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Subchondral Stainless Steel Implants

An Experimental Investigation in Sheep

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ABSTRACT

In a previous investigation concerning reincorporation of avascular osteochondral autografts a discoloration was observed on the joint surface corresponding to the course of the inserted subchondral A0-screws. This study was performed to find out if the internal fixation material had any influence on the articular cartilage or bone. Stainless steel A0-screws of the A.I.S.I 316 type were inserted subchondrally in the proximal end of the tibia. At observation times of up to 8 months the ferroxyl test revealed no corrosion of the screws. The screws did not give rise to any local morphological reaction in the articular cartilage, and the cancellous bone around the screws showed only a slight increase in density, consisting of newly formed bone. It is suggested that the discoloration may be caused by diffusion into the tissue of haemoglobin or some breakdown product of haemoglobin that has not reached the stage of ionized iron.

INTRODUCTION

In the reconstruction of fractures involving the articular surface and in osteotomies close to the joint, internal fixation is often necessary for maintenance of articular movement by active exercise during the fracture healing process. This is considered a prerequisite for optimal restoration of the joint function. Over the years, great interest has centred on the development of suitable material for internal fixation and on the corrosion resistance of different alloys (3, 5, 6, 7, 8, 9, 16, 17, 18, 21, 25, 27, 30, 33). The effect of a metallic implant on biological tissue varies depending on the metal (4, 5, 19, 33). Several authors (6, 17, 20, 23, 27) have described mechanical, physical, chemical and even carcinogenic effects.

Corrosion of the metallic implant, which may be either macro- or micro-corrosion (6, 11, 19), is an important cause both of mechanical defectiveness of an internal fixation device (6, 20, 30) and of different effects on the biological tissue (6, 19, 23, 25, 33). The effect of the corrosion products on the surrounding tissue is believed by some authors to be due to electrolysis (23, 31, 33), while others are in favour of a toxico-chemical theory (4, 19, 25, 27). According to many investigators, micro-corrosion of a metallic implant, with solving out of metallic ions into the surrounding tissue, always occurs, even with highly inert alloys (3, 11, 18, 19, 22, 23, 26). The A0 group claim, however, that there has been no clinical or experimental evidence of corrosion of their internal fixation material (Austenitic stainless steel, type A.I.S.I. 316), as long as it has not been subjected to rough handling (9, 21).

In so far as corrosion does occur, it is reported to be of a lesser degree in single metallic implants than in metallic implants with several components, e.g. a screw-fixed plate (3, 9, 15, 16, 25, 30). The effect of corrosion around a metallic implant is manifested as fibrosis, pigment granules, positively stained metallic ions and perivascular round cell infiltration (19). Corrosion and corrosion products can be demonstrated by many methods. One simple, reliable method is the Ferroxyl test, which has been described by Emneus et al. in several reports (12, 13, 14, 16, 17).

Experimental and clinical investigations on the effect of a metallic implant on the surrounding biological tissues include both its effect on soft tissues (14, 15, 18) and the reaction of the bone (3, 4, 5, 23, 30). Nicole made experimental studies of the effect of a stainless steel implant placed intra-articularly, and his findings contra-indicated the use of metallic material in a joint (23); he found extensive metallosis in the joint and detectable amounts of iron, chromium and nickel.

In a previous experimental study concerning reincorporation of articular surface bearing bone fragments, we inserted A0 screws close to the joint for internal fixation (32). The aim of the present investigation was to find out whether the

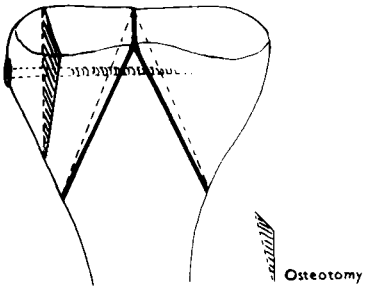

Fig. 1. (*a*) Schematic drawing of the proximal tibia with the osteotomy. The thick lines indicate the sawing plane for excision of the preparations.

subchondral bone or the articular cartilage adjacent to such a screw would show any signs of reaction to the implanted metal.

MATERIAL AND METHODS

Twenty-four sheep were used—16 adult sheep with closed epiphyses and 8 immature sheep with the epiphyses still open.

In the *adult sheep* an osteotomy was performed on the medial tibial condyle and the fragment was refixed with an A0 screw and a Kirschnerwire (Fig. 1). Postoperatively 9 animals had the knee joint immobilized in a plaster cast, while the other 7 were allowed free joint movement. The implantation time varied between 2 and 10 weeks in this group (Table I).

