BIOMECHANICAL PROBLEMS OF THE ORIGINAL JUDET PROSTHESIS

BY

JOHN T. SCALES, M.R.C.S., L.R.C.P.

Medical Officer i/c Plastics Research Unit; Senior Lecturer,
Institute of Orthopaedics (University of London); Honorary
Senior Registrar, Royal National Orthopaedic Hospital,
London

AND

J. M. ZAREK, Ph.D., B.Sc., A.M.I.Mech.E.

Lecturer in Mechanical Engineering, King's College
(University of London), London

[WITH SPECIAL PLATE]

In the treatment of pathological conditions of the hip-joint much surgical ingenuity has been exercised in the development of various types of arthroplasty. Recently the Judet technique seemed to offer a considerable prospect of success, and indeed the preliminary results published by J. and R. Judet (1950) were encouraging. The results achieved in this country, however, have been less satisfactory than those claimed by the Judets in 1952. In their later report they state that "fracture of the stem of the prosthesis has not occurred in 500 operations since the stem of the prosthesis has been reinforced with a steel core. Undue wear of the surface of the head has occurred in three cases, and we are seeking its cause."

In view of the number of breakages and instances of wear of prostheses manufactured in this country, however, it was decided to investigate the reasons for these mechanical failures. The work has been made possible only by the generous co-operation of a number of orthopaedic surgeons. Our investigations suggest that both the design of the prosthesis and the combination of materials used in this country are unsatisfactory.

It seems that delayed failures of the operation are commonly attributable to one or more of the following: (1) failure of the materials; (2) malposition of the prosthesis; (3) interference with the local blood supply to the bone.

Before giving examples of causes of failure it is important to consider the mechanics of the hip-joint, the materials used in the prosthesis, the design, the method of manufacture, and the blood supply of the neck of the femur.

Mechanics of the Hip-joint

In a person standing erect with both feet together the weight of the head, arms, and trunk is distributed equally between both hip-joints. For example, assuming the total weight of the patient to be 70 kg., and the weight of each lower limb 15 kg., there will be 20 kg. carried by each femoral head, with the body weight acting vertically downwards in a sagittal plane. If now the patient stands on one leg, keeping the pelvis horizontal, the hip-joint becomes the fulcrum of a lever (Fig. A). The weight of the body carried by the supporting hip-joint becomes 40 kg. for head, arms, and trunk, plus 15 kg. for the non-weight-bearing limb. Because the femoral head represents a fulcrum of a lever, the total moment about this point which has to

be resisted by the contraction of the glutei, tensor fasciae latae, etc., can be calculated as follows from Fig. A:

Assuming that the distance OW from the symphysis pubis to the centre of the area of contact of the femoral head with the acetabulum is 10 cm., then the moment due to the weight of the head, upper limbs, and trunk is $40 \text{ kg.} \times 10 \text{ cm.} = 400 \text{ kg.cm.}$ The moment due to the non-weight-bearing limb is $15 \text{ kg.} \times 20 \text{ cm.} = 300 \text{ kg.cm.}$ The total moment is therefore 700 kg.cm.

Assuming that the resultant force due to muscle pull acts on the great trochanter at a distance OQ of 5 cm. from the centre of the femoral head and at an angle of 45 degrees, then, from the consideration of moments, $Q = 140 \text{ kg.}$, and the vertical reactive force (R_1) is equivalent to $140 + 40 + 15 \text{ kg.} = 195 \text{ kg.}$

From a consideration of statics the total reactive force carried by the head is equal to 240 kg. (R) and acts at 36 degrees to the vertical. Therefore the angle between the axis of the prosthesis in the bull's-eye position and the direction of the force transmitted by this joint is 12 degrees. As in the process of obtaining this result a certain number of assumptions had to be made, the results will vary from patient to patient, but they give an indication of the magnitude and direction of the acting forces under static conditions.

When the patient is walking, accelerating and retarding forces come into operation and, according to their magnitude, may produce a load on the joint which will exceed the static value. At times the line of body weight may move further from the hip-joint, and this will also increase the load carried by the joint. Under shock load conditions, as when a patient accidentally steps off a kerb, the instantaneous loading value will be even greater. Considerable work on the mechanics of the hip-joint has been done by Ros y Codorniu (1949), by Osborne and Fahrni (1950), and by Endler (1953b).

Materials, Design, and Method of Manufacture

Materials.—The development of organic synthetic materials has resulted in a range of materials which appear suitable for use in contact with body tissues. Any material to be used inside a joint must fulfil certain requirements (Scales, 1951). It should be chemically inert, physically unaffected by tissue fluids, incapable of provoking an inflammatory or foreign-body response in the tissues, non-carcinogenic, incapable of producing a state of allergy or hypersensitivity, capable of standing up to the mechanical strains imposed upon it, and capable of being fabricated simply into the form required. Because polymethyl methacrylate satisfies most

FIG. A.—Patient standing on one leg, assuming pelvis horizontal. $W = 40 \text{ kg.}$ $L =$ pendant limb $= 15 \text{ kg.}$ $O =$ fulcrum of joint. $O'A =$ axis of femur. $O'B =$ direction of resultant force transmitted through joint. $O'C =$ axis of neck of femur and prosthesis when inserted in bull's-eye position.

of these requirements, the Judets, in 1946, used it for their reconstructive procedure. In this country the material used is unplasticized polymethyl methacrylate produced by Imperial Chemical Industries, Ltd., under the trade name "perspex." The mechanical properties of thermoplastics are a function of temperature, and it may be taken that the following values for perspex apply at 37° C.: maximum tensile stress, 490 kg./cm.²; modulus of elasticity, 2.625×10^4 kg./cm.²; Vickers pyramid hardness, 15-18. The linear coefficient of thermal expansion at 37° C. is 9.7×10^{-5} per °C.*

Design.—The standard Judet acrylic prosthesis used in this country up to the time of writing is a "mushroom-like" structure. Various stem lengths and head diameters are available. The head is approximately two-thirds of a sphere and is recessed to take the shaped basal part of the head and adjacent neck of the femur. The grooves on the stem and the squared taper are devices to prevent rotation, and vary according to the manufacturer. The stem is reinforced with a metal rod which is totally enclosed by the resin.

