THE USE OF SEMI-RIGID CARBON-FIBRE-REINFORCED PLASTIC PLATES FOR FIXATION OF HUMAN FRACTURES

RESULTS OF PRELIMINARY TRIALS

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Semi-rigid plates have been constructed from epoxy resin reinforced with carbon fibre. These have been used in animal trials and also for internal fixation of 20 fractures of the human tibia. The results are generally very satisfactory, and support the view that semi-rigid fixation is not only desirable theoretically, but also works in practice. However, the results are from preliminary trials only, and it is emphasised that further experience is necessary before widespread use of such plates can be advocated.

The arguments and indications for the internal fixation of fractures of the shaft of the tibia will not be discussed here, since few would deny that there are occasional fractures which can only be treated properly by such means. This paper will concentrate on the method by which internal fixation is achieved, once the decision to use it has been taken.

To achieve the maximal benefit from fixation, unrestricted movement of the neighbouring joints should be allowed, with freedom from external splintage. Such a fixation must be very strong, and if steel plates are used the thickness necessary for this strength imposes rigidity of the fracture. The concept has evolved that this rigidity is not only necessary but also desirable (Müller et al. 1979), and it is with this concept that we take issue.

Increasing experience with rigid fixation has brought to light two important complications, both of which stem from the fact that the virtual elimination of movement at a fracture totally inhibits the formation of external callus, and union has to take place directly between the bone ends: the so-called primary or remodelling bony union. However desirable this may be in theory, clinical experience has shown that in the human subject it is an extremely slow process and current recommendations for the tibia suggest that steel plates cannot be removed safely for at least 18 months after the injury (Müller et al. 1979). Such necessarily prolonged dependence on the plate inevitably leads to problems of implant failure in a proportion of cases, particularly if there have been any shortcomings in surgical technique. More common and equally serious is the osteopenia which develops beneath very strong steel plates as a result of the protection against stress which they confer (Tonino et al. 1976; Paavolainen et al. 1978). The weakening of the bone from this is so troublesome that rates of refracture of up to 1.5 per cent are reported (Müller et al. 1979); and since reface can occur for up to two years after removal of the plate, all patients have to submit to a certain amount of restricted activity once this has been done.

The problem, therefore, is to preserve the advantages of rigid internal fixation while eliminating, if possible, prolonged dependence on the implant. It has been pointed out elsewhere (Mckibbin 1978) that security of fixation and rigidity are not necessarily synonymous, and that the ideal fixation for a fracture is one which offers security to the extent that normal use of the limb is possible, and flexibility sufficient to allow movement at the fracture site, and hence promote rapid bony union by the development of external bridging callus—in other words, semi-rigid fixation. Dependence on such a system would be limited to a short period, and with the flexibility offering only a small degree of stress protection to the bone, the development of osteopenia should be minimised.

It would appear that this goal cannot be achieved by persisting with steel plates, whose low resistance to fatigue stresses will not tolerate the repetitive small movements required, and an unacceptable rate of implant failure would result. Clearly an alternative implant material is necessary, whose elasticity and fatigue tolerance is higher than steel, but whose strength is similar.

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After testing a number of alternative materials in animals, our choice fell finally on epoxy resin reinforced with carbon fibre which has been successfully used in animals by Claes and his colleagues (1980), although their objective was the avoidance of stress protection. In conjunction with the Bioengineering Department of the North Staffordshire Polytechnic, Stoke-on-Trent, a plate was developed for use in the tibia (Bradley, Hastings and Johnson-Nurse 1980). The preliminary results of its use, first in animals and then in a limited clinical trial, are now reported.

MATERIALS AND METHODS

The semi-rigid plate used is constructed from one of the carbon-fibre-reinforced plastics (CFRP), the plastic in this case being an epoxy resin. The plate is multilaminated with the reinforcing carbon fibres running in different directions in each lamina of the resin (Figs 1 and 2).

![Figure 1](image1.png)

**Figure 1**—The eight-hole “standard” design of CFRP plate shown above an eight-hole broad steel DCP of the AO design. Figure 2—Diagram of the CFRP plate to illustrate the laminated structure and varying directions of the carbon fibres within the layers.

