radiographies pour établir s'il y avait de l'arthrose. **Résultats :** Après un suivi moyen de 39 mois, plus de 90 % des patients éprouvaient de la douleur résiduelle : chez 80 %, la douleur la plus intense était au niveau de la cheville, tandis que moins de 10 % ressentaient la douleur la plus intense au genou ou au site de la fracture. Les résultats relatifs à l'arthrose de la cheville s'établissaient en moyenne à 3,4 pour la douleur et à 4,0 pour l'incapacité, comparativement à 0,76 et 0,90, respectivement, chez des témoins jumelés selon l'âge. Les résultats moyens relatifs à la cheville et à l'arrière-pied étaient de 64 à 100. **Conclusion :** La douleur à la cheville et l'incapacité connexe constituent la principale source d'incapacité résiduelle après l'utilisation réussie de l'appareil Ilizarov dans le traitement de la non-consolidation d'une fracture du tibia.

Application of the Ilizarov frame to treat complex tibial nonunion has become an established orthopedic procedure. The results in achieving union and eradicating infection are well documented.[1–5] McKee and colleagues[6] demonstrated marked improvement with respect to the patient's general health status in the course of treatment using the Ilizarov device to correct post-traumatic lower-limb deformity. In the same study, however, they noted that patients' health status remained well below normal, 2 years after completion of treatment. The causes for this require further investigation. Residual dysfunction after successful treatment

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may have several causes. Complications are common in the course of treatment of ununited fractures with the Ilizarov device.[4,7] In particular, the effect of the Ilizarov device on adjacent joints is of concern since it has been shown to increase the pressure on articular cartilage of adjacent joints.[8] Joint stiffness is another well-recognized complication.[4,6,7] However, these potential sources of residual morbidity are not factored into standard outcome measures of the use of the Ilizarov device.

In this study, a group of patients who had undergone reconstructive surgery that included use of the Ilizarov frame for the treatment of post-traumatic tibial nonunion were reviewed. Our purpose was to identify sources and potential causes of residual disability. Because we perceived a high rate of ankle dysfunction, we included 2 joint-specific outcome measures for the ankle.

Patients and methods

Between 1992 and 1997, 19 patients with post-traumatic tibial nonunion were treated with the Ilizarov device at our institution. Patients who had the Ilizarov frame applied to treat deformity or limb-length discrepancy without a tibial nonunion were excluded. All patients were able to communicate in English sufficiently to complete the clinical review.

Three patients were excluded due to treatment failure resulting in amputation. Two of the 3 failures were due to inability to control infection in medically fragile patients. The third amputation was performed in a patient who could not tolerate the Ilizarov device and elected to undergo amputation. Of the remaining 16 limbs in 16 patients (3 limbs in patients with bilateral nonunion were amputated), 15 (94%) underwent complete radiographic and clinical review. One patient moved more than 500 km away and was available only for review of the clinical results. There were 12 men and 3 women. Mean age was 45 (range from 20–78) years. The mean time from injury to Ilizarov application was 28 months. The initial injuries were classified according to the Orthopaedic Trauma Association comprehensive classification.[9] There were 9 tibial diaphyseal fractures and 6 distal tibia and fibula fractures. Of the diaphyseal fractures, 1 was type A (simple), 5 were type B (wedge) and 3 were type C (complex). Of the distal fractures, 3 were type B (partial articular) and 3 were type C (complete articular fracture). The mean (and standard deviation) distance of the fractures to the ankle averaged 6.1 (6.0) cm (range from 0–20 cm) and 8 fractures were within 5 cm of the ankle joint. Skeletal stabilization at the time of injury was achieved with a cast in 2 limbs, an external fixator in 4, a cast and fibular plate in 1, open reduction with internal fixation in 6 and an intramedullary nail in 2.

