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Introduction of new implant

Medical and practical ethics

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Unlike abortion practices, in vitro fertilization, and sterilization procedures, biomaterials are of rather limited moral concern. Apart from problems that appear when new products are introduced on the market, where risk-benefit estimations are called for (Should a new product that is of great benefit to some, but may have unforeseen negative consequences for others, be introduced?), there are mainly two general problems to bear in mind.

1. *Allocation.* On the "political" level it might be asked if research about biomaterial will give greater general benefit than, for example, research in other areas (and – are benefits to be determined in terms of economy, in terms of "lives saved" or "better lives lived"?). On the level where physicians decide and rule, it will often be asked who should be singled out for benefit from new and scarce resources, and *what* shall determine the choice? (First come, first go? The young before the old? Parents before the childless?).
2. *Information. When* shall the news of an important discovery be brought out into the open? (Before colleagues learn about it?). To *whom*? (Only to colleagues? To practicing physicians? To patients who could benefit by it? To all of these, or only to some? To the general public?). And *how* should it be done? (By word of mouth? In medical journals? By the daily press?). The answers to these and related questions presuppose basic ethical theories, but as long as clarity and consistency are observed, the widespread common sense opinions in the more specific areas of this field will do, at least for the time being.

The importance of comparative studies: Preliminary results of a prospective randomized study comparing results of cemented and noncemented endoprosthetic fixation in the surgical treatment of arthrosis of the hip

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Any method, the efficacy of which is to be evaluated and against which some criticism has been raised, must be tested against another method in common use for the same ailment. For this reason, of utmost importance is to carry out a prospective, randomized study. The assessment must consider accuracy, sensitivity, specificity, and predictive value. *Accuracy* is the measure of a screening test's ability to provide a true measure of quantity or quality. *Sensitivity* is a measure of a test's accuracy in correctly identifying persons with a certain condition. *Specificity* is a measure of a test's accuracy in correctly identifying persons who either have or do not have the condition. *Predictive value* of a test is its ability to predict the presence or absence of a condition.

Further, the difficulty should be pointed out in evaluating joint function by using certain scoring systems. The use of different scores will yield different results on the same material, and consequently the score used has to be adapted to the type of material to be investigated. In a survey of different methods, it has been demonstrated that the one and same material evaluated by seven different scores yielded seven different results.

Finally, the patient's own assessment of the value of an operation might be thought to be the most reliable estimate of its worth. In all the summaries of results of operations in which the number of patients is given under the two headings "Surgeon pleased" and "Patient pleased"; the patients are more often pleased than the surgeons. It is important in all surgical practice for the

surgeon to inspire confidence, and when the patient's active cooperation is required, as in the postoperative treatment of an arthroplasty, it is essential. A firm belief in the ability of the surgeon to improve this condition together with a natural reluctance to admit that any ordeal endured has not been worth while are largely responsible for the patient's optimism. The relief of pain may mean so much to a patient that he is delighted with the result, although it has not achieved the aim for which the surgeon hoped and planned. Psychologically, the contrast between the preoperative condition of advancing arthrosis when steady deterioration is observed and the postoperative stage, in which improvement since operation has occurred, makes further improvement seem probable and results in a much happier outlook.

We embarked on a comparative study in April 1982, which comprised 150 patients, to study any differences that might develop in patients operated on with either a cemented or noncemented total hip replacement. The study is expected to be finished by 1987, and consequently the results now reported are *preliminary*. Controls have been carried out after 6 months, 1 year, and then annually. We are now able to present some results regarding the following: 1) Clinical examination (the Harris Hip Score has been used), 2) A roentgen stereophotogrammetry investigation, 3) Gait analysis, 4) Stabilometry.

1. Clinical result

The cemented group has initially done much better than the noncemented group. The latter is, however, with time beginning to reach results comparable to those obtained, at a much earlier stage, in the cemented group. A problem is pain arising in the noncemented patients. Pain of a midthigh type appears in some 30 percent, and is mostly localized in the anterior midthigh, and can last for a year.

2. Roentgen stereophotogrammetry

Tantalum balls have been placed in the acetabulum, the femur, the acetabular cup, and in the femoral stem. By consecutive radiographic examination, it has become possible to discover changes in the prosthetic position and the subsidence of the noncemented prostheses was greater than that of the cemented ones.

3. Gait analysis

The patients were tested on a 5-meter-long walkway. Tests made on line recording were based on an average of five gait runs (2–12 per patient), i.e., 25 meters registered walk and 15–25 gait cycles. The tests were carried out before total hip replacement and 6 and 12 months postoperatively. The Charnley group had better results in all the variables at both postoperative examinations. The greatest differences were found at 6 months. Numerical information was obtained in an objective way in this study supporting and making more elaborate the impression noted at the clinical examination, thus making gait analysis a useful tool in the evaluation of locomotor function after surgical procedures.

4. Stabilometry

As the peripheral sensory mechanisms in total hip replacements are removed, the postural stability may be interfered with. In this study, special interest was focused on the question if the mode of osseous contact with the implant in any way influenced perception of proprioceptive impasses. The measurements were carried out on a specially prepared platform and sway was recorded during 60 seconds. The tests were performed before and 6 months and 1 years after total hip replacement. All the patients operated on with noncemented prostheses showed greater improvement as compared with those with cemented implants.

As stated, the study is not yet concluded and the above information is only *preliminary*.

Reduced risk of loosening of hip prostheses with a new cold-curing bone cement

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Mechanical loosening of the cemented hip prosthesis may be initiated by heat injury of bone during the polymerization of bone cement (Lundskog 1972, Feith 1975, Huiskes 1980, Mjöberg et al. 1984, 1986). In cases of heat injury, most necrotic bone created at polymerization will be resorbed during the first 4 postoperative months, allowing a rather rapid migration. Later on, migration may be slow (Mjöberg et al. 1986, Ryd 1986). Roentgen stereophotogrammetric analysis (RSA) makes it possible to detect prosthetic displacement with high accuracy, and allows discrimination between a migrating and a nonmigrating prosthetic component within 4 months after surgery (Mjöberg et al. 1986).

The specific heat production of bone cement is directly proportional to the amount of monomer in the dough and all commercial cements (e.g., Palacos, Merck) have been prepared by mixing 20 ml liquid monomer with about 40 g powder polymer. This amount of liquid is required to fill out the interspaces between the powder beads and because of absorption of liquid

into the powder beads. A new cement (Coolfix, Ferring, Malmö, Sweden) has been developed where the amount of liquid needed for complete wetting has been reduced (11.5 ml monomer per 40 g polymer) by an optimized bimodal particle size distribution resulting in closer bead packing and thus diminished mean interspace; the reduced specific heat production of the new cement brings about reduced risk of heat injury of bone.

