RESEARCH CRITERIA IN THE DEVELOPMENT OF BIOCOMPATIBLE IMPLANTS FOR PREVENTION OF FRACTURE

A. Engelhardt*, H. Grell**, H. Scharbach*** and D. Kooke*

In the development of permanent implants the selection of materials is often overemphasized, whereas the significance of biomechanical principles is not sufficiently considered. In our opinion this is the main reason for loosening of prostheses as well as micro or macro fractures of the surrounding osseous tissue. Based on calculations and tests the reasons for failures and processes of their development can be predicted and imitated.

Certainly, the use of bone cement leads to negative reactions weakening the bone for, among others, the following reasons:

1. Heat of polymerization causes protein degeneration and coagulations in the adjacent vascular region.

2. Liberation of monomers which, as a lipophil substance, can also act on the surrounding cell membranes.

3. The chemical surrounding is changed by the chemical and physical characteristics of the foreign body.

In addition the chemical and biophysical effects of the implant itself may also be mentioned, as e.g.:

1. Liberation of corrosion products by metal implants, in some cases development of galvanic elements.

2. Alteration of the chemical and/or physical intracorporal behaviour of plastics such as volume changes, chemical reactions of embrittling.

3. Change of the flow of forces dependent on the shape of the implant in the skeletal element with resulting disturbance of bone remodelling.

A number of investigations have been made of temporary implants applied for osteosyntheses by Perren [1] (Davos) and Hutzschenreuter [2] (Ulm). They show spongy bone formation instead of cortical bone in areas with minor stress. Similar reactions of rarefaction as evidence of reduced loading can be observed after the implantation of total endoprostheses, because the relatively inelastic shaft of the prosthesis prevents a physiological stress distribution. As an example the atrophy of the calcar femoris or the medial proximal femur should be mentioned which can already be identified on the X-ray (see Figure 1c). According to Wolff's Law [3]

* Orthopadische Universitatsklinik und Poliklinik Friedrichsheim, 6 Frankfurt/Main-Niederrad 71, Marienburgstrasse 2, Postfach 710209, West Germany.
** Ing. Fachhochschule, Aalen, West Germany.
***Pfaudler-Werke, Schwetzingen, West Germany.

and the findings by Roux et al. [4], Pauwells [5], Kummer [6], Perren, Hutzschrenreuter and others this reaction is understandable. It can even reach the symptoms of a partial disuse atrophy.

Alteration of the stress distribution caused by the implant results in a lack of physiological stimulus for bone growth and remodelling. It is known that, in normal cases, the arrangement of the osteons is dependent on the stress distribution. In connection with implants, stress concentrations can occur which may lead to primary or secondary defects followed by fatigue fractures. Sometimes they are later visible on X-rays. Furthermore, micro fractures may occur as well, which cannot always be radiologically identified.

If a conventional hip joint implant is loaded we have the following situation. During the load peak, which is dependent on the gait phases, the resultant F_R of all forces acting on the hip joint runs in a mediolateral direction through the centre of the joint. Moreover, there is usually a slight ventro-dorsal deviation. Investigations by Paul [7], Rydell [8], and de Arvicar [9] have shown that the point of penetration of F_R through the surface of the caput femoris is not considerably changed during the gait sequence. It is therefore allowable to make calculations on the frontal plane as a basis for examination.

Spatial and planar investigations of the force distribution in intact femura by finite elements, the photoelastic method strain gauges, etc. prove the conformity of the direction of osteons and the flow of forces. This condition is disturbed by the introduction of a relatively inflexible implant element. The E-modulus relation between bone and metal can be assumed to be approximately 1:10. Provided that a fitting implant is firmly fixed in the femur, theoretically unphysiological uniform forces occur acting vertically to the resection plane (see Figures 1a and 1b). In the area of the upper part of the implant shaft medially oriented forces with different values develop which cross the axes of the osteons. At the tip they run in a lateral direction (see Figure 1c).

A formfitting adaptation, however, is not possible, even if cement is applied which is in a plastic condition during the operation. It is prevented by defects resulting from mechanical treatment and surface conditions of the bone, presence of blood and necroses generated by polymerization.

The following possibilities may arise as a result:

1. Partial attachment areas in the shaft region can become the pivots of moments. As a result forces occur in the distal or proximal interface area which act at an angle to the axis of the osteons, dependent on the length of the lever arm.

