BIODEGRADABLE PIN FIXATION OF ELBOW FRACTURES IN CHILDREN

A RANDOMISED TRIAL

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A prospective randomised clinical trial was undertaken to compare biodegradable polyglycolic acid pins with standard Kirschner wires used to fix displaced elbow fractures in children. Twenty-four children were enrolled in the trial; 14 had fractures of the lateral condyle of the humerus, eight of the medial epicondyle and two had olecranon fractures. Eleven fractures were fixed with Kirschner wires and 13 with polyglycolic acid pins. Fracture union with full function occurred in all cases within six months. Kirschner wires caused problems including infection in three cases, soft-tissue ossification in one and they required removal under general anaesthesia in nine cases. No such complications occurred with polyglycolic acid pins but one patient in this group developed avascular necrosis and premature fusion of the medial epicondyle.

Synthetic polyesters, particularly polyglycolic acid (PGA), polylactic acid and polydioxanone are used extensively as biodegradable suture materials (Craig et al 1975). This report concerns the use of PGA in the form of pins developed for bone fixation (Törmälä et al 1988). In adults, they have been reported to provide satisfactory internal fixation of fractures of the ankle (Böstmann et al 1989a, 1990b), elbow (Hirvensalo et al 1988b) and distal radius (Hoffmann et al 1989), and to secure osteotomies of metatarsals (Hirvensalo et al 1988a). The only report of their use in children has been in three cases with supracondylar fractures of the humerus (Böstman et al 1989b). As a result, we undertook a randomised trial to compare the results of fixation of selected fractures of the elbow in children with either PGA pins or Kirschner wires. The PGA pins provided secure fixation and had the distinct advantage over Kirschner wires of not requiring removal.

Table I. Clinical details of patient groups

	Kirschner wire group	PGA pin group
Number of cases	11	13
Sex:		
Male:female	9:2	8:5
Mean age in years (range)	7.7 (3 to 12)	8.5 (2 to 16)
Fracture type		
Lateral condyle	5	9
Medial epicondyle	5	3
Olecranon	1	1

PATIENTS AND METHODS

Study design. We undertook a prospective randomised trial comparing Kirschner wire fixation with PGA pin fixation of metaphyseal fractures, arthrodeses and osteotomies in children with the approval of the hospital ethics committee. During the study period (October 1989 to July 1990) the parents of 24 children with elbow fractures requiring open reduction and internal fixation were offered the opportunity for their child to be included in the trial. Only one family refused. Signed consent was given by the parents and randomisation to either treatment group was made by the surgeon using sealed cards in the operating theatre. The clinical details of the treatment groups are given in Table I.

Operative technique. Open reduction under general anaesthesia was performed using standard techniques.

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In the Kirschner wire group, fractures of the lateral condyle and medial epicondyle were fixed with two divergent wires of diameter between 1.2 and 1.8 mm (most were 1.2 mm). The olecranon fracture was treated by tension band wiring with two buried Kirschner wires and a figure-of-eight wire loop.

In the PGA pin group, each fracture was reduced and held with bone forceps. Fine Kirschner wires were also used, when necessary, to provide temporary fixation whilst the PGA pins were inserted. Two PGA pins of 1.5 or 2 mm diameter were used to fix each fracture. Two divergent 1.5 or 2 mm drill holes were made across the fracture and into the opposite cortex. The drill holes were made through the metaphyseal fragment of the lateral condylar fractures to avoid the growth plate of the distal humerus. Drill holes were, however, made across the growth plate of the medial epicondyle in fixing fractures of this part. The position and depth of the drills were controlled radiographically. The correct length of pin was selected from the graduated drill bit. The lengths used varied between 30 and 60 mm, the most common being 30 and 40 mm. The first drill bit was removed and a PGA pin was inserted with an introducer, taking care to ensure that the fracture was held firmly in place. The pin was advanced until its end was flush with the bone surface. The second pin was inserted in a similar manner and any Kirschner wires used for temporary fixation were removed. Divergent PGA pins were also inserted into an olecranon fracture in a similar manner and the fixation was supported by a tension band figure-of-eight polyglycolic acid suture.

The remainder of the treatment and after-care was the same for both groups except that the Kirschner wires were removed after four weeks. A radiograph was taken during the operation to check the position of the fracture and the fixation. Although the PGA pins were radiolucent the drill holes could be seen. All wounds were closed with subcuticular polyglycolic acid sutures. The elbow was supported in a plaster cast for four weeks. Antibiotics were not given. The children returned home the day after operation. Clinical and radiographic reviews were undertaken at one, three and six months following operation to assess complications, fracture union, range of movement, growth, deformity, physal appearance and symptoms.

RESULTS

The security of fixation achieved at operation did not seem to differ between the treatment groups. Radiographs confirmed that the fractures had been anatomically reduced. The only operative complication was a broken 2 mm drill bit. The wounds healed normally in all children. Three children developed an infection around the Kirschner wires. In two of these, the wires had been left protruding through the skin and in one, they had been buried but backed out later. There was no loss of

fracture fixation and the infections resolved rapidly following removal of the wires.

