THE CONTROL OF NEW PROSTHETIC IMPLANTS

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The recent well-publicised problem of early failure of the 3M Capital Hip has led both the public and orthopaedic surgeons to question the effectiveness of existing controls in the UK which govern the introduction of new prostheses for joint replacement. It has also resulted in renewed demands for a National Hip Register, similar to those successfully developed by Sweden and Norway,\(^1,2\) to provide better long-term surveillance of different designs of implant. The Scandinavian Registers have certainly been successful in drawing attention to poorly performing prostheses, such as the Christiansen Hip,\(^3\) as well as identifying problems in the materials used for joint replacement, as with ‘Boneloc’ cement.\(^4,5\) Their long-term data confirm that selection of the prosthesis is the factor which has the greatest influence on long-term survivorship. The problem of early failure of the implant is not new, nor is it confined to Europe, since major difficulties have also been reported recently from North America in a number of roughened femoral stems used with acrylic ‘precoat’ technology.\(^6,7\)

Should we be able to predict these types of failure? To do so requires a better understanding of the mechanism of early breakdown, which must be different from the well-recognised late failure resulting from the production of prosthetic wear particles characterised by the formation of excessive granulation tissue and osteolysis.

The Capital Hip, which was introduced by the 3M Company in 1991, was marketed as a femoral stem with a shape similar, but not identical, to the current version of the Charnley stem. The emphasis at the time of its introduction was on the low cost of the prosthesis and the outstanding performance of the existing hip replacement based on the Charnley principles. The femoral implant was manufactured in two materials; a modular design with a titanium-alloy stem and either a chrome-cobalt or titanium-nitride head, and a monobloc in stainless steel. A number of stem shapes were available for each of these. Modularity allowed the use of heads of various sizes and different materials. The titanium alloy used for the stem was chosen to give the advantages of a lower modulus of elasticity, better biocompatibility, and reduced tissue toxicity. The stem design featured round corners proximally to ensure a more uniform load transfer to the supporting cement, a slightly roughened matt surface texture, and an acrylic centraliser at its tip. It was inserted using specially designed instruments with broaches and rasps that were oversized by 2 mm to allow a cement mantle of 1 mm around the prosthesis.

Between 1991 and 1997 it was estimated that 5000 Capital prostheses were used in the UK, and a further 1000 elsewhere in the world. By 1995 there was some anecdotal evidence of early failures in various centres in the UK. The 3M Company responded by circulating a guidance note recommending extra removal of trabecular bone proximally in order to improve interdigitisation of cement. In 1997 Massoud et al.\(^8\) published a paper in the British Volume of the Journal documenting the early rates of failure. In a series of 76 patients with a mean follow-up of just over two years, they reported a revision rate of 9%; 16% of cases had definite radiological loosening and a further 10% possible early loosening. All the femoral stems used in the series were of titanium alloy combined with modular chrome-cobalt or titanium heads. The authors suggested that the significant increase in the incidence of loosening was associated with an inadequate proximal cement mantle of less than 2 mm thickness. When information emerged from at least four other centres in the UK reporting unacceptably high rates of early revision for the Capital Hip, the Medical Devices Agency (MDA) issued a Hazard Notice in February 1998.

This unfortunate sequence of events calls into question the claims for progress in the development of hip replacement during the past 40 years. Since the pioneering designs of Charnley, McKee, and Ring, a greater number of new prostheses and biomaterials have been introduced in an attempt to increase the longevity of the joint replacement. Unfortunately, in many cases, the result has been the
opposite, with much earlier failure than that seen in the long follow-up of the early designs. The tight control which Charnley kept on the use of his prosthesis in the early years after its introduction may now appear idiosyncratic. Nevertheless, the long-term results for the Charnley prosthesis justify his conservatism when compared with many of the newer designs which have frequently been released for uncontrolled clinical use as manufacturers of orthopaedic implants competed with each other for a lucrative and expanding worldwide market in joint replacement. The rapid increase in the number of implants and the wide variation in their cost have been reported by the Oxford group, which also highlighted the lack of documented scientific evidence to support most of the new designs. This raises other questions as to how long is a long-term clinical trial and where these reports would be published?

The Department of Health and its regulatory body, the MDA, have now placed controls and standards on the introduction of new designs and prosthetic materials. They, in turn, are subject to outside influences, since the UK is now governed by European Community Standards. These bodies may be able to test new implants, but face greater difficulties when clones of existing designs are introduced by the same or other companies, often with minimal alterations in the properties of the materials or in surface finish. Such a ‘look-alike’ prosthesis may be difficult to identify and test, but can cast major doubt on a successful design, such as occurred when a higher rate of loosening was observed when the polished stem of the Exeter prosthesis was replaced with a matt surface.

