CARBON FIBRE COMPOSITE BONE PLATES

DEVELOPMENT, EVALUATION AND EARLY CLINICAL EXPERIENCE


From Hartshill Orthopaedic Hospital, Stoke-on-Trent

We compared the mechanical properties of carbon fibre composite bone plates with those of stainless steel and titanium. The composite plates have less stiffness with good fatigue properties. Tissue culture and small animal implantation confirmed the biocompatibility of the material.

We also present a preliminary report on the use of the carbon fibre composite plates in 40 forearm fractures. All fractures united, 67% of them showing radiological remodelling within six months. There were no refractures or mechanical failures, but five fractures showed an unexpected reaction; this is discussed.

In a retrospective review of AO plating in 133 forearm fractures (unpublished data) we found that some mechanical failure had occurred in 9% (fracture of plate 3%, loosening 6%) while biological failure had occurred in 13% (non-union 5%, cross union 3%, infection 5%). Hadden, Reschauer and Seggl (1984) have reported a similar experience.

This led us to consider the use of a less rigid implant which would provide a more biological method of fixation. Tayton et al (1982) have reported the clinical use of a similar plate for tibial fractures. We now report further developmental and experimental work on these plates, and have analysed our results with special attention to the biological responses.

M. S. Ali, FRCS, Consultant Orthopaedic Surgeon
Consulting Rooms, 31 Priory Street, Dudley DY1 1HD, England.
T. A. French, FRCPath, Consultant Pathologist
Central Pathology Laboratory, Stoke-on-Trent, England.
G. W. Hastings, DSc, PhD, CChem, FRCS, FPRI, Professor of Bio-
Medical Engineering
North Staffordshire Polytechnic, College Road, Stoke-on-Trent ST4
T. Rae, BSc, PhD, Senior Research Assistant
Orthopaedic Research Unit, Addenbrooke's Hospital, Cambridge,
England.
N. Rushton, MD, FRCS, Director
Orthopaedic Research Unit, University of Cambridge, Cambridge,
England.
E. S. R. Ross, FRCS, FRACS, Consultant Orthopaedic Surgeon
Hope Hospital, Eccles Old Road, Salford, Lancs M6 8HD, England.
C. H. Wynn-Jones, FRCS, Consultant Orthopaedic Surgeon
Hartshill Orthopaedic Hospital, Hartshill Road, Stoke-on-Trent ST4
7NZ, England.

Correspondence should be sent to Mr C. H. Wynn-Jones.

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MATERIALS

Bone plates made from carbon fibre-reinforced epoxy resin were developed from work on bone substitutes (Hastings and Wyatt 1972; Hastings and Thanh Thuy 1976; Hastings 1978; Bradley, Hastings and Johnson-Nurse 1980). The plates are made by the heat lamination, under pressure, of sheets of carbon fibre pre-impregnated with epoxy resin (CIBA-Geigy Ltd, Fibredux 920TS) and placed in a mould in a predetermined order and orientation. Screw holes and countersinks are machined into the plate, which is then cleaned ultrasonically.
Sterilisation is by autoclaving. The number of laminations and the fibre orientation in each plate design varies with the intended use. The outermost layers always have fibres aligned along the long axis of the plate; inner layers are alternatively angled left and right at 45° to this axis. A total of 21 laminations is used for the forearm plates.

**Mechanical properties.** Figure 1 shows a typical load-deflection curve for a carbon composite forearm plate loaded in 4-point bending (British Standards Institution DD27: 1983) before and after the drilling of screw holes, in comparison with standard stainless steel and titanium alloy plates (Bradley 1980; Hastings 1985). Comparative fatigue studies were also made, using a constant amplitude, reversed bending, cyclic loading system in which two-thirds of each cycle was applied in distraction. None of the carbon composite plates failed in one million cycles for a range of loadings. Change in stiffness was used as a measure of fatigue damage and by this means an endurance limit was derived (Fig. 2).

**COMPATABILITY**

Carbon fibre-reinforced epoxy resin was obtained in particulate form from the surface of a bone plate by dental burring. The particles produced were subjected to a sedimentation procedure (Rushton and Rae 1984) to separate out those smaller than about 10 nm. The remaining particles were sterilised by immersion in 70% ethanol and dried.

**In vivo.** In groups of Tuck TO female mice of 10 to 20 g body-weight, about 0.5 mg of material was injected either into the right knee (Rae 1986) or as close as possible to the periosteum of the femur, accepting that some of the material was then deposited intramuscularly.

There were 30 animals in each group; five were killed after each of 4, 8, 16, 26 and 52 weeks. Tissue from the knee or around the femur was dissected out and fixed in 10% buffered formal saline, specimens which included bone being decalcified in 5% trichloroacetic acid. Sections approximately 8 μm thick were cut from wax-embedded tissue and stained with either haematoxylin and eosin or Masson trichrome stain.

