INTERNAL PROSTHESES

The Problem in Relation to Materials

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During the last twenty years advances in various branches of medicine have made possible more extensive operative procedures involving the replacement or repair of tissues by prosthetic devices. An increasing number of apparently suitable materials but with widely differing properties have become available to the surgeon and appliance manufacturer. While there have been many apparent successes with implants, there have also been a number of failures. It is important not to reject out of hand the failures, because much valuable information can be gained from an analysis of these cases which may help in the future to prevent the misapplication of materials.

Prostheses may be required to be permanent or temporary, weight bearing or non-weight bearing, free or fixed. Whatever the purpose of the implant, the following interrelated factors must always be considered: 1) the properties of the material used; 2) the forces to which the implant will be subjected; 3) the response of the tissues of the patient in relation to the implant; 4) the surgical technique to be employed.

It is only possible here to look at some of the facets of what may be termed the "prosthetic problem."

NON-METALLIC IMPLANTS

If polymethyl methacrylate, Nylon, polythene, stainless steels or chrome-cobalt alloys in the form of pellets, five millimetres long and three millimetres in diameter, are implanted in the muscle of guinea pigs, there is a minimal tissue response. A thin, non-adherent, fibrous tissue envelope is formed which may be thickened in relation to any sharp edge. No inflammatory cells are found, there is no increased vascularity and no change in the surrounding muscle. The implants are apparently tolerated by the host tissues and are not in themselves modified by the action of tissue fluids. They can be said to be biologically suitable materials. However, they are not subjected to any significant mechanical forces. The resistance of plastics to abrasion is low compared with that of bone or metals, and if these polymers are used for weight-bearing hip prostheses, the tissue reaction to the implant may be very different. Abrasion of the prosthesis may occur, with the formation of considerable quantities of particulate material. The quantity and size of these particles depends on the polymer used, the activity of the patient, whether the acetabulum has been reamed, the accuracy of fit of the implant, and the method of sterilisation of the prosthesis. In the hip, abrasion of acrylic resins results in the formation of particles which are probably colloidal in size. It has never been possible to demonstrate with certainty powdered polymer in those cases in which there has been extensive wear of the prosthesis. Considerable fibrous tissue formation is, however, often found in association with worn prostheses.

With Nylon, which has a surface hardness approximately one half that of acrylic resin, most particles formed are of the order of 1 to 10μ in size although larger fragments of up to 300μ in size may be produced. The tissue reaction is different from that found with acrylic resins. At operation, on opening the joint capsule, which is distended by synovial fluid, collections of proliferating tissue are found in saucer-like depressions in adjacent bone (Fig. 1). Histological examination of the tissues shows that there is a proliferative histiocytic

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response, the particulate Nylon being phagocytosed by the histiocytes (Fig. 2). Zones of necrotic material, separated by vascular fibrous tissue, contain large concentrations of Nylon particles (Fig. 3). From the periphery of the zone towards its centre the histiocytes can be seen in various stages of dissolution.

With polythene, a material which has a surface hardness approximately one half that of Nylon, the particles produced by abrasion vary in size from 30µ to 1000µ. The capsule of the joint is distended with synovial fluid and there is erosion of bone. Histologically the foreign-body giant cell is conspicuous. Zones of necrosis in the reactive tissue are not found. The degree and type of cellular response is dependent on the abrasion-resistance of the implant.