Any regulatory function will inevitably be expensive as the number of prosthetic joint replacements increases. Who should pay for this? Should it fall on the Department of Health, the patient who receives the hip, or the Company which manufactures the implant, perhaps by a levy on the cost of production. In Britain, the MDA is discussing an initiative with the Department of Health and the British Orthopaedic Association, to develop a three-level surveillance scheme for new implants. First, there would be further work to develop European and International Standards for preclinical laboratory testing of wear and fatigue using hip-joint simulators. Much of this has now reached a reliable level, but may still not simulate the conditions experienced by implants once they are introduced into the body. The second-level premarket clinical trial may identify problems of premature wear and loosening by the use of more sophisticated measurement techniques, such as roentgen stereophotogrammetric analysis, to identify early migration of the device. These facilities are only available in a few specialised centres and would be difficult to apply to every new device. Less expensive techniques, using digitisation of standard radiographs, have been reported as capable of measuring migration at a level to indicate outcome, but require validation over a wider range of prostheses.

Most early failures will only be recognised by the third level of surveillance using tightly controlled post-market clinical trials in selected centres, ideally other than those of the innovators. These should continue to collect long-term clinical data on selected designs with periodic radiological assessment. Whether this type of information collection can be broadened to the concept of Implant Registers is more questionable. Regional, rather than national, Joint Replacement Registers may be needed in the UK, where they have already been shown to be of value in measuring the rates of complication and mortality. To be successful, a Register must collect sufficient data in a secure format to ensure clinician compliance and must be backed by a guarantee of continued funding. It must incorporate a system for periodic radiological follow-up including the important baseline film after operation to identify evidence of poor surgical technique. The numbers should be sufficiently large to remove the influence of variation in operative competence, but must include the key outcome measures of revision or death. This requires the introduction of a unique numerical identifier for all patients and improved record linkage between regional databases. The pressure to move in this direction can only come from Government, but given the increasing emphasis on clinical governance resulting from the publicised failures in orthopaedics, as well as other branches of surgery, this may soon occur.

It is therefore important that orthopaedic surgeons involve themselves in this process and ensure that the methods of implant testing are appropriate, the clinical trials are adequate, and that reliable outcome measures are used. To do this will require more time to be spent in assessing and informing patients and will add to the pressures in the already overstretched delivery of elective orthopaedic services. Nevertheless, this time must be found if orthopaedic surgery is to retain the confidence and support of the public and to have any prospect of achieving real improvement in the longevity of joint replacements.

References

Editorial

NEONATAL DETECTION OF DEVELOPMENTAL DYSPLASIA OF THE HIP (DDH)

David Jones

Thirty years after the introduction of a national screening programme for congenital dislocation of the hip (CDH) and 12 years after the publication of guidelines, neonatal clinical examination is failing in its objectives and we are uncertain as to how best to proceed.

The spectrum of presentation of what is now termed developmental dysplasia of the hip (DDH) is wide. It includes neonatal instability, an infant with limited abduction, a limping toddler, a child or adolescent with painful deformity, breech presentation or torticollis. There is general agreement that the earlier the diagnosis the better the outcome and that neonatal examination has been a cornerstone of our management of DDH.

The initial optimism, however, that early clinical examination would eliminate late presentation after three months has long since faded. Over the years, a list of failures of the technique has steadily accumulated. In particular, the experience of the Malmö group is sobering. In the hands of these pioneers of clinical screening the incidence of later presentation has risen.

Nevertheless, there is evidence that well-conducted neonatal clinical examination can favourably influence rates of late presentation, especially when performed by expert examiners.

Ultimately, however, we have a clinical test which has a high specificity (100%) because there are no false-positive results, but a low sensitivity, probably less than 60%. This is why we need to continue surveillance throughout infancy.

Ultrasound examination either by static or dynamic means is now well established and its role and influence have spread widely. It offers specificity and sensitivity in excess of 90%, but it is not infallible. The images can be difficult to interpret, it overdiagnoses the condition, it does not tell us whom to treat and it poses logistical problems in organisation. Opinion is divided among those supporting universal screening as being effective and those favouring selective use when there is clinical suspicion or in babies at risk because of family history, a foot deformity, breech presentation or torticollis. Others are firmly against universal screening by ultrasound.

Universal ultrasound examination requires a national policy with guidelines, the establishment of centres to train screeners and interpreters, agreement on whom should be treated and a long-term outcome study. If a selective policy is adopted we must accept that there will continue to be children who are diagnosed late.

This year the Medical Research Council (MRC) Report on Congenital Dislocation of the Hip concluded that neonatal clinical examination had not reduced the incidence of late presentation requiring a surgical procedure, defined as one requiring a general anaesthetic, including an arthrogram or application of a cast, not necessarily a major open operation. It stated that the scientific basis for the screening programme was weak and advised a formal evaluation of current and alternative policies, including

References


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