To test the hypothesis that loosening can be prevented by avoidance of heat injury, the initial 4-month migration of the components in hip prostheses was studied following randomized use of Coolfix and Palacos® cum gentamicin.

Patients and methods

The initial 4-month migration of the components in 24 Scan total hip prostheses for arthrosis was studied following randomized use of Coolfix and Palacos® cum gentamicin.

The two types of cement were used in 12 hips each. The operative technique included reaming, brushing, high-pressure lavage, and injection of cement into the plugged femoral canal. The cement ingredients were chilled to 4° C prior to mixing to prolong the handling time. No attempt was made to pressurize the cement onto bone prior to insertion of the prosthetic components. Tantalum balls were implanted in the pelvis and in the proximal femur during the operation. The acetabular components were supplied with tantalum balls by the manufacturer. One acetabular component (with Coolfix) was excluded because of inadequate bone marking with the tantalum balls.

RSA was performed 1 week and 4 months postoperatively. Migration of the prosthetic components was recorded (Mjöberg et al. 1985). Displacements were not considered significant unless they exceeded 0.4, 0.2, and 0.8 mm for the x-(transversal), y-(longitudinal), and z-(sagittal) axis, respectively (Mjöberg et al. 1986).

Results

Five of the 12 acetabular components and one of the 12 femoral components with Palacos® migrated. The acetabular components migrated 0.2–0.6 mm cranially and the femoral component 0.3 mm distally. Not one of the 11 acetabular and 12 femoral components with Coolfix migrated.

Discussion

The reduced rate of initial migration with Coolfix compared with Palacos ($P = 0.01$, Fisher's exact test) may be explained by the reduced risk of heat injury.

Inadequate preparation and cementing technique was probably the most important cause of mechanical loosening of the femoral component during the 1960s and the early 1970s; greatly reduced rates of femoral component loosening after improved technique have been demonstrated (Paterson et al. 1986). However, even if adequate preparation and cementing technique is used, loosening may still be initiated by heat injury during the polymerization (Lundskog 1972, Feith 1975, Huiskes 1980, Mjöberg et al. 1984, 1986).

Many studies on loosening have contended with the issue how to best define loosening, so that it provides a predictive value concerning future clinical failure. Loosening defined as significant migration as revealed by RSA (i.e., more than 0.2 mm along the longitudinal axis) may appear to be too broad to some readers; prosthetic components with a slight initial migration postoperatively will not result in clinical failure, at least not for may years (Ryd 1986). However, prosthetic components with no initial migration should have an even better prognosis. Lasting close contact between viable bone and cement is possible (Linder & Hansson 1983), and by using RSA some of those prosthetic components that will *not* result in clinical failure can be identified 4 months postoperatively.

Thus, avoiding heat injury when using the modern technique of cemented hip arthroplasty should allow permanent prosthetic fixation.

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Long-term evaluation of titanium implants

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In 1977, Brånemark and coworkers presented a 10-year clinical report on the outcome of dental implants of c.p. titanium. Evidence was presented that indicated a far better clinical result than previously had been reported with oral implants. The reason for the improved level of success was by the authors referred to titanium implants becoming integrated in bone, i.e., there was no fibrous tissue interposed between the foreign material and the hard tissue. At the time, such a direct bone-to-metal interface was regarded impossible to achieve. The general consensus was that a fibrous tissue interface was unavoidable around a metallic implant and that such a soft-tissue anchored implant never became more stable in bone than it was at the time of its insertion. Ever increasing failure rates had been reported with longer times of follow-up. Brånemark et al. (1977) presented clinical evidence that this increased failure rate with time did not seem to occur with the so-called osseointegrated dental implants. This hypothesis seems to be verified today with more than 20 years of clinical follow-up of osseointegrated dental implants. To date, more than 18,000 c.p. titanium dental impants have been inserted in partially or completely edentulous jaws. The Brånemark screw is the only oral implant that has been acknowledged as provisionally accepted by the American Dental Association. The results of various teams indicate a 5-year success rate of individual mandibular screws in the range of 95 percent. Almost all implant losses have occurred during the first year of clinical function and have depended on failure to achieve osseointegration. Once osseointegration is established, there seems to be almost no further losses, i.e., quite contrary to conventionally used orthopedic implants that tend to have an increased failure rate with time.

In the facial skeleton, apart from the oral cavity, bone-anchored, skin-penetrating titanium implants have been used to treat deformities due to cancer surgery, trauma, or congenital deformities, or for direct bone anchorage of external hearing aids. Altogether, more than 400 osseointegrated screws have been used clinically on these indications since 1977 (Tjellström 1986). In nonirradiated cases, there is roughly a 98 percent success rate, whereas previously irradiated bone has functioned less well as implant site, but nevertheless given clinical success rates of the order of 85 percent. All the success rates with osseointegrated fixtures are related not only to the implant still being in function, but also to factors, such as lack of implant mobility, minimal adjacent bone loss, and to absence of severe soft-tissue inflammation (Albrektsson et al. 1986). In the case of metacarpophalangeal joint replacements, c.p. titanium devices have been used in clinical restorations of rheumatoid and primary arthrosis patients. To date, only one clinical report of the first five joints operated on for primary arthrosis has been published (Hagert et al. 1986). The follow-up time in these cases varied between 3 and 5 years. There were radiographic and clinical indications of the implants being stable, although some problems (in the form of polyethylene wear and implant fracture (1 case) were reported. The functional result was quite acceptable, as all patients had been able to return to their previous occupations involving, among other things, heavy manual labor. Other clinical indications for osseointegrated implants, such as preformed splinted jaw grafts (Lindström et al. 1981) or moulded ossicular grafts (Tjellström et al. 1978), have been reported. The presently most interesting application for osseointegrated screws is that of knee replacement where a clinical trial program is to be started in 1987.

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Design, material, and operative technique – influence on implant survival

Design, mechanical properties, and testing of implants

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It is possible to use laboratory test results to anticipate certain failed procedures and to optimize design features and material. Aspects that can be measured are the following: 1) Adequacy of sizes, consequences of placement errors, and incongruency; 2) Material properties; 3) Effects of radiation and degradation; 4) Load transfer and stress patterns; 5) Motion; 6) Friction and wear.

