Acta orthop. scand. 47, 193–202, 1976

THE BASIC REQUIREMENTS AND DESIGN CRITERIA FOR TOTAL JOINT PROSTHESES

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In the past some joint prostheses have been used in which the fundamental requirements of joint replacement were not fully considered. This paper lists the basic requirements for joint replacement and thirteen criteria which should be employed in designing a prosthesis to meet these requirements. The criteria are discussed in detail. The requirements and criteria are important but, because some may conflict with others, joint design is often a compromise.

Key words: prostheses; joints; orthopaedic; arthroplasty; articulation

Accepted 3.xii.75

In recent years there has been a great deal of activity on the subject of prosthetic joint replacement, and many new implants have ensued. Commonly, these devices have been designed by their proponents to overcome specific problems but often the more general requirements of joint replacement have not been fully considered. Thus many prostheses have been devised without either a clear understanding of the specifications which must be met, or sufficient thought being given to the problems involved. This has naturally led to clinical problems with some replacements.

The purpose of this paper is to discuss the basic requirements and design criteria in the hope that they will prove useful to others involved in prosthetic joint design.

BASIC REQUIREMENTS

Before discussing the design criteria for a joint replacement it is necessary to first consider the basic requirements. The following eight are essential requirements for a joint arthroplasty:

1. Relief of pain
2. Adequate function
3. Correction of deformity
4. Durability
5. Satisfactory salvage potential
6. Chemical passivity
7. Sterility
8. Appropriate size

In addition the following, whilst not being essential, are desirable:

9. Simple operative procedure
10. Minimal operative trauma
11. Early mobilisation
12. Not subcutaneous
13. Universality
14. Convenient packaging
15. Reasonable cost

Some of these requirements and features need no explanation; others are discussed briefly.

Durability implies that neither the prosthesis nor the adjacent bone will fail through fracture or excessive wear. Ideally a prosthetic joint should have a useful life at least equal to the remaining life span of the patient, and in elderly and relatively inactive patients this might be attained quite easily. However, in the younger and much more active patient, with a longer life expectancy, the implant may wear out, in which case the facility to replace the failed parts would be useful. An implant life of at least 15 years is desirable.

In the event of failure due to infection, technical errors, or mechanical causes it must be possible to carry out a salvage procedure. This must be achieved without excessive limb shortening whether the salvage involves the use of another prosthesis, a pseudoarthrosis, or arthrodesis of the joint.

Chemical passivity implies that the implant must not corrode in the body, and neither the implant nor any wear particles which may be produced should be toxic or invoke an adverse tissue reaction.

A simple operative procedure is desirable to reduce the risk of surgical error, minimise operative time and make the procedure available to less experienced surgeons. Where needed special purpose instrumentation should be available.

Minimal operative trauma will reduce postoperative complications and recovery time. If the joint is immobilised during the formation of a new capsule and soft tissue healing, these may severely limit articulation until stretched.

A subcutaneous implant should be avoided whenever possible, for wound healing may be retarded and the risk of implant infection increased.

Universality, i.e. a minimum number of necessary implant variants, is desirable for technical and economic reasons. Ideally a single implant configuration suitable for bilateral use and sized to suit all adult patients is preferred, as the risk of an inappropriate implant being used is eliminated, and a lower unit cost will be possible.

A convenient packaging will allow the implant to be presented at operation clearly marked, sterile and undamaged.

Cost is an important consideration if the prosthesis is to be widely available. This is especially true for finger joint replacement where up to eight similar prostheses might be used in a single patient.

DESIGN CRITERIA

We consider that there are thirteen criteria which should be employed in designing a prosthesis to meet the basic requirements. These are:

1. Appropriate articulation
2. Good stability
3. Adequate strength
4. Good fixation
5. Correct choice of materials
6. Low friction forces
7. Acceptable wear rate
8. Good salvage potential
9. Fail safe feature
10. Standardisation
11. Sterilisation
12. Cost effectiveness
13. Surgical instrumentation

Appropriate articulation

Four factors are important in articulation.

(a) The degrees of freedom should be appropriate to the joint being replaced. For example, we consider that a simple hinge is not appropriate for use in the metacarpophalangeal finger joint, as two degrees of freedom are required, not one.