The mechanical characteristics of plates made from this material have been reported elsewhere (Bradley et al. 1980), and their ultimate strength compares with that of steel AO plates of similar design (Fig. 3). However, the fatigue strength of these new plates is far greater than their steel counterparts (when submitted to constant strain amplitude tests), as also is their elasticity (Young’s modulus for the CFRP being approximately one-third that of steel).

The CFRP plate is fixed to bone using stainless steel AO screws of 4.5 millimetres diameter.

**Animal trial.** Two groups of sheep were used. In the first, a single transverse osteotomy was performed through the mid-shaft of one tibia, this osteotomy then being reduced and fixed with an eight-hole broad dynamic compression plate (DCP) made of the CFRP. The second group of sheep had a double osteotomy performed through the mid-shaft of one tibia, with the production of an avascular segment of bone approximately one centimetre long between the two osteotomy sites, an animal model similar to that of Olerud and Danckwardt-Lillieström (1971). This double osteotomy was then reduced and fixed with an identical plate.

The sheep were killed at approximately two-weekly intervals from the fifth until the twenty-fifth week. After death, both fractured and intact tibiae were removed from each animal, and stripped of all soft tissues. The bones were then submitted to four-point bending tests to establish their stiffness and ultimate bending strength. Owing to wide variations in the measurements between individual animals, it was felt that the ratio of strength between the osteotomised tibia and the intact tibia in the same animal would be the only useful figure.

**Clinical trial.** Transverse and short oblique fractures of the mid-shaft of the tibia, including those with butterfly fragments, were chosen for study, all compound and undisplaced fractures being excluded. All plates were applied to the tibia within a few days of injury, the wounds were routinely drained with vacuum drainage for two days and were dressed with pressure bandages, a back slab of plaster of Paris being applied to maintain the ankle in a neutral position. All patients remained in bed for a few days, until the dressings and plaster were removed. As soon as the leg felt sufficiently comfortable, which varied between individuals from 3 to 10 days, the patients were mobilised bearing weight on the fixed fracture but, in most cases, with the assistance of walking-sticks. The progress of all patients was followed up both clinically and radiologically at regular intervals. When the fracture was judged to be sound the plates were removed from the tibia through the original incision and, as soon as the wound was healed, unrestricted activity was allowed.

RESULTS

**Animal trial.** In Group 1 all osteotomies healed rapidly with the production of abundant external callus (Fig. 4), normal strength in the bone being achieved after about 20 weeks. In Group 2, again all osteotomies healed rapidly with good external callus formation (Fig. 5), normal strength being achieved by about 25 weeks.

**Clinical trial.** Details of the 20 patients who entered the trial are summarised in Table I. Nineteen of them were male, and one was female, their average age being 21
years. Ten of the fractures were sustained in road traffic accidents and 10 were football injuries.

The first seven patients were treated with plates designed on the AO dynamic compression model with the intent of reducing the fracture gap to a minimum in order to limit the strain on the implant. However, this idea proved to be counterproductive since the additional protection to the plate was more than offset by the loss of strength produced by having large oval screw holes. Although six of these seven patients went on to sound union, three of them complained of severe aching pain at the fracture site on bearing weight. The only patient to develop a hypertrophic non-union (Case 6) suffered a mechanical failure of the plate due to a manufacturing defect. Because of these initial experiences, the stiffness of the plate was increased by substituting round screw holes for the DCP slots, and no attempt was made to compress subsequent fractures. The effects of this definite modification on the physical properties of the plate are illustrated in Figure 3.

