



Original Article

The management of tibial fracture non-union using the Taylor Spatial Frame

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ABSTRACT

We reviewed 40 complex tibial non-unions treated with Taylor Spatial Frames. 39 healed successfully. Using the ASAMI scoring, we obtained 33 excellent, 5 good, 1 fair and 1 poor bone results. The functional results were excellent in 29 patients, good in 8, fair in two and poor in one. Mean patient satisfaction score was 95%. All but one patient would have the same treatment again. 28 of the 36 patients in work when injured, returned to work at the time of their final review. Four patients had an adverse event requiring significant intervention. Average treatment cost was approximately £26,000/patient.

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1. Introduction

Internal fixation of tibial fracture non-union, augmented by graft or external stimulus is effective in many cases. However internal fixation is problematic in cases complicated by infection, bone exposure or bone loss, severe deformity and shortening, or internal fixation failure.¹ In some of these complex non-unions, a circular frame represents the only realistic prospect of achieving a good result or avoiding amputation.

The senior author has been using circular frames to manage non-union of tibial fractures for more than 20 years. Although stability, regeneration, lengthening and correction of deformity can be achieved, such techniques do, however, carry significant implications for healthcare resources.²

In a previous assessment of Ilizarov treatment of non-union using functional and radiological outcomes,³ we found that whilst patient satisfaction was high, the cost of such treatment with Ilizarov frames was considerable at around £30,000 per case.⁴

The senior author has since adopted the Taylor Spatial Frame (TSF)⁵ in the management of these complex cases because of the ease and accuracy of deformity correction. Frame alterations in clinic have been greatly reduced, increasing general efficiency.

During the treatment of the non-union, the TSF allows multiplanar deformity corrections simultaneously, rather than sequentially as in the Ilizarov frame.⁶ Whilst differences have been identified between frame philosophies,⁶ none of the previous papers have reflected the sequential practice of a single surgeon.

In order to explore the clinical and financial implications of the use of two different frame systems, we present a single surgeon case series of the management of tibial fracture non-union with the TSF in terms of outcome and resource utilisation.

2. Patients and methods

We defined non-union as failure to achieve or progress towards union after at least 6 months of treatment. This was deemed to be complex if it was associated with one or more of the following criteria: infection at the non-union site, bone defect of more than 4 cm, or a previous failed attempt to achieve union after a minimum of one supplementary intervention such as exchange nailing.

Our definition of union was the presence of bridging trabeculae on three cortices, absence of pain on dynamisation, and absence of movement at the union site when screened using fluoroscopy.³

Patients were identified on presentation to the limb reconstruction clinic at our hospital over 63 months. These patients were treated by monofocal or bifocal Ilizarov techniques, but using the TSF.

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Table 1
Infected non-union cases.

| | Number of cases |
|--|-----------------|
| A1, Quiescent infection, defect <4 cm | 3 |
| A2, Quiescent infection, defect >4 cm | 0 |
| B1, Actively discharging sinus, defect <4 cm | 7 |
| B2, Actively discharging sinus, defect >4 cm | 5 |

The large majority were fixed using 6 mm hydroxyapatite coated screws, 3 per segment if possible. 1.8 mm wires, in plain or olive configurations, were used if bone quality was poor, and this is applicable if there were multiple previous screw holes, or for bone transport segments. In practice, the majority of wires that were used were used in the distal tibia, where prior fixation holes can easily use up the available options as far as screw fixation is concerned.

In most cases 3 or 4 TSF rings were used for increased fixation stability, rather than a 2-ring construct as commonly used in fresh fractures. Pin site care followed the Russian pattern, with weekly cleansing and chlorhexidine dressings.

The notes and radiographs of these patients were reviewed and all patients who met the criteria for complex non-union were included in the study. There were 40 such patients, 30 of which were tertiary referrals from other NHS trusts.

Following completion of treatment an independent reviewer assessed the patients for gait, limb-length discrepancy, and range of movement of the adjacent joints. Functional and radiological outcomes were assessed using the Association for the Study and Application of Methods of Ilizarov (ASAMI) criteria.⁷

There were 28 males and 12 females with an average age of 39.5 years (9–69). 5 patients were alcohol-dependent. Despite being warned that it might delay bone healing, 12 of the 40 patients continued to smoke during treatment. Of the 40 patients, 11 had received non-steroidal anti-inflammatory drugs (NSAIDs) at some stage during treatment of their original fracture.

Road traffic accidents accounted for initial injury mechanism in 26 and fall from a height in 11 patients. Of the 40 non-unions, 24 had an open fracture; 3 were grade 1, 5 were grade 2, 8 were grade 3a and 8 grade 3b according to the Gustilo–Anderson system.⁸

15 patients had an infection at presentation (Table 1). The remainder were not infected, but satisfied at least one other criterion of complex non-union.

The mean number of procedures undergone by each patient prior to referral was 2 (1–5). 15 patients were treated initially by plating, 11 by external fixation, 2 by plaster cast and 12 by intramedullary nailing. With regard to the skin envelope, 10 patients had undergone a soft tissue procedure on presentation (3 split thickness skin grafts, 7 free tissue transfer flaps).