**In vitro.** Mouse peritoneal macrophages in vitro were used to screen the material for toxicity and inflammatory potential. The release of a cytoplasmic enzyme marker, lactate dehydrogenase (LDH) was used as an indicator of cell death, and two lysosomal enzyme markers, B-glucuronidase (B-G) and N-acetyl-D-glucosaminidase (NAG), were used as measures of inflammatory potential.

Macrophages were grown in culture at a density of $2 \times 10^6$ cells ml in 1.7 cm diameter multi-well dishes in Medium 199 (no supplements). Cells were exposed to particulate material for periods of 0, 2, 4, 8 and 16 hours at doses of 0, 0.25, 0.05 or 0.1 mg/well. LDH was assayed using a kinetic assay (Rae 1975) and the lysosomal enzymes were assayed using a fluorimetric technique (Rae 1986).

**Results.** No satisfactory stain was found to identify deposits of epoxy polymer specifically, which was not birefringent under polarised light. Positive identification was therefore not possible, but could be inferred by the presence of carbon fibre. On this basis, deposits of carbon fibre were taken also to indicate the presence of epoxy resin.

In the joint tissues the particles produced only a very mild response (Fig. 3). Deposits were seen in fatty tissue adjacent to the cruciate ligaments and in the synovium, but even after one year of implantation there was little...
evidence of chronic inflammation. Although the macrophage-like cells of the synovium had phagocytosed the material (Fig. 4), there was no obvious thickening or infiltration of macrophages. Multinucleate giant cells were rarely seen.

In muscle, despite the relatively large deposit of material visible (Fig. 5) there was little reaction at 16 weeks after implantation, with no marked macrophage infiltration. Giant cells were rarely seen. This generally mild response was unchanged at 52 weeks, and sections stained with Masson trichrome showed no evidence of the formation of collagen. Fibroblasts were never a prominent feature; their absence accounts for the low degree of fibrosis.

![Fig. 4](image)

**Fig. 4**

Synovium 52 weeks after implantation of particulate material. There are no macrophages or multinucleated giant cells.

The marker enzyme release studies show that the particulate material caused no additional release of LDH or B-G above that released from control cells over the 16-hour incubation period. Microscopic examination of the cells exposed to CFRP showed that, although particulate matter less than about 5 μm had been phagocytosed, the macrophages had maintained a normal appearance, and did not appear to be toxic. Such a finding is consistent with the absence of release of LDH.

**CLINICAL SERIES**

From 1980 to 1984, carbon fibre composite plates (Ali et al 1986) were used for 40 fractures of a forearm bone in 29 patients. The plates had six or seven holes and were identical in size and shape to an AO 3.5 mm dynamic compression plate. The patients' mean age was 26 years; 21 were men. One patient had fractures of both forearms. The distribution of fractures in the radius and ulna is shown in Figure 6: 70% were transverse or short oblique, 16% had butterfly fractures and the remainder were comminuted. Two were compound fractures, one contaminated from without.

The radius was approached anteriorly and the ulna posteriorly. The fracture was reduced and fixed with a six- or seven-hole plate using standard AO stainless steel screws with minimal soft tissue dissection.

![Fig. 5](image)

**Fig. 5**

Muscle specimen 16 weeks after implantation. Reaction is confined to the immediate vicinity of the material. A few mononuclear cells are present but there is no evidence of a fibrogenic response.

Early in the series, using AO principles, an interfragmentary compression screw was commonly used (30% of fractures). This technique seemed to suppress callus formation, so, as confidence increased, no such screws were used. All the plates and screws were removed when union was complete.

![Fig. 6](image)

**Fig. 6**

Distribution of the plated fractures in the radius and ulna.

**Results.** We recorded complete radiological union when the fracture line had been completely abolished and the medullary cavity had reformed. Functional union, defined as the stage at which there was enough callus to allow normal activity by the patient, occurred much
earlier, but 67% of the fractures showed radiological remodelling within six months (Fig. 7). The three patients with delayed union were all over 50 years of age, one had a compound, contaminated injury.

Macroscopic appearance. At removal of the plates, in five of the 40 fracture sites, there was some reaction with opalescent free fluid and varying amounts of gelatinous granulation tissue. In one of these cases there was excavation of screw holes in the bone under the plate: this had been visible at the two distal screws on the radiographs (Fig. 8). The other 35 sites showed only a thin fibrous capsule with little or no soft tissue under the plate.