This revised "standard" plate was used on the remaining 13 patients. All progressed most satisfactorily

\[ \begin{array}{|c|c|c|c|c|c|} \hline \text{Case} & \text{Site} & \text{Fracture} & \text{Time until:} & \text{Complications} \\ \hline & & \text{First sign of} & \text{Plate removed} & \\ & & \text{external callus} & (weeks) & \\ & & \text{(days)} & \\ \hline \text{Eight-hole dynamic compression plate} & & & & \\ \hline 1 & R tibia & Short oblique & 45 & 43 & — \\ \hline 2 & R tibia and fibula & Short oblique & 24 & 53 & — \\ \hline 3 & R tibia and fibula & Traverse & 92 & 47 & — \\ \hline 4 & R tibia and fibula & Oblique with butterfly & 32 & 16 & Deep infection \\ \hline 5 & R tibia and fibula & Traverse & 44 & 57 & Severe ache at fracture site \\ \hline 6 & L tibia and fibula & Short oblique & 167 & 37 & Hypertrophic non-union. Bone graft performed \\ \hline 7 & R tibia & Short oblique & 42 & 39 & — \\ \hline \text{Eight-hole standard plate} & & & & \\ \hline 8 & R tibia and fibula & Transverse & 90 & 46 & — \\ \hline 9 & R tibia and fibula & Transverse & 42 & 39 & — \\ \hline 10 & L tibia and fibula & Transverse & 78 & 47 & — \\ \hline 11 & R tibia and fibula & Short oblique & 83 & 54 & — \\ \hline 12 & R tibia and fibula & Oblique with butterfly & 119 & 52 & — \\ \hline 13 & L tibia and fibula & Short oblique with butterfly & 66 & 51 & Deep infection \\ \hline 14 & R tibia & Oblique & 56 & 59 & Associated fracture of R femur \\ \hline 15 & L tibia and fibula & Transverse & 48 & 29 & Deep infection \\ \hline 16 & L tibia and fibula & Transverse & 48 & 48 & — \\ \hline 17 & R tibia and fibula & Short oblique with butterfly & 54 & 48 & — \\ \hline 18 & L tibia and fibula & Large butterfly & 72 & 33 & — \\ \hline 19 & R tibia and fibula & Short oblique & 42 & 39 & — \\ \hline 20 & R tibia and fibula & Short oblique & 55 & 41 & — \\ \hline \end{array} \]
to sound bony union, with the production of external callus, and all but two were able to take weight virtually painlessly on the fixed fractures. In the two exceptions the pain was found to be due to the presence of deep infection, further details of which will be given later.

Some illustrative case histories will now be described.

ILLUSTRATIVE CASE HISTORIES

Case 1. A 17-year-old youth sustained a short oblique fracture of the lower mid-shaft of his right tibia as a result of playing football. He was initially treated with an above-knee plaster, but after three weeks the tibia had displaced into varus (Fig. 6) and so the fracture was internally fixed with an eight-hole DC style CFRP plate (Fig. 7). The wound healed well and on the tenth day he was discharged home bearing weight with the assistance of walking-sticks.

He returned two weeks after discharge from hospital (49 days after fracture) with a red painless swelling over the fixed fracture and a considerable amount of superficial bruising, which he admitted cheerfully was due to playing football. He continued without any restraints, and after six months a large callus was noted to have developed at the fracture site. However, a radiograph (Fig. 8) showed a persistent line through the centre of this callus and therefore the plate was kept untouched for a further 17 weeks, by when the line had disappeared (Fig. 9). Forty-three weeks after injury the plate was removed and the patient was allowed to return to normal activities. He has had no further troubles.

This case illustrates that even with an intact fibula sufficient movement can occur in the semi-rigidly plated tibia to enable a good external callus to develop.

Case 17. A 20-year-old man was involved in a football accident in which he sustained an oblique fracture of the lower shaft of the right tibia and fibula, with a butterfly fragment still partially attached to the lower fragment of the tibia (Fig. 10). The tibia was internally fixed with a standard CFRP plate, the day after injury (Fig. 11), and after one week in bed the patient was allowed home bearing weight. Four weeks after the injury he was clinically normal and requested permission to

return to playing football. At first this was refused, but by the eighth week he had developed a good external callus (Fig. 12) and so returned to his job as an erector of scaffolding. By the forty-eighth week the fracture was judged to be sound, the plate was removed and the patient returned to unrestricted activities.