In 7 of the *immature sheep*, without preceding osteotomy, an A0 screw was placed subchondrally between the epiphyseal line and the articular cartilage at the proximal end of the tibia (Fig. 2). On the other knee, in the same sheep, drilling and tapping alone were performed. One immature sheep underwent drilling and tapping alone between the epiphyseal line and the articular cartilage at the proximal end of the tibia. In the immature animals the joint was not opened, and the operation was performed under TV monitoring. The implantation time varied between 2 and 36 weeks in the immature group (Table I).

Table I. *Characteristica of material* (n=24)

Observation time (weeks)	Number of sheep knees		
	Adult sheep with osteotomy and screw	Immature sheep with screw only	Immature sheep drilled and tapped
2	2	1	1
3	–	1	2
4	2	–	–
5	2	–	–
6	3	3	3
7	2	–	–
8	3	–	–
10	2	–	–
36	–	2	2
Total	*16*	*7*	*8*

When the animals had been killed the proximal end of the tibia was resected and deep-frozen. The internal fixation material was removed. In the *immature animals* 0.5 mm thick slices were sawn out at right angles to the drill hole in both the medial and lateral tibial condyles. Between the sawing of each slice a control condyle was sawn into in order to check whether any metal was transferred from the saw. Some of the sawn-out slices were decalcified with a mixture

Fig. 1. (*b*) Roentgenogram of the proximal tibia. After osteotomy the fragments were refixed with an A0 screw.

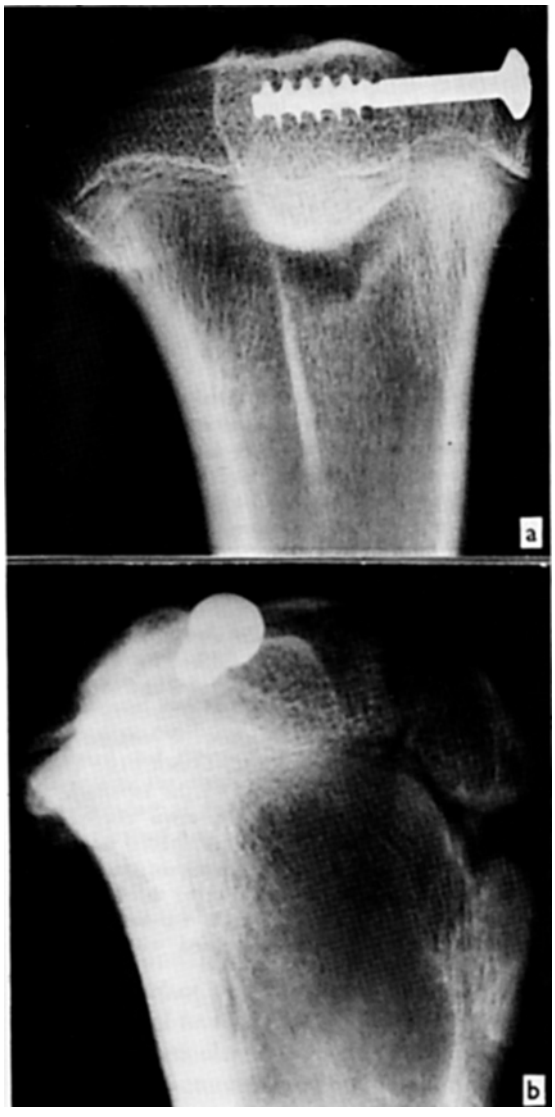

Fig. 2. (*a, b*) The proximal tibia in immature sheep, with an A0 screw inserted between the epiphyseal line and the articular cartilage.

of sodium citrate and formic acid, embedded in paraffin, sectioned and stained with haematoxylin-eosin and by the Turnbull-blue method for demonstration of ionized iron (24).

As decalcification solutions of all kinds have a tendency to solve out metallic ions (28), some of the sawn-out slices were placed directly, without fixation, into transparent disches containing ferroxyl solution (Fig. 3).

In the *adult, osteotomized* sheep histological sections were cut at right angles to the osteotomy, and thus parallel to the drilling canal. They were stained with haematoxylin-eosin and the Turnbull-blue method.