Method of Manufacture.—The shape of the prosthesis having been turned from the solid block, a hole of slightly less diameter than the metal rod is drilled up the stem into the head. The method of insertion of the rod depends on the ideas of the manufacturer. The hole is filled with a solvent or cement in order to soften the surrounding acrylic locally, thus allowing a metal rod to be forced into the cavity—a type of "shrinking" fit being obtained. A perspex plug is next inserted to fill the remainder of the hole, and the tapered end of the stem is subsequently fashioned. The coefficient of expansion of polymethyl methacrylate is eight times that of steel, and consequently the bond between the acrylic and the metal rod is subject to disturbance when the temperature of the prosthesis is raised either during sterilization by heat or, to a less extent, when it is placed in the body after formalin sterilization. For greatest reinforcement of a structure there must be, of course, adequate bonding between the two materials used, and a sufficient anchorage. We have found that in a number of cases the reinforcing rod had such a loose fit that it rattled. One manufacturer drilled a hole through the metal rod; the acrylic cement filled this hole and thus prevented the rod from rattling.

Biomechanical Analysis of the Design.—The design of the prosthesis should be such that: (1) it is strong enough to transmit the forces due to body weight and the action of the gluteal muscles to the shaft of the femur, without danger of mechanical failure; (2) it can distribute the load on the femur as uniformly as possible without endangering the blood supply and without producing local crushing of the bone; (3) the dimensions of the head will give greatest loading area with least limitation of movement of the femur.

Theoretical Considerations

Fig. B shows a prosthesis with a stem correctly penetrating the cortex; it rests on an area represented by the point B₁, where the bone may be either cancellous or cortical or both. The resultant action of the weight of the body and the action of muscles is represented by force P acting medially to B. This force can be resolved into two components, P₁ and P₂. Thus the prosthesis is subjected to bending and shearing due to P₁ and direct stress in the direction of the stem due to P₂. Torsional stresses should be negligible. Owing to the penetration of the cortex the direct stresses due to the component P₂ are taken up by the annular part of the prosthesis under the skirt. The stem will thus be subject only to bending and shearing stresses due to P₁ as indicated diagrammatically by I and II in Fig. B.

As the angle i increases, the component in bending P₁ also increases, since $P_1 = P \sin \alpha$, the angle α being directly

proportional to angle i . The moment about B thus increases, since it is a product of $P_1 \times AB$.

Should AB increase because of the movement of the point of support laterally, as occurs with absorption of the cancellous bone or fracture of the inferior cervical cortex, then there will be a further increase in the value of the moment about B₁ (Fig. C). This distance AB is necessarily large when a prosthesis with an extended head is used. As the value of the bending moment increases, so the value of R₁ must also increase. There are thus three situations which may arise: (1) a state of equilibrium of the structure is reached; (2) the flexural strength of the stem of the prosthesis is exceeded and failure occurs; and (3) fracture of the bone takes place.

When the stem does not penetrate but abuts against the lateral cortex, or where there is incomplete penetration of the cortex by the taper of the stem and the annular part of the prosthesis is not in contact with the transected neck, then direct stress will be additionally introduced in the stem. Should the stem not be long enough to reach the cortex, the direct stress will again be taken up by the annular surface, but the prosthesis will undoubtedly be in a less stable equilibrium.

When comparing the loading of the neck of a normal femur with that in which a Judet prosthesis has been inserted, it is clear that the distribution of load through the prosthesis is far from favourable. As seen in Figs. B and C, the reactive force R₁, which may be either local at B₁, or distributed along a greater or lesser extent of the lower surface of the stem, may be excessive; nor does its direction of action correspond with the normal anatomical "lines of force" in the region of the calcar femorale.

As the ratio of the modulus of elasticity of stainless steel to that of polymethyl methacrylate is as high as 86:1, full advantage of the metal insertion can be achieved only if adequate anchorage of the reinforcing rod is provided and the bonding stress between the two materials is high enough to ensure that no movement between the plastic and the metal insert takes place during straining. If the bond is poor or the insert is actually loose, then failure of the plastic part of the stem will take place under a very low load.

Experimental Findings

Preliminary tests on the prosthesis under static load were carried out. A prosthesis of the Judet type but without a metal reinforcement, fitted into a femur, failed under a vertically applied load of 470 kg., giving a failing stress in bending in the stem of 490 kg./cm.² This result agreed with the one obtained by Endler (1953a).

In order to test prostheses reinforced with steel, a metal reproduction of the femur was made. The failing stresses

FIG. B.—Prosthesis in bull's-eye position. I = Bending moment diagram. II = Shearing force diagram.

FIG. C.—Shift of fulcrum B₁ due to absorption.

*Values as given by Imperial Chemical Industries.

for the plastic part of the stem of a number of tested prostheses were in the range of 420–560 kg./cm.²

If the prosthesis is correctly fitted the forces involved during normal movement of a patient produce much lower stresses in the stem, but nevertheless cause failure. It was evident that other factors such as fatigue of the materials and stress corrosion must be responsible. Examination of a number of prostheses which had failed in the body confirmed this belief. The results of a typical metallurgical investigation are given below.