At the time of Ilizarov application, the nonunions were classified radiographically as atrophic in 7 patients, oligotrophic in 6 patients and hypertrophic in 2. Prior to Ilizarov application, 8 patients had varus malalignment greater than 5°, 1 patient had valgus malalignment and 3 patients had a hyperextension deformity greater than 10°. Three patients had neutral alignment. Only 1 patient had evidence of osteoarthritis of the ankle joint, and it was mild, with 80% of the joint space remaining compared with the contralateral side. One further patient had previously undergone ankle fusion.

Patients underwent an average of 3.6 operative procedures before application of the Ilizarov frame. Six patients had an active infection at the time of Ilizarov treatment. Five patients had a segmental defect or significant leg-length discrepancy requiring a mean bone transport of 8 cm (range from 4.5–12 cm). All patients who required bone transport were also treated with autogenous bone grafting at the docking site. Seven patients had malalignment requiring correction of a deformity with a hinged frame concomitant with treatment to obtain union. The total time in the frame averaged 7.3 (5.6) months (range from 3–22 mo). The mean follow-up was 39 months (range from 9–72 mo).

The construction and application of the Ilizarov device varied according to nonunion location. In 6 of the 16 patients, a "foot frame" was used to give additional fixation of distal tibial nonunions and to position the foot in space. In these patients, the ankle, subtalar joint and midfoot were immobilized for a minimum of 6 weeks at a position of 0° ankle dorsiflexion and neutral hindfoot position. No compression or distraction was applied across the ankle. As well, 10 patients had a tensioned wire crossing the distal tibiofibular syndesmosis. Both of these frame modifications are thought to potentially affect ankle function; comparative analysis was performed but may have limited value owing to the small numbers in the treatment groups.

At the time of review, patients underwent standard history-taking and physical examination, including assessment of joint motion using a goniometer. Functional status, including employment, disability and use of walking aids was determined, as was the use of analgesic agents. Patient satisfaction was determined from a visual analogue scale in which patients were asked about their level of satisfaction, whether they would recommend their treatment to others and their current level of function compared to that before injury. Standard radiographic measurements, including assessment of alignment and arthrosis were determined from the radiographs obtained before Ilizarov application, after application and at the time of follow-up. For nonunion of the middle third of the tibia, malalignment was defined as a deviation of the anatomic axis of the tibia. Varus or valgus malalignment was defined as more than 5° of malunion, and flexion–extension malalignment was defined as more than 7° of malunion.

Translational malalignment was defined as greater than 5 mm of deviation of the anatomic axis of the bone or 1 cm of shortening. For distal third malunion, alignment was determined by measuring the orientation of the ankle joint relative to the long axis of the tibia. This was compared to the opposite side, and angular or translational deformities as described above were defined as malunion. Arthrosis was measured by comparing the joint space remaining to that in the patient's contralateral uninjured leg. A loss of 25% of joint space was considered significant and a loss of 50% was indicative of severe arthrosis.

All patients completed 2 scoring tools specific to foot and ankle outcome: the Ankle Osteoarthritis Scale[10] and the Ankle-Hindfoot Scale.[11] The Ankle Osteoarthritis Scale is a visual analogue-based scale consisting of 18 items of which 9 relate to pain and 9 to disability.[10] It is a reliable, valid instrument to measure patient symptoms and disability.[10] The Ankle-Hindfoot Scale is 1 of 4 clinical rating systems recommended by the American Orthopaedic Foot & Ankle Society. It incorporates subjective and objective criteria and is graded with a possible 100 points: 50 are allotted to function, 40 to pain and 10 to alignment.[11]

Statistical analysis

The means and standard deviations for the clinical and radiographic outcome measures, including patient satisfaction, Ankle Osteoarthritis Scale and Ankle-Hindfoot Scale were calculated and compared with the following factors: age, fracture location, time in the Ilizarov frame, use of transport techniques, radiographic alignment, radiographic arthrosis and range of motion. This univariate analysis was performed using the *t*-test (for fracture location, use of transport, alignment, arthritis and range of motion) or the Pearson correlation coefficient (for age, time in the frame and range of motion), with a value of $p < 0.05$ considered to be significant.