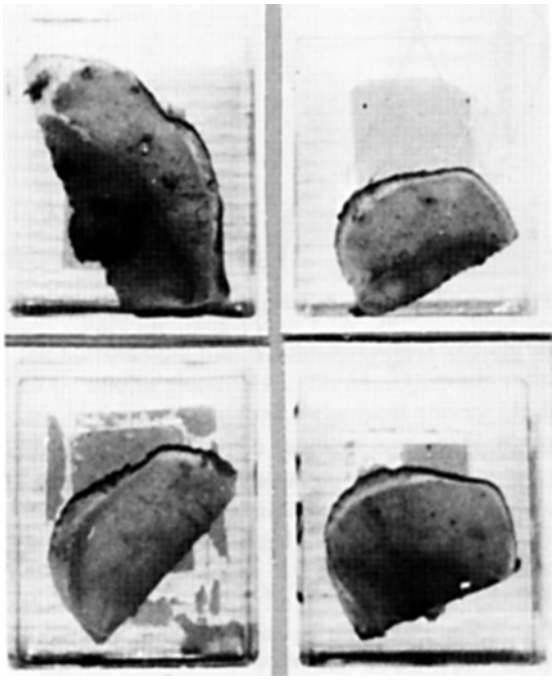

Fig. 3. Ferroxyl test, immature, non-osteotomized sheep; 0.5 mm thick untreated preparations were placed in transparent dishes containing ferroxyl solution. The results were read directly and also in a stereomicroscope, and were recorded photographically.

Non-decalcified parts of the tibial condyles were sawn at right angles to the line of the osteotomy into 0.5 mm thick slices, and were placed in dishes containing ferroxyl solution.

In the adult, osteotomized sheep Indian ink microangiography was performed by the Spalteholz technique. This has been reported elsewhere (32). Microangiography was not performed on the immature sheep, as the Indian ink pigmentation would have made evaluation of Turnbull-negative pigment difficult.

The removed screws were examined in ferroxyl solution for any corrosion. The findings at the ferroxyl test were photographed (Fig. 4). This test was carried out as described by Emneus, Stenram and Petersen in several articles (12, 13, 16, 17). The activity of the test gel was tested on galvanized nails. The results of the ferroxyl test were read hourly during the first days, both macroscopically and in a stereomicroscope. They were then read daily for up to 3 weeks after the start of the test. Preparations from the osteotomized tibial condyles were only examined for the presence of Turnbull-positive pigment, as Indian ink angiography had also been performed, giving black pigmentation. On sections from the immature sheep observations were made for both negative and positive Turnbull pigment, positive Turnbull pigment consisting in blue staining of ionized iron, and negative Turnbull pigment other, non-blue stained pigment.

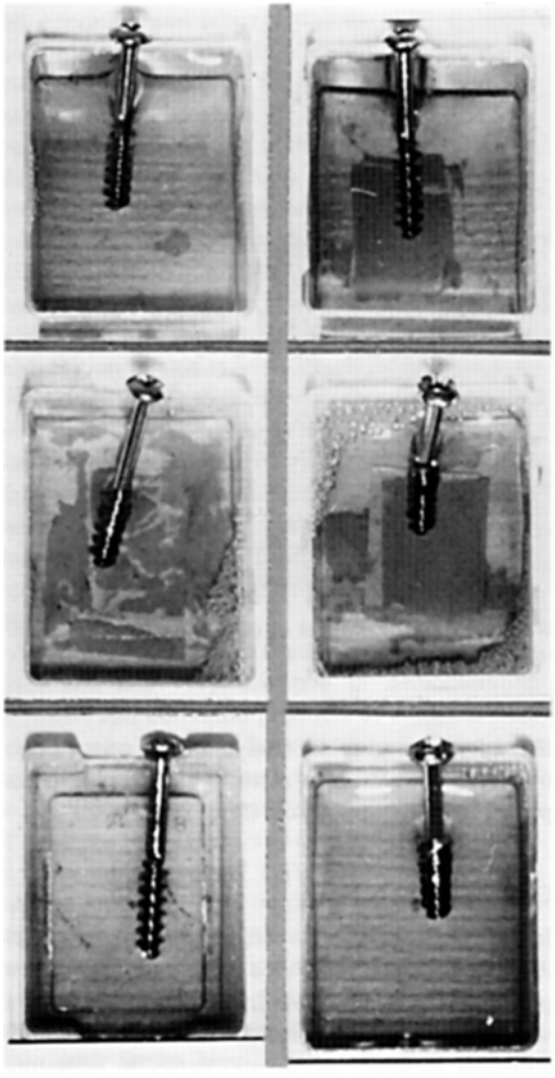

Fig. 4. Ferroxyl test on removed A0 screws after implantation times of up to 36 weeks. No corrosion was found.

RESULTS

Macroscopic observations on the articular surface of the tibial condyle

A slight reddish brown discoloration of the articular cartilage, corresponding to the course of the internal fixation material was observed in the osteotomized adult sheep. Such discoloration was not seen in the non-operated controls or in animals that underwent arthrotomy alone. The articular cartilage in the immature animals that were not osteotomized appeared completely normal in most cases. Only in one of the 7 animals in which a screw had been inserted subchondrally was a slight yellowish discoloration of the cartilage observed. The same observation was made in one of the 8 animals subjected to subchondral drilling and tapping alone.

