AXIAL MOVEMENT AND TIBIAL FRACTURES

A CONTROLLED RANDOMISED TRIAL OF TREATMENT

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Diaphyseal fractures of the tibia in 80 patients were treated by external skeletal fixation using a unilateral frame, either in a fixed mode or in a mode which allowed the application of a small amount of predominantly axial micromovement. Patients were allocated to each regime by random selection. Fracture healing was assessed clinically, radiologically and by measurement of the mechanical stiffness of the fracture.

Both clinical and mechanical healing were enhanced in the group subjected to micromovement, compared to those treated with frames in a fixed mode possessing an overall stiffness similar to that of others in common clinical use. The differences in healing time were statistically significant and independently related to the treatment method. There was no difference in complication rates between treatment groups.

External skeletal fixation is used widely in the management of open tibial fractures, but delayed healing is common. There is concern that this might be due not only to the severity of injury but also to the mechanical conditions imposed at the fracture site by the fixator. Some degree of motion of the fracture fragments stimulates callus formation, according to Sarmiento et al (1977, 1989) and McKibbin (1978). Since fractures treated by external skeletal fixation can rarely be reduced to perfection nor held with absolute stability, union occurs by indirect healing, which is acutely sensitive to both the characteristics and timing of mechanical stimulation. Therefore, the achievement of the optimum mechanical environment is particularly important where delay in bone healing is likely.

Clinical studies reporting the influence of methods of stabilisation upon the healing of tibial fractures have been retrospective and not matched for severity nor mechanical conditions (Burny 1979a,b; De Bastiani, Aldegheri and Brivio 1984) and an earlier study by ourselves was not properly randomised (Kenwright et al 1986).

In our new prospective study, patients have been distributed randomly to each treatment group to test the hypothesis that controlled axial micromovement applied early after injury, will enhance the healing of tibial fractures managed by external skeletal fixation.

PATIENTS AND METHODS

Selection. Initially a total of 82 patients were judged to require external skeletal fixation for diaphyseal fractures of the tibia with associated serious soft-tissue injury and were entered in the trial at two centres (Oxford and Bristol). Their ages ranged from 17 to 75 years. The frame was applied within one week of injury in every case. Fractures were included if the overlying skin was of doubtful viability or following decompression for compartment syndrome, but those with bone loss, or with associated wounds of grade IIIC severity were excluded. Of the 82 patients entered into the trial, one died and another emigrated. The remaining 80 patients were followed through to radiological consolidation of the fracture.

The severity of injury was classified into grades A to D (Table I) depending on the degree of comminution (Johner and Wruhs 1983) and soft-tissue injury (Gustilo and Anderson 1976). If frames were applied because the skin was of doubtful viability or because of compartment syndrome, the soft-tissue wound was classified as of Gustilo grade I severity.

Treatment protocol. A unilateral frame (Dynabrace, Richards Medical (UK) Ltd), designed to provide stable

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Table I. Severity of injury related to mean time to independent weight-bearing in each group

			Mean time in weeks (number of patients)	
Severity grade	Soft-tissue* injury	Bone injury†	Group I Micromovement	Group II Fixed
A	Grade I	Not comminuted	16.15 (8)	22.3 (10)
B	Grade II/III	Not comminuted	25.5 (10)	48.6 (6)
C	Grade I	Comminuted	20.6 (7)	22.2 (7)
D	Grade II/III	Comminuted	26.8 (14)	28.9 (18)
Total			23 (39)	29 (41)

* Gustilo and Anderson (1976)
† Johner and Wruhs (1983)