1. Extensive research has already been done regarding joint anatomy, sizes, and motion. This has to be taken into account when designing a new implant.
2. International standards exist regarding the mechanical strength of various biomaterials used in orthopedic surgery today. In Scandinavia, there is no obligation for a company to fulfill these standards. The responsibility for achieving and evaluating the information is today solely that of the orthopedic surgeon.
3. There are certain degradating effects on polymers, for instance, by using irradiation or heating during the sterilization procedure. It is important to use an appropriate sterilization method depending on the type of material. The sterilization procedures are controlled for efficacy of killing bacteria though not always taking into account the change in material properties.
4. Load transfer mechanism and stress patterns could be analyzed by strain-gauge technique, photoelastic and finite element analyzes. This could give valid information regarding stress concentration leading to modification of the implant even before production is started.
5. Impingement between two prosthetic components will lead to wear and increase micromotion around the prosthetic implant. The risk for impingement could be reduced by optimizing the design keeping the material strength intact.
6. The wear in a plastic-to-metal joint depends on the density of high-density polyethylene, surface finish of the metal part, and the joint load. If a prosthesis with a totally new design is to be used or a new type of material is added, tribologic long-term studies should be carried out before the implant is used.

The influence of surgical technique on the survival of knee and hip implants

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Most papers on artificial joints deal with patients, different implants, and results. The technique at the primary replacement of a joint is decisive for the result in the long run.

The experience and skill of the surgeon strongly influence the result (Holmberg and Kalén 1986). In Hierton's thesis (1982) the surgeon was one of the significant factors influencing the survival of a hip prosthesis. It must be emphasized that preoperative planning of the replacement from good radiographs and from knowledge of the clinical situation must be made before and not during the operation. The possibility of alternative procedures and the possibility of salvage procedures that might come in the future must be kept in mind. It is recommended to control the patient's position on the operation table and to have a well-dressed wide exposure of the surgical field. In both hips and knees the whole leg must be seen. The anesthesia can influence the result negatively, especially if the muscle relaxation is bad. Epidural anesthesia is preferable because of less bleeding and the possibility of good postoperative analgesia. The manipulation of the soft tissues covering the joint is often forgotten. Bad tissue treatment, especially in knee replacements, might result in bad wound healing and even infection of the artificial joint.

The choice of correct implant in relation to disease and deformity influences the survival rate of the implant. From national studies (Ahnfelt 1986, Bauer et al. 1985), we fairly well know what is good and what is bad. Thus, the choice of implant can be done with accuracy. A correct position according to the mechanical axis of the leg must be achieved and helpful jigs are available. The cementing technique is a chapter in itself. The surgeon must learn to be able to optimize the fixation. A badly positioned implant and a bad cementing technique guarantee a short survival of the artificial joint.

In THR, trochanteric osteotomy is often discussed.

Use it if you need it! There must be a good exposure of the joint if the stem shall be seated correctly. However, it should be remembered that a bad view might depend on bad anesthesia with tense muscles. In that case, it is preferable to have good muscle relaxation rather than to perform a trochanteric osteotomy, which increases the complication rate somewhat. The socket in THR has to be seated in well-prepared bone especially in RA, where a high loosening rate is to be expected. The mediolateral position of the socket should be such that the resultant forces are directed into the massa lateralis (Poss and Sledge 1981). In protrusio acetabuli and/or severe osteoporosis metal backing of the socket or a metal netting support and bone transplantation might be necessary. The femur stem is best seated in a neutral position and with at least a 2–5 mm layer of bone cement around the whole stem.

Conclusion

The surgical technique strongly influences the survival rate of the implant. Preoperative planning of the surgery and an experienced and skilled surgeon using an established implant with which he is familiar and optimal anesthesia establish the best basis for a long-lasting good function of an artificial joint. Bad primary technique can never be fully replaced by revision surgery.

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Mixing of acrylic bone cement

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Acrylic bone cement is made by mixing prepolymerized methylmethacrylate and liquid monomer in an approximate ratio of 2:1. Use of such a prepolymerized methylmethacrylate reduces the reaction temperature to a level acceptable from the clinical point of view.

The mechanical properties can be changed by different mixing techniques, and the amount of air introduced. Initially, air surrounds the powdered polymer beads. Air will also be introduced during conventional hand mixing. Transfer of cement from a bowl to a cement cartridge or stepwise insertion (finger packing) of cement are other sources of porosity.

Mixing methods

To eliminate the porosity in bone cement, different methods have been tried and compared: viz., 1) conventional mixing, 2) vibration, 3) centrifugation, and 4) partial vacuum.

Vibration gave only slight improvement as compared with conventional mixing, and will therefore be excluded from the comparison (Lidgren et al. 1984).

Porosity

The porosity can be determined 1) optically by studying the cut surfaces and 2) physically by sizing and weighing technique.

Both centrifugation and vacuum mixing give a significant reduction in porosity. In regular mixed cement, larger pores – several millimeters in diameter, as well as smaller pores of micron size, will be found.

Centrifugation eliminates mainly larger pores, but reduces only slightly the microporosity in contrast to vacuum mixing, which also eliminates the smaller pores (Burke et al. 1984, Wixson et al. 1985, Lidgren et al. 1987, Rimnac et al. 1986, Noble et al. 1987) (Table 1).

Table 1. Percent porosity*

	By Videoplan	By Physical Measurement	
	% Porosity	Density (g/cm^3)	% Porosity
Regular	9.4	1.15	7.2
Centrifugated	3.4	1.18	4.8
Vacuum mix	0.1	1.23	0.8

* From Wixson et al. 1985.

Compression, diametral and uniaxial tension

Centrifugation and mixing under partial vacuum result in an improvement of 10–30 percent (Burke et al. 1984).

Fatigue strength

The greatest improvement of the mechanical properties will be that of the fatigue strength – tolerance of cyclic load. As compared with regular mixed cement, mixing under a partial vacuum gives an almost tenfold improve-

Table 2. Uniaxial tension fatigue – Weibull means*. Cycles to failure (1000's)

	20 MPa	25 MPa	30 MPa
Regular	19.5 ± 24.0	3.6 ± 2.0	1.76 ± 1.1
Centrifuged	82.3 ± 36.5	14.9 ± 7.6	5.2 ± 2.9
Vacuum	143.3 ± 89.3	38.7 ± 34.9	13.1 ± 14.3

* From Wixson et al. 1985.

ment (Wixson et al. 1985, Lidgren et al. 1987) (Table 2).