**FERROUS ALLOYS**

Problems still arise when metals, particularly the ferrous alloys, are used in place of plastics. All implants are liable to corrosion to a greater or lesser degree. The causes and mechanism of corrosion are complex and often not clearly understood. Iron rusts in the presence of oxygen; that is, a film of iron oxide forms on the outer surface, rapidly at first, but at a gradually decreasing rate as the oxide film shuts off the remainder of the iron from the oxygen. If now the metal is placed in water in the presence of carbon dioxide and other electrolytes, a further change becomes possible. The iron oxide film is destroyed and there is a passage of metal as cations into solution. Although oxygen may be present in solution it is not able to reform the oxide layer fast enough. The process of corrosion is accelerated when substances of differing electrode potential are present in the system. A familiar example is the dissolving of the zinc electrode in a voltaic cell. Some metals, for example chromium, form a stable oxide layer in air which protects them from further corrosion even when they are placed in an electrolyte, providing that this surface oxide layer is not damaged. By incorporating 18 per cent of chromium in ferrous alloys their resistance to corrosion is greatly enhanced. The addition of nickel and molybdenum, while still further contributing to their

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*Fig. 1*

Destruction of head and neck of femur and roof of acetabulum, after insertion of a nylon hip cup one year before.
FIG. 2
Histiocytes loaded with birefringent particulate nylon. (M.300. × 430. Crossed polaroids.)

FIG. 3
Section of tissue from joint showing zones of necrosis separated by vascular fibrous tissue. Around the periphery of the necrotic area are found histiocytes containing particulate nylon. (M.302. × 12. Partially crossed polaroids.)
resistance to corrosion, improves their mechanical properties. Steels containing 18 per cent of chromium, 8 per cent of nickel and 2 per cent of molybdenum are known as 18-8-SMo in America and in this country as EN58J (Firth Vickers F.M.B.). The full effect, however, of these passivating agents, as they are termed, can be achieved only if care is taken in the handling and treatment of the alloy during all stages of manufacture of the implant, and at the time of implantation in the patient. The polishing and surface finishing of the implant, which may be carried out by electro-chemical or mechanical means, is all important. Many implants removed from patients showing macroscopic signs of corrosion are found to have a poor surface finish, small fissures and pits having been left which have become centres of corrosion. All alloys in their solid state are crystalline in nature. Crystal growth occurs while a metal is freezing into a solid. The crystals are known in metallurgy as grains, and when coalescence of the grains occurs, grain boundaries are formed. If the rate of growth and size of grain is not carefully controlled, considerable grain stress may result. The grain size is one of the factors determining the physical properties of an alloy. It is known that the boundaries of stressed grains are more liable to corrosion, one reason probably being that at the surface of the implant the chromium oxide layer is either strained or not continuous.

Stressing of grain boundaries can result from methods of cold working the alloy or by overheating during milling, drilling or grinding operations, by distortion of an implant to make it fit the patient, or by excessive stressing of an implant within the patient.

Fatigue—Scales and Zarek (1954), have pointed out that all implants are liable to fatigue—that is, to the action of alternating stressing to a greater or lesser degree. As a result the grain boundaries become stressed and corrosion may result. The term corrosion fatigue is used to describe the simultaneous action of corrosion and fatigue. Before a metal is inserted in the body, stress may be relieved by heat-treating or annealing and, if this process is carried out under carefully controlled conditions, molecular reorientation of the distorted structure of the crystal can occur. Over-annealing, however, will result in a change of grain size and a lowering of strength, hardness and ductility of the metal. Professor Mercer and Mr Wheble have very kindly sent me stainless steel hip cups that have failed (Figs. 4 and 5). It is difficult from the radiographs of Mr Wheble's patient to see how long after insertion the failure occurred, and in any case it is often impossible to detect cracks in hip cups radiographically (Fig. 6). Both the cups are of an austenitic variety of stainless steel. In both cases corrosion fatigue is probably the cause of the failure. The whole thickness of
the spherical part of the cup appears to be somewhat below that usually found. There is no evidence of gross wear and presumably the thinning occurred during manufacture.

The hip cup is particularly liable to be heavily stressed, as it is a mobile joint interposition which is both hemispherical and cylindrical. When downward tilting of the cup occurs, the skirt impinges on the calcar femorale, the cylindrical portion being brought into contact with the spherical sectioned acetabulum. No longer is the cup a floating member, but rather a fixed member which is subject to high localised alternating stressing both at the base of the skirt in contact with the calcar and in the region of the junction of the spherical portion of the cup with the cylindrical skirt.