(b) The range of movement need not necessarily be as great as in the normal joint but it must be more

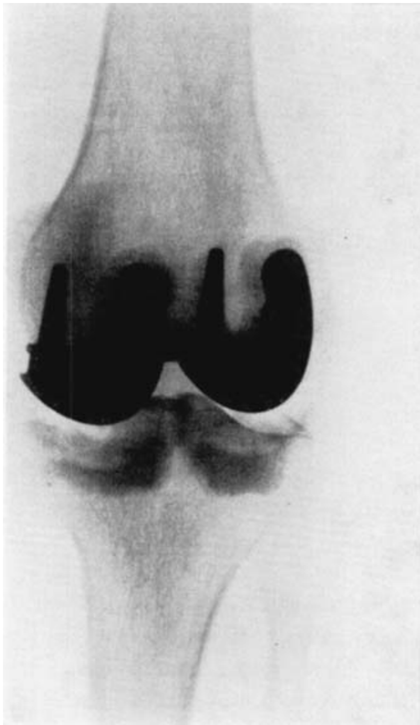

Figure 1. Oblique X-ray of a Liverpool knee prosthesis. Near normal articulation and accurate insertion ensured by special instruments give good stability and range of movement with minimal operative trauma (in this view the plastic components are invisible).

than sufficient to provide adequate function. If movement in a prosthesis is normally limited by a mechanical interference then unacceptable stresses may be imposed on the implant or its fixation.

(c) The components of the prosthesis should only articulate with each other, and not with bone or cartilaginous parts of the joint.

(d) The locus of the centre of rotation should closely approximate to that of the normal joint so that normal muscle and ligament actions may be restored as for example in the Liverpool knee (Figure 1) described by Cavendish & Wright (1974). Some designs of a bicondylar knee prosthesis, such as that pioneered by Gunston (1971), use semicircular femoral components and the locus of the centre of flexion follows an unnatural path, but normal ligaments are retained for joint stability. The result is that, with an implanted position which gives good semi-flexed stability, ligament tightening can prevent full extension, particularly if the cruciate ligaments are intact.

Stability

The stability of the normal joint derives from a proper relationship between the shape of the articular surfaces, the muscles acting about the joint, and the length and position of ligaments. Examples are the medial and lateral ligaments of the elbow and the collateral and cruciate ligaments of the knee. The manner in which they also control knee articulation is described by Girgis et al. (1975). It is invariably erosion of the joint surfaces, loss of integrity of these ligaments and perhaps loss of muscle tone due to inactivity which cause instability of the diseased joint. In many cases preservation of the ligaments and reconstruction of the articular surfaces will restore adequate stability. Exceptions are the rheumatoid shoulders, fingers, and other joints in which there is severe involvement of soft tissues in the disease process. In these circumstances it is necessary to design intrinsic stability into the prosthesis otherwise prolonged postoperative immobilisation of the joint is required. Examples of inherently stable joints are the Leeds shoulder described by Reeves et al. (1974) and the Liverpool shoulder (Figure 2).

Loading

It is clearly necessary that the implant be capable of supporting the loads to which it will be subjected within the body. Direct measurements of these loads

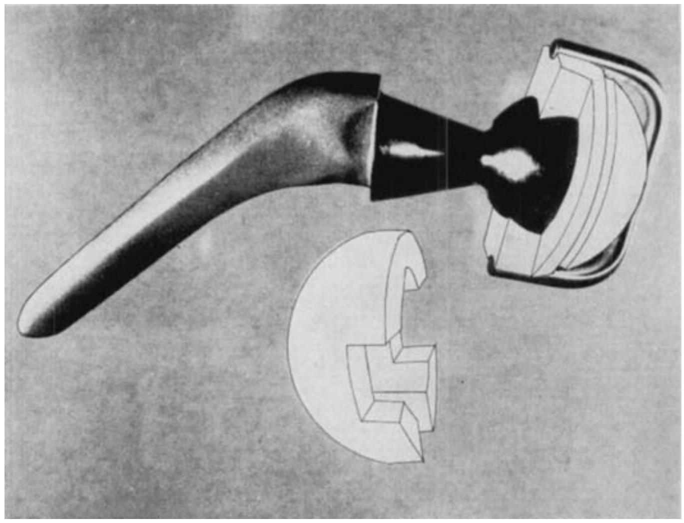

Figure 2. The Liverpool shoulder prosthesis which combines a full range of articulation with controlled inbuilt stability. A protective cap (shown below) protects the bearing surface of the metal scapular component and ensures correct orientation of the plastic humeral component during insertion. The plastic parts have been outlined for clarity of illustration.