Antibiotic release

In vitro investigations performed during 10 days have not shown any significant differences when comparing vacuum-mixed cement to hand-mixed cement (Wahlig and Dingeldein 1986)

Vacuum technique

To achieve an optimal porefree cement, it is important to a apply a vacuum before starting the mixing and continue with a vacuum during and shortly after mixing (Chan 1987, Wixson et al. 1985). The use of a pressure regulator will ensure an effective vacuum level. For high-viscosity cement, chilling to 4° C prior to mixing is necessary to improve the flow characteristics (Lidgren et al. 1987).

Conclusions

Elimination of porosity in acrylic bone cement will improve the mechanical properties. The best results will be achieved by mixing under a partial vacuum, which gives an almost nonporous cement. In cemented joint replacement surgery, a vacuum-mixing system seems preferable.

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Cementation technique

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Successful joint replacement is today achieved by using a good prosthetic design, precise surgery, and cementing technique (Miller et al. 1970, Harris et al. 1982, Insall 1983).

In the foreseeable future, the use of bone cement will remain a viable method. The overall long-term function (at 10 years) is good in about 95 percent for cemented hip and knee prostheses implanted in specialized centers using good technique and prosthetic designs (Knutson 1985, Ahnfelt 1986, Johnsson 1987). Mechanical loosening is, however, still a long-term problem especially in younger more active patients, occurring in 10 to 30 percent (Johnsson 1987).

There are three ways of improving cemented prosthetic fixation: 1. Reduce the tissue necrosis of the bone adjacent to the cement. 2. Improve the cement interface strength. 3. Improve the cement strength.

1. The heat generated in the bone during drilling and sawing can reach 90–100° C, thus, far exceeding the maximum temperature achieved during the setting of bone cement (Larsen 1986). By using heat abductors as the femoral stem or metal-backed tibial or acetabular components, the heat generation caused by bone cement seems to be a minor problem. However, with large amounts of cement used around, for instance, an isolating HDPE acetabular cup, the regenerative capacity of bone is probably impaired (Eriksson and Albrektsson 1984).

   Reduction of the maximum temperature at hardening of bone cement could be achieved by using vacuum mixing (Lidgren et al. 1987) and/or by using cement with better particle size gradation (Mjöberg 1986).

2. An improved cement interface strength could be achieved by good preparation of the bone (Ling 1986). By using a brush and high-pressurized irrigation, it is possible to obtain a clean, dry bone. This will also reduce the risk of hypotensive reaction due to intravasation of thromboplastic products during prosthetic insertion (Sherman et al. 1983).

   Uniformity and thickness of the cement mantle will significantly influence the cement strength (LaRochelle et al. 1987).

   Distal femoral plugging and retrograde injection of cement using a delivery system and proximal sealing until prosthetic insertion will ensure a good filling (Ling 1986).

   The use of sealing in acetabulum and proximal tibia are as important to achieve a good cement support.

   A better penetration and fixation have been found using low viscosity cement, and makes the use of a delivery system easier.

   The spongious bone should be removed medially in the proximal femur and dorsally in the proximal tibia to achieve a better initial postoperative stability. The surgical technique including careful soft tissue and bone handling with appropriate prosthetic alignment is, of course, of importance for the longevity (Boegård et al. 1984). An improved prosthetic positioning could be achieved by using stem centralizer, prosthetic-guide instruments, etc. (Lindstrand et al. 1982). An optimal surgical technique today also includes adequate mixing and delivery of bone cement. This could best be trained in workshops simulating clinical situations (Wixson et al. 1985).

3. If a well-cemented joint prosthesis is fully supported by bone, the mechanical strength is sufficient (Kölbel et al. 1976). However, in the proximal femoral and tibial shaft, this is often not the case, and cement failures are often seen (Carlsson and Gentz 1980, Knutson 1985). If, by using existing bone cement, an improvement of the fatigue strength without major changes of other properties, such as the stiffness of the cement, could be achieved, this will probably increase the prosthetic survival time.

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Wear of artificial joint materials in laboratory tests

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Pin-on-disk wear study

The UCLA 12-channel pin-on-disk machine has been described in detail in several previous publications (McKellop et al. 1978, McKellop et al. 1981, McKellop and Clarke 1984). Briefly, the machine oscillated polymer pins against polished metal or ceramic counterfaces in a flat-on-flat configuration under constant load. Bovine blood serum was used as a lubricant. Wear of the polymer pin was measured by cleaning and weighing the specimens at periodic intervals. Control specimens, simultaneously soaking in serum, were also cleaned and weighed to provide a correction for fluid absorption. Three types of experiments were run:

1. Wear as a function of test conditions (lubricant, surface finish, load, etc.). These were usually run with ultra-high molecular weight (UHMW) polyethylene bearing against 316 stainless steel flats.
2. Wear of various polymeric materials bearing against 316 stainless steel fats.
3. Wear of UHMW polyethylene pins bearing against various counterface materials (metal or ceramic flats).

Results of the pin-on-disk experiments

Lubricant: Distilled water and saline solution were found to have lubricating properties very different from those of serum or synovial fluid. This was evident by the heavy transfer of polymer that occurred on the metal counterfaces lubricated with distilled water or saline solution, but not with serum or synovial fluid, presumably due to the proteins present (McKellop et al. 1978). All the subsequent experiments were run with serum as a lubricant.

Surface finish: Polyethylene wear increased with increasing surface finish, as expected. However, except for very rough surfaces, there was a sharp drop in wear rate during the initial one million cycles (Figure 1), due to progressive smoothing of the metal surface by the rubbing action of the polymer pins. Polymer debris also became deposited in the surface scratches on the metal, effectively reducing the surface roughness.

Load: Tests were run with polyethylene against various metals at contact stresses of 3.45 or 6.90 MPa. The wear rate at the higher load was approximately double that at the lower load.

Wear of alternate polymers: Seventeen different polymers were tested (McKellop et al. 1981). No polymers were found to wear less than conventional UHMW polyethylene. Table 1 compares the pin-on-disk wear rates for those polymers that have been used clinically.