Nine of the 11 children treated with Kirschner wires needed a further admission to hospital for removal of the wires under general anaesthesia. This procedure was planned in the four children in whom the wires were buried but was unexpected in five of the seven children in whom the wires had been left protruding through the skin. The wires were fixed firmly in the bone and attempts to remove them were too painful for children under the age of six years. No child in the PGA group required further admission or operation.

Reduction was maintained in all children and healing was normal. In the 13 children treated with PGA pins, tracks were visible at three months, had faded at six months and virtually disappeared by 12 months (Fig. 1). There was no evidence of infection, seroma, foreign-body reaction or loss of fracture fixation in any of the children treated with PGA pins. In one child, ectopic bone formed along the Kirschner wire track producing a painless subcutaneous swelling but with no dysfunction. In a child with an avulsion fracture of the medial epicondyle, treated with PGA pins, the fragment developed avascular necrosis and fused prematurely to the humerus.

Long-term review showed that all children had a normal carrying angle, full elbow movement and normal function at six months. Apart from the child with premature fusion of the medial epicondyle there was no evidence of abnormal physal growth in either of the treatment groups.

DISCUSSION

Displaced fractures of the lateral condyle of the humerus are usually treated by open reduction and internal fixation to ensure union and normal growth (Rang 1983). Fractures of the medial epicondyle and olecranon need such treatment less often. However, when surgery is indicated, the objectives are to reduce the fracture and to hold it securely for at least ten days while callus forms.

In the present study, Kirschner wires provided adequate fixation but despite considerable care three children developed infections and one developed ectopic bone along the wire track. A further disadvantage of the wires was the need to remove most of them under general anaesthesia which required an extra day in hospital. At three or four weeks following fracture, the wires still held firmly in the bone so that children less than six years of age could hardly tolerate having them removed in the outpatient clinic.

The PGA pins also provided satisfactory fixation and had the distinct advantage over the Kirschner wires of not requiring removal and there were no instances of inflammation. In man, PGA pins cause little immune response (Santavirta et al 1990) but are associated with the occurrence of subcutaneous foreign-body reaction or

Fig. 1a

Fig. 1b

Fig. 1c

Fig. 1d

Displaced fracture of the lateral condyle of the humerus in an eight-year-old boy (a); Immediate postoperative appearance after open reduction and fixation with two 1.5 mm PGA pins inserted through the posterior metaphyseal fragment; note the lucent pin tracks (b); appearance six months later (c); after 12 months the pin tracks have almost disappeared (d).

seroma in 8% of adults (Böstman et al 1990a). This reaction is reported to develop between seven and 16 weeks after implantation as a painful, fluctuant swelling which may discharge spontaneously. The fluid is sterile and contains lymphocytes and monocytes. In the surrounding tissue are macrophages and multinucleate giant cells containing phagocytosed implant material. The reaction resolves spontaneously and does not appear to affect fracture healing.

The lack of any evidence of seroma formation in the present study may be due to the thin PGA pins and consequently a lesser amount of material to degrade than is often the case in adults. More children will need to be studied to determine the frequency of this complication.

The cause of the one case of avascular necrosis and premature fusion of the medial epicondyle of the humerus in the PGA treatment group was not determined. It may have been due to the injury or dissection at operation. This complication has been reported previously in a patient treated with Kirschner wires, without subsequent ill effect (Fahey and O'Brien 1971). There was no evidence of premature growth plate arrest in any of the other children with medial epicondyle fractures, in either treatment group. Reattachment of displaced medial epicondyle fractures always involved placing wires or pins across a growth plate. In contrast, fractures of the lateral condyle were fixed by placing pins through the metaphyseal fragment. However, animal studies and one human study suggests that PGA pins could be safely inserted across the growth plate of the distal humerus if the metaphyseal fragment was too small for pin fixation (Mäkelä et al 1987; Böstman et al 1989b).

The PGA pins are made by hot compression moulding of polyglycolic acid fibres in a matrix of the same material (Vasenius et al 1989). They have an initial bending strength three times greater than cortical bone

(Vainionpää et al 1987). The strength diminishes progressively after implantation in bone as the pins are invaded by capillaries and replaced with bone or fibrous tissue in three months (Vainionpää et al 1986; Vasenius et al 1989). Degradation of the implant occurs by hydrolysis to glycolic acid and further degradation to glycine (Williams 1982; Hollinger and Battistone 1986). PGA pins are not recommended for fixation of load-bearing cortical bone where they might be subjected to excessive mechanical stress. Biodegradable materials have been made into plates and screws suitable for stronger osseous fixation and these are being evaluated (Vainionpää et al 1986; Partio et al 1988; Törmälä 1988).

We have shown that PGA pins are a suitable alternative to Kirschner wires in the management of common elbow fractures of childhood. The major advantage of the PGA pins is that they do not need removal. This applies particularly to young children who are intolerant of attempts to remove protruding Kirschner wires without general anaesthesia.

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