The metal pin under investigation was part of a prosthesis which failed in service after insertion. It was supposed to be made from austenitic stainless steel of the 18% chromium and 8% nickel variety, but when reference was made to the makers no indication of the exact type or condition of the steel could be obtained. Examination of the surface of the pin showed that it was badly polished, having the appearance of a "filed" type of finish. The fractured surface (Plate, Fig. 1) of the rod consisted of two parts: first, a fairly smooth area marked with a series of concentric rings, the centre of which was a point on the periphery of the pin; and, secondly, an area with a fine-grained "crystalline" type of fracture. These findings are typical of a fatigue failure.

In order to examine the micro-structure of the rod, a longitudinal section was polished and examined in the unetched condition. The following observations were made: no sign of cracking was noticed either immediately adjacent to the fracture, or anywhere on the specimen; and the steel did not contain any non-metallic inclusions, or any other signs of defects.

Subsequently the specimen was etched in Murakami's reagent to examine for carbides, and the following observations were made: the structure now showed a number of black particles and pits; these particles appeared to be parallel to the direction of the working of the pin; no other structure was visible.

It was considered that free carbides were present in the material. Finally, the specimen was repolished and etched in aqua regia and the following observations were made: (a) The general structure was typical of an 18/8 austenitic stainless steel. (b) The structure again showed the presence of particles elongated by working, which were assumed to be carbides; another constituent, the nature of which was not established, was probably free chromiferous ferrite. (c) There was no plastic deformation of the surface of the grains over the fractured surface, or any signs of defects.

The hardness of the steel was of the order of 230 Brinell, which is equivalent to a tensile strength of 7,560 kg./cm.² and represents a nominal figure for this type of steel. In conclusion it may be said of the fracture that: (a) It is a fatigue fracture. (b) It may have been due to either too low a fatigue limit of the material used or a lowering of the fatigue limit by structural or corrosive effects. (c) The material, although an 18/8 stainless steel, shows in its microstructure the presence of a certain amount of included material. These inclusions, unusual in this type of steel, may consist of free ferrite or free carbide, and could act as stress raisers and thus seriously reduce the fatigue strength of the steel. (d) The presence of these constituents in the structure would seriously reduce the corrosive resistance of the steel, and only a slight corrosion of the pin would be sufficient to reduce the fatigue strength even further. No evidence of corrosion was found in the specimens, but it should be noted that corrosion effects are rarely seen in stainless steels when failure occurs by corrosion fatigue.

Polymethyl methacrylate, according to the makers' tests, loses 50% of its strength when subjected to a constant load well below its breaking strength for about 1,000 hours at 20° C. (Hoff, 1952). Its ultimate static strength also depends on the straining rate (Maxwell and Harrington, 1952). Fluid absorption, which according to the makers may reach 2%, will also have some effect on its mechanical properties.

When a material is subject to cyclic stressing well below the value of the static failing stress, a progressive deterioration of its strength takes place and may finally result in failure. For the investigation of the behaviour of metals suitable methods of testing have been developed, resulting in reliable information.

It is realized that the characteristics of metals and plastics differ widely. As there are no suitable methods of fatigue testing for plastic materials, we have adopted the well-established method used in the investigation of metals, which, we believe, should give an approximately correct result.

Specimens of perspex made from rods as supplied by the makers were fatigued in flexure with full reversal of stresses at 2,000 cycles a minute. Curve A in Fig. D shows that the stress fatigue limit is in the range of 110 kg./cm.²

As it is a customary procedure to sterilize the prosthesis by boiling, a series of tests were performed as for Curve A, but, before testing, the specimens were boiled for 30 minutes and then plunged into cold water. It is evident from

FIG. D.—Fatigue test results on polymethyl methacrylate. Curve A=material as supplied by the makers. Curve B=test specimen, boiled and cooled before testing.

Curve B (Fig. D) that this procedure has reduced the fatigue limit to approximately 70 kg./cm.² The same degree of reduction in strength was observed when, after boiling, the specimen was allowed to cool very slowly.

From these tests the following comments can be made: (1) The fatigue strength of polymethyl methacrylate when subjected to rapidly fluctuating stresses is from 15% to 25% of its ultimate strength. In both tests the results indicate a high degree of scatter which may, in part, be attributed to poor heat conductivity of the material and high hysteresis losses. (2) The decrease of strength of the material after boiling may be due to water absorption or to an alteration in the structure of the polymer. (3) In application to the human body the frequency of 30 cycles per minute may be accepted as around normal and therefore a certain percentage of strain recovery is possible.

Fig. E shows results of fatigue tests in flexure on prostheses with a 6.3 mm. stainless-steel reinforcing rod. In

FIG. E.—Fatigue tests in flexure on prosthesis with a 6.3-mm. diameter metal reinforcing rod.

two cases the plastic and the rod failed simultaneously. In all others the plastic part of the stem failed and slipped off the metal rod. The tests suggest that the value of the moment of resistance of 41 kg.cm. may be accepted as a fairly safe limit. From simple calculations, assuming the force transmitted by the joint to be 240 kg. and the angle of insertion θ to be 56 degrees, it is found that in the human body the above moment of resistance will be exceeded only if the point of application A of

load P (Fig. B) is further than 8.2 mm. from the point of support B. This figure was obtained using the experimentally determined safe value for stress in the plastic part of a stem with a 6.3 mm. reinforcing rod. Again, simple calculations indicate that if an 8.0 mm. steel rod were used the critical value for the distance AB would be about 18 mm.