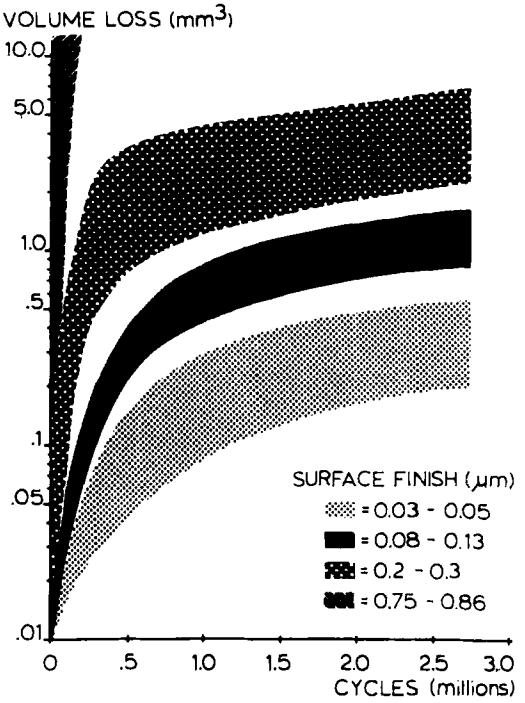

Figure 1. Polyethylene wear for four grades of surface finish on the stainless steel counterfaces. The bands cover the data scatter for three tests with each roughness. Except for the roughest surface, polymer wear droped markedly during the initial 1 million cycles.

Table 1. Pin-on-disk wear rates for polymers used clinically

Material	Relative wear rate	Clinical status
UHMW polyethylene		
machined	1.0	
moulded	0.9	In use
Carbon fiber-polyethylene composite	6.3	
Polyacetal (Delrin 150)	28	Withdrawn due to excessive wear
Polyester	95	
Teflon	1,600	

Hip prostheses using PTFE (Charnley and Kamangar 1969), polyester (Willert and Semlitsch 1976), and polyacetal (Semlitsch 1974, Sudmann et al. 1983) have been found to undergo excessive wear, generating severe tissue reactions and bone resorption that eventually required revision surgery. The close correspondence between high laboratory and clinical wear rates for these polymers provided evidence that the pin-on-disk format was a useful method for screening candidate materials.

Table 2. Pin-on-disk wear of UHMW polyethylene against various counterface materials

Material	Coefficient of friction	Relative polymer wear rate
316 stainless steel	0.03–0.09	1.0
Cobaltchrome alloy	0.05–0.11	0.9
Multiphase alloy	0.04–0.10	0.7
Titanium 6–4	0.05–0.12	0.4
Nitrided titanium 6–4	0.07–0.11	1.4
Aluminum oxide ceramic	0.06–0.10	0.6
Macor glassceramic	0.04–0.10	0.5
Pyrolytic carbon	0.14–0.24	0.7

Wear of polyethylene against alternate counterface materials: All the counterface materials (metal or ceramic) provided acceptably low polyethylene wear (Table 2). Whereas there was a *statistical* significance between some materials, this was unlikely to have *clinical* significance in terms of the ability of the tissues to accommodate the resultant wear debris. The sliding friction with the polyethylene-pyrolytic graphite combination was significantly higher than with the other materials tested. However, the polymer wear was equally low.

Titanium 6–4 alloy was found to be susceptible to severe abrasive wear when particles of PMMA "bone cement" were placed between the contacting surfaces of the pin-on-disk specimens. However, later experiments with the joint simulator did not reproduce this effect (Clarke et al. 1983). Whether this type of wear occurs *clinically* has not yet been established. Nitrided titanium alloy was impervious to damage by acrylic cement particles.

Joint simulator wear study: The USC 10-channel wear machine (McKellop and Clarke 1985) was designed to run actual specimens of ball-in-socket hip prostheses. Tests were run at 60 cycles per minute under a Paul-type hip load curve with 2,000 N peak. The tests lasted one million cycles. As with the pin-on-disk study, the specimens were lubricated with bovine blood serum, and wear was measured by weight loss of the polymer acetabular cups with soak controls to correct for fluid absorption.

Five separate sets of experiments have been run on the simulator:

1. Three stainless steel T-28 components and three titanium alloy STH components run against 28-mm diameter polyethylene cups from a single batch, to evaluate the effect of metal alloy on cup wear.
2. Three cobalt-chrome alloy Anitomic components and three titanium alloy Anitomic components run against a set of 32-mm diameter polyethylene cups, again to evaluate the effect of metal alloy on cup wear.
3. Three cobalt-chrome Link components and three *diffusion hardened* titanium alloy Link components run against a second set of 32-mm polyethylene cups (not the same batch of material as was used in experiment *2).
4. Three pyrolytic carbon-coated graphite femoral components run against a fourth set of 32-mm diameter polyethylene cups, to compare with previously tested metal-polyethylene components.
5. Three cobalt-chrome hip surface replacements and three prototype polyacetal surface replacements run against 41-mm-diameter polyethylene cups, to evaluate the wear properties of the polymer- polymer system.

Results of the joint simulator experiments

Figure 2 shows the acetabular cup wear for the 27 individual prostheses tested to date. There was significantly more scatter in the results from the first 12 tests (T-28, STH, Anitomic cobalt-chrome, and Anitomic titanium alloy) than in subsequent tests. We found that ensuring that the ball-to-cup diametral clearance was in the range 0.2 to 0.4 mm dramatically reduced the variation in the results (Link, Intermedics, Surface replacements).

The following specific observations were determined in these experiments:

1. All the metals (316 stainless steel, cobalt-chrome alloy, titanium alloy) underwent much more surface

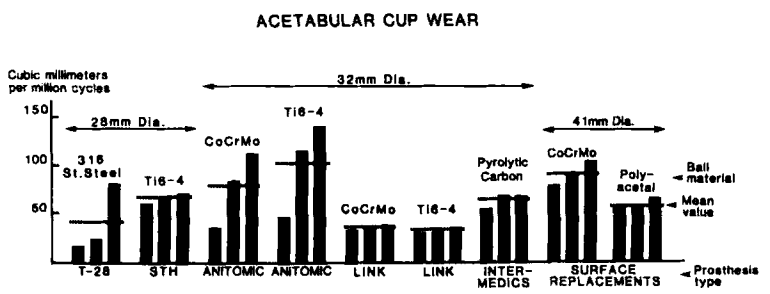

Figure 2. Wear rates for the polyethylene acetabular cups for femoral heads run for 1 million cycles each. The relatively large amount of variation with the Anitomic prostheses was caused by unusually tight ball-cup clearance (see text).

abrasion in the simulator than was typically evident on prostheses removed from patients. This was probably due to the unavoidable presence of minute contaminants (dust, etc.) in the laboratory tests. Thus, the resultant polyethylene wear rates are probably somewhat higher than occur in vivo.