Microscopic changes. Soft tissue specimens taken at plate removal were all examined by one pathologist (TAF). In general, carbon rods and occasional granules were found lying inertly in the fibrous tissue together with a few giant cells (Fig. 9). In six fractures there was a microscopic reaction which varied from a few polymorphs and lymphocytes to a frank acute inflammatory reaction in two cases. One of these was shown to have a *Staphylococcus aureus* infection; no organism was grown from the other. Five fractures, therefore, showed a reaction for which no cause could be established.

![Fig. 7](image)

**Fig. 7**

Period taken for complete radiological remodelling related to percentage of patients.

![Fig. 8](image)

**Fig. 8**

Radiographs showing excavation of bone under the plate at two distal screws.

![Fig. 9](image)

**Fig. 9**

Histological section of soft tissue at plate removal showing carbon fibre fragments (× 100).

![Fig. 10](image)

**Fig. 10**

Healing by close-knit callus was seen in 70% of cases.

Callus response. Only 20% of the fractures showed no external callus; all these had had interfragmentary compression by a lag screw. There was desirable close knit early external callus in 70% (Fig. 10). Most of these had not had a compression screw; the rest probably had an inadequate one.
Four fractures showed exuberant callus, one due to bone grafting and three perhaps due to excessive soft tissue stripping. There was usually some bone growth around the edges of the plate but in two cases this was excessive, and in one of these the plate was completely buried by the callus.

**Complications.** Two patients had superficial infection; no organisms were isolated and they settled without antibiotics. A third had deep infection due to *Staphylococcus aureus*. This compound fracture with contamination healed satisfactorily with the appropriate antibiotics.

Two patients had cross union. Both had fractures of radius and ulna at the same level, with comminution due to high velocity injuries. One of these patients then had external fixation applied to a grossly contaminated compound fracture of the ulna. One of its screws touched the radius at its fracture which was plated. The fixator was removed and the forearm mobilised. The patient regained 50% of rotation within six months. The second patient had been grafted primarily for a comminuted fracture and, in spite of excision of the cross union, the arm remained stiff.

Four patients had temporary radial nerve paraesthesia but all recovered. One patient with exuberant callus had partial limitation of thumb function due to interference with the tendon of flexor pollicis longus.

**DISCUSSION**

This is a small series. In comparison with our retrospective series, using metal AO plates we found no statistically significant increase in the rate of union, but functional union, as defined above, occurred much earlier. We had no mechanical failures and no non-unions. Since there was no observable osteopenia we now believe that the plates could be left in situ unless there were local symptoms.

No cause could be established for the reactions in five cases. Howard, Taylor and Gibbs (1985) found no abnormal response in their human material and our tissue culture and animal studies showed a low inflammatory response to the composite material. However, we recommend the use of titanium screws or carbon fibre composite bone pegs (Sell et al 1989) for fixation of the plates to avoid the effect of material mismatch. We found that compression at the fracture site appeared to suppress the formation of external callus and therefore recommend that fractures should be stabilised rather than compressed.

The composite plates combine lower stiffness with improved fatigue properties, and therefore produce minimal stress protection (Tonino et al 1976). The principles of less rigid fixation have been discussed by several authors (McKibbin 1978; Paavolainen et al 1978; Claes et al 1980; Tayton and Bradley 1983). Composite plates cannot be bent at the time of surgery but this has not been a disadvantage, since their use has been restricted to the relatively straight portion of the long bones. The elastic nature of the plates provides for good conformation.

The surface of a composite plate must present both fibres and resin to the cells and it may be the carbon fibre which produces the active response (Jenkins et al 1977; Forster et al 1978; Tayton et al 1982). Our mouse studies, however, show a low level of response; fibres covered with epoxy resin do not appear to integrate as well with the tissues (Burri and Helbing 1986). If these effects are related to the carbon fibre, are they due to a chemical or a morphological effect? Our in vivo studies differ from our clinical results in that in the latter the fibres are loaded: there may be a strain-dependent effect. Carbon fibres carry different polar chemical groups, which aid the bonding of the fibre to the resin matrix; these groups could be possible sites for cell membrane interaction. The physical structure of carbon fibre is very complex and in particular the electron system contributes a unique diamagnetism. It may not be surprising that these highly specific and oriented electron fields should exert an effect on cell behaviour and on osteogenesis.

**Conclusions.** We believe that carbon fibre plating provides adequate mechanical fixation for comfortable early use of the limb, yet allows sufficient stress-sharing by the bone and soft tissue to enhance callus formation and limit osteopenia. With increasing experience and confidence we are now using a thinner carbon plate (2.6 mm thickness) with four 3.5 mm titanium screws with fine AO buttress threads, provided that a full double cortical hold can be achieved with each screw. The use of a fracture distractor minimises soft tissue stripping and promotes more load sharing by the soft tissue. Our limited clinical experience with this technique has shown that a more close-knit callus is produced.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

**REFERENCES**