This critical condition could be satisfied with much greater ease if the 0.67 sphere of the Judet head could be replaced by a hemisphere. All these calculations are based on experimental results obtained under laboratory conditions with a frequency of 2,000 cycles a minute. It is realized, however, that the carrying capacity of the Judet stem may be greater under actual working conditions, because the less frequent straining may allow strain recovery. Nevertheless it seems that the distance AB should not exceed 2 cm.

The average failing strength of the prostheses in which both the steel reinforcing rod and the acrylic failed was appreciably higher than that in which the acrylic alone failed. The two different types of failure of the stem may be explained in terms of anchorage and bonding stress between the acrylic and the metal rod. The better the bond the higher is the fatigue failing strength of the prosthesis. Sterilization by boiling disturbs the bond, and therefore other methods not involving a rise in temperature should be used. Qualitative analysis of bonding stresses in a great number of prostheses, by means of the photo-elastic method, indicated that the bonding stress between the acrylic and the metal rod of an initially good prosthesis was reduced considerably in the process of boiling. Immediately after boiling, residual thermal stresses were present in the head of the prosthesis, causing high stress concentration at the point of junction of the stem and the head. These decreased slowly, disappearing in about two hours.

A prosthesis in a state of stress will be more vulnerable to impact, which may cause failures during insertion.

The grooves in the stem vary in length, depth, shape, and surface finish. When a structure is subjected to cyclic stresses it is of the utmost importance that a perfect polished-surface finish should be obtained, as a rough finish is a source of stress raisers (Plate, Fig. 2).

Examination of new prostheses which failed in fatigue under laboratory conditions revealed a brown deposit on the inner wall of the acrylic stem and the surface of the reinforcing rod. A chemical analysis indicated that this was iron oxide, and the quantity formed was directly related to the magnitude of the stress in the metal rod, the deposit being greatest at the point of maximum bending moment.

It is known that materials which in an unstressed condition show no signs of corrosion may behave differently when in a stressed condition. In engineering practice the term "corrosion fatigue" is used to describe the simultaneous action of corrosion and fatigue. It has also been found that corrosion which takes place in a material before subjection to cyclic stress has a far less damaging effect than a slight corrosion taking place simultaneously with the applied stresses. It is thus of great importance to investigate the behaviour of materials under the action of body fluids and the chemical constituents of the resins and solvents, both in the stressed and in the unstressed condition.

In an effort to overcome the shortcomings of the Judet prosthesis, some surgeons have resorted to the use of stainless steel or vitallium prostheses. It is only in recent years that materials have been used in orthopaedics in situations where they will be subjected to constant fatigue stresses in contact with tissue fluids. Most metal appliances have been used for temporary fixation of fractures and have rarely been exposed to prolonged fatigue stresses once union of the fracture has occurred. A metal prosthesis may initially have a better load-carrying capacity, but the problem of stress corrosion remains.

Polymethyl methacrylate is also subject to crazing (Russell, 1948; Sauer and Hsiao, 1953) which is defined as

fine mechanical cracking over the surface of the material, penetrating to a depth which depends on the intensity of the cause. It may be brought about by the simple or compound action of such factors as mechanical stressing, solvents, and high energy radiation. Only the first two factors, however, are significant. It has been found that only tensile stresses produce crazing, the direction of cracks taking place at right angles to the direction of action of the tensile stress. The intensity depends on the magnitude, rate, and duration of the stress applied, the dimensions of the specimen, and its heat treatment. Solvent crazing patterns are irregular, in contrast to the well-orientated ones produced by tensile stresses, although the physical effects are the same. Stresses due to the forced fitting of the metal rod in the presence of solvent cause crazing of the inner wall of the stem; it has been found that the penetration of crazing was considerable even before stressing the prosthesis externally (Plate, Figs. 3 and 4). It is evident that serious defects exist in the prosthesis *even before it is put into use*.

Blood Supply

The blood supply to the head and upper neck of the femur is derived from three main sources: the nutrient artery, the retinacular vessels, and the trochanteric fossa anastomosis.

The proportion of flow from each of these sources is variable from patient to patient. The retinacular vessels are arranged in three main groups (Tucker, 1949)—postero-superior; postero-inferior; anterior—which pass up beneath the synovial membrane reflection and penetrate the base of the head and upper neck through a number of foramina to anastomose with branches of vessels from the nutrient artery and trochanteric fossa. We have found that the vessels supplying the cortex of the femur originate mainly from the medullary network (J. T. Scales, unpublished observations). Any reaming of the neck to take the skirt may cause considerable damage to the retinacular vessels. The insertion of the stem of the prosthesis must further interfere with the vascularity of the bone. Revascularization is made more difficult by occlusion of parts of the neck by the skirt. It is vital that the cortex should be interfered with as little as possible and that prostheses with occlusive cuffs should not be used.

Analysis of Clinical Material: Prostheses

Thirty prostheses removed because of structural failure have been examined. In most cases the clinical notes and radiographs have been made available to us.

Of the 30 prostheses sent to us 21 were removed because of fracture of the stem. In 17 cases the site of the failure was within 2 cm. of the base of the head. This was found to coincide with the most probable position of the point of support B₁ (Fig. B)—that is, the position of the greatest bending moment. Here also the surface of the stem is interrupted by the beginning of the milled grooves. The stems of six were broken near the distal end of the rod, in the region of C. Two stems had fractured in both regions.

Coarse crazing of the surface due to the milling operation was present in all stems examined. In many cases deductions made about the position of the fulcrum B₁ and the distally situated point of reaction C on radiographs were confirmed by worn areas on the acrylic stem in the corresponding positions.