2. Titanium alloy with normal, acid-passivated surfaces (STH, Anitomic) showed more surface damage in the simulator than stainless steel or cobalt-chrome components. Diffusion hardening of the titanium alloy (Link) virtually eliminated this surface damage.
3. Normally passivated titanium alloy tended to generate more polyethylene wear than comparable prostheses of stainless steel (T-28) or cobalt-chrome (Anitomic). However, this was not a statistically significant difference, and it would probably not be clinically significant.
4. Introduction of PMMA bone cement chips did *not* induce severe abrasive wear of the STH titanium alloy prostheses run in the joint simulator. This was in contrast to the earlier results with the pin-on-disk format. The reason for this discrepancy in laboratory results has not yet been determined. The most recent *clinical* reports also show a contradiction in results. While occasional incidences of apparently excessive metal wear have been reported with other designs of titanium alloy prostheses, the experience at USC with over 1,000 titanium alloy STH prostheses implanted for as long as 10 years has shown no evidence of excess abrasive wear of the titanium alloy components in vivo. This observation was based on detailed histologic examination of tissue samples obtained during 19 revision operations (Sarmiento and Gruen 1985, Harwin et al. 1987).

   The cause of occasional excessive wear of some designs of titanium alloy prostheses in clinical use has not yet been established. If excessive wear of normally passivated titanium alloy is shown to be a significant clinical problem, then special surface hardening by one of the currently available methods (nitriding, diffusion, ion implantation, etc.) would appear to be a feasible cure.
5. The pyrolytic carbon-coated balls produce slightly more polyethylene wear than the most comparable cobalt-chrome-polyethylene combination (Link).
6. The low wear with the polyacetal ball bearings against polyethylene cups was surprising in view of the poor clinical performance of polyacetal cup-metal ball designs. Apparently, the wear mechanisms for a relatively hard polyacetal ball bearing against a softer polyethylene cup are significantly different than for a hard metal ball bearing against a softer polyacetal cup. This illustrates the importance of evaluating materials in the *actual configuration* that they are intended to be used clinically.

In summary, the 10-station joint simulator combined with highly accurate wear measurements based on weight loss provide a convenient method for *accurate* and *reproducible* measurements of the wear properties of candidate prosthetic joint materials.

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Registration of complications

Complications in total hip arthroplasties

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The results of total hip replacements in their modern form were initially very good. Both Charnley (1972) and Müller (1970) reported 5-year follow-ups with good results in 85–90 percent. However, the complications that occurred were often very severe and necessitated new operations, caused considerable suffering, and in many case permanent invalidity.

Different studies report a varying number of complications and often show considerable differences in follow-up time. This fact strongly affects the occurrence of early and late complications in the literature.

A standardized study of reoperations after total hip arthroplasty is an accepted method for recording important problems, and this realization was the guideline when the project "Reoperated hip arthroplasties in Sweden" was started in January 1979.

The goal of this investigation is to map the occurrence of serious complication to hip arthroplasty and to evaluate the importance of different factors causing these complications. Thus, both the factors related to the patient and the nonpatient-related factors are studied.

This study, covering the entire country, gives such a large material that new operative techniques and prosthetic designs can be evaluated within a relatively short time.

Method

The project "Reoperated total hip arthroplasties" was started on January 1, 1979. The charts of all the patients who undergo a reoperation after total hip arthroplasty in Sweden are collected, registered, and computer analyzed. The study is prospective and engages all departments performing total hip arthroplasties.

The results of the enterprise are shown in tables and frequency diagrams. Statistical comparisons between different patient- and nonpatient-related causes of serious complications have been analyzed, and different prosthetic designs have been evaluated against one another. Survival analyses for the different implants are based on the functional risk for each prosthesis according to Kaplan-Meier (1958). An annual report is made of the entire material, and also for every single clinic.

Patients

The annual number of reoperations in Sweden has been increasing since 1979 (Table 1). In order to enable a uniform evaluation of the material, we report only those patients who have been reoperated on for the first time with prosthetic revision. During the period from 1979 up to and including 1983, there were 3,151 reoperations reported with this criterion. The reoperations have been divided into four groups.

Group 1 consists of revision of the arthroplasty with exchange of one or both components or removal of the prosthesis.

Group 2 includes major surgical operations, such as open reduction, removal of ectopic bone, etc.

Group 3 consists of small surgical hip operations, e.g., removal of cerclage wires, drainage, etc.

Group 4 consists of closed reduction after dislocation.

In Table 2 the reoperations for each group are shown for the 5-year period under examination.

Table 2. Grouping according to treatment for patients who have not undergone previous prosthetic revision. Percentage given in brackets (n 3,151)

	1979	1980	1981	1982	1983	Total
Group 1	320 (70.8)	333 (72.1)	478 (76.8)	576 (76.8)	677 (78.3)	2 384 (75.7)
Group 2	32 (7.1)	23 (5.0)	34 (5.5)	36 (4.9)	31 (3.6)	156 (5.9)
Group 3	35 (7.7)	28 (6.1)	23 (3.7)	34 (4.5)	11 (1.3)	131 (4.1)
Group 4	65 (14.4)	78 (16.9)	87 (14.0)	104 (13.9)	146 (16.9)	480 (15.2)
Total	452	462	622	750	865	3 151

Table 1. Number of reoperations in Sweden 1979–1983

	1979	1980	1981	1982	1983
Reoperations	571	555	753	892	1,077
Primary operations	4,902	5,159	5,802	6,230	6,729
Relations between reoperations and primary operations expressed in percent	11.6	10.8	13.0	14.3	16.0

Results

The sex distribution is even, but varies if the original diagnosis is taken into account. With arthrosis the men dominate and with rheumatoid arthritis and previous hip fractures, there is a marked predominance of women.

In accordance with other material, we find that disease mainly affects the right side, whereas accidents mainly occur on the left side. The age distribution is typical and corresponds to other studies. Patients with coxarthrosis have an age distribution (mean 70 years) that agrees with that of the entire material. Patients with rheumatoid arthritis (mean 60 years) and previous pediatric disease (mean 59 years) display a lower mean age.

Almost one third of the material has undergone previous operations apart from the insertion of the primary prosthesis. The most usual operation is osteosynthesis after a hip fracture, but femoral osteotomy and operations with hemiprostheses are also frequent.