Histology

Adult sheep: The articular cartilage on osteotomized tibial condyles from knee joints that were not immobilized was normal and without degenerative changes either on the osteotomized or on the contralateral condyle. Degeneration of the articular cartilage was noted in 5 of the 9 animals whose knee joint had been immobilized; these findings are reported elsewhere (32). The walls of the screw canal showed normal bone—in a few preparations lined with a thin, fibrous tissue adjacent to the screw. Some increase in density of the bone around the screw canal was also observed. On staining for iron with the Turnbull-blue method (24), neither phagocytized nor non-phagocytized Turnbull-positive pigment was observed in the walls of the screw canal in subchondral bone or in articular cartilage. Evaluation of Turnbull-negative pigment was not possible because of the pigmentation from the Indian ink used for microangiography.

Immature sheep: In immature control sheep a relatively large number of blood vessels were seen to traverse the borderline between cartilage and subchondral bone. Staining with the Turnbull-blue method gave no pigmentation. The screwed condyles exhibited a slight increase in density of the bone around the screw canal, which in some preparations was lined with a thin layer of connective tissue (Fig. 5). The subchondral bone and the articular cartilage were completely normal. The Turnbull-blue method showed no positive or negative pigment, either intra- or extracellularly in the wall of the screw canal, the subchondral bone or the articular cartilage. The condyles subjected only to drilling and tapping showed normal articular cartilage and subchondral bone. The drill canal was often impossible to find. On staining with the Turnbull-blue method no pigmentation was seen.

Ferroxyl test

The "nail test" was strongly positive after 15 seconds in the gel (Fig. 6). The ferroxyl test was

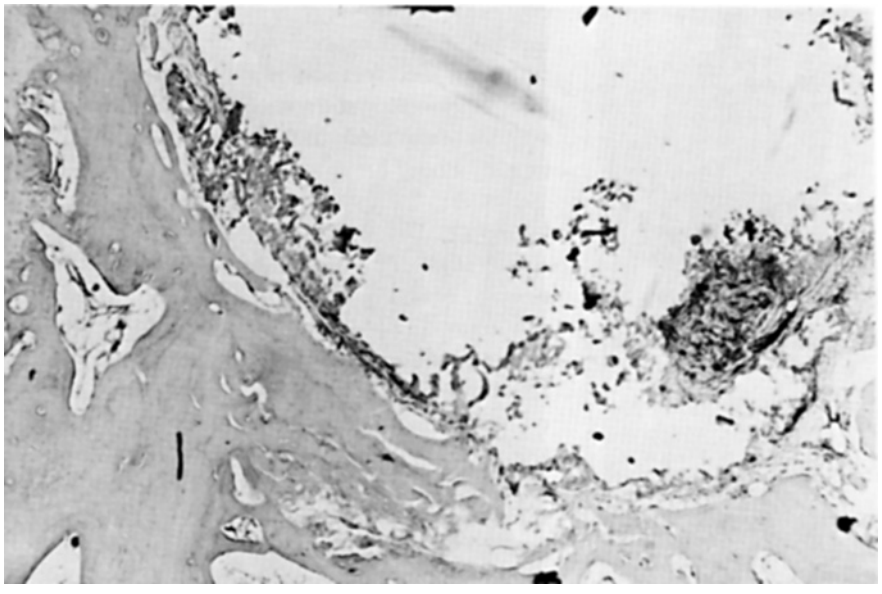

Fig. 5. A screw canal with some increase in density of the cancellous bone around it; the walls of the canal are lined with a thin layer of connective tissue. Haematoxylin-eosin, ×50.

negative in preparations from adult, osteotomized sheep, and also from immature sheep whose tibial condyles were screwed or only drilled and tapped. None of the removed A0 screws showed any signs of corrosion, even after an implantation time of 8 months (Fig. 4). Occasional ferroxyl test-positive iron pigment was observed on two of the preparations, but was clearly located on their surfaces, far from the screw canal, and was therefore considered to be due to contamination from the saw.

Microangiography

No definite vascular reaction arising from the screw or from the screw canal was observed in the microangiographic study, which was carried out by the Spalteholz method and has been reported in a previous article (32).

DISCUSSION

In an experimental investigation, stainless steel A0 screws were implanted subchondrally in the proximal end of the tibia in sheep. These screws were used partly for fixation of an osteochondral autograft in adult sheep, and partly in immature sheep after drilling and tapping, without serving any fixation purpose.