Table 2
Radiographic and functional scoring using ASAMI scoring system.

| <i>Bone results</i> | | |
|---------------------------|---|----------------|
| Excellent | Union, no infection, deformity <7°, limb length discrepancy <2.5 cm | 33 |
| Good | Union + any 2 of the following: absence of infection, <7° deformity and limb length discrepancy <2.5 cm | 5 |
| Fair | Union + only one of the following: absence of infection, <7° deformity and limb length discrepancy <2.5 cm | 1 |
| Poor | Non-union/re-fracture/union + infection + deformity >7° + limb length discrepancy >2.5 cm | 1 |
| <i>Functional results</i> | | |
| Excellent | Active, no limp, minimum stiffness (loss of <15° knee extension/<15° ankle dorsiflexion), no reflex sympathetic dystrophy (RSD), insignificant pain | 29 |
| Good | Active with 1 or 2 of the following: limp, stiffness, RSD, significant pain | 8 |
| Fair | Active with 3 or all of the following: limp, stiffness, RSD, significant pain | 2 |
| Poor | Inactive (unemployment or inability to return to daily activities because of injury) | 0 ^a |
| Failure | Amputation | 1 |

^a Although 12 patients were out of employment at the time of their review, 4 of them were unemployed prior to their injury, and none of them required help with activities of daily living.

Table 3
Complications during treatment.

| | Number of cases |
|-------------------------------|--|
| <i>Problems</i> | |
| Pin site infection | 23 |
| Poor quality regenerate | 2 |
| <i>Obstacles</i> | |
| Wire breakage | 1 |
| Stress fracture at pin site | 1 |
| <i>True complications</i> | |
| Deep vein thrombosis | 1 |
| Pulmonary embolism | 1 |
| Persistent pin site infection | 1 (wire repositioning) |
| Knee flexion deformity | 1 (required above knee extension of the frame) |

Table 4
Details of treatment.

| | |
|---------------------------------------|-----------------|
| Mean length of frame treatment (days) | 323 (95–1195) |
| Mean length of hospitalisation (days) | 20.78 (8–141) |
| Mean number of follow-up appointments | 13.52 (4–54) |
| Mean theatre utilisation (min) | 271.87 (25–827) |

A bifocal compression-distraction technique (compression of the non-union with distraction at a distant corticotomy) was used in 15 non-unions. Monofocal treatment (simple stabilisation and deformity correction of the non-union with stimulation of union by distraction or other methods) was used in 25 non-unions. Bone grafting was undertaken in 12 cases, bone morphogenetic protein (BMP-7) was used in 8 and ultrasound in nine. Electromagnetic induction was not used. Some patients required more than one of these adjuncts.

3. Results

Radiological assessment using ASAMI criteria revealed 33 excellent, 5 good, 1 fair, and 1 poor result.

Functional assessment using ASAMI criteria graded 29 patients as excellent, 8 as good, and 2 as fair (Table 2).

Mean duration of follow-up was 26 months (3–70) and of the 40 non-unions, 39 healed successfully, with mean time to union of 10.5 months (3–38.5). One patient, whilst achieving bony union, ultimately required amputation due to persistent neuropathic pain subsequent to compartment syndrome in the original injury episode.

Mean patient satisfaction score on a numerical scale from 0 to 100 was 95 (80–100).⁹ All but one patient would have the same treatment if they were to suffer from the same condition again. 28 of the 36 patients who were in work at the time of injury, had

Table 5
Particulars of cost estimation.

| Particulars | Cost | Mean cost/patient |
|-------------------------------------|-------------|-------------------|
| In-patient treatment | £314/night | £6524 |
| First out-patient appointment | £144 | £144 |
| Subsequent outpatient follow-up | £125 | £1625 |
| Main theatre running cost | £19/min | £5168 |
| Day case theatre cost | £19/min | £341 |
| Plain radiographs | £73/film | £1952 |
| In-patient physiotherapy | £21/session | £873 |
| Taylor Spatial Frame (average cost) | £9518 | £9518 |
| Sub-total cost | | £26,145 |

returned to work at the time of their final review, and all patients save the amputee walked unaided.

All patients with pin site problems settled with antibiotics apart from one requiring wire repositioning. There were 2 patients with poor quality regenerate; of which one resulted in a deformity requiring secondary correction. There were two thromboembolic events.

We classified the adverse effects of our treatment as problems, obstacles and true complications (Table 3).

Mean duration of frame application was 323 days (95–1195) (Table 4). The 7 patients requiring the frame to be on over one year were all complex cases with 2–3 out of the 3 criteria we used to define complex non-unions present.

Economic analysis carried out for demonstrating an average cost of £26,000 per patient (Table 5). As with our previous work,³ this total excludes the cost of CT scans, bone morphogenetic protein, ultrasound induction and outpatient antibiotic therapy.