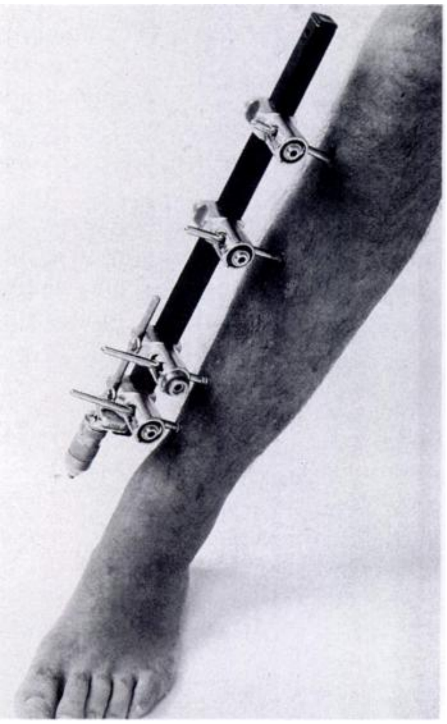

Fig. 1

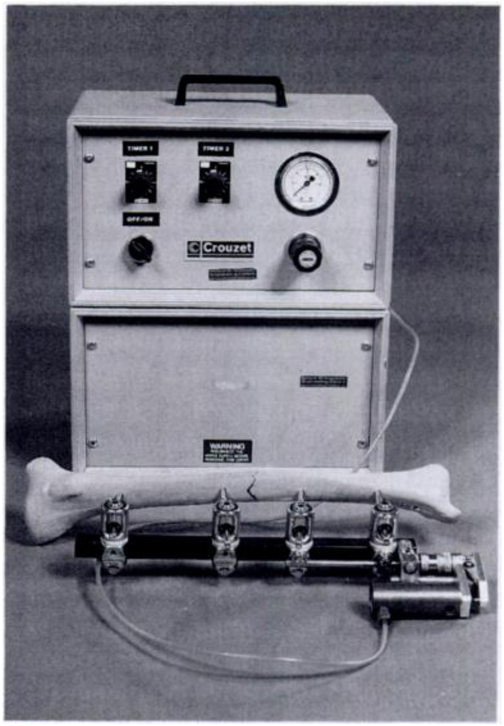

Fig. 2

Figure 1 – The unilateral frame is attached to the medial surface of the tibia by four Schantz screws. Figure 2 – Two sliding clamps are attached to the fixator column and to a spring assembly. They provide complete control of longitudinal displacement and load. A pneumatic pump is attached to the spring module and hence to the sliding clamps so that small controlled increments of axial displacement can be applied.

external fixation, was applied to the medial surface of the tibia (Evans 1985). The geometrical configuration was constructed to resemble, as closely as possible, that shown in Figure 1. The following day, each patient was randomly assigned to one treatment group.

In patients in treatment group I the frame could be modified to allow controlled displacement of two clamps on one side of the fracture with respect to the fixator column; these two clamps fitted closely to the column but could slide longitudinally.

A pneumatic pump was attached to these sliding clamps for a short period each day in the early stages of healing to allow a controlled programme of cyclical axial displacement to be applied to the fracture (Fig. 2). Mechanical stimulation started as soon as the patient was comfortable and always within seven days of fixation, 1.0 mm axial displacement was applied at 0.5 Hz in one session of 20 minutes each day. This regime was similar to that shown to stimulate healing of experimental tibial fractures (Goodship and Kenwright 1985). This externally imposed micromovement was continued daily until patients were ambulant and weight-bearing, or for a maximum period of three weeks. As soon as each patient could bear weight, the tension of the spring which attached the sliding clamps to the column was adjusted to allow axial movement on loading above a level of 12 kg. This allowed an initial axial excursion of the sliding clamps to a preset maximum of 1 mm; a mechanical stop ensured that this amount of displacement was not exceeded. This level of spring tension was maintained throughout treatment in all patients in group I.

Some fractures were stable in the longitudinal axis and little or no movement was seen from the onset of stimulation. In these and in all other patients in group I, the pump was adjusted to apply a maximum force of 300 N to the sliding clamps. This level was chosen to avoid excessive stress at the bone–screw interface (Pope and Evans 1982).

In treatment group II, the micromovement spring was locked from the first day so that no axial movement of the sliding clamps could take place. Early partial weight-bearing was encouraged in both groups. Frames were left on for a minimum of 12 weeks. The decision to remove the external fixator was made by surgeons, based on their own clinical and radiological assessment of fracture union; most preferred to apply a lightweight functional cast after frame removal, until it was considered safe to allow unsupported weight-bearing.