The patient's original diagnosis is of great importance for later complications and requirements for a reoperation. With arthrosis the distribution of the indication for reoperations is the same as in the whole material. Rheumatic patients have, on the other hand, a significantly increased proneness for infection. Operated on hip fractures have a significantly increased risk of dislocation and a significantly lower risk of loosening.

Table 3. Indication for reoperation when the procedure was revision of the prosthesis or other major surgery. (Group 1 and 2 of the reoperations)

Indication for reoperations	Number	Percent
Aceptic loosening	1,664	65.5
Deep infection UNS	292	11.5
Implant failure	153	6.0
Dislocation	146	5.7
Bone fracture combined with prosthetic loosening	72	2.8
Technical failures	58	2.3
Pain	49	1.9
Bone fracture without prosthetic loosening	24	0.9
Hematogenous deep infection	21	0.8
Trochanteric problems	19	0.7
Ectopic bone growth	19	0.7
Other reasons	23	0.9

In Table 3 is shown the cause for the reoperation over the 5-year period when the procedure was major surgery (groups 1 and 2). Aseptic loosening increases year from year (Table 4).

In the material, there are 331 deep infections registered, and 21 of these are hematogenous. The cumulative infection frequency has been calculated (Table 5). It is 1 percent after 5 years. If we exclude patients who have been operated on in the hip before the primary arthroplasty, the cumulative infection frequency is considerably lower, and this difference is statistically significant.

The measures that have been undertaken for deep infection are known. The most common procedure is revision of both components (73 percent), removal of the prosthetic components (12 percent), and in a few cases, revision of one component (8 percent).

In the material, 1,889 aseptic loosenings are registered. Of these, 1,644 are pure loosenings, and the rest are combined with broken implants and bone fractures. Table 6 shows the cumulative loosening frequency of prostheses inserted from 1974 to 1980. Since the study started in 1979, there are only reoperations included that were performed within 4–10 years after the primary THR. This loosening frequency is greater than in many international materials. The reason for this difference can be found in the Christiansen prosthesis, which was used during the second half of the 1970s. This prosthesis gave many and early mechanical prosthetic failures. If the Christiansen prosthesis is excluded, we arrive at the cumulative loosening frequency shown in Table 7.

Table 4. Distribution in percent between prosthetic loosening and infection 1976–1983

Cause	1976–77	1979	1980	1981	1982	1983
Deep infection (incl hematogenous)	33.5	13.8	11.9	10.4	8.5	9.2
Loosening (incl. bone fracture and implant failure)	33.5	45.1	48.3	57.0	59.9	64.4
Other causes	33.0	41.1	39.8	32.6	31.6	26.4

Table 5. Reoperations as a result of deep infection after 1–6 years (n 3,151)

Prosthesis inserted year	Number of reoperated on patients in percent within					
	1 year	2 years	3 years	4 years	5 years	6 years
1978	0.4	0.5	0.7	0.9	1.0	1.1
1979	0.4	0.6	0.8	1.0	1.0	
1980	0.3	0.5	0.6	0.7		
1981	0.4	0.5	0.6			
1982	0.4	0.7				
1983	0.1					

Table 6. Reoperations due to loosening within 4–10 years after primary THR (1,664)

Prosthesis inserted year	Number of reoperated on patients in percent within						
	4 years	5 years	6 years	7 years	8 years	9 years	10 years
1974	0.3	0.7	1.3	2.2	3.2	4.2	5.1
1975	0.5	1.2	2.2	3.5	4.9	6.1	
1976	1.2	2.2	3.7	5.3	6.7		
1977	2.2	3.4	5.1	6.6			
1978	3.1	4.9	6.4				
1979	3.3	4.8					
1980	3.1						

Table 7. Reoperations due to loosening within 4–10 years after primary THR. Christiansen prosthesis excluded from the material

Prosthesis inserted year	Number of reoperated on patients in percent within					
	4 years	5 years	6 years	7 years	8 years	9 years
1974		0.7	1.3	2.2	3.2	4.2
1975	0.3	0.7	1.6	2.8	3.9	4.9
1976	0.6	1.3	2.2	3.0	4.0	
1977	1.1	1.7	2.5	3.3		
1978	1.6	2.8	3.5			
1979	1.5	2.4				
1980	1.8					

The operative measures in 1,664 aseptic loosenings are mainly revision of one or both components (97 percent). Removal without implantation of a new prosthesis was undertaken when the bony tissue had been severely destroyed (2 percent).

The variables not related to the patient that are reported are type of prosthesis, geographic region, and hospital type. From 1967 up to and including 1984, 52 different prosthetic designs were used in Sweden. Of these, there are 37 in the reoperation material. The prostheses have changed over the years both with respect to design and choice of material.

With regard to separate regions in the country, there is no difference as to the frequency of revisions or infections. Some hospitals have an increased number of loosenings and others a significantly lower number. With respect to infections, there is no difference between hospitals.

Based on survival analysis, there are three main groups of prostheses with respect to loosening frequency. The better types are the CAD, Charnley, and Lubinus prostheses. In the second best group, we find the Charnley-Müller, Stanmore, and Müller prostheses. The group of prostheses with a high loosening frequency consists of the Christiansen and Wagner models.

The survival of the Charnley prosthesis with regard only to aseptic loosening can be seen in Table 8. After 10 years about 7 percent have been revised because of loosening. These figures correspond well with reports form England and the United States as to the survival of this prosthesis (Stauffer 1982).

Table 8. Risk and survival analyses of the Charnley prosthesis with respect to aseptic loosening in the Swedish reoperation material

Years after primary operation	Risk	Survival
0	0.0000	1.0000
1	0.0042	0.9959
2	0.0056	0.9903
3	0.0037	0.9866
4	0.0049	0.9818
5	0.0047	0.9772
6	0.0071	0.9703
7	0.0101	0.9606
8	0.0089	0.9520
9	0.0145	0.9383
10	0.0131	0.9261
11	0.0066	0.9199
12	0.0171	0.9044
13	0.0276	0.8797

Conclusions

The following conclusions can be drawn from this investigation. Reoperations of total hip arthroplasty in Sweden increase linearly, and in 1985, more than 1,100 reoperations were carried out.

The patient's basic disease is significant for the risk of being afflicted by a specific complication. Infection is more common in rheumatoid arthritis, and loosening occurs more often in arthrosis.

The risk of deep infection increases with the number of operations that have previously been carried out on the hip joint. This risk also increases with the appear-

ance of superficial wound infections at the primary arthroplasty.