Results

Clinical results

Of the 19 limbs for which there was adequate follow-up at the time of review, 16 had achieved union and 3 had been amputated. According to criteria set forth by the Association for the Study and Application of the Method of Ilizarov (ASAMI),[12] there were 9 excellent results, 4 good results, 1 fair result and 5 poor results. The limbs with a good result had a residual leg-length discrepancy in 1 case and extension deformity in 3 cases. The limb with a fair result had a residual leg-length discrepancy and an extension deformity. The 3 limbs that were amputated, the limb associated with nonunion of the proximal corticotomy after transport and the limb that refractured after frame removal make up the subgroup with a poor result. The 3 patients whose limbs were amputated were excluded from further review.

Only 1 patient denied having pain. Of the remaining 15 patients all complained of some pain: 14 (94%) complained of ankle pain, 7 (47%) complained of knee pain, 6 (40%) complained of pain at the healed fracture site and 3 (20%) complained of pain at the previous pin sites. Three others complained of ipsilateral hip or foot pain. Twelve (80%) of the 15 felt the worst pain at the ankle joint (Fig. 1).

With regard to function, 10 of 16 patients had returned to work. All patients were fully weight-bearing on the affected limb. One patient continued to use a fracture brace for comfort and 3 used canes. Two patients continued to use narcotic analgesia, and 6 required either nonsteroidal anti-inflammatory medication or acetaminophen.

Complications included pin-track infection (10 cases in 8 patients), adjacent joint stiffness (3), osteomyelitis adjacent to a pin site (1), cellulitis (1), premature consolidation (1), nonunion of a corticotomy (1) and superficial peroneal nerve palsy (1).

The patients completed a visual analogue scale questionnaire to answer 3 questions regarding their overall satisfaction and function. The patients graded their overall satisfaction with the results of their treatment as 77% (23%). The likelihood of the patients recommending similar treatment to other patients was 79% (26%). The patients graded their current level of function, compared with their function before injury at 74% (23%).

Radiographic results

All patients had radiographic evidence of solid union. Alignment was neutral in 11 out of 15. The 4 patients with malalignment all had an extension deformity of greater than 10°, and 1 patient also had a valgus deformity of 8°. Eight patients had radiographic evidence of ankle arthrosis that was severe in 3, with less than 50% of the joint space remaining compared with the contralateral side (Fig. 2). Five patients had radiographic evidence of subtalar arthrosis, which was severe in 2.

Osteopenia was noted in 7 patients at follow-up. Two patients had a leg-length discrepancy greater than 2 cm and 3 patients had a leg-length discrepancy of 1 to 2 cm.

Foot and ankle scores

On the Ankle Osteoarthritis Scale a lower score reflects less pain and less disability. The mean (and SD) pain subscale score was 3.5 (1.9), and the mean disability subscale score was 4.0 (1.6). The average total indexed score was 3.7 (1.6). The population means for patients in similar age groups to the patients studied are 1.13 for pain, 1.33 for disability and 1.3 (1.74) for the index total.[10]

The second questionnaire for ankle status was the American Orthopaedic Foot & Ankle Society Ankle-Hindfoot Scale. On this a higher

score reflects less pain, better function and better alignment. The average (and SD) pain score of our patients was 23.3 (11.8), and the average function score was 32.9 (7.3). The average alignment score was 8.3 (3.1). The average total score was 65.3 (16) (range from 31–87).

Subgroup analysis

We analyzed overall functional scores and foot and ankle scale scores within various subgroups, including range of motion, age, time spent in the frame, radiographic alignment, radiographic arthrosis, use of transport, fracture location and infection.