**Use of dissimilar metals**—When dissimilar steel alloys are placed in the tissues, corrosion due to a difference of electrical potential with a transference of ions can occur (Venable and Stuck 1938). Changes also occur in the surrounding tissues which have been described by Fink (1944) as "electrolyte inflammation." There is a local increased vascularity with rarefaction of bone; inflammatory cells and fibroblasts appear, and deposits of intra-cellular and extra-cellular iron can be demonstrated. In August 1954 three Moore's pins were inserted into a slipped upper femoral epiphysis of a boy aged twelve. Two months later an area of rarefaction could be seen where two of the pins were adjacent to each other. On the radiograph a notch on one of the pins indicated that corrosion was taking place. There was rarefaction of bone with inhibition of callus formation at the cuter cortex of the femur around the nuts at the distal ends of the pins (Fig. 7). In January 1955 the pins were removed. It was found difficult to remove one of the pins because it broke at the notch, but after extensive chiselling the proximal part was withdrawn. The nuts were brightly polished and were non-magnetic and showed no macroscopic evidence of corrosion. The pins, however, were strongly magnetic and poorly polished, and two of them were badly corroded; the threads

**Fig. 6**
Radiograph of the cup seen in Figure 5 showing only one crack passing through the skirt of the cup.
at their proximal ends were dull. This case illustrates what may happen when dissimilar alloys are used, and this is not an isolated case.

Even when every care has been exercised in the design, manufacture and use of stainless steel implants, it is sometimes found that callus formation is inhibited, the implant becomes loose or breaks. Stainless steel screws are often preferred to those of Vitallium or Vinertia because it is said that they can be taken out more easily. This is true because stainless steel implants are usually surrounded by a layer of some thickness of fibrous tissue, the bone failing to form in such intimate contact with the structure as to key or lock it in position. Bowden, Williamson and Laing (1954), using an isotope technique, investigated the transference of metals from screwdrivers and spanners, and showed that appreciable quantities of metal were transferred to the implant. Spectroscopic examination of the surrounding tissues revealed that in those areas in contact with the instrument-handled part of the implant there was an abnormally high metallic concentration. Shaw and Scales (1954) investigated the transference of metal from radioactive mechanically operated tools used to cut and drill bone and found a transference of metals as shown in Table I.

These investigations suggest that some past failures with stainless steel implants may be explained on the basis of transfer of dissimilar metals from instruments, used at the time of operation, to implants. (For example, saw blades are made from Firth Vickers F.H. steel and drills from F.S.T., while others are produced from ferrous alloys of a non-stainless variety. Saw blades cannot be made from F.M.B. steel to wear nearly as well as those made from F.H. steel.)

![Radiograph showing areas of rarefaction of bone around nuts on Moore's pins. Area of rarefaction with corrosion of one pin can be seen where two of the pins approximate.](image)

**CHROME-COBALT ALLOYS**

In view of these problems with the ferrous alloys, why is it that they have been used for so long, and what are the alternatives? Until recently, the manufacture of chrome-cobalt alloy implants was controlled by the Austenal Laboratories in America and a great deal of technical information has been amassed by them. These alloys are difficult to cut, drill or machine, and hence the implant has to be cast by the lost-wax technique. In this process a wax pattern, produced by injecting wax into a metal master mould, is invested in a refractory medium and the wax melted out leaving a cavity into which is cast the alloy. For the individual prosthesis a pattern in metal or plastic has to be made and an impression with either a solid or flexible medium taken. From this a number of individual wax positives can be prepared. With a casting technique, radiographic inspection of the casting is important to detect voids and cracks which often occur. This results in a number of rejects which adds to the cost of the implant.

Our own industry, while willing to help in this work, is given little encouragement to undertake what is relatively a costly process of manufacture, and thus the facilities for the production of the individual or experimental chrome-cobalt alloy prostheses do not exist in this country to the same extent as in the United States.