Leakage of tissue fluid around the stem plug was seen in a number of cases. This is a serious matter when the reinforcing rod is not inert.

Of the 30 broken prostheses studied the metal rod had failed in 15. In 12 cases the site of the fracture was about the mid-point of the rod, coinciding with the position of failure of the acrylic part of the stem. In three instances in which the metal rod had been drilled at its distal end failure occurred in the cross-section of the rod. In six cases the rod was intact, although the stem had fractured,

and the site of failure in these cases was either immediately adjacent to the base of the head or at the distal end of the metal rod. The rods examined were from prostheses produced by five different manufacturers. Their diameters, together with the number of failures in each category, are given in the Table. Nitric acid (S.G. 1.200) was applied to

Diameter of Metal Rods, With Number of Failures in Each Size

Diameter of Metal Rod (mm.)	No. of Rods	No. Broken
4.5-	1	1
5.0-	1	1
5.5-	19	11
6.0-	3	1
6.5-	3	1
7.0-	0	0
7.5-8.0	3	0

28 rods and a positive reaction was obtained in 11 cases, indicating that these rods were *not* stainless steel. Of the 17 that were negative to nitric acid, eight were magnetic and were therefore most probably not of the austenitic variety of steel. (Austenitic steel can become slightly magnetic during working, but usually loses this property in a short time.) Corrosion pits were visible in nine of the rods (Plate, Fig. 5), all giving a reaction to nitric acid. One manufacturer used rods of a copper-zinc-nickel alloy, which had been chromium-plated and had the appearance of stainless steel. The surface finish of most of the rods was poor. A mirror finish should be obtained, as small scratches and grooves are apt to be centres of corrosion.

In a few instances, when the acrylic stem was cut and the metal rod withdrawn, a quantity of liquid was found which smelt strongly of burnt sugar. After a few minutes the inner surface of the stem turned yellow. This phenomenon was unexplained. A number of rods were surrounded by a white powder which fluoresced under ultra-violet light. In a number of instances the surface of the polymethyl methacrylate and the metal rod were not every-

FIG. F.—Voids at metal/acrylic interface. Note also leakage around plug and crack in acrylic at pointed end of metal rod. ($\times 3$.)

where in contact (Fig. F), so there was a very poor bond between the metal and plastic. Wear of the weight-bearing area of the acrylic head was plainly visible in 12 of the 30 prostheses. The Vickers diamond test (1 kg. load at 20° C.) gave hardness numbers between 22 and 26, with one at 18, on 23 prostheses, the worn areas giving slightly higher values.

Examination of 21 heads by ultra-violet light revealed crazing of the surface (Plate, Fig. 17)—never in the worn part, but always in the surrounding area. In the nine heads showing no apparent wear, crazing could not be demonstrated, suggesting that crazing precedes wear.

It is possible that wear of the head is a cause of pain and limitation of movement in those patients in whom the prosthesis appears to be mechanically satisfactory.

The movement of any synovial joint has two components—sliding and rotation. The conditions for efficient lubrication are critical, being related to the nature of the two surfaces in contact, their relative velocities during move-

ment, and their area of contact (MacConaill, 1950). Even if a cartilaginous acetabular roof is present initially, it is unlikely that the dimensions of any implant made in eight sizes of head and having a surface which is not congruous with the acetabulum will fulfil the critical requirements. The surface hardness of a foreign body used as a component of a joint must be such that it will not wear when in contact with bone. If local wear of the prostheses takes place, then in certain positions during movement an excess loading/unit area will result.

Our radiographic studies suggest that the load-carrying capacity of a joint is determined early in life. It is possible that one of the causes of osteoarthritis is an increase in load per unit area which the head of the femur has to carry when the weight of the patient increases in middle and later life. It is suggested that the acetabulum therefore should be reamed so as to accommodate an artificial head of abnormally large diameter, so that the load should be distributed over a greater area.

It has not been possible to correlate wear of the prosthesis with sclerosis of the roof of the acetabulum or with irregularity of its radiographic outline. It was found, however, that wear occurred when the depth of the acetabulum exceeded two-thirds of the diameter of the prosthesis, or, in other words, when the head was relatively small. Thus the femoral head selected should be as nearly congruous with the acetabular cavity as possible.

Examples of Mechanical Failure of Prostheses in Patients

In view of the many interdependent mechanical features, it is not possible to assign a simple reason for failure on radiographic evidence. It is clear from Figs. B and C, however, that where the angle of insertion is large and where the fulcrum B_1 occurs some distance down the stem, the prosthesis is subject to a large bending moment. Both these factors may be assessed qualitatively on the radiograph. As the direction and point of application of the forces acting through the hip-joint cannot be estimated accurately, it is not possible to predict quantitatively the values of the transverse force P_1 and the direct force P_2 , and the bending moment ($P_1 \times AB$). A standardized radiographic technique could be developed which would enable these values to be measured. The method would include the use of the scanogram technique.

Two main methods have been used in the examination of the available radiographs. (1) The dimensions of the radiograph shadow of the metal rod, and the metal rod of the Judet prosthesis which was removed from the patient, have been measured. From these measurements the magnification was determined for each x-ray film. In this manner a reproduction of the outline of the prosthesis was made from transparent cellulose acetate film. (2) The angle of insertion of the prosthesis is defined as the acute angle included between the line of the stem and the axis of the femoral shaft with the limb in the neutral position. This angle may be called the stem-shaft angle. It is, of course, realized that there are a few degrees difference in anteversion from patient to patient.

It has been found that when it was possible to measure the angle of insertion, and either the stem or the skirt, or both, were broken, *the angle of insertion always exceeded 40 degrees*. In the radiographs of nine patients in which the prosthesis was apparently satisfactory the angle of insertion was in the region of 40 degrees or less.