4. Discussion

As noted by Dammerer et al., differing techniques of external fixation exhibit individual mechanical characteristics that influence osteogenesis, healing, lengthening and deformity correction.⁶

The TSF concept, utilising the Ilizarov method, involves two or more rings connected at the non-union and corticotomy levels by six telescopic struts creating a virtual hinge, allowing for multi-axial manipulation and the simultaneous correction of length, angulation, translation and rotation.^{10,11} A web link to TSF software allows calculation of the strut adjustments that are necessary to bring this about.

Prior to the introduction of TSF, Ilizarov frames have been utilised in non-union management with good results, including in our own previous series.^{3,7,12–14} Circular frame techniques are not without complications and require both patient compliance and significant healthcare resource. Slow maturation of regenerate, particularly in smokers,^{15,16} residual ankle pain,⁹ requirement for multiple procedures and protracted time in frame alongside the ubiquitous concerns over pin site infection characterises circular frame tibial non-union management.^{2,17,18}

This evaluation allows a useful comparison to our own and other Ilizarov series of similar size. It is unique, however, as it is the only sequential single surgeon comparison available in the literature.

Our outcomes, assessed by the widely used ASAMI classification of Paley et al., allow for generalisation to both our own and other series of tibial non-union surgery. With 38 of 40 cases having excellent or good bone scores, and 36 with excellent or good functional scores, this series reinforces the place of the TSF in the armamentarium of surgeons managing tibial non-union.

Such outcomes achieve parity with, or exceed, previously reported studies of non-union management.^{3,7,12–14} This is of particular note in the context of the considerable soft tissue

compromise, infection and persistence of smoking which characterises this patient group.

The key comparator of this series and the only English language report of TSF use in tibial non-union is that of Rozbruch et al. detailing the outcomes of 38 cases of similar complexity with significant bone defects, infection and numerous previous surgeries.¹⁹

Illustrating the challenging nature of managing these cases, only 27 of the cases of Rozbruch et al. achieved union with the first application of the frame, the remainder requiring a range of secondary surgeries.

Rozbruch et al. similarly used the ASAMI classification and report that bone and functional outcomes were excellent or good in 36 and 34 patients respectively, demonstrating that whilst no attempt has been made to match either numbers or case variables, the two series demonstrate remarkably similar outcomes.

Patient satisfaction in this series is high, and all apart from one would have the same treatment should it be required in the future. Again, as with the bone and functional scores, Rozbruch et al.'s generic outcomes are comparable with significant improvement of both Short Form-36 and AAOS lower-limb scores.¹⁹

Complications were encountered in our series, although when classified as problems, obstacles and true complications (Table 3), only four cases had an adverse event requiring significant intervention. This distribution of minor and major untoward events in our series with predominance of minor pin site infection is similar to established series of frame management of tibial defects and deformity.²⁰

23 out of 40 of our patients developed a pin site infection, an improvement from every patient in our previous study.³ We attribute this to the use of the Russian pin site care regime and the use of hydroxyapatite coated pins in this later series. All cases of pin site infection responded to antibiotic therapy except for one, in which pin repositioning was required.

Aside from the complication profile, the financial cost and duration of treatment have to be considered. Comparisons between lower limb salvage and amputation for complex tibial injury have shown that whilst reconstructive and salvage surgeries demand considerable resource and compliance, mean lifetime cost per patient per year after limb salvage is significantly less than the published cost for amputation.²¹ One series calculated the projected lifetime health-care cost for patients undergoing amputation as three times higher than those treated with reconstruction.²²

Previous attempts have been made to analyse the cost of limb reconstruction for complex non-unions, with Williams et al. reporting the mean cost of managing tibial non-union using the Ilizarov method to be \$59,213 (approx. £33,752).⁴ We report an estimated cost per case of £26,145, less than the £29,204 published seven years earlier where Ilizarov frames were used.³

In addition to the decrease in overall cost, inpatient stay was 48 days at a cost of £12,108 per patient in our Ilizarov frame cohort versus 21 days and £6524 with a TSF. Similarly, total theatre costs are £9794 in the Ilizarov frame cohort versus £5509 for the TSF. It can be seen, therefore, that the actual cost of the frame is the main determinant of cost balance between the two treatment modalities as the TSF at £9518 is three times the cost of the Ilizarov frame.

This study has demonstrated, with the largest series to date, that the Taylor Spatial Frame allows for effective management of tibial non-union. Patient satisfaction, bone and functional parameters reflect good outcomes in a challenging population at a cost which is less than in other series using Ilizarov frames.

Comparison to a single surgeon series of similar non-union cases with Ilizarov frames places the results in a context previously unavailable in the study of tibial non-union management, and adds to the evidence base.

Both the bone and function results are superior to our previous series and when this is achieved in a setting of improved simultaneous correction and at a lesser cost despite the effects of inflation, the true benefits are realised.

In particular, we have shown that the overall financial burden is heavily influenced by frame costs, which overshadow valuable savings in healthcare resource such as significant disparities in theatre costs and inpatient stay. If the considerable costs associated with the TSF could be reduced, the clinical benefits of simultaneous correction of length, angulation, translation and rotation it affords, will be thrown into sharper focus.

Conflicts of interest

The authors have none to declare.

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