2. Depending on their geometrical extension the attachment areas may come to be overload points.

3. The prosthesis can subside and be wedged at its distal part in the marrow cavity, provided that the cement cone is intact.

4. After the wedging fractures are also possible, especially if the cement is not uniformly distributed. They may lead to stress corrosion, an intensified bending moment in the shaft, and its fracture. The resulting unphysiological stress concentrations in the bone may cause

static and/or fatigue fractures, depending on the intensity and frequency of loading.

5. These phenomena occur more frequently in the case of bone defects, either because the cortex has been mostly dorso-laterally perforated by an incorrect implantation, or because during reoperations access has been gained to take out the cement.

From radiological and histological investigations it is known, however, that there is a gap of up to 3 mm in the implant/bone interface area. It is filled with hydroelastic connective soft tissue. Furthermore, the load is often transmitted across the cement into the diaphysis because the implant does not primarily or secondarily rest upon the bony resection plane. Some possible reasons for this are:

1. The collar of the implant is too small.

2. Resorption of the resection plane.

3. Partial spreading of cement protrusions between the collar and the resection plane of the bone resulting from deformation of the methamethacrylate during insertion of the implant.

Thus the resection plane is not at all, or only partially, loaded. As a result we find:

1. Atrophy of the bone which is not used as an abutment.

2. Possible subsidence of the implant with micro fractures in the new implant/bone contact area. They show in an X-ray as temporary densifications.

3. Medial bursting of the residual corticalis caused by the wedge-effect of the implant, overload and/or the effect of the force component acting in medial direction. An increasingly atrophied bone in the calcar region offers less and less resistance to these processes.

These previous theoretical results were confirmed by static load tests performed on femura of corpses, including an endoprosthesis which had been implanted during life. For this purpose the bones used were taken shortly after death. They were coated to avoid loss of water and provided strain gauges. A comparison was made with the contralateral femur. An initial visual inspection revealed:

1. Resection area and implant surface were not parallel.

2. Unevenly cut resection plane or

3. outbreaks or

4. cracks starting from it.

5. Different intermediate protrusions of cement.

6. Combinations 1 - 5.

These samples were then loaded to fracture. The preliminary results presented typical evidence of processes leading to fracture:

1. The implant subsided.

2. The circumference of the bone in the distal area was dilated by the cement conus.

3. In the proximal region the bony load carrying zone adjoining the shaft was shifted in the medial direction.

4. The tip of the implant perforated the lateral corticalis; the proximal implant part was pressed in the medial direction, thereby breaking the bone.

However, this final result is seldom seen, generally in cases with additional defects, because in the majority of cases the patients first experience pain and instinctively take care. Thus the load is reduced. It is assumed that loosening is not any higher as most patients with hip endoprostheses are old. Due to their limited mobility they apply relatively low loads. According to the opinion of others the rate of loosening increases in younger people, although in general they have a greater ability of bone regeneration. The interval between the operation and loosening is often shorter.

It should be considered that the intracorporal life processes are subject to interconnecting regulating systems, into which the implant, with its chemical and physical effects, has to be included. On this basis it is essential to satisfy the following requirements:

1. Physiological transmission of forces.

2. Avoidance of bone cement.

3. Application of inert surfaces.

4. Wear resistant sliding faces.

5. Primary fixation by formfitting under consideration of a corresponding surgical process.

6. Secondary fixation by adaptive bone growth and ingrowth.

7. Avoidance of relative motion, which otherwise causes growth of connective tissue, as in the case of pseudarthrosis. See point 5 and 6.

8. Uncomplicated and safe operation process.

9. Earliest possible loading in order to avoid secondary complications.

10. Bone-adapting variation possibilities of implants.

To Point 1:
This is achieved by interposing an additional joint into the implant. Thus compressive forces are directly transmitted into the bony abutment in a physiological manner (see Figures 2a and 2b). Minor shear forces are eliminated through friction. This is reached by a rough or porous implant surface facing the resection plane. In addition the implant is formfittingly inserted, i.e. the bone is exactly shaped in accordance with the measurements of the implant. Thus the spongiosa is retained to

the maximum extent (see Point 5). The resection of the femur neck is done vertically to the resulting axis of the osteons.