To obviate problems with wound healing, the first 16 patients in this series had their plates well buried under muscle on the lateral side of the tibia. This patient, and all subsequent ones, had the plate positioned on the medial side of the bone, and they all appeared to be most satisfactory clinically. In this patient the external callus

Fig. 6
Fig. 7
Fig. 8
Fig. 9

Case 1. Figure 6—Radiograph showing the fractured tibia displacing into a position of varus. Figure 7—Radiograph showing the fracture fixed with a radiotranslucent CFRP plate. Figure 8—Six months after fracture, a large external bridging callus has developed, with a radiotranslucent centre. Figure 9—Ten months after fracture the large callus has almost uniform radiodensity.

Fig. 10
Fig. 11
Fig. 12

Case 17. Figure 10—Radiograph showing the initial fracture. Figure 11—The fracture fixed with a CFRP plate. Figure 12—Eight weeks after fracture a good external bridging callus has developed.
appeared about the same time as with the others but no transverse line was seen in it.

Case 11. An 18-year-old youth sustained a short oblique fracture of the lower third of the right tibia and fibula as a result of a sports injury (Fig. 13). The tibia was internally fixed four days later with an eight-hole standard CFRP plate without compression. The patient mobilised extremely well, walking completely unaided on the ninth day. By the sixteenth week a very large callus had developed at the fracture site (Fig. 14), although a line was still noted through its centre. This line gradually faded (Fig. 15) and then, 54 weeks after the fracture, the plate was removed and normal activity allowed.

This case illustrates the typical double fracture of the lower leg, and subsequent development of a large external bridging callus at the fracture site following semi-rigid fixation. As in the preceding case, the line through the centre of the callus was seen, but appeared to be clinically irrelevant.

Case 15. An 18-year-old youth sustained a transverse fracture of the mid-shaft of the left tibia and fibula as a result of a road traffic accident (Fig. 16). The tibia was internally fixed on the lateral side with a standard CFRP plate two days after the accident, but the wound became infected and healed rather slowly over the following three weeks (Fig. 17). The patient was then allowed to bear weight on this leg, but six weeks from his accident he complained of severe pain at the

![Fig. 13](image13.jpg)
![Fig. 14](image14.jpg)
![Fig. 15](image15.jpg)

Case 11. Figure 13—Radiograph showing the initial fracture. Figure 14—Radiograph 16 weeks after fracture and subsequent fixation with a radiotranslucent CFRP plate. Because of difficulty with contouring the plate, the fracture was fixed with five screws above and three below. Note the development of a large external callus with a somewhat radiotranslucent centre similar to that in Figure 8. Figure 15—Radiograph 54 weeks after fracture, showing a uniformly radiodense external callus.

![Fig. 16](image16.jpg)
![Fig. 17](image17.jpg)
![Fig. 18](image18.jpg)
![Fig. 19](image19.jpg)

Case 15. Figure 16—Radiograph showing the initial fracture. Figure 17—The fixed fracture. Figure 18—Six weeks after fracture there is rarefaction of bone caused by deep infection. Figure 19—Radiograph 24 weeks after injury showing a large external callus on the medial side of the tibia. The old fracture line is still visible on the lateral side of the tibia.
fracture site which(101,168),(923,194)(101,168),(923,194) was reddened and very tender to touch. A radiograph (Fig. 18) showed bone rarefaction occurring and the presence of deep infection was diagnosed. He was therefore treated with antibiotics and a plaster gaiter, which totally controlled his symptoms. He was allowed to carry on weight-bearing normally and by the ninth week external callus began to appear. Although a sinus, which grew Staphylococcus aureus, appeared on the medial side of the fracture, the patient progressed well and by the sixteenth week he was able to walk painlessly on the unsupported leg. At 24 weeks the external callus looked well developed (Fig. 19) and so a few weeks later the CFRP plate was removed from the bone, and the sinus excised and packed open. Both sinus and wound healed rapidly, and after a precautionary four weeks of guarded weight-bearing, the patient was finally allowed unrestricted activities 33 weeks after first sustaining his fracture. He is now free of symptoms and without problems.