are not usually possible although Rydell (1966) obtained the walking forces in the hips of two subjects by implanting strain gauged prostheses. His results showed peak forces of about 3.5 times body weight. Because of the technical and ethical difficulties involved with such tests, indirect load measurements may have to be used. For example, Paul (1969), using measurements from a foot force plate, cinematography and myography, calculated that typical hip forces during normal walking peaked at about four times body weight. Indirect measurements have also been made of knee forces (Morrison 1968) and similar work on other normal and prosthetic joints (McGrouther 1974) is presently being conducted at various centres. Several workers including Seireg & Arvikar (1975) have shown that static analyses can be used to estimate the order of forces acting on joints. Information on loading thresholds may also be inferred from a measurement of those forces which will disrupt the soft tissues about cadaveric joints. For example Reeves (1968) in tests on 110 cadavers measured forces to tear the capsules of shoulder joints. These results could be used for assessing dislocating forces.

Fixation

Adequate fixation of the prosthesis is necessary for two reasons. Firstly, to prevent unwanted movements between the implant and bone, and secondly, to transmit joint loads into the bone in such a way that they will not cause excessive stresses in bone or implant. This requirement can be met by ensuring a good surface contact between prosthesis and bone over a sufficiently large surface area. It is most readily achieved by the effective use of bone cement which also has the advantage of giving good initial fixation and permitting early mobilisation, as reported by Charnley (1970). It should be emphasised that acrylic bone cement is a filling agent and *not* an adhesive. It follows that the prosthesis and the bone must have suitable surface configurations to key the cement. The shape should be such that it will ensure adequate distribution of the cement and also force it into the interstices of the cancellous bone.

In designing the fixation one should take into account the natural load distributing structures of the bone. Several workers including Milch (1940), and Seireg & Arvikar (1975), using photoelastic models or finite element analyses,

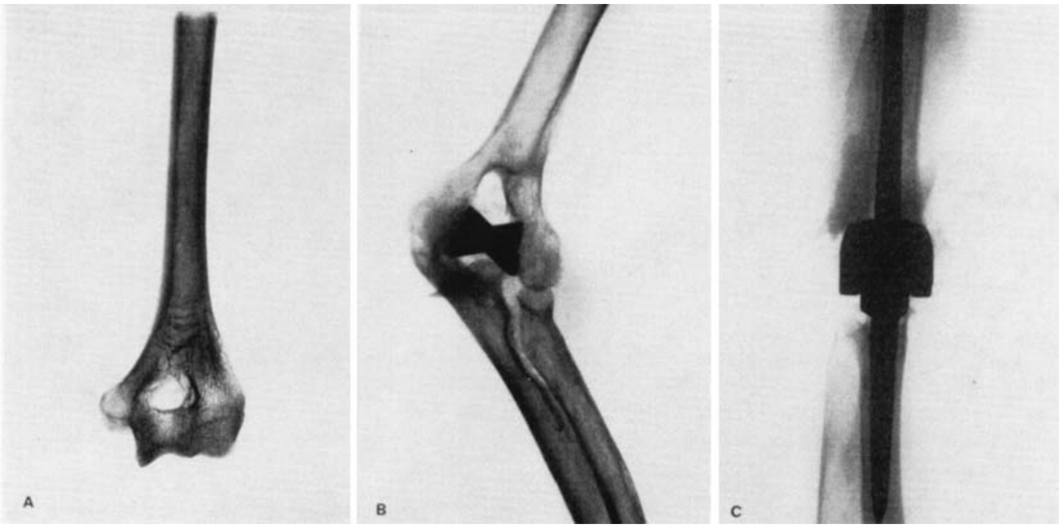

Figure 3 (a). Anterior-posterior X-ray of the distal end of the humerus showing the trabeculae of the supracondylar ridges.