Of the factors analyzed, range of motion correlated most closely with outcome. Ankle range of motion was considered in 2 ways. First, patients with intact "functional" range of motion, including dorsiflexion greater than 0° and a total arc of motion greater than 30° (11 patients) were compared to patients who did not meet these criteria (4 patients). The patients with intact functional range of motion had better scores on overall function (p = 0.01), Ankle Osteoarthritis Scale pain, function and total score (p = 0.02, 0.04 and 0.01 respectively) and Ankle-Hindfoot Scale pain, function and total score (p = 0.05, 0.004 and 0.002 respectively). Second, patients' total arc of motion was correlated with outcome scores. A positive correlation was noted between ankle motion and overall function (r = 0.58, p = 0.02), Ankle-Hindfoot Scale function (r = 0.6, p = 0.02) and total score (r = 0.53, p = 0.04). Of note is that the range of motion domain of the Ankle-Hindfoot score was excluded from this calculation to avoid interaction among the variables, such that the total possible score was 90 instead of 100.

There was a positive correlation between age and disability (r = 0.54, p = 0.04). However, age did not significantly correlate with overall satisfaction or function ($p > 0.05$).

Increased time wearing the Ilizarov frame led to a decrease in overall function (r = –0.6, p = 0.02) and overall satisfaction(r = –0.57, p = 0.03). However, there was no significant correlation with Ankle Osteoarthritis score, Ankle-Hindfoot score or range of motion ($p > 0.05$).

The patients with neutral alignment (less than 5° varus or valgus and less than 10° flexion or extension) were compared to patients with residual malalignment. Patient satisfaction (p = 0.05) and overall function (p = 0.006) were higher in the patients with neutral alignment.

The patients with severe radiographic ankle arthrosis, defined as less than 50% of joint space remaining, were compared to patients with mild or no arthrosis. The patients with arthrosis had higher pain scores on the Ankle Osteoarthritis Scale (p = 0.07) and lower functional scores on the Ankle-Hindfoot Scale (p = 0.02).

The following factors demonstrated no significant differences with respect to overall function, Ankle Osteoarthritis Scale and Ankle-Hindfoot Scale score: use of transport versus no transport, metaphyseal versus diaphyseal initial fracture location and presence or absence of active infection before Ilizarov treatment. Frame construction, including use of a foot frame and use of a tensioned wire across the distal tibiofibular syndesmosis, was not shown to affect outcome. This may reflect inadequate statistical power due to the relatively small size of the treatment groups for this comparison.

Discussion

This study demonstrated that although nonunion can be successfully healed using the techniques of Ilizarov, residual morbidity remains significant at a mean follow-up of 39 months. Ninety percent of patients

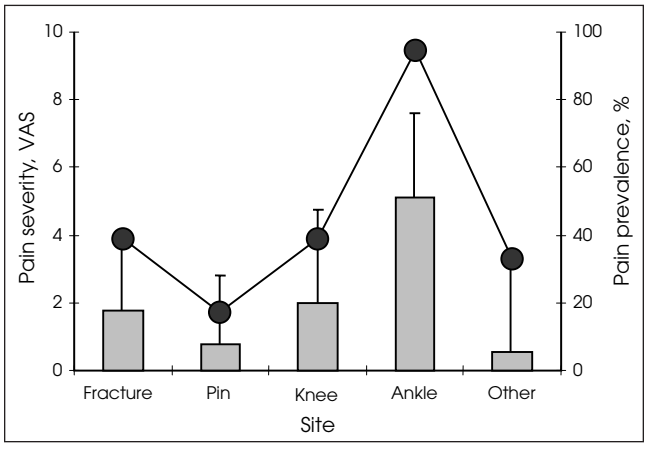

FIG. 1. Mean (and standard deviation) pain severity (columns) according to a visual analogue scale score (VAS) and pain prevalence (circles) at follow-up after application of the Ilizarov frame to treat tibial nonunion. Fracture = nonunion site; pin = site of Ilizarov fine wire or pins; other = ipsilateral hip in 2 patients, ipsilateral foot in 2 patients and back in 1 patient.