Assessment of healing. Clinical and radiographic examination was made every two weeks. Complications were recorded as well as the total time from injury to unsupported weight-bearing. Mechanical stiffness at the fracture site was measured at the same intervals by attaching a calibrated strain-gauge transducer to the fixator column (Evans, Kenwright and Cunningham 1988). A known bending moment was applied across the fracture and simultaneous recordings made of the deformation of the bar in two planes. As a fracture heals, more load is taken through the fracture, and deformation of the frame/fracture system decreases (Burny 1979a). The specific frame geometry was measured for each patient, and fixator bending stiffness determined from these measurements by direct testing of a reconstructed frame in the laboratory. Absolute levels of fracture bending stiffness (Fig. 3) were then calculated (Churches, Tanner and Harris 1985a,b; Cunningham et al 1987). Fracture stiffness measured in this way is known to increase exponentially with time over the period of healing (Richardson 1989). Logarithmic values were therefore plotted every two weeks and the time taken to reach a bending stiffness of 15 Nm per degree was recorded. This level of bending stiffness represents clinical union; if it is reached it has been shown that consolidation always follows. Early refracture has not been seen even if immediate unsupported weight-bearing has been permitted after frame removal (Richardson 1989).

Statistical methods. Non-orthogonal three-way analysis of variance allowed examination of possible interaction between the variables of soft-tissue injury, comminution and treatment method; this enabled variables to be examined independently. Analysis was made for both clinical healing times and for the time to reach a bending stiffness of 15 Nm per degree. The distribution of the data after logarithmic transformation permitted parametric analysis to be performed.

RESULTS

Clinical results. (Table I)

i) The mean healing time, measured from injury to unsupported weight-bearing, was 29 weeks for patients treated with the frame in fixed mode and 23 weeks for those with micromovement ($p < 0.05$).

ii) The grading of soft-tissue injury influenced healing; the mean time for grade 1 soft-tissue injuries was 20 weeks and for more serious open wounds graded II and III was 30 weeks ($p < 0.01$).

iii) No significant difference in healing times was observed when the degree of comminution was analysed independently. We thought that the use of micromovement and the degree of bony comminution were related, the effect of applied movement on healing times possibly being more beneficial in non-comminuted fractures ($p = 0.06$).

Complications. (Table II) There were no instances of fracture infection in either group and the incidence of screw track infection was not significantly different between the two treatment groups. In seven patients

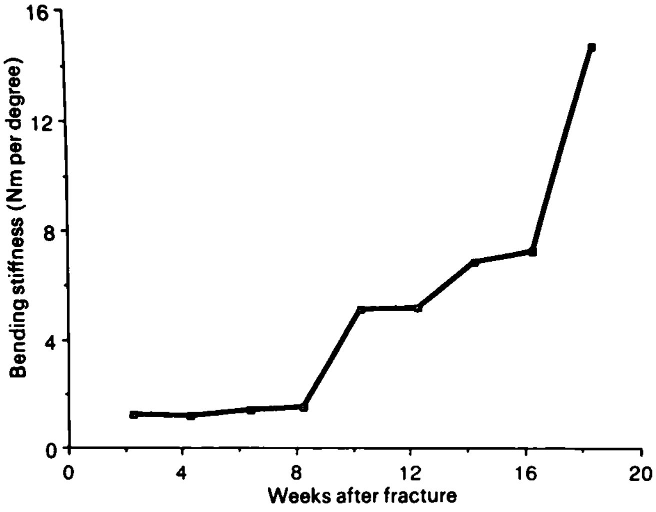

Fig. 3

Fracture bending stiffness rose in an exponential manner during healing in this example of a grade A severity fracture.

Table II. Complications by number and *percentage*

	Group I Micromovement	Group II Fixed
Minor screw track problems	15 (*10*)	28 (*17*)
Major screw track problems	3 (*2*)	4 (*2.2*)
Refracture	0	3
Secondary surgery to achieve bone union	2	3
Fracture infection	0	0

there was distinct loosening of more than one screw. Refracture occurred in three patients in the fixed-mode treatment group. Secondary surgery had to be performed to achieve bony union in a total of five patients, but there was no significant difference between the treatment groups.