Figure 3 (b). X-ray of a semi-flexed elbow joint with a Liverpool prosthesis implanted. This is an example of the use of natural load bearing structures for fixation (in this view the plastic component is invisible.

Figure 3 (c). X-ray of a Shiers elbow joint prosthesis showing the long intramedullary stems typical of some hinged prostheses.

have shown that stress trajectories in the proximal femur bear a remarkable resemblance to the trabecular patterns. On the assumption that this is also true of bone adjacent to other joints, a study of these trabecular patterns should give a good indication of the optimal fixation design. For example Figure 3 a is an anterior/posterior X-ray of the distal end of the humerus, in which elbow joint forces are naturally transmitted from the trochlea to the shaft by means of the trabeculae of the supracondylar ridges. In designing an elbow prosthesis we preferred to make use of these natural load bearing structures for fixation (Figure 3 b) rather than to bypass them with a long intramedullary stem as used in the Shiers prosthesis (Figure 3 c).

Consideration must be given to the viability of bone adjacent to the prosthesis, for whilst living bone tends to remodel, accommodating stresses imposed upon it and improving fixation, dead bone may fail by a fatigue mechanism which could result in loosening of the implant. The viability of the bone may be jeopardised either by avascular necrosis or by thermal damage resulting from heat generated by the cement whilst hardening. These difficulties are best avoided in three ways. Firstly, the implant design and the surgical procedure which it necessitates should not seriously disturb the existing blood supply or impair the revascularisation of the remaining bone. Secondly, the quantity of cement required for satisfactory fixation should be minimised. Thirdly, the design should avoid the necessity of using cement on small fragments of bone unless they have a good independent blood supply. When using a tourniquet during joint replacement, some surgeons attempt to minimise thermal damage by releasing the tourniquet during the critical setting period of the bone cement, thus providing a cooling flow of blood.

Table 1. Typical mechanical properties

Material	Ultimate tensile strength (U.T.S.) $N/m^2 \times 10^{-7}$	Fatigue limit $N/m^2 \times 10^{-7}$	Modulus of elasticity $N/m^2 \times 10^{-10}$
Stainless steel 316 S16 & S17, 317 S16	65–100	28–30	20
Co – Cr – M cast alloy	69	30	20
Co – Cr – W wrought alloy	154	49	23
Titanium wrought	40–67	17–30	11
Polymethylmethacrylate	7	0.68	0.3
Polymethylsiloxane	0.5	......	up to 0.001
Ultra high molecular wt. polyethylene	2–4	......	0.055–0.07
Human bone (wet) a) cortical	6.5–11.7 (Compressive)	......	1.1–2.3
b) cancellous	0.03–1.59	......	0.003–0.1

Materials

There are six basic requirements for joint implant materials. They must have adequate strength to carry the loads, be non-toxic, not corrode in the body nor produce the adverse tissue reaction described by Williams (1975). Bearing surfaces should have low friction and good wear characteristics. The materials most commonly used are the four metals and three polymers listed below:

Wrought Austenitic stainless steel (types 316 S16, 316 S12 and 317 S16).

Cobalt-chromium-molybdenum cast alloy (known variously as Stellite, Vinertia, Vitallium, Alvium, etc.).

Cobalt-chromium-tungsten wrought alloy (also known as wrought vitallium).

Pure Titanium and titanium alloy.

Ultra high molecular weight polyethylene (UHMWP, incorrectly known as high density polyethylene or HDP).

Polymethylmethacrylate cement (known as acrylic bone cement).

Polydimethylsiloxane (known as silicone rubber or Silastic).

The mechanical properties of these materials and those of bone are given in Table 1. It is the fatigue limit (i.e. the stress to which the material may be indefinitely cycled without failure), which should be used in the design calculations rather than the ultimate tensile strength (U.T.S.).