Loosening occurs statistically less often if the primary arthroplasty is carried out with a trochanteric osteotomy. The type of prosthesis has a bearing on the frequency of mechanical loosening and dislocation.

The cumulative reoperation frequency for infection in the total material was 1 percent after 6 years; if no earlier surgical operations had been carried out on the hip, this figure is 0.7 percent. The cumulative frequency of reoperations because of loosening is in the total material 6–7 percent between 4 to 10 years after the arthroplasty. Loosening during the first 4 postoperative years can be estimated at 4 percent, and thus the total frequency of loosening is 10–11 percent. If the Christiansen prosthesis had never been introduced in Sweden, these figures would be 3 percent less. We can thus conclude that the 10-year results of primary THR surgery in Sweden with good prostheses is equal to most other studies with 7–8 percent revised for aseptic loosening.

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Analysis of knee arthroplasty failures

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A report on knee arthroplasty including surgical precision, relief of symptoms, gain in function and activity of daily living, interface reactions, morbidity, mortality, and a cost analysis is best done in a one-unit report on a selected number of well-studied arthroplasties. However, for the analysis of failure and revision rates, a large number of cases, followed for a sufficient period, are needed.

The Swedish Knee Arthroplasty Project is a multicenter study of 14,000 arthroplasties performed during an 11-year period. One object of the project was to identify poor prosthetic designs. This is a report on some of the experiences from this project.

At the beginning of the project, attempts were made to report the complication rates for different prostheses. It was soon obvious that in a multicenter study there were many opinions about when a failure should be reported and registered as such. Which size of radiolucency or which extent of migration should be regarded as a loosening of the prosthesis? Should the extent of dysfunction be decisive? Is a red and swollen knee with negative cultures a deep infection? Some of the failure mechanisms are gradual and the actual point of time when the arthroplasty has failed is difficult to establish and will vary with how often the patient is seen. For these reasons later reports have been based on revision rates instead of complication rates. Revision is better defined as to when it happened and often the indication for revision or the actual complication is obvious at revision. When analyzing revision rates, one has to take into account that the prostheses have been used during different periods and on various degrees of knee degeneration. Another problem is that indication for revision may vary at different centers. Finally, the population studied is old, and some patients are lost to follow-up and other diseases. The latter group of patients has been identified from central population registers. Patients that have moved to other areas have been reported if they were revised elsewhere thanks to the multicenter design of the study.

The only method suitable for revision rate estimation has been the survivorship method. The alternative methods are the life-table technique and and the Kaplan-Meier method. The former is based on the occurrence of revisions each postoperative year, and the latter on the chance of revision for each revised case related to the number of remaining cases in the studied group. The Kaplan-Meier method has more sensitive statistical methods, but can only be performed with computer assistance.

The 10-year revision rate for rheumatoid patients was 19 percent for hinged prostheses, 11 percent for stabilized prostheses, 10 percent for bicompartmental and tricompartmental prostheses, 20 percent for medial and lateral unicompartmental prostheses, and 39 percent for demiarthroplasties.

The 6-year revision rate for arthrotic patients operated on from 1975 to 1980 inclusive was 35 percent for hinges and about 10 percent for the other prosthetic types. One early design of bicompartmental type, the Freeman-Swanson Prosthesis had, however, a revision rate of 25 percent. There was no difference between the Marmor and St. Georg demiarthroplasties.

Later used tricompartmental prostheses have had a much lower 6-year revision rate (5 percent), and the only low-performing modern design so far has been the Dean prosthesis.

Regulation of biomaterials

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Regulation of medical devices in Scandinavia has hitherto been concentrated to sterile disposables, and implants are not covered. A discussion is going on concerning the inclusion of implants in a new act to cover all types of medical devices.

On the other hand, eventual legislation should include an obligation from the manufacturer to supply on request from the user information concerning the safety evaluation of the product. As regards implants within the orthopedic sector, many different kinds of materials have been used for a number of decades, and for the past 20 years there have been international standards for the most commonly used materials, so that a safety evaluation chiefly covers safety of function and, what is more important, the continuous quality supervision during the manufacturing process.

When testing new materials and implants clinically, the division of responsibility between doctor and manufacturer is often not clear, but should be defined before starting the clinical trial. An increased official control of biomaterials and implants is regarded by many established companies as beneficial if it is coupled to effective supervision of all manufacturers in order to exclude nonserious producers. The increase in costs for the products may, however, have a negative effect on innovations and new undertakings.

The manufacturing process for medicotechnical articles has advanced during the last 10 years, and this can partly be related to the manufacture of pharmaceuticals. It is bound by law for all kinds of medicotechnical products in the United States, whereas in Europe only sterile disposables are included, and thus not implants. It is called Good Manufacturing Practice, shortened to GMP and is applied by most serious producers. In brief, GMP means that development, testing, clinical evaluation, and manufacturing are carried out in accordance with strictly specified norms that are documented in detail and shall be available to the regulatory authorities.

In order to achieve increased safety as regards implants, the introduction of GMP requirements should have the greatest effect, for most incidents occur with wrongly constructed or faulty made products.

GMP also covers the handling of complaints, which must be dealt with in writing by the manufacturer, and action must be taken that is subjected to regulation by the authorities.

Retrieval of implants

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Analysis of failed joint prostheses has helped identify inferior implant materials, and has been helpful in suggesting new designs and concepts. The analysis has also demonstrated the danger of extrapolating to real life the material performance in laboratory tests. Teflon and Delrin are examples of materials showing discrepancies between in vitro and in vivo performance.

Retrieved implants are naturally subjected to technical analysis. Histologic analysis of the interfacing tissue is also a necessity in order to document the biological consequences of material failure. However, in many cases the primary cause of failure is difficult to establish, as the process creates a vicious circle that includes several destructive phenomena that may or may not be related to the implant material.

It has become clear that in order to predict the long-term value of a specific implant material or a prosthetic concept only perfectly functioning implants should be studied. In practice, this is difficult to accomplish unless a system of postmortem retrieval is organized (Charnley 1979). Although the amount of accessible material would be limited, the information contained in it is of immense importance, since it is possible not only to assess the tissue reaction to an implant material, but also to assess the performance of the mode of implant anchorage.

Methods for histologic evaluation of the interface are available. By using plastic embedding of the entire implant-tissue composite, it is possible to obtain large saw-cut sections, or smaller tissue sections intended for light or even electron microscopy (Donath and Breuner 1982, Linder 1985).

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