Acta Orthop. Scand. *58*, 477–478, 1987

Editorial

Quality control of implants

The Judet hemiarthroplasty of the hip in the 1950s was the first widely accepted orthopedic operation using an artificial substitute for a natural anatomic component. The operation was important 1) because its early success proved the potential *biofunction* of the artificial hip and 2) because the high failure rate demonstrated the importance of *biocompatibility* and *biostability* – e.g., the plastic material disintegrated into small fragments that caused severe inflammation and the stem lost its support in the femoral neck. This experience provided the incentive for Charnley's spectacular progress toward improved compatibility, stability, and function of the artificial hip; also he successfully addressed the problem of postoperative infection. Today, Charnley's contributions still form the basis for further improvements of the arthroplasties.

The report by Aspenberg et al. of hip prosthesis fractures through faulty welding in this issue of *Acta Orthopaedica Scandinavica* should cause great concern. Clearly, we do not have sufficient assurance that implants supplied by a highly competitive market are properly manufactured. Further, retrospective clinical studies of hip and knee arthroplasties have identified widely used designs with unacceptably high failure rates.

In terms of manufacture control and clinical reports on failures, the situation in the implant field is unsatisfactory when compared with that of drugs, which rests on rigid product specification, animal experiments, and clinical trials before release for general use is approved. Further, the medical community is requested to report complications associated with both new and established drugs. This information rapidly gains wide attention through national and international organizations. Naturally, material and implant failures have not yet been documented and published with the same efficiency. Organizations for drug control were established even before forceful political action was taken in the wake of the thalidomide disaster of 25 years ago. At that time, implants were still in their infancy.

However, cardiac valves, lens substitutes, endoprostheses, and arterial grafts have now been used for a quarter of a century. The pioneer years are over, and the public has a right to be assured that artificial implants do not introduce unexpected hazards associated with poor design, incompatible materials, or deficient manufacturing procedure and quality control. In several countries, notably the United States and Great Britain, producers are following so-called good manufacturing programs, i.e., quality assurance open to inspection by official organizations. In Scandinavia, regulation of biomaterials is now being considered; hopefully, legislation will be forthcoming in Sweden in 1988. This type of control should effectively prevent such accidents as reported by Aspenberg et al. However, existing or future systems for manufacturing control do not provide information on long-term biofunction; the situation today, for example, is that more than half of the patients will survive 10–15 years after a hip or knee arthroplasty, whereas the majority of the implants on the market have a documented life of

less than 5–6 years. Also, the majority of long-term reports on these implants have been published by their inventors, who might well be expected to obtain better results than the average orthopedic surgeon.

The Swedish Orthopedic Society has addressed this problem by initiating, in 1975, nationwide follow-up studies of virtually all the arthroplasties of the hip and knee, providing important data on the failure rates of individual prosthetic designs, results of revision and salvage procedures, and of the use of endoprostheses in relatively rare conditions.

Systems for more efficient quality control of implants and information on implant failures may impede the development of new biomaterials, designs, and indications for implants. For example, in the United States it took an unreasonably long time before bone cement was approved, and cement containing gentamicin has still not been approved for general use in arthroplasties; moreover, multicenter arthroplasty studies have met resistance associated with the malpractice situation. On the other hand, fears that regulated implant quality control may incur unreasonable costs may be unfounded. In Sweden, manufacturer quality control on an earlier date could even have reduced the overall costs of arthroplasty.