Stainless steel is especially useful during the development phase of new prostheses because it can be forged and is readily machined. Disadvantages are that for implants it may not be welded or cast. Cobalt-chromium-molybdenum cast alloy, however, whilst being more difficult to machine, can be cast to fine limits and is therefore generally more suitable for the commercial production of implants with complex shapes. Wrought cobalt-chromium-tungsten alloy may be used as an alternative to stainless steel where cold working and higher strengths are required. Titanium has the disadvantage of having poorer bearing properties but Williams (1975) indicated its superior corrosion resistance. Williams & Roaf (1973) emphasise the need for great care to avoid galvanic corrosion when more than one metallic component is used in an implant. Silicone rubber has limited application in joint prostheses, its main use being confined to flexural elements in finger joints.

Friction

The co-efficient of friction of all these materials is an order of magnitude greater than that of articular cartilage.

of common implant materials and bone

Yield stress $N/m^2 \times 10^{-7}$	Ductility (plastic deformation) % elongation	Density g/ml	Comment
28–97	9–45	7.9	BS 3531 (1968)
49	8	8.3	BS 3531 (1968)
105	9–60	9.2	BS 3531 (1968)
28–54	12–35	4.5	BS 3531 (1968)
7	5	1.2	Beadle (1970)
0.83	up to 600	1.17	Williams & Roaf (1973)
2.1	up to 800	0.935 min.	At 23° C
......	0.36–3.29	1.6–2.1	Evans (1973)
......	0.01–0.29	1.39–2.19	Evans (1973)

Duff-Barclay & Spillman (1966) confirmed Charnley's early work in which he showed that UHMWP against metal gave the lowest friction of the materials listed above. Although the patient may not be aware of friction forces on his prosthesis, they have to be transmitted across the implant/bone interface and therefore should not be ignored, for high friction loads could endanger implant fixation.

Wear

In metal-metal prostheses, such as the McKee-Farrar hip, finely divided metallic wear particles are produced. These particles impregnate the tissues around the arthroplasty and can cause a tissue reaction. Systematic absorption of metal has been reported by Coleman et al. (1973) and cobalt has been shown to be carcinogenic in experimental animals (Heath et al. 1971); however, there have been no published cases of sarcoma in man attributed to this cause.

The best combination of currently available materials for joint replacement are considered to be cobalt-chromium-molybdenum alloy or stainless steel in conjunction with ultra high molecular weight polyethylene. Duff-Barclay & Spillman (1966) showed that the combination caused minimal wear to the metal component. The remarkably good bearing properties of this plastic against metal are in part due to its ability to plastically deform under load which improves congruity between the sliding surfaces and reduces bearing pressures. Because of this deformation the initial surface finish on the plastic is not critical. However, the plastic deformation can result in microscopic flowing of the material into bearing surface imperfections of the metallic component, so that relative motion could result in high shear stresses and a high wear rate of the plastic component. Good surface finish and avoidance of surface discontinuities on the metallic component are therefore essential. When using soft and hard materials as opposing bearing surfaces, it is usual engineering practice to make the concave surface of the softer material. This not only minimises the effect described above but is usually consistent with placing the weaker material in the less stressful situation.

Wear or geometric changes in joint prostheses are usually confined to the plastic components and these should be replaceable, if bearing life is in doubt. As UHMWP is transparent to X-rays it is necessary to embed metallic X-ray markers in the plastic in order that its position and wear status may be determined after implantation. It is less satisfactory to rely on radio-opaque additive to cement, although this is useful for delineating cement boundaries.

It is impossible at present to confidently predict the life expectancy of a new design of prosthesis. *In vitro* tests cannot reproduce the load and environmental conditions of the implanted joint. However, such tests may be of use in placing various prostheses in order of mechanical merit, thus preventing some unsatisfactory devices reaching clinical trial. The actual useful life of a prosthesis can only be determined from clinical experience.

Salvage potential

It must be possible to salvage the joint in the event of failure. Clearly the smaller the amount of bone removed in the initial operation, the greater the choice of procedures during a second intervention. Cemented implants with long intramedullary stems can be particularly difficult to remove.