Case 1

This case illustrates the effect of too great an angle of insertion.

The patient, a married woman aged 65, developed osteoarthritis of the left hip after a fall four years previously. On November 12, 1952, a Judet prosthesis, 43/80, was inserted, the neck being reamed to take the skirt of the prosthesis. On January 13, 1953, she was discharged, the movements being as

follows: flexion with extended knee, 90°; flexion, 90°; extension, 10°; abduction, 15°; adduction, 10°; external rotation, 10°; internal rotation, 10°.

When seen as an out-patient on March 13 she was not complaining of any pain and could walk one mile. Fig. 6 (Special Plate) is a radiograph taken at four and a half months and shows the angle of insertion to be approximately 60 degrees. Thus from Fig. B, since $P = P \sin \alpha$, the value of the transverse component is large. Also the distance AB exceeds the theoretical value of 8.2 mm.

On April 13 the patient felt a sudden snap in the left hip with pain down the leg. Radiographs showed fracture of the prosthesis (Plate, Fig. 7).

The skirt would, of necessity, be broken, because the neck of the femur is displaced upwards. Other factors such as crazing of the acrylic and the use of unsuitable metal were found to have contributed to the failure.

Case 2

This case shows the combined effect of a large angle of insertion, too short a metal reinforcing rod, and the use of an extended neck.

The patient, a man aged 59, had a five-years history of osteoarthritis of the right hip. A Judet arthroplasty was performed in May, 1952. A large cystic space was found in the postero-inferior aspect of the neck, and consequently the stem was inserted as high as possible (Plate, Fig. 8). A radiograph taken in October, 1952, showed a fracture of the acrylic part of the stem of the prosthesis near the distal end of the metal rod (Fig. 9). From the radiographs it will be seen that the stem pierced the lateral cortex, and that the fulcrum was slightly medial to the position of the break. Note that here again the angle of insertion is large and the distance AB is greatly in excess of the theoretical value. The fracture was due to the discontinuity of structure of the stem at a point near the fulcrum.

At operation in November, 1952, it was found that there had been a fracture of the inferior aspect of the femoral neck. It is probable that fracture of the bone, under high bending moment, occurred first, resulting in a shift of the fulcrum laterally. The primary cause of fracture may have been interference with the blood supply at the time of operation. The prosthesis was not available for examination.

The neck was further cut back and reamed and a second prosthesis with an extended head was inserted; Fig. 10 shows that the skirt is impinging on the lower portion of the neck. The distance AB has been further increased. Ten weeks later this prosthesis broke (Fig. 11). The design of the second prosthesis and the unsuitable metal used for reinforcement were contributory factors in its failure. The metal rod, diameter 6.1 mm., was of non-austenitic steel. There was no bonding between the metal rod and the acrylic. The radius at the junction of the skirt with the base of the head was insufficient and there was crazing of the head and stem. There was a visible leak around the acrylic plug.

Case 3

This case illustrates excessive bone absorption and fracture of the stem of the prosthesis through a weak part.

A married woman aged 79, suffering from osteoarthritis, had a right Judet arthroplasty performed in August, 1952. The angle of insertion was approximately 43 degrees (Fig. 12). Progress was satisfactory with no pain until April, 1953, when she complained of severe pain in the hip with some crepitus on movement. A radiograph shows that the stem of the prosthesis had fractured at the cross-section where the metal rod had been drilled, and that there had been considerable widening of the track, the angle of insertion having now increased to 55 degrees (Fig. 13). No fracture of the neck of the femur was visible, but there had been considerable bone absorption of the neck, and the base of the head no longer appeared to be in contact with the bone. The stem was apparently firmly held at its distal end, but with gradual bone absorption the fulcrum was shifted laterally, and this resulted in a high bending moment in the region of the fracture site. This bone absorption was probably caused by interference with the blood supply to the proximal part of the neck. Wear of the head of the prosthesis could not be demonstrated. The surface hardness was 23.2. There was no crazing of the surface of the head or skirt, although crazing was present along the stem. The metal rod was of a non-austenitic steel and was positive to the nitric acid test. Corrosion pits were found in the region of the fracture. No leakage of the stem plug could be demonstrated. The reasons for failure were both anatomical and structural.

Case 4

This case illustrates the detection of a failure by means of a transparent outline model.

The patient, a man aged 71, suffering from bilateral osteoarthritis, had a Judet arthroplasty performed on the left side in July, 1951 (Fig. 14). In November he was free from pain and walking well. Movements were as follows: flexion, 45°; extension, 0°; abduction, 20°; adduction, 20°; external rotation, 20°; internal rotation, 20°.

From January to October, 1952, attacks of pain were relieved by diathermy and other physical treatment, but in November the left hip became much worse. A radiograph revealed widening of the track with downward displacement of the prosthesis (Fig. 15). In December, 1952, movements were: flexion, 70°; extension, -20°; abduction, 20°; adduction, 20°; external rotation, 30°; internal rotation, 40°. There was squeaking of the joint on movement.

His condition deteriorated until March, 1953, when little movement was present (Fig. 16). The hip was re-explored and the skirt of the prosthesis was found to be broken. The larger fragments of the skirt were not found. There was considerable wear of the head and eburation of the stem just below the base of the head.

On examination the prosthesis was found to have a surface hardness in the worn area of the head of 24.7 and in the unworn area of 23.3. There was considerable crazing of the surface of the unworn part of the head although none was visible on the worn area. There was also crazing of the stem and skirt. The nitric acid test on the metal rod was positive, and it was found to be a chromium-plated copper-nickel-zinc alloy rod.