Radiography. A long periosteal sheath of callus frequently developed around the bone adjacent to the fracture in the micromovement group (Fig. 4) ; this was not seen in patients treated with frames in fixed-mode. The amount of callus was not quantified.

Biomechanical assessment. Previous investigations have shown that considerable loosening of more than one screw could lead to falsely high stiffness readings (Churches et al 1985a). For this reason, seven patients who had gross loosening of more than one screw were excluded from this part of the study. No bias was noted in the distribution of these fractures according to their severity of injury. Valid gradients of bending stiffness were thus available for 73 patients (Fig. 5). In the five patients who required further surgery and in whom 15 Nm/degree of bending stiffness had not been reached at the time of such surgery, the bending stiffness gradient was extrapolated to reach 15 Nm/degree, and the time taken to reach this level was recorded. No interaction was found between the use of micromovement, soft-tissue injury and comminution, when considering bending stiffness.

There was a significantly shorter healing time, 13 weeks, for fractures treated with micromovement compared with 18 weeks for fractures treated in fixed mode ($p = 0.004$, non-orthogonal three-way analysis of variance).

DISCUSSION

Following a fracture, functional loading of the injured limb is reduced in the early stages. Most methods of treatment involve the application of a supporting device that further reduces the level of mechanical stimulation at a time when a maximal rate of new bone production is required. It has been shown that only short daily periods of appropriate mechanical stimulation are required to perpetuate bone formation in experimental fractures

Fig. 4

Radiograph showing the proliferative callus which formed on either side of the fracture site in many patients treated with superimposed micromovement.

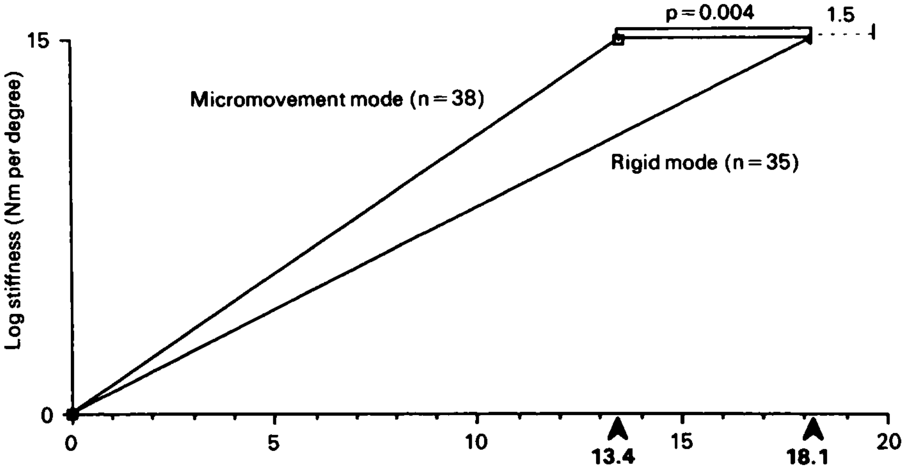

Fig. 5

The overall gradient of increase in bending stiffness for the two treatment groups. The time in weeks taken to reach a bending stiffness of 15 Nm per degree is recorded.

(Goodship and Kenwright 1985). The present clinical trial confirms that this regime, applied in the early stages of healing, can be used in the treatment of clinical fractures in patients.

There are, however, imperfections in this type of clinical study which could bias results; these need to be recognised and considered. Fractures were classified into the four grades of severity, A to D, but such stratification probably over-simplifies the problem of using severity of injury as a prognostic factor. Fractures with associated bone loss were excluded from the study, as were grade IIIC open fractures. Excluding the most severe types of fracture may have decreased mean healing times but should not have led to any bias due to mismatching of the treatment groups. Patients were randomly allocated to treatment groups but there were small differences between the groups according to severity; this potential source of bias was accounted for in the statistical analysis. Patients were also clearly aware of receiving micromovement and as such, were not blind to treatment.

Patients differ considerably in their activity and their level of confidence to apply loading to the fracture, resulting in variation in the mechanical conditions acting at each fracture site. Perhaps too, the attitude of the patient may reflect an inherent feedback mechanism which regulates the level of load applied to the fracture. Small differences between the frame geometry and the fracture pattern would have also contributed to variation in the mechanical conditions acting upon the healing tissues. Such variations should have been distributed randomly throughout the two treatment groups. However, the difference in mechanical conditions caused by the pulsed micromovement will have produced changes in the environment of an order of magnitude greater than those other uncontrolled factors.

