Observations on removal of metal implants

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A total of 86 adult patients who underwent routine surgery to remove metal internal fixation devices were studied prospectively. At the time of surgery, 46 patients were symptomatic, but only 27 requested surgery; 59 were admitted for routine surgery on medical advice. There was no correlation between symptoms, the length of time the implant had been in situ *or the location of the implant. Good results were achieved in 91 per cent of symptomatic patients and no problems occurred in 95 per cent of asymptomatic cases. Overall there was a 3 per cent complication rate including one refracture, one radial nerve injury and one haematoma. No wound infections occurred.*

Potential difficulties in the removal of implants and possible risks of retained implants are discussed, relating to refracture, osteopenia, metal toxicity and neoplasia. In conclusion, it may be appropriate to leave asymptomatic implants in situ, *except for femoral and tibial diaphyseal plates.*

Introduction

The current trend in the management of fractures is frequently to use methods of open reduction and internal fixation. If the policy of routine removal of metal hardware is adopted, this will have serious implications for the workload of orthopaedic units. The purpose of this study was to investigate the reasons for removal, estimate the annual workload, assess the results and complications and to attempt to formulate a sensible working policy for the removal of metal implants.

Method and materials

The patients studied were all admitted between April and December 1989 to the short stay ward in the orthopaedic unit at Southampton General Hospital from the routine waiting list. The only exclusions were children under the age of 16 years and adults admitted as an emergency with problems relating to their implants, such as osteomyelitis or breakage of both implant and limb. Before surgery, all the cases were seen by one of the authors (RHR or JDP) who then completed a standard questionnaire.

Information was obtained on the site of fracture, date of initial surgery, type of implant and the length of time *in situ*. Patients were asked about the presence of symptoms, which were classified as none, subcutaneous prominence, local irritation or pain. Complications of the original treatment such as infection, malunion or non-union were recorded. Finally, each patient was asked whether the implant was to be removed at their request or at the suggestion of the orthopaedic surgeon.

Surgery was performed under general anaesthesia by consultant surgeons or their middle grade staff using standard techniques. The implants were not analysed after removal and were returned to the patients. After removal of lower limb implants, patients were allowed to bear partial weight with crutches.

Follow-up of patients took place at 2 weeks after surgery and was continued as necessary. Patients were assessed for any change or improvement in symptoms and any complications of surgery were noted. Follow-up for major complications such as refracture was continued for a minimum of 1 year until December 1990. The results were analysed using Student's *t* test.

Results

A total of 88 patients was admitted to the study over a 9-month period between April and December 1989, but two refused surgery due to lack of symptoms and awareness of the possible risks involved. The average age of the 86 patients was 37 years (range 16–85 years) of which 56 were male (65 per cent).

Implants comprising plates, intramedullary nails and tension band wires were removed from sites, the distribution of which and the proportion with symptoms are displayed in *Figure 1*. Of the patients, 46 (53 per cent) were symptomatic, of which 32 had a single complaint and 14, two or more. Pain was the most frequent complaint, being present in 30 (65 per cent) patients. Local irritation featured in 19 (41 per cent) patients and subcutaneous prominence in 13 (28 per cent) patients (*Table I*). There was no significant difference in the incidence of symptoms in females, 20 out of 30 (66 per cent) and in males, 26 out of 56 (46 per cent) ($0.1 > P > 0.05$). The site, or more specifically a subcutaneous location was an indicator of likely symptoms rather than the type of implant.

The implants had been present for an average time of 28 months (range 3–148 months) and there was no correlation between symptoms and the period of implantation. Only

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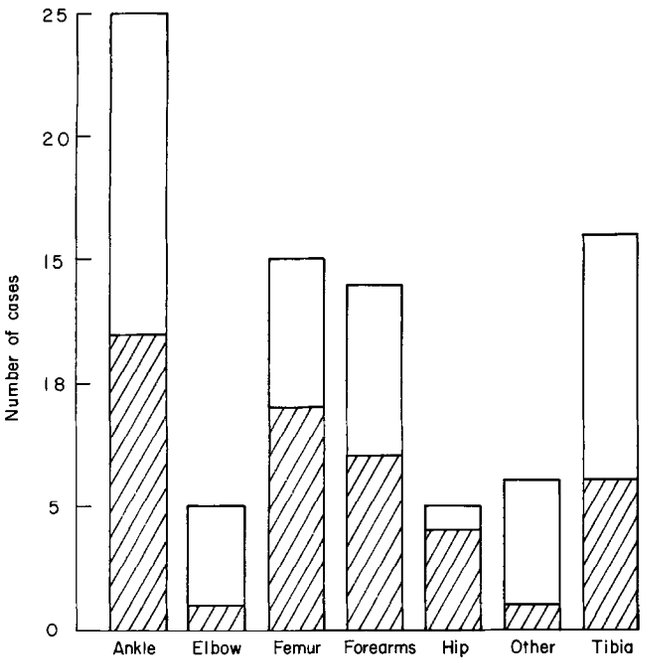