Fail safe

In case of extraordinary loads being applied, as in trauma, it is an advantage if the prosthesis can luxate, otherwise fracture of the bone, the implant or its fixation may occur. Most hip prostheses are luxatable and examples of other luxatable joints are shown in Figures 1, 2 and 3b. Further examples are described by Gunston (1971), Lettin & Scales (1972) and Neer (1974). However, many prostheses have been designed which are incapable of dislocation, such as that shown in Figure 3 c and those described by Shiers (1960), and Reeves et al. (1974).

Standardisation and cost effectiveness

To achieve universality the designer should aim at producing one size and configuration of prosthesis for either side of any patient, and if possible, a simple geometric shape which can be economically manufactured. For example, this has been achieved with the elbow (Figure 3b) by avoiding intramedullary stem fixation and by sacrificing the conjunct rotation of the natural joint. Universality has been implemented in different ways in other joint prostheses.

Sterilisation

The metal parts of prostheses may be steam autoclaved and thus easily sterilised. Heat sterilisation is not satisfactory for UHMWP which has a melting point in the range 130–140° C (close to steam autoclave temperature) and a heat distortion temperature of 70–80° C at which stress relieving and dimensional changes can occur.

There are various methods for sterilising plastic components, but of these, gamma radiation of at least 2.5 M rad is widely used and this method is also suitable for sterilising metallic components. As this process must be carried out at specialist centres, implants which contain plastic components should be supplied pre-sterilised.

Handling and protection

The bearing surfaces of prostheses are necessarily manufactured to close tolerances and fine finishes. Protection of these surfaces must be provided to prevent damage during handling as this could adversely affect the function or life of the implant. Consideration of the packaging and handling facilities should be made during the design of a prosthesis. It is an advantage if the design provides for protection of these surfaces during handling and implantation, as in the Judet Monoblock hip and the Liverpool shoulder prosthesis (Figure 2).

Instrumentation

Special purpose instrumentation may be necessary to ensure accuracy of insertion of the prosthesis, or for the convenience of the surgeon. The need or otherwise of such instrumentation should be considered together with the intended operative procedure throughout the design phase of the prosthesis.

Prostheses which do not require special instruments are at an advantage provided that the surgical procedure or their implanted function are not compromised. However, in some circumstances elaborate instruments which ensure accuracy or serve to reduce the operative trauma are justified.

CONCLUSIONS

There is much scope for optimisation of designs using established bio-compatible materials, for which a wealth of knowledge and experience has already been accumulated.

However, some total joint replacements have been ill-considered and are not likely to give good clinical results. We have avoided direct reference to these. On the other hand some designs have found wide acceptance with high clinical success, the outstanding example being the low friction hip arthroplasty with cemented fixation as pioneered by Charnley.

In presenting the basic requirements and design criteria we hope that this paper will achieve two objectives. Firstly, to highlight the important requirements and criteria for those involved in joint design. Secondly, to give other clinicians a basis on which to judge the relative merits of various prostheses.

The design of total joint replacements is of necessity a compromise because some of the requirements and criteria may conflict with others. It is therefore important to clearly understand all the requirements if the best compromise is to be made. Because of these conflicts it is likely that different teams will place emphasis on different aspects of the requirements and will thus arrive at alternative prostheses which may prove equally effective in treating patients.

We firmly believe that prosthetic joint design should be a team effort, and the team should consist of both surgeon and engineer. In the final analysis, even with satisfactory joint designs, the clinical results will depend upon the surgeon's skill. For example, insufficient cement could jeopardise fixation, and excess cement limit the range of articulation or cause gross wear if cement particles are introduced between the bearing surfaces. It is therefore desirable that designers devise joint prostheses and instruments that will minimise the surgical difficulties. A particular design is unlikely to be suitable for all cases and so it is necessary to clearly define the limitations of its use.

The designers are invariably faced with gaps in their knowledge. These must be bridged initially by experienced judgement or even intuition and consolidated by a process of empirical development. Although it is impossible from *in vitro* tests to accurately predict the life of a newly-designed prosthesis a good estimate of its viability may be made from a critical comparison with others of proven clinical success.

The criteria presented are not intended as firm rules, but rather as a statement of the design philosophy which we have developed over recent years. Other workers may feel that different criteria are equally or more important. Accepting this, we feel that there may be many satisfactory solutions to any one problem with much scope for inventive flair and the lateral thinking described by de Bono (1972).

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