Although no attempt is made to conceal the near-disastrous consequences of open operation in this case, it must be emphasised that serious infection is a problem of all forms of internal fixation. Furthermore, it is salutary to speculate on how long this patient might have been incapacitated had the fracture originally been fixed with a rigid plate and then become infected—76 weeks being the usual time recommended for such tibial fixation to remain in position even in the absence of infection.

**Case 3.** A 26-year-old man sustained a transverse fracture of the mid-shaft of the right tibia and fibula as a result of a football injury (Fig. 20). The fracture was internally fixed the following day, using a compression CFRP plate, and after three days in bed he was mobilised, bearing weight with the aid of a walking-stick. The wound healed well, but the patient required the assistance of a walking-stick for about six weeks. Radiographs showed that when the fracture was fixed a very large cortical defect remained on the medial side of the tibia (Fig. 21). Very little reaction was observed for the first nine weeks, but external callus finally appeared by the twelfth week; after 23 weeks a good strong union was quite evident radiographically (Fig. 22) and by 47 weeks after the injury the callus was well developed and the plate removed. The patient was allowed normal activities after healing of the wound and he has had no further trouble.

Had the fracture been fixed in this manner with a rigid steel plate, then the risks of plate failure due to metal fatigue would have been very high. In this case the plate not only sustained the stress, but allowed rapid bony union to occur and the patient returned to a normal life style in less than a year.

**DISCUSSION**

It was quite clear that the CFRP plate worked as predicted in sheep tibiae subjected to the single osteotomy, with strong union being achieved quickly while the animals walked about relatively normally. However, in the human diaphysis such rapid union can only take place via external bridging callus and therefore, in order to be quite certain that in these sheep osteotomies none of the strength was due to rapid "primary bone union", the second experiment was devised. With an avascular segment of bone in the healing area there is obviously no question of union by the linking of living bone ends, and hence in the early weeks all the strength of the healing bone must lie in the external callus. Once again the CFRP plate allowed the bone to heal quickly with the production of external callus and the attainment of normal strength by about 25 weeks.

The purpose of the clinical study was to demonstrate that the undoubted, theoretical advantages of semi-rigid fixation are borne out in practice in the human subject. As far as we are aware, this series of deliberately semi-rigidly plated fractures in human subjects is the first published and, as can be seen, the initial results are most encouraging.
The desirability of movement at a fracture site has been shown clearly, for external bridging callus appeared in all cases, although in varying quantities, and went on to produce a fairly rapid sound union in all patients except one. In that one (Case 6) the cause of non-union was failure of the implant, of a design which has now been abandoned, leading to excessive movement at the fracture site. Unfortunately, although we have shown that some movement at the fracture site is desirable, it is well known that excessive movement leads to non-union (Watson-Jones 1955) and the important boundary between excessive and desirable movement has never been established. It is tempting to suggest that the excessive flexibility, which developed in the plate in Case 6 (see Fig. 3), represents a limit beyond which non-union is bound to take place in the human tibia; however, this is highly speculative at present and it has to be conceded that no one knows the amount of movement desirable at any particular fracture, nor whether this amount varies between bones or between subjects.

Three further advantages of semi-rigid fixation have become apparent and warrant emphasis. First, accurate juxtaposition of the fragments is clearly not essential (Case 3), since external bridging callus has a most "forgiving nature" in this respect and bridges small defects. Secondly, experience in Case 15 offers the hope that the problems with deeply infected fixed fractures may not be so prolonged or potentially disastrous with semi-rigid plates as with other forms of internal fixation. Thirdly, in no case has there been any radiographic evidence of the development of osteopenia. As a result all patients have been allowed to return immediately to their normal life style after removal of their plates, and so far there have been no problems.

Despite the very encouraging results, these plates are experimental and the work needs to be restricted for some time to come. However, using the stronger "standard" design of CFRP plate, only minimal problems have been encountered, and we believe that this design will eventually prove satisfactory for general use.

Finally, although the problems arising from this new method of fracture fixation have been outlined in some detail, it should be remembered that even including the complicated cases all patients were permanently discharged to totally unrestricted activities is less than 14 months from the date of their fracture.

REFERENCES