Figure 1. Distribution of sites where metal implants were removed showing the proportion of cases that were symptomatic (□) and asymptomatic (▨). All the femoral implants were intramedullary nails and all the tibial implants were plates.

Table I. Distribution of symptoms

Symptoms	*Number*
Pain	20
Local irritation	7
Subcutaneous prominence	5
Two or more	14
Total	46

27 patients (31 per cent), all of whom were symptomatic, requested admission for surgery, while the remainder (69 per cent) were admitted on medical advice.

Considerable improvement or complete relief was obtained in 42 out of 46 symptomatic patients (91 per cent), while in 38 out of the 40 patients without symptoms (95 per cent) no problems were seen after surgery. The results of surgery were deemed poor or no improvement in four out of the 46 patients with symptoms, including one case where, for technical reasons, a sliding screw and plate was unable to be removed from a hip. Complications occurred in three cases (3 per cent): In one patient with symptoms a refracture of the radius occurred 3 weeks postoperatively, when the plate had been removed at 15 months after fracture. In two patients who were asymptomatic, there was one transient superficial radial nerve palsy after removal of a radial plate and a postoperative gluteal haematoma after removal of a femoral nail. There were no wound infections or dehiscences recorded.

Discussion

The increasing trend in modern orthopaedic practice for internal fixation of fractures inevitably leads to increasing numbers of patients with indwelling metal implants. The question must therefore be asked 'do we need to remove these implants?' Clearly, if there have been complications such as non-union, infection or implant breakage, or the patient has local symptoms related to the metal implant, then removal is indicated. The incidence of symptoms relating to metal implants in patients with united fractures varies widely: 10 per cent (Anderson et al., 1975); 25 per cent (Cook et al., 1985); 36 per cent (Langkamer and Ackroyd, 1990); 50 per cent (French et al., 1984). Causes of symptoms related to implants have been attributed either to local prominence, formation of bursae over implants and local tissue reaction, either of chronic inflammatory or allergic type (French et al., 1984). Most series report good improvement of symptoms in 80–90 per cent of cases after removal of the implant. Clearly, in this group there is no problem regarding justification of surgery.

In cases where the implant is asymptomatic, what is the justification for subjecting the patient to further surgery? Opinions in the literature are divided on the desirability of implant removal. Authors highlight the risks of surgery (Anderson et al., 1975; Hidaka and Gustilo, 1984; Langkamer and Ackroyd, 1990) and other possible complications if these devices are left (Walker, 1983; Hughes et al., 1987; Black, 1988) and these will now be reviewed.

Complications after surgery for removal of metal implants include refracture, neurovascular damage and wound infection. The rate of refracture after removal of forearm plates is 1–1.5 per cent according to the AO group (Müller et al., 1979), but in other series it is much highe Hidaka and Gustilo (1984) had seven refractures in a group of 23 patients; Deluca et al. (1988) reported seven out of 37 patients; Anderson et al. (1975) in their review of 244 patients with plated forearm fractures removed the plates in 10 per cent of these and there were eight refractures. Kristensen (1979) in his review of plated tibial fractures had a refracture rate of 5 per cent after removal. Langkamer and Ackroyd (1990) report a 40 per cent complication rate after removal of forearm plates from 55 patients. Their refracture rate was low, with only two cases, but they had three wound infections and 30 per cent incidence of neurological damage. Recent work on removal of condylar plates from the distal third of the femur (Bostman, 1990) showed a 10 per cent refracture rate, in which five of the six cases were associated with a supplementary lag screw. The routine removal of condylar blade plates was not recommended.

Raahave (1976), in a large series of removal of 269 metal implants found an infection rate of 3.2 per cent from the lower limb and none from the upper limb, but made no mention of symptoms or other complications.