As the stem of the prosthesis did not penetrate the cortex, it was able to rotate downwards about a point situated near the distal end of the stem, the cancellous bone not offering enough resistance to the reactive force at the fulcrum. A transparent model of the outline of the prosthesis when superimposed on the radiograph taken in November, 1952, suggested that failure of the skirt had already occurred.

Intramedullary new bone formation in the neck of the femur has not been seen in any of the radiographs that have been examined. The normal head of the femur is a structure designed to carry considerable load and to distribute it to the neck and shaft by means of the trabeculae, each one being subjected to a small portion of the stress. Insertion of any prosthesis must destroy the three-dimensional structure and result in the overloading of too few trabeculae. The Judet prosthesis is particularly apt to produce this effect, because of the relatively small surface area of the stem and base of the head. The survival of trabeculae and cortical bone depends on maintenance of their blood supply. As part of the blood supply comes through the great trochanter, it would seem advisable not to remove it at operation.

It has not been possible to correlate failure of the prosthesis with the sex, weight, or post-operative activity of the patient. The time between insertion and removal of the prosthesis has varied between two and twenty months.

Discussion

Various defects in the British manufactured prosthesis could have been avoided if a detailed specification had been available. There is no doubt that the design and method of manufacture of all implants should be very carefully considered, so as to avoid the great number of mechanically unsound features with which the original design of the Judet prosthesis as made in this country is overloaded. It is interesting to note that an improved design has recently been developed by Judet *et al.* (1954) in an endeavour to solve some of the problems. They have, for example, abandoned the skirt of the prosthesis. The head has been set at an angle of 60 degrees to the shaft in order to retain more of the head and neck and so distribute the load to a greater area of bone and reduce the distance AB (Fig. B).

There are a number of problems associated with the properties of synthetic materials and metals, especially when they are combined to form a structure which is subjected to the simultaneous action of stress and tissue fluids at body temperature.

Not the least important point is the individual operative technique. This, however, is beyond the scope of this paper, and those primarily concerned with the use of this prosthesis will be able to draw their own conclusions from the observations we have made.

Summary

The mechanics of the hip-joint have been examined, with special reference to the Judet prosthesis. The materials used in the manufacture of the prosthesis and its ultimate strength have been investigated under laboratory conditions. Thirty prostheses which were removed from patients either because of pain and/or mechanical failure were examined in conjunction with the clinical records of the patients concerned.

The disadvantages of the present design can be summarized as follows: (1) The stem is not strong enough. Flexural strength is diminished by fatigue; the acrylic is weakened by crazing and the metal by stress corrosion. Unless the prosthesis is placed in the most favourable position its load-carrying capacity will be exceeded. (2) The skirt is weak and vulnerable, and interferes with revascularization. (3) The head has not sufficient surface hardness. The distribution of the forces acting upon the prosthesis has been examined. It is clear that both the angle of insertion *i* and the distance AB (Fig. B) must be as small as possible. (4) The local blood supply should be interfered with as little as possible. The great trochanter should not be divided, for both mechanical and anatomical reasons.

The reasons for the large number of worn prostheses require further investigation. In the light of our present knowledge, the use of any prosthesis must be regarded as an experimental procedure. The need for a standardized method of radiological follow-up of cases has been apparent in this work, as well as for a method of recording the clinical results of treatment.

While there are many reasons for failure over which no one can have control, the development of standards governing the materials to be used in the manufacture of prostheses could by now have been devised.

Since writing this paper a further 20 prostheses that have had to be removed from patients have been examined. The information gained has further substantiated the conclusions drawn from our previous work.

We wish to express our thanks to Professor S. J. Davies, Faculty of Engineering, King's College, University of London, for his enthusiastic support in carrying out this work; Professor D. H. Hey and Mr. L. Singlehurst-Ward, King's College, University of London, for their help on metallurgical and chemical problems; and to Mr. G. D. Winter, technical assistant, Plastics Research Unit, for his unfailing willingness in working long hours while engaged with us on the Judet problem. We are indebted to Messrs. Down Bros. Ltd., Lusterlite Ltd., the London Splint Co. Ltd., and the Medical Supply Association Ltd. for supplying samples of material and Judet prostheses.

The following very kindly responded to our appeal for notes, x-ray films, and prostheses, and thus made the work possible: G. Arden, E. H. Bannister, J. Bastow, J. Briggs, H. J. Burrows, St. J. D. Buxton, P. Cromack, F. W. T. Davies, E. O. Davis, M. B. Devas, E. A. Devenish, G. R. Fisk, A. Fletcher, A. T. Fripp, J. Garden, W. Gissane, L. C. Gonet, C. Gray, W. Herschell, S. L. Higgs, K. F. Hulbert, J. P. Jackson, A. W. L. Kessel, T. King (Australia), W. B. Law, P. S. London, K. Lucas, D. V. Marshall, M. L. Mason, J. S. Maxwell, K. I. Nissen, G. Platt, E. Shephard, N. A. Stephens, D. Trevor, W. Waugh, W. A. Watt-Maney, K. G. Westcombe, V. H. Wheble, B. L. Whitaker, P. Wiles.