The mean time from injury to unsupported weight-bearing was used as one measure of healing because of its clinical relevance, though the judgement of the safest time to discard all splints was based on subjective assessment of clinical and radiological signs. A more objective measure of fracture healing was obtained from strain-gauge monitoring and calculation of fracture bending stiffness. The results from such assessments have been shown previously to be a reliable indicator of the progression of fracture healing (Burny 1979a,b; Cunningham et al 1987). Williams et al (1987) have stressed that stiffness as measured by strain gauges is not the same as strength and resistance to refracture; in clinical practice, however, the correlation between bending stiffness levels and risk of refracture is strong (Richardson 1989). It can also be argued that a measure of the restoration of mechanical integrity of the healing bone is relevant for both patient and surgeon.

Although the defined mechanical regime selected for this trial influenced the pattern of healing, it would be naive to consider that this is the optimal environment. The mechanical conditions required for the various stages of healing for different patterns and sites of fracture have yet to be defined, although it is known there are probably limits of beneficial strain; too little movement inhibits healing and too much prevents it (Sarmiento et al 1977; Kenwright and Goodship 1989). The strain magnitude, rate, force and time of application of mechanical stimulation have all been shown to influence bone healing under experimental conditions (Goodship et al 1987).

The components of applied stimulus in our micromovement group were controlled accurately during the early weeks, the regime of stimulus chosen being similar to that found to enhance healing in experimental studies. This predominantly axial stimulus was superimposed upon the background flexibility of the frame in its fixed mode as used in treatment group II, and similar to that of many frames in common use (Kempson and Campbell 1981). Such studies have shown that these frames allow axial movement to reach 1 mm at a simulated fracture site with a complete gap between bone ends when tested in the laboratory under loads between 20 and 30 kg. However, patients with tibial fractures treated with external fixators can rarely bear sufficient weight to produce such movement at the fracture site in the first few weeks after injury. Axial movements at the fracture site have been recorded during walking when using external skeletal fixation (Cunningham, Evans and Kenwright 1989) and are found to be very small in the early weeks after injury especially if compared with those recorded for patients treated for tibial fractures in long-leg casts (Lippert and Hirsch 1974). Cunningham et al (1989) showed that with external fixation a mean maximum movement of 0.3 mm was not reached until five to nine weeks from injury. In our micromovement treatment group a defined amount of axial movement (1 mm) was imposed upon the fracture within one week of frame application; this was continued for between one and three weeks until the second phase when patients were able to produce axial movement by weight-bearing. It was noted, however, that the excursion of the clamps decreased very rapidly in this second phase. It would seem probable, therefore, that the main influence of the axial movement upon fracture healing seen in this study was associated with the early movement applied via the pump.

There is now a trend towards using more flexible frames, or the adjustment of frames to allow 'dynamisation' of the fracture, increasing the strain acting at the fracture site (Burny 1979b; De Bastiani et al 1984; Behrens and Searls 1986). Dynamisation is an imprecise term and often involves adjustment of the frame to permit unconstrained axial loading of the fracture, with characteristics of interfragmentary motion impossible to define. It is usually prescribed several weeks after fracture when bridging has occurred, though Burny advocated the use of flexible frames throughout treatment. Sliding frames have also been devised which allow axial stress to be applied through weight-bearing (Lazo-Zbikowski et al 1986). In the present study the stimulus was applied early when patients with severe tibial fractures are normally very inactive, whether treated with casts, traction or external skeletal fixation. At the same time there was sufficient stability to retain reduction.

It may prove important to adjust the prescribed regime according to the phase of healing: different movement characteristics may be needed later in serious open fractures, where no granulation tissue may appear for many weeks. Our study has demonstrated the extreme sensitivity of healing fractures to mechanical stimuli. A bone may heal more rapidly in an external fixator if the mechanical environment can be tailored to the needs of the individual fracture and patient.

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