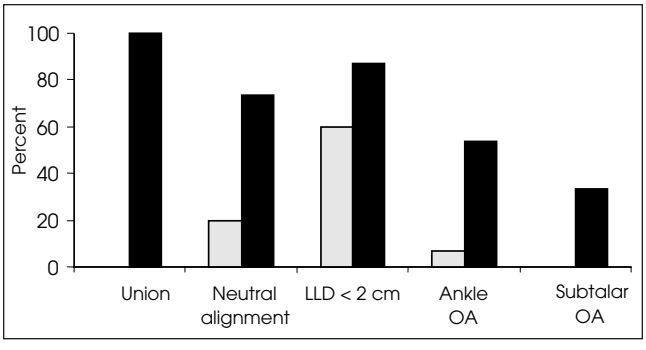

FIG. 2. Percentage of patients with various radiographic outcomes before application of the Ilizarov frame (white bars) and at final follow-up (black bars). Union = clinical and radiographic union, Neutral alignment = < 5° of varus or valgus and < 10° of flexion or extension deformity; LLD = leg-length discrepancy; ankle OA and subtalar OA = osteoarthritis defined as > 25% joint space loss.

in this series had pain even though union had been achieved. The ankle was the major site of morbidity. Nonetheless, patients were also satisfied with the results of their treatment and would generally recommend it to others. This reflects their overall improvement once healing was achieved, as shown by others.[3,4,6]

Ankle and hindfoot morbidity was significant. Radiographically, 7 patients had ankle osteoarthrosis and 5 had subtalar arthrosis over the course of the treatment and follow-up period. Furthermore, the Ankle Osteoarthritis Scale scores were 3 times those seen in normal age-matched controls and Ankle-Hindfoot Scale scores demonstrated significant pain and dysfunction.

The development of ankle dysfunction and arthritis was the finding of most concern in this study. There are several possible explanations. The use of a ring fixator around the distal tibia results in ankle stiffness, with subsequent development of dysfunction and joint space narrowing. Alternatively, ankle dysfunction may result because patients are generally quite immobile and inactive in the first stages of nonunion treatment. Pin-track sepsis may occur, and intra-articular pin placement may ultimately result in joint sepsis. Finally, the development of arthritis in some patients will reflect the natural history of a problematic fracture of the tibial plafond.

The analysis of the various subgroups demonstrated that, in this group of patients, ankle range of motion was closely correlated with outcome. Patients with a functional ankle range of motion scored better in overall function, satisfaction and the 2 ankle-specific outcome systems with regard to both pain and function. Older patients had worse scores for pain and disability, but age had no effect on satisfaction or overall function compared with preoperative status. Age has previously been shown to affect the Ankle Osteoarthritis Scale scores even in normal controls.[10] Therefore, our findings should not be used to suggest that Ilizarov treatment cannot be successful in the elderly.

The other subgroups that correlated with outcome were length of time in the frame, malalignment and ankle arthritis. Although the length of time required to achieve union in the Ilizarov frame was correlated with patient satisfaction, it did not impact otherwise on outcome. Malalignment seemed to correlate with lower satisfaction and more dysfunction but not pain. Radiographic ankle osteoarthrosis was associated with more dysfunction and more pain, but the correlation was less strong than for range of motion.

The overall results and complication rates that we reported are similar to those of previous studies.[1–7] The use of joint- and disease-specific outcome measurement tools provided us with more specific information than would be provided by generic health measures, such as the Medical Outcomes Study Short Form 36 scores. These outcome tools are also more responsive than generic health measures[13,14] and provide information not considered with standard ASAMI data.[9]

The major weaknesses of this study were the retrospective design, relatively small patient numbers and the lack of preoperative foot and ankle data. The patient population was homogeneous in that all patients had a post-traumatic tibial nonunion; however, it should be noted that Ilizarov treatment in fact encompasses a diverse group of therapeutic options, including distraction, compression, transport and various combinations of these.

In this study, the ankle was the major source of morbidity after Ilizarov treatment of tibial nonunion. Of the factors analyzed, range of motion was most closely associated with ankle morbidity. Ankle arthritis, malalignment, time in the frame and age were also correlated with outcome. The Ilizarov device is effective at treating tibial nonunion, as demonstrated in this group of patients. However, residual morbidity appears to be pervasive. Further study should be directed to decreasing this morbidity.

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