REFERENCES

- Endler, F. (1953a). *Ver. dtsh. orthop. Ges.*, **83**, 300.
 — (1953b). *Z. Orthop.*, **84**, 1.
 Hoff, E. A. W. (1952). *J. appl. Chem.*, **2**, 441.
 Judet, J. and R. (1950). *J. Bone Jt Surg.*, **32B**, 166.
 — (1952). *Ibid.*, **34B**, 173.
 Lagrange, J., and Dunoyer, J. (1954). *Resection-Reconstruction of the Hip-Joint*, translated from the French by Karl Nissen. Livingstone, Edinburgh.
 MacConaill, M. A. (1950). *J. Bone Jt Surg.*, **32B**, 244.
 Maxwell, B., and Harrington, J. P. (1952). *Trans. Amer. Soc. mech. Engrs.*, **p. 579**.
 Osborne, G. V., and Fahrni, W. H. (1950). *J. Bone Jt Surg.*, **32B**, 148.
 Ros y Codorniu, A. H. (1949). *Cirug. Apar. locomotor*, **6**, 11.
 Russell, E. W. (1948). *Report Chem.*, **447**. R.A.E., Farnborough, Hants.
 — (1950). *Nature, Lond.*, **165**, 91.
 Sauer, J. A., and Hsiao, C. C. (1953). *Trans. Amer. Soc. mech. Engrs.*, **p. 895**.
 Scales, J. T. (1951). *Plastics Progress*, **p. 295**. Iliffe, London.
 Tucker, F. R. (1949). *J. Bone Jt Surg.*, **31B**, 82.

HEPARIN AND ETHYL BISCOUMACETATE IN PREVENTION OF EXPERIMENTAL VENOUS THROMBOSIS

BY

PAMELA JEWELL, M.B., B.S.

Lecturer in Bacteriology

THOMAS PILKINGTON, M.D., M.R.C.P.

Medical First Assistant

AND

BRIAN ROBINSON, M.B., M.R.C.P.

Late Resident Clinical Pathologist

St. George's Hospital Medical School

[WITH SPECIAL PLATE]

In recent years anticoagulant drugs have been increasingly used for the treatment of thrombo-embolic disease. There are two groups of these drugs—those which lengthen the clotting-time (heparin group), and those which lengthen the so-called prothrombin time (coumarin derivatives): of the latter group ethyl biscoumacetate ("tromexan") is a typical example.

Many clinicians believe that heparin is more efficient in preventing thrombosis, and choose ethyl biscoumacetate only because it can be given by mouth. We have, however, found no clinical or experimental evidence for this belief; the only experiment reported in the literature which compares the ability of heparin with that of dicoumarol in preventing thrombosis following damage to the vein wall was one performed in rabbits, and led to the conclusion that neither drug was effective (Moses, 1945). This lack of support for clinical impressions prompted us to study the relative actions of heparin and ethyl biscoumacetate in preventing thrombosis following experimentally induced phlebitis in rabbits. The drugs were given in a manner as closely comparable as possible to the methods of administration used in clinical practice.

Methods

Buck rabbits weighing from 1.8 to 3 kg. were used; they were fed on a mixture of bran and oats, with fresh greens and an unrestricted amount of water.

Administration of anticoagulants was controlled by frequent examinations of venous blood taken from a marginal ear vein reserved for this purpose. In the case of heparin, clotting-times were estimated by Wright's capillary

J. T. SCALES AND J. M. ZAREK: BIOMECHANICAL PROBLEMS OF THE ORIGINAL JUDET PROSTHESIS

FIG. 1.—Fracture surface of metal rod. ($\times 8$.) Oblique illumination.

FIG. 2.—Transverse section of fractured part of stem which failed in fatigue. Note grooves acting as stress raisers. ($\times 10$.)

FIG. 3.—Longitudinal section of stem of new prosthesis illustrating depth of crazing. Fragments of polymethyl methacrylate 1-2 mm. in thickness adhering to metal rod. ($\times 15$.)

FIG. 4.—Metal rod seen through head of prosthesis, showing crazing. ($\times 10$.)

FIG. 5.—Surface of metal rod showing corrosion pits. Prosthesis of which this rod was a part was in body for 18 months. ($\times 11$.)

FIG. 6.—Case 1. (March 30, 1953.) Rarefaction of inferior cervical margin with enlargement of track resulting in shift of fulcrum laterally.

FIG. 7.—Case 1. (May 4, 1953.) Fracture of stem of prosthesis and of bone inferiorly.

FIG. 8.—Case 2. (July 21, 1952.) Excessive varus insertion of prosthesis. Note short metal reinforcing rod.

FIG. 9.—Case 2. (October 30, 1952.) Widening of track.

J. T. SCALES AND J. M. ZAREK: BIOMECHANICAL PROBLEMS OF THE ORIGINAL JUDET PROSTHESIS

FIG. 10.—Case 2. (December 1, 1952.) Following insertion of second prosthesis with extended head. Length of neck further reduced.

FIG. 11.—Case 2. (February 16, 1953.) Shows fracture of stem at theoretical position.

FIG. 12.—Case 3. (September 26, 1952.) Five weeks after insertion of prosthesis. Appearance of avascular necrosis of superior medial portion of neck. No widening of track.

FIG. 13.—Case 3. (May 21, 1953.) 29 weeks later. Great trochanter not united. Absorption of femoral neck and widening of track with shift of fulcrum to region of fracture of stem.

FIG. 14.—Case 4. (July 30, 1951.) Prosthesis does not penetrate lateral cortex.

FIG. 15.—Case 4. (November 17, 1952.) 68 weeks post-operative. Widening of track. Superimposed outline shows skirt must have impinged upon superior margin of neck of femur. Fracture of skirt has probably occurred, giving rise to pain and limitation of movement.

FIG. 16.—Case 4. (March 25, 1953.) 18 weeks later. Further widening of track with fracture of inferior part of neck of femur. There is reorientation of trabeculae in relation to distal end of stem.

FIG. 17.—Judet prosthesis after 21 months in the body, showing crazing of unworn area of the surface of the head. ($\times 100$.)