To Point 2:
The implant is fixed by an intramedullary screw to which the remaining part of the implant is attached.

To Point 3:
The implant is coated with different ceramics according to the specific requirements.

To Point 4:
This is met by a combination of two relatively wear resistant but different ceramics in accordance with the general design principles of sliding faces.

To Point 5:
The proximal implant part is formfittingly inserted with most considerate care of the load bearing spongiosa. Simultaneously the resection plane is prepared in accordance with the resulting osteon axis. In addition the intramedullary screw, which is conically designed in order to avoid stress concentrations, is formfittingly fixed, taking great care of the corticalis.

To Point 6:
Porous surfaces give the possibility of ingrowth processes.

To Point 7:
Points 1, 5 and 6 as well as 3 and 4 and the avoidance of bone cement enable a reduction of the relative motion to an extent which, according to our recent results, is less than 1/2 diameter of a medium osteon.

To Point 8:
Appropriate instruments were developed which make it possible to comply exactly with previously taken measurements, e.g. angles and axes. The ventro-lateral access is applied.

To Point 9:
The formclosed fixation should enable an early mobilisation with increasing partial loading.

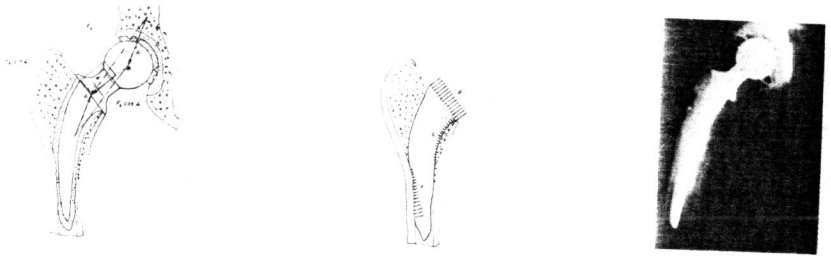
To Point 10:
216 variations of the implants can be made in accordance with preoperatively taken measurements.

The socket is anchored with three eccentric protrusions without cement. They are installed in such a way that the resultant F_R runs through the centre of the triangle bordered by these protrusions (see Figure 3).

In summary we can say that our present investigations, laboratory tests, animal experiments, and experiments on corpses confirm the results which had been previously anticipated. They are supplemented by an adequate selection of material and development of instruments so that an implant of a high degree of compatibility has been designed. The series of tests is being continued.

REFERENCES

1. PERREN, S. et al., "The Reaction of Cortical Bone to Compression", Acta. Orthop. Scand. Suppl. 125, 19, 1969.
2. BICK, R. and HUTZSCHRENREUTER, L.CLAES, "Computergesteuerte Transmissionsmethode fur Spannungsanalysen bei Knochenheilung", Biomed. Technik, 21, Suppl. 1976, 317.
3. WOLFF, J., "Das Gesetz der Transformation der Knochen", 1892.
4. ROUX, W., "Gessamelte Abhandlungen uber Entwicklungsmechanik der Organismen", I and II, 1895.
5. PAUWELS, F., "Atlas zur Biomechanik der gesunden und der kranken Hufte", 1973.
6. KUMER, B., "Bauprinzipien des Saugetierskeletes", 1959.
7. PAUL, J. P., "Forces at the Human Hip Joint", Ph.D. Thesis, University of Glasgow, 1967.
8. RYDELL, N. W., "Forces Acting on the Femoral Head Prosthesis", Acta Orthop. Sand. Suppl. 88 and 37, 1966.
9. SEIREG, A. and ARVICAR, de, R. J., "The Prediction of Muscular Load Sharing and Joint Forces in the Lower Extremities During Walking", J. Biomech., 8, 1975, 89.



(a) (b) (c)

Figure 1 (a) Load Distribution in Conventional Hip Replacements
(b) Load Transmission in Conventional Hip Replacements
(c) X-Ray of Total Hip Replacement

(a) (b)

Figure 2 (a) Qualitative Distribution of Physiological Load Transmission
(b) Principle of Hip Endoprosthesis with Physiological Load Transmission

Figure 3 X-Ray after Implantation of a Ceramic-Coated Total Hip Endoprosthesis in the Skeleton