It will never be possible to assess the number of failures of implants, but I know of no
case of failure of a chrome-cobalt alloy from corrosion. A further advantage in the use of these alloys is that surgical instruments can be tipped with the same alloy, and thus the problems associated with the transfer of metals would probably cease to exist. As these alloys have much greater resistance to corrosion than the ferrous alloys, implants do not need to be polished, and unavoidable surface damage does not result in corrosion.

In the future, metallic elements such as Titanium and Zirconium may offer possibilities. It might seem preferable to use elements rather than alloys because one would only be dealing with problems of a single and not a compound material.

<table>
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<th>TABLE I</th>
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<tr>
<td>Transfer of Metal from Surgical Tools to Bone</td>
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<table>
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<tr>
<th>Operation</th>
<th>Approximate weight of swarf (milligrams)</th>
<th>Weight of steel per 100 milligrams (µgrams)</th>
<th>Weight of steel adhering to bone (µgrams)</th>
<th>Weight of steel adhering after brushing (µgrams)</th>
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<tbody>
<tr>
<td>A</td>
<td>300</td>
<td>91</td>
<td>40</td>
<td>—</td>
</tr>
<tr>
<td>B</td>
<td>250</td>
<td>290</td>
<td>300</td>
<td>160</td>
</tr>
<tr>
<td>C</td>
<td>240</td>
<td>18</td>
<td>7.5</td>
<td>—</td>
</tr>
<tr>
<td>D</td>
<td>140</td>
<td>28</td>
<td>8.5</td>
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Specimens of bone taken from bone bank and allowed to thaw.

A Two transverse cuts through hemi-section mid-shaft of tibia, marrow removed, swarf pooled, one face counted.
B Three transverse cuts through mid-shaft of femur, marrow not removed.
C Two holes drilled transversely through cancellous part of tibia, swarf pooled, bone sectioned across both holes, one face counted.
D One hole through both cortices of fibula, bone sectioned through hole, one face counted.
Drill, \( \frac{1}{8} \) inch diameter, of stainless steel, Type F.S.T.
Saw blade, 2 inches diameter, of stainless steel, Type F.H.

MECHANICAL AND TECHNICAL PROBLEMS

The satisfactory use of materials can only be established by a study of their mechanical properties, coupled with investigations into the biological response of the cell in contact with the implant. The chemico-physical properties of the implant are partly dependent on the effects produced by the forces acting on the implant. Thus in their design, the magnitude and direction of application of these forces, after a surgical procedure, must be taken into account. All bones are struts which are relatively weak, and that they are capable of transmitting forces of such a high value is because of balanced muscle control, design of joint at which movement occurs, and the stabilising effects of ligaments on these joints. Many implants are used for temporary fixation, and when bony union occurs they become purely passive members, subject to little stress. Other implants, such as a knee joint, are required to remain as active components for the life of the patient. Thus the method of attachment of the implant to the bone, the action of muscles and the reconstitution of their attachments to the implant, are aspects of the prosthetic problem which demand careful consideration. The possibilities of surgical technique have always to be borne in mind. An implant is of little value if it is found at operation that in order to insert it extensive resection and transposition of tissue is necessary. For example, it is mechanically undesirable to plate a fracture of the shaft of the femur with one plate and four or six screws. It is technically much more difficult, however, to use bilateral slotted plates and bolts which mechanically would be the more desirable method.

There is no doubt that unless the resources of other branches of science, particularly engineering, are brought to bear on many problems, there will be an ever increasing number
of implant failures. Standards of composition, design and manufacture of existing implants, in everyday use, do not exist in this country, although in the United States they are being developed. These standards are necessary to safeguard both the patient and the surgeon. New materials are continually being produced and methods of manufacture are changing. Thus standards will have to be revised after systematic experiment and clinical observation. Some day a start must be made on this problem. The longer it is deferred, the more complex it becomes.

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REFERENCES