The background of the investigation is the fact

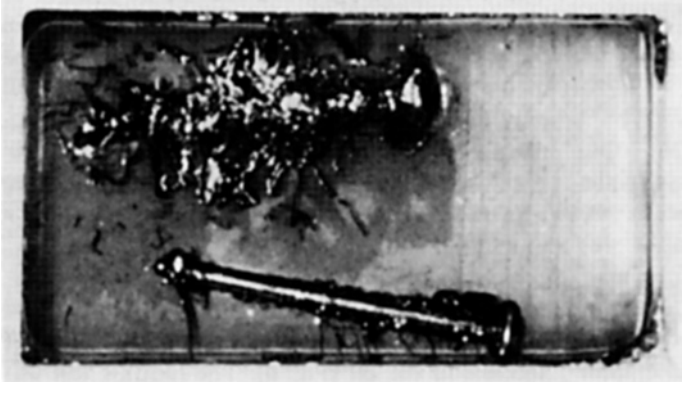

Fig. 6. Galvanized nail with a distinct, strong reaction after 15 seconds in the ferroxyl gel.

that operation and internal fixation with stainless steel material often leads to good functional restoration of a joint after an intraarticular fracture, but that several authors (3, 11, 18, 19, 26) have found microcorrosion in metallic implants even in alloys with high corrosion resistance. The A0 screw used here was of A.I.S.I. 316 Austenitic stainless steel, which contains 17.5% chromium, 12% nickel, 2.5% molybdenum, less than 3% silicon-manganese combined, a maximum of 0.06% carbon and the remaining part being iron (21). On implantation of this type of stainless steel there is a possibility of so-called microcorrosion (19), which gives *local* fibrosis in surrounding tissue. The corrosion product iron also gives siderosis, while chromium, because of its strong toxicity, causes cell death and nickel can give rise to chemical inflammation. Little is known about the local effects of the other components of A.I.S.I. 316.

The ferroxyl test was used because it is simple to handle and very sensitive in demonstrating corrosion and corrosion products of stainless steel —it is more sensitive for this purpose than biological tests (12). The test was also used directly on non-decalcified preparations, as decalcification of cartilage-bone preparations for histological sections entails a risk of solving out metallic pigments. This has been exemplified by Stenram, who treated liver sections containing iron-rich pigment with the decalcification solution RDO[1] for a few hours and then stained them with Berlin blue. Sections treated in this way showed no blue stain with Berlin blue, while untreated sections stained blue (28). Decalcification solutions dissolve calcium and other metallic compounds, which thus become removed from the preparation. The evaluation of Turnbull-blue stained sections after decalcification is therefore uncertain.

Neither with the ferroxyl test, haematoxylin-eosin staining, nor with Turnbull-blue staining was metallic pigmentation observed in the screw canal or subchondral bone. Further, no certain fibrosis, indicating microcorrosion, was seen in the walls of the screw canal. According to Maroudas, cartilage has a tendency to irreversible absorption of ionized iron (10), but no iron pigment was observed in the articular cartilage in our experiments. Preparations subjected to drilling and tapping alone showed no metallic pigmentation either, and the ferroxyl test on removed screws revealed no tendency to corrosion. This conforms with the information given by the A0 group and other authors (9, 21) on the corrosion resistance of stainless steel metallic implants of the A.I.S.I. 316 type.

The macroscopically observed discoloration over osteotomized condyles was probably caused by the osteotomy, since it was not seen in tibial condyles that were only drilled and screwed. No histological explanation was obtained, but the discoloration might possibly have been due to a very thin layer of fibrin and blood cell residues of the type observed by Fiala & Bartős (1, 2) in osteochondral operations on the knee joint in dogs. Another conceivable cause of the discoloration is diffusion into the tissue of haemoglobin or some breakdown product of haemoglobin which has not reached the stage of ionized iron.

No bone resorption was observed around the internal fixation material. It is true that a thin layer of connective tissue was seen in the wall of the screw canal in some preparations, which according to Wagner (30) is a sign of loosening of the screw, but this layer was always very thin. According to Uhthoff (29) such a connective tissue layer is always present around an A0 screw inserted after drilling and tapping, up to 4–8 weeks after the insertion. The bone in the walls of the screw canal showed normal osteocytes, and no local effect on the articular cartilage and bone due to mechanical insufficiency of the screw was observed. The increase in bone density that was observed around the A0 screws has also been reported by Bechtol around screws in cancellous bone, and consists of newly formed bone (3).

[1] Rapid bone decalcifier, Bethlehem Trading Company, Gothenburg.

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