There is conflicting advice as to the removal of femoral nails. Kempf and Grosse (1985) remove all implants at 18–24 months; Winquist et al. (1984) advise removal in young people, while Harper (1985) removed only 36 from 119 patients who had local discomfort. Problems may be encountered in the removal of nails because of the range of different nails and fittings from various manufacturers that need specialized extraction devices that may not be interchangeable.

The problems associated with retained metal implants include local osteopenia, fracture, metal toxicity from corrosion products and risk of malignancy, and these will now be discussed individually.

Localised osteopenia beneath metal plates has been reported by many authors and is thought to arise from difference in the modulus of elasticity between the metal and bone leading to stress protection. Alteration in local blood

supply is also thought to be important. Less rigid plates cause less osteopenia but union is thought to be compromised. Walker (1983) describes stress protection beneath plates and also increased stress at the junction between normal bone and the bone/implant region and advises removal on these grounds. In a study of plate fixation in canine femora (Uhtoff and Finnegan, 1983) there was a reduction in bone mass beneath the plate and a delay in remodelling that was worse with more rigid plates. After removal, there was an increase in bone mass with remodelling but this was more pronounced when the plate was removed early.

Using CT scanning on human femurs and tibias after plate removal, Terjesen et al. (1985) found that there was a reduction in cortical density but the cortical thickness remained the same. He also found no increase in the osteopenia after 1–2 years. This implies that an equilibrium had been reached with the weakened bone and its stress-protecting implant.

There have been five cases of fractures associated with retained metal fixation devices reported recently (Bransby-Zachary et al., 1989), where the devices had been *in situ* for between 22 and 62 years. The relatively small number of such reported cases either suggests this aspect is less important or not considered of sufficient interest to publish.

All metallic implants are subject to corrosion and the metallic ions released have the potential to interact with cellular and biochemical processes. Studies looking at corrosion affecting retrieved metal implants show an incidence of 87 per cent (Cook et al., 1985) with pitting affecting the surface of implants and fretting affecting the screw and plate interface. Fibrous tissue associated with metal implants showed evidence of a chronic inflammatory response that was proportional to the degree of corrosion (Thomas et al., 1988). The degree of tissue reaction was noted to diminish with time and this implied that most corrosion occurs early after the trauma to the metal of implantation. The same workers (French et al., 1984) found an allergic type appearance in the overlying fibrous tissue in a small proportion of cases of symptomatic implants, suggesting this as one possible mechanism for the local symptoms. These workers suggested that metal toxicity was not a problem in that the corrosion products were dealt with by the body. In a recent editorial, Black (1988) stated that modern implants made from high-purity alloys rarely underwent frank corrosion, but all implants are subject to some degree of corrosion. Various effects of metallic ions released into the body have been postulated, including aluminium as a neurotoxin, and chromium and nickel playing a role in allergic responses and inhibiting white cell function.

Lastly, there have been 13 reports in the literature citing an association of malignancy with retained implants. Hughes et al. (1987), in reporting a case of malignant fibrous histiocytoma associated with a single screw and reviewing the other cases, could find no clear causal relationship. In the 12 cases that were reviewed, five had retained implants for more than 5 years and seven less than 5 years. Of the 13 reported cases of malignancy associated with metal implants, seven involved joint replacements (Hughes et al., 1987; Haag and Adler, 1989) that clearly are not subject to routine removal. Considering the number of cases of implantation of metal and joint replacements performed, the relationship between metal implants and neoplasia is not yet proven.

The AO Group (Müller et al., 1979), advise removing implants on grounds of the differences in the modulus of elasticity between bone and metal implant, but make exceptions for non-weight-bearing bones such as the humerus and for single screws in metaphyses. They appear to be only concerned with the biomechanics in weight-bearing bones and not the potential risks of metal toxicity, corrosion or neoplasia. It appears that the risks of removal of metal implants from various series (Hidaka and Gustilo, 1984; Deluca et al., 1988; Langkamer and Ackroyd, 1990) in terms of refracture or neurovascular damage is much higher than the apparent risks of leaving it in place.

With the experience gained from this study and from the literature review and subject to results from any future research, in our department we have adopted a protocol for removal of retained internal fixation devices. All patients who have local symptoms related to their implants and patients with compression plates on the femoral or tibial diaphysis are advised to undergo removal, followed by a period of protection in a splint or reduced weight bearing. In the remaining cases that are asymptomatic, then the risks and benefits of surgery are discussed with each individual and a decision reached based on informed consent. Applying these criteria retrospectively to this series, the number of cases operated on would have decreased by up to 40